R-test Cholera Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-25050

INTENDED USE

The R-test Cholera Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of Vibrio Cholerae (V. Cholerae) O139 antigen and O1 antigen in human fecal specimen. It is intended to be used as a screening test by professionals and provides a preliminary test result to aid in the diagnosis of infection with V. Cholerae. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

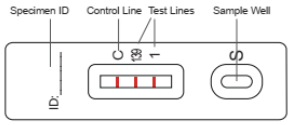
Cholera is an acute infectious disease that is characterized by massive loss of body fluids and electrolytes through severe diarrhea. The etiological agent of cholera has been identified as V. Cholerae, a gram-negative bacterium, which is generally transmitted to humans via contaminated water and food.

The species V. Cholerae is divided into several serogroups on the basis of O antigens. The subgroups O1 and O139 are of special interest because both can cause epidemic and pandemic cholera. It is critical to determine as quickly as possible the presence of V. cholerae O1 and O139 in clinical specimens, water, and food so that appropriate monitoring and effective preventive measures can be undertaken by public health authorities.

The R-test Cholera Ag Rapid Test can be used directly in the field by minimally skilled personnel and the result is available within 10 minutes, without the use of cumbersome laboratory equipment.

TEST PRINCIPLE

The R-test Cholera Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti- V. Cholera O1and O139 antibodies conjugated with colloid gold (O1/O139-antibody conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test line (1line). The 1 line is pre-coated with monoclonal anti- V. Cholera O1 antibody. The 139 line is pre-coated with monoclonal anti- V. Cholera O139 antibody. The C line is pre-coated with a control line antibody.



When an adequate volume of test specimen is applied into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The V. Cholera O1/O139 antigen if present in the specimen will bind to the corresponding O1/O139-antibody gold conjugate. This immunocomplex is then captured on the membrane by the pre-coated anti- V. Cholera O1/O139 antibody, forming a burgundy colored test line, indicating a Cholera O1/O139 positive test result. Absence of the test line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of the color development on the test line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Stool collection devices, each containing 2 mL sample extraction buffer
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of oral-food borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 10-minute window should be considered invalid and must be repeated
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

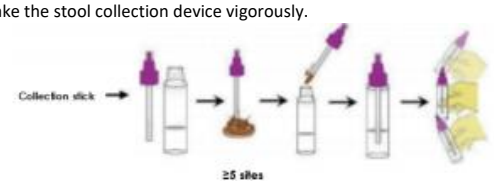
SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below. Procedure A: Solid stool samples.

Procedure A: Solid stool samples

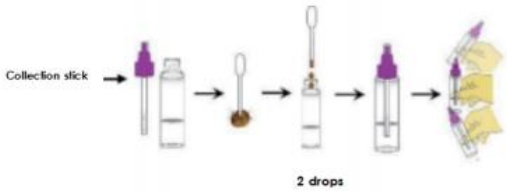
1. Collect a random stool sample in a clean, dry receptacle.
2. Open the stool collection device by unscrewing the top, and then use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.
3. Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.
4. Replace the collection stick and tighten securely to close the stool collection device.
5. Shake the stool collection device vigorously.



The specimen is now ready for testing, transportation or storage.

Procedure B: Watery stool samples

1. Collect a random stool sample in a clean, dry receptacle.
2. Open the stool collection device by unscrewing the top.
3. Fill the plastic dropper with the sample; dispense 2 drops (70- 90 µL) into the stool collection device.
4. Replace the collection stick and tighten securely to close the stool collection device.
5. Shake the stool collection device vigorously.



The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2°C-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.

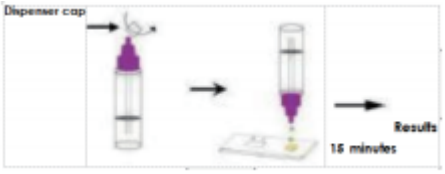
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if they`re refrigerated or frozen.

Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure a homogenous liquid suspension.

Step 4: Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution into the sample well of the test device. Do not overload sample.



Step 5: Set up the timer Step

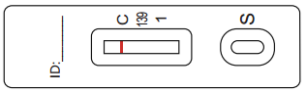
Step 6: Results can be read within 15 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute. Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

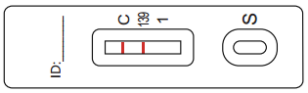
- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

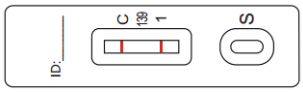
- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable V. Cholera antigen is present in the specimen. The result is non-reactive or negative.



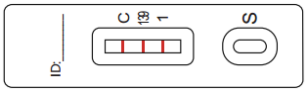
- **POSITIVE RESULT:** If both C and 1 lines develop, the test indicates for the presence of V. Cholera O1 antigen in the specimen. The result is V. Cholera O1 reactive or positive.



- If both C and 139 lines develop, the test indicates for the presence of V. Cholera O139 antigen in the specimen. The result is V. Cholera O139 reactive or positive.

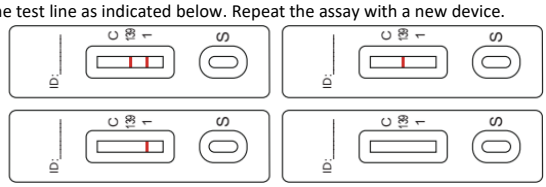


- In addition to the presence of C line, both 1 and 139 lines develop, the test indicates for the presence of V. Cholera O1 antigen and O139 antigen. The result is both V. Cholera O1 and O139 reactive or positive.



Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic decision is made.

- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the test line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

A clinical study was performed with 230 patient fecal samples using a commercial Cholera Rapid Test as a reference test. Comparison for all subjects is shown in the table below.

	R-test Cholera Ag Rapid Test		
HIv Ag/Ab Patients	**Positive**	**Negative**	**Total**
V. cholera O1 Positive	70	2	72
V. cholera O1 Negative	2	156	158
V. cholera O1 Total	72	158	230

Sensitivity: 96.7%, Relative Specificity: 98.8%, Overall Agreement: 98.3%

2. **Limit of Detection**

The limit of detection of the R-test Cholera Ag Rapid Test was determined using suspension of V. Cholera O1 and O139 cultures. Serial dilutions (in triplicate) were made and the number of colony forming units (cfu) was calculated by plating the bacteria on TCBS (thiosulfate citrate bile salts sucrose) agar plate. The limit of detection is defined as the number of bacteria in a specimen that gives 95% detection rate (detected 95% of the time). The R-test Cholera Ag Rapid Test consistently detects suspensions containing at least 105 cfu/mL V. Cholera O1 and/or at least 105 cfu/mL V. Cholera O139Limit of Detection.

3. **Precision**

Three specimens composed of strong, weak and negative cholera antigen were tested against 10 devices at each condition. All of the devices identified the specimens correctly with the same line intensity at each given condition.

4. **Cross-Reactivity**

The cross-reactivity of the R-test Cholera Ag Rapid Test with other organisms was assessed using suspension of cultures of the following organisms at a concentration of 108 cfu/mL. None of the organisms show any cross-reactivity in the test:

Escherichia coli	Salmonella typhi	Shigella dysenterae type 1
Pseudomonas aeruginosa	Vibrio damsela	Vibrio vulnificus
Serratia marcescens	Vibrio hollisae	Vibrio harveyi
Vibrio cincinnatiensis	Vibrio ordalii	

5. **Interference**

The effects of multiple elevated analytes on the test performance of R-test Cholera Ag Rapid Test were assessed.

Analytes	Concentration Tested
Uric Acid	600 to 940 pmol/L
Hemoglobin	18 to 20 mg/dL
Total Bilirubin	34 to 65 pmol/L
Triglycerides	200 to 500 mg/dL

The results indicated that none of the above conditions interfered with R-test Cholera Ag Rapid Test.

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Results must be followed closely when testing the presence of V.Cholera antigens in human fecal specimen from individual subject.
- Failure to follow the procedure may give inaccurate results.
- The R-test Cholera Ag Rapid Test is limited to the qualitative detection of V. Cholera O1 and O139 antigen in human fecal specimen. The intensity of the test line does not have linear correlation with the antigen concentration of the specimen.
- A nonreactive result for an individual subject indicates absence of detectable V. Cholera antigen. However, a nonreactive test result does not preclude the possibility of exposure to or infection with V. Cholera bacteria.
- A nonreactive result can occur if the quantity of the V. Cholera antigen present in the specimen is below the detection limits of the assay or the antigen that are detected are not present in the fecal specimen picked by the stool collection device.
- Infection may progress rapidly. If the symptom persists, while the result from R-test Cholera Ag Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

REFERENCES

1. Sanyal SC. Cholera in its present day scenario. Curr Opin Infect Dis. J Indian Med Assoc. 2000 98(7):371-6.
2. Gardner, A.D., and Venkatraman, K.V. The antigens of the cholera group of vibrios. 3. Hyyg. 35:262-282, 1935.
3. Ramamurthy T, Yamasaki S, Takeda Y, Nair GB. Vibrio cholerae O139 Bengal: odyssey of a fortuitous variant. Microbes Infect. 2003, 5(4):329-44.
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5. Hasan JA, Huq A, Tamplin ML, Siebeling RJ, Colwell RR. A novel kit for rapid detection of Vibrio cholerae O1. J Clin Microbiol. 1994 32(1):249-52

Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test

50 tests per kit
Ref: R-24050

INTENDED USE

The R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of dengue NS1 antigen (DEN1, 2, 3, 4), Plasmodium falciparum (Pf) and vivax (Pv) antigen in human serum, plasma or whole blood specimen. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue & Plasmodium. Any reactive specimen with R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Dengue virus is an enveloped, single-stranded, positive-sense RNA virus that comprises four related but distinct serotypes (DEN1, 2, 3, and 4). The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally Aedes aegypti and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Malaria is a mosquito -borne, hemolytic, febrile illness that infects over 200 million people and kills more than 1 million people per year. It is caused by four species of Plasmodium: P. falciparum, P. vivax, P. ovale, and P. malariae. These plasmodia all infect and destroy human erythrocytes, producing chills, fever, anemia, and splenomegaly. P. falciparum causes more severe disease than the other plasmodial species and accounts for most malaria deaths. P. falciparum and P. vivax are the most common pathogens; however, there is considerable geographic variation in species distribution.

The R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test detects the circulating dengue NS1 antigen (DEN1, 2, 3, 4) & utilizes antibodies specific to P. falciparum Histidine Rich Protein II (pHRP-II) and to P. vivax Lactate Dehydrogenase (Pv-LDH) to simultaneously detect and differentiate infection with P. falciparum and P. vivax in human serum, plasma or whole blood. The test can be performed within 20-25 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test is a lateral flow chromatographic immunoassay.

The test strip for Dengue NS1 consists of: 1) a burgundy colored conjugate pad containing antibodies to dengue NS1 antigen conjugated with colloidal gold (dengue Ab conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with antibodies to dengue NS1 antigen, and the C line is pre-coated with a control line antibody. The antibodies to dengue NS1 recognize the antigens from all four dengue virus serotypes. When an adequate volume of specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Dengue NS1 antigen, if present in the specimen, will bind to the dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibodies to dengue NS1 antigen forming a burgundy colored T line. Suggested result interpretation: Ag positive: Early acute primary or secondary infection. Absence of T lines suggests a negative result.

The test strip for Malaria Pf/Pv Ag consist of: 1) a burgundy colored conjugate pad containing mouse anti-Pv-LDH antibody conjugated with colloidal gold (Pv-LDH-gold conjugates) and mouse anti-pHRP-II antibody conjugated with colloidal gold (pHRP-II-gold conjugates), 2) a nitrocellulose membrane strip containing two test bands (Pv and Pf bands) and a control band (C band). The Pv band is pre-coated with another mouse anti-Pv-LDH specific antibody for the detection of Pv infection, the Pf band is pre-coated with polyclonal anti-pHRP-II antibodies for the detection of Pf infection, and the C band is coated with Goat Anti Rabbit IgG. During the assay, an adequate volume of the blood specimen is dispensed into the sample well (S) of the test cassette, and a diluent buffer is added to the buffer well (B). The buffer contains a detergent that lyses the red blood cells and releases various antigens, which migrate by capillary action across the strip held in the cassette. Pv-LDH if present in the specimen will bind to the Pv-LDH-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Pv-LDH antibody, forming a burgundy colored Pv band, indicating a Pv positive test result. Alternatively, pHRP-II if present in the specimen will bind to the pHRP-II-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-pHRP-II antibodies, forming a burgundy-colored Pf band, indicating a Pf positive test result. Absence of any test bands suggests a negative result.

Each test contains an internal control (C lines) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies in both the left and right panels, regardless of color development on any of the test lines. If the C line does not develop in a panel, the test result is invalid and the specimen must be retested with another device. An invalid result in one panel does not invalidate the test result in the other panel.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One test device
  - One desiccant
- Diluent Buffer for Dengue NS1 in 5ml bottle
- Diluent Buffer for Malaria Pf/Pv in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Capillary tubes (20 µL)
- Clock or timer
- Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 20-30 minutes after a specimen is applied to the sample well or sample well of the device. Reading result after 30 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e., electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Collect whole blood in a clean container containing anti-coagulant (EDTA, citrate or heparin) by venipuncture. Blood can be obtained by fingertip puncture as well. Whole blood specimen should be stored in refrigeration (2°C-8°C) if not tested immediately for up to 3 days. The specimen should be frozen at -20°C for longer storage. Avoid repeat freeze and thaw cycles.

ASSAY PROCEDURE

Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Be sure to label the device with the specimen's ID number.

For Dengue NS1 Antigen

Fill the plastic dropper with specimen. Holding the dropper vertically, dispense 2 drops (about 60 µL) of serum/plasma or 2 drops of whole blood (about 70 µL) into the center of the sample well (S well), making sure that there are no air bubbles. Immediately add 1 drop (about 30-40 µL) of diluent buffer to the sample well (S well) with the bottle positioned vertically.

Read results at 20 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 25 minutes only. However, any results interpreted outside of the 20 to 25-minute window should be considered invalid and must be repeated.

For Malaria Pf/Pv Antigen

Fill the blood transfer device (sample loop, mini plastic dropper or capillary tube) with the specimen. The volume of the specimen is around 5 µL. Practice a few times prior to testing if you are not familiar with the blood transfer device. For better precision, transfer specimen by pipette capable of delivering a 5µL volume. Holding the blood transfer device (sample loop, mini plastic dropper or capillary tube) vertically, dispense the entire specimen into the center of the sample well making sure that there are no air bubbles. Then add 3 drops (about 105-150 µL) of Diluent Buffer immediately.

Results can be read in 30 minutes. It may take more than 20 minutes to have the background become clearer. Don't read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in the test bands (T, Pv, Pf) indicates that no antigens are detected. The result is negative.
- **INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands. Repeat the assay with a new device.
- **POSITIVE RESULT:** In addition to the presence of the C band, if the T band is developed, the test indicates the presence of NS1 antigen. The result is Dengue NS1 positive.
- In addition to the presence of the C band, if only the Pf band is developed, the test indicates the presence of pHRP-II antigen. The result is Pf positive.

- In addition to the presence of the C band, if only the Pv band is developed, the test indicates the presence of Pv-LDH antigen. The result is Pv positive.

- In addition to the presence of the C band, both the Pv and Pf bands are developed, the test indicates the presence of both Pv-LDH and pHRP-II antigens. The result is both Pv and Pf positive.

Samples with reactive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a final diagnostic decision is made.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for Dengue NS1 Ag Test

A total of 120 specimens were collected from susceptible subjects and normal healthy control subjects, and tested by the R-test Dengue NS1 Ag Rapid Test and by a commercial Dengue Ag ELISA. Comparison for all subjects is shown in the following table:

Table 1

	R-test Dengue NS1 Ag Rapid Test		
Ag EIA Test	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	1	99	100
Total	21	99	120

Relative Sensitivity: 100%, Relative Specificity: 99%, Overall Agreement: 99.2%

2. Clinical Performance for Malaria Pf/Pv Ag

A total of 200 blood samples were collected and tested by R-test Malaria Pf/Pv Ag Rapid Test and by thick blood smear test. Comparison for all subjects is shown in the following table.

Table 1

	Pf		Pv	
	Positive	**Negative**	**Positive**	**Negative**
Smear Test	90	110	100	100
R-Test Malaria Pf/Pv Ag Rapid test	85	115	98	102

Pf detection: Sensitivity:94.4%, Specificity: 100%;

PV Malaria detection: Sensitivity: 98 %, Specificity: 100 %; Kappa value: 92%

3. Cross-Reactivity

Pv and Pf cross reaction:

The negative blood specimen was spiked with recombinant Pv-LDH, Pf-LDH and pHRP-II antigen, and tested with the R-test Malaria Pf/Pv Ag Rapid Test, respectively. The result showed that the Pv detection system did not cross-react to the Pf Ag and vice versa.

Antigen Concentration	Pf - Reactivity	Pv - Reactivity
1.0 mg/mL pHRP-II	Positive	Negative
1.0 mg/mL Pv-LDH	Negative	Positive
1.0 mg/mL Pf-LDH	Negative	Negative

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assy Result sections must be followed closely when testing the presence of plasmodium protozoa / Dengue NS1 antigen in whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test is limited to the qualitative detection of plasmodium protozoa / Dengue NS1 antigen in whole blood. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.
- A negative result for an individual subject indicates absence of detectable antigen. However, a negative test result does not preclude the possibility of exposure to or infection with plasmodium protozoa/ Dengue Virus.
- A negative result can occur if the quantity of the antigen present in the specimen is below the detection limits of the assay or the antigens that are detected are not present during the stage of disease in which a sample is collected.
- A recent study showed that due to their genetic diversity some Pf isolates collected in the Peruvian Amazon lack the HRP2 gene7. Therefore, a negative result in the Pf band may not rule out infection of Pf in this area.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Dengue NS1 Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-22050

INTENDED USE

The R-test Dengue NS1 Ag Rapid Test is a lateral flow chromatographic immunoassay for the detection of dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with dengue virus.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

Dengue virus is an enveloped, single-stranded, positive-sense RNA virus that comprises four related but distinct serotypes (DEN1, 2, 3, and 4). The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally Aedes aegypti and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Serological detection is a common method for the diagnosis of infection with dengue virus. Detection of antigens, such as dengue NS1, released during virus replication in the infected patient show very promising results; it enables diagnosis from the first day after the onset of fever up to day 9 once the clinical phase of the disease is over, thus, allowing early detection and prompt treatment.

The R-test Dengue NS1 Ag Rapid Test circulating dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It can be performed within 20-25 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test Dengue NS1 Ag Rapid Test is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing antibodies to dengue NS1 antigen conjugated with colloidal gold (dengue Ab conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with antibodies to dengue NS1 antigen, and the C line is pre-coated with a control line antibody. The antibodies to dengue NS1 recognize the antigens from all four dengue virus serotypes.

When an adequate volume of specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Dengue NS1 antigen, if present in the specimen, will bind to the dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibodies to dengue NS1 antigen forming a burgundy colored T line.

Suggested result interpretation: Ag positive: Early acute primary or secondary infection. Absence of T lines suggests a negative result. Each test contains an internal control (C lines) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies in both the left and right panels, regardless of color development on any of the test lines. If the C line does not develop in a panel, the test result is invalid and the specimen must be retested with another device. An invalid result in one panel does not invalidate the test result in the other panel.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Capillary tubes (20 µL)
- Plastic droppers
- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test result should be read 20-25 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 20-25 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e., electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

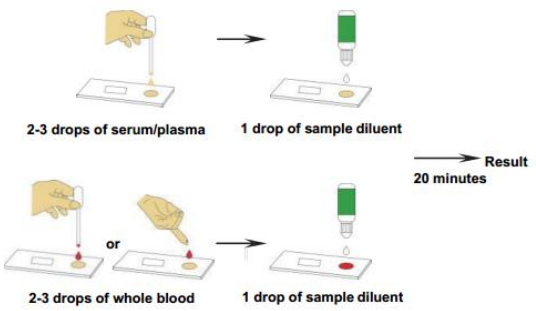
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with specimen. Holding the dropper vertically, dispense 2 drops (about 60 µL) of serum/plasma or 2 drops of whole blood (about 70 µL) into the center of the sample well (S well), making sure that there are no air bubbles. Immediately add 1 drop (about 30-40 µL) of diluent buffer to the sample well (S well) with the bottle positioned vertically.



Step 5: Set up the timer.

Step 6: Read results at 20 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 25 minutes only. However, any results interpreted outside of the 20 to 25-minute window should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in the T line indicates that no dengue virus NS1 antigen is detected. The result is negative or non-reactive.
- **INVALID:** If no C line develops, the assay is invalid regardless of any burgundy color in the T line as indicated below. Repeat the assay with a new device.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of dengue virus NS1 antigen in the specimen. The result is positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.*

PERFORMANCE CHARACTERISTICS

1. Limit of Detection

The R-test Dengue NS1 Ag Rapid Test was found to detect NS1 protein in all 4 types of dengue virus lysate I, II, III, and IV. The limit of detection is 0.25 ng/mL as determined on recombinant dengue NS1 antigen from serotype 2 (DEN2).

2. Clinical Performance

A total of 120 specimens were collected from susceptible subjects and normal healthy control subjects, and tested by the R-test Dengue NS1 Ag Rapid Test and by a commercial Dengue Ag ELISA. Comparison for all subjects is shown in the following table:

Table 1

	R-test Dengue NS1 Ag Rapid Test		
Ag EIA Test	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	1	99	100
Total	21	99	120

Relative Sensitivity: 100%, Relative Specificity: 99%, Overall Agreement: 99.2%

3. Cross-Reactivity

Specimens from other infectious diseases were tested for cross-reactivity with the R-test Dengue NS1 Ag Rapid Test according to the standard procedure. The results showed that the following specimens (n=1-10) did not cross-react with the R-test Dengue NS1 Ag Rapid Test.

Chikungunya	**CMV**	**HAV**	**HBV**	**HCV**
HIV	**hCG**	***H.pylori***	**TB**	***T. gondii***
Typhoid	**Rubella**	**ANA**	**HAMA**	**RF (up to 8,400 IU/mL)**

4. Interference

Common substances (such as pain and fever medication, blood components) may affect the performance of the R-test Dengue NS1 Ag Rapid Test. This was studied by spiking these substances into negative and positive standard controls for dengue NS1 antigen. The results are presented in the following table and demonstrate, at the concentrations tested, the substances studied do not affect the performance of the R-test Dengue NS1 Ag Rapid Test.

List of potentially interfering chemical analytics and concentrations tested:

1. Albumin	60 g/L	5. Glucose	5.5 mmol/L
2. Bilirubin	20 mg/dL	6. Heparin	3,000 U/L
3. Creatinine	442 µmol/L	7. Sodium citrate	3.8%
4. EDTA	3.4 µmol/L	8. Salicylic acid	4.34 mmol/L

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to dengue virus and dengue NS1 antigen in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test Dengue NS1 Ag Rapid Test is limited to the qualitative detection of antibodies to dengue virus and dengue NS1 antigen in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibodies and NS1 antigen titers in the specimen.
- Information about the dengue virus serotype(s) present in a specimen cannot be provided from this test.
- Serological cross-reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile virus, yellow fever, etc.). Therefore, it is possible that patients who were exposed to these viruses may show some level of reactivity with this test.
- A negative or non-reactive result for an individual subject indicates absence of detectable dengue virus antibodies or NS1 antigen. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with dengue virus.
- A negative or non-reactive result can occur if the quantity of antibodies to dengue virus or dengue NS1 antigen present in the specimen is below the detection limits of the assay or the antibodies and antigen that are detected are not present during the stage of disease in which a sample is collected.
- Infection may progress rapidly. If the symptoms persist while the result from the R-test Dengue NS1 Ag Rapid Test is negative or non-reactive, it is recommended to test with an alternative method, such as PCR or ELISA.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Flu A/B & RSV Rapid Test

RELIABLE TESTING

25 tests per kit

Ref: R-27025

INTENDED USE

The R-test Flu A/B & RSV Rapid Test is qualitative in-vitro immunoassay for the rapid detection of influenza A/B antigens and respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab specimens for symptomatic patients. The test is intended for use as an aid in the differential diagnosis of influenza A/B viral and RSV infections in humans in conjunction with clinical and epidemiological risk factors.

SUMMARY AND EXPLANATION OF THE TEST

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not a severe as that caused by the type A virus.

RSV is a causative agent of highly contagious, acute, viral infection of the respiratory tract in pediatric populations. Respiratory syncytial virus is a single-stranded RNA virus, spherical with a medium-sized diameter 80-150 nm. The virus could easily affect infants with bronchiolitis and bronchiolar pneumonia, it is cause for 60% of acute infant asthmatic bronchitis and pneumonia. Adolescents and adults are mainly affected by upper respiratory tract infection.

An accurate diagnosis of influenza and RSV based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing. Early differential diagnosis of RSV and influenza type A or type B can allow for proper treatment with appropriate antiviral therapy. Early diagnosis and treatment are of particular value in a clinical setting where accurate diagnosis can assist the healthcare professional with management of 2019-nCoV and influenza patients who are at risk for complications.

The R-test Flu A/B & RSV Rapid Test is a rapid immunoassay to be used as an aid for the differential diagnosis of influenza type A and type B and RSV.

TEST PRINCIPLE

The R-test Flu A/B & RSV Rapid Test is an immunochromatographic membrane assay and contains two independent tests, the FLU A/B antigen test and the RSV antigen test. In the test procedure, a specimen is collected and placed for one minute into the Extraction Well of the test device containing extraction solution, during which time antigen is extracted from disrupted virus particles. The test device is then raised, tapped and laid back down onto a level surface to allow the solution in the Extraction Well to migrate through the pads containing lyophilized detector antibodies conjugated to gold dye and then through the test membrane.

The Flu A/B antigen test uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasal swab specimens. These antibodies and a control protein are immobilized onto a membrane support as three distinct lines and are combined with other reagents/pads to construct a Test Strip. The Flu A/B antigen test has two Test lines, one for influenza A and one for influenza B. The two Test lines allow for the separate and differential identification of influenza A and/or B from the same specimen. If either Test line appears in the test result window, together with the Control line, the test result is positive for influenza.

The RSV antigen test is a qualitative lateral flow immunoassay technology for the rapid detection of RSV antigen in human nasopharyngeal samples. The membrane is pre- coated with monoclonal antibodies against RSV antigens on the test line region. During testing, the sample reacts with particles coated with the anti-RSV antibodies which was pre-dried on the conjugate release pad. The resulting complex overflows a nitrocellulose membrane where a specific capture reagent is pre-coated and a red line can be seen at the test zone (T). Un-reacted colloidal gold-labeled antibody in the sample is captured at the control zone (C).

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Swabs
- Diluent Buffer in Vial
- Buffer Tube / Dripper
- One package Insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not use expired devices.
3. Use only the swabs provided for collecting swab samples. Other swabs may not work properly.
4. Do not use the components in any other type of test kit as a substitute for the components in this kit.
5. Extraction Reagent is slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If the reagent comes in contact with skin or eyes, flush with a large volume of water.
6. Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
7. All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and test devices.
8. The Test device should remain in its original sealed pouch until ready for use.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Collect nasopharyngeal/oropharyngeal swab according to the clinical collection guidelines of laboratory test samples. Avoid contamination during sample collection, transfer and storage;

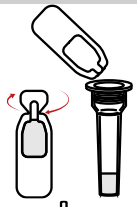
To collect the nasopharyngeal/oropharyngeal swab sample, carefully insert the swab into the nostril and pharynx exhibiting the most visible drainage, or the nostril and pharynx that are most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates and pharynx posterior wall. Rotate the swab 5 times or more against the nasopharyngeal wall then slowly remove from the nostril and pharynx.

Specimen storage

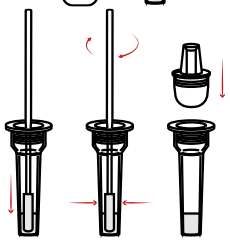
For best performance, direct nasopharyngeal/oropharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasopharyngeal/oropharyngeal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the nasopharyngeal/oropharyngeal swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

SPECIMEN EXTRACTION

Insert the extraction tube into the test tube rack;
Twist off the head of the buffer, dispense all the buffer into the extraction tube;



Insert the swab into the extraction tube containing extraction buffer;
Rotate the swab at least 6 times while pressing the head against the bottom and sides of the extraction tube;
Place the swab in the extraction tube for 1 minute;
The extracted solution will be used as a test sample.



ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature (15-30°C) before use.
2. Open foil pouch, take out the test and lay it on an even and flat surface.
3. Hold the Extraction tube vertically and dispense 3 drops (about 90-100ul) of Extraction reagent with specimen into the sample well of the test device.
4. Read the result after 15 minutes.

INTERPRETATION OF ASSAY RESULT

- **POSITIVE RESULT:** A reddish-purple Control line (C position) and T Test line indicate that RSV antigen has been detected.

  A reddish-purple Control line (C position) and a reddish-purple Test line (A) indicate that Influenza A antigen has been detected. A reddish-purple Control line (C position) and a reddish-purple Test line (B position) indicate that Influenza B antigen has been detected. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

  Determination of a positive result can be made as soon as a visible Test line (either T, A, or B) and Control line appear. The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.
- **NEGATIVE RESULT:** Only a reddish-purple Control line (C position), with no Test line at either T, A, or B indicates that neither RSV antigen nor Influenza A or B antigen has been detected. A negative result does not exclude RSV or influenza A / B viral infection. Determination of negative results should not be made before 15 minutes. If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new Test device.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T, A, or B lines. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for Influenza A Test

A total of 316 samples from susceptible subjects were tested with the R-test Flu A/B Rapid Test. Comparison for all subjects is shown in the following table.

	R-test Flu A Rapid Test		
DFA Test Result	**Positive**	**Negative**	**Total**
Positive	110	5	115
Negative	0	201	201
Total	110	206	316

Relative Sensitivity: 100%, Relative Specificity: 97.6%

2. Clinical Performance for Influenza B Test

A total of 316 samples from susceptible subjects were tested with the R-test Flu A/B Rapid Test. Comparison for all subjects is shown in the following table.

	R-test Flu B Rapid Test

RT-PCR Test Result	Positive	Negative	Total
Positive	91	0	91
Negative	6	219	225
Total	97	219	316

Relative Sensitivity: 100%, Relative Specificity: 97.3%

3. Clinical Performance of RSV Ag

The R-test RSV Rapid Test was used to evaluate the clinical performance with specimens collected from 240 patients. The test result showed that the positive coincidence rate is 89.2%, the negative coincidence rate is 100% and the total coincidence rate is 97.1%, and the consistency coefficient Kappa (K) value is 0.924 (P < 0.05).

	R-test RSV Rapid Test		
DFA	**Positive**	**Negative**	**Total**
Positive	89	0	89
Negative	14	137	151
Total	103	137	240

4. Cross-Reactivity

To determine the specificity of the R-test Flu A/B & RSV Rapid Test, the following organisms were tested and produced a negative result.

- Pneumococcus
- Flu A virus
- Flu B virus 4
- EB virus
- Streptococcus A

None of the organisms or viruses listed in the table below gave a positive result with the Test at the tested concentration.

LIMITATIONS OF PROCEDURE

- This test is for in- vitro diagnostic use only and cannot be re-used.
- The used test should be treated as potentially infectious materials and should be disposed of properly.
- The test kit should be kept away from direct sunlight, moisture and heat.
- Please check if the test kit has any damage and check the expiry date before use.
- The sample volume will affect the accuracy of the test result. Inaccurate sample volume may cause a false positive or negative result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.
- Please be very careful when collecting nasopharyngeal swab specimen from children.
- Components from different batches are not allowed to be used in combination.

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2. Rodriguez WJ: Management strategies for respiratory syncytial virus infection. Journal of Pediatrics, 1999; 135: S45-S50.
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5. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC, 2007.

Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
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Revised:02/2022

R-test FOB Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-37050

INTENDED USE

The R-test FOB Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of fecal occult blood (FOB) in human fecal specimens in laboratories or physician offices. It is intended to be used by healthcare professionals to aid in the detection of bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

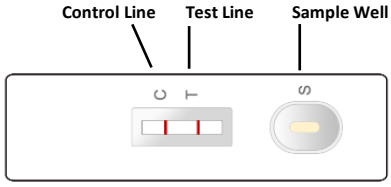
SUMMARY AND EXPLANATION OF THE TEST

The American Cancer Society and Centers for Disease Control recommend an occult blood feces test annually after age 50 to aid in the early detection of colorectal cancer. Two types of FOB tests are commercially available: guaiac dye tests and immunochemical tests (iFOBT). The guaiac tests are widely used but lack accuracy. The guaiac dye is a naturally occurring phenolic compound that can be oxidized to quinone by hydrogen peroxidase activity of human hemoglobin (hHb) resulting in a detectable color change. The sensitivity and specificity of guaiac tests are much lower than those of immunochemical assays. The low accuracy of the guaiac tests is related to dietary peroxidases, including hemoglobin from meat and uncooked fruits and vegetables. Non-cancerous gastrointestinal tract bleeding and iron intake may also cause false positive results with guaiac tests.

Immunochemical tests are highly accurate for the detection of hHb compared to the guaiac method. The results of immunochemical FOB tests (iFOBT) are not affected by dietary peroxidases, animal blood or ascorbic acid. A Japanese study demonstrated that iFOB screening tests reduced mortality of colorectal cancer by 60%. The R-test FOB Rapid Test is an iFOBT designed to specifically detect low levels of human fecal occult blood. It can be performed within 10 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test FOB Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a colored conjugate pad containing monoclonal anti-hHb antibody conjugated with colloid gold (anti-hHb conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another monoclonal anti-hHb antibody, and the C line is pre-coated with a control line antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. hHb, if present in the specimen at or higher than 25 ng/mL, will bind to the anti-hHb conjugates. The immunocomplex is then captured by the pre-coated reagent forming a colored T line, indicating a FOB positive test result. Absence of the T line suggests a negative result. Each test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control line antibodies regardless of the color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.



REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Stool collection devices, each containing 2 mL sample extraction buffer
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
3. Do not open the sealed pouch unless ready to conduct the assay.
4. Do not use any kit components beyond their stated expiration date.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Bring all reagents to room temperature (15-30°C) before use.
7. Do not scoop fecal specimen as this may lead to excess fecal specimen that may block the sample well and result in an invalid test result.
8. Do not use specimens for testing if blood is visible.
9. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
10. Users of this test should follow the US CDC Universal Precautions for bio-safety.
11. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
12. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
13. The testing results should be read 10 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside 10 minutes should be considered invalid and must be repeated.
14. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

Patient Preparation

Specimens should not be collected from patients with the following conditions which may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding

Dietary restrictions are not necessary. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, and produce positive reactions. On the advice of a physician, these medicines may be temporarily discontinued for 7 days prior to and during the test period.

Specimen Collection

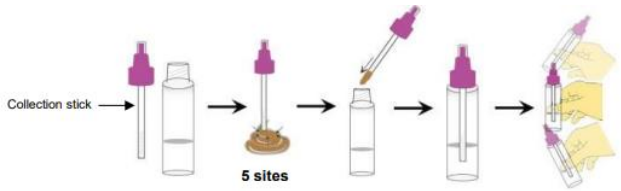
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Step 1: Collect a random sample of feces in a clean, dry receptacle.

Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool specimen in at least five different sites. Do not scoop stool specimen. Ensure that stool specimen is only in the grooves of the collection stick. Excess stool specimen may lead to an invalid test result.

Step 3: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously to extract the hHb in the specimen. The specimen is now ready for testing, transportation or storage.



Note: It is recommended to test the specimen immediately after extraction. If not tested immediately, the extracted specimen may be stored at room temperature (20-37°C) for up to 10 days or at 2-8°C for up to 21 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple freeze-thaw cycles.

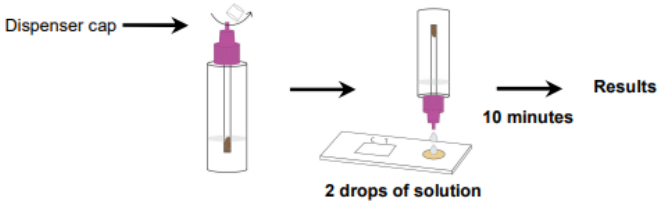
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure a homogenous liquid suspension.

Step 4: Hold the stool collection device vertically. Twist off the tip. Dispense 2 drops (70-90 µL) of the solution into the sample well of the cassette. Do not overload samples.



Step 5: Set up timer.

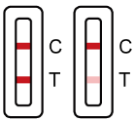
Step 6: Results can be read at 10 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of the 10 minutes only. However, any results interpreted outside 10 minutes should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.

QUALITY CONTROL

- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher-than-expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

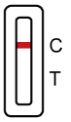
INTERPRETATION OF ASSAY RESULT

Positive (+):



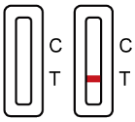
In addition to the presence of the C line, if the T line develops, the test indicates that the concentration of hHb in the sample is equal to or higher than 25 ng/mL in buffer. The result is FOB positive or reactive.
Specimens with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

Negative (-):



If only the C line develops, the test indicates that the concentration of hHb in the sample is below 25 ng/mL in buffer. The result is negative or non-reactive.

Invalid:



If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new device. If caused by an excess amount of fecal specimen collected, collect a new specimen and retest.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The analytical sensitivity of the test is 25 ng/mL hHb in buffer or 3.5 µg/g hHb in feces.

2. Specificity

The R-test FOB Rapid Test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

Chicken Hemoglobin 2 mg/mL	Horse Hemoglobin 2 mg/mL
Turkey Hemoglobin 2 mg/mL	Sheep Hemoglobin 2 mg/mL
Pig Hemoglobin 2 mg/mL	Fish Hemoglobin 2 mg/mL
Beef Hemoglobin 2 mg/mL	Rabbit Hemoglobin 2 mg/mL
Goat Hemoglobin 2 mg/mL	

3. Dose Hook Effect

The R-test FOB Rapid Test cassettes do not show any hook effect or prozone effect up to the concentration of 4 mg/mL hHb in buffer.

4. Reproducibility

Known positive specimens were tested in multiple assays and identically positive results were observed. Similarly, known negative specimens produced negative results when tested in multiple assays.

5. Clinical Performance

A total of 135 specimens were collected and tested by the R-test FOB Rapid Test and by a leading commercial FOB rapid test. Comparison for all specimens is shown in the following table:

	R-test FOB Rapid Test		
Reference Test	**Positive**	**Negative**	**Total**
Positive	46	2	48
Negative	1	86	87
Total	47	88	135

Relative Sensitivity: 95.8% (95% CI: 85.7-99.5%), Relative Specificity: 98.9% (95% CI: 93.8-100%), Overall Agreement: 97.8% (95% CI: 93.6-99.5%).

6. Interference

Common substances (such as pain and fever medication, blood components) may affect the performance of the R-test FOB Rapid Test. This was studied by spiking these substances into negative serum and negative serum samples spiked with two levels of FOB standard controls (negative and positive). The results demonstrate, at the concentrations tested, the substances studied do not affect the performance of the R-test FOB Rapid Test.

List of potentially interfering substances and concentrations tested:

Ascorbic acid 20 mg/dL	Glucose 2,000 mg/dL
Dietary iron (Fe2+/Fe3+) 5 mg/dL	Caffeine 40 mg/dL
Bilirubin 100 mg/dL	Horseradish Peroxidase 20 mg/mL

LIMITATIONS OF PROCEDURE

- The Test Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of occult blood in feces. Failure to follow the procedure may give inaccurate results.
- The R-test FOB Rapid Test is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.
- A negative or non-reactive result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. A negative or non-reactive result can also be obtained if the quantity of occult blood present in the specimen is below the detection limit of the assay.
- The R-test FOB Rapid Test has not been validated for testing of patients with hemoglobinopathies.
- Specimens containing visible blood may produce negative results due to the hook effect.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:02/2022

R-test H. pylori Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-16050

INTENDED USE

The R-test H. pylori Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Helicobacter pylori antigens in human stool samples in vitro, and is suitable for the auxiliary diagnosis of Helicobacter pylori infection.

The R-test H. pylori Ag Rapid Test is not intended for quantitative results. It provides only preliminary analytical data. For a final diagnosis of Helicobacter pylori infection, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

SUMMARY AND EXPLANATION OF THE TEST

Helicobacter pylori is a spiral-shaped, micro-anaerobic, Gram-negative bacillus that requires very harsh growth conditions. It is the only microbial species known to survive in the human stomach. Helicobacter pylori is parasitic in the gastric mucosa, and 67% to 80% of gastric ulcers and 95% of duodenal ulcers are caused by Helicobacter pylori. Helicobacter pylori settled on the surface of gastric epithelial cells is shed with the rapid renewal of gastric mucosal epithelium, and Helicobacter pylori is also shed and excreted from the feces through the gastrointestinal tract. There are many diagnostic methods for Helicobacter pylori infection, such as biopsy, isolation and culture of Helicobacter pylori, rapid urease test, urea breath test, urine ammonia excretion test, serological test and polymerase chain reaction. This product is used as an auxiliary diagnosis for Helicobacter pylori infection by detecting the Helicobacter pylori antigen in human stool samples.

The R-test H. pylori Ag Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of Helicobacter pylori infection via assay of H. pylori Ag. The test can be performed within 5 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test H. pylori Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-HP antibody conjugated with colloid gold (HP Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (Cline). The T line is pre-coated with another anti-HP antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. If it is a positive sample, it will bind to the HP Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-HP Ab, forming a burgundy colored T band, indicating an HP positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer
- A container to collect stool specimen

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of oral-food borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 5-10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 5-10-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Collect a stool specimen in a clean glass, plastic, or wax coated container.

Samples should be sent for inspection in time after collection. If they need to be stored, they should be refrigerated at 2-8°C for 72 hours.

ASSAY PROCEDURE

Step 1: Unscrew the cap of the sample tube, take out the stool sample, and be careful not to spill the solution in the bottle.

Step 2: Randomly sample about 50 mg from at least 3 different locations of the sample with a stool stick. Then insert it into the sample tube, tighten the cap, and stir well.

Step 3: Equilibrate the test reagents and samples to room temperature, tear open the aluminum foil bag, take out the test card, and place it flat.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90 μL) of specimen into the sample well making sure that there are no air bubbles.

Note: Add 1 drop of Diluent buffer into the sample well if flow migration is not observed within 30 seconds in the result window when tested with serum samples, which could occur with a highly viscous specimen.

Step 5: Set up the timer.

Step 6: Result should be read at 5 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15-30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable HP is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of HP in the specimen. The result is HP positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.*
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

300 fecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with the R-test H. pylori Ag Rapid Test and with the UBT as reference test. A comparison of the results for all subjects is shown in the table below.

	R-test H. pylori Ag Rapid Test		
UBT	**Positive**	**Negative**	**Total**
Positive	115	5	120
Negative	2	178	180
Total	117	183	300

Sensitivity: 95.8%, Relative Specificity: 98.9%, Overall Agreement: 97.7%

2. Limit of Detection

The detection limit for the R-test H. pylori Ag Rapid Test is 5 ng/ml of H. pylori lysate. Fecal specimen extractions containing H. pylori lysate equal to or greater than 5 ng/ml routinely test positive. Specimens containing H. pylori lysate less than 5 ng/ml may also produce a very faint positive line, especially with an assay time extended beyond 15 minutes.

3. Analytic Sensitivity

The following experiments were done to validate the sensitivity of the R-test H. pylori Ag Rapid Test:

Normal fecal specimen extractions were spiked with H. pylori lysate to concentrations of 0, 1.25, 2.5, 5, 10, 20 ng/ml. The specimens were run on the H. pylori Ag Cassette Rapid Test. Results are shown in the table below.

H. pylori lysate ng/mL	**0**	**1.25**	**2.5**	**5**	**10**	**20**
Number of positive	0	0	12	20	20	20
Number of negative	20	20	8	0	0	0

n=20 relative sensitivity at 5 ng/mL = 20/20 x 100% = 100%

PRECAUTIONS

- Please operate in strict accordance with this manual and strictly control the reaction time.
- This kit is a one-time-use product for in vitro diagnosis only. Reagents beyond the expiration date or with damaged packaging shall not be used in the test.
- The testing of the samples must be carried out in a specific environment, and the samples that come into contact during the testing process should be operated in accordance with the laboratory inspection procedures for infectious diseases.
- It is recommended to complete the test within 6 hours after sample collection.
- The small cup that holds the feces must be clean and not reusable to avoid contamination. Test samples should avoid repeated freezing and thawing, and samples contaminated with bacteria should not be used for testing, so as not to affect the test results. Samples stored at 4°C should be equilibrated to room temperature before use.
- Samples should be collected according to the sample collection method described in this manual. Samples should not be collected during the menstrual period, hemorrhoid bleeding and hematuria, so as not to affect the test results.
- Because there may be substances in the sample to be tested that interfere with the test results, and there may be errors in actual operation, the experimental results may be wrong. Therefore, suspicious test results should be re-examined or combined with other detection methods to clarify the experimental results.
- Beware of getting the test strip/card wet, use it as soon as possible within 30 minutes after opening the inner package, and do not use the test card when it is wet.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HBsAg Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-12050

INTENDED USE

The R-test HBsAg Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with hepatitis B virus (HBV). Any reactive specimen with the R-test HBsAg Rapid Test must be confirmed with alternative testing method(s) such as ELISA and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis virus B (HBV) is the most common cause of persistent viremia and the most important cause of chronic liver disease and hepatocellular carcinoma. Clinically apparent HBV infections may have been in existence for several millennia. It is estimated that there are 300 million chronic carriers of HBV in the world. The carrier rates vary from as little as 0.3% (Western countries) to 20% (Asia, Africa).

HBV is a hepatotropic, DNA virus. The core of the virus contains a DNA polymerase, the core antigen (HBcAg) and the e antigen (HBeAg). The core of HBV is enclosed in a coat that contains lipid, carbohydrate and protein including an antigen termed hepatitis B surface antigen (HBsAg).

HBsAg is the first marker to appear in the blood in acute hepatitis B, detectable 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. Three weeks after the onset of acute hepatitis almost half of the patients will still be positive for HBsAg. In the chronic carrier state HBsAg persists for long periods (6-12 months) with no seroconversion to the corresponding antibodies. Therefore, screening for HBsAg is highly desirable for all donors, pregnant women and people in high-risk groups.

The R-test HBsAg Rapid Test detects HBsAg in human serum, plasma or whole blood in 15 minutes and can be performed by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test HBsAg Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-HBsAg antibody conjugated with colloidal gold (HBsAg Ab conjugates) and a control antibody conjugated with colloidal gold, and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another mouse anti-HBsAg antibody and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the strip. HBsAg, if present in the specimen, will bind to the HBsAg Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated HBsAg antibody forming a burgundy colored T line, indicating a HBsAg positive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of control antibodies regardless of the color development on T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer
- Lancing device

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test result should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15–20-minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

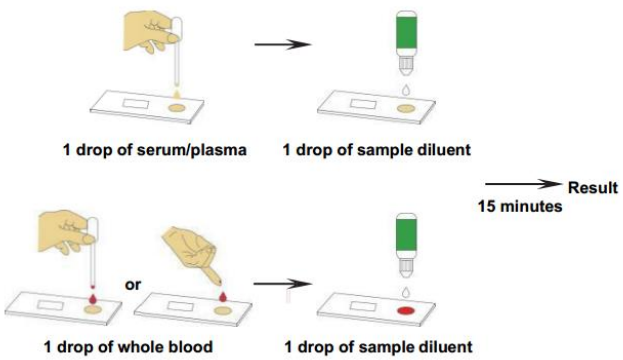
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (45 -50 µL) of serum/plasma or 1 drop (45 -50 µL) of whole blood into the center of sample well making sure that there are no air bubbles.

Immediately add 1 drop (30 - 40 µL) of Diluent buffer into the sample well with the bottle positioned vertically.



Step 5: Set up the timer.

Step 6: Read the result in 15 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 20 minutes only. Any results interpreted outside of the 15 to 20-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that HBsAg is not detected in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates that the specimen contains HBsAg. The result is positive or reactive.
  Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Analytic Detection Limit

The test has been shown to detect HBsAg at a concentration as low as 0.5 ng/ml in some specimens.

2. Clinical Performance

A total of 920 samples from susceptible subjects were tested with the R-test HBsAg Rapid Test and with a commercial HBsAg ELISA kit. Comparison for all subjects is shown in the following table.

Table 1

	R-test HBsAg Rapid Test		
HBsAg Elisa	**Positive**	**Negative**	**Total**
Positive	210	0	210
Negative	0	710	710
Total	210	710	920

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

3. Cross-Reactivity

Cross-reactivity with specimens from other infectious diseases is shown in the following table.

Table 2

Specimen	Sample Size	R-test HBsAg Rapid Test
Dengue Positive Serum	10	Negative
HAV Positive Serum	20	Negative
HCV Positive Serum	20	Negative
HIV Positive Serum	20	Negative
Syphilis Positive Serum	20	Negative
TB Positive Serum	20	Negative
H. Pylori Positive Serum	20	Negative
ANA Positive Serum	6	Negative
HAMA Positive Serum	4	Negative
RF Positive Serum (≤2,500 IU/ ml)	3	Negative

4. Interference

Common substances (such as pain and fever medication and blood components) may affect the performance of the R-test HBsAg Rapid Test. This was studied by spiking these substances into three levels of HBsAg standard controls. The results are presented in the following table and demonstrate that at the concentrations tested, the substances studied do not affect the performance of the R-test HBsAg Rapid Test.

Table 3

Potential Interfering Substance Spiked	HBsAg Reactivity		
	Negative	**Positive**	**Medium Positive**
Control	-	+	++
Bilirubin 20 mg/dL	-	+	++
Creatinine 442 µmol/L	-	+	++
Glucose 55 mmol/L	-	+	++
Albumin 50 g/L	-	+	++
Salicylic Acid 4.34 mmol/L	-	+	++
Heparin 3,000 U/L	-	+	++
EDTA 3.4 µmol/L	-	+	++
Human IgG 1,000 mg/dL	-	+	++
Sodium Citrate 3.8%	-	+	++

Note: -: Negative, +: Positive, ++: Medium Positive

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of HBsAg in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- The R-test HBsAg Rapid Test is limited to the qualitative detection of HBsAg in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the concentration of HBsAg in the specimen.
- A negative or non-reactive test result does not preclude the possibility of exposure to or infection with HBV. A negative or non-reactive result can occur if the concentration of HBsAg present in the specimen is below the level detectable by the assay or HBsAg was not present during the stage of disease in which a sample was collected.
- If the symptoms persist and the result from the R-test HBsAg Rapid Test is negative or nonreactive, it is recommended to re-sample the patient two weeks later or test with an alternative test method.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (>2,500 IU/ml) may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test hCG Rapid Test

RELIABLE TESTING

150 tests per kit
Ref: R-11150S

INTENDED USE

The R-test hCG Rapid Test is a lateral flow chromatographic immunoassay for the early detection of pregnancy, by providing a quick direct visual test for the placental hormone, hCG, at the cut-off level of 10 mIU /mL of human urine or serum.

The R-test hCG Rapid Test is not intended for quantitative results. It provides only preliminary analytical data. For a final diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) is produced by trophoblastic tissue and it appears around the 8-9th day after ovulation where fertilization has occurred, or around the 4th day after conception. In a 28-day cycle with ovulation occurring at day 14 hCG can be detected in urine or serum in minute quantities around day 23, or 5 days before the expected menstruation. Its function includes facilitation of implantation as well as maintenance and development of the corpus luteum. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/mL. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester. In normal subjects, hCG in urine provides an early indication of pregnancy. Since elevated hCG levels are also associated with trophoblastic disease and certain nontrophoblastic neoplasms, the possibility of having these diseases must be eliminated before a diagnosis of pregnancy can be made.

The R-test hCG Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of early pregnancy detection via assay of hCG, a placental hormone that may be present in human serum or urine. The test can be performed within 5 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test hCG Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-hCG antibody conjugated with colloid gold (hCG Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (Cline). The T line is pre-coated with another anti-hCG antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. hCG if present in the specimen at the level equal or higher than 10mIU/mL will bind to the hCG Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-hCG Ab, forming a burgundy colored T band, indicating an hCG positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One test strip
  - One desiccant
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- A container to collect urine specimen or serum specimen
- Saline or Phosphate-Saline buffer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 5-10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Urine:

- First morning urine usually contains the highest concentration of hCG and is therefore the best sample when performing the urine test. However, randomly collected urine specimens may be used. Collect a urine specimen in a clean glass, plastic, or wax coated container.
- Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 48 hours.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

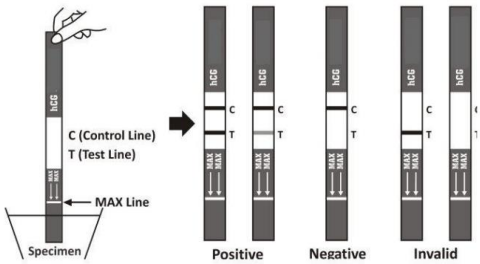
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test strip on a clean, flat surface.

Step 3: Be sure to label the test with the specimen's ID number.

Step 4: Immerse the strip vertically into the sample with the arrow end pointing towards the sample. Do not immerse past the "Mark" Line. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface.

Step 5: Result should be read at 5 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.



INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable hCG is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of hCG in the specimen. The result is hCG positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made*.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher-than-expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The detection limit for the R-test hCG Rapid Test is 10 mIU/mL. The urinary or serum hCG levels equal to or greater than 10 mIU/mL routinely test positive. Samples containing hCG less than 10 mIU/mL may also produce a very faint positive line, especially with extended assay time from 10 to 30 minutes.

The following experiments were done to validate the sensitivity of the R-test hCG Rapid Test:

Six groups of urine specimens from 20 normal non-pregnant individuals were spiked with hCG to the standard (3rd IS) concentrations of 0, 2.5, 5, 10, 20, and 40 mIU/mL. The specimens were run on the R-test hCG Rapid Test. Results are tabulated in Table 1 below.

Table 1

hCG mIU/mL	0	2.5	5	10	20	40
Number of positive	0	4	10	20	20	20
Number of negative	20	16	10	0	0	0

n=20 relative sensitivity at 10 mIU/mL = 20/20 x 100% = 100%

2. Specificity

Specificity of the R-test hCG Rapid Test was determined from studies on specimens with 500 mIU/mL of human luteinizing hormone (hLH), 1,000 mIU/mL of human follicle stimulating hormone (hFSH), and 1,000 µIU/mL of human thyroid stimulating hormone (hTSH), each standard obtained from SIGMA. Specimens containing these structurally related hormones at tested concentrations were found not to significantly cross-react with hCG antibodies as to yield false positive or false negative results.

3. Accuracy

The accuracy of the R-test hCG Rapid Test was determined by a comparison study with a currently marketed hCG pregnancy test device, and was conducted at an external clinical site. A total of 172 fresh urine specimens, including 91 hCG positive and 81 hCG negative were randomly collected from the patients who visited an OB-GYN office. The two assays gave a complete agreement as shown in Table 2 below:

Table 2

	Reference hCG device (+)	Reference hCG device (-)	Total
R-test hCG Rapid Test (+)	91	0	91
R-test hCG Rapid Test (-)	0	81	81
Total	**91**	**81**	**172**

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

4. Interference

The chemicals commonly found in OTC, prescription, or abuse drugs were spiked into both hCG negative and 10 mIU/mL hCG in urine specimens. Spiked samples were tested against following substances or pHs at the indicated concentrations. There was no interference observed.

Biological Analytics			pH	
1.	Albumin	2,000 mg/dL	1.	pH 5
2.	Glucose	2,000 mg/dL	2.	pH 9
3.	Bilirubin	1,000 µg/dL	3.	pH 6.8
4.	Hemoglobin	1,000 µg/dL		

List of potentially interfering chemical analytics and concentrations tested:

1.	Acetaminophen	20 mg/dL	2.	EDTA	80 mg/dL
3.	Acetylsalicylic acid	20 mg/dL	4.	Benzoylecgonine	10 mg/dL
5.	Ascorbic acid	20 mg/dL	6.	Atropine	20 mg/dL
7.	Caffeine	20 mg/dL	8.	Cannalbinol	10 mg/dL
9.	Gentesic acid	20 mg/dL	10.	Ethanol	1%
11.	Phenylpropanoamine	20 mg/dL	12.	Methanol	1%
13.	Salicylic acid	20 mg/dL			

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of hCG in urine or serum from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- If a urine specimen is too diluted, it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the person and the test repeated. The hCG concentration less than 10 mIU/mL will be detected as negative.
- A number of disease conditions other than pregnancy such as trophoblastic disease, proteinuria hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of hCG. The diagnosis should be considered if appropriate to the clinical evidence.
- Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.
- Samples containing very high levels of hCG ≥600,000 mIU/mL may yield a test band with color intensity lighter than that, which is expected. When high dose "hook effect" is suspected, it is recommended the test be repeated with a 1:10 dilution of the specimen with DI H2O.
- Grossly hemolyzed or lipemic samples should not be used since they may give inaccurately lower or erratic results.
- Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
- Samples from patients on chemotherapy for cancer should be ruled out before running the assay.
- Positive hCG levels may be detectable for several weeks following delivery or abortion.
- Specimens testing positive during the initial days after conception may be negative later due to natural termination of the pregnancy.
- Results obtained with the R-test hCG Rapid Test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

Healthy men and healthy non-pregnant women do not have detectable hCG by the R-test hCG Rapid Test. The hCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period. The hCG levels peak about 7-12 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal shortly after parturition.

STANDARDIZATION

The R-test hCG Rapid Test has been calibrated against World Health Organization the Third International Standard (3rd IS).

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HCV Ab Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-13050

INTENDED USE

The R-test HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the R-test HCV Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV), which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH)1, causes chronic disease in 50% of cases. HCV can also be transmitted through intravenous drug abuse and sexual contact.

Hepatitis C virus is a single-stranded RNA virus with structural similarities to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provide the basis for the construction of recombinant peptides representing putative hepatitis C virus proteins. Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins helped to identify apparently healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus. Therefore, the R-test HCV Ab Rapid Test is a useful tool for blood bank screening safety.

The R-test HCV Ab Rapid Test was developed to detect anti-HCV antibodies (IgG, IgM, IgA) in human serum or plasma. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment

TEST PRINCIPLE

The R-test HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloid gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre coated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and C line is pre coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample pad of the test device, the specimen migrates by capillary action across the strip. The antibodies to HCV, if present in the specimen, will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line, indicating a HCV Ab positive or reactive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line), which should exhibit a burgundy-colored line of the immunocomplex of control antibodies regardless of the color development on T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15-20-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (approximately 45 µL) of specimen into the sample well making sure that there are no air bubbles.

Immediately add 1 drop (35 - 50 µL) of Diluent buffer into the sample well with the bottle positioned vertically.

Step 5: Set up the timer.

Step 6: Read the result in 15 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 20 minutes only. Any results interpreted outside of the 15 to 20-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable antibodies to HCV is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of antibodies to HCV in the specimen. The result is positive or reactive.
  Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

A total of 1050 samples from susceptible subjects were tested with the R-test HCV Ab Rapid Test and by a commercial HCV ELISA kit. Comparison of the results for all subjects is shown in the following table.

Table 1

	R-test HCV Ab Rapid Test		
HCV Elisa	**Positive**	**Negative**	**Total**
Positive	312	4	316
Negative	3	731	734
Total	315	735	1050

Relative Sensitivity: 98.7%, Relative Specificity: 99.6%, Overall Agreement: 99.3%

2. Worldwide Performance Panel

BBI's (Boston Biomedica Inc.) worldwide performance panel (WWHV301) were tested with the R-test HCV Ab Rapid Test. The result is shown in the following table.

Table 2

Member	Origin	Genotype	Abbott EIA	R-test HCV Ab Rapid Test
301-01	Argentina	1b	Positive	Positive
301-02	Argentina	1b	Positive	Positive
301-03	Argentina	3a/b	Positive	Positive
301-04	Argentina	2a/c	Positive	Positive
301-05	Argentina	Not tested	Negative	Negative
301-06	Uganda	4c/d	Positive	Positive
301-07	Uganda	Not tested	Positive	Positive
301-08	Ghana	Not tested	Negative	Negative
301-09	China	1b, 2a/c	Positive	Positive
301-10	China	2	Positive	Positive
301-11	China	1b	Positive	Positive
301-12	China	2	Positive	Positive
301-13	China	1a/b, 2a/c	Positive	Positive
301-14	Egypt	3a	Positive	Positive
301-15	Egypt	4	Positive	Positive
301-16	Egypt	4h	Positive	Positive
301-17	Egypt	Not tested	Positive	Positive
301-18	USA	1b	Positive	Positive
301-19	USA	1a	Positive	Positive
301-20	USA	1a	Positive	Positive

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HCV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test HCV Ab Rapid Test is limited to the qualitative detection of antibodies to HCV in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
- A non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
- A non-reactive result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- If the symptoms persist and the result from R-test HCV Ab Rapid Test is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HIV 1/2 Ab Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-14050

INTENDED USE

The R-test HIV 1/2 Ab Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of HIV-1 and HIV-2 antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with HIV.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped, single stranded, positive-sense RNA viruses. The causative relationship between HIV-1 and HIV-2 virus and acquired immunodeficiency syndrome (AIDS) has been established over several decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex and from healthy individuals with a high risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals.

The two types of HIV have significant variation in sequences. HIV-1 has been divided into three groups: group M (for major) including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O). Similarly, HIV-2 has been classified into at least five subtypes (A through E). Some HIV-1 variants share up to 50% homology in their envelope genes with the sequences of more common prototype strains.

Both HIV-1 and HIV-2 can elicit strong immune responses including the production of anti-virus antibodies. Presence of specific anti-HIV-1 and/or anti-HIV-2 in blood, serum or plasma indicates exposure of an individual to HIV-1 and/or HIV-2 and thus is of great value for clinical diagnosis.

The R-test HIV 1/2 Ab Rapid Test detects and differentiates anti-HIV-1 and anti- HIV-2 (IgG, IgM, IgA) in serum, plasma or whole blood. The test can be performed within 15 minutes by minimally skilled personnel and without the use of cumbersome laboratory equipment.

TEST PRINCIPLE

The R-test HIV 1/2 Ab Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HIV-1 antigen conjugated with colloidal gold (HIV-1 conjugates), recombinant HIV-2 antigen conjugated with colloidal gold (HIV-2 conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (1 and 2) and a control line (C). Test line 1 is pre-coated with HIV-1 antigen for the detection of antibodies to HIV-1, test line 2 is pre-coated with HIV-2 antigen for the detection of antibodies to HIV-2, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the strip. HIV-1 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1 antigen forming a burgundy colored line at test line 1, indicating a HIV-1 antibody positive or reactive test result. Lack of color development on test line 1 suggests an HIV-1 antibody negative or non-reactive result.

HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-2 antigen forming a burgundy colored line at test line 2, indicating a HIV-2 antibody positive or reactive test result. Lack of color development on test line 2 suggests a HIV-2 antibody negative or non-reactive result.

The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of color development on the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Capillary tubes (20 µL)
- Clock or timer
- Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test result should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

The specimens must be tested within 24 hours of collection. Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately.

ASSAY PROCEDURE

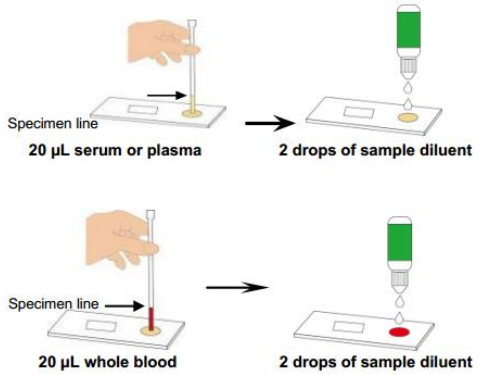
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the capillary tube with specimen (about 20 µL) not to exceed the specimen line as shown in the images below. For better precision, transfer specimen using a pipette capable of delivering a 20 µL volume. Holding the capillary tube vertically, dispense the entire specimen into the center of the sample well making sure that there are no air bubbles.

Immediately add 2 drops (60-80 µL) of Diluent buffer into the sample well with the bottle positioned vertically.



Step 5: Set up the timer.

Step 6: Read the result in 15 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 20 minutes only. Any results interpreted outside of the 15 to 20-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops the test indicates that there is no presence of HIV antibodies in the specimen. The result is HIV-1 and HIV-2 antibodies negative or non-reactive.
- **POSITIVE RESULT:** If both the C line and test line 1 develop, the test indicates that the specimen contains anti-HIV-1 antibodies. The result is HIV-1 positive or reactive.
  If both the C line and test line 2 develop, the test indicates that the specimen contains HIV-2 antibodies. The result is HIV-2 positive or reactive.
  If the C line and both test lines (1 and 2) develop, the test indicates that the specimen is HIV positive or reactive. To differentiate the type of HIV infection, dilute the sample with diluent buffer 1:50 or 1:100 and begin the test again in a new test cassette. (See Limitations of Test section, No. 5).
  Samples with reactive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a final diagnostic decision is made.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for HIV-1 Ab Test

A total of 1,275 samples from susceptible subjects were tested with the R-test HIV 1/2 Ab Rapid Test and with a commercial HIV-1 Ab EIA. Comparison for all subjects is shown in the following table.

Table 1

	R-test HIV 1/2 Ab Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive	315	0	315
Negative	0	960	960
Total	315	960	1275

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

2. Clinical Performance for HIV-2 Ab Test

A total of 190 samples from susceptible subjects were tested with the R-test HIV 1/2 Ab Rapid Test and with a commercial HIV-2 Ab EIA. Comparison for all subjects is shown in the following table.

Table 2

	R-test HIV 1/2 Ab Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	0	170	170
Total	20	170	190

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

3. Cross-Reactivity

No false positive anti-HIV-1 and anti-HIV-2 results were observed on 3-19 specimens from the following disease states or special conditions, respectively:

HBsAg	**HAV**	**HCV**	**Dengue**	**Syphilis**
H. pylori	**ANA**	**HAMA**	**RF (up to 8400 IU/mL)**	**TB**

4. Interference

Common substances (such as pain and fever medication and blood components) may affect the performance of the R-test HIV 1/2 Ab Rapid Test. This was studied by spiking these substances into three levels (negative, weak positive and strong positive) of HIV-1 Ab and HIV-2 Ab standard controls. The results are presented in the following table and demonstrate that at the concentrations tested, the substances studied do not affect the performance of the R-test HIV 1/2 Ab Rapid Test.

List of potentially interfering chemical analytics and concentrations tested:

1.	Bilirubin	20 mg/dL	2.	Creatinine	442 µmol/L
3.	Salicylic acid	4.34 mmol/L	4.	Glucose	55 mmol/L
5.	Heparin	3,000 U/L	6.	Albumin	60 g/L
7.	EDTA	3.4 µmol/L			

LIMITATIONS OF PROCEDURE

- The Assay Procedure and Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HIV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate test results.
- The R-test HIV 1/2 Ab Rapid Test is limited to the qualitative detection of HIV-1 or HIV-2 antibodies in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer of the specimen.
- A non-reactive result for an individual subject indicates absence of detectable HIV-1 or HIV-2 antibodies. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
- A non-reactive result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- As illustrated in the Interpretation of Assay Result, Section 2.3, all three test lines (1, 2 and C) may develop when tested with samples containing high titers of HIV-1 antibodies. To differentiate and to resolve antibody cross-reactivity, dilute the test specimen with diluent buffer 1:50 or 1:100, then re-test the diluted specimen with a new test device. Only test line 1 and the C line will appear if the specimen contains antibodies to HIV-1. If test line 1, test line 2 and the C line all appear, the test indicates presence of antibodies to both HIV-1 and HIV-2.
- If symptoms persist while the result from the R-test HIV 1/2 Ab Rapid Test is non-reactive, it is recommended to re-sample the patient and test with an alternative test method.
- Unusually high titers of heterophile antibodies or rheumatoid factor in specimens may affect expected results. False positive results can be obtained due to high levels of HAMA, RF or other unknown factors in the specimens. This may occur in less than 0.3% of tests performed.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Malaria Pf/Pv Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-20050

INTENDED USE

The R-test Malaria Pf/Pv Ag Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium falciparum (Pf) and vivax (Pv) antigen in human whole blood specimen. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with plasmodium. Any reactive specimen with R-test Malaria Pf/Pv Ag Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Malaria is a mosquito -borne, hemolytic, febrile illness that infects over 200 million people and kills more than 1 million people per year. It is caused by four species of Plasmodium:

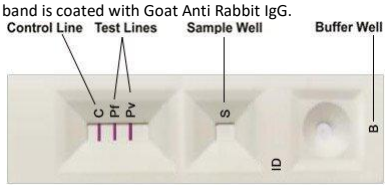
P. falciparum, P. vivax, P. ovale, and P. malariae. These plasmodia all infect and destroy human erythrocytes, producing chills, fever, anemia, and splenomegaly. P. falciparum causes more severe disease than the other plasmodial species and accounts for most malaria deaths. P. falciparum and P. vivax are the most common pathogens; however, there is considerable geographic variation in species distribution.

Traditionally, malaria is diagnosed by the demonstration of the organisms on Giemsa-stained thick smears of peripheral blood, and the different species of plasmodium are distinguished by their appearance in infected erythrocytes. The technique is capable of accurate and reliable diagnosis, but only when performed by skilled microscopista using defined protocols, which presents major obstacles for the remote and poor areas of the world.

The R-test Malaria Pf/Pv Ag Rapid Test is developed for solving these obstacles. It utilizes antibodies specific to P. falciparum Histidine Rich Protein II (pHRP-II) and to P. vivax Lactate Dehydrogenase (Pv-LDH) to simultaneously detect and differentiate infection with P. falciparum and P. vivax. The test can be performed by untrained or minimally skilled personnel, without laboratory equipment.

TEST PRINCIPLE

The R-test Malaria Pf/Pv Ag Rapid Test is a lateral flow chromatographic immunoassay. The strip test components consist of: 1) a burgundy colored conjugate pad containing mouse anti-Pv-LDH antibody conjugated with colloidal gold (Pv-LDH-gold conjugates) and mouse anti-pHRP-II antibody conjugated with colloidal gold (pHRP-II-gold conjugates), 2) a nitrocellulose membrane strip containing two test bands (Pv and Pf bands) and a control band (C band). The Pv band is pre-coated with another mouse anti-Pv-LDH specific antibody for the detection of Pv infection, the Pf band is pre-coated with polyclonal anti-pHRP-II antibodies for the detection of Pf infection, and the C band is coated with Goat Anti Rabbit IgG.



During the assay, an adequate volume of the blood specimen is dispensed into the sample well (S) of the test cassette, and a Diluent buffer is added to the buffer well (B). The buffer contains a detergent that lyses the red blood cells and releases various antigens, which migrate by capillary action across the strip held in the cassette. Pv-LDH if present in the specimen will bind to the Pv-LDH-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Pv-LDH antibody, forming a burgundy colored Pv band, indicating a Pv positive test result.

Alternatively, pHRP-II if present in the specimen will bind to the pHRP-II-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-pHRP-II antibodies, forming a burgundy-colored Pf band, indicating a Pf positive test result.

Absence of any test bands suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy-colored band of the immunocomplex of goat anti-mouse IgG / mouse IgG (anti-Pv-LDH and anti-pHRP-II)-gold conjugates regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Capillary tubes (20 µL)
- Clock or timer
- Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 30 minutes after a specimen is applied to the sample well or sample well of the device. Read result after 30 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e., electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Blood:

Collect whole blood in a clean container containing anti-coagulant (EDTA, citrate or heparin) by venipuncture. Blood can be obtained by fingertip puncture as well. Whole blood specimen should be stored in refrigeration (2°C-8°C) if not tested immediately for up to 3 days. The specimen should be frozen at -20°C for longer storage. Avoid repeat freeze and thaw cycles.

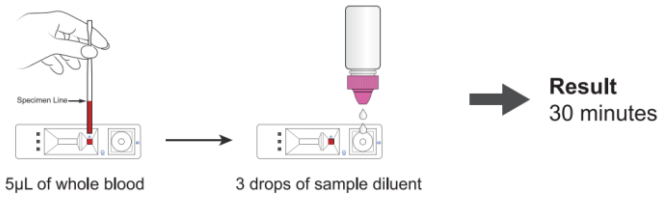
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Pour 5 µL sample in well into the center of the sample well making sure that there are no air bubbles. Then add 3 drops (about 90-120 µL) of sample Diluent Buffer immediately.



Step 5: Set up the timer.

Step 6: Results can be read in 30 minutes. It may take more than 20 minutes to have the background become clearer.

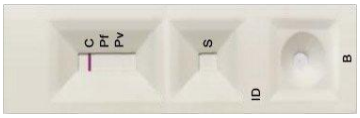
Don't read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

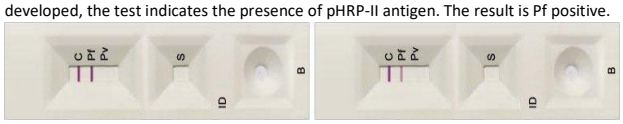
- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15-30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in both test bands (Pv and Pf) indicates that no plasmodium antigens are detected. The result is negative.

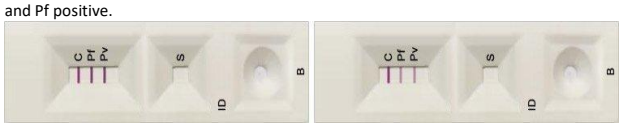


- **POSITIVE RESULT:** In addition to the presence of the C band, if only the Pf band is developed, the test indicates the presence of pHRP-II antigen. The result is Pf positive.



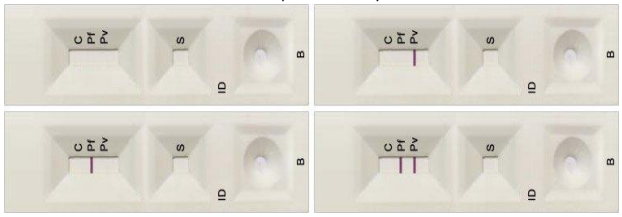
- In addition to the presence of the C band, if only the Pv band is developed, the test indicates the presence of Pv-LDH antigen. The result is Pv positive.

- In addition to the presence of the C band, both the Pv and Pf bands are developed, the test indicates the presence of both Pv-LDH and pHRP-II antigens. The result is both Pv and Pf positive.



Samples with reactive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a final diagnostic decision is made.

- **INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance

A total of 200 blood samples were collected and tested by the R-test Malaria Pf/Pv Ag Rapid Test and by thick blood smear test. Comparison for all subjects is shown in the following table.

Table 1

	Pf		Pv	
	Positive	**Negative**	**Positive**	**Negative**
Smear Test	90	110	100	100
R-Test Malaria Pf/Pv Ag Rapid test	85	115	98	102

Pf detection: Sensitivity:94.4%, Specificity: 100%;

PV Malaria detection: Sensitivity: 98 %, Specificity: 100 %; Kappa value: 92%

2. Cross-Reactivity

Pv and Pf cross reaction:

The negative blood specimen was spiked with recombinant Pv-LDH, Pf-LDH and pHRP-II antigen, and tested with the R-test Malaria Pf/Pv Ag Rapid Test, respectively. The result showed that the Pv detection system did not cross-react to the Pf Ag and vice versa.

Antigen Concentration	Pf - Reactivity	Pv - Reactivity
1.0 mg/mL pHRP-II	Positive	Negative
1.0 mg/mL Pv-LDH	Negative	Positive
1.0 mg/mL Pf-LDH	Negative	Negative

Cross reaction with common microbe antigens:

The negative blood specimen was spiked with antigens from common microbes and then tested according to the standard procedure. The results showed that the R-test Malaria Pf/Pv Ag Rapid Test had no cross-reaction with the following antigens at the concentration tested.

Antigen (Ag)	Concentration Spiked	Pf - Reactivity	Pv - Reactivity
HIV-1 P24 Ag	1.0 mg/mL	Negative	Negative
HBsAg	1.0 mg/mL	Negative	Negative
Dengue virus NS1 Ag (I, II, III, IV)	1.0 mg/mL	Negative	Negative
Chikungunya virus Ag	1.0 mg/mL	Negative	Negative

Cross reactivity with specimens from other infectious diseases:

Specimen	Sample size	Pf Reactivity	Pan Reactivity
Dengue serum	10	Negative	Negative
HBsAg serum	10	Negative	Negative
HAV serum	10	Negative	Negative
HCV serum	10	Negative	Negative
HIV serum	10	Negative	Negative
Syphilis serum	10	Negative	Negative
TB serum	10	Negative	Negative
H. pylori serum	10	Negative	Negative
ANA serum	8	Negative	Negative
HAMA	19	Negative	Negative
RF (≤2,500 IU/mL)	10	Negative	Negative

3. Interference

Common substances (such as pain and fever medication, blood components) may affect the performance of the R-test Malaria Pf/Pv Ag Rapid Test. This was studied by spiking of these substances to the three levels of the pHRP-II and Pv-LDH standard control. The results are presented in the following table and demonstrate that the substances studied did not affect the performance of the R-test Malaria Pf/Pv Ag Rapid Test.

Note: -: Negative, +: Positive, ++: Medium Positive

Potential Interfering Substance Spiked	Pf Reactivity			Pv Reactivity		
	Negative	**Weak Positive**	**Strong Positive**	**Negative**	**Weak Positive**	**Strong Positive**
Control	-	++	+++	-	++	+++
Bilirubin 20 mg/dL	-	++	+++	-	++	+++
Creatinine 442 µmol/L	-	++	+++	-	++	+++
Glucose 55 mmol/L	-	++	+++	-	++	+++
Albumin 50 g/L	-	++	+++	-	++	+++
Salicylic Acid 4.34 mmol/L	-	++	+++	-	++	+++
Heparin 3,000 U/L	-	++	+++	-	++	+++
EDTA 3.4 µmol/L	-	++	+++	-	++	+++
Human IgG 1,000 mg/dL	-	++	+++	-	++	+++

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assy Result sections must be followed closely when testing the presence of plasmodium protozoa antigen in whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test Malaria Pf/Pv Ag Rapid Test is limited to the qualitative detection of plasmodium protozoa antigen in whole blood. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.
- A negative result for an individual subject indicates absence of detectable malaria plasmodium antigen. However, a negative test result does not preclude the possibility of exposure to or infection with plasmodium protozoa.
- A negative result can occur if the quantity of the plasmodium protozoa antigen present in the specimen is below the detection limits of the assay or the antigens that are detected are not present during the stage of disease in which a sample is collected.
- A recent study showed that due to their genetic diversity some Pf isolates collected in the Peruvian Amazon lack the HRP2 gene7. Therefore, a negative result in the Pf band may not rule out infection of Pf in this area.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test

50 tests per kit
Ref: R-26050

INTENDED USE

The R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test is an in vitro immunochromatographic assay for the qualitative detection of 2019-nCoV antigen and influenza A/B antigens in nasal swab specimens collected from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of 2019-nCoV and influenza A/B viral infections in humans in conjunction with clinical and epidemiological risk factors.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not a severe as that caused by the type A virus.

An accurate diagnosis of 2019-nCoV and influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing. Early differential diagnosis of 2019-nCoV and influenza type A or type B can allow for proper treatment with appropriate antiviral therapy. Early diagnosis and treatment are of particular value in a clinical setting where accurate diagnosis can assist the healthcare professional with management of 2019-nCoV and influenza patients who are at risk for complications.

The R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test is a rapid immunoassay to be used as an aid for the differential diagnosis of 201 9-nCoV and influenza type A and type B.

TEST PRINCIPLE

The R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test is an immunochromatographic membrane assay and contains two independent tests, the 2019-nCoV antigen test and the FLU A/B antigen test. In the test procedure, a specimen is collected and placed for one minute into the Extraction Well of the test device containing extraction solution, during which time antigen is extracted from disrupted virus particles. The test device is then raised, tapped and laid back down onto a level surface to allow the solution in the Extraction Well to migrate through the pads containing lyophilized detector antibodies conjugated to gold dye and then through the test membrane.

For the 2019-nCoV antigen test: The 2019-nCoV antigen test uses highly sensitive monoclonal antibodies to detect 2019-nCoV antigen in nasal swab specimens. These antibodies and a control protein are immobilized onto a membrane support as two distinct lines and are combined with other reagents/pads to construct a Test Strip. The 2019-nCoV antigen test has one test lines and one control line. If either Test line appears in the test result window, together with the Control line, the test result is positive for 2019- nCoV.

For the Flu A/B antigen test: The Flu A/B antigen test uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasal swab specimens. These antibodies and a control protein are immobilized onto a membrane support as three distinct lines and are combined with other reagents/pads to construct a Test Strip. The Flu A/B antigen test has two Test lines, one for influenza A and one for influenza B. The two Test lines allow for the separate and differential identification of influenza A and/or B from the same specimen. If either Test line appears in the test result window, together with the Control line, the test result is positive for influenza.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Swabs
- Diluent Buffer in Vial
- Buffer Tube / Dripper
- One package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette
- Clock or timer
- Gloves

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not use expired devices.
3. Use only the swabs provided for collecting swab samples. Other swabs may not work properly.
4. Do not use the components in any other type of test kit as a substitute for the components in this kit.
5. Extraction Reagent is slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If the reagent comes in contact with skin or eyes, flush with a large volume of water.
6. Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
7. All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and test devices.
8. The Test device should remain in its original sealed pouch until ready for use.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

Store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products. The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use. The buffer should be used immediately after dropping into the dropper. MFD date and EXP date: marked on the label. The product will be expired after 24 months.

SPECIMEN COLLECTION AND HANDLING

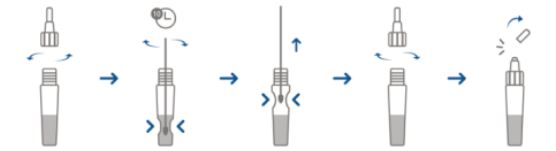
- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended because of the importance of specimen quality.
- To collect nasal swab specimens, the swab provided in the Test kit should only be used.
- The buffer provided in the kit should only be used. Use fresh samples for best performance.
- Freshly collected specimens should be tested immediately. If necessary, aspirate specimens may be stored for up to 8 hours at room temperature or up to 24 hours at 2–8°C, and swab samples for up to 4 hours at room temperature or up to 8 hours at 2–8°C. Aspirate samples can be frozen for up to 7 days.

ASSAY PROCEDURE

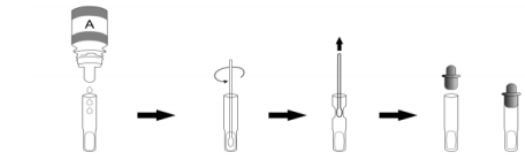
Sample Processing

1. Open the dripper head OR take out the tube, add about 300μL of Diluent buffer (to 300uL mark line or 9 drops vertically) to the tube.
2. Completely immerse the swab head of the collected sample into the buffer in the tube.
3. Rotate the sample against the inner wall of the tube approximately 10 times or squeeze the tube 10 times to elute the sample to ensure that the sample on the swab is fully eluted into the buffer.
4. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.
5. Discard the swab and cover the drip head to mix the liquid thoroughly.
6. Samples should be eluted and used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.

*Note: Recommend to use a pipette to transfer the samples to reduce deviations.



OR

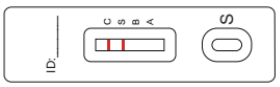


Test Procedure

1. Take the required reagents and test cassette to equilibrate to room temperature
2. Unpack the aluminum foil bag, place the test cassette horizontally on the table and mark it.
3. Break the dripper head
4. Add 100μL (2-3 drops) of the processed sample to each sample well, and timed. Recommended to use a pipette to take buffer/samples to reduce deviations.
5. As the test begins to work, you will see purple color move across the result window in the center of the test device.
6. Wait for 15 minutes and read the results. Do not read results after 20 minutes.

INTERPRETATION OF ASSAY RESULT

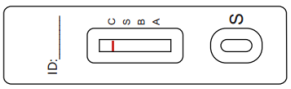
- **POSITIVE RESULT:** A reddish-purple Control line (C position) and S Test line indicate that 2019-nCoV antigen has been detected.



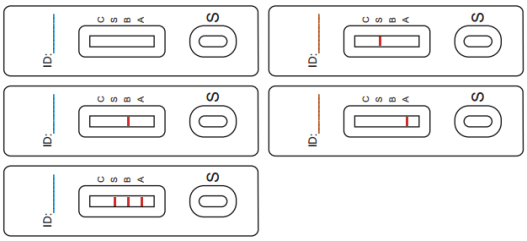
A reddish-purple Control line (C position) and a reddish-purple Test line (A) indicate that Influenza A antigen has been detected. A reddish-purple Control line (C position) and a reddish-purple Test line (B position) indicate that Influenza B antigen has been detected. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

Determination of a positive result can be made as soon as a visible Test line (either S, A, or B) and Control line appear. The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.

- **NEGATIVE RESULT:** Only a reddish-purple Control line (C position), with no Test line at either S, A, or B indicates that neither 2019-nCoV antigen nor Influenza A or B antigen has been detected. A negative result does not exclude 2019-nCoV or influenza A / B viral infection. Determination of negative results should not be made before 15 minutes. If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new Test device.



- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance for SARS-CoV-2 Ag Test

The performance of 2019-nCoV Ag established with 565 nasopharyngeal swabs collected from symptomatic patients, who with symptoms onset within 7 days.

	R-test SARS-CoV-2 Ag Rapid Test		
qPCR SARS-CoV-2	**Positive**	**Negative**	**Total**
Positive	96	14	110
Negative	0	455	455
Total	96	469	565

Sensitivity: 87.27%, Specificity: 100.00%, Accuracy: 97.52%

The performance of 2019-nCoV Ag with positive results stratified by the comparative method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, As presented in the table below, the positive agreement of the 2019-nCoV Ag is higher with samples of a Ct count <25.

Sample Groups	Ct ORF lab gene	Sample Size
High Positive	Ct < 25	57
Medium Negative	25 < Ct < 30	33
Low Positive	Ct > 30	20

2. Clinical Performance for Influenza A Test

A total of 316 samples from susceptible subjects were tested with the R-test Flu A/B Rapid Test. Comparison for all subjects is shown in the following table.

	R-test Flu A Rapid Test		
DFA Test Result	**Positive**	**Negative**	**Total**
Positive	110	5	115
Negative	0	201	201
Total	110	206	316

Relative Sensitivity: 100%, Relative Specificity: 97.6%

3. Clinical Performance for Influenza B Test

A total of 316 samples from susceptible subjects were tested with the R-test Flu A/B Rapid Test. Comparison for all subjects is shown in the following table.

	R-test Flu B Rapid Test		
RT-PCR Test Result	**Positive**	**Negative**	**Total**
Positive	91	0	91
Negative	6	219	225
Total	97	219	316

Relative Sensitivity: 100%, Relative Specificity: 97.3%

4. Limit of Detection

SARS-CoV-2-Ag: When the virus culture concentration was 100 $TCID_{50}$/mL and above, the positive rate was greater than or equal to 95%. At virus culture concentration of 50 $TCID_{50}$/mL and below, the positive rate is not higher than 95%, so the minimum detection limit of the SARS-CoV-2 Ag test is $1.6x10^2TCID_{50}$/mL.

Flu A/B Ag: The analytical sensitivity (limit of detection or LOD) of the test was determined using quantified ($TCID_{50}$/mL) cultures of three influenza A strains and two influenza B strains, serially diluted in negative nasopharyngeal matrix. Each dilution was run as 30 replicates in the test. Analytical sensitivity (LOD) is defined as the lowest concentration at which at least 95% of all replicates tested positive.

5. Cross-Reactivity

The potential cross-reactivity of the non-influenza respiratory pathogens and other microorganisms with which the majority of the population may be infected was tested using the Test at medically relevant levels, 106 CFU/mL for bacteria and 105 PFU/mL for non-flu viruses. None of the organisms or viruses listed in the table below gave a positive result with the Test at the tested concentration.

Virus Tested				
Adenovirus	Cytomegalovirus	Human coronavirus	Respiratory syncytial virus; Type B	Epstein Barr Virus
Measles	Enterovirus	Human metapneumovirus	Human para influenza; Type 1, 2, 3	
Bacteria Tested				
Bordetella pertussis	Chlamydia pneumoniae	Corynebacterium sp	Escherichia coli	Hemophilus influenzae
Lactobacillus sp	Legionella sp	Moraxella catarrhalis	Mycobacterium tuberculosis avirulent	Mycoplasma pneumoniae
Neisseria meningitides	Neisseria sp.	Pseudomonas aeruginosa	Staphylococcus aureus	Staphylococcus epidermidis
Streptococcus pneumoniae	Streptococcus pyogenes	Streptococcus salivarius		

6. Interference

The performance of R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid was evaluated with potentially interfering substances that may be present in nasal specimens. The potentially interfering substances were evaluated with influenza A (A/Taiwan/42/06), influenza B (B/Malaysia/2506/2004) and 201 9-nCoV at concentrations of 2x LOD. There was no evidence of interference caused by the substances tested at the concentrations shown below:

Whole Blood	1%	**Beclomethasone**	1mg/ml
Mucin	1mg/ml	**Dexamethasone**	1mg/ml
Benzocaine	1mg/ml	**Flunisolide**	1mg/ml
Menthol	1mg/ml	**Triamcinolone**	1mg/ml
Zanamivir	1mg/ml	**Mometasone**	1mg/ml
Mupirocin	1mg/ml	**NaCl with Preservative**	20%
Tobramycin	1mg/ml	**Phenylephrine**	1mg/ml
Fluticasone	1mg/ml	**Oxymetazoline**	1mg/ml

LIMITATIONS OF PROCEDURE

- A negative test result does not exclude infection with 2019-nCoV or influenza A / B. Therefore, the results obtained with the Test should be used in conjunction with clinical findings to make an accurate diagnosis.
- The performance of this test has not been evaluated for sample types other than those specified in the Intended Use.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The Flu A/B antigen test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.
- The Test uses highly target specific monoclonal antibodies. As in most immunoassays, it may fail to detect, or detect with less sensitivity.
- Performance of the Test has not been established for monitoring antiviral treatment of 2019-nCoV or influenza.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza A vaccine may produce positive test results for up to three days after vaccination.
- The performance of this assay has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The performance of this test has not been evaluated for immunocompromised individuals.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Syphilis Ab Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-19050

INTENDED USE

The R-test Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to Syphilis in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Syphilis. Any reactive specimen with the R-test Syphilis Ab Rapid Test must be confirmed with alternative testing methods and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Treponema Pallidum (Tp), a spirochete bacterium, is the causative agent of the venereal disease syphilis. In 1995, WHO (World Health Organization) reported 12 million new cases of syphilis. At present, the rate of positive syphilis serological tests among HIV-infected individuals continues to rise.

Serological detection of anti-Tp antibodies has long been recognized as an aid in the diagnosis of syphilis since the natural course of the infection is characterized by periods without clinical manifestations. Both IgM and IgG antibodies were detected in sera from patients with primary and secondary syphilis. The IgM antibody may be detectable towards the second week of an infection while IgG antibodies appear later at approximately 4 weeks. These antibodies can last for several years or even decades in the serum of a patient with untreated latent syphilis.

Antigens such as Rapid Plasma Reagin (RPR) and Tp bacterial extracts have been used in syphilis serological tests for decades. However, RPR antigen is a non-Treponema antigen derived from bovine heart. Antibodies to RPR antigen do not develop until 1-4 weeks after the appearance of the chancre, thus this antigen lacks sensitivity to primary syphilis. The Tp extracts are prepared from inoculated rabbit testis and contain a certain number of contaminated materials, such as flagella, which can lead to cross-reactions with borrelia and leptospires in the serological test. In addition, the composition of extracts may vary from lot to lot. Recently, several highly immunogenic Tp specific antigens have been identified and used as an alternative to the traditional antigens with the advantage of having high specificity and reproducibility.

The R-test Syphilis Ab Rapid Test is developed to detect antibodies (IgG, IgM and IgA) to recombinant antigens of Tp in serum or plasma within 15 minutes. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment.

TEST PRINCIPLE

The R-test Syphilis Ab Rapid Test cassette consists of: 1) a burgundy-colored conjugate pad containing recombinant Tp antigens conjugated with colloid gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant Tp antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-Tp antibody, if present in the specimen will bind to the Tp conjugates. The immunocomplex is then captured on the membrane by the pre-coated Tp antigen, forming a burgundy-colored T band, indicating a Tp antibody positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy-colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic Droppers
- Clock or timer
- Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test result should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e., electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

- Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®). Do not use hemolyzed blood for testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Add 1 drop (about 30µL~45µL) of the specimen into the specimen well making sure there are no air bubbles. Immediately add 1 drop (about 35-50 µL) of Diluent Buffer to the sample well with the bottle positioned vertically.

Step 5: Set up the timer.

Step 6: Read the test result within 15 minutes. Positive results could be visible in as soon as 1 minute.

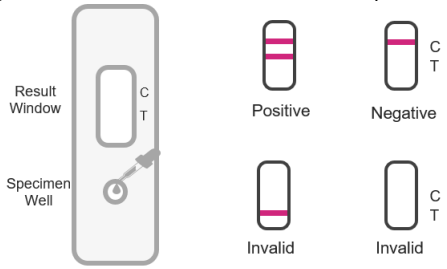
Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15-30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** Only one-color band appearing at the control line (C), indicates negative result.
- **POSITIVE RESULT:** Two purple bands appearing at both test line (T) and control line (C) indicates positive result.
  Samples with reactive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a final diagnostic decision is made.
- **INVALID:** No purple band at the control line (C) indicates incorrect assay process or failure of the kit. Read this instruction carefully and repeat test with a new device. If the problem persists, you should immediately stop using the kit with the same LOT No. and contact your local supplier.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance

A total of 1123 specimens from susceptible subjects were tested by R-test Syphilis Ab Rapid Test and a TPPA test.

Table 1

	R-test Syphilis Ab Rapid Test		
TPPA	**Positive**	**Negative**	**Total**
Positive	321	0	321
Negative	2	800	802
Total	323	800	1123

The relative Sensitivity is 100%, relative specificity is 99.8% and the overall agreement is 99.8%.

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-Tp antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test Syphilis Ab Rapid Test is limited to the qualitative detection of anti-Tp antibody in human serum or plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable anti-Tp antibody. However, a negative test result does not preclude the possibility of exposure to or infection with Tp.
- A negative result can occur if the quantity of the anti-Tp antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test TB IgG/IgM Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-34050

INTENDED USE

The R-test TB IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-Mycobacterium tuberculosis (M. TB) and IgG anti M. TB in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with M. TB.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

Tuberculosis is a chronic, communicable disease caused principally by M. TB hominis (Koch's bacillus), occasionally by M. TB bovis. The lungs are the primary target, but any organ may be infected. The risk of TB infection exponentially declined in the 20th century. However, the recent emergence of drug-resistant strains, particularly among patients with AIDS2, has rekindled interest in TB. The incidence of infection was reported to be around 8 million cases per year with a death rate of 3 million per year. The mortality exceeded 50% in some African countries with high HIV rates.

The initial clinical suspicion and radiographic findings with subsequent laboratory confirmation by sputum examination and culture are the traditional method(s) in the diagnosis of active TB. However, these methods either lack sensitivity or are time consuming, and are particularly not suitable for patients who are unable to produce adequate sputum, smear-negative or are suspected to have extrapulmonary TB.

The R-test TB IgG/IgM Rapid Test is developed to alleviate these obstacles. The test detects IgM and IgG anti-M. TB in serum, plasma or whole blood in 15 minutes. An IgM positive result indicates a fresh M. TB infection, while an IgG positive result suggests a previous or chronic infection. Utilizing M. TB specific antigens, it also detects IgM anti-M. TB in patients vaccinated with BCG. In addition, the test can be performed by untrained or minimally skilled personnel without cumbersome laboratory equipment.

TEST PRINCIPLE

The R-test TB IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing M. TB antigens conjugated with colloidal gold (M. TB conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti- M. TB, the G band is pre-coated with reagents for the detection of IgG anti-M. TB, and the C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. IgM anti-M. TB if present in the specimen will bind to the M. TB conjugates. The immunocomplex is then captured on the membrane by the precoated anti-human IgM antibody forming a burgundy colored M line, indicating a M. TB IgM positive test result.

IgG anti-M. TB if present in the specimen, will bind to the M. TB conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane forming a burgundy colored G line, indicating a M. TB IgG positive test result. Absence of any test lines (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy-colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on any of the T lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Sample Diluent (1x5ml)
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- Plastic Dropper

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The testing results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading the results after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2°Ċ -8°Ċ) if not tested immediately. The specimens must be tested within 24 hours of collection.

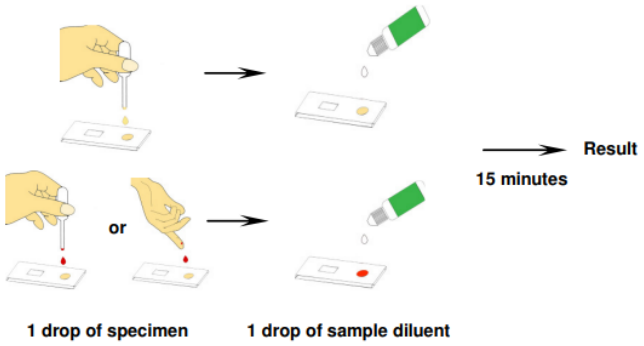
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of serum/plasma or 1 drop of whole blood (about 40-50 µL) into the sample well making sure that there are no air bubbles. Immediately add 1 drop (about 35-50 µL) of Sample Diluent to the sample well.



Step 5: Set up timer.

Step 6: Results can be read at 10 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of the 10 minutes only. However, any results interpreted outside 10 minutes should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.

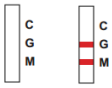
QUALITY CONTROL

- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in both the test lines (M and G) indicates that no anti-M. TB antibodies are detected. The result is negative.

- **INVALID:** If no C line is developed, the assay is invalid regardless of any burgundy color in the test lines as indicated below. Repeat the assay with a new device.



- **POSITIVE RESULT:** In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of IgM anti- M.TB. The result is positive.

In addition to the presence of the C line, if only the G line is developed, the test indicates the presence of IgG anti-M.TB. The result is positive.

In addition to the presence of the C line, if both the M and the G lines are developed, the test indicates the presence of IgG and IgM anti-M.TB. The result is also positive.

Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for IgM test

A total of 200 specimens from non-TB patients and 35 specimens from patients under anti-TB treatment were tested by the R-test TB IgG/IgM Rapid Test and a commercial TB IgM ELISA kit. Comparison of the results for all subjects is shown in the following table:

	R-test TB IgG/IgM Rapid Test		
IgM ELISA Test	**Positive**	**Negative**	**Total**
Positive	30	5	35
Negative	7	193	200
Total	37	198	235

Relative Sensitivity: 85.7%, Relative Specificity: 96.5%, Overall Agreement: 94.9%

2. Clinical Performance for IgG test

A total of 200 specimens from the non-TB patients and 35 specimens from the patients under anti-TB treatment were tested by the R-test TB IgG/IgM Rapid Test and a commercial TB IgG ELISA kit. Comparison of the results for all subjects is shown in the following table:

	R-test TB IgG/IgM Rapid Test		
IgG ELISA Test	**Positive**	**Negative**	**Total**
Positive	31	4	35
Negative	7	193	200
Total	38	197	235

Relative Sensitivity: 88.6%, Relative Specificity: 96.5%, Overall Agreement: 95.3%

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to M. TB in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test TB IgG/IgM Rapid Test is limited to the qualitative detection of IgG and IgM anti M. TB in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
- The test also recognizes antibodies to M. bovis and M. africanum.
- An IgG positive response may be detected in BCG vaccinated personnel.
- A negative result for an individual subject indicates absence of detectable antibodies to M.TB. However, a negative test result does not preclude the possibility of exposure to or infection with M.TB.
- A negative result can occur if the quantity of the antibodies to M. TB present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Immunocompromised conditions such as HIV infection may reduce the test sensitivity.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:02/2022

R-test Typhoid Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-17050

INTENDED USE

The R-test Typhoid Ag Rapid Test is a lateral flow chromatographic immunoassay by providing a quick direct visual test for the Salmonella typhi of human urine or serum.

The R-test Typhoid Ag Rapid Test is not intended for quantitative results. It provides only preliminary analytical data.

SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever is an acute intestinal infectious disease caused by salmonella. It is still one of the more common infectious diseases in many developing countries in the world. The diagnosis of typhoid fever is mainly based on clinical features and laboratory tests. Widal is the classic test, while blood culture remains the gold standard. A positive Widal test usually occurs 5 to 6 days after infection, and the positive rate is low. It is easily affected by a variety of factors, and false negatives and false positives may occur, which has no early diagnostic significance. Blood culture is the most commonly used diagnosis. Because the bacterial culture time is long, the detection process is cumbersome, and affected by various factors, it is difficult to achieve the purpose of early diagnosis.

The R-test Typhoid Ag Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of typhoid fever via assay of typhoid Ag that may be present in human serum or urine. The test can be performed within 5 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test Typhoid Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-TP antibody conjugated with colloid gold (TP Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another anti-TP antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. TP if present in the specimen at the level equal or higher than the detection limit will bind to the TP Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-TP Ab, forming a burgundy colored T band, indicating an TP positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer
- A container to collect urine specimen or serum specimen

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 5-10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 5-10-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Urine:

- Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 48 hours.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90 µL) of specimen into the sample well making sure that there are no air bubbles.

Note: Add 1 drop of Diluent buffer into the sample well if flow migration is not observed within 30 seconds in the result window when tested with serum samples, which could occur with a highly viscous specimen.

Step 5: Set up the timer.

Step 6: Result should be read at 5 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable TP is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of TP in the specimen. The result is TP positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made*.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The detection limit for the R-test Typhoid Ag Rapid Test is 0.5 ng/mL. The urinary or serum TP levels equal to or greater than 0.5 ng/mL routinely test positive. Samples containing TP less than 0.5 ng/mL may also produce a very faint positive line, especially with extended assay time from 10 to 30 minutes.

The following experiments were done to validate the sensitivity of the R-test Typhoid Ag Rapid Test:

Six groups of urine specimens from 20 normal non-typhoid fever individuals were spiked with TP to the concentrations of 0, 2.5, 5, 10, 20, and 40 ng/mL. The specimens were run on the R-test Typhoid Ag Rapid Test. Results are tabulated in Table 1 below.

Table 1

TP ng/mL	0	2.5	5	10	20	40
Number of positive	0	4	10	20	20	20
Number of negative	20	16	10	0	0	0

n=20 relative sensitivity at 0.5 ng/mL = 20/20 x 100% = 100%

2. Specificity

Specificity of the R-test Typhoid Ag Rapid Test was determined from studies on specimens with 200 cfu/mL of Vibrio parahaemolyticus, Shigella baumannii, Proteus mirabilis, Salmonella typhimurium, Salmonella choleraesuis. Specimens containing these structurally related hormones at tested concentrations were found not to significantly cross-react with TP antibodies as to yield false positive or false negative results.

3. Accuracy

The accuracy of the R-test Typhoid Ag Rapid Test was determined by a comparison study with a currently marketed TP test device, and was conducted at an external clinical site. A total of 172 fresh urine specimens, including 100 TP positive and 90 TP negative were randomly collected from the patients who visited an OB-GYN office. The two assays gave a complete agreement as shown in Table 2 below:

Table 2

	Reference TP device (+)	Reference TP device (-)	Total
TP Ag Rapid Test +	100	0	100
TP Ag Rapid Test -	0	90	90
Total	**100**	**90**	**190**

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

4. Interference

The chemicals commonly found in OTC, prescription, or abuse drugs were spiked into both TP negative and 0.5 ng/mL TP in urine specimens. Spiked samples were tested against following substances or pHs at the indicated concentrations. There was no interference observed.

Biological Analytics			**pH**	
1.	Albumin	2,000 mg/dL	1.	pH 5
2.	Glucose	2,000 mg/dL	2.	pH 9
3.	Bilirubin	1,000 µg/dL	3.	pH 6.8
4.	Hemoglobin	1,000 µg/dL		

List of potentially interfering chemical analytics and concentrations tested:

1.	Acetaminophen	20 mg/dL	2.	EDTA	80 mg/dL
3.	Acetylsalicylic acid	20 mg/dL	4.	Benzoylecgonine	10 mg/dL
5.	Ascorbic acid	20 mg/dL	6.	Atropine	20 mg/dL
7.	Caffeine	20 mg/dL	8.	Cannalbinol	10 mg/dL
9.	Gentesic acid	20 mg/dL	10.	Ethanol	1%
11.	Phenylpropanoamine	20 mg/dL	12.	Methanol	1%
13.	Salicylic acid	20 mg/dL			

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of TP in urine or serum from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- If a urine specimen is too diluted, it may not contain representative levels of TP. The TP concentration less than 0.5 ng/mL will be detected as negative.
- Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.
- Samples containing very high levels of TP ≥600,00 ng/mL may yield a test band with color intensity lighter than that, which is expected. When high dose "hook effect" is suspected, it is recommended the test be repeated with a 1:10 dilution of the specimen with DI H_2O.
- Grossly hemolyzed or lipemic samples should not be used since they may give inaccurately lower or erratic results.
- Samples from patients on chemotherapy for cancer should be ruled out before running the assay.
- Positive TP levels may be detectable for several weeks following delivery or abortion.
- Specimens testing positive during the initial days after conception may be negative later due to natural termination of the pregnancy.
- Results obtained with the R-test Typhoid Ag Rapid Test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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5. Anke Brüning, Bellamy K, Talbot D, et al. A rapid chromatographic strip test for the pen-side diagnosis of rinderpest virus[J]. Journal of Virological Methods, 1999, 81(1-2):143-154.

Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

Lab Diagnostic Systems (SMC) Pvt Ltd

R test SARS-CoV-2 Ag

Ref: R-10050

User Manual / 50 tests

1. INTENDED USE

The **R test SARS-CoV-2 Ag** is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19. The kit is intended for professional use only.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

2. INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasopharyngeal congestion, runny nose, sore pharynx, myalgia and diarrhea are found in a few cases.

3. PRINCIPLE

This product uses capture colloidal gold immunochromatography to qualitatively detect SARS-CoV-2 nucleocapsid protein antigen in human nasal swab samples. Colloidal gold labeled antibody and chicken IgY antibody are used. The SARS-CoV-2 antibody-colloidal gold complex and the chicken IgY antibody-colloidal gold complex are coated on the conjugate pad. The test line is coated with SARS-CoV-2 antibody, and the control line (C) is coated with goat anti-chicken IgY antibody. If the SARS-CoV-2 nucleocapsid protein antigen is present in the sample, the SARS-CoV-2 antigen and the colloidal gold-labeled antibody form a complex. Under the action of chromatography, the complex moves forward along the strip, and when reaching the test line, it reacts with the pre-coated SARS-CoV-2 antibody to form an immune complex and show a red line. Colloidal gold-labeled chicken IgY antibody combined with goat anti-chicken IgY antibody on the control line (C) showed a red line. The control line (C) should have lines when testing samples. The red line displayed on the control line (C) is the standard for judging whether the chromatography process is normal, and also serves as the internal control standard for reagents.

4. COMPONENTS

Components	Components	Quantity
Test Cassette	Test line (T): coated with SARS-CoV-2 antibodies; Control line (C): coated with goat anti-chicken IgY antibodies; Conjugate pad: coated with SARS-CoV-2 antibody colloidal gold complex and chicken IgY antibody-colloidal gold complex.	1 test cassette/bag, 50 bags/kit
Desiccant	/	1 piece/bag, 50 bags/kit
Extraction buffer	/	50 vials
Extraction tube	/	50 pieces
Nasal swab	/	50 pieces

5. STORAGE and EXPIRATION DATE

- Test should be stored at 2-30°C in dark and dry place for 18 months. DO NOT freeze the test;
- Test cassette is recommended to be used within 0.5 hour after opening the pouch;
- Refer to the labels to check the production date and expiry date of the kit.

6. MATERIALS NEEDED but NOT SUPPLIED

- Timer

7. SPECIMEN COLLECTION and PREPARATION

7.1 R test SARS-CoV-2 Ag is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasal swabs, without viral transport media;

7.2 Collect nasal swab according to the clinical collection guidelines of laboratory test samples. Avoid contamination during sample collection, transfer and storage;

7.3 To collect the nasal swab sample, carefully insert the swab into the nostril and pharynx exhibiting the most visible drainage, or the nostril and pharynx that are most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates and pharynx posterior wall. Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril and pharynx.

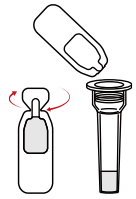
7.4 Specimen storage

For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the nasal fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

8. SPECIMEN EXTRACTION

8.1 Insert the extraction tube into the test tube rack;

8.2 Twist off the head of the buffer, dispense all the buffer into the extraction tube;

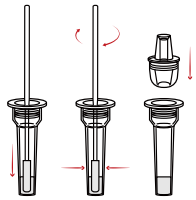


8.3 Insert the swab into the extraction tube containing extraction buffer;

8.4 Rotate the swab at least 6 times while pressing the head against the bottom and sides of the extraction tube;

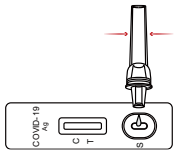
8.5 Place the swab in the extraction tube for 1 minute;

8.6 The extracted solution will be used as a test sample.



9. TEST PROCEDURE

9.1 Carefully refer to the instruction for use prior to performing the test;

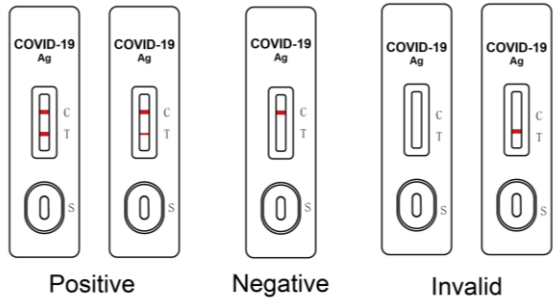


9.2 Take out the kits 30 mins before test, ensure that tests and samples are at room temperature;

9.3 Place test cassettes on flat and clean bench; add 4 drops unknown extracted samples into sample pad;

9.4 Read and record the results after 15 minutes (No longer than 20 minutes). Abnormal results may occur after 20 minutes.

10. INTERPRETATION of RESULTS



Positive (+):	Presence of two red lines, test line (T) and control line (C), indicates SARS-CoV-2 nucleocapsid protein antigens present in samples.
Negative (-):	Appearance of single control line (C), no red test line (T), indicates the absence of SARS-CoV-2 nucleocapsid protein antigens present in samples.
Invalid:	No red control line (C) appears. Invalid results may be due to incorrect operation or loss of efficacy in tests. Repeat test firstly, if problem remains, stop using products in same lot number and contact with local distributor for support.

11. Product Performance

11.1 Cross Reactivity

No false positive SARS-CoV-2 test results were observed on 1-45 specimens from the following disease states or specific conditions, respectively

Virus/Bacteria	Result
Human Coronavirus HKU1	Negative
Human Coronavirus OC43	Negative
Human Coronavirus NL63	Negative
Human Coronavirus 229E	Negative
New Type H1N1 Influenza Virus (2009)	Negative
Seasonal H1N1 influenza virus	Negative
H3N2	Negative
H5N1	Negative
H7N9	Negative
Yamagata positive sample for influenza B	Negative

Influenza B Victoria positive sample	Negative
Rhinovirus Group A positive sample	Negative
Rhinovirus Group B positive sample	Negative
Rhinovirus Group C positive sample	Negative
Human cytomegalovirus virus positive sample	Negative
Norovirus positive samples	Negative
Mumps virus positive sample	Negative
Varicella-zoster virus positive sample	Negative
Respiratory syncytial virus (RSV)	Negative
Epstein-Barr virus	Negative
Adenovirus (ADV) Type 1	Negative
Adenovirus (ADV) Type 2	Negative
Adenovirus (ADV) Type 3	Negative
Adenovirus (ADV) Type 4	Negative
Adenovirus (ADV) Type 5	Negative
Adenovirus (ADV) Type 7	Negative
Adenovirus (ADV) Type 55	Negative
HRV	Negative
Enterovirus group A	Negative
Enterovirus group B	Negative
Enterovirus group C	Negative
Enterovirus group D	Negative
MAE	Negative
Mycoplasma pneumoniae	Negative
Candida albicans	Negative
Normal sample	Negative
HAV	Negative
HBV	Negative
HCV	Negative
HEV	Negative
HIV	Negative
TB	Negative
Dengue	Negative
Helicobacter pylori	Negative
MERS	Negative

11.2 Interference Substances Studies

There was no interference for potential interfering substances listed below:

Potential Interfering Substance	Concentration	Results
Blood	60 mg/mL	Negative
Mucin	2.5 mg/mL	Negative
Zanamivir	5.25 mg/mL	Negative
Ribavirin	5 mg/mL	Negative
Oseltamivir	7.5 mg/mL	Negative
Levofloxacin	3 mg/L	Negative
Azithromycin	1.35 mg/mL	Negative
Tobramycin	1.8 mg/L	Negative
Triamcinolone acetonide	25 µg/mL	Negative
Budesonide	16.7 µg/mL	Negative
Fluticasone	1 mg/mL	Negative
Beclomethasone	10 mg/mL	Negative
Dexamethasone	375 µg/mL	Negative
Mometasone furoate	41.7 µg/mL	Negative
Normal saline	1 mg/mL	Negative
Oxymetazoline	15% v/v	Negative

11.3 Limit of Detection (Analytical Performance)

The limit of detection (LOD) of **R test SARS-CoV-2 Ag** was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus. Presumed negative nasal swab specimens were eluted in buffer and mixed thoroughly to be used as the clinical diluent. Inactivated SARS-CoV-2 virus was diluted in this nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

R test SARS-CoV-2 Ag LOD was confirmed as $1.6x10^2$ $TCID_{50}$/mL.

11.4 Clinical Performance

The **R test SARS-CoV-2 Ag** has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the **R test SARS-CoV-2 Ag** has a high overall relative accuracy. From the clinical evaluation results, the clinical sensitivity of this product is 95.7%, the clinical specificity is 99.1%, and the total accuracy rate is 97.9%.

R-test SARS-CoV-2 Ag	PCR result		Total
	Positive	Negative	
Positive	110	2	112
Negative	5	209	214
Total	115	211	326

12. LIMITATIONS of METHODOLOGY

- The contents of this kit are to be used for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
- False negative results may occur if inadequate extraction buffer is used.
- False negative results may occur if swabs are stored in their paper sheath after specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

13. PRECAUTIONS

- The product is only for in vitro diagnosis. The test result shall not be used as the only index for evaluating the patient's condition, and the patient's clinical manifestation and other laboratory tests must be combined to conduct a comprehensive analysis of the condition.
- Inspection of product packing and sealing as well as expiration date is necessary prior to performing the test.
- Test should be performed as quickly as possible. Long-time exposure of test to air and moisture will cause invalid results.
- Overload of specimens may result in unexpected results, such as false positives.
- Accuracy of test can be affected by environment temperature (<10°C or >40°C) and relative humidity (>80%).

14. MANUFACTURER

Lab Diagnostic Systems (SMC) Pvt Ltd
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 111 145 236
Web: www.ldspak.com

[SYMBOLS USED]

Symbol	Description
	Use-by date
	Lot Number
	Manufacture Date
	Manufacturer
	Keep Away from Sunlight
	Temperature Limitation
	In Vitro Diagnostic Medical Device
	Do not Re-use

R-test Cholera Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-25050

INTENDED USE

The R-test Cholera Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of Vibrio Cholerae (V. Cholerae) O139 antigen and O1 antigen in human fecal specimen. It is intended to be used as a screening test by professionals and provides a preliminary test result to aid in the diagnosis of infection with V. Cholerae. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

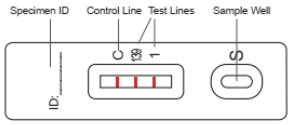
Cholera is an acute infectious disease that is characterized by massive loss of body fluids and electrolytes through severe diarrhea. The etiological agent of cholera has been identified as V. Cholerae, a gram-negative bacterium, which is generally transmitted to humans via contaminated water and food.

The species V. Cholerae is divided into several serogroups on the basis of O antigens. The subgroups O1 and O139 are of special interest because both can cause epidemic and pandemic cholera. It is critical to determine as quickly as possible the presence of V. cholerae O1 and O139 in clinical specimens, water, and food so that appropriate monitoring and effective preventive measures can be undertaken by public health authorities.

The R-test Cholera Ag Rapid Test can be used directly in the field by minimally skilled personnel and the result is available within 10 minutes, without the use of cumbersome laboratory equipment.

TEST PRINCIPLE

The R-test Cholera Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti- V. Cholera O1and O139 antibodies conjugated with colloid gold (O1/O139-antibody conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test line (1line). The 1 line is pre-coated with monoclonal anti- V. Cholera O1 antibody. The 139 line is pre-coated with monoclonal anti- V. Cholera O139 antibody. The C line is pre-coated with a control line antibody.



When an adequate volume of test specimen is applied into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The V. Cholera O1/O139 antigen if present in the specimen will bind to the corresponding O1/O139-antibody gold conjugate. This immunocomplex is then captured on the membrane by the pre-coated anti- V. Cholera O1/O139 antibody, forming a burgundy colored test line, indicating a Cholera O1/O139 positive test result. Absence of the test line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of the color development on the test line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Stool collection devices, each containing 2 mL sample extraction buffer
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of oral-food borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 10-minute window should be considered invalid and must be repeated
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

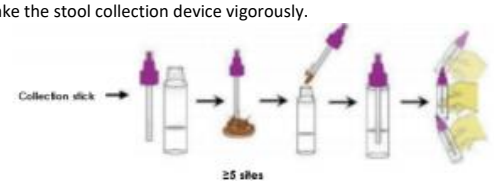
SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below. Procedure A: Solid stool samples.

Procedure A: Solid stool samples

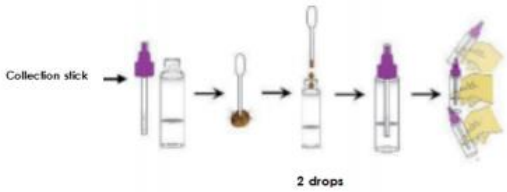
1. Collect a random stool sample in a clean, dry receptacle.
2. Open the stool collection device by unscrewing the top, and then use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.
3. Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.
4. Replace the collection stick and tighten securely to close the stool collection device.
5. Shake the stool collection device vigorously.



The specimen is now ready for testing, transportation or storage.

Procedure B: Watery stool samples

1. Collect a random stool sample in a clean, dry receptacle.
2. Open the stool collection device by unscrewing the top.
3. Fill the plastic dropper with the sample; dispense 2 drops (70- 90 µL) into the stool collection device.
4. Replace the collection stick and tighten securely to close the stool collection device.
5. Shake the stool collection device vigorously.



The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2°C-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.

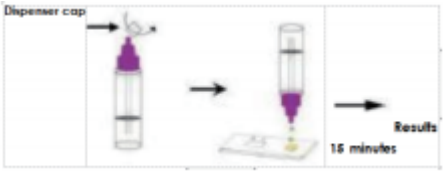
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if they`re refrigerated or frozen.

Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure a homogenous liquid suspension.

Step 4: Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution into the sample well of the test device. Do not overload sample.



Step 5: Set up the timer Step

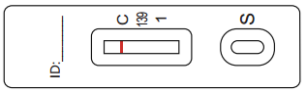
Step 6: Results can be read within 15 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute. Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

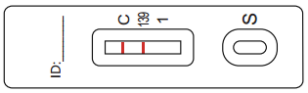
- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

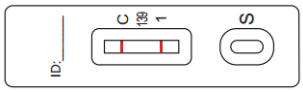
- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable V. Cholera antigen is present in the specimen. The result is non-reactive or negative.



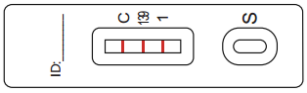
- **POSITIVE RESULT:** If both C and 1 lines develop, the test indicates for the presence of V. Cholera O1 antigen in the specimen. The result is V. Cholera O1 reactive or positive.



- If both C and 139 lines develop, the test indicates for the presence of V. Cholera O139 antigen in the specimen. The result is V. Cholera O139 reactive or positive.

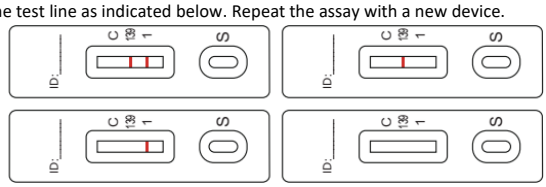


- In addition to the presence of C line, both 1 and 139 lines develop, the test indicates for the presence of V. Cholera O1 antigen and O139 antigen. The result is both V. Cholera O1 and O139 reactive or positive.



Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic decision is made.

- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the test line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

A clinical study was performed with 230 patient fecal samples using a commercial Cholera Rapid Test as a reference test. Comparison for all subjects is shown in the table below.

	R-test Cholera Ag Rapid Test		
HIv Ag/Ab Patients	**Positive**	**Negative**	**Total**
V. cholera O1 Positive	70	2	72
V. cholera O1 Negative	2	156	158
V. cholera O1 Total	72	158	230

Sensitivity: 96.7%, Relative Specificity: 98.8%, Overall Agreement: 98.3%

2. **Limit of Detection**

The limit of detection of the R-test Cholera Ag Rapid Test was determined using suspension of V. Cholera O1 and O139 cultures. Serial dilutions (in triplicate) were made and the number of colony forming units (cfu) was calculated by plating the bacteria on TCBS (thiosulfate citrate bile salts sucrose) agar plate. The limit of detection is defined as the number of bacteria in a specimen that gives 95% detection rate (detected 95% of the time). The R-test Cholera Ag Rapid Test consistently detects suspensions containing at least 105 cfu/mL V. Cholera O1 and/or at least 105 cfu/mL V. Cholera O139Limit of Detection.

3. **Precision**

Three specimens composed of strong, weak and negative cholera antigen were tested against 10 devices at each condition. All of the devices identified the specimens correctly with the same line intensity at each given condition.

4. **Cross-Reactivity**

The cross-reactivity of the R-test Cholera Ag Rapid Test with other organisms was assessed using suspension of cultures of the following organisms at a concentration of 108 cfu/mL. None of the organisms show any cross-reactivity in the test:

Escherichia coli	Salmonella typhi	Shigella dysenterae type 1
Pseudomonas aeruginosa	Vibrio damsela	Vibrio vulnificus
Serratia marcescens	Vibrio hollisae	Vibrio harveyi
Vibrio cincinnatiensis	Vibrio ordalii	

5. **Interference**

The effects of multiple elevated analytes on the test performance of R-test Cholera Ag Rapid Test were assessed.

Analytes	Concentration Tested
Uric Acid	600 to 940 pmol/L
Hemoglobin	18 to 20 mg/dL
Total Bilirubin	34 to 65 pmol/L
Triglycerides	200 to 500 mg/dL

The results indicated that none of the above conditions interfered with R-test Cholera Ag Rapid Test.

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Results must be followed closely when testing the presence of V.Cholera antigens in human fecal specimen from individual subject.
- Failure to follow the procedure may give inaccurate results.
- The R-test Cholera Ag Rapid Test is limited to the qualitative detection of V. Cholera O1 and O139 antigen in human fecal specimen. The intensity of the test line does not have linear correlation with the antigen concentration of the specimen.
- A nonreactive result for an individual subject indicates absence of detectable V. Cholera antigen. However, a nonreactive test result does not preclude the possibility of exposure to or infection with V. Cholera bacteria.
- A nonreactive result can occur if the quantity of the V. Cholera antigen present in the specimen is below the detection limits of the assay or the antigen that are detected are not present in the fecal specimen picked by the stool collection device.
- Infection may progress rapidly. If the symptom persists, while the result from R-test Cholera Ag Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

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2. Gardner, A.D., and Venkatraman, K.V. The antigens of the cholera group of vibrios. 3. Hyyg. 35:262-282, 1935.
3. Ramamurthy T, Yamasaki S, Takeda Y, Nair GB. Vibrio cholerae O139 Bengal: odyssey of a fortuitous variant. Microbes Infect. 2003, 5(4):329-44.
4. Hasan JA, Huq A, Nair GB, Garg S, Development and testing of monoclonal antibody- based rapid immunodiagnostic test kits for direct detection of Vibrio cholerae O139 synonym Bengal. J Clin Microbiol. 1995, 33(11):2935-9.
5. Hasan JA, Huq A, Tamplin ML, Siebeling RJ, Colwell RR. A novel kit for rapid detection of Vibrio cholerae O1. J Clin Microbiol. 1994 32(1):249-52

Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Cryptococcus Capsular Polysaccharide Rapid Test

50 tests per kit
Ref: R-39050

INTENDED USE

The R-test Cryptococcus Capsular Polysaccharide Rapid Test is a lateral flow chromatographic immunoassay for the detection of cryptococcus neoformans capsular polysaccharide in human cerebrospinal fluid or serum samples.

SUMMARY AND EXPLANATION OF THE TEST

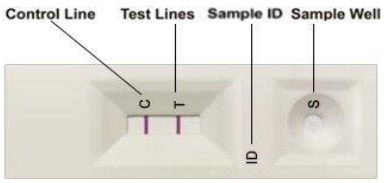
Cryptococcus neoformans is an important conditionally pathogenic fungus, which often invades meninges, lungs and skin and causes infection in corresponding parts. Cryptococcus neoformans meningitis (CNM) is the most common type of fungal infection in the central nervous system. In recent years, the morbidity and mortality of CNM have increased significantly. According to statistics, about 5%~10% of AIDS patients in the United States have cryptobrain, while in some developing countries, the incidence of cryptobrain in AIDS patients is higher. The pulmonary cryptococcosis caused by Cryptococcus neoformans infection in respiratory system is also increase annually.

The R-test Cryptococcus Capsular Polysaccharide Rapid Test uses the specific antibody of Cryptococcus neoformans capsular polysaccharide and colloidal gold technology to provide an effective auxiliary means for monitoring susceptible people.

TEST PRINCIPLE

The R-test Cryptococcus Capsular Polysaccharide Rapid Test is a lateral flow chromatographic immunoassay. This product is based on the principle of colloidal gold immunochromatography and double antibody sandwich method.

Gold labeled Cryptococcus antibody is pre-embedded on glass fiber, and Cryptococcus antibody and sheep anti-mouse antibody are respectively coated on detection line (T) and quality control line (C) on nitrocellulose membrane. When the detect sample is positive, Cryptococcus capsular polysaccharide in the sample combines with colloidal gold labeled antibody to form a complex. Due to chromatography, the complex moves forward along the paper strip and reacts with the pre-coated antibody when passing through the detection line (T), forming an immune complex and showing a red band. The free gold labeled antibody principle combines with sheep anti-mouse antibody in the quality control line (C) to show a red band. Negative samples only develop color on quality control line (C). The red band of quality control line (C) is the standard to judge whether the chromatography process is normal or not, and it is also the internal control standard of reagents.



REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- ample extraction buffer
- One package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components of any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Controls in the same manner as patient specimens.
12. The testing results should be read 15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15-minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Collect samples according to standard laboratory procedures. Avoid cross-contamination among samples. Sample labelling should be clear and correct without mistake. Samples with severe hemolysis and high viscosity are not applicable.

Samples should be frozen during transportation. Sample transportation should comply with biosafety requirements. Samples may be stored at 2°C-8°C for up to 24 hours. If longer storage is required, freezing at ≤-20°C is recommended. Avoid repeated freezing and thawing

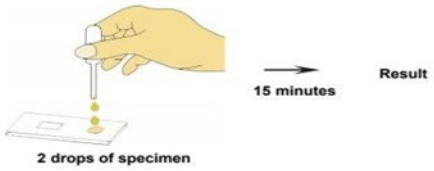
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2 drops of specimen (about 60~70µL) into the sample well, making sure there are no air bubbles.



Step 5: Set up the timer

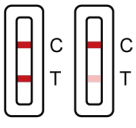
Step 6: Results can be read within 15 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute. Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30°C.
  - The temperature of the test area falls outside of 15 -30°C.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

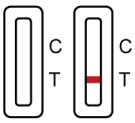
Positive (+):



Two red bands appear, one on the detection line (T) and the other on the quality control line (C), indicating the presence of Cryptococcus capsular polysaccharide in the sample.

Negative (-):

Only one red band appears on the quality control line (C), but no red band appears on the detection line (T), indicating that there is no capsular polysaccharide in the sample or the capsular polysaccharide is lower than the detected level.

Invalid: 

If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

A total of 100 specimens from non-cryptococcus neoformans capsular polysaccharide infected patients and 20 specimens from patients undergoing anti-cryptococcus neoformans capsular polysaccharide treatment were tested with the R-test Cryptococcus Capsular Polysaccharide Rapid Test. Comparison for all subjects is shown in the following table.

	R-test Cryptococcus Capsular Polysaccharide Rapid Test		
Patients	**Positive**	**Negative**	**Total**
Positive	18	2	20
Negative	1	99	100
Total	19	101	120

Relative Sensitivity: 90%, Relative Specificity: 99%, Overall Agreement:97.5%

LIMITATIONS OF PROCEDURE

- This product is only used for in vitro diagnosis.
- Please check whether the product is within the validity period and the sealing condition of the package before use.
- Severe hemolytic samples should be re-sampled for detecting.
- The reagent can be stored at room temperature. Beware of damp and avoid freezing. Reagents stored at low temperature should be balanced to room temperature before use.
- After the reagent is taken out of the package, the experiment should be carried out as soon as possible. If it is placed in the air for too long, it will become damp and fail.
- Excessive sample addition may lead to sample reflux, resulting in false positive and other abnormal results.
- The sensitivity of detection cannot be guaranteed when the ambient temperature is lower than 10℃ or higher than 40℃ and the relative humidity is higher than 80%.

REFERENCES

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test

50 tests per kit
Ref: R-15050

INTENDED USE

The R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG anti-dengue virus, IgM anti-dengue virus and dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with dengue virus.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

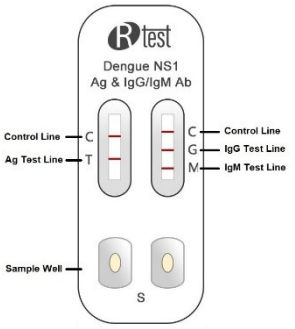
Dengue virus is an enveloped, single-stranded, positive-sense RNA virus that comprises four related but distinct serotypes (DEN1, 2, 3, and 4). The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally Aedes aegypti and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Serological detection is a common method for the diagnosis of infection with dengue virus. IgM anti-dengue virus starts to appear 3 days after initial exposure and remains in circulation for about 30-60 days. IgG anti-dengue virus rises around 7 days, peaks at 2-3 weeks and persists for the duration of life. Detection of antigens, such as dengue NS1, released during virus replication in the infected patient show very promising results; it enables diagnosis from the first day after the onset of fever up to day 9 once the clinical phase of the disease is over, thus, allowing early detection and prompt treatment.

The R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test detects IgG and IgM anti-dengue virus and circulating dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It can be performed within 20-25 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test contains two test strips (left side: Dengue Ag test; right side: Dengue IgG/IgM test).



The **Dengue Ag Rapid Test** on the left-side is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing antibodies to dengue NS1 antigen conjugated with colloidal gold (dengue Ab conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with antibodies to dengue NS1 antigen, and the C line is pre-coated with a control line antibody. The antibodies to dengue NS1 recognize the antigens from all four dengue virus serotypes.

The **Dengue IgG/IgM Rapid Test** on the right-side is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant dengue envelope antigens conjugated with colloidal gold (dengue Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with antibodies for the detection of IgG anti-dengue virus, the M line is pre-coated with antibodies for the detection of IgM anti-dengue virus, and the C line is pre-coated with a control line antibody.

When an adequate volume of specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Dengue NS1 antigen, if present in the specimen, will bind to the dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibodies to dengue NS1 antigen forming a burgundy colored T line. IgG and/or IgM anti-dengue virus, if present in the specimen, will bind to the dengue Ag conjugates. The immunocomplex is then captured by the pre-coated reagent forming a burgundy colored G and/or M line, respectively.

Suggested result interpretation: Ag positive: Early acute primary or secondary infection. IgM positive: acute primary or secondary infection. IgG positive: secondary or past infection. IgM and IgG positive: Late primary or early secondary acute infection.

Absence of any G, M or T lines suggests a negative result. Each test contains an internal control (C lines) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies in both the left and right panels, regardless of color development on any of the test lines. If the C line does not develop in a panel, the test result is invalid and the specimen must be retested with another device. An invalid result in one panel does not invalidate the test result in the other panel.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle x 2
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Capillary tubes (20 µL)
- Plastic droppers
- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The test result should be read 20-25 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 20-25 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4:

For detection of Dengue NS1 Ag

a) Fill the plastic dropper with specimen. Holding the dropper vertically, dispense 1 drop (about 40µL) of serum/plasma or 2 drops of whole blood (about 60µL) into the center of the sample well (S well), making sure that there are no air bubbles.

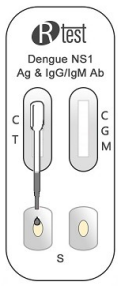
b) Immediately add 2 drops (about 40-80 µL) of diluent buffer to the same sample well (S well) with the bottle positioned vertically.

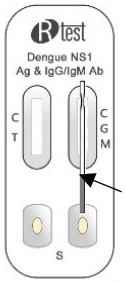
For detection of Dengue IgG/IgM

a) Fill the capillary tube or dropper with serum/plasma/whole blood specimen not to exceed the specimen line as shown in the images below.

b) For better precision, transfer the serum/plasma by a pipette capable of delivering 10µL of volume or add 1 drop (about 30µl) of whole blood. Holding the capillary tube vertically/pipette, dispense the entire specimen into the center of the sample well (S well) making sure that there are no air bubbles.

c) Immediately add 2 drops (about 40-80 µL) of diluent buffer into the same sample well (S well) with the bottle positioned vertically.





Step 5: Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 25 minutes only. However, any results interpreted outside of the 20 to 25-minute window should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.

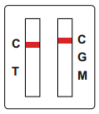
Step 6: Read results at 20 minutes.

QUALITY CONTROL

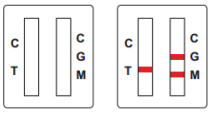
- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

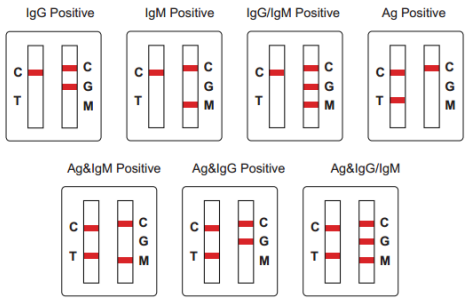
- **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in the G, M or T lines indicates that neither anti-dengue virus antibodies nor dengue virus NS1 antigen are detected. The result is negative or non-reactive.



- **INVALID:** If no C line develops, the assay is invalid regardless of any burgundy color in the G, M or T lines as indicated below. Repeat the assay with a new device.



- **POSITIVE RESULT:**



Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection

The R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test was found to detect NS1 protein in all 4 types of dengue virus lysate I, II, III, and IV. The limit of detection is 0.25 ng/mL as determined on recombinant dengue NS1 antigen from serotype 2 (DEN2).

2. Clinical Performance for Ag Test

A total of 120 specimens were collected from susceptible subjects and normal healthy control subjects, and tested by the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test and by a commercial Dengue Ag ELISA. Comparison for all subjects is shown in the following table:

Table 1

	R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test		
Ag EIA Test	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	1	99	100
Total	21	99	120

Relative Sensitivity: 100%, Relative Specificity: 99%, Overall Agreement: 99.2%

3. Clinical Performance for IgG Test

A total of 326 specimens were collected from susceptible subjects, and tested with the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test and by a commercial EIA. Comparison for all subjects is shown in the following table:

Table 2

	R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test		
IgG EIA Test	**Positive**	**Negative**	**Total**
Positive	36	1	37
Negative	2	287	289
Total	38	288	326

Relative Sensitivity: 97.3%, Relative Specificity: 99.3%, Overall Agreement: 99.1%

4. Clinical Performance for IgM Test

A total of 314 specimens were collected from susceptible subjects and tested with the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test and by a commercial EIA. Comparison for all subjects is shown in the following table:

Table 3

	R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test		
IgM EIA Test	**Positive**	**Negative**	**Total**
Positive	31	1	32
Negative	3	279	282
Total	34	280	314

Relative Sensitivity: 96.9%, Relative Specificity: 98.9%, Overall Agreement: 98.7%

5. Cross-Reactivity

Specimens from other infectious diseases were tested for cross-reactivity with the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test according to the standard procedure. The results showed that the following specimens (n=1-10) did not cross-react with the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test.

Chikungunya	**CMV**	**HAV**	**HBV**	**HCV**
HIV	**hCG**	***H.pylori***	**TB**	***T. gondii***
Typhoid	**Rubella**	**ANA**	**HAMA**	**RF (up to 8,400 IU/mL)**

6. Interference

Common substances (such as pain and fever medication, blood components) may affect the performance of the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test. This was studied by spiking these substances into negative and positive standard controls for dengue NS1 antigen, dengue IgG and IgM. The results are presented in the following table and demonstrate, at the concentrations tested, the substances studied do not affect the performance of the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test.

List of potentially interfering chemical analytics and concentrations tested:

1. Albumin	60 g/L	5. Glucose	5.5 mmol/L
2. Bilirubin	20 mg/dL	6. Heparin	3,000 U/L
3. Creatinine	442 µmol/L	7. Sodium citrate	3.8%
4. EDTA	3.4 µmol/L	8. Salicylic acid	4.34 mmol/L

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to dengue virus and dengue NS1 antigen in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test is limited to the qualitative detection of antibodies to dengue virus and dengue NS1 antigen in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibodies and NS1 antigen titers in the specimen.
- Information about the dengue virus serotype(s) present in a specimen cannot be provided from this test.
- Serological cross-reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile virus, yellow fever, etc.). Therefore, it is possible that patients who were exposed to these viruses may show some level of reactivity with this test.
- A negative or non-reactive result for an individual subject indicates absence of detectable dengue virus antibodies or NS1 antigen. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with dengue virus.
- A negative or non-reactive result can occur if the quantity of antibodies to dengue virus or dengue NS1 antigen present in the specimen is below the detection limits of the assay or the antibodies and antigen that are detected are not present during the stage of disease in which a sample is collected. For example, some patients may not produce detectable levels of IgM antibodies in early infection or repeat infection.
- Infection may progress rapidly. If the symptoms persist while the result from the R-test Dengue NS1 Ag & IgM/IgG Ab Combo Rapid Test is negative or non-reactive, it is recommended to test with an alternative method, such as PCR or ELISA.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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3. Monath TP. Dengue: the risk to developed and developing countries. Proc Natl Acad Sci U S A 1994; 91:2395-400.
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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test FOB Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-37050

INTENDED USE

The R-test FOB Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of fecal occult blood (FOB) in human fecal specimens in laboratories or physician offices. It is intended to be used by healthcare professionals to aid in the detection of bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

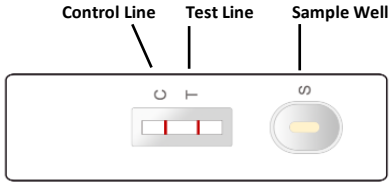
SUMMARY AND EXPLANATION OF THE TEST

The American Cancer Society and Centers for Disease Control recommend an occult blood feces test annually after age 50 to aid in the early detection of colorectal cancer. Two types of FOB tests are commercially available: guaiac dye tests and immunochemical tests (iFOBT). The guaiac tests are widely used but lack accuracy. The guaiac dye is a naturally occurring phenolic compound that can be oxidized to quinone by hydrogen peroxidase activity of human hemoglobin (hHb) resulting in a detectable color change. The sensitivity and specificity of guaiac tests are much lower than those of immunochemical assays. The low accuracy of the guaiac tests is related to dietary peroxidases, including hemoglobin from meat and uncooked fruits and vegetables. Non-cancerous gastrointestinal tract bleeding and iron intake may also cause false positive results with guaiac tests.

Immunochemical tests are highly accurate for the detection of hHb compared to the guaiac method. The results of immunochemical FOB tests (iFOBT) are not affected by dietary peroxidases, animal blood or ascorbic acid. A Japanese study demonstrated that iFOB screening tests reduced mortality of colorectal cancer by 60%. The R-test FOB Rapid Test is an iFOBT designed to specifically detect low levels of human fecal occult blood. It can be performed within 10 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test FOB Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a colored conjugate pad containing monoclonal anti-hHb antibody conjugated with colloid gold (anti-hHb conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another monoclonal anti-hHb antibody, and the C line is pre-coated with a control line antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. hHb, if present in the specimen at or higher than 25 ng/mL, will bind to the anti-hHb conjugates. The immunocomplex is then captured by the pre-coated reagent forming a colored T line, indicating a FOB positive test result. Absence of the T line suggests a negative result. Each test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control line antibodies regardless of the color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.



REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Stool collection devices, each containing 2 mL sample extraction buffer
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
3. Do not open the sealed pouch unless ready to conduct the assay.
4. Do not use any kit components beyond their stated expiration date.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Bring all reagents to room temperature (15-30°C) before use.
7. Do not scoop fecal specimen as this may lead to excess fecal specimen that may block the sample well and result in an invalid test result.
8. Do not use specimens for testing if blood is visible.
9. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
10. Users of this test should follow the US CDC Universal Precautions for bio-safety.
11. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
12. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
13. The testing results should be read 10 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside 10 minutes should be considered invalid and must be repeated.
14. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

Patient Preparation

Specimens should not be collected from patients with the following conditions which may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding

Dietary restrictions are not necessary. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, and produce positive reactions. On the advice of a physician, these medicines may be temporarily discontinued for 7 days prior to and during the test period.

Specimen Collection

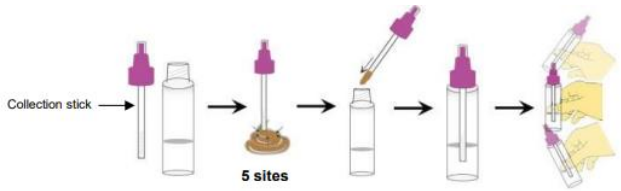
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Step 1: Collect a random sample of feces in a clean, dry receptacle.

Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool specimen in at least five different sites. Do not scoop stool specimen. Ensure that stool specimen is only in the grooves of the collection stick. Excess stool specimen may lead to an invalid test result.

Step 3: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously to extract the hHb in the specimen. The specimen is now ready for testing, transportation or storage.



Note: It is recommended to test the specimen immediately after extraction. If not tested immediately, the extracted specimen may be stored at room temperature (20-37°C) for up to 10 days or at 2-8°C for up to 21 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple freeze-thaw cycles.

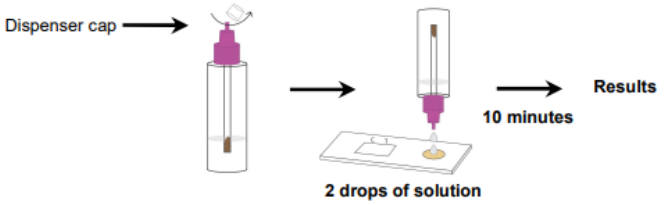
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure a homogenous liquid suspension.

Step 4: Hold the stool collection device vertically. Twist off the tip. Dispense 2 drops (70-90 µL) of the solution into the sample well of the cassette. Do not overload samples.



Step 5: Set up timer.

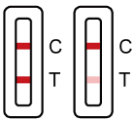
Step 6: Results can be read at 10 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of the 10 minutes only. However, any results interpreted outside 10 minutes should be considered invalid and must be repeated. Discard used device after interpreting the result following local laws governing the disposal of device.

QUALITY CONTROL

- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 -30℃.
  - To verify a higher-than-expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

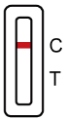
INTERPRETATION OF ASSAY RESULT

Positive (+):



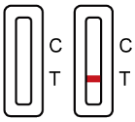
In addition to the presence of the C line, if the T line develops, the test indicates that the concentration of hHb in the sample is equal to or higher than 25 ng/mL in buffer. The result is FOB positive or reactive.
Specimens with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

Negative (-):



If only the C line develops, the test indicates that the concentration of hHb in the sample is below 25 ng/mL in buffer. The result is negative or non-reactive.

Invalid:



If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new device. If caused by an excess amount of fecal specimen collected, collect a new specimen and retest.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The analytical sensitivity of the test is 25 ng/mL hHb in buffer or 3.5 µg/g hHb in feces.

2. Specificity

The R-test FOB Rapid Test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

Chicken Hemoglobin 2 mg/mL	Horse Hemoglobin 2 mg/mL
Turkey Hemoglobin 2 mg/mL	Sheep Hemoglobin 2 mg/mL
Pig Hemoglobin 2 mg/mL	Fish Hemoglobin 2 mg/mL
Beef Hemoglobin 2 mg/mL	Rabbit Hemoglobin 2 mg/mL
Goat Hemoglobin 2 mg/mL	

3. Dose Hook Effect

The R-test FOB Rapid Test cassettes do not show any hook effect or prozone effect up to the concentration of 4 mg/mL hHb in buffer.

4. Reproducibility

Known positive specimens were tested in multiple assays and identically positive results were observed. Similarly, known negative specimens produced negative results when tested in multiple assays.

5. Clinical Performance

A total of 135 specimens were collected and tested by the R-test FOB Rapid Test and by a leading commercial FOB rapid test. Comparison for all specimens is shown in the following table:

	R-test FOB Rapid Test		
Reference Test	**Positive**	**Negative**	**Total**
Positive	46	2	48
Negative	1	86	87
Total	47	88	135

Relative Sensitivity: 95.8% (95% CI: 85.7-99.5%), Relative Specificity: 98.9% (95% CI: 93.8-100%), Overall Agreement: 97.8% (95% CI: 93.6-99.5%).

6. Interference

Common substances (such as pain and fever medication, blood components) may affect the performance of the R-test FOB Rapid Test. This was studied by spiking these substances into negative serum and negative serum samples spiked with two levels of FOB standard controls (negative and positive). The results demonstrate, at the concentrations tested, the substances studied do not affect the performance of the R-test FOB Rapid Test.

List of potentially interfering substances and concentrations tested:

Ascorbic acid 20 mg/dL	Glucose 2,000 mg/dL
Dietary iron (Fe2+/Fe3+) 5 mg/dL	Caffeine 40 mg/dL
Bilirubin 100 mg/dL	Horseradish Peroxidase 20 mg/mL

LIMITATIONS OF PROCEDURE

- The Test Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of occult blood in feces. Failure to follow the procedure may give inaccurate results.
- The R-test FOB Rapid Test is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.
- A negative or non-reactive result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. A negative or non-reactive result can also be obtained if the quantity of occult blood present in the specimen is below the detection limit of the assay.
- The R-test FOB Rapid Test has not been validated for testing of patients with hemoglobinopathies.
- Specimens containing visible blood may produce negative results due to the hook effect.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:02/2022

R-test H. pylori Ag Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-16050

INTENDED USE

The R-test H. pylori Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Helicobacter pylori antigens in human stool samples in vitro, and is suitable for the auxiliary diagnosis of Helicobacter pylori infection.

The R-test H. pylori Ag Rapid Test is not intended for quantitative results. It provides only preliminary analytical data. For a final diagnosis of Helicobacter pylori infection, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

SUMMARY AND EXPLANATION OF THE TEST

Helicobacter pylori is a spiral-shaped, micro-anaerobic, Gram-negative bacillus that requires very harsh growth conditions. It is the only microbial species known to survive in the human stomach. Helicobacter pylori is parasitic in the gastric mucosa, and 67% to 80% of gastric ulcers and 95% of duodenal ulcers are caused by Helicobacter pylori. Helicobacter pylori settled on the surface of gastric epithelial cells is shed with the rapid renewal of gastric mucosal epithelium, and Helicobacter pylori is also shed and excreted from the feces through the gastrointestinal tract. There are many diagnostic methods for Helicobacter pylori infection, such as biopsy, isolation and culture of Helicobacter pylori, rapid urease test, urea breath test, urine ammonia excretion test, serological test and polymerase chain reaction. This product is used as an auxiliary diagnosis for Helicobacter pylori infection by detecting the Helicobacter pylori antigen in human stool samples.

The R-test H. pylori Ag Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of Helicobacter pylori infection via assay of H. pylori Ag. The test can be performed within 5 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test H. pylori Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-HP antibody conjugated with colloid gold (HP Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (Cline). The T line is pre-coated with another anti-HP antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. If it is a positive sample, it will bind to the HP Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-HP Ab, forming a burgundy colored T band, indicating an HP positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer
- A container to collect stool specimen

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of oral-food borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 5-10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 5-10-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air- conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Collect a stool specimen in a clean glass, plastic, or wax coated container.

Samples should be sent for inspection in time after collection. If they need to be stored, they should be refrigerated at 2-8°C for 72 hours.

ASSAY PROCEDURE

Step 1: Unscrew the cap of the sample tube, take out the stool sample, and be careful not to spill the solution in the bottle.

Step 2: Randomly sample about 50 mg from at least 3 different locations of the sample with a stool stick. Then insert it into the sample tube, tighten the cap, and stir well.

Step 3: Equilibrate the test reagents and samples to room temperature, tear open the aluminum foil bag, take out the test card, and place it flat.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90 μL) of specimen into the sample well making sure that there are no air bubbles.

Note: Add 1 drop of Diluent buffer into the sample well if flow migration is not observed within 30 seconds in the result window when tested with serum samples, which could occur with a highly viscous specimen.

Step 5: Set up the timer.

Step 6: Result should be read at 5 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15-30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable HP is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of HP in the specimen. The result is HP positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.*
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

300 fecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with the R-test H. pylori Ag Rapid Test and with the UBT as reference test. A comparison of the results for all subjects is shown in the table below.

	R-test H. pylori Ag Rapid Test		
UBT	**Positive**	**Negative**	**Total**
Positive	115	5	120
Negative	2	178	180
Total	117	183	300

Sensitivity: 95.8%, Relative Specificity: 98.9%, Overall Agreement: 97.7%

2. Limit of Detection

The detection limit for the R-test H. pylori Ag Rapid Test is 5 ng/ml of H. pylori lysate. Fecal specimen extractions containing H. pylori lysate equal to or greater than 5 ng/ml routinely test positive. Specimens containing H. pylori lysate less than 5 ng/ml may also produce a very faint positive line, especially with an assay time extended beyond 15 minutes.

3. Analytic Sensitivity

The following experiments were done to validate the sensitivity of the R-test H. pylori Ag Rapid Test:

Normal fecal specimen extractions were spiked with H. pylori lysate to concentrations of 0, 1.25, 2.5, 5, 10, 20 ng/ml. The specimens were run on the H. pylori Ag Cassette Rapid Test. Results are shown in the table below.

H. pylori lysate ng/mL	**0**	**1.25**	**2.5**	**5**	**10**	**20**
Number of positive	0	0	12	20	20	20
Number of negative	20	20	8	0	0	0

n=20 relative sensitivity at 5 ng/mL = 20/20 x 100% = 100%

PRECAUTIONS

- Please operate in strict accordance with this manual and strictly control the reaction time.
- This kit is a one-time-use product for in vitro diagnosis only. Reagents beyond the expiration date or with damaged packaging shall not be used in the test.
- The testing of the samples must be carried out in a specific environment, and the samples that come into contact during the testing process should be operated in accordance with the laboratory inspection procedures for infectious diseases.
- It is recommended to complete the test within 6 hours after sample collection.
- The small cup that holds the feces must be clean and not reusable to avoid contamination. Test samples should avoid repeated freezing and thawing, and samples contaminated with bacteria should not be used for testing, so as not to affect the test results. Samples stored at 4°C should be equilibrated to room temperature before use.
- Samples should be collected according to the sample collection method described in this manual. Samples should not be collected during the menstrual period, hemorrhoid bleeding and hematuria, so as not to affect the test results.
- Because there may be substances in the sample to be tested that interfere with the test results, and there may be errors in actual operation, the experimental results may be wrong. Therefore, suspicious test results should be re-examined or combined with other detection methods to clarify the experimental results.
- Beware of getting the test strip/card wet, use it as soon as possible within 30 minutes after opening the inner package, and do not use the test card when it is wet.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HAV IgM/IgG Rapid Test

RELIABLE TESTING

50 tests per kit

Ref: R-28050

INTENDED USE

The R-test HAV IgM/IgG Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of antibodies (IgG and IgM) to hepatitis A virus (HAV) in human serum, plasma or whole blood. It is intended to be used as a screening test by professionals and provide a preliminary result to aid in the diagnosis of active and/or past HAV infection.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

HAV, a positive-sense RNA virus, is a unique member of the Picornaviridae family. HAV is highly contagious and is primarily transmitted by the fecal-oral route, either through person to person contact or consumption of contaminated food or water. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate can increase following oral-anal contact.

The presence of anti-HAV IgM in blood samples suggests an acute or recent HAV infection. In most infected individuals, anti-HAV IgM rapidly increases in titer over a period of 4-6 weeks post-infection, and then declines to non-detectable levels within 3 to 6 months. Anti-HAV IgG can be detected at the onset of symptoms, and levels remain elevated throughout the life of an individual. Protective immunity from an infection with HAV is indicated by an anti-HAV IgG level ≥20-33 mIU/mL, however these levels do not necessarily ensure protection from a future HAV infection. A patient without protective levels of anti-HAV IgG (< 20-33 mIU/mL) is considered at risk of acquiring an HAV infection.

The R-test HAV IgM/IgG Rapid Test is a lateral flow immunoassay for the qualitative detection of antiHAV IgG (LoD 70 mIU/mL) and IgM in serum, plasma or whole blood. Results can be obtained within 15 minutes by minimally skilled personnel without the use of laboratory equipment

TEST PRINCIPLE

The R-test HAV IgM/IgG Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: 1) a burgundy colored conjugate pad containing HAV antigens conjugated with colloidal gold (HAV conjugates) and a control antibody conjugated with colloidal gold; 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with mouse anti-human IgG for detection of antiHAV IgG. The M line is pre-coated with mouse anti-human IgM for detection of anti-HAV IgM. The C line is pre-coated with a control antibody.

When an adequate volume of test specimen and sample diluent are dispensed into the sample and buffer wells, respectively, the specimen migrates by capillary action across the test strip. If anti-HAV IgG is present in the specimen, it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgG forming a burgundy colored G line, indicating an HAV IgG positive test result. If anti-HAV IgM is present in the specimen it will bind to the HAV conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-human IgM forming a burgundy colored M line, indicating an HAV IgM positive test result.

Absence of any test lines (G or M) suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color development on the test lines (G and M). If no control line (C line) develops, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Sample Diluent (1x5ml)
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- Plastic Dropper

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The testing results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading the results after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood:

Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2°Ċ -8°Ċ) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.

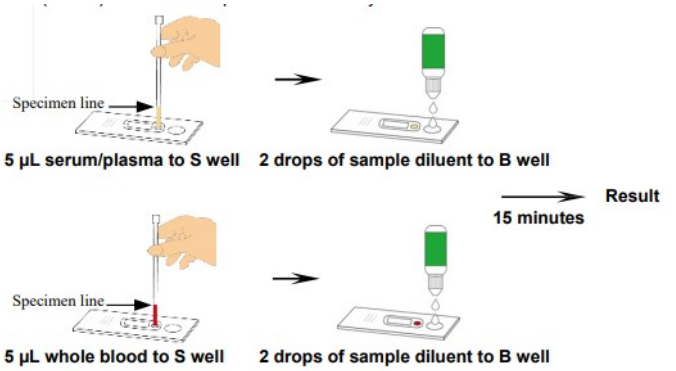
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the capillary tube with specimen not exceeding the specimen line as shown in the images below. The volume of the specimen is approximately 5 µL. For maximum precision, transfer the specimen using a pipette capable of delivering a volume of 5 µL.

Holding the capillary tube vertically, dispense the entire specimen into the center of the sample well (S well), making sure that there are no air bubbles.

Immediately add 2 drops (approximately 60-80 µL) of sample diluent into the buffer well (B well) with the bottle positioned vertically 1 drop (30-35 µL) of the specimen into the sample well, then add 1 drop (about 30 -35 µL) of Sample Diluent immediately.



Step 5: Set up timer.

Step 6: Read results at 15 minutes. Positive results may be visible as soon as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. However, any results interpreted outside 15-20 minutes should be considered invalid and must be repeated. Discard used device after interpreting the results following local laws governing the disposal of device.

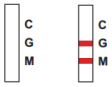
QUALITY CONTROL

- **Internal Control:** Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in both the test lines (M and G) indicates that the result is negative.

- **INVALID:** If no C line is developed, the assay is invalid regardless of any burgundy color in the test lines as indicated below. Repeat the assay with a new device.



- **POSITIVE RESULT:** In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of IgM. The result is positive.

In addition to the presence of the C line, if only the G line is developed, the test indicates the presence of IgG. The result is positive.

In addition to the presence of the C line, if both the M and the G lines are developed, the test indicates the presence of IgG and IgM The result is also positive.

Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for IgM test

A total of 306 specimens were collected and tested with the R-test HAV IgM/IgG Rapid Test and by a reference commercial anti-HAV IgM ELISA. Comparison for all subjects is shown in the following table:

	R-test HAV IgM/IgG Rapid Test		
IgM ELISA Test	**Positive**	**Negative**	**Total**
Positive	91	5	96
Negative	1	203	210
Total	98	208	306

Relative Sensitivity: 94.8%, Relative Specificity: 96.7%, Overall Agreement: 96.1%.

2. Clinical Performance for IgG test

A total of 200 clinical specimens were collected and tested with the R-test HAV IgM/IgG Rapid Test and with a reference commercial test kit. Comparison for all subjects is shown in the following table:

	R-test HAV IgM/IgG Rapid Test		
IgG ELISA Test	**Positive**	**Negative**	**Total**
Positive	125	0	125
Negative	4	71	75
Total	129	71	200

Relative Sensitivity: 100.0%, Relative Specificity: 98.0%, Overall Agreement: 98.3%

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HAV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- The R-test HAV IgM/IgG Rapid Test is limited to the qualitative detection of antibodies to HAV in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
- A negative or non-reactive test result does not preclude the possibility of exposure to or infection with HAV. A negative or non-reactive result can occur if the titer of HAV antibodies present in the specimen is below the level detectable by the assay or if HAV antibodies were not present during the stage of disease in which the sample was collected.
- A negative result does not rule out an acute infection with HAV. Samples collected too early in the course of an infection may have levels of IgM that are below the limit of detection of this test.
- Infection may progress rapidly. If the symptoms persist, even if the result from R-test HAV IgM/IgG Rapid Test t is negative or non-reactive, it is recommended to test with an alternative test method.
- Unusually high titers of heterophile antibodies or rheumatoid factor (≥1,000 IU/mL) may affect expected results.
- The presence of anti-Hepatitis A IgG antibodies can be observed due to past infections and/or vaccination11.
- Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:02/2022

R-test hCG Rapid Test

RELIABLE TESTING

150 tests per kit
Ref: R-11150S

INTENDED USE

The R-test hCG Rapid Test is a lateral flow chromatographic immunoassay for the early detection of pregnancy, by providing a quick direct visual test for the placental hormone, hCG, at the cut-off level of 10 mIU /mL of human urine or serum.

The R-test hCG Rapid Test is not intended for quantitative results. It provides only preliminary analytical data. For a final diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) is produced by trophoblastic tissue and it appears around the 8-9th day after ovulation where fertilization has occurred, or around the 4th day after conception. In a 28-day cycle with ovulation occurring at day 14 hCG can be detected in urine or serum in minute quantities around day 23, or 5 days before the expected menstruation. Its function includes facilitation of implantation as well as maintenance and development of the corpus luteum. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/mL. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester. In normal subjects, hCG in urine provides an early indication of pregnancy. Since elevated hCG levels are also associated with trophoblastic disease and certain nontrophoblastic neoplasms, the possibility of having these diseases must be eliminated before a diagnosis of pregnancy can be made.

The R-test hCG Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of early pregnancy detection via assay of hCG, a placental hormone that may be present in human serum or urine. The test can be performed within 5 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE

The R-test hCG Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-hCG antibody conjugated with colloid gold (hCG Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (Cline). The T line is pre-coated with another anti-hCG antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. hCG if present in the specimen at the level equal or higher than 10mIU/mL will bind to the hCG Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-hCG Ab, forming a burgundy colored T band, indicating an hCG positive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One test strip
  - One desiccant
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- A container to collect urine specimen or serum specimen
- Saline or Phosphate-Saline buffer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 5-10 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Urine:

- First morning urine usually contains the highest concentration of hCG and is therefore the best sample when performing the urine test. However, randomly collected urine specimens may be used. Collect a urine specimen in a clean glass, plastic, or wax coated container.
- Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 48 hours.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

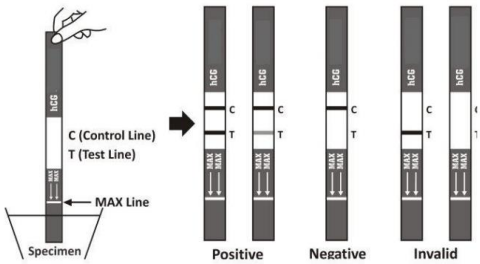
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test strip on a clean, flat surface.

Step 3: Be sure to label the test with the specimen's ID number.

Step 4: Immerse the strip vertically into the sample with the arrow end pointing towards the sample. Do not immerse past the "Mark" Line. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface.

Step 5: Result should be read at 5 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 10 minutes only. Any results interpreted outside of the 5 to 10-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.



INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable hCG is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of hCG in the specimen. The result is hCG positive or reactive. *Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made*.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher-than-expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The detection limit for the R-test hCG Rapid Test is 10 mIU/mL. The urinary or serum hCG levels equal to or greater than 10 mIU/mL routinely test positive. Samples containing hCG less than 10 mIU/mL may also produce a very faint positive line, especially with extended assay time from 10 to 30 minutes.

The following experiments were done to validate the sensitivity of the R-test hCG Rapid Test:

Six groups of urine specimens from 20 normal non-pregnant individuals were spiked with hCG to the standard (3rd IS) concentrations of 0, 2.5, 5, 10, 20, and 40 mIU/mL. The specimens were run on the R-test hCG Rapid Test. Results are tabulated in Table 1 below.

Table 1

hCG mIU/mL	0	2.5	5	10	20	40
Number of positive	0	4	10	20	20	20
Number of negative	20	16	10	0	0	0

n=20 relative sensitivity at 10 mIU/mL = 20/20 x 100% = 100%

2. Specificity

Specificity of the R-test hCG Rapid Test was determined from studies on specimens with 500 mIU/mL of human luteinizing hormone (hLH), 1,000 mIU/mL of human follicle stimulating hormone (hFSH), and 1,000 µIU/mL of human thyroid stimulating hormone (hTSH), each standard obtained from SIGMA. Specimens containing these structurally related hormones at tested concentrations were found not to significantly cross-react with hCG antibodies as to yield false positive or false negative results.

3. Accuracy

The accuracy of the R-test hCG Rapid Test was determined by a comparison study with a currently marketed hCG pregnancy test device, and was conducted at an external clinical site. A total of 172 fresh urine specimens, including 91 hCG positive and 81 hCG negative were randomly collected from the patients who visited an OB-GYN office. The two assays gave a complete agreement as shown in Table 2 below:

Table 2

	Reference hCG device (+)	Reference hCG device (-)	Total
R-test hCG Rapid Test (+)	91	0	91
R-test hCG Rapid Test (-)	0	81	81
Total	**91**	**81**	**172**

Relative Sensitivity: 100%, Relative Specificity: 100%, Overall Agreement: 100%

4. Interference

The chemicals commonly found in OTC, prescription, or abuse drugs were spiked into both hCG negative and 10 mIU/mL hCG in urine specimens. Spiked samples were tested against following substances or pHs at the indicated concentrations. There was no interference observed.

Biological Analytics			pH	
1.	Albumin	2,000 mg/dL	1.	pH 5
2.	Glucose	2,000 mg/dL	2.	pH 9
3.	Bilirubin	1,000 µg/dL	3.	pH 6.8
4.	Hemoglobin	1,000 µg/dL		

List of potentially interfering chemical analytics and concentrations tested:

1.	Acetaminophen	20 mg/dL	2.	EDTA	80 mg/dL
3.	Acetylsalicylic acid	20 mg/dL	4.	Benzoylecgonine	10 mg/dL
5.	Ascorbic acid	20 mg/dL	6.	Atropine	20 mg/dL
7.	Caffeine	20 mg/dL	8.	Cannalbinol	10 mg/dL
9.	Gentesic acid	20 mg/dL	10.	Ethanol	1%
11.	Phenylpropanoamine	20 mg/dL	12.	Methanol	1%
13.	Salicylic acid	20 mg/dL			

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of hCG in urine or serum from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- If a urine specimen is too diluted, it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the person and the test repeated. The hCG concentration less than 10 mIU/mL will be detected as negative.
- A number of disease conditions other than pregnancy such as trophoblastic disease, proteinuria hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of hCG. The diagnosis should be considered if appropriate to the clinical evidence.
- Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.
- Samples containing very high levels of hCG ≥600,000 mIU/mL may yield a test band with color intensity lighter than that, which is expected. When high dose "hook effect" is suspected, it is recommended the test be repeated with a 1:10 dilution of the specimen with DI H2O.
- Grossly hemolyzed or lipemic samples should not be used since they may give inaccurately lower or erratic results.
- Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
- Samples from patients on chemotherapy for cancer should be ruled out before running the assay.
- Positive hCG levels may be detectable for several weeks following delivery or abortion.
- Specimens testing positive during the initial days after conception may be negative later due to natural termination of the pregnancy.
- Results obtained with the R-test hCG Rapid Test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

Healthy men and healthy non-pregnant women do not have detectable hCG by the R-test hCG Rapid Test. The hCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period. The hCG levels peak about 7-12 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal shortly after parturition.

STANDARDIZATION

The R-test hCG Rapid Test has been calibrated against World Health Organization the Third International Standard (3rd IS).

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HCV Ab Rapid Test

RELIABLE TESTING

50 tests per kit
Ref: R-13050

INTENDED USE

The R-test HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the R-test HCV Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV), which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH)1, causes chronic disease in 50% of cases. HCV can also be transmitted through intravenous drug abuse and sexual contact.

Hepatitis C virus is a single-stranded RNA virus with structural similarities to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provide the basis for the construction of recombinant peptides representing putative hepatitis C virus proteins. Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins helped to identify apparently healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus. Therefore, the R-test HCV Ab Rapid Test is a useful tool for blood bank screening safety.

The R-test HCV Ab Rapid Test was developed to detect anti-HCV antibodies (IgG, IgM, IgA) in human serum or plasma. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment

TEST PRINCIPLE

The R-test HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloid gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre coated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and C line is pre coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample pad of the test device, the specimen migrates by capillary action across the strip. The antibodies to HCV, if present in the specimen, will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line, indicating a HCV Ab positive or reactive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line), which should exhibit a burgundy-colored line of the immunocomplex of control antibodies regardless of the color development on T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- Diluent Buffer in 5ml bottle
- One package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic droppers
- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15-20-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop (approximately 45 µL) of specimen into the sample well making sure that there are no air bubbles.

Immediately add 1 drop (35 - 50 µL) of Diluent buffer into the sample well with the bottle positioned vertically.

Step 5: Set up the timer.

Step 6: Read the result in 15 minutes. Positive results may be visible in as soon as 1 minute. Negative results must be confirmed at the end of 20 minutes only. Any results interpreted outside of the 15 to 20-minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
    - A new operator uses the kit, prior to performing testing of specimens.
    - A new lot of test kit is used.
    - A new shipment of kits is used.
    - The temperature during storage of the kit falls outside of 2-30℃.
    - The temperature of the test area falls outside of 15 -30℃.
    - To verify a higher than expected frequency of positive or negative results.
    - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable antibodies to HCV is present in the specimen. The result is negative or non-reactive.
- **POSITIVE RESULT:** If both C and T lines develop, the test indicates for the presence of antibodies to HCV in the specimen. The result is positive or reactive.
  Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.
- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

A total of 1050 samples from susceptible subjects were tested with the R-test HCV Ab Rapid Test and by a commercial HCV ELISA kit. Comparison of the results for all subjects is shown in the following table.

Table 1

	R-test HCV Ab Rapid Test		
HCV Elisa	**Positive**	**Negative**	**Total**
Positive	312	4	316
Negative	3	731	734
Total	315	735	1050

Relative Sensitivity: 98.7%, Relative Specificity: 99.6%, Overall Agreement: 99.3%

2. Worldwide Performance Panel

BBI's (Boston Biomedica Inc.) worldwide performance panel (WWHV301) were tested with the R-test HCV Ab Rapid Test. The result is shown in the following table.

Table 2

Member	Origin	Genotype	Abbott EIA	R-test HCV Ab Rapid Test
301-01	Argentina	1b	Positive	Positive
301-02	Argentina	1b	Positive	Positive
301-03	Argentina	3a/b	Positive	Positive
301-04	Argentina	2a/c	Positive	Positive
301-05	Argentina	Not tested	Negative	Negative
301-06	Uganda	4c/d	Positive	Positive
301-07	Uganda	Not tested	Positive	Positive
301-08	Ghana	Not tested	Negative	Negative
301-09	China	1b, 2a/c	Positive	Positive
301-10	China	2	Positive	Positive
301-11	China	1b	Positive	Positive
301-12	China	2	Positive	Positive
301-13	China	1a/b, 2a/c	Positive	Positive
301-14	Egypt	3a	Positive	Positive
301-15	Egypt	4	Positive	Positive
301-16	Egypt	4h	Positive	Positive
301-17	Egypt	Not tested	Positive	Positive
301-18	USA	1b	Positive	Positive
301-19	USA	1a	Positive	Positive
301-20	USA	1a	Positive	Positive

LIMITATIONS OF PROCEDURE

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HCV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The R-test HCV Ab Rapid Test is limited to the qualitative detection of antibodies to HCV in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
- A non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
- A non-reactive result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- If the symptoms persist and the result from R-test HCV Ab Rapid Test is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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Lab Diagnostic Systems (SMC) Pvt. Ltd.
Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan
TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

Revised:10/2022

R-test HCV/HBsAg/HIV Combo Rapid Test

50 tests per kit
Ref: R-21050

INTENDED USE

The R-Test HCV/HBsAg/HIV Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C Virus, & antibodies to HIV type 1 and type 2 in serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST

The HCV Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

The HBsAg Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

The HIV 1/2 Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in serum or plasma specimen.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
  - One cassette device
  - One desiccant
- 3 Diluent Buffer Bottles (5ml each)
- One package insert (instructions for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Plastic Dropper
- Clock or timer

WARNINGS AND PRECAUTIONS

For *In-Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The test result should be read 10-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 10-20-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e., electric fan or strong air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures.

Plasma:

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

- Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

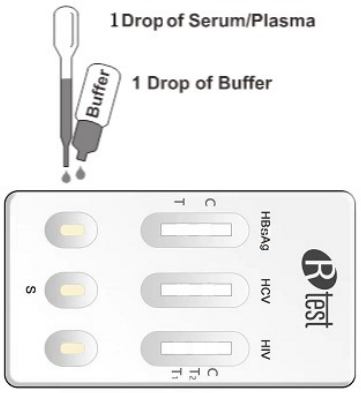
Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Step 1: Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

Step 2: Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25µl-30µl) to the specimen area, then add 1 drop of buffer (approximately 30µl-40µl), respectively. Start the timer. See the illustration below.

Step 3: Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



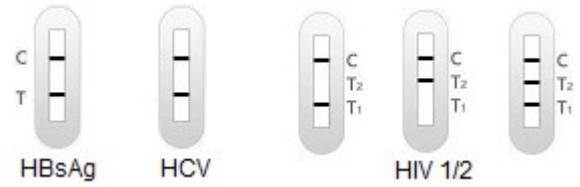
QUALITY CONTROL

- **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.
- **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
  - A new operator uses the kit, prior to performing testing of specimens.
  - A new lot of test kit is used.
  - A new shipment of kits is used.
  - The temperature during storage of the kit falls outside of 2-30℃.
  - The temperature of the test area falls outside of 15 - 30℃.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- **NEGATIVE RESULT:** If only the C line develops the test indicates that there is no presence of reactive antibodies in the specimen. The result is negative or non-reactive.

- **POSITIVE RESULT:** In case of HBsAg and HCV, if both the C line and T line develop, the test indicates that the specimen is positive or reactive.
  In case of HIV 1/2, if both the C line and T1 line develop, the test indicates that the specimen contains anti-HIV-1 antibodies. The result is HIV-1 positive or reactive. If both the C line and T2 line develop, the test indicates that the specimen contains HIV-2 antibodies. The result is HIV-2 positive or reactive. If the C line and both T1 and T2 lines develop, the test indicates that the specimen is HIV positive or reactive.



Samples with reactive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a final diagnostic decision is made.

- **INVALID:** If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance for HCV Ab Test

The recombinant antigen used for the HCV Rapid Test Cassette (Serum /Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test Cassette (Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens.

The results show that the relative sensitivity of the HCV Rapid Test Cassette (Serum/Plasma) is 99.1%, and the relative specificity is 99.5%.

Table 1

	R-test HCV Ab Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive	107	1	110
Negative	3	599	600
Total	110	602	710

Relative sensitivity: 99.1% (95%CP: 94.9%～100.0%);
Relative specificity: 99.5% (95%CI*: 98.6%～99.9%);
Accuracy: 99.4% (95%CI*: 98.6%～99.8%).
*Confidence Intervals

2. Clinical Performance for HBsAg Test

The HBsAg Rapid Test (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300ng/ml. All 10 HBsAg subtypes produced positive results on The HBsAg Rapid Test (Serum/Plasma). The test can detect 1 PEI ng/ml of HBsAg in serum/plasma.

Antibodies used for the HBsAg Rapid Test (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Table 2

	R-test HBsAg Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive	205	0	205
Negative	3	310	313
Total	208	310	518

Relative Sensitivity: >99.9% (97.5%CI*: 98.2%-100%)
Relative Specificity: 99.0% (95%CI*: 97.2%-99.8%)
Accuracy: 99.4% (95%CI*: 98.3%-99.9%)
*Confidence Intervals

3. Clinical Performance for HIV 1/2 Ab Test

The HIV 1/2 Rapid Test (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the relative sensitivity of the HIV 1/2 Rapid Test (Serum/Plasma) is >99.99% and the relative specificity is 99.88%.

Table 3

	R-test HIV 1/2 Ab Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive	130	0	132
Negative	2	1683	1683
Total	130	1685	1815

Relative sensitivity: >99.99% (97.5%CI*: 97.20%～100.0%);
Relative specificity: 99.88% (95%CI*: 99.57%～99.99%);
Accuracy: 99.89% (95%CI*: 99.60%～99.99%).
*Confidence Intervals

4. Precision

Intra-Assay: Within-run precision has been determined by using 20 replicates of four different specimens containing different concentrations of HBsAg, HCV antibody and HIV 1.2 antibody. The negative; positive values were correctly identified 100% of the time.

Inter-Assay: Behveen-run precision has been determined by 20 independent assays on the same four different specimens containing different concentrations of HBsAg, HCV antibody and HIV 1.2 antibody. Three different lots of R-Test HCV/HBsAg/HIV Combo Rapid Test have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

5. Cross-reactivity

The HCV Rapid Test (Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

The HBsAg Rapid Test (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella, HCV, HEV and TOXO positive specimens. The results showed no cross-reactivity.

The HIV 1/2 Rapid Test (Serum/Plasma) has been tested by HAMA: RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, Syphilis, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

6. Interfering Substance

The following potentially interfering substances were added to HBsAg, HCV antibody and HIV 1/2 antibody negative and positive specimens.

1.	Acetaminophen	20 mg/dL	2.	Caffeine	20 mg/dL
3.	Acetylsalicylic Acid	20 mg/dL	4.	Gentisic Acid	20 mg/dL
5.	Ascorbic Acid	2g/dL	6.	Albumin	2g/dL
7.	Creatinine	200 mg/dL	8.	Hemoglobin	1000mg/dL
9.	Bilirubin	1g/dL	10.	Oxalic Acid	60mg/dL

LIMITATIONS

- This test is for in vitro diagnostic use only.
- This test has been developed for testing serum/ plasma specimens only. The performance of the test using other specimens has not been substantiated.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HBsAg; HCV antibody or HIV 1/2 antibody.
- The HBsAg Rapid Test cannot detect less than 1 PEI ng/ml of HBsAg in specimens.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of HBsAg and/or Hepatitis C Virus and/or HIV1/2.

TEL: +92 51 4949567
Web: www.ldspak.com
DRAP Establishment License No.: ELM-0028

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