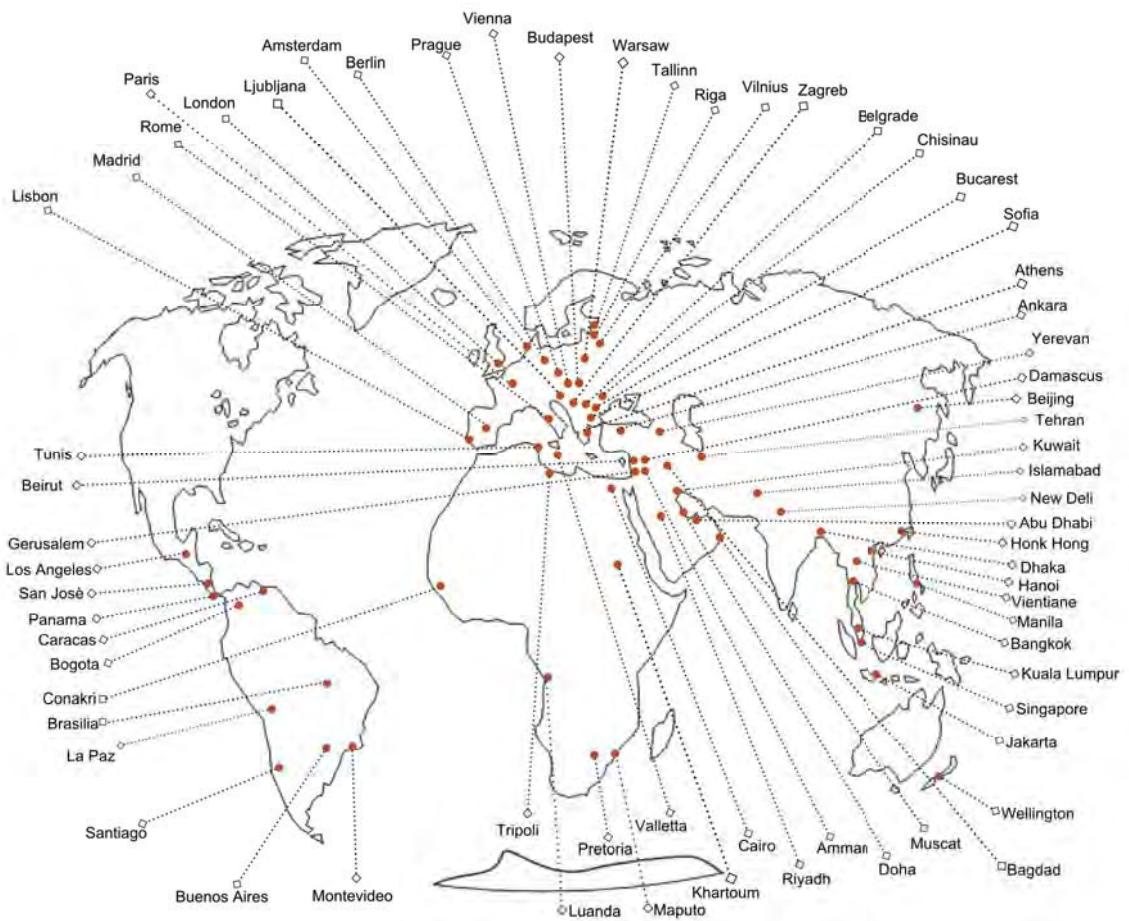




NEW CATALOGUE

Molecular diagnostics
kits and instruments

Sacace Biotechnologies products are available globally through distributors:



Algeria, Austria, Argentina, Armenia, Azerbaijan, Belgium, Bangladesh, Bahrain, Bolivia, Bosnia, Bulgaria, Burkina Faso, Cambodia, Chile, Croatia, Costa Rica, Colombia, Cyprus, Czech Republic, Denmark, Egypt, Ecuador, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, Hungary, India, Indonesia, Israel, Italy, Iran, Iraq, Jamaica, Japan, Jordan, Kenya, Kosovo, Kuwait, Laos, Latvia, Lebanon, Libya, Lithuania, Luxembourg, Macedonia, Malaysia, Malta, Mauritania, Mexico, Moldova, Montenegro, Morocco, Mozambique, Myanmar, Netherlands, Nepal, New Zealand, Nigeria, Norway, Oman, Panama, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Seychelles, Serbia, Singapore, Slovenia, South Africa, Spain, Sudan, Syria, Sweden, Switzerland, Sri Lanka, Taiwan, Thailand, Tunisia, Turkey, Uganda, Uruguay, U.S.A., United Arab Emirates, Venezuela, Vietnam, Yemen, Zimbabwe.

Our distributor network is constantly evolving. For the most updated list and detailed contact information of your regional distributor, please contact us by email: info@sacace.com to learn more about our company and products.

Company portrait

Sacace Biotechnologies s.r.l., is an innovative Italian company, located in **Como (Italy) founded in 2001**. From the very beginning this company was focused on innovation and on establishing an international presence. This multinational presence reinforces our ability to offer our healthcare solutions and to anticipate needs in all regions of the world. The company supplies its products to the international diagnostics and pharmaceutical industry, as well as to hospitals and laboratories through a global network of distributors located in more than **60 countries** all over the world.

Sacace prime objective is to identify and meet the customers' needs. This implies solving their problems and anticipating their future needs by maintaining close contact with them and listening to what they say.

Sacace incorporates all functions required – research & development, manufacturing, logistics, technical support, marketing and sales of an extensive line of molecular biology diagnostic tests that accurately screen for the presence of disease in human and food fields – to provide adequate support to its customers.

The kits produced by Sacace include all the required reagents for nucleic acid extraction, reverse transcription, amplification of specific genomic regions and detection by agarose gel electrophoresis and **Real Time PCR (qPCR)**.

The products are designed to provide ease-of-use, they are **CE marked** in compliance with **Directive 98/79EC** as well as with the new **IVDR Regulation (EU Reg. 2017/746)** and incorporate the highest quality reagents to ensure consistency, reliability and long shelf life.

We have a dedicated team of experienced research scientists who are committed to researching and developing new products and improved test methods to aid patient diagnosis.

Customer consultation is a key element in our strategy for the development and production of kits that meet market needs and exceed expectations.

Quality assurance is the cornerstone of the company's success. The quality management has obtained **ISO 13485:2016** certification and all aspects of product design and manufacture are carried out in accordance with this standard.



Organismo accreditato da ACCREDIA
Body accredited by ACCREDIA

CERTIFICATE

Kiwa Certificati Italia S.p.A.
Socetà con sede unica,
soggetta all'attivita di
distribuzione e coordinamento di
Cermet Testing Srl
Via Cagliano, 22
21057 Castellanza (VA) Italia
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Fax +39 031 793 082
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CERMET

Quality Management System Certificate ISO 13485:2016

We certify that the Quality Management System of the Organization:
SACACE BIOTECHNOLOGIES S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Development and production of diagnostic kits

Chief Operating Officer
Giampiero Belcadi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Certificati Italia contractual requirements.

This certificate is composed of 1 page.

SACACE BIOTECHNOLOGIES S.r.l.

Registered Headquarters
- Via Santissi SNC - 21019 Sant'Agata De' Goti (BN) Italia
Certified Sites
- Via Scalabrinii 44 22100 Como Italia



NuO N° 101/4

Molecular Diagnostics

The analysis of **DNA, RNA** and proteins at the molecular level performed in clinical laboratories, known as molecular diagnostics, is our core business.

Modern analyses based on the detection of nucleic acids offer considerable advantages over traditional methods of pathogen detection in humans. These procedures detect viruses, bacteria, and parasites more rapidly and with far greater sensitivity and specificity. At genetic and protein level, the cause of a disease can now be found more precisely, enabling the most suitable therapy to be developed. Likewise, the analysis of an individual's genetic makeup enables physicians to predict the course of certain diseases. Therewith, molecular diagnostics provide modern medicine with the necessary tools for developing completely new, personalized strategies in the battle against many diseases. Hospitals and diagnostics laboratories using these techniques have different needs than customers in other markets. They ask for products which guarantee the highest levels of reliability and maximum speed. The advent of molecular biology diagnostics has particularly revolutionized the diagnosis and treatment of diseases.

The company offers a wide range of assays for **real-time polymerase chain reaction (PCR)** applications and these products are sold either direct to an end user or through a distribution relationship.

These products are 'platform independent' and are used by customers on different platforms like Rotor-Gene™ (Qiagen), LineGeneK™ (Bioer Technologies), iQ5, CFX-96™ (BioRad), SmartCycler™ (Cepheid), Applied Biosystems 7300/7500/StepOne/QuantStudio5™, MX3005P™ (Agilent Technologies), SaCycler-96™ and Sa2Res™ (Sacace Biotechnologies).

Examples of the diseases tested for include: **HCV, HBV, HIV, sexually transmitted infections, cardiovascular diseases, the herpetic family of viruses (CMV, EBV, and HSV)** as well as seasonal infectious diseases such as **enterovirus, coronaviruses and influenza**.

Sacace offers different kits for HCV qualitative, quantitative and genotyping tests.

The company's portfolio consists also of multiplexing assays which allow for the testing of several different pathogens in one single run: for example we have a kit for simultaneous multiplex detection of HCV/HBV/HIV, CMV/EBV/HHV6, Chlamydia/Neisseria/Trichomonas/Mycoplasma and others.

One of the most important products lines of Sacace is sexually transmitted diseases (STD) kits. STD refer to a variety of bacterial, viral and parasitic infections that are acquired through sexual activity.

In light of the epidemic spread of animal diseases such as avian flu or swine flu and the recent international food safety scandals, molecular testing is continuously gaining importance in veterinary medicine and agricultural industry. Our molecular tests enable for reliable and rapid detection of infectious diseases and food-borne pathogens.

Sacace offers also a range of nucleic acid purification products that are used to investigate bacterial and viral infections, furthermore proposes a wide range of applications for bacterial drug resistance detection and **molecular genetics**.



Sacace Biotechnologies Srl

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Kits Table Legend:

V4-50FRTG, iQ, SC, MX, A, LC, B, SA	HAV Real-TM Qual NEW Complete Real Time Test with Ribo-Sorb extraction kit	R Type of PCR kit: R=RealTime; A=Agarose gel kit;	CE n° of tests	50 Kit sensitivity and linear range	5×10^2 copies/ml
Kit name and description					

RG=RotorGene ; IQ=Biorad iQ5; MX=MX3005P;
SC=SmartCycler; A=Applied; LC=LightCycler2.0;
B=CFX-96 Biorad, SA=SaCycler-96.

presence of this symbol indicates that the kit is CE-IVD marked

Hepatitis Viruses

Hepatitis Viruses

Hepatitis Viruses are a group of infectious liver diseases caused by hepatotropic viruses belonging to different families. There are 5 major viruses that cause hepatitis. They make up two groups of hepatitis: enteric (HAV and HEV) and parenteral (HBV, HCV and HDV).

	HEPATITIS A	HEPATITIS B	HEPATITIS C	HEPATITIS D	HEPATITIS E
AGENT	Hepatitis A virus (HAV); single stranded RNA; no envelope	Hepatitis B virus (HBV); double stranded DNA; envelope	Hepatitis C virus (HCV); single stranded RNA; envelope	Hepatitis D virus (HDV); single stranded RNA; envelope from HBV	Hepatitis E virus (HEV); single stranded RNA; no envelope
FAMILY	Picornaviridae	Hepadnaviridae	Flaviviridae	Deltavirus (viroid)	Calicivirus
GENOME	RNA: 7500 nc	DNA: 3200 nc	RNA: 9500 nc	RNA: 1700 nc	RNA: 7500 nc
TRANSMISSION WAY	Fecal-Oral	Parenteral	Parenteral	Parenteral	Fecal-Oral
CHRONIZATION	No	Yes	Yes	Yes	No
INCUBATION TIME	15-50 days	45-160 days	14-180 days	Uncertain	15-50 days
MANIFESTATION OR SYMPTOMS	Mostly subclinical; severe cases: fever, headache, malaise, jaundice	Mostly subclinical; similar to HAV, but fever, headache absent, and often progress to severe liver damage	Similar to HBV	Severe liver damage, high mortality rate	Similar to HAV, but pregnant women may have high mortality rate
VACCINES	Yes	Yes	None	HBV vaccine is protective because coinfection required	None

Hepatitis A (HAV)

The **hepatitis A (HAV)** virus is the enteric infection most widely spread in the world. This is the acute infectious disease of liver transmitted by fecal-oral way, the causative agent of which is hepatitis A virus (HAV) belonging to the family Picornaviridae. Virus hepatitis A is one of the five most economically significant infectious diseases and one of the priority problems of the public healthcare.

Detection of the causative agent RNA by PCR method has significant advantages as related to ELISA and biochemical tests at detection of the virus in blood of contact persons as RNA of the hepatitis A virus manifests itself in the blood on the third week from the moment of contamination and is detected at the average within 20 days after appearance of the disease symptoms. Thus, RNA is the first diagnostic marker detected in the patient blood, occurs earlier than HAV IgM and gives no false negative reactions.

Hepatitis A Virus Kits

V4-50FRT
SA, RG, iQ, SC, MX, A,B,LC

HAV Real-TM Qual
Real Time Amplification kit with the RNA extraction controls R CE 50 5×10^2 copies/ml

Hepatitis B (HBV)

Hepatitis B virus (HBV) is a widely spread human infection caused by DNA-containing virus of hepatitis B belonging to the family Hepadnaviridae. Transmission of hepatitis B virus results from exposure to infectious blood or body fluids containing blood. Possible forms of transmission include unprotected sexual contact, blood transfusions, re-use of contaminated needles & syringes, and vertical transmission from mother to child during childbirth. The viral hepatitis B presents a serious problem for public healthcare due to its universal spread. At present in accordance with the WHO data the population infected with hepatitis B virus makes 500 million people.

Detection of HBV DNA is used for:

- Early diagnostics of acute viral hepatitis B;
- Detection of latent forms of viral hepatitis B;
- Detection of mutant strains of hepatitis B virus by HBsAg;
- Establishment of diagnosis of chronic viral hepatitis B;
- Monitoring of effectiveness of the antiviral therapy;

ADVANTAGES OF SACACE™ HBV REAL-TM QUANT DX CE-IVD MARKED KIT

Key Features

- Primers and probes in highly conserved 5'-gene (coding the surface antigen of the hepatitis B virus HBsAg) region of the HBV genome.
- **Reagents lyophilized** and aliquoted
- Excellent **sensitivity** of 7 IU/ml (1 ml input)
- Results expressed directly in International Units
- Use of exogenous **internal control** to check extraction and amplification
- 1 Low and 1 High concentrated extraction positive controls, to be extracted as the samples
- Reagents can be **stored at 4°C** and **shipped at room temperature**
- Very long shelf life (1 year)

Advantages

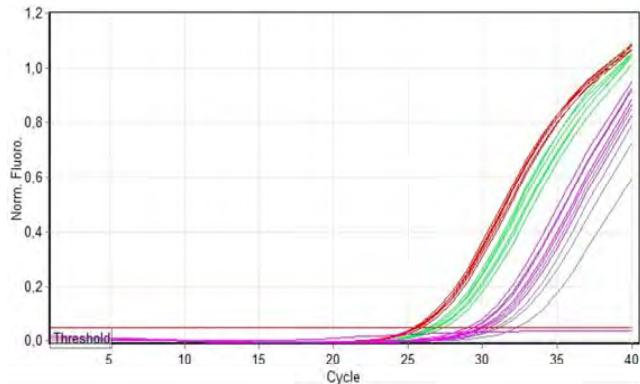
- No need of PCR mix setup
- No possibility of mistake during reagent dispensing
- No problem with storage
- No need for refrigerated transportation
- No possibility of reagent components contamination

Very Easy To Use

No more need to prepare PCR mastermix! The HBV Real-TM Quant DX kit contains **96 ready to use 0.2 ml PCR tubes where you just need to add your extracted viral DNA. That's it!**

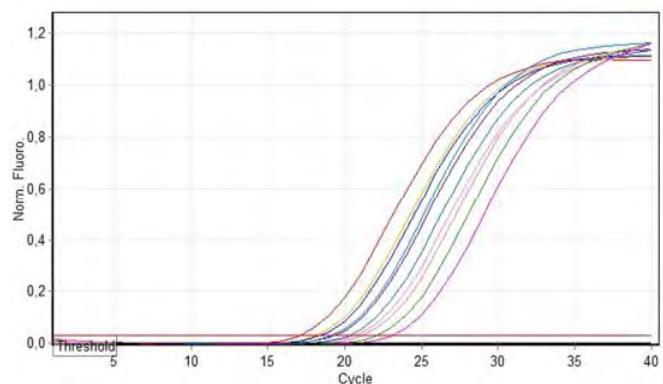
The reaction tubes are ready to be transferred into the Real Time PCR thermal cycler.

Excellent sensitivity (LOD)



The Limit Of Detection of 7 IU/ml was determined by testing dilutions of the 3rd WHO International Standard for Hepatitis B Virus for Nucleic Acid Amplification Techniques (NIBSC code: 10/264) prepared in HBV negative human plasma. The results were determined by Probit analysis.

Optimal specificity

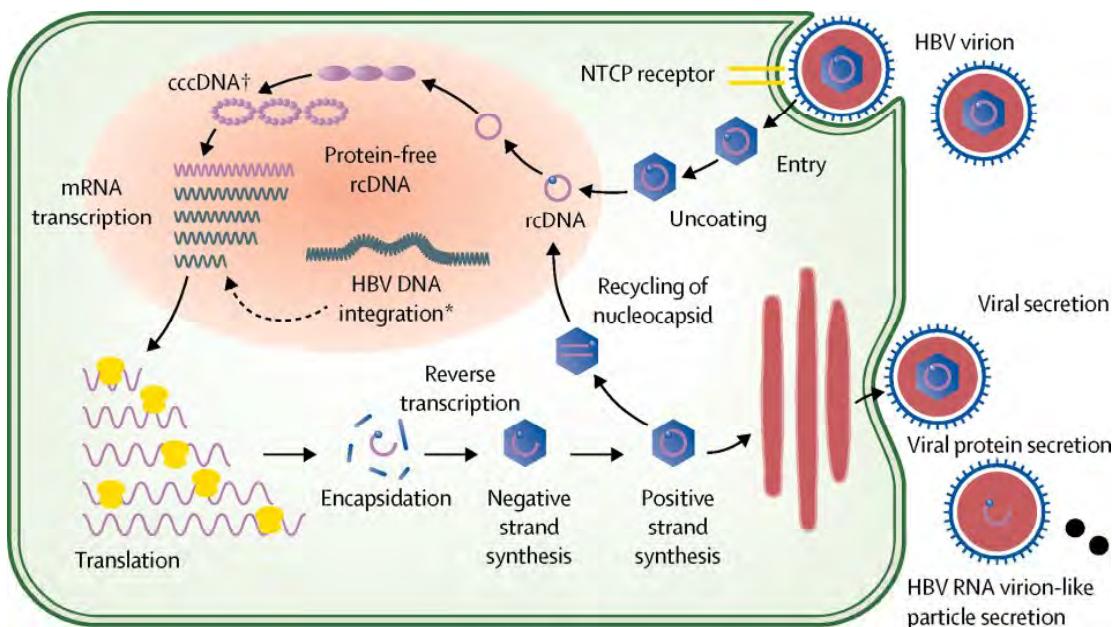


Most relevant HBV genotypes (A-B-C-D-H) were tested analyzing dilution series and results showed good and clear sigmoid-shaped fluorescence curves and a Cycle threshold (Ct) less than 35.

Hepatitis Viruses

Hepatitis B Virus Kits

V5-96/3FRT SA, RG*	HBV Real-TM Quant DX Real Time Amplification kit with positive controls and standards, 96 ready to use lyophilized PCR tubes * validated on SA and RG, but optimized also on iQ,SC,MX,A,B	R	CE	96	Linearity: 7 - 10 ⁸ IU/ml
V5-100/2FRT SA, RG, iQ, SC,MX, A,B	HBV Real-TM Quant Real Time Amplification kit with the DNA extraction controls (25 µl Reaction Mix)	R		100	Linearity: 50 -10 ⁸ copies/mL
V5-100FRT SA, RG, iQ, SC,MX, A,B,LC	HBV Real-TM Qual Real Time Amplification kit with the DNA extraction controls (25 µl Reaction Mix)	R		100	50 copies/ml



Hepatitis B Genotyping

Hepatitis B virus (HBV) infects nearly two billion people worldwide. The hepatitis B virus (HBV) is currently categorized into eight genotypes (A to H). Genotypes have been found to be geographically distributed. Numerous studies have investigated the clinical implications of HBV genotypes to disease severity, response to IFN, disease chronicity and hepatocellular carcinoma (HCC).

Hepatitis B Genotyping Kits

R5-Gen SA, RG, iQ, SC,MX, A,B	HBV Genotype A, B, C, D Real-TM Real Time Amplification kit	R	50
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Hepatitis C (HCV)

Hepatitis C virus (HCV) is RNA-containing, hepatotropic virus belonging to the Flaviviridae family. Contamination with hepatitis C virus occurs at direct entering of the virus in blood (at parenteral interventions or during blood transfusions). Most people with acute HCV infection are asymptomatic or have mild symptoms (fatigue, nausea, jaundice) but they are unable to clear the virus and in approximately 80% of cases this leads to chronic infection. In 15 to 20% of patients chronic HCV infection progresses at a variable rate to cirrhosis, with a 1 to 4% annual risk of developing hepatocellular carcinoma.

ADVANTAGES OF SACACE™ HCV REAL-TM QUANT DX CE-IVD MARKED KIT

Key Features

- Primers and probes in highly conserved 5' UTR region of the HCV genome
- **Reagents lyophilized** and aliquoted
- Excellent **sensitivity** of 13 IU/ml (1 ml input)
- Results expressed directly in International Units
- Use of exogenous **internal control** (RNA) to check extraction and amplification
- 1 Low and 1 High concentrated extraction positive controls, to be extracted as the samples
- Reagents can be **stored at 4°C** and **shipped at room temperature**
- Very **long shelf life** (1 year)

Advantages

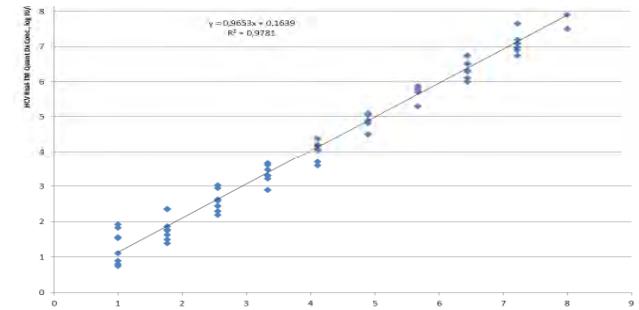
- No need of PCR mix setup
- No possibility of mistake during reagent dispensing
- No problem with storage
- No need for refrigerated transportation
- No possibility of reagent components contamination

Very Easy To Use

No more need to prepare PCR mastermix! The HCV Real-TM Quant DX kit contains **96 ready to use 0.2 ml PCR tubes where you just need to add your extracted viral RNA. That's it!**

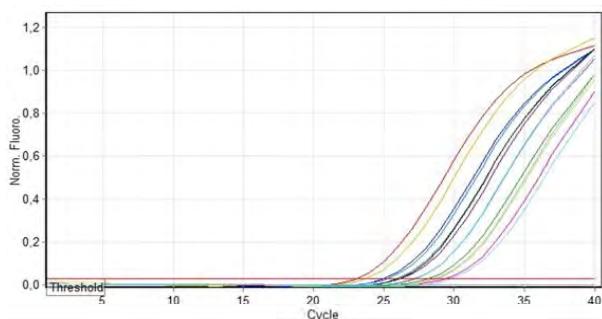
The reaction tubes are ready to be transferred into the Real Time PCR thermal cycler.

Wide linear range



The linear range of the HCV Real-TM Quant DX kit has been determined by analyzing a dilution series (8,00 log IU/ml to 1,00 log IU/ml) of an HCV synthetic quantitative standard calibrated against the 4th WHO International HCV RNA Standard.

Optimal specificity



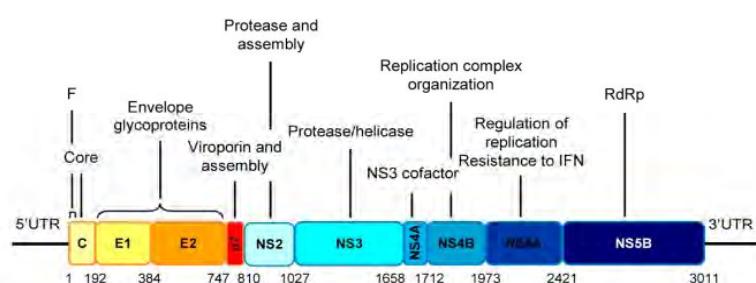
Most relevant HCV genotypes (1-2-3-4-5) were tested analyzing dilution series and results showed good and clear sigmoid-shaped fluorescence curves and a Cycle threshold (Ct) less than 35.

Hepatitis Viruses

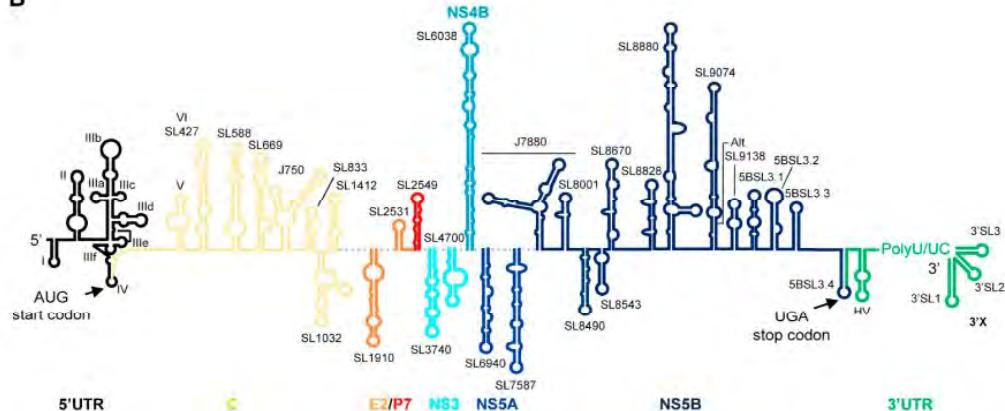
Hepatitis C Virus Kits

V1-96/3FRT SA, RG*	HCV Real-TM Quant DX Real Time Amplification kit with positive controls and standards, 96 ready to use lyophilized PCR tubes * validated on SA and RG, but optimized also on iQ,SC,MX,A,B	R	CE	96	Linearity: 13 - 10 ⁸ IU/ml
V1-100/2FRT SA, RG, iQ, SC,MX, A,B	HCV Real-TM Quant Real Time PCR kit with the RNA extraction controls (25 µl Reaction Mix)	R		100	Linearity: 50 - 5 x10 ⁷ IU/mL
V1-100FRT SA, RG, iQ, SC,MX, A,B,LC	HCV Real-TM Qual Real Time PCR kit with the RNA extraction controls (25 µl Reaction Mix)	R		100	50 IU/mL

A



B



HCV associated infection kits

Interleukin-28 (IL28) is a cytokine that plays a role in immune defense against viruses. IL28B belongs to the type III interferon family of cytokines. Its classification as interferon is due to its ability to induce an antiviral state. Polymorphisms in the IL28B gene region are important in predicting outcome following therapy for chronic hepatitis C virus (HCV) infection.

Combined therapy IFN pegylated (PEG-IFN) and ribavirin (RBV) is the current standard therapy against HCV infection and to know in detail the polymorphism in IL28B gene region of patients infected with HCV can be an important component of the decision to initiate treatment with PEG-IFN and RBV.

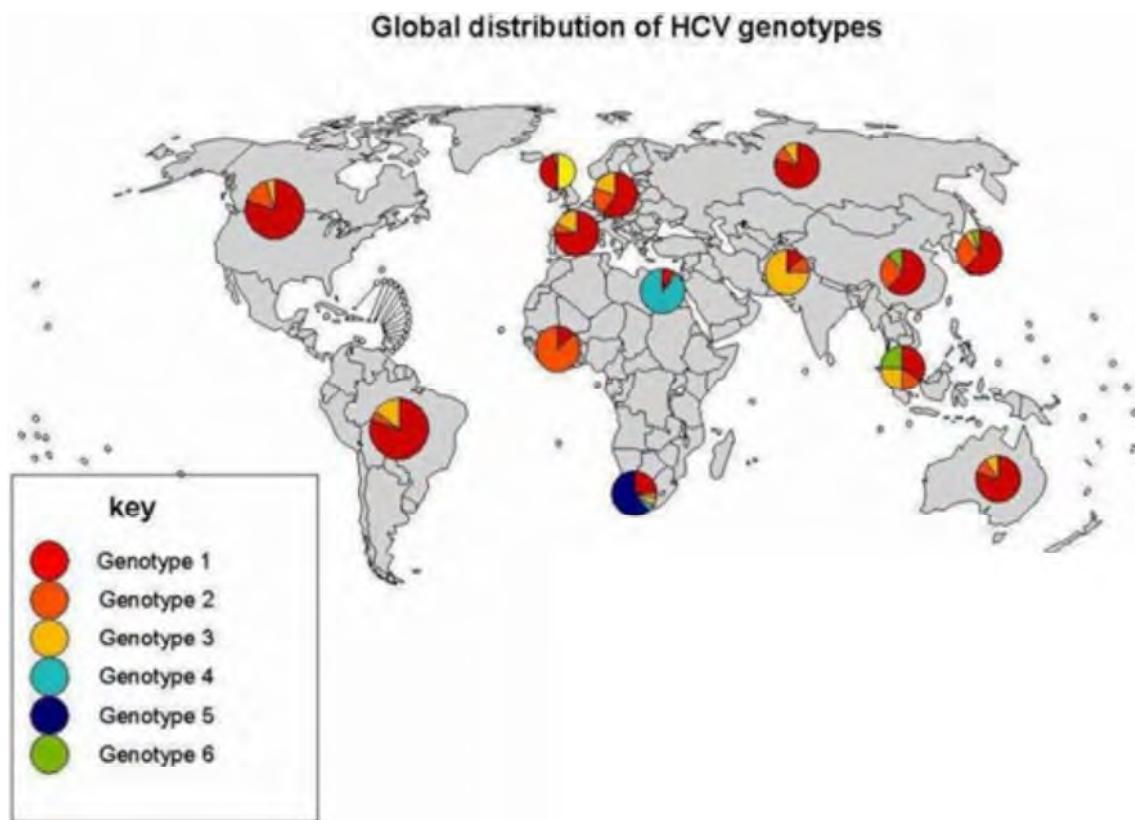
HCV associated infection kits

R05-100FRT SA, RG, iQ, MX, A, B	IL28B rs17 / rs60 Real-TM Real Time amplification kit	R	100
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Hepatitis C Virus Genotyping

HCV is classified into eleven major genotypes (designated 1-11), many subtypes (designated a, b, c, etc.), and about 100 different strains (numbered 1,2,3, etc.) based on the genomic sequence heterogeneity. Genotypes 1-3 have a worldwide distribution. Types 1a and 1b are the most common, accounting for about 60% of global infections. They predominate in Northern Europe and North America, and in Southern and Eastern Europe and Japan, respectively. Type 2 is less frequently represented than type 1. Type 3 is endemic in south-east Asia and is variably distributed in different countries. Genotype 4 is principally found in the Middle East, Egypt, and central Africa. The determination of the infecting genotype is important for the prediction of response to antiviral treatment: genotype 1 and 4 are generally associated with a poor response to interferon alone, whereas genotypes 2 and 3 are associated with more favourable responses. At patients with subtype 1b the disease progresses to a chronic condition 90 % of cases, in that time as with genotypes 2 and 3b in 33-50 %. In a number of works it is mentioned, that infection with 1b genotype have heavier current of disease with development of a cirrhosis and hepatocarcinoma.

The International Consensus European Association for the Study of the Liver (EASL) recommends before beginning of antiviral therapies to carry out a liver biopsies and to determine HCV genotype.



Hepatitis C Virus Genotyping Kits

R1-Gen-4X SA, RG, IQ, MX, SC, A, B	HCV 1/2/3 Genotype Real-TM Real Time PCR kit with the RNA extraction controls	R	48	1 x 10 ² IU/mL
R1-Gen-6 SA, RG, IQ, SC, MX, A, B	HCV Genotype Plus (1a,1b, 2, 3a, 4, 5a, 6) Real-TM Real Time PCR kit with the RNA extraction controls	R	48	1 x 10 ² IU/mL

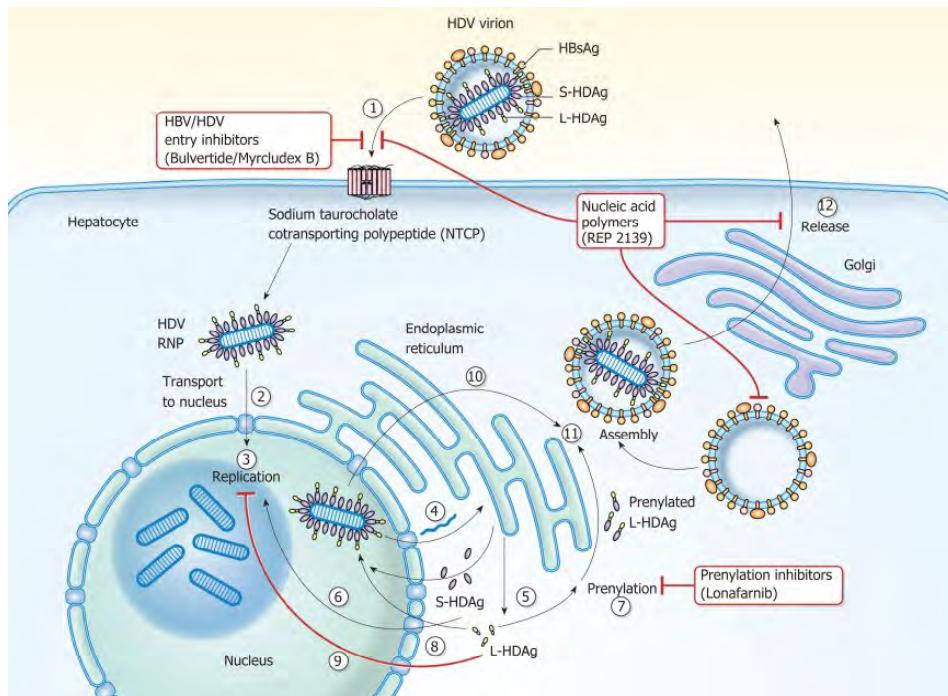
Hepatitis D (HDV)

Hepatitis D virus (HDV) is RNA containing, hepatotropic viroid (uncompleted virus) belonging to Deltavirus family. HDV needs helper function of hepatitis B virus that provides to HDV proteins of the superficial membrane (HBsAg) that's why HDV can replicate itself only in presence of HBV. Transmission of HDV can occur either via simultaneous infection with HBV (coinfection) or via infection of an individual previously infected with HBV (superinfection). Both superinfection and coinfection with HDV results in more severe complications compared to infection with HBV alone. These complications include a greater likelihood of experiencing liver failure in acute infections and a rapid progression to liver cirrhosis, with an increased chance of developing liver cancer in chronic infections. In combination with hepatitis B virus, hepatitis D has the highest mortality rate of all the hepatitis infections of 20%.

Detection of HDV RNA by PCR allows detection of the causative agent in the period of introduction of infection before seroconversion, which is very important for early diagnostics.

Hepatitis D Virus Kits

V3-100/2FRT SA, RG, iQ, SC,MX, A, B	HDV Real-TM Quant Real Time PCR kit with the DNA extraction controls	R	100	1 x 10 ² copies/mL
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Hepatitis G (HGV)

Hepatitis G virus (HGV) is another virus causing post-transfusion hepatitis. The same as hepatitis C virus, hepatitis G virus belongs to the flaviviruses. The hepatitis G virus is detected with the help of PCR (serological methods are less reliable). It's detected in 1.5 percent of donors and in some patients with acute fulminant and chronic hepatitis. The coinfection of hepatitis G with hepatitis B, C or D is detected frequently.

Hepatitis G Virus Kits

V2-50FRT SA, RG, iQ, SC,MX, A,B,LC	HGV Real-TM Real Time PCR kit with the DNA extraction controls	R	€	50	3 x 10 ² copies/mL
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Human immunodeficiency virus (HIV)

HIV is a lentivirus (a member of the retrovirus family) differentiated on structural and antigenic properties into two virus types: HIV-1 and HIV-2. HIV-2 occurs considerably less often than HIV-1. In accordance with 1991 Nomenclature, there are three independent HIV-1 groups: «M» (main); «O» (outlier); «N» (non-V/non-O). Groups O and N are less widely spread and occur in African countries population. Group M includes 11 subtypes: A1, A2, B, C, D, F1, F2, G, H, J, K.

Transmission ways of the virus are very important for the virus spread. HIV is transmitted by three ways: at heterosexual and homosexual intercourse, parenteral with blood and blood products and vertically: from the infected mother to the child by an intrauterine way, during the child delivery or soon after the childbirth at breast feeding.

This method has a lot of advantages:

- detection of virus DNA/RNA allows reducing the length of the “serological window”;
- PCR is an indispensable approach for HIV-diagnostics in children born from HIV-infected mothers;
- determination of HIV RNA in the blood plasma (viral load) is an obligatory procedure to monitoring of the therapy effectiveness

ADVANTAGES OF SACACE™ HIV REAL-TM QUANT KIT

- Application of primers and probes in the most conservative area of the HIV-1 polymerase gene that allow effective detection of the majority of HIV-1 subtypes.
- Use of the Quantitative Internal Control (concentration reported in Data Card) which allows not only to monitor the extraction procedure and to check possible PCR inhibition but also to verify possible losses of the RNA during extraction procedure thus enabling to calculate precisely the HIV viral load.
- Presence in the reagents supplied with the kit of two positive controls of the extraction: Pos1 – low viral load and Pos2 – medium viral load that are quantitatively described in Data Card and allow quality control of the conducted analysis.
- Use of Quantitative Standards for HIV RNA and HIV IC enabling to calculate precisely the HIV viral load.
- The reagent kit possesses a wider linear range of measurements (from 25 to 5 x 10⁶ copies/ml).

HIV RNA Quant Kits

V0-96/3FRT SA, RG*	HIV Real-TM Quant Dx Real Time PCR Test with positive controls and standards (96 ready to use lyophilized tubes - 50 µl Reaction Mix) * validated on SA and RG, but optimized also on IQ,SC,MX,A,B	R	96	Linearity: 48 - 1 x10 ⁷ IU/mL
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HIV DNA

HIV-infection diagnostics in children born from HIV-infected mothers is difficult due to the fact that mother's antibodies to HIV persist in such children's blood for a long time. The problem of earlier HIV-infection diagnostics in newborns was solved with development of molecular-genetic methods that allow detection of HIV genome fragments in the peripheral blood at early infection stages.

HIV DNA kit

R-V1-D SA, RG, IQ, MX, SC, A	HIV DNA Real-TM Qual Real Time PCR kit with controls included	R	100	1 x10 ² copies/ml
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HIV Infection associated Kits

Hypersensitivity reaction to abacavir is strongly associated with the presence of the HLA-B*5701 allele. Abacavir (Ziagen, also in the combination pills Kivexa and Trizivir) is a potent antiretroviral drug that is a popular choice for first-line antiretroviral HIV therapy. Its main disadvantage is a hypersensitivity reaction that occurs in between 5% - 8% of patients treated with this drug. **HLA-B*5701 Real-TM** test can predict who will develop a severe allergic reaction to the **anti-HIV drug abacavir** as the presence of HLA-B*5701 is significantly associated with an abacavir hypersensitivity.

HIV Infection associated kits

H53-100FRT SA, RG, iQ, SC,MX, A,B,LC	HLA B*5701 Real-TM Real Time Amplification Kit	R	CE	100	1 x10 ³ cells/ml
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Pneumocystis pneumonia (PCP) or pneumocystosis is a form of pneumonia, caused by the yeast-like fungus (which had previously been erroneously classified as a protozoan) **Pneumocystis jirovecii (carinii)**.

P jiroveci is now one of several organisms known to cause life-threatening opportunistic infections in patients with advanced HIV infection worldwide.

P2-50FRT SA, RG, iQ, SC,MX, A,B,LC	Pneumocystis jirovecii (carinii) Real-TM Real Time Amplification kit	R	CE	50	5 x10 ² copies/ml
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Cryptococcosis, caused by **Cryptococcus neoformans**, is the most common fungal disease in HIV infected persons and it is the AIDS-defining illness in 60-70% of HIV infected patients.

F4-100FRT SA, RG, iQ, SC,MX, A,IL,B,LC	Cryptococcus neoformans Real-TM Real Time Amplification Kit	R	CE	100
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HCV/HBV/HIV Real-TM

Transfusion-associated transmission risk of infectious diseases has been reported worldwide. For screening of blood donations in order to reduce the residual risk of transmission of bloodborne viruses, viral nucleic acid testing (NAT), has been introduced by the European plasma industry in 1995, and subsequently introduced for blood donations in many countries. NAT was implemented to reinforce the safety of the blood supply; it can detect acute viral infections during the 'window period', that are not detected by the serological screening methods. Current NAT procedures usually demand pooling of blood donation samples due to the format of the employed platforms.

ADVANTAGES OF SACACE™ HCV/HBV/HIV REAL-TM KIT

- Simultaneously amplification (multiplex) in 1 PCR tube of nucleic acids from HIV, HCV, HBV;
- Separate real-time detection and differentiation of nucleic acids from HIV, HCV and HBV on different channels (FAM – HCV, JOE/HEX/Cy3 – HIV, ROX – HBV, Cy5 – internal control);
- Optimization on different equipments;
- Possibility of pooling (5-10 samples in pool format is recommended);
- High sensitivity*: **HCV RNA** – 10 IU/ml; **HBV DNA** – 5 IU/ml; **HIV RNA** – 20 copies/ml.

* values obtained using the "Magno-Virus" extraction kit (Sacace REF K-2-16/1000)

Hepatitis C / Hepatitis B / HIV multiplex detection kits

V50-100FRT/L SA, RG, iQ, MX, A	HCV/HBV/HIV-1/HIV-2 Real-TM Real Time PCR kit (lyophilized format)	R	100	10/5/20/20 IU/mL
V62-100FRT RG, SA	HCV/HBV/HIV1/HIV2 Real-TM Real Time PCR Test (liquid format)	R	100	10/5/20 IU/mL

Human Papilloma Virus

Cervical cancer (CC) is one of the most widely spread oncological pathologies that ranks second by the incidence in women in the world. Each year about 600 thousand of new CC cases are registered in the world with more than 250 thousand lethal outcomes. The virus nature of this cancer is confirmed by the World Health Organization and HPV is detected practically in 100 percent of cases of cervical precancer and cancer. Based on the frequency of detection of HPV genotypes from different grades of Cervical Intraepithelial Neoplasia (CIN Grades I – III), HPV genotypes are subdivided into High-risk HPV types (16, 18, 31 and 45), Intermediate-risk types (33, 35, 39, 51, 52, 56, 58, 59, and 68), and Low-risk types (6, 11, 42-44).

Owing to the fact that the cervical cancer (CC) has a long development period and a fail-safe recognizable pre-clinical phase there's a possibility to detect and prevent the disease on its early stage.

Kits for screening of high carcinogenic risk HPV genotypes

The **NEW** kit **HPV 14 Screening & 16,18,45 Typing Real-TM Quant** is an *in vitro* Real Time amplification test for quantitative detection and genotyping of HPV 16,18,45 and simultaneous quantitative detection of of HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 (total 14 genotypes detected). It is known, that the parameter of viral load has a prognostic value and the viral load less than 10^5 HPV genomic equivalents in the swab or 10^3 genomic equivalents for 10^5 cells is considered as insignificant and indicates the presence of transitory infection, however such level of load may have a value only in cases of treatment monitoring. Viral load of more than 10^5 genomic equivalents for 10^5 cells is considered to be important with high significance and indicates the existence of dysplastic changes or high risk of their occurrence. Quantitative detection of viral load allows to evaluate the character of the infection and to make a forecast concerning the stage of the disease.

HPV High Risk Screen Kits

V31-100/F FRT
SA, RG, B, iQ, MX, A

HPV 14 Screening &16,18,45 Typing Real-TM Quant
Real Time Amplification kit

R

CE

100

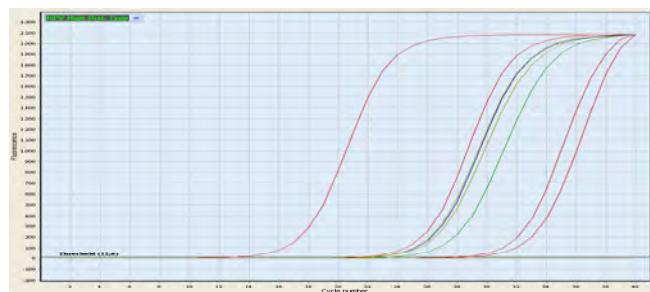
5×10^2 copies/ml

Kits for typing of high carcinogenic risk HPV genotypes

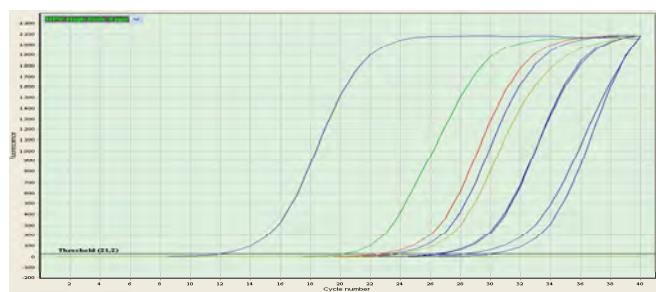
The **NEW** **HPV Genotypes 14 Real-TM** kit is an *in vitro* multiplex Real Time amplification test for qualitative detection and genotyping of up to 14 genotypes of *Human Papillomavirus* (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) in urogenital swabs and biopsies.

The **HPV Genotypes 14 Real-TM** kit is based on two major processes: isolation of DNA from specimens and multiplex Real Time amplification of 4 tubes for each sample. The test uses primers directed against regions of HPV types and β -globine gene used as Internal Control. If the swab is not correctly prepared (high quantity of mucous or insufficient quantity of epithelial cells) the Internal Control will not be detected.

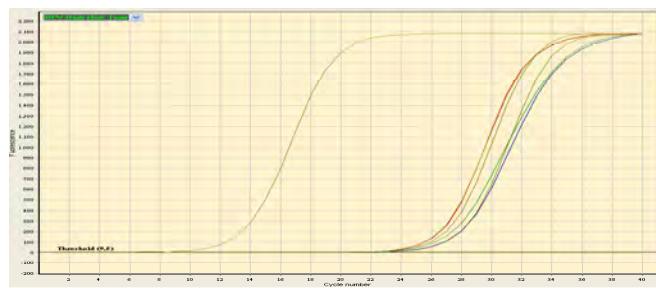




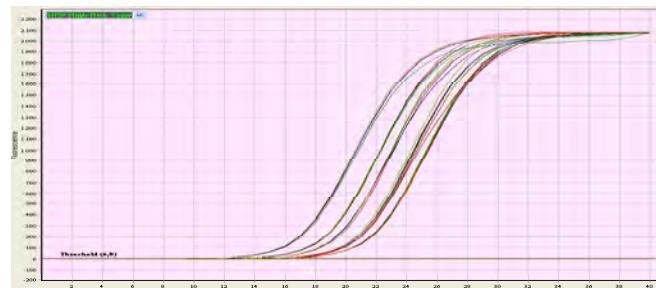
FAM/Green channel: HPV genotypes 16, 39, 33 and 58



JOE/HEX channel: HPV genotypes 31, 45, 35 and 52



ROX channel: HPV genotypes 18, 59, 68 and 66



Cy5 channel: HPV genotypes 56, 51 and β -Globine

HPV High Risk Typing Kits

V67-100FRT
SA, RG, MX,iQ,A, B

HPV genotypes 14 Real-TM Quant

Real Time Amplification kit for detection and quantification of high risk genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

R € 100 5×10^2 copies/ml

V12-100FRT
SA, RG, iQ, SC, MX, A,B

HPV 16/18 Real-TM Quant

Real Time Amplification kit

R € 100 5×10^2 copies/ml

V21-100FRT
SA

HPV Genotype 21 Real-TM Quant NEW

Real Time PCR test for quantitative detection and genotyping of HPV (6, 11, 16, 18, 26, 31, 33, 35, 39, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82)

R € 96 1×10^3 copies/ml

Low carcinogenic risk

A group of **low carcinogenic risk HPV** is represented by more than 12 genotypes and they are called “low risk” because they cannot cause cervical cancer. Sometimes low-risk HPV types can cause visible changes in the genital area, called genital warts. Genital warts are growths or bumps in the genital areas of men and women. They usually are painless. They may be raised, flat, small or large, and single or multiple. Among low risk HPV the genotypes **6** and **11** are of greatest importance as they are responsible for the overwhelming amount of low-carcinogenic pointed condylomas of genital organs and for more than 90 percent of cases of condylomatosis of the larynx in children.

HPV Low Risk Typing Kits

V11-100FRT
SA, RG, iQ, SC, MX, A,IL,B

HPV 6/11 Real-TM

Real Time Amplification kit

R € 100 5×10^2 copies/ml

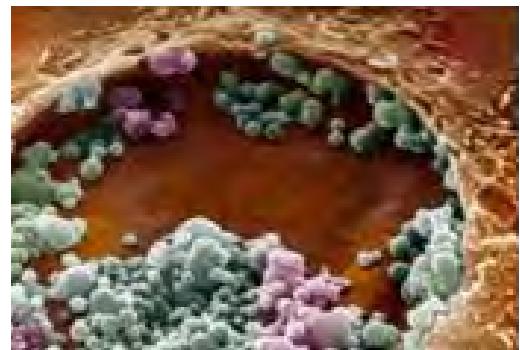
Sexually Transmitted Diseases

STDs (sexually transmitted diseases) refer to a variety of bacterial, viral and parasitic infections that are acquired through sexual activity. Common STDs include: chlamydia, gonorrhea, herpes, HIV, HPV, syphilis, gardherella, mycoplasma and trichomoniasis. Many STDs affecting women show no early signs or symptoms. As a result, they go undetected and untreated until complications arise. The consequences of untreated STDs are often more serious in women, including: infertility, tubal pregnancy, chronic pain, cervical cancer and other complications. Early screening, diagnosis, counseling and treatment can stop the spread of STDs.

Enzyme immunoassay(EIA) is the diagnostic method most commonly used for the laboratory diagnosis of STD infections, but EIA has a lower detection limit of 10000 elementary bodies and thus lacks sensitivity required for a screening assay, especially in asymptomatic men. Culture has been the “gold standard” for the diagnosis of many STD and have high sensitivity and specificity however due to a slow-growing tendency it takes 2-3 days to get a result and also requires an invasively taken specimen. Nucleic acid based amplification assays using polymerase chain reaction (PCR) have a lower detection limit of one to 10 elementary bodies and specificities comparable with culture. They also offer all the advantages of non-culture tests in terms of specimen transport, batching, and rapid processing time of approximately 2-3 hours . The improved sensitivity of these assays allows the use of non-invasive specimens such as first catch urine (FCU) specimens. PCR tests using FCU specimens have been shown to have sensitivities ranging from 87% to 97% for men and 82% to 93% for women with specificities of 98–100%.

Chlamydia trachomatis

C. trachomatis can be differentiated into 18 serovars (serologically variant strains) based on monoclonal antibody-based typing assays. Serovars A, B, Ba, and C are associated with trachoma (a serious eye disease that can lead to blindness), serovars D-K are associated with genital tract infections, and L1-L3 are associated with lymphogranuloma venereum (LGV). *Chlamydia trachomatis* is an obligate intracellular pathogen (i.e. the bacterium lives within human cells) and can cause numerous disease states in both men and women. Both sexes can display urethritis, proctitis (rectal disease and bleeding), trachoma, and infertility.



Chlamydia trachomatis Kits

B1-100FRT
SA, RG, IQ, SC, MX, A,B,LC

Chlamydia trachomatis Real-TM
Real Time Amplification kit

R € 100 5×10^2 copies/ml

Ureaplasma species and Mycoplasma

Ureaplasma species and Mycoplasma are causes of nonchlamydial nongonococcal urethritis. Mycoplasma species do not cause vaginitis, but they may proliferate in patients with bacterial vaginosis and may contribute to the condition. *Ureaplasma species* can cause placental inflammation and may invade the amniotic sac early, causing persistent infection and adverse pregnancy outcomes, including premature birth.

Ureaplasma Kits

B2-100FRT
SA, RG, IQ, SC, MX, A,B,LC

Ureaplasma species Real-TM
Real Time Amplification kit

R € 100 5×10^2 copies/ml

Sexually Transmitted Diseases

Ureaplasma Kits

B19-100FRT
SA, RG, iQ, SC,MX, A,B

Ureaplasma parvum/urealyticum Real-TM
Real Time Amplification kit

R CE 100 1×10^3 copies/ml

Mycoplasma Kits

B3-100FRT
SA, RG, iQ, SC,MX, A,B,LC

Mycoplasma hominis Real-TM
Real Time Amplification kit

R CE 100 5×10^2 copies/ml

B4-100FRT
SA, RG, iQ, SC,MX, A,B,LC

Mycoplasma genitalium Real-TM
Real Time Amplification kit

R CE 100 5×10^2 copies/ml

Neisseria gonorrhoeae

Gonorrhea, which is caused by **Neisseria gonorrhoeae**, is an important public health problem and is the most common reportable infectious disease. An estimated 700,000 new gonococcal infections occur annually in the United States. Gonorrhea is most frequently spread during sexual contact. However, it can also be transmitted from the mother's genital tract to the newborn during birth, causing ophthalmia neonatorum and systemic neonatal infection. The incubation period is usually 2-8 days.

Neisseria gonorrhoeae Kits

B5-100FRT
RG, iQ, SC,MX, A,B,LC

Neisseria gonorrhoeae Real-TM
Real Time Amplification kit

R CE 100 5×10^2 copies/ml



Trichomonas vaginalis

Trichomonas vaginalis trophozoite is oval as well as flagellated. Five flagella arise near the cytostome; four of these immediately extend outside the cell together, while the fifth flagellum wraps backwards along the surface of the organism. Trichomoniasis is the most common, curable sexually transmitted disease in the world. It is also one of the three most common vaginal infections in women. Trichomoniasis is caused by a one-celled parasite, Trichomonas vaginalis. Trichomoniasis affects both women and men. The most common location of infection in women is the vagina, and in men it is the urethra. In women, the symptoms of trichomoniasis may include yellow-green vaginal discharge, fishy odor, pain during urination and sexual intercourse, and genital itching or irritation. Men usually do not show trichomoniasis symptoms, but some may experience discharge from the penis or burning during urination or ejaculation.



Trichomonas vaginalis

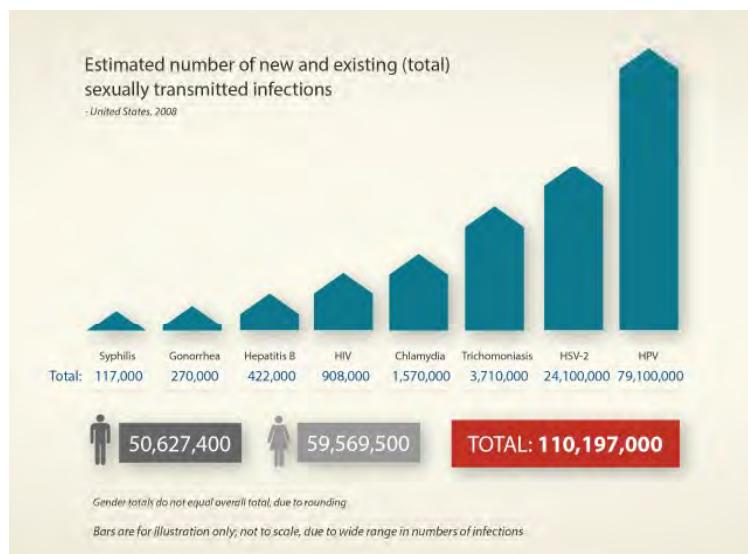
B6-100FRT
SA, RG, iQ, SC,MX, A,B,LC

Trichomonas vaginalis Real-TM
Real Time Amplification kit

R CE 100 5×10^2 copies/ml

Sexually Transmitted Disease: Multiplex qPCR Kits

B43-100FRT SA, RG, iQ, MX, SC, A, B	Chlamydia trachomatis/Ureaplasma/M.hominis Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B46-100FRT SA, RG, iQ, MX, SC, A, B	Chl. trachomatis/Ureaplasma/M.genitalium Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B60-100FRT RG, SA-5, B	C.trachomatis/Ureapl./M.hominis/M.genitalium Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B61-100FRT RG, SA-5, B	N.gonor./C.trachomatis/T.vaginalis/M.genitalium Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B65-100FRT SA, RG, iQ, MX, SC, A, B	T. vaginalis/N.gonorrhoeae Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B75-100FRT Q SA, RG, iQ, MX, SC, A, B	Ur. parvum/Ur.urealyticum/M.hominis Quant Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B83-100FRT SA, RG, iQ, MX, SC, A, B	Tr. vaginalis/N.gonorrhoeae/Chl.trachomatis Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
B67-100FRT SA, RG, iQ, MX, SC, A, B	N.gonorrhoeae/Chl. trachomatis/M.genitalium Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml



Candida albicans

Candida albicans is a diploid fungus (a form of yeast) and a causal agent of opportunistic oral and genital infections in humans. *C. albicans* is commensal and is among the gut flora, the many organisms that live in the human mouth and gastrointestinal tract. Under normal circumstances, *C. albicans* lives in 80% of the human population with no harmful effects, although overgrowth results in candidiasis. Candidiasis is often observed in immunocompromised individuals such as HIV-positive patients but may also occur in the blood and in the genital tract. Candidiasis, also known as "thrush", is a common condition, usually easily cured in people who are not immunocompromised. To infect host tissue, the usual unicellular yeast-like form of *C. albicans* reacts to environmental cues and switches into an invasive, multicellular filamentous forms.

Candida albicans Kits

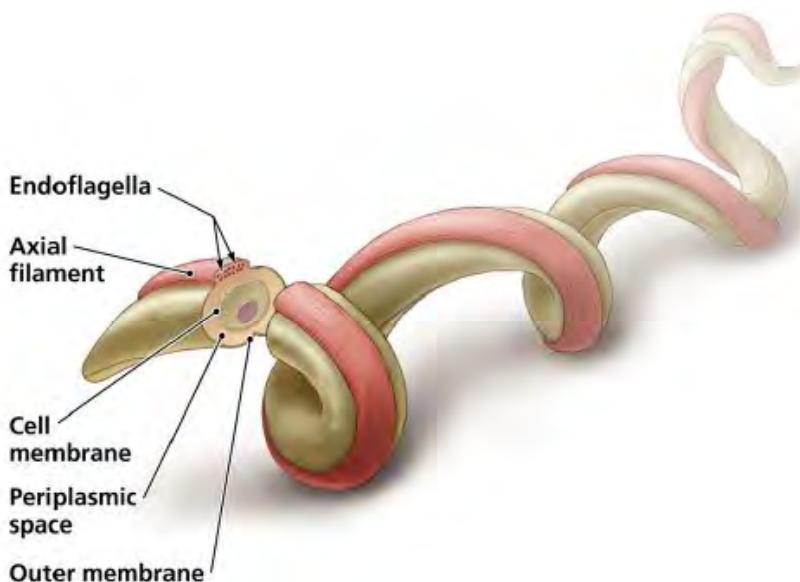
F1-100FRT SA, RG, iQ, SC,MX, A,B,LC	Candida albicans Real-TM Real Time Amplification kit	R	CE	100	1×10^3 copies/ml
F3-100FRT SA, RG, iQ, MX, SC, A, B	Candida albicans/C.glabrata/C.krusei Real-TM Real Time Amplification kit	R	CE	100	1×10^3 copies/ml
F5-100FRT SA, RG, B	Candidosis Real-TM Quant Real Time Amplification kit for detection of <i>C.albicans</i> , <i>C.glabrata</i> , <i>C.krusei</i> , <i>C.parapsilosis</i> , <i>C.tropicans</i>	R	CE	100	1×10^3 copies/ml

Treponema pallidum

Treponema pallidum is a species of spirochaete bacterium with subspecies that cause a disease such as syphilis. Syphilis is a sexually transmitted disease whose route of transmission is almost always through sexual contact, although there are examples of congenital syphilis via transmission from mother to child in utero or at birth. *T pallidum* is transmitted via penetration of the spirochetes through mucosal membranes and abrasions on epithelial surfaces. Incubation time from exposure to development of primary lesions, which occur at the primary site of inoculation, averages 3 weeks but can range from 10-90 days. Syphilis can generally be treated with antibiotics, including penicillin. If left untreated, syphilis can damage the heart, aorta, brain, eyes, and bones. In some cases these effects can be fatal.

Treponema pallidum Kits

B20-100FRT SA, RG, iQ, SC,MX, A,B,LC	Treponema pallidum Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
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Bacterial vaginosis

Bacterial vaginosis (BV) is considered to be the most common cause of vaginal inflammation among both pregnant and non-pregnant women and prevalences between 4.9% and 36.0% have been reported from European and American studies. It previously was called nonspecific vaginitis or Gardnerella-associated vaginitis. The adult human vagina is a complex ecosystem containing an abundance of microorganisms. In women of childbearing age this system is dominated by *Lactobacillus spp.*, a genus of gram-positive, nonmotile rod-like bacteria, a defining characteristic of which is the ability to grow in acid media and tolerate acid conditions ($\text{pH} < 4.5$); lactobacilli also ferment carbohydrates to produce lactic acid and produce H_2O_2 which provides a natural defense against *Gardnerella vaginalis*. In bacterial vaginosis (BV) the balance of flora is changed with reduced numbers of lactobacilli (normal concentration $10^6 - 10^{10}$ CFU/ml) and an increase in numbers of other facultative and anaerobic species such as anaerobic cocci *Prevotella spp.*, *Gardnerella vaginalis*, and *Mobiluncus spp.* (normal concentration $< 10^3\text{-}10^5$ CFU/ml). *G. vaginalis* is virtually always present at high concentrations in women who have BV but is also detected frequently in normal women and in some cases the concentration of *Gardnerella vaginalis* can reach $10^7\text{-}10^8$ CFU/ml also in absence of BV, so the most important marker of BV is the ratio of logarithm concentration *Lactobacillus spp* and *G. vaginalis*.

The clinical significance of studying vaginal flora is that it helps determine the quantity of microorganisms and assess the ratio between the different groups of conditionally pathogenic microorganisms and the normal flora. The total quantity of bacteria serves as an indicator of infection level in the vaginal environment: under normal conditions it can vary between 10^6 and 10^9 (6-9 Log). The ratio between lactobacilli and the total bacterial quantity can be used as an indicator of the balance between the normal and conditionally pathogenic flora: the normal proportion of lactobacilli should be 95 to 100% of the total bacterial quantity.

Bacterial vaginosis Kits

R-B7-100FRT SA, RG, iQ, SC,MX, A, B	G.vaginalis/Lactobac. species Real-TM Quant Real Time Amplification kit	R	€	100	$2,5 \times 10^3$ copies/ml
B7-100FRT SA, RG, iQ, MX, SC, A, B	Gardnerella vaginalis Real-TM Real Time Amplification kit	R	€	100	$2,5 \times 10^3$ copies/ml
B74-100FRT SA, RG, iQ, MX, SC, A, B	Bacterial Vaginosis Real-TM Quant Multiplex RT-PCR for quantitative detection of Gardnerella vaginalis, Atopobium vaginae, Lactobacillus spp. and total bacteriae quantity in the vaginal biotope	R	€	100	$2,5 \times 10^3$ copies/ml

Men's Health

Chronic bacterial prostatitis (CBP) represents a bacterial infection of the prostate gland. CBP causes an associated symptom complex, the hallmark of which is the occurrence of relapsing urinary tract infections. Approximately half of all men eventually develop symptoms consistent with prostatitis. This symptom complex accounts for approximately 25% of urologic evaluations in men.

Men's Health Kits

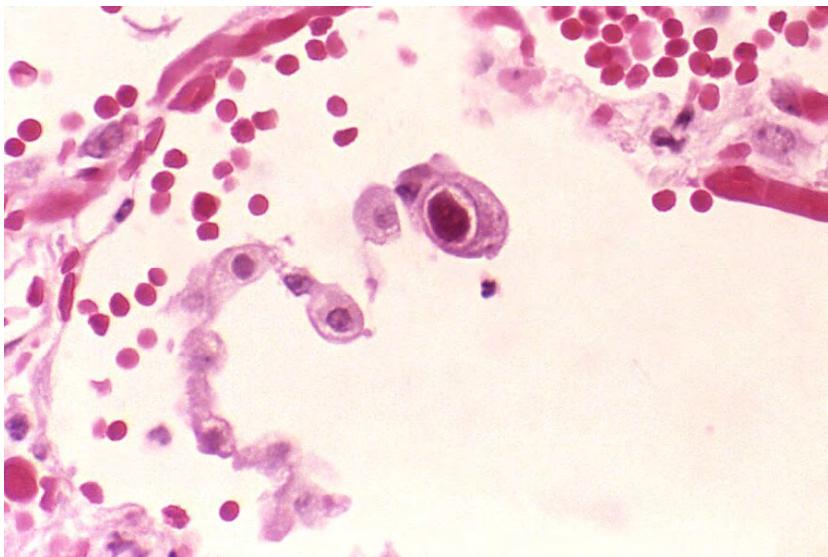
01765-50 SA,RG,iQ,MX,A,B	ProstateScreen Real-TM Real Time PCR test for diagnosis of chronic bacterial prostatitis (<i>Enterobacter spp.</i> , <i>Klebsiella spp.</i> , <i>Enterococcus faecalis</i> , <i>E. faecium</i> , <i>Escherichia coli</i> , <i>Proteus spp.</i> , <i>Pseudomonas aeruginosa</i> , <i>Serratia spp.</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus spp.</i>) 12 x 8 strip format	R	12
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Cytomegalovirus (CMV)

Cytomegalovirus (CMV) is a double-stranded DNA virus and is a member of the Herpesviridae family. The other family members include herpes simplex virus type 1 (HSV-1 or HHV-1) and herpes simplex virus type 2 (HSV-2 or HHV-2), varicella zoster virus (VZV), human herpesvirus (HHV)-6, HHV-7, and HHV-8. CMV shares many attributes with other herpes viruses, including genome, virion structure, and the ability to cause latent and persistent infections. Human CMV grows only in human cells and replicates best in human fibroblasts. About 58.9% of individuals aged 6 and over are infected with CMV while 90.8% of individuals aged 80 and over are positive for CMV antibodies. Symptomatic CMV disease in immunocompromised individuals can affect almost every organ of the body, resulting in fever of unknown origin, pneumonia, hepatitis, encephalitis, myelitis, colitis, uveitis, retinitis, and neuropathy. In patients coinfected with HIV, CMV infection leads to progression to AIDS and eventually death, even in those receiving highly active antiretroviral therapy (HAART).

CMV Kits

V7-100FRT SA, RG, iQ, SC, MX, A, B, LC	CMV Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml
V7-100/2FRT SA, RG, iQ, SC, MX, A, B	CMV Real-TM Quant Real Time PCR kit with the DNA extraction controls	R	CE	100	2×10^2 copies/ml
V48-100FRT SA, RG, iQ, SC, MX, A	CMV/EBV/HHV6 Real-TM Quant Real Time Amplification kit	R	CE	100	2×10^2 copies/ml



Herpes simplex

Herpes simplex is a viral disease caused by both herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2). Infection with the herpes virus is categorized into one of several distinct disorders based on the site of infection. Oral herpes, the visible symptoms of which are colloquially called *cold sores* or *fever blisters*, infects the face and mouth. Oral herpes is the most common form of infection. Genital herpes, known simply as *herpes*, is the second most common form of herpes. Other disorders such as herpetic whitlow, herpes gladiatorum, ocular herpes (keratitis), cerebral herpes infection encephalitis, Mollaret's meningitis, neonatal herpes, and possibly Bell's palsy are all caused by herpes simplex viruses. Varicella zoster virus (VZV) is an herpes viruses known to infect humans (and other vertebrates) that commonly causes chicken-pox in children.

Herpes simplex Kits

V8-100FRT SA, RG, iQ, SC, MX, A, B, LC	HSV 1/2 Real-TM Real Time Amplification kit for detection of HSV 1 and HSV2 without differentiation	R	CE	100	5×10^2 copies/ml
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Herpes simplex Kits

V38-100FRT SA, RG, iQ, SC,MX, A,B	HSV 1/2 Typing Real-TM Real Time Amplification kit for detection and differentiation of HSV1 and HSV2	R	CE	100	5 x10 ² copies/ml
V61-50FRT SA, RG, iQ, SC,MX, A,B	VZV Real-TM Real Time Amplification kit	R	CE	50	5 x10 ² copies/ml

Epstein-Barr virus (EBV)

Epstein-Barr virus (EBV), or human herpesvirus 4, is a gammaherpesvirus that infects more than 95% of the world's population. The most common manifestation of primary infection with this organism is acute infectious mononucleosis, a self-limited clinical syndrome that most frequently affects adolescents and young adults. Classic symptoms include sore throat, fever, and lymphadenopathy. However, Epstein-Barr virus is also a human tumor virus, the first virus associated with human malignancy (nasopharyngeal carcinoma and Burkitt lymphoma).

EBV Kits

V9-100FRT SA, RG, iQ, SC,MX, A,B	EBV Real-TM Quant Real Time Amplification kit with the DNA extraction controls	R	CE	100	2 x10 ² copies/ml
V9-50FRT SA, RG, iQ, SC,MX, A,B	EBV Real-TM Quant Real Time Amplification kit with the DNA extraction controls	R		50	2 x10 ² copies/ml

Human Herpes Virus 6, 7 and 8 (HHV6, HHV7 and HHV8)

Human herpesvirus 6 (HHV-6) was the sixth herpesvirus discovered. Isolated in 1986 during attempts to find novel viruses in patients with lymphoproliferative diseases, HHV-6 is now recognized as a T-cell lymphotrophic virus with high affinity for CD4 lymphocytes. It can cause the childhood illness roseola infantum, and it has been isolated in immunocompromised hosts. HHV-6 also has been implicated in the pathogenesis of white-matter demyelination in persons with AIDS dementia complex. HHV-6 has been isolated from various tissues, cells, and fluid in association with the following conditions: Kikuchi lymphadenitis, Lymphoma, Lymphadenopathy, Sjögren syndrome, Sarcoidosis, Systemic lupus erythematosus, Guillain-Barré syndrome, Multiple sclerosis. **HHV-7** virus often acts together with HHV-6. HHV-7 can contribute to the following conditions: pityriasis rosea, drug-induced hypersensitivity syndrome, encephalopathy, hemiconvulsion-hemiplegia-epilepsy syndrome, hepatitis infection, postinfectious myeloradiculoneuropathy and the reactivation of HHV-4, leading to "mononucleosis-like illness". Complications associated with HHV-7 infection have been reported in a great variety of transplant types.

HHV-6

V10-100FRT SA, RG, iQ, SC,MX, A,B	HHV6 Real-TM Quant Real Time Amplification kit	R	CE	100	2 x10 ² copies/ml
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HHV-7

V17-100FRT SA, RG, iQ, SC,MX, A,B	HHV7 Real-TM Quant Real Time Amplification kit	R		100	
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HHV-8

V203-100FRT SA, iQ, A, RG	HHV8 Real-TM Quant NEW Real Time Amplification kit	R		96	
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Rubella

The name rubella is derived from a Latin term meaning “little red.” Rubella is generally a benign communicable exanthematous disease. It is caused by ***Rubella virus***, which is a member of the Rubivirus genus of the family Togaviridae. Nearly one half of individuals infected with this virus are asymptomatic. Infection in younger children is characterized by mild constitutional symptoms, rash, and suboccipital adenopathy; conversely, in older children, adolescents, and adults, rubella may be complicated by arthralgia, arthritis, and thrombocytopenic purpura. Rare cases of rubella encephalitis have also been described in children. The major complication of rubella is its teratogenic effects when pregnant women contract the disease, especially in the early weeks of gestation. The virus can be transmitted to the fetus through the placenta and is capable of causing serious congenital defects, abortions, and stillbirths.

Rubella virus Kits

V24-50FRT SA, RG, iQ, SC, MX, A,B	Rubella Real-TM Real Time Amplification kit	R	CE	50	1 x 10 ³ copies/ml
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Toxoplasmosis

Toxoplasmosis is caused by infection with ***Toxoplasma gondii***, an obligate intracellular parasite. The infection produces a wide range of clinical syndromes in humans, land and sea mammals, and various bird species. In most immunocompetent individuals, primary or chronic (latent) *T gondii* infection is asymptomatic. A small percentage of these patients eventually develop chorioretinitis, lymphadenitis, or, rarely, myocarditis and polymyositis. However, certain individuals are at high risk for severe or life-threatening toxoplasmosis. Individuals at risk for toxoplasmosis include fetuses, newborns, and immunologically impaired patients. Congenital toxoplasmosis is usually a subclinical infection. Among immunodeficient individuals, toxoplasmosis most often occurs in those with defects of T-cell-mediated immunity, such as those with hematologic malignancies, bone marrow and solid organ transplants, or AIDS.

Toxoplasma gondii Kits

P1-50FRT SA, RG, iQ, SC, MX, A,B,LC	Toxoplasma gondii Real-TM Real Time Amplification kit	R	CE	50	4 x 10 ² copies/ml
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Parvovirus B19

Parvovirus B19 (B19V) is a single-stranded DNA virus of the family Parvoviridae and genus Erythrovirus. Human parvovirus B19 was shown to be the etiologic agent of erythema infectiosum in hematologically normal persons. Erythema infectiosum was originally named Fifth disease because it was the fifth of 6 classic exanthematous diseases of childhood to be described. Later, cases of nonimmune hydrops fetalis were reported when infection in a woman occurred during pregnancy. Patients who are immunocompromised (eg, receiving chemotherapy or immunosuppressive drugs or have immune defects [congenital and acquired]) may develop chronic parvovirus B19 infection that results in chronic anemia. Pure red cell aplasia (PRCA) persists until the virus is cleared and should be distinguished from the transient anemia described above. Chronic parvovirus B19 infection in transplant recipients has been linked to anemia, other hematologic abnormalities, myocarditis, and pneumonitis.

Parvovirus B19 Kits

V49-50FRT SA, RG, iQ, SC, MX, A,B,LC	Parvovirus B19 Real-TM Real Time Amplification kit	R	CE	50	2 x 10 ² copies/ml
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Influenza Virus

Influenza virus infection, one of the most common infectious diseases, is a highly contagious airborne disease that causes an acute febrile illness and results in variable degrees of systemic symptoms, ranging from mild fatigue to respiratory failure and death. These symptoms contribute to significant loss of workdays, human suffering, mortality, and significant morbidity. Influenza results from infection with 1 of 3 basic types of influenza virus—A, B, or C—which are classified within the family Orthomyxoviridae. These single-stranded RNA viruses are structurally and biologically similar but vary antigenically. The most common prevailing influenza A subtypes that infect humans are H1N1 and H3N2.

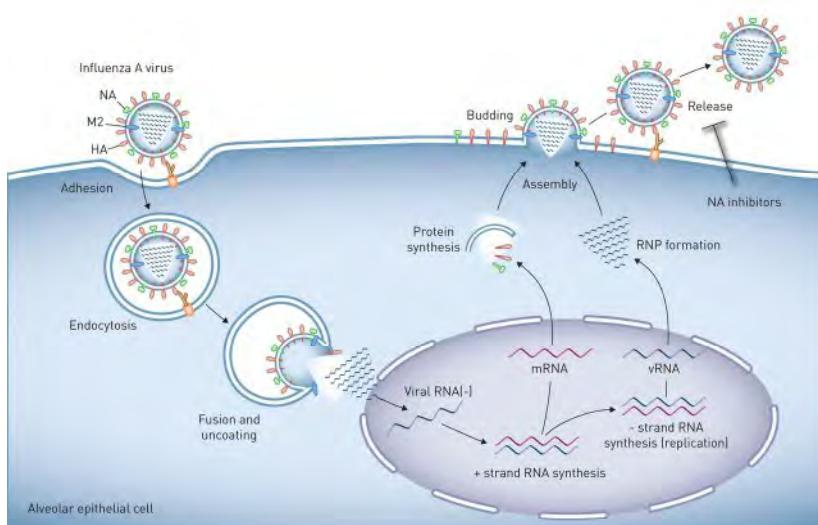


In 1997, an Avian subtype of influenza A, H5N1, was first described in Hong Kong. In 2008, more than 390 human cases had been documented and more than 246 persons had died following H5N1 outbreaks among poultry and resulting bird-to-human transmission.

On April 26, 2009, the US Department of Health and Human Services issued a nationwide public health emergency regarding Swine Influenza A (H1N1) virus infections in humans. As of early June 2009, H1N1 influenza had infected 28,774 people in 74 countries, and 144 deaths were confirmed to have been caused by the disease.

Influenza Kits

V36-100FRT SA, RG, IQ, SC,MX, A,B	Influenza A, B Real-TM Real Time Amplification kit	R	CE	100	1 x10 ³ copies/ml
R-V33-FRT SA, RG, IQ, SC,MX, A,B	Avian A Screening & Avian H5N1 Typing FRT Real Time Amplification kit	R	CE	50	1 x10 ³ copies/ml
V55-50FRT SA, RG, IQ, SC,MX, A,B	Swine Influenza Virus H1 Real-TM Real Time Amplification kit	R	CE	50	5 x10 ² copies/ml
V47-50FRT SA, RG, IQ, SC,MX, A,B	Influenza A H5 H7 H9 Typing FRT Real Time Amplification kit	R	CE	50	1 x10 ³ copies/ml
V54-50FRT SA, RG, IQ, B	Influenza A H1N1 & H3N2 Real-TM Real Time Amplification kit	R	CE	50	1 x10 ³ copies/ml



Chlamydia & Mycoplasma pneumoniae

Chlamydophila (formerly *Chlamydia*) *pneumoniae* causes mild pneumonia or bronchitis in adolescents and young adults. Older adults may experience more severe disease and repeated infections. Approximately 50% of young adults and 75% of elderly persons have serological evidence of previous infection. The pathogen is estimated to cause 10-20% of community-acquired pneumonia cases among adults. The estimated number of cases of C pneumoniae pneumonia is 300,000 cases per year.

Chlamydia pneumoniae Kits

B42-4-50FRT SA, RG, iQ, B	Mycoplasma pneumoniae / Chl. pneumoniae Real-TM Real Time Amplification kit, pre-aliquoted format in 0.2 ml PCR tubes	R	50	5×10^2 copies/ml	
B42-4-100FRT SA, RG, iQ, B	Mycoplasma pneumoniae / Chl. pneumoniae Real-TM Real Time Amplification kit	R	CE	100	5×10^2 copies/ml

Pseudomonas aeruginosa

Pseudomonas is a gram-negative rod that belongs to the family Pseudomonadaceae. More than half of all clinical isolates produce the blue-green pigment pyocyanin. These pathogens are widespread in nature, inhabiting soil, water, plants, and animals (including humans). **Pseudomonas aeruginosa** has become an important cause of infection, especially in patients with compromised host defense mechanisms. Pseudomonal bacteremia occurs in association with malignancy, chemotherapy, AIDS, burn wound sepsis, and diabetes. It is a frequent cause of nosocomial infections such as pneumonia, endocarditis, meningitis, urinary tract infections (UTIs) and bacteremia.

Pseudomonas aeruginosa Kits

B76-50FRT SA, RG, iQ, SC, MX, A, B	Pseudomonas aeruginosa Real-TM Quant Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
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Legionella pneumophila

Legionella pneumophila is a thin, pleomorphic, flagellated Gram-negative bacterium of the genus Legionella. L. pneumophila is the primary human pathogenic bacterium in this group and is the causative agent of legionellosis or Legionnaires' disease. Legionella pneumophila (named in memory of the deceased veterans) is ubiquitous to aquatic environments worldwide and resided as an intracellular parasite of amoeba and protozoa provided a link between natural environment and human disease. Thus, environmental monitoring, especially of potable water, cooling towers, and related sources, is a major focus in efforts to control the spread of this disease, which has a 25% of mortality rate.

Legionella pneumophila Kits

B50-50FRT RG, SA, iQ, B	Legionella pneumophila Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
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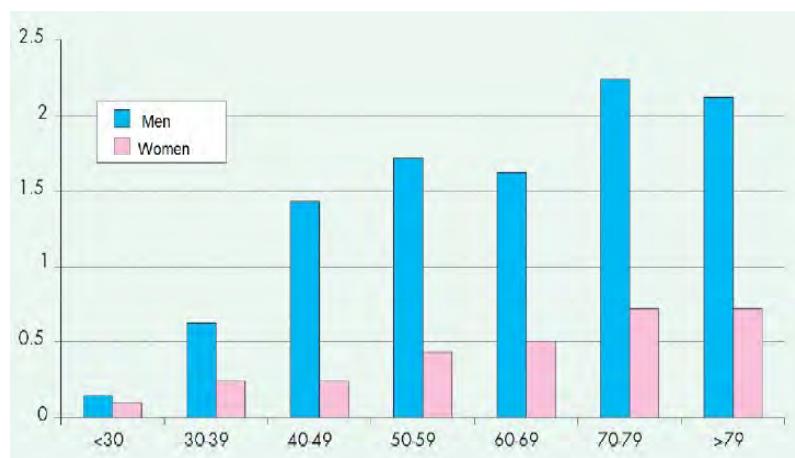


Figure. Incidence of Legionella related to sex and age.

Coronaviruses (MERS + SARS + COVID-19)

Coronaviruses are species in the genera of virus belonging to the subfamily Coronavirinae in the family Coronaviridae. Coronaviruses are enveloped viruses with a positive-sense RNA genome and with a nucleocapsid of helical symmetry. The most known human coronaviruses, SARS-CoV and SARS-CoV-2 which causes SARS and COVID-19 respectively, have a unique pathogenesis because it causes both upper and lower respiratory tract infections and can also cause gastroenteritis.

SARS-CoV-2 virus and its variants caused the 2020 global pandemic of COVID-19.

Coronavirus Kits

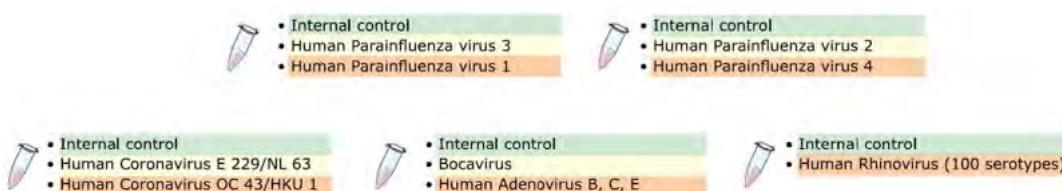
	MERS-CoV Real-TM				
V65-50FRT SA, RG, iQ, MX, SC, A, B	Real Time Amplification kit for detection and differentiation of MERS-CoV (Middle East Respiratory Syndrome Coronavirus) and SARS-CoV (Severe Acute Respiratory Syndrome Coronavirus)	R	CE	50	
V435-100FRT SA, RG, iQ, MX, A, B	SARS-CoV-2 Real-TM NEW Real-Time PCR test for the qualitative detection of SARS-CoV-2 (COVID-19 virus, 2019-nCoV) RNA in clinical samples. It detects E-gene, N-gene and a conserved region of SARS-like viruses	R	CE	96	
V448-100FRT SA, RG, iQ, MX, A, B	SARS-CoV-2/hRSV/Influenza A/B Real-TM NEW Real Time PCR kit for multiplex detection and differentiation of SARS-CoV-2 (COVID-19)/hRSV/Influenza A&B in clinical samples	R		96	
V440-100FRT SA, RG, iQ, MX, A, B	SARS-CoV-2/Influenza A/B multiplex Real-TM NEW Real-Time PCR test for the multiplex detection of SARS-CoV-2 (COVID-19 virus, 2019-nCoV) / Influenza A / Influenza B RNA in clinical samples.	R	CE	96	

Acute Respiratory Viral Infections

ARVI Screen Real-TM

Real Time PCR kit for detection of 11 respiratory pathogens in one clinical sample:

- human parainfluenza virus-1-4 (hPiv) RNA;
- HKU1 human coronavirus (hCov) RNA;
- human rhinovirus (hRv) RNA;
- human B, C, and E adenovirus (hAdv) DNA;
- human bocavirus (hBov) DNA



ARVI Kits

	ARVI Screen Real-TM			
V57-100FRT SA, RG, iQ, MX, SC, A, B	Multiplex RT-PCR detection and identification of human parainfluenza virus-1-4 (hPiv) RNA; OC43, E229, NL63, and HKU1 human coronavirus (hCov) RNA; human rhinovirus (hRv) RNA; human B, C, and E adenovirus (hAdv) DNA; and human bocavirus (hBov) DNA with Ribo-Sorb extraction kit	R	CE	100
V439-48FRT SA, iQ, MX, A	ARVI Plus Real-TM NEW Multiplex RT-PCR detection and identification of 16 respiratory viruses: SARS-CoV-2 coronavirus, Influenza A virus, Influenza B virus, Human parainfluenza virus-1-2-3-4 RNA, OC43, 229E, NL63, and HKU1 human coronavirus (hCov) RNA, Human bocavirus, Human rhinovirus, hRSV, human Adenovirus, human metapneumovirus	R	CE	48

Bordetella pertussis

Pertussis, also named whooping cough, is a highly contagious bacterial disease caused by *Bordetella pertussis*. Symptoms are initially mild, and then develop into severe coughing, which produce the namesake high-pitched “whoop” sound in infected babies and children when they inhale air after coughing. The coughing stage lasts for approximately six weeks before subsiding.

Pertussis Kits

B84-100FRT SA, RG, MX, SC, IQ, A, B	Bordetella pertussis/B.parapertussis/B.bronchiseptica Real-TM Real Time Amplification kit	R	€	100	1 x10 ³ copies/ml
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Tuberculosis

Tuberculosis (abbreviated as TB for tubercle bacillus) is a common and deadly infectious disease caused by mycobacteria, mainly *Mycobacterium tuberculosis*. Tuberculosis most commonly attacks the lungs (as pulmonary TB) but can also affect the central nervous system, the lymphatic system, the circulatory system, the genitourinary system, bones, joints and even the skin. Other mycobacteria such as *Mycobacterium bovis*, *Mycobacterium africanum* and *Mycobacterium microti* can also cause tuberculosis.

Early diagnosis of tuberculosis makes effective treatment possible and increases the probability of clinical outcome owing to quite effective antituberculosis therapy, however the tuberculosis diagnosis has certain difficulties. The application of molecular biology methods allow to overcome the difficulties in the diagnosis of *Mycobacterium tuberculosis*, but due to the biological peculiarities of this microorganism and immune response of human organism, tuberculosis cannot be diagnosed only by one method.

The development of test to differentiate between infection with *Mycobacterium tuberculosis* or *Mycobacterium bovis* and vaccination with *M. bovis* BCG could greatly assist in the diagnosis of early infection as well as enhance the use of tuberculosis vaccines on a wider scale.

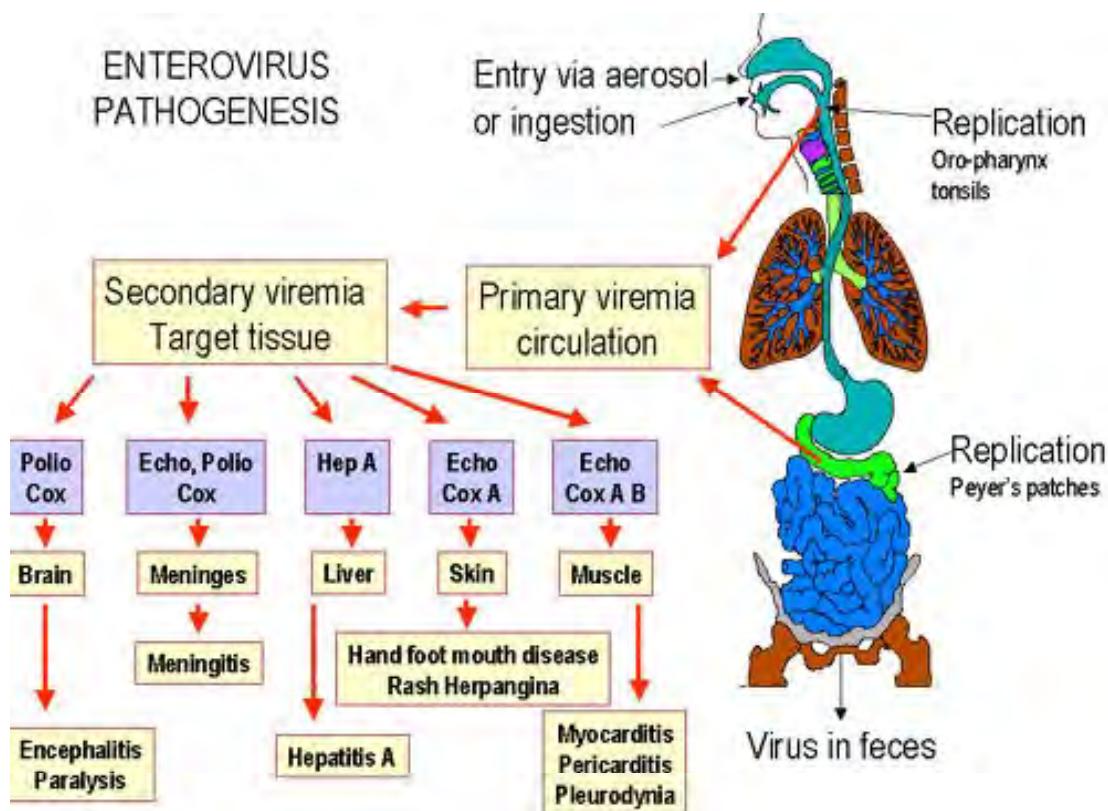


TB Kits

B15-50FRT SA, RG, iQ, SC, MX, A, B, LC	MTB Real-TM Real Time Amplification kit	R	€	50	2 x10 ² copies/ml
B41-50FRT SA, RG, iQ, SC, MX, A, B	Mycobacterium tuberculosis Diff Real-TM Real Time Amplification kit	R	€	50	5 x10 ² copies/ml
H-3611-50FRT	MTB MDR Real-TM Real Time Amplification kit for detection of MTB antibiotic resistance	R		50	

Enteroviruses

Human **Enteroviruses** are ubiquitous viruses transmitted from person to person via direct contact with virus shed from the gastrointestinal or upper respiratory tract. Enteroviruses belong to the Picornaviridae family of viruses and are traditionally divided into 5 subgenera based on differences in host range and pathogenic potential. Each subgenus contains a number of unique serotypes, which are distinguished basing on neutralization by specific antisera. The subgenera include polioviruses, coxsackievirus (groups A and B), and echoviruses. Enteroviruses cause a wide range of infections. **Poliovirus**, the prototypical enterovirus, can cause a subclinical or mild illness, aseptic meningitis, or paralytic poliomyelitis, a disease that has been eradicated in the United States and other developed countries. The nonpolio viruses (group A and B coxsackieviruses, echoviruses, enteroviruses) continue to be responsible for a wide spectrum of diseases in persons of all ages, although infection and illness occur most commonly in infants.

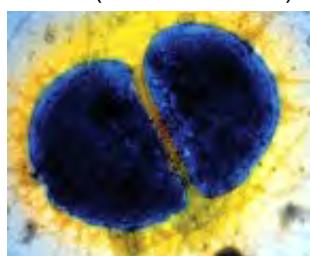


Enteroviruses Kits

V16-50FRT RG, iQ, SA, B	Enterovirus Real-TM Real Time Amplification kit	R	CE	50	1×10^3 copies/ml
V64-50FRT SA, RG, iQ, SC, MX, A, B	Enterovirus 71-Type Real-TM Real Time Amplification kit for detection of Enterovirus 71	R	CE	50	

Meningitis

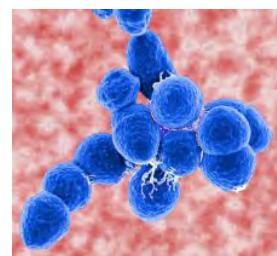
Meningitis is a clinical syndrome characterized by inflammation of the meninges. Clinically, this medical condition manifests with meningeal symptoms (eg, headache, nuchal rigidity, photophobia) and an increased number of white blood cells in the cerebrospinal fluid (CSF). Depending on the duration of symptoms, meningitis may be classified as acute or chronic. Acute bacterial meningitis denotes a bacterial cause of this syndrome. Depending on the specific bacterial cause, the syndrome may be called, for example, Streptococcus pneumoniae meningitis, Neisseria meningitis, or Haemophilus influenzae meningitis. Kit NHS Meningitis Real-TM is a Real-Time test for the detection and differentiation of Neisseria meningitidis, Haemophilus influenzae and Streptococcus pneumoniae in the biological materials. DNA is extracted from specimens, amplified using RT-amplification and detected using fluorescent reporter dye probes specific for N.meningitidis, H.influenzae, S.pneumoniae DNA and IC (Internal Control).



N.meningitidis



H.influenzae



Str. pneumoniae

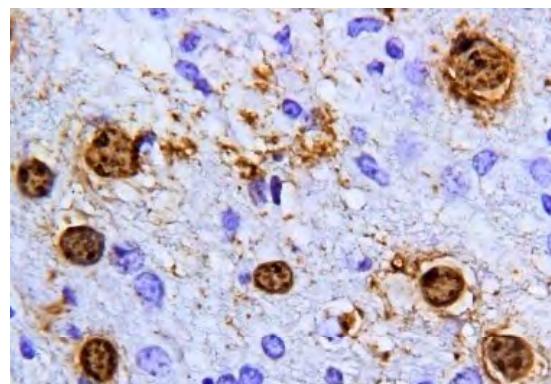
Meningitis Kits

B25-50FRT SA, RG, iQ, SC, MX, A, B	NHS Meningitis (N.meningitidis, H.influenzae, Str.pneumoniae) Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
B14-50FRT SA, RG, iQ, SC, MX, A, B	Listeria monocytogenes Real-TM Quant Real Time Amplification kit	R	CE	50	1×10^3 copies/ml

Poliomaviruses (JCV and BKV)

JC Virus and BK Virus are the most important Poliomaviruses. **JCV** is causing progressive multifocal leukoencephalopathy in patients suffering immunodeficiency, as in AIDS or during treatment with drugs causing immunosuppression for example in case of organ transplants.

BKV virus also targets immunosuppressed patients, for example during renal transplant it can cause a disease called BK nephropathy involving massive viral replication in the graft.



JCV-BKV Virus Kits

V71-50FRT SA, RG, iQ, SC, MX, A	JCV/BKV Virus Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
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Intestinal Infections

Acute Intestinal Infections (A.I.I) are one of the primary causes of hospitalization in infectious disease departments. In accordance with the data provided by the contemporary literature the following bacterial and viral agents are the most often detectable and generally spread etiological agents of AII:

1. Bacterial agents:
 - Shigella species microorganisms and enteroinvasive E coli (EIEC);
 - Salmonella species microorganisms;
 - Thermophilic group of Campylobacter species microorganisms;
 - Enteropathogenic E coli (EPEC) and enteroaggregative E coli (EAEC);
2. Viral agents
 - Group A rotaviruses;
 - Genotype 2 noroviruses;
 - Group F adenoviruses (Types 40 and 41);
 - Astroviruses.

The following causative agents are less widely or not universally spread but are no less important for epidemic outbreaks:

1. Vibrio cholerae;
2. Yersinia pseudotuberculosis;
3. Clostridium difficile;
4. Enterotoxigenic E. coli (ETEC), Enterohemorrhagic E. coli (EHEC);
5. Genotype 1 Enteroviruses;
6. Group C Rotaviruses.

Intestinal Infections Kits

V40-50FRT SA, RG, iQ, SC, MX, A, B	Rotavirus/Norovirus/Astrovirus Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
B44-50FRT SA, RG, iQ, SC, MX, A, B	Shigella/Salmonella/Campylobacter Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
B45-50FRT SA, RG, iQ, SC, MX, A, B	A.I.I. (Acute Intestinal Infections) Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
B62-50FRT SA, RG, iQ, MX, SC, A, B	Escherichioses Screen & Diff Real-TM Real Time Amplification kit	R	CE	50	5×10^2 copies/ml
B88-100FRT SA, RG, iQ, SC, MX, A , B	Aerobic complex Real-TM Real Time Amplification kit for detection of Enterobacteriaceae (E. coli, Klebsiella spp, Proteus spp, Streptococcus spp)	R	CE	100	
B-1972-100FRT	Clostridium difficile + ToxA + ToxB Real-TM Real Time Amplification kit	R		100	



Helicobacter Pylori

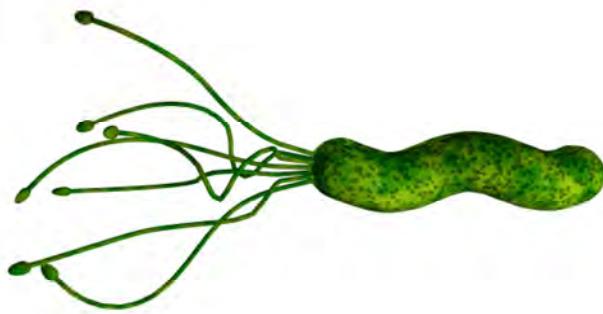
Helicobacter pylori is a gram-negative bacillus responsible for one of the most common infections found in humans worldwide. It's usually found in the stomach.

Helicobacter Pylori Kits

B9-50FRT
SA, RG, iQ, SC, MX, A,B,LC

H.pylori Real-TM
Real Time Amplification kit

R CE 50 1×10^3 copies/ml



Dangerous microrganisms and parasites

Parasites are one of the four main agents of infection known to man, the other three being bacterial, fungal and viral. The diseases are less prevalent in temperate climates, partly because of the occurrence of a cold season, which controls the insect population by forcing hibernation. Insects such as mosquitoes and flies are one of the most common disease carrier. These insects may carry a parasite, bacteria or virus that is infectious to humans and animals.



Leishmania Kits

N3-50FRT SA, RG, IQ, SC,MX, A	Leishmania spp. Real-TM Real Time Amplification kit	R	€	50	1×10^3 copies/ml
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Zika Virus Kits

V73-50FRT SA, RG, IQ, SC,MX, A	Zika Virus Real-TM Real Time Amplification kit	R	€	50	5×10^2 copies/ml
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Yellow fever Kits

H2461-50FRT SA, RG, IQ, SC,MX, A	Yellow Fever Virus Real-TM Real Time Amplification kit	R		50	
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Rickettsia Kits

H2741-50FRT SA, RG, IQ, SC,MX, A	Rickettsia conorii Real-TM Real Time Amplification kit	R	€	50	
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Diphtheria Kits

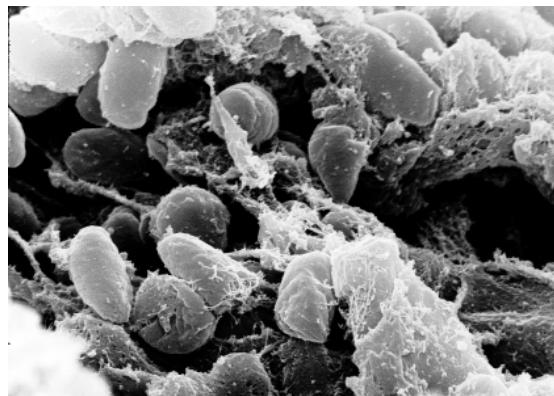
B2842-50FRT SA, RG, IQ, SC,MX, A	Corynebacterium diphtheriae / tox-genes Real-TM Real Time Amplification kit	R		50	
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Pestis

Yersinia pestis is a Gram-negative rod-shaped bacterium. It is a facultative anaerobe able to infect humans and other animals. Many evidence suggest that it was a contributing factor in many plagues throughout human history. The reservoir commonly associated with *Y. pestis* is several species of rodents (marmot, rats).

Pestis Kits

B79-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Yersinia pestis Real-TM Real Time Amplification kit	R	€	50	5×10^3 copies/ml
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Lyme disease

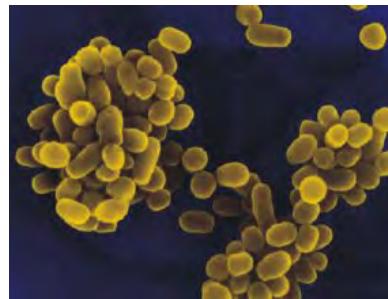
Lyme disease (LD) is a vector-borne, multisystem inflammatory disease caused by the spirochete ***Borrelia burgdorferi sensu lato***. It is transmitted to humans by infected ticks of the *Ixodes* genus. After entering the circulation, the organism invades the cutaneous, synovial, cardiac, and nervous systems. Spirochetes have also been demonstrated histologically in bone marrow, the spleen, lymph nodes, the liver, testes, and the placenta during early hematogenous dissemination. Similar condition is caused also by ***Borrelia miyamotoi***.

Borrelia burgdorferi Kits

B37-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Borrelia burgdorferi sensu lato Real-TM Real Time Amplification kit	R	CE	50	1 x 10 ³ copies/ml
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Brucellosis

Brucellosis is a worldwide zoonosis caused by infection with the bacterial genus *Brucella*. These organisms, which are small aerobic intracellular coccobacilli, localize in the reproductive organs of host animals, causing abortions and sterility. They are shed in large numbers in the animal's urine, milk, placental fluid, and other fluids. Exposure to infected animals and animal products causes brucellosis in humans. Human brucellosis causes more than 500,000 infections per year worldwide.



Brucella Kits

B10-50FRT SA, RG, iQ, MX, B	Brucella Real-TM Real Time Amplification kit	R	CE	50	1 x 10 ³ copies/ml
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Dengue virus

Dengue virus (DENV) is the cause of dengue fever. It is a mosquito-borne single positive-stranded RNA virus of the family Flaviviridae; genus Flavivirus. Four serotypes can cause the full spectrum of disease. There are not yet any vaccines to prevent infection with dengue virus and the most effective protective measures are those that avoid mosquito bites. When infected, early recognition and prompt supportive treatment can substantially lower the risk of developing severe disease.

Dengue Kits

V63-50FRT SA, RG, A, iQ, SC, MX, B, A	Dengue genotype Real-TM Real Time PCR kit for detection and differentiation of Dengue genotypes 1, 2, 3 and 4	R	CE	50	500 copies/ml
V63-S-50FRT	Dengue Real-TM Real Time PCR kit for detection of Dengue Virus	R	CE	50	500 copies/ml

Bacillus Anthracis

Bacillus anthracis is a Gram-positive spore-forming, rod-shaped bacterium, with a width of 1-1.2µm and a length of 3-5µm. Three forms of anthrax disease are recognized based on their form of inoculation: Cutaneous - the most common form (95%), causes a localized inflammatory black necrotic lesion (eschar), Pulmonary - highly fatal and characterized by sudden massive chest edema followed by cardiovascular shock, Gastrointestinal - rare but also fatal (causes death to 25%) type results from ingestion of spores

Bacillus Anthracis Kits

B101-50FRT SA, RG, iQ, MX, B	Bacillus anthracis Real-TM Real Time Amplification kit	R	50	5 x10 ² copies/ml
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Vibrio Cholerae

Cholera is caused by **Vibrio cholerae**, the most feared epidemic diarrheal disease because of its severity. Dehydration and death can occur within hours of infection. Robert Koch discovered *V cholerae* in 1883 during an outbreak in Egypt. The organism is a comma-shaped, gram-negative aerobic bacillus whose size varies from 1-3 µm in length by 0.5-0.8 µm in diameter. Its antigenic structure consists of a flagellar H antigen and a somatic O antigen.

Cholera Kits

B53-50FRT SA, RG, iQ, MX, B	Vibrio cholerae Real-TM Real Time Amplification kit	R	50	5 x10 ² copies/ml
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Leptospira

Leptospirosis is a worldwide zoonosis caused by pathogenic species of the genus **Leptospira**. In 90% of cases, leptospirosis manifests as an acute febrile illness with a biphasic course and an excellent prognosis. Nonspecific signs and symptoms of leptospirosis (eg, fever, headache, nausea, vomiting) are often confused with viral illness. In 10% of cases, the presentation is more dramatic, and the infection has a mortality rate of 10%. Known as Weil disease or icteric leptospirosis, the classic definition of this form of leptospirosis includes fever, jaundice, renal failure, and hemorrhage.

Leptospirosis Kits

B49-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Leptospira 16s RNA Real-TM Real Time Amplification kit	R	CE	50	1 x10 ³ copies/ml
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Congo Crimea

Congo-Crimea hemorrhagic fever is a widespread tick-borne viral disease, a zoonosis of animals that may affect humans. The pathogenic virus, commonly present in East and West Africa, is a member of the Bunyaviridae family of RNA viruses. Clinical disease is rare in infected mammals, but commonly severe in infected humans, with a 30% mortality rate.

Congo Crimea Kits

V22-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Congo Crimea Real-TM Real Time Amplification kit	R	CE	50	1 x10 ³ copies/ml
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Tick-Borne diseases

Ticks are arachnids, relatives of spiders that commonly live in wooded areas, brushy fields. They survive by eating blood from their hosts and they can pass infections from one host to another, including humans. Common tick-borne diseases are: **Tick-Borne Encephalitis (TBE)**, **Anaplasmosis**, **Ehrlichiosis**.

TBEV Kits

V59-100FRT SA, RG, iQ, SC, MX, A, B	TBEV, B.burgdorferi, A.phagocytophilum, E.chaffeensis / E.muris Real-TM Real Time Amplification kit	R	CE	100	1 x10 ³ copies/ml
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West Nile Virus

The West Nile virus is one of the many members of the genus Flavivirus that are known to cause human disease. The life cycle of the West Nile virus involves the microbe's transmission from nonhuman animals to humans by way of Aedes, Culex, or Anopheles mosquitoes. The West Nile virus can infect horses, birds, dogs, and other mammals. In hospitalized patients, neurologic sequelae of the West Nile virus included severe muscle weakness, with approximately 10% of patients developing a complete flaccid paralysis. One in 150 West Nile virus infections results in encephalitis or meningitis, and the mortality rate from severe illness is 3-15%.

West Nile Virus Kits

V53-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	West Nile Virus Real-TM Real Time Amplification kit	R	€	50	5×10^2 copies/ml
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Coxiella burnetii

Q fever is a zoonosis caused by **Coxiella burnetii**, an obligate gram-negative intracellular bacterium. Most commonly reported in southern France and Australia, Q fever occurs worldwide. *C. burnetii* infects various hosts, including humans, ruminants (cattle, sheep, goats), and pets. The bacterium is highly infectious, and only a few organisms can cause disease.

Coxiella burnetii Kits

B85-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Coxiella burnetii Real-TM Real Time Amplification kit	R	€	50	1×10^3 copies/ml
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Bacterial pyogenic infections and Pseudomonas aeruginosa

Pyogenic refers to bacterial infections that make pus, that is destroyed by bacteria such as *Streptococcus pyogenes* and *Staphylococcus aureus* through the release of leukocidins.

Bacterial pyogenic infections Kits

B77-100FRT SA, RG, A, iQ, SC, MX, B, A	Streptococcus B Real-TM Quant Real Time Amplification kit	R	€	100	
B82-100FRT SA, RG, A, iQ, SC, MX, B, A	Streptococcus pyogenes Real-TM Quant Real Time Amplification kit	R	€	100	
B76-50FRT SA, RG, A, iQ, SC, MX, B, A	Pseudomonas aeruginosa Real-TM Quant Real Time Amplification kit	R	€	50	

Ebola

Ebola virus disease (EVD), formerly known as Ebola haemorrhagic fever, is a severe, often fatal illness in humans. The virus is transmitted to people from wild animals and spreads in the human population through human-to-human transmission. The average EVD case fatality rate is around 50%. Case fatality rates have varied from 25% to 90% in past outbreaks.



Ebola Kits

V69-50FRT SA, RG, A, iQ, SC, MX, B, A, LC	Ebola Zaire Real-TM Real Time PCR kit for detection of Ebola Zaire virus	R	€	50	
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Fungal infections

A fungal infection, also called mycosis, is a skin disease caused by a fungus. There are many different species of fungi causing different diseases from mild in the skin to severe in the lungs or in the bloodstream.

Fungal Infections Kits

F23-96FRT SA, iQ, A	MycoScreen Real-TM NEW Real Time Amplification kit for detection of Meyerozyma guilliermondii (C.guilliermondi), Candida albicans, Pichia kudriavzevii(C.krusei), Saccharomyces cerevisiae, Candida auris, Candida tropicalis, Clavispora lusitaniae (Candida lusitaniae), Debaryomyces hansenii(C.famata), Candida dubliniensis, Candida glabrata, Candida parapsilosis, Malassezia spp., Malassezia furfur, Kluyveromyces marxianus(C.kefyr)	R	€	96	
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Bacterial Drug Resistance

More commonly, the term Drug Resistance is used in the context of resistance that pathogens have “acquired”. When a microorganism is resistant to more than one drug, it is said to be multidrug-resistant (MDR). Resistance to β-lactam antibiotics which include the penicillins (oxacillin, methicillin, dicloxacillin, nafcillin etc.) and the cephalosporins make difficult to treat infections with standard types of antibiotics. In addition to β-lactam/carbapenem resistance, Enterobacteriaceae often carry genes that confer high levels of resistance to many other antimicrobials, often leaving very limited therapeutic options.

Drug resistance Kits

B1772-96FRT SA, RG, MX, iQ, SC, A, B	Staphilococcus aureus Real-TM Real Time Amplification kit	R	96
B78-100FRT SA, RG, MX, iQ, SC, A, B	MRSA Quant Real-TM Real Time Amplification kit for quantitative detection of Meticillin-Resistant-Staphilococcus aureus	R	€ 100
C1-100FRT SA, RG, A, B	MDR MBL (VIM, IMP, NDM) Real-TM Real Time Amplification kit for detection of genes VIM, IMP and NDM in Enterobacteriaceae and NFGNB*	R	€ 100
C2-100FRT SA, RG, A, B	MDR KPC/OXA Real-TM Real Time Amplification kit for detection of genes KPC, OXA-48 and OXA-162 in Enterobacteriaceae and NFGNB	R	€ 100
T01781-50-T SA, RG, iQ, MX, A, B	Resistance cephalosporins-1 Real Time PCR test for Enterobacteriaceae resistance, genes CTX-M - ready to use 0,2 ml tube format	R	60
T01782-50-T SA, RG, iQ, MX, A, B	Resistance cephalosporins-2 Real Time PCR test for S.aureus resistance, genes MecA - ready to use 0,2 ml tube format	R	60
T01784-50-T SA, RG, iQ, MX, A, B	Resistance carbapenems-1 Real Time test for Enterobacteriaceae e Pseudomonas resistance, genes VIM - ready to use 0,2 ml tube format	R	60
T01785-50-T SA, RG, iQ, MX, A, B	Resistance carbapenems-2 Real Time PCR test for Enterobacteriaceae resistance, genes NDM - ready to use 0,2 ml tube format	R	60
T01786-50-T SA, RG, iQ, MX, A, B	Resistance carbapenems-3 Real Time PCR test for Enterobacteriaceae resistance, genes OXA-48 - ready to use 0,2 ml tube format	R	60
T01746-50-T SA, RG, iQ, MX, A, B	Resistance carbapenems-4 Real Time PCR test for Enterobacteriaceae resistance, genes KPC - ready to use 0,2 ml tube format	R	60
T01787-50-T SA, RG, iQ, MX, A, B	Resistance glycopeptides Real Time PCR test for Enterococcus faecalis and E. faecium resistance to Vancomycin and Teicoplanin, genes VanA and VanB - ready to use 0,2 ml tube format	R	60
T01747-50-T SA, RG, iQ, MX, A, B	Resistance macrolides-1 Real Time PCR test for Streptococcus spp Staphylococcus spp resistance to macrolides, lincosamides, streptogramins, gene ErmB - ready to use 0,2 ml tube format	R	60
T01748-50-T SA, RG, iQ, MX, A, B	Resistance macrolides-2 Real Time PCR test for Streptococcus spp resistance to macrolides; genes Mef - ready to use 0,2 ml tube format	R	60
R1-P028-12-S SA, iQ, A	Bac Multi-Screen Real-TM NEW RT PCR test for detection of opportunistic infections caused by Streptococcus pyogenes,Citrobacter freundii,Citrobacter koseri,Burkholderia spp.,Streptococcus pneumoniae,Streptococcus spp..Staphylococcus aureus,Staphylococcus spp.,Klebsiella oxytoca,Klebsiella pneumoniae,Acinetobacter spp.,Enterobacter cloacae,Serratia marcescens,Stenotrophomonas maltophilia,Haemophilus spp.,Haemophilus influenzae,Morganella morganii,Enterobacteriales,Enterococcus spp., Escherichia coli,Pseudomonas aeruginosa,Streptococcus agalactiae,Proteus spp.,Achromobacter ruhlandii,Achromobacter xylosoxidans (ready to use 0,2 ml strip format)	R	€ 12
R1-P026-24-S SA, iQ, A	Bac Multi-Resist Real-TM NEW RT PCR test for analysis of bacteria resistant to glycopeptide and beta-lactam antibiotics (imp, TBM4, oxa-51-like, ctx-M-1, tem, van A/B, mec A, oxa-48-like, oxa-40-like, vim, kpc, oxa-23-like, ndm, shv, ges) (ready to use 0,2 ml strip format)	R	€ 24

*NFGNB: Non Fermenting Gram Negative Bacteria

Molecular Genetics

Cardiovascular diseases (CVD) are lifethreatening conditions which affect up to 10% of the human population. Thrombotic complications, such as an acute myocardial infarction, ischemic stroke, pulmonary embolism, deep venous thrombosis are the major causes of morbidity and mortality in the world. A wide spectrum of CVD with inherited genetic susceptibilities is now known and genetic susceptibility may be caused by mutations and single nucleotide polymorphisms in a variety of genes mainly involved in blood coagulation, regulation of blood pressure, and metabolism of lipids, glucose, homocysteine or iron.

Among the cardiovascular diseases markers have important role variations in the genes for blood coagulation factors V (**FV**), II (**protrombin**), XIII (**FXIII**), plasminogen activator inhibitor-1 (**PAI-1**), methylenetetrahydrofolate reductase (**MTHFR**), apolipoprotein B (**Apo B**), platelet glycoprotein IIIa (**GPIIIa**), β -fibrinogen (**FGB**). Moreover, an increased tendency to develop thrombosis, called also "thrombophilia", underlies the significant proportion of cases in the most common obstetric complications (recurrent pregnancy loss, fetal growth retardation, preeclampsia, abruptio placenta).

Coagulation / Fibrinolysis System

T01001-96-S SA,iQ,MX,A	Cardio Trombophilia Panel RT-PCR kit for detection of 8 mutations (F2 20210 G>A, F5 1691 G>A (Arg506Gln), F710976 G>A (Arg353Gln), F13 G>T (Val34Leu), FGB -455 G>A, ITGA2 807 C>T (Phe224Phe), ITGB3 1565 T>C(Leu33Pro), SERPINE1(PAI1) -675 5G>4G) in ready to use 12 x 8 strip format	R	12
T01002-96-S SA,iQ,MX,A	Folates Metabolism Panel RT-PCR kit for detection of 4 mutations: MTHFR 677 C>T (Ala222Val), MTHFR 1298A>C (Glu429Ala), MTR 2756 A>G (Asp391Gly), MTRR 66 A>G (Ile22Met) in ready to use 12 x 8 strip format	R	24
T01101-50-T SA,RG,iQ,MX,A,B	FV (G1691A) Leiden SNP-Screen RT-PCR test for detection of Leiden mutation (Arg506Gln; rs6025) - ready to use 0,2 ml tube format	R	CE 60
T01101-96-S SA,iQ,MX,A,B	FV (G1691A) Leiden SNP-Screen RT-PCR test for detection of Leiden mutation (Arg506Gln; rs6025) - ready to use 12 x 8 strip format	R	CE 96
T01102-50-T SA,RG,iQ,MX,A,B	FII Protrombin (G20210A) SNP-Screen RT-PCR test for detection of prothrombin F2 gene mutation (rs1799963) - ready to use 0,2 ml tube format	R	CE 60
T01102-96-S SA,RG,iQ,MX,A,B	FII Protrombin (G20210A) SNP-Screen RT-PCR test for detection of prothrombin F2 gene mutation (rs1799963) - ready to use 12 x 8 strip format	R	CE 96
T01105-50-T SA,RG,iQ,MX,A,B	FVII (G1238A) SNP-Screen RT-PCR test for detection of FVII gene mutation (Arg353Gln; rs6046) - ready to use 0,2 ml tube format	R	60
T01105-96-S SA,RG,iQ,MX,A,B	FVII (G1238A) SNP-Screen RT-PCR test for detection of FVII gene mutation (Arg353Gln; rs6046) - ready to use 12 x 8 strip format	R	96
T01103-50-T SA,RG,iQ,MX,A,B	MTHFR (C677T) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Ala222Val; rs1801133) - ready to use 0,2 ml tube format	R	CE 60
T01103-96-S SA,iQ,MX,A,B	MTHFR (C677T) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Ala222Val; rs1801133) - ready to use 12 x 8 strip format	R	CE 96

Coagulation / Fibrinolysis System

T01273-50-T SA,RG,iQ,MX,A,B	MTHFR (A1298C) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Glu429Ala; Rs1801131) - ready to use 0,2 ml tube format	R	60
T01273-96-S SA,RG,iQ,MX,A,B	MTHFR (A1298C) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Glu429Ala; Rs1801131) - ready to use 12 x 8 strip format	R	96
T01124-50-T SA,RG,iQ,MX,A,B	MTRR (A 66 G) SNP-Screen RT-PCR test for detection of methioninesynthase gene mutation (Ile22Met; rs1801394) - ready to use 0,2 ml tube format	R	60
T01124-96-S SA,RG,iQ,MX,A,B	MTRR (A 66 G) SNP-Screen RT-PCR test for detection of methioninesynthase gene mutation (Ile22Met; rs1801394) - ready to use 12 x 8 strip format	R	96
T01143-50-T SA,RG,iQ,MX,A,B	MTR (A2756G) SNP-Screen RT-PCR test for detection of methionine synthase gene mutation (Asp919Gly; rs1805087) - ready to use 0,2 ml tube format	R	60
T01143-96-S SA,RG,iQ,MX,A,B	MTR (A2756G) SNP-Screen RT-PCR test for detection of methionine synthase gene mutation (Asp919Gly; rs1805087) - ready to use 12 x 8 strip format	R	96
T01120-50-T SA,RG,iQ,MX,A,B	PAI SERPINE (-675 5G/4G) SNP-Screen RT-PCR test for detection of insertion/deletion polymorphism of SERPINE1 or plasminogen activator inhibitor type 1 gene (rs1799768) - ready to use 0,2 ml tube format	R	60
T01120-96-S SA,RG,iQ,MX,A,B	PAI SERPINE (-675 5G/4G) SNP-Screen RT-PCR test for detection of insertion/deletion polymorphism of SERPINE1 or plasminogen activator inhibitor type 1 gene (rs1799768) - ready to use 12 x 8 strip format	R	96
T01107-50-T SA,RG,iQ,MX,A,B	FGB (G-455A) SNP-Screen RT-PCR test for detection of fibrinogen beta gene (rs1800790) - ready to use 0,2 ml tube format	R	60
T01107-96-S SA,RG,iQ,MX,A,B	FGB (G-455A) SNP-Screen RT-PCR test for detection of fibrinogen beta gene (rs1800790) - ready to use 12 x 8 strip format	R	96
T01356-50-T SA,RG,iQ,MX,A,B	FXII (C -4T) SNP-Screen RT-PCR test for detection of factor XII gene mutation (rs1801020) - ready to use 0,2 ml tube format	R	60
T01356-96-S SA,RG,iQ,MX,A,B	FXII (C -4T) SNP-Screen RT-PCR test for detection of factor XII gene mutation (rs1801020) - ready to use 12 x 8 strip format	R	96
T01355-50-T SA,RG,iQ,MX,A,B	FXIII (V35L) SNP-Screen RT-PCR test for detection of factor XIII A1 gene mutation (Val35Leu; rs5985) - ready to use 0,2 ml tube format	R	60
T01355-96-S SA,iQ,MX,A,B	FXIII (V35L) SNP-Screen RT-PCR test for detection of factor XIII A1 gene mutation (Val35Leu; rs5985) - ready to use 12 x 8 strip format	R	96

Coagulation / Fibrinolysis System

T01155-50-T SA,RG,iQ,MX,A,B	ITGA2 (C807T) SNP-Screen RT-PCR test for detection of Integrin alpha2 gene mutation (Phe224Phe;rs1126643) - ready to use 0,2 ml tube format	R	60
T01155-96-S SA,iQ,MX,A,B	ITGA2 (C807T) SNP-Screen RT-PCR test for detection of Integrin alpha2 gene mutation (Phe224Phe;rs1126643) - ready to use 12 x 8 strip format	R	96
T01106-50-T SA,RG,iQ,MX,A,B	ITGB3 (T176C) SNP-Screen RT-PCR test for detection of Integrin beta-3 gene mutation (Leu33Pro; rs5918) - ready to use 0,2 ml tube format	R	60
T01106-96-S SA,iQ,MX,A,B	ITGB3 (T176C) SNP-Screen RT-PCR test for detection of Integrin beta-3 gene mutation (Leu33Pro; rs5918) - ready to use 12 x 8 strip format	R	96
T01179-50-T SA,RG,iQ,MX,A,B	GPIBA1b (C482T) SNP-Screen RT-PCR test for detection of platelet glycoprotein Iba gene mutation (Thr145 Met; rs6065) - ready to use 0,2 ml tube format	R	60
T01179-96-S SA,iQ,MX,A,B	GPIBA1b (C482T) SNP-Screen RT-PCR test for detection of platelet glycoprotein Iba gene mutation (Thr145 Met; rs6065) - ready to use 12 x 8 strip format	R	96
T01354-50-T SA,RG,iQ,MX,A,B	GPIBA1b (T -5C) SNP-Screen RT-PCR test for detection of platelet glycoprotein Iba gene mutation (Kozak sequence polymorphism; rs2243093) - ready to use 0,2 ml tube format	R	60
T01354-96-S SA,iQ,MX,A,B	GPIBA1b (T -5C) SNP-Screen RT-PCR test for detection of platelet glycoprotein Iba gene mutation (Kozak sequence polymorphism; rs2243093) - ready to use 12 x 8 strip format	R	96
T01357-50-T SA,RG,iQ,MX,A,B	SELPLG (G186A) SNP-Screen RT-PCR test for detection selectin P ligand gene mutation (Met62Ile; rs2228315) - ready to use 0,2 ml tube format	R	60
T01357-96-S SA,iQ,MX,A,B	SELPLG (G186A) SNP-Screen RT-PCR test for detection selectin P ligand gene mutation (Met62Ile; rs2228315) - ready to use 12 x 8 strip format	R	96

Hemochromatosis

Hemochromatosis or HFE-related hereditary hemochromatosis is a hereditary disease characterized by excessive intestinal absorption of dietary iron resulting in a pathological increase in total body iron stores. Most patients with the manifest of hereditary hemochromatosis are homozygous for the Cys282Tyr mutation, and a small proportion are heterozygous for both the Cys282Tyr and His63Asp (rs1799945 C/G or H63D) mutation of the HFE gene. There is evidence that 63Asp allele may confer some advantage in endurance sport performance.

Hemochromatosis

HM1-50FRT SA,RG,iQ,MX,A,B	Hemochromatosis Real-TM Real Time PCR test panel for detection of HFE gene mutations 187 C>G (H63D), 193 A>T (S65C), 845 G>A (C282Y) - in ready to use strip format	R	24
HM-1-50FRT SA	Hemochromatosis Real-TM Real Time PCR test panel for detection of HFE gene mutations 187 C>G (H63D), 193 A>T (S65C), 845 G>A (C282Y) with melting curve analysis	R	48
S01191-50FRT SA,RG,iQ,MX,A,B	HFE His63Asp Real Time PCR test panel for detection of HFE mutation His63Asp	R	50
S01192-50FRT SA,RG,iQ,MX,A,B	HFE Ser65Cys Real Time PCR test panel for detection of HFE gene mutation Ser65Cys	R	50
S01193-50FRT SA,RG,iQ,MX,A,B	HFE Cys282Tyr Real Time PCR test panel for detection of HFE gene mutation Cys282Tyr	R	50

Pharmacogenetics

Pharmacogenetics is the study of genetic differences in metabolic pathways which can affect individual responses to drugs, both in terms of therapeutic effect and adverse effects.

Warfarin (also known by the brand names Coumadin, Jantoven, Marevan, Uniwarfin) is an anticoagulant normally used in the prevention of thrombosis and thromboembolism, the formation of blood clots in the blood vessels and their migration elsewhere in the body, respectively. Polymorphisms in two genes, VKORC1 and CYP2C9, can affect the sensitivity of an individual patient to warfarin.

Warfarin Sensitivity

T01104-50-T SA,RG,iQ,MX,A,B	CYP2C9*2 (C430T) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (Arg144Cys; rs1799853) - ready to use 0,2 ml tube format	R	60
T01104-96-S SA,iQ,MX,A,B	CYP2C9*2 (C430T) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (Arg144Cys; rs1799853) - ready to use 12 x 8 strip format	R	96
T01111-50-T SA,RG,iQ,MX,A,B	CYP2C9*3 (A1075C) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (Ile359Leu; rs1057910) - ready to use 0,2 ml tube format	R	60
T01111-96-S SA,iQ,MX,A,B	CYP2C9*3 (A1075C) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (Ile359Leu; rs1057910) - ready to use 12 x 8 strip format	R	96
T01144-50-T SA,RG,iQ,MX,A,B	VKORC1 (C1173T) SNP-Screen RT-PCR test for detection Vitamin K epoxide reductase complex subunit 1 gene mutation, Warfarin sensitivity (rs9934438) - ready to use 0,2 ml tube format	R	60
T01144-96-S SA,iQ,MX,A,B	VKORC1 (C1173T) SNP-Screen RT-PCR test for detection Vitamin K epoxide reductase complex subunit 1 gene mutation, Warfarin sensitivity (rs9934438) - ready to use 12 x 8 strip format	R	96
T01145-50-T SA,RG,iQ,MX,A,B	VKORC1 (G3730A) SNP-Screen RT-PCR test for detection Vitamin K epoxide reductase complex subunit 1 gene mutation, Warfarin resistance (rs7294) - ready to use 0,2 ml tube format	R	60
T01145-96-S SA,iQ,MX,A,B	VKORC1 (G3730A) SNP-Screen RT-PCR test for detection Vitamin K epoxide reductase complex subunit 1 gene mutation, Warfarin resistance (rs7294) - ready to use 12 x 8 strip format	R	96

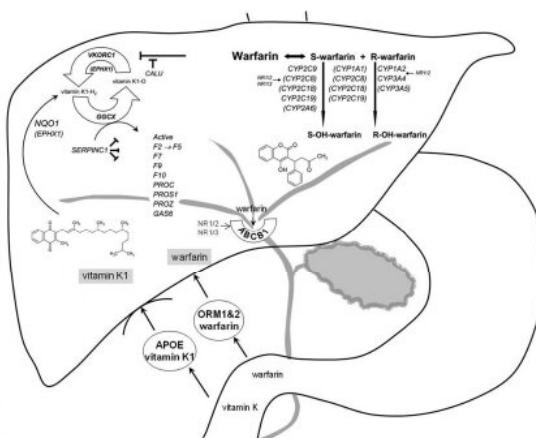


Fig. Warfarin mechanism of action

Clopidogrel (Plavix)

The anti-platelet agent clopidogrel bisulfate (sold under the trade name Plavix or Clopidogrel) is a widely prescribed medication for the prevention of blood clots in patients with acute coronary syndrome. This drug requires activation by CYP2C19, therefore individual carriers of alleles with reduced activity like CYP2C19*2 and CYP2C19*3 are likely at risk of therapeutic failure.

T01323-50-T SA,RG,iQ,MX,A,B	CYP2C19*2 (G681A) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (rs4244285) - ready to use 0,2 ml tube format	R	60
T01323-96-S SA,iQ,MX,A,B	CYP2C19*2 (G681A) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (rs4244285) - ready to use 12 x 8 strip format	R	96
T01324-50-T SA,RG,iQ,MX,A,B	CYP2C19*3 (G636A) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (rs4986893) - ready to use 0,2 ml tube format	R	60
T01324-96-S SA,iQ,MX,A,B	CYP2C19*3 (G636A) SNP-Screen RT-PCR test for detection of CYP2C19 gene mutation (rs4986893) - ready to use 12 x 8 strip format	R	96

Tacrolimus (FK-506 or Fujimycin)

Tacrolimus, also known as FK-506 or Fujimycin, is the generic name for a calcineurin inhibitor drug. It is an immunosuppressive agent for treating autoimmune disease, including myasthenia gravis and rheumatoid arthritis, as well as for preventing allograft rejection in organ transplantation. Tacrolimus is primarily metabolized by CYP3A5. CYP3A5*3 is a nonfunctional variant, so heterozygous and especially homozygous carriers of this allele tend not to break down tacrolimus as much as normal allele, leading to higher blood concentrations of tacrolimus in these (CYP3A5*3) individuals.

T01331-50-T SA,RG,iQ,MX,A,B	CYP3A5*3 (G6986A) SNP-Screen RT-PCR test for detection of CYP3A5 gene mutation (rs776746) - ready to use 0,2 ml tube format	R	60
T01331-96-S SA,iQ,MX,A,B	CYP3A5*3 (G6986A) SNP-Screen RT-PCR test for detection of CYP3A5 gene mutation (rs776746) - ready to use 12 x 8 strip format	R	96

Statins

The SLCO1B1 gene encodes for the organic anion transporting polypeptide 1B1 (OATP1B1), an influx transporter produced in the liver that mediates the hepatic uptake and metabolism of statins. Inherited variations in the SLCO1B1 gene known as SNPs (single nucleotide polymorphisms) affect the function of this transporter. The presence of this variant, especially in homozygotes, results in significantly decreased ability to take up statins, less effectiveness of the statin in lowering LDL-C, higher blood levels after dosing, and an increased risk of myopathy. Studies show that people who have particular inherited variations on the SLCO1B1 gene are four- to 17-times more likely to suffer myopathy as a side effect.

T01303-50-T SA,RG,iQ,MX,A,B	SLCO1B1 (T37041C) SNP-Screen RT-PCR test for detection of SLCO1B1 gene mutation (Val174Ala; rs4149056) - ready to use 0,2 ml tube format	R	60
T01303-96-S SA,iQ,MX,A,B	SLCO1B1 (T37041C) SNP-Screen RT-PCR test for detection of SLCO1B1 gene mutation (Val174Ala; rs4149056) - ready to use 12 x 8 strip format	R	96

Diabetes and obesity

Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have a negative effect on health, leading to reduced life expectancy and/or increased health problems. Obesity increases the likelihood of various diseases, particularly heart disease, type 2 diabetes, obstructive sleep apnea, certain types of cancer, and osteoarthritis. Obesity is most commonly caused by a combination of excessive food energy intake, lack of physical activity, and genetic susceptibility.

Diabetes and obesity

T01335-50-T SA, RG, iQ, MX, A, B	PPARG2 (C34G) SNP-Screen Real Time PCR test for detection of Peroxisome Proliferator-Activated Receptor-Gamma-2 gene mutation (Pro12Ala, rs1801282) - ready to use 0,2 ml tube format	R	60
T01335-96-S SA, iQ, MX, A, B	PPARG2 (C34G) SNP-Screen Real Time PCR test for detection of Peroxisome Proliferator-Activated Receptor-Gamma-2 gene mutation (Pro12Ala, rs1801282) - ready to use 12 x 8 strip format	R	96
T01358-50-T SA, RG, iQ, MX, A, B	ADRB2 (C5318G) SNP-Screen RT-PCR test for detection adrenoceptor beta 2, surface gene (Gln27Glu, rs1042714) - ready to use 0,2 ml tube format	R	60
T01358-96-S SA, iQ, MX, A, B	ADRB2 (C5318G) SNP-Screen RT-PCR test for detection adrenoceptor beta 2, surface gene (Gln27Glu, rs1042714) - ready to use 12 x 8 strip format	R	96
T01359-50-T SA, RG, iQ, MX, A, B	ADRB2 (G46A) SNP-Screen RT-PCR test for detection adrenoceptor beta 2, surface gene (Arg16Gly, rs1042713) - ready to use 0,2 ml tube format	R	60
T01359-96-S SA, iQ, MX, A, B	ADRB2 (G46A) SNP-Screen RT-PCR test for detection adrenoceptor beta 2, surface gene (Arg16Gly, rs1042713) - ready to use 12 x 8 strip format	R	96
T01360-50-T SA, RG, iQ, MX, A, B	ADRB3 (T190C) SNP-Screen RT-PCR test for detection of β-adrenergic receptor genes mutation (Trp64Arg, rs4994) - ready to use 0,2 ml tube format	R	60
T01360-96-S SA, iQ, MX, A, B	ADRB3 (T190C) SNP-Screen RT-PCR test for detection of β-adrenergic receptor genes mutation (Trp64Arg, rs4994) - ready to use 12 x 8 strip format	R	96
T01361-50-T SA, RG, iQ, MX, A, B	FABP2 (A163G) SNP-Screen RT-PCR test for detection of Fatty Acid Binding Protein 2 gene (Ala54Thr, rs1799883) - ready to use 0,2 ml tube format	R	60
T01361-96-S SA, iQ, MX, A, B	FABP2 (A163G) SNP-Screen RT-PCR test for detection of Fatty Acid Binding Protein 2 gene (Ala54Thr, rs1799883) - ready to use 12 x 8 strip format	R	96
T01329-50-T SA, RG, iQ, MX, A, B	FTO (A23525T) SNP-Screen RT-PCR test for detection of FTO gene mutation (rs9939609) - ready to use 0,2 ml tube format	R	60
T01329-96-S SA, iQ, MX, A, B	FTO (A23525T) SNP-Screen RT-PCR test for detection of FTO gene mutation (rs9939609) - ready to use 12 x 8 strip format	R	96
T01372-96-S SA, iQ, MX, A, B	Obesity & Diabetes Screen NEW Real Time PCR test for detection of PPARG Pro12Ala, ADRB2 Gln27Glu and Arg16Gly, ADRB3 Trp64Arg, FABP2 Ala54Thr, LPLHindIII, INS -23Hpl, FTO gene mutations - ready to use 12 x 8 strip format	R	12

Hepatitis C treatment prognosis

Chronic infection with hepatitis C virus (HCV) affects 170 million people worldwide and is the leading cause of cirrhosis in North America. Although the recommended treatment for chronic infection involves a 48-week course of peginterferon- α -2b (PegIFN- α -2b) or - α -2a (PegIFN- α -2a) combined with ribavirin (RBV), it is well known that many patients will not be cured by treatment.

Recent research has shown that genetic variation in the IL28B gene predicts both chronicity of HCV infection and sustained virological response (SVR) to antiviral standard therapy.

Single nucleotide polymorphisms (SNPs) near **interleukin-28B (IL-28B)** gene were shown to be highly associated with treatment response (SVR) in patients with chronic hepatitis C virus (HCV) infection.

Hepatitis C treatment prognosis

R05-100FRT SA,RG,iQ,SC,MX,A,B	IL28B rs17 / rs60 Real-TM RT-PCR test for detection of Interleukin mutations	R	100
T01349-50-T SA,RG,iQ,MX,A,B	IL28B (T>G) SNP-Screen RT-PCR test for detection of Interleukin mutation 1 (rs8099917) - ready to use 0,2 ml tube format	R	60
T01349-96-S SA,iQ,MX,A,B	IL28B (T>G) SNP-Screen RT-PCR test for detection of Interleukin mutation 1 (rs8099917) - ready to use 12 x 8 strip format	R	96
T01371-50-T SA,RG,iQ,MX,A,B	IL28B (C>T) SNP-Screen RT-PCR test for detection of Interleukin mutation 2 (rs12979860) - ready to use 0,2 ml tube format	R	60
T01371-96-S SA,iQ,MX,A,B	IL28B (C>T) SNP-Screen RT-PCR test for detection of Interleukin mutation 2 (rs12979860) - ready to use 12 x 8 strip format	R	96

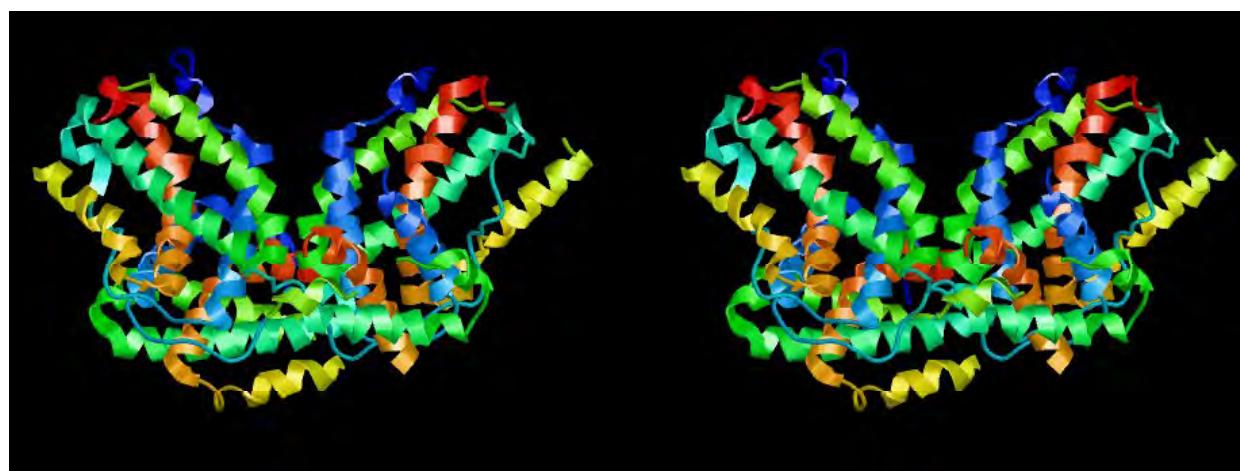


Fig. 3D image of IL28B protein structure

Hypertension

Hypertension (HTN) or high blood pressure, sometimes called arterial hypertension, is a chronic medical condition in which the blood pressure in the arteries is elevated. Blood pressure is summarised by two measurements, systolic and diastolic, which depend on whether the heart muscle is contracting (systole) or relaxed between beats (diastole). As of 2000, nearly one billion people or ~26% of the adult population of the world had hypertension. It was common in both developed (333 million) and undeveloped (639 million) countries. In Europe hypertension occurs in about 30-45% of people as of 2013.

Genes most involved in Hypertension are the ones coding for angiotensin (**AGT**), Nitric oxide synthase 3 (**NOS3**) and Angiotensin Receptor (**AGTR**).

A genetic variant of the AGT gene leads to increased production of angiotensinogen. Therefore, carriers of this AGT variant have a higher risk for hypertension.

Nitric oxide is catalyzed by endothelial nitric oxide synthase (NOS), an enzyme with multiple genetic variants that might confer risk for hypertension. Single Nucleotide Polymorphism C786T has been associated with hypertension.

Polymorphism in the angiotensin II type 1 receptor (AGTR) gene is associated with the incidence of essential hypertension and increased coronary artery vasoconstriction.

Hypertension

T01118-50-T SA, RG, iQ, MX, A, B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 0,2 ml tube format	R	60
T01118-96-S SA, iQ, MX, A, B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 12 x 8 strip format	R	96
T01119-50-T SA, RG, iQ, MX, A, B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 0,2 ml tube format	R	60
T01119-96-S SA, iQ, MX, A, B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 12 x 8 strip format	R	96
T01182-50-T SA, RG, iQ, MX, A, B	NOS3 (C786T) SNP-Screen RT-PCR test for detection of Nitric oxide synthase 3 mutation (rs2070744) - ready to use 0,2 ml tube format	R	60
T01182-96-S SA, iQ, MX, A, B	NOS3 (C786T) SNP-Screen RT-PCR test for detection of Nitric oxide synthase 3 mutation (rs2070744) - ready to use 12 x 8 strip format	R	96
T01131-50-T SA, RG, iQ, MX, A, B	AGTR1 (A1166C) SNP-Screen RT-PCR test for detection of angiotensin II receptor, type 1 mutation (rs5186) - ready to use 0,2 ml tube format	R	60
T01131-96-S SA, iQ, MX, A, B	AGTR1 (A1166C) SNP-Screen RT-PCR test for detection of angiotensin II receptor, type 1 mutation (rs5186) - ready to use 12 x 8 strip format	R	96
T01272-50-T SA, iQ, MX, A, B	ACE Alu Ins/Del SNP-Screen RT-PCR test for detection of ACE Insertion / Deletion I > D (rs4646994) - ready to use 0,2 ml tube format	R	60
T01272-96-S SA, iQ, MX, A, B	ACE Alu Ins/Del SNP-Screen RT-PCR test for detection of ACE Alu Insertion / Deletion I > D (rs4646994) - ready to use 12 x 8 strip format	R	60

Myocardial infarction / Ischemic stroke

Thrombotic complications, such as an acute myocardial infarction, ischemic stroke, pulmonary embolism, deep venous thrombosis are the major causes of morbidity and mortality in the world.

Myocardial infarction / Ischemic stroke

T01118-50-T SA,RG,iQ,MX,A,B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 0,2 ml tube format	R	60
T01118-96-S SA,iQ,MX,A,B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 12 x 8 strip format	R	96
T01119-50-T SA,RG,iQ,MX,A,B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 0,2 ml tube format	R	60
T01119-96-S SA,iQ,MX,A,B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 12 x 8 strip format	R	96
T01182-50-T SA,RG,iQ,MX,A,B	NOS3 (C786T) SNP-Screen RT-PCR test for detection of Nitric oxide synthase 3 mutation (rs2070744) - ready to use 0,2 ml tube format	R	60
T01182-96-S SA,iQ,MX,A,B	NOS3 (C786T) SNP-Screen RT-PCR test for detection of Nitric oxide synthase 3 mutation (rs2070744) - ready to use 12 x 8 strip format	R	96
T01148-50-T SA,RG,iQ,MX,A,B	APOE Leu48Pro SNP-Screen RT-PCR test for detection of apolipoprotein E mutation (T3100C, rs769452) - ready to use 0,2 ml tube format	R	60
T01148-96-S SA,iQ,MX,A,B	APOE Leu48Pro SNP-Screen RT-PCR test for detection of apolipoprotein E mutation (T3100C, rs769452) - ready to use 12 x 8 strip format	R	96
T01179-50-T SA,RG,iQ,MX,A,B	GP1BA1b (C482T) SNP-Screen RT-PCR test for detection of Platelet glycoprotein Iba mutation (Thr161Met, rs6065) - ready to use 0,2 ml tube format	R	60
T01179-96-S SA,iQ,MX,A,B	GP1BA1b (C482T) SNP-Screen RT-PCR test for detection of Platelet glycoprotein Iba mutation (Thr161Met, rs6065) - ready to use 12 x 8 strip format	R	96
T01354-50-T SA,RG,iQ,MX,A,B	GP1BA1b (T -5C) SNP-Screen RT-PCR test for detection of Platelet glycoprotein Iba mutation (rs2243093) - ready to use 0,2 ml tube format	R	60
T01354-96-S SA,iQ,MX,A,B	GP1BA1b (T -5C) SNP-Screen RT-PCR test for detection of Platelet glycoprotein Iba mutation (rs2243093) - ready to use 12 x 8 strip format	R	96
T01155-50-T SA,RG,iQ,MX,A,B	ITGA2 (C807T) SNP-Screen RT-PCR test for detection of integrin, alpha 2 mutation (Phe253Phe, rs1126643) - ready to use 0,2 ml tube format	R	60
T01155-96-S SA,iQ,MX,A,B	ITGA2 (C807T) SNP-Screen RT-PCR test for detection of integrin, alpha 2 mutation (Phe253Phe, rs1126643) - ready to use 12 x 8 strip format	R	96

Woman's Health / Miscarriage

Hypercoagulability in pregnancy, particularly due to inheritable thrombophilia, can lead to placental vascular thrombosis. This can in turn lead to complications like early-onset hypertensive disorders of pregnancy, pre-eclampsia and small for gestational age infants (SGA). Among other causes of hypercoagulability, Antiphospholipid syndrome has been associated with adverse pregnancy outcomes including recurrent miscarriage. Deep vein thrombosis has an incidence of one in 1,000 to 2,000 pregnancies in the United States, and is the second most common cause of maternal death in developed countries after bleeding.

Woman's Health / Miscarriage

T01101-50-T SA,RG,iQ,MX,A,B	FV (G1691A) Leiden SNP-Screen RT-PCR test for detection of Leiden mutation (Arg506Gln; rs6025) - ready to use 0,2 ml tube format	R	CE	60
T01101-96-S SA,iQ,MX,A,B	FV (G1691A) Leiden SNP-Screen RT-PCR test for detection of Leiden mutation (Arg506Gln; rs6025) - ready to use 12 x 8 strip format	R	CE	96
T01102-50-T SA,RG,iQ,MX,A,B	FII Prothrombin (G20210A) SNP-Screen RT-PCR test for detection of prothrombin F2 gene mutation (rs1799963) - ready to use 0,2 ml tube format	R	CE	60
T01102-96-S SA,RG,iQ,MX,A,B	FII Prothrombin (G20210A) SNP-Screen RT-PCR test for detection of prothrombin F2 gene mutation (rs1799963) - ready to use 12 x 8 strip format	R	CE	96
T01105-50-T SA,RG,iQ,MX,A,B	FVII (G1238A) SNP-Screen RT-PCR test for detection of FVII gene mutation (Arg353Gln; rs6046) - ready to use 0,2 ml tube format	R		60
T01105-96-S SA,RG,iQ,MX,A,B	FVII (G1238A) SNP-Screen RT-PCR test for detection of FVII gene mutation (Arg353Gln; rs6046) - ready to use 12 x 8 strip format	R		96
T01103-50-T SA,RG,iQ,MX,A,B	MTHFR (C677T) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Ala222Val; rs1801133) - ready to use 0,2 ml tube format	R	CE	60
T01103-96-S SA,iQ,MX,A,B	MTHFR (C677T) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Ala222Val; rs1801133) - ready to use 12 x 8 strip format	R	CE	96



Woman's Health / Miscarriage

T01273-50-T SA, RG, iQ, MX, A, B	MTHFR (A1298C) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Glu429Ala; Rs1801131) - ready to use 0,2 ml tube format	R	60
T01273-96-S SA, RG, iQ, MX, A, B	MTHFR (A1298C) SNP-Screen RT-PCR test for detection of MTHFR gene mutation (Glu429Ala; Rs1801131) - ready to use 12 x 8 strip format	R	96
T01124-50-T SA, RG, iQ, MX, A, B	MTRR (A 66 G) SNP-Screen RT-PCR test for detection of methioninesynthase gene mutation (Ile22Met; rs1801394) - ready to use 0,2 ml tube format	R	60
T01124-96-S SA, RG, iQ, MX, A, B	MTRR (A 66 G) SNP-Screen RT-PCR test for detection of methioninesynthase gene mutation (Ile22Met; rs1801394) - ready to use 12 x 8 strip format	R	96
T01143-50-T SA, RG, iQ, MX, A, B	MTR (A2756G) SNP-Screen RT-PCR test for detection of methionine synthase gene mutation (Asp919Gly; rs1805087) - ready to use 0,2 ml tube format	R	60
T01143-96-S SA, RG, iQ, MX, A, B	MTR (A2756G) SNP-Screen RT-PCR test for detection of methionine synthase gene mutation (Asp919Gly; rs1805087) - ready to use 12 x 8 strip format	R	96
T01120-50-T SA, RG, iQ, MX, A, B	PAI SERPINE (-675 5G/4G) SNP-Screen RT-PCR test for detection of insertion/deletion polymorphism of SERPINE1 or plasminogen activator inhibitor type 1 gene (rs1799768) - ready to use 0,2 ml tube format	R	60
T01120-96-S SA, RG, iQ, MX, A, B	PAI SERPINE (-675 5G/4G) SNP-Screen RT-PCR test for detection of insertion/deletion polymorphism of SERPINE1 or plasminogen activator inhibitor type 1 gene (rs1799768) - ready to use 12 x 8 strip format	R	96
T01107-50-T SA, RG, iQ, MX, A, B	FGB (G-455A) SNP-Screen RT-PCR test for detection of fibrinogen beta gene (rs1800790) - ready to use 0,2 ml tube format	R	60
T01107-96-S SA, RG, iQ, MX, A, B	FGB (G-455A) SNP-Screen RT-PCR test for detection of fibrinogen beta gene (rs1800790) - ready to use 12 x 8 strip format	R	96
T01118-50-T SA, RG, iQ, MX, A, B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 0,2 ml tube format	R	60
T01118-96-S SA, iQ, MX, A, B	AGT 1 (C521T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 1 (Thr207Met, rs4762) - ready to use 12 x 8 strip format	R	96
T01119-50-T SA, RG, iQ, MX, A, B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 0,2 ml tube format	R	60
T01119-96-S SA, iQ, MX, A, B	AGT 2 (C4072T) SNP-Screen RT-PCR test for detection of Angiotensinogen mutation 2 (Met235Thr, rs699) - ready to use 12 x 8 strip format	R	96

Immunity

TNF polymorphism influences immune function and regulation and moreover has been reported to be associated with Non-Hodgkin Lymphoma (NHL) risk. IL17A polymorphism is associated with a significant increase risk for specific type of cancer, especially in gastric cancer.

Immunity

T01177-50-T SA, RG, iQ, MX, A, B	TNF (G-308A) SNP-Screen RT PCR test for detection of Tumor necrosis factor mutation (rs1800629) - ready to use 0,2 ml tube format	R	60
T01177-96-S SA, iQ, MX, A, B	TNF (G-308A) SNP-Screen RT PCR test for detection of Tumor necrosis factor mutation (rs1800629) - ready to use 12 x 8 strip format	R	96
T01171-50-T SA, RG, iQ, MX, A, B	IL17A (G-197A) SNP-Screen RT PCR test for detection of Interleukin-17A gene mutation (rs2275913) - ready to use 0,2 ml tube format	R	60
T01171-96-S SA, iQ, MX, A, B	IL17A (G-197A) SNP-Screen RT PCR test for detection of Interleukin-17A gene mutation (rs2275913) - ready to use 12 x 8 strip format	R	96

Lipid Metabolism

Lipid metabolism refers to the processes that involve the intercourse and degradation of lipids. Certain abnormalities in these enzymes can lead to the buildup of specific fatty substances that normally would have been broken down by the enzymes. Over time, accumulations of these substances can be harmful to many organs of the body.

Lipid Metabolism

T01148-50-T SA, RG, iQ, MX, A, B	APOE Leu48Pro SNP-Screen RT PCR test for detection of Apolipoprotein E gene mutation (T3100C, rs769452) - ready to use 0,2 ml tube format	R	60
T01148-96-S SA, iQ, MX, A, B	APOE Leu48Pro SNP-Screen RT PCR test for detection of Apolipoprotein E gene mutation (T3100C, rs769452) - ready to use 12 x 8 strip format	R	96
T01149-50-T SA, RG, iQ, MX, A, B	LPL (Ser447Ter) SNP-Screen RT PCR test for detection of lipoprotein lipase gene mutation (1421C>G, rs328) - ready to use 0,2 ml tube format	R	60
T01149-96-S SA, iQ, MX, A, B	LPL (Ser447Ter) SNP-Screen RT-PCR test for detection of CYP3A5 gene mutation (rs776746) - ready to use 12 x 8 strip format	R	96
T01125-50-T SA, RG, iQ, MX, A, B	PON1 (Gln192Arg) SNP-Screen RT PCR test for detection of paraoxonase 1 gene mutation (575A>G, rs662) - ready to use 0,2 ml tube format	R	60
T01125-96-S SA, iQ, MX, A, B	PON1 (Gln192Arg) SNP-Screen RT PCR test for detection of paraoxonase 1 gene mutation (575A>G, rs662) - ready to use 12 x 8 strip format	R	96
T01161-50-T SA, RG, iQ, MX, A, B	LIPC (-250 G>A) SNP-Screen RT PCR test for detection of Hepatic lipase gene mutation (rs2070895) - ready to use 0,2 ml tube format	R	60
T01161-96-S SA, iQ, MX, A, B	LIPC (-250 G>A) SNP-Screen RT PCR test for detection of Hepatic lipase gene mutation (rs2070895) - ready to use 12 x 8 strip format	R	96

Men's Health

The Y chromosome accumulates male-related genes including sex-determining region of Y-chromosome (SRY) and several spermatogenesis-related genes. The long arm contains azoospermia factor (AZF) region (including sub-regions AZFa, AZFb and AZFc). Microdeletions in this region are responsible for azoospermia and oligospermia and result in the male infertility.

Men's Health

01200-50 SA,RG,iQ,MX,A,B	AZF System Y-chromosome RT-PCR test for detection of the microdeletions in AZF regions: AZFa (sY84, sY86), AZFb (sY127, sY134), AZFc (sY254, sY255) of the human Y chromosome	R	CE	60
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Cystic fibrosis

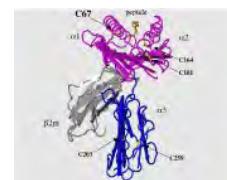
Cystic fibrosis is an autosomal recessive genetic disease caused by mutations in the CFTR gene. The CFTR protein (Cystic Fibrosis Transmembrane conductance Regulator) is not produced in case both alleles are mutated. Cystic fibrosis is the most common genetic disease in the caucasian population.

Cystic fibrosis

H943-48FRT SA,iQ,A	CFTR Genetics Real-TM Genotyping NEW Real Time PCR kit for detection of 8 most common CFTR gene mutations: F508del, E92K, W1282X, N1303K, 2143delT, 1677delTA, 3849+10kbC>T, dele2,3 (21kb)	R	48
H948-48FRT SA,iQ,A	CFTR Genetics Real-TM Rare mutations NEW Real Time PCR kit for detection of 16 rare CFTR gene mutations: L138ins, G542X, R117H, 604insA, 621+1G>T, S1196X, 3821delT, 3667insTCAA, R334W, 394delTT, R553X, K598ins, 2184insA, 2183AA>G, 2789+5G>A, 3944delGT	R	48

HLA

Human Leukocyte Antigen (HLA) B27 (subtypes B*2701-2759) is a class I surface antigen encoded by the B locus in the major histocompatibility complex (MHC) on chromosome 6 and presents antigenic peptides (derived from self and non-self antigens) to T cells. HLA-B27 is strongly associated with ankylosing spondylitis (AS), and other associated inflammatory diseases referred to collectively as "spondyloarthritis".



HLA

R116-50FRT SA,RG,iQ,SC,MX,A,B	HLA B27 Real-TM Real Time PCR kit	R	CE	48
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Other

Other

T01352-50-T SA,RG,iQ,MX,A,B	COMT Val158Met SNP-Screen Real-TM RT PCR test for detection of COMT Val158Met gene mutation (rs4680) - ready to use 0,2 ml tube format	R	60
H953-48FRT SA, iQ, A	MEFV E148Q Real-TM NEW RT PCR test for detection of MEFV E148Q gene mutation relevant in Mediterranean Fever virus infection - ready to use 0,2 ml strip tube format	R	48
H952-48FRT SA	MEFV Real-TM Screen NEW RT PCR test for detection of 12 MEFV gene mutations relevant in Mediterranean Fever Virus infection: 1437 C>G (F479L), 2040 G>C (M680I (G/C)), 2076_2078del (I692del), 2040 G>A (M680I (G/A)), 2080 A>G (M694V), 2082 G>A (M694I), 2177 T>C (V726A), 2084 A>G (K695R), 2230 G>T (A744S), 2282 G>A (R761H), 1105 C>T (P369S), 1223 G>A (R408Q) - ready to use 0,2 ml strip tube format	R	48
H944-48FRT SA	Osteoporosis Real-TM Typing NEW RT PCR test with melting analysis for detection of 16 osteoporosis-related genes mutations: COL1A1: -1997 C>A, COL1A1: 1546 (6252) G>T [Sp1 S-s], CYP19A1: A>G [rs2414096], CYP19A1: C>T [rs936306], ESR1: -397 T>C [PvuII], ESR1: -351 G>A [XbaI], IL6: -174 G>C, LRP5: 1999 G>A (Val667Met), LRP5: 3989 C>T (Ala1330Val), RANKL: C>T [rs9594738], RANKL: C>T [rs9594759], TNFRSF11B (OPG): 245 A>C, TNFRSF11B (OPG): A>G [rs4355801], TNFRSF11B (OPG): 163 (160) T>C, VDR: 283 A>G (BsmI), VDR: 2 A>G (Lys2Arg) [FokI]	R	48

Oncological diseases

Chronic myelogenous leukaemia (CML) results from the neoplastic transformation of a haematopoietic stem cell. The hallmark genetic abnormality of CML is a t(9;22)(q34;q11) translocation, which was first discovered as an abnormal, small chromosome, named the ‘Philadelphia chromosome’. This translocation generates the BCR - ABL fusion gene.

CML Kits

R-O1 SA, RG, IQ, MX, SC, A, B	Mbcr-abl FRT Real-TM Real Time Amplification kit	R	CE	100
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The **JAK2 V617F (Val617Phe)** mutation is a genetic mutation that is clinically significant because it is strongly associated with several hematologic disorders, most notably a group of diseases called myeloproliferative neoplasms (MPNs). The presence of the JAK2 V617F mutation is an important diagnostic marker for these MPNs. Testing for this mutation is often part of the workup when a healthcare provider suspects an MPN based on clinical symptoms and blood counts. It can also have prognostic implications. In some cases, the mutation is associated with a more aggressive disease course and a higher risk of complications such as transformation to acute leukemia.

JAK2 Kits

T01154-50-T SA,RG,iQ,SC,MX,A,B	JAK2 Real-TM NEW Real Time Amplification kit for detection of mutation JAK2 V617F (Val617Phe)	R	60
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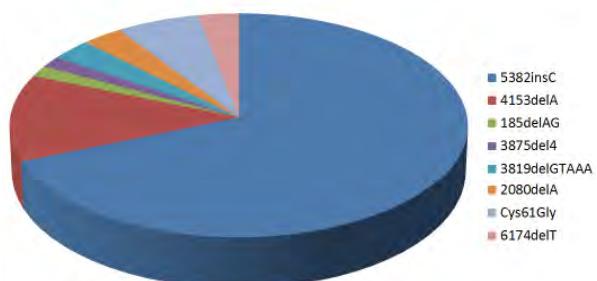
Detection of epidermal growth factor receptor (**EGFR**) **gene mutations** is critically important in **NSCLC lung cancer** treatment decisions.

EGFR Kits

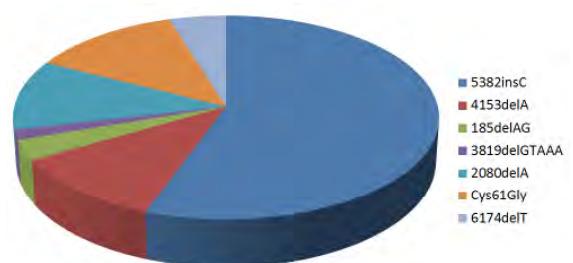
H807-24FRT SA	EGFR-8 Real-TM NEW Real Time Amplification kit for detection of 53 somatic mutations of the EGFR: 37 deletions in exon 19, 5 insertions in exon 19, 3 insertions in exon 20, 2 mutations L858R, T790M, L861Q, S768I, G719X (A / S / C)	R	24
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BRCA mutations are involved in development **breast and ovarian cancer**. BRCA1 and BRCA2 are tumor suppressor genes that are inactivated during neoplastic development in breast cancer. Germline mutations of the two genes are transmitted in the autosomal dominant way and predispose carriers to the development of ovarian and/or breast cancers. Mutations in BRCA1 are present in approximately one-half of the early-onset breast cancer families and 80% of the early-onset breast and ovarian cancer families, whereas BRCA2 mutations are believed to account for a comparable percentage of inherited breast cancer cases. Women with germline mutations in BRCA1 have a lifetime risk of 85% and up to 50% for breast and ovarian cancers, respectively.

BRCA mutations frequency in breast cancer (caucasian population)



BRCA mutations frequency in ovarian cancer (caucasian population)



BRCA Kits

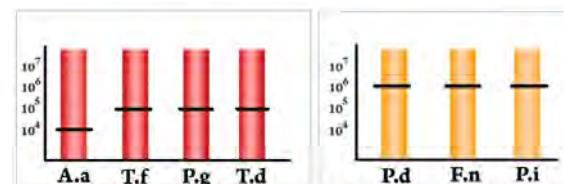
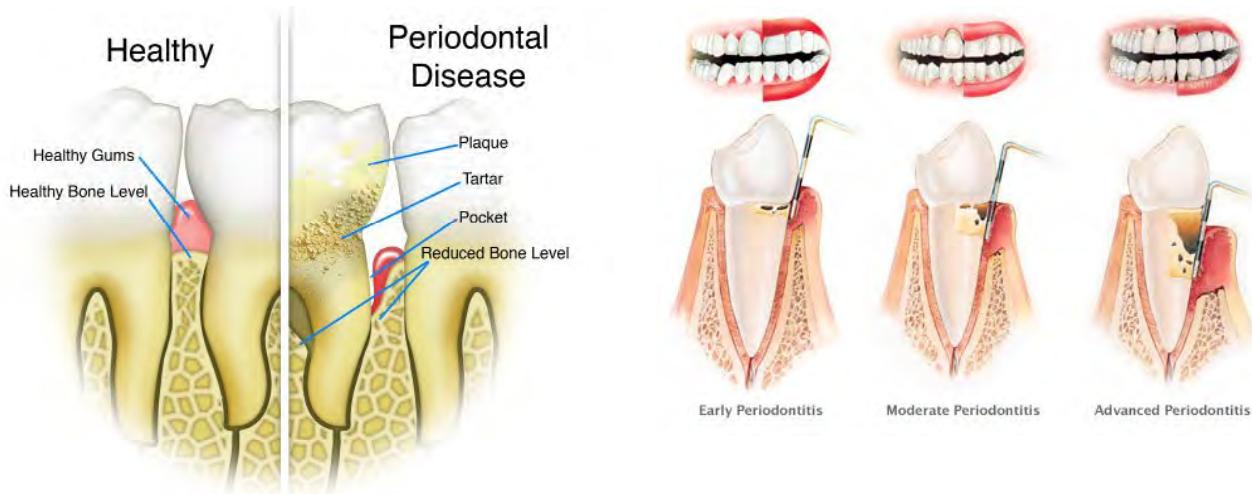
R-27/P-48FRT SA, MX, iQ, B, A	Oncogenetics BRCA Panel Real-TM Real Time Amplification kit	R	CE	48
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Periodontitis

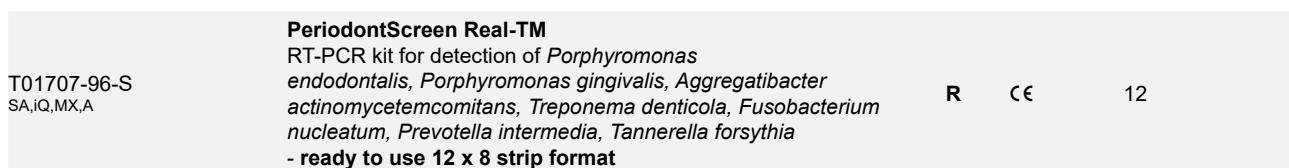
Periodontitis

Periodontitis is a serious gum infection that damages the soft tissue and destroys the bone that supports the tooth. Periodontitis can cause tooth loss or worse, an increased risk of heart attack or stroke and other serious health problems. Bacterial plaque is believed to be the principal etiological factor in the onset and progression of periodontitis.

Porphyromonas gingivalis and *Tannerella forsythia* are strong markers of periodontitis in adults, and these species have been linked to the progression of the disease.

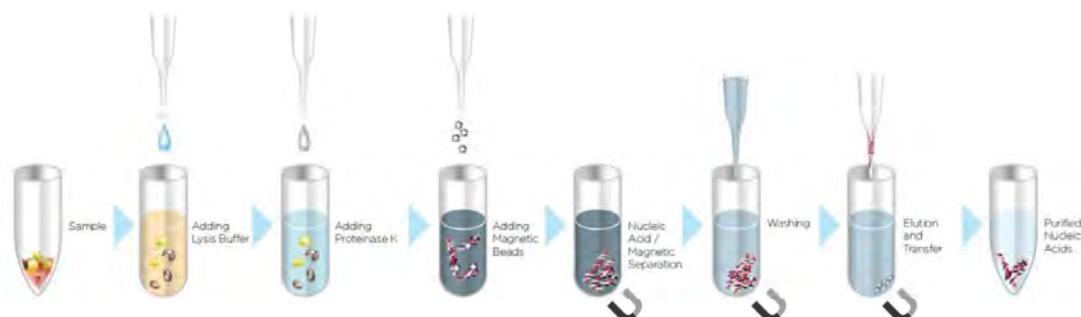


Periodontitis Kit



Automatic Nucleic Acids Extraction System kits

	SaMag Viral Nucleic Acids Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of Viral nucleic acids (DNA/RNA) from human biological specimens such as serum, plasma, and other cell-free fluids	CE	48
SM003			
	SaMag Plant Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of DNA from Plant (leaf, seeds and spores) and fungal tissues.	48	
SM014			
	SaMag Bacterial DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of genomic DNA from both Gram-positive and Gram-negative bacteria starting from various sample types	CE	48
SM006			
	SaMag STD DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of STD DNA from human biological specimens such as cervical, urethral, conjunctival swabs, urine sediment, prostatic liquid, seminal liquid	CE	48
SM007			
	SaMag TB DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of genomic DNA of Mycobacteria spp. (e.g. <i>Mycobacterium tuberculosis</i>) from clinical specimens or cultures	CE	48
SM008			
	SaMag Tissue DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of genomic DNA from a variety of tissues	CE	48
SM004			
	SaMag Blood DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of genomic DNA from whole blood, peripheral blood mononuclear cells or buffy coat	CE	48
SM001			
	SaMag FFPE DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of genomic DNA from FFPE samples	CE	48
SM009			
	SaMag Total RNA/DNA Extraction kit For use with SaMag-12 or SaMag-24 instruments; extraction of total RNA/DNA from whole blood, blood cells, animal tissue, plant tissue, yeast or cultured cells samples	CE	48
SM015			
	M-Sorb-S NEW RNA/DNA Extraction Kit from clinical material (nasopharyngeal swabs, sputum, bronchoalveolar lavage and urogenital swabs) using magnetic beads technology and compatible with automated extraction instruments like SaMag-96 and KingFisher FLEX equivalents	CE	96
K502/100/A			



SaMag magnetic beads-based nucleic acids purification process scheme.

Heat-based Thermic Manual Method

K-1-1/R	RAPID DNA Fast heat-based DNA extraction with pre-aliquoted ready to use extraction tubes, minimal hands-on time	100
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Chemical-based Manual Method

K-2-9/NA	DNA/RNA Prep NA C€ Guanidine/isopropanol RNA/DNA extraction kit from clinical materials: peripheral blood, plasma, cerebrospinal fluid, amniotic fluid, sputum, swabs, tissue, feces, etc	50
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Spin Column Purification Manual Method

K-2/C	Ribo Virus C€ For rapid purification of viral RNA and DNA (HCV, HBV, HAV, HIV, CMV, HSV, VZV, EBV, parvovirus B19, H5N1) from cell-free biological fluids	50
K-2/C/100	Ribo Virus C€ For rapid purification of viral RNA and DNA (HCV, HBV, HAV, HIV, CMV, HSV, VZV, EBV, parvovirus B19, H5N1) from cell-free biological fluids	100
K-1-1/E	Genomic column DNA Express C€ Genomic DNA from whole blood, serum, plasma, buffy coat, platelets, body fluids	50

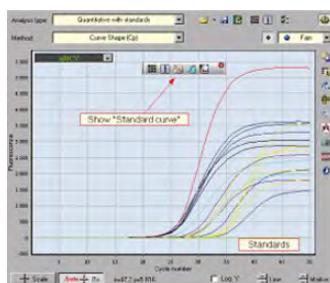
Step	Description	
1. Lyse	 600 µl RAV1 150 µl sample 70°C 5 min	
2. Adjust DNA	600 µl Ethanol	
3. Bind	 Load sample  1 min 8000 x g	
4. Wash	 1 st wash: 500 µl RAW  2 nd wash: 600 µl RAV3  3 rd wash: 200 µl RAV3  1 st and 2 nd 1 min 8000 x g  3 rd 5 min 11000 x g	
5. Elute	 50 µl RNase-free H ₂ O or Buffer RE (70°C)  1-2 min  1 min 11000 x g	

Table. RNA/DNA RiboVirus short protocol

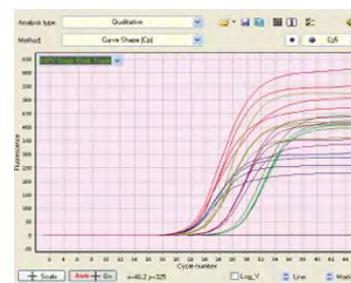
SaCycler-96 Real Time PCR System CE - IVD

Features

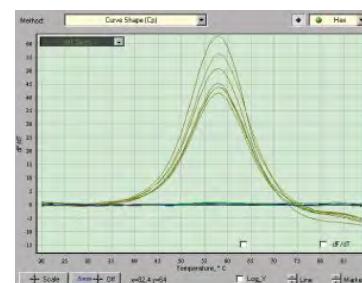
- 5 fluorescence channels multiplexing for discrimination of up to five targets in a single reaction well
- Strong flexibility thanks to the 96-well format suited for standard PCR microplates, test tubes and strips
- Possibility to use tubes with different heights with regulation of the matrix block
- Optimal signal/noise ratio and absence of crosstalk ensured by the unique design of the optical track including a separate light source for each channel and a matrix CCD camera
- Light emitting diodes (LED) as a light source with a lifetime of about 100,000 hours that does not require maintenance or constant monitoring
- Wide dynamic range of detection using multiple exposure method, which leads the optimization of signal registration conditions to a whole new level, greatly simplifying or even eliminating the need for fluorescence settings
- Main applications are Real-Time quantitation, single nucleotide polymorphisms (SNPs) genotyping, melting curve and gene expression analysis
- Instrument comes with the most used Sacace protocols already installed in the software minimizing possibility of error during programming.



Quantitative analysis with the use of calibration standards, allows to determine the quantity of DNA target in the sample



Qualitative analysis allows to determine presence or absence of target DNA in a sample



Melting curves are applied to analysis for determination of polymorphisms of single nucleotide

Product code

SC-96R

Description

SaCycler-96 Real Time PCR Open System

Real Time PCR Thermalcycler open system with 5 fluorescence channels

CE

SaMag-12™ Automatic Nucleic Acids Extraction System

Features

- Fully automated high yield nucleic acid extraction with magnetic beads and PCR setup (for Sacace kits like HCV, HBV, HIV Dx)
- Full traceability with barcode scanner
- Pre-programmed protocols, easy touchscreen interface
- Flexible batch size from 1 up to 12 samples in parallel
- All required tubes, tips, plastics are inside the provided extraction kits
- Ready to use reagents
- Very fast extraction protocol (~ 40 minutes)
- Very simple operation (easy to install, operate, maintain)
- Real Time Video Recorder



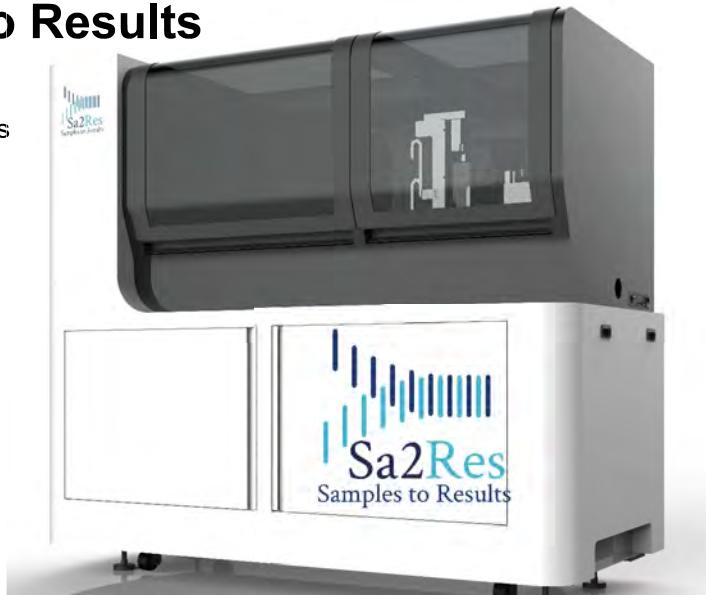
SaMag - 12™ CE - IVD

SaMag-12™ system is a compact bench-top extractor for automated nucleic acid purification. It is able to process 1-12 samples in parallel, recommended for labs with **small-medium** sample throughputs

Sa2Res™ Samples to Results

Automatic all-in-one instrument including:

- Sample preparation, id with barcode scanners
- DNA/RNA extraction
- PCR setup and PCR amplification
- Real Time results analysis
- Flexible batch size up to 48 samples
- Ready to use reagents
- Bi-directional traceability of data



SaMag-96™ CE - IVD

Automatic Nucleic Acids Extraction System

SaMag-96™ system is an automatic DNA/RNA extractor for isolation of high purity nucleic acids. With easy touch-screen interface, it is able to process 1-96 samples in parallel, recommended for labs with **medium-high** sample throughputs. Compatib

Product code	Description
SM-12	SaMag-12 Automatic Nucleic Acid Extraction System for processing up to 12 samples per run
SM-96	SaMag-96 NEW Automatic Nucleic Acid Extraction System for processing up to 96 samples per run, compatible with M-Sorb-S (K502/100/A) extraction kit
S2R-48	Sa2Res NEW Samples to Results automatic instrument including sample preparation+DNA/RNA extraction+PCR amplification+Results analysis all-in-one or processing up to 48 samples

Instruments

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