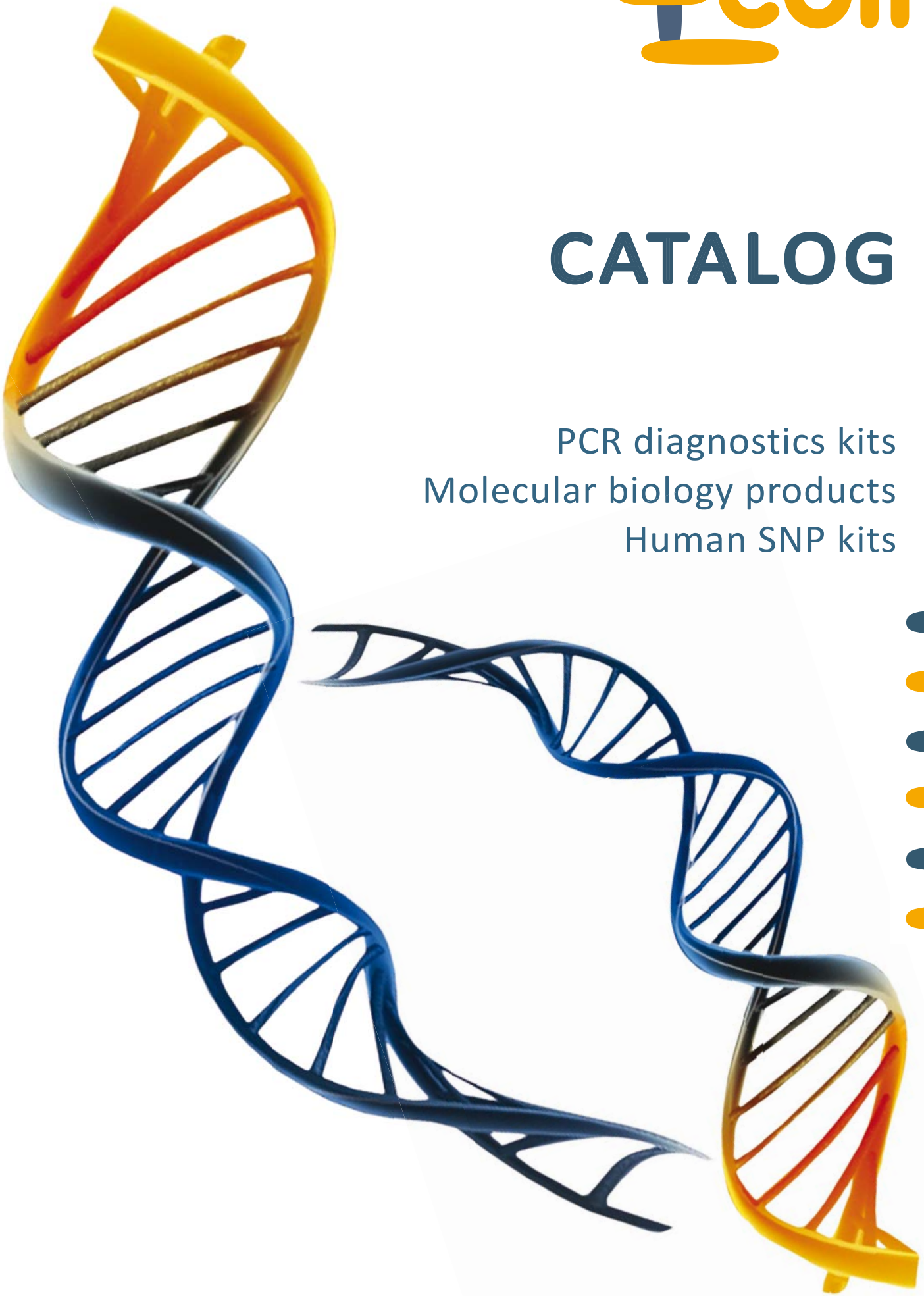
CATALOG

PCR diagnostics kits
Molecular biology products
Human SNP kits



CATALOG

PCR Diagnostics Kits

Molecular Biology Reagents

Human SNP Kits

www.pcrdiagnostics.eu

Catalog Content

Legend

Explanation of Symbols in Catalog

What Cyclers Can Be Used?

Cycler type abbreviation in catalog number determines, for what qPCR cycler is a **detail manual** included:

- **RG** Rotor-Gene Q/3000/6000,
- **iQ** iCycler iQ/iQ5/CFX (Bio-Rad),
- **Mx** Mx3000P/3005P (Stratagene),
- **SC** SmartCycler (Cepheid),
- ...for non-listed Real-Time PCR cyclers, ask us for application data.

Kits in **non-aliquoted** format can be used on **any cycler with needed channels**:

- Rotor-Gene Q/3000/6000,
- iCycler iQ/iQ5/CFX (Bio-Rad),
- Mx3000P/3005P (Stratagene),
- SmartCycler (Cepheid),
- Bioneer Exicycler™ 96,
- ABI™ 7300/7500/StepOne,
- EcoqPCR™ (Illumina),
- LineGeneK® (Bioer),
- ...and similar.

Real-Time detection

Fluorescent End-Point detection

*TaqMan™ technology based kits. PCR is performed in a **standard thermal cycler**, analyzis is performed in a multichannel fluorescent reader **ALA 1/4***

Electrophoresis detection

Catalog number

Number of reactions including controls

Shelf life (months)

R-X1-F(RG,iQ,Mx,SC)-CE	110	⑥
X1-100-R0,2-FEP-CE	100	⑨
X1-100-R0,2-CE	100	⑫

Kit reagents are non-aliquoted

*Kits in non-aliquoted format can be used on **any cycler with needed channels**:*

- *Rotor-Gene Q/3000/6000,*
- *iCycler iQ/iQ5/CFX (Bio-Rad),*
- *Mx3000P/3005P (Stratagene),*
- *SmartCycler (Cepheid),*
- *Bioneer Exicycler™ 96,*
- *ABI™ 7300/7500/StepOne,*
- *EcoqPCR™ (Illumina),*
- *LineGeneK® (Bioer),*
- *...and similar.*

Kit reagents are aliquoted

PCR reactions are aliquoted in individual PCR tubes, ready-to-use

CE	CE-marked kits, comply with EU Directives 93/42/EEC and 98/79/EC (Medical Products and IVD)
IVD	*In vitro* diagnostics

About Us

Ecoli s.r.o. is an european company situated in Slovakia with worldwide distribution network.

Ecoli s.r.o. provides more than 350 different types of AmpliSens® PCR diagnostics kits developed and produced by CRIE (Central Research Institute for Epidemiology, Moscow) for clinical, veterinary diagnostics and human genome testing. Kits are designed according to laboratory facilities for electrophorese, FEP (Fluorescence End-Point) and Real-Time PCR detection, as well as for pyrosequencing technology.

PCR diagnostic kits have very high sensitivity, high specificity and a very reasonable price. Most of the kits are produced as *in vitro* diagnostics and have CE IVD certificate.

MultiPlex Real-Time/FEP PCR kits allow to establish the presence of several infectious agents (multiplex analysis) during just one reaction. That increases the speed of detection and reduces the cost of examinations.

New product line consists of wide range of **SNP kits**. Human SNP kits, by using of pyrosequencing technology, allow to determine and quantify specific point mutations in a human genome by very simple and non-expensive way.

Ecoli Distribution Network

- Afghanistan
- Austria
- Bangladesh
- Bosnia i Herzegovina
- Bulgaria
- Canada
- Chile
- China
- Colombia
- Croatia
- Czech Republic
- Denmark
- Germany
- France
- Greece
- Hungary
- India
- Iraq
- Ireland
- Jordan
- Kenya
- Macedonia
- Malta
- Morocco
- Mexico
- Nigeria
- Norway
- Poland
- Portugal
- Romania
- UAE
- Serbia
- Spain
- Sweden
- Switzerland
- UK
- Venezuela

Ecoli Headquarters

Ecoli s.r.o, Studenohorská 12, 841 03 Bratislava, Slovak Republic

tel: +421 2 6478 9336, fax: +421 2 6478 9040 cell: +421 903 514 184

ecoli@ecoli.sk www.pcrdiagnostics.eu

PCR Diagnostics Kits

Index of Catalog

Ordering

How to Order

Orders can be sent to us by:

- email: ecoli@ecoli.sk
- fax: +421 2 6478 9040
- address:

Ecoli s.r.o.
Studenohorská 12
841 03 Bratislava
Slovak Republic

Ordered products are sent out to you within app. 4 weeks after the deadline.

If you do not receive confirmation of your order, please contact us as by return.

The ordering dates are listed on our web page www.pcrdiagnostics.eu

Required Information

Following informations are required by ordering:

- Product names
- Catalog numbers
- Specification (like number of reactions)
- Shipping address
- Billing address
- VAT number (EU only)
- Contact person
- Phone or cell number

Customer Care

We are committed to provide supreme services for our customers. All inquiries are answered and to all technical questions is given high priority and our full attention.

Shipping

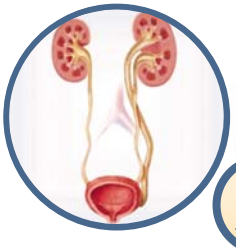
Shipping costs are calculated for every shipment separately, because every box has different dimensions and weight. This system is customer-friendly because you pay for real shipping costs.

Terms of Payment

Ecoli s.r.o. accepts payments by wire transfer. Other payment methods are allowed after discussion.

Be Informed About DEADLINES!

Ask for regular sending of info about our orders deadlines. Sending of your order before deadline reduces delivery time to the minimum (approx. 4 weeks). If you send your order after deadline, it will be processed in the next deadline.



Sexually Transmitted Infections

Sexually transmitted disease (STD), also known as a sexually transmitted infection (STI), or venereal disease (VD), is an illness that has a significant risk of transmission between humans by means of human sexual behavior. While in the past these illnesses have mostly been referred to as STDs or VD, in recent years the term sexually transmitted infections (STIs) has been preferred, as it has a broader range of meaning; a person may be infected, and may potentially infect others, without having a disease. Some STIs can also be transmitted via the use of IV drug needles after its use by an infected person, as well as through childbirth or breastfeeding.

STI is a broader term than STD. An infection is a colonization by a parasitic species, which may not cause any adverse effects. In a disease the infection leads to impaired or abnormal function. In either case the condition may not exhibit signs or symptoms. Increased understanding of infections like HPV, which infects most sexually active individuals, but cause disease in only a few has led to increased use of the term STI.

The diseases on this list are most commonly transmitted solely by sexual activity. Many infectious diseases, including the common cold, influenza, pneumonia and most others that are transmitted person-to-person can also be transmitted during sexual contact, if one person is infected. However, even though these diseases may be transmitted during sex, they are not considered STDs.

MultiPlex Real-Time PCR technology allows to use primers and probes for several (for up to 5) DNA targets in one tube. Amplification products identification runs for each DNA target on a different optical channel. Sensitivity of these tests are not affected by changing the number of infections.

Each mono- and multiplex **PCR kit** contains independent **Internal Control** (IC) for determination of DNA extraction efficiency and PCR process. Presence of the Internal Control signal/band shows, that DNA extraction process and amplification steps were sufficient for significant results interpretation.

CE *Chlamydia trachomatis*

Chlamydia is a common STD caused by *Chlamydia trachomatis*, which can damage a woman's reproductive organs. Even though symptoms of chlamydia are usually mild or absent, serious complications can occure, like pelvic inflammatory disease or ireversible damage, including infertility. In men, the infection is usually symptomatic, with dysuria and a discharge from the penis. Untreated chlamydial infection in men can spread to the epididymis. Most women with chlamydial infection have minimal or no symptoms, but some develop. Chlamydial infection in newborns can cause ophthalmia neonatorum.

AmpliSens® ***Ch. trachomatis*** **PCR kits** are built for fast and accurate detection or **quantitation** of the pathogen in clinical samples - urogenital, rectal and throat swabs, urine, eye discharge and prostate secretion. Kits contain Internal Control for detection of DNA extraction efficiency, and amplification process.

Analytical sensitivity is 5 x 10^2 copies/ml (qPCR).

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-B1-F(RG,iQ)-CE			♦	110	⑨
R-B1(RG)-CE			::	110	⑨
R-B1-100-FT(RG,iQ,Mx)-CE	***QUANTITATIVE***	***RUO***	♦	110	⑨
B1-100-R0,2-FEP-CE			::	110	⑨
B1-100-R0,2-CE		***RUO***	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE *Neisseria gonorrhoeae*

Gonorrhea is a common STD caused by the bacterium *N. gonorrhoeae*. The usual symptoms in men are burning with urination and penile discharge. Women are asymptomatic half the time or have vaginal discharge and pelvic pain. Infection of the genitals in females can result in pelvic inflammatory disease if left untreated, which can result in infertility.

If left untreated, gonorrhea may spread locally causing epididymitis, disseminated infections can result in endocarditis, meningitis or gonococcal dermatitis-arthritis syndrome.

Neonatal gonorrheal conjunctivitis can lead to corneal scarring or perforation, resulting in blindness in the neonate.

AmpliSens® ***Neisseria gonorrhoeae Screen*** kit is recommended for screening of clinical samples. AmpliSens® ***Neisseria gonorrhoeae Test*** kit is an alternative method for detection of *N. gonorrhoeae* markers and is recommended for confirmation of results obtained by other kits.

Analytical sensitivity: 5 x 10^2 copies/ml (Screen), 1 x 10^3 copies/ml (Test),

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-B51-F(RG,iQ)-CE	***Screen***		♦	110	⑨
R-B56-F(RG,iQ)-CE	***Test***		♦	110	⑨
B51-100-R0,2-FEP-CE	***Screen***		::	110	⑨
B56-100-R0,2-FEP-CE	***Test***		::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

PCR Diagnostics Kits

Sexually Transmitted Infections

CE *Treponema pallidum*

Infection by *T. pallidum* has diverse clinical manifestations - initial genital tract lesion followed by disseminated lesions and cardiovascular and neurologic problems and CNS disease manifested as acute syphilitic meningitis. Infection during pregnancy results in numerous birth defects or fetal death. Infections in adults are usually chronic, death or serious disability is rare.

AmpliSens® ***Treponema pallidum*** **PCR kits** are amplification tests for qualitative detection of *T. pallidum* DNA in the clinical materials (scrapes/swabs of urogenital tract mucous membranes; serous exudate of vesicles, ulcers or erosions). Internal Control allows to control DNA extraction efficiency, as well as amplification process.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection chasnnels: **FAM/Green** and **JOE/Yellow**.

R-B20-F(RG,iQ)-CE		110	⑨
B20-100-R0,2-FEP-CE	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE *Trichomonas vaginalis*

T. vaginalis is a parasitic protozoan flagellate, generally restricted to the genitourinary tract by the host's immune system and is the etiological agent of human trichomoniasis.

In women symptoms of infection include vaginal secretion that is scanty and mixed with mucus; malodorous discharge that is frothy, yellow or green, mycopurulent and copious. Complications may result in cervical erosion, cervical cancer, infertility, adnexitis, pyosalpinx and endometritis. Premature rupture of the placental membranes can occur in pregnant women, resulting in premature birth and low-birth weight. In men is the prevalence lower and infection is often asymptomatic. Infection in men can be present in the prostate, seminal vesicles and epididymis. Complications are rare, but can potentially lead to genitourinary inflammation disease, sterility, scanty, clear to mucopurulent discharge, dysuria, non-gonococcal urethritis, prostatitis and urethral disease.

AmpliSens® ***T. vaginalis*** **PCR kits** are qualitative amplification tests for fast and accurate detection of the pathogen in clinical material. Kits contain Internal Control that allows detection of DNA extraction efficiency as well as amplification process.

Analytical sensitivity is 5 x 10^2 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-B6-F(RG,iQ)-CE		110	⑨
B6-100-R0,2-FEP-CE	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE *Mycoplasma genitalium*

Mycoplasma genitalium is an often asymptomatic, bacterial, STD which bears some similarities to gonorrhoea and chlamydia. Because *M. genitalium* often occurs in association with other infections in both men and women, it is quite difficult to diagnose the condition on its own.

M. genitalium in women has been linked to conditions such as bacterial vaginosis, cervicitis, pelvic inflammatory disease and endometritis. *M. genitalium* has also been found in women who have given birth prematurely. Often, *M. genitalium* is diagnosed in men who suffer from urethritis (inflammation of the urethra) which is not caused by gonorrhoea or chlamydia.

AmpliSens® ***M. genitalium*** **PCR kits** are built for detection of the pathogen in clinical materials (cervical, urethral scrapes/ swabs, urine sediment, prostate gland secrete). Kits contain Internal Control for detection of DNA extraction efficiency, as well as for control of amplification process.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels **FAM/Green** and **JOE/Yellow**.

R-B4-F(RG,iQ)-CE		110	⑨
R-B4(RG)-CE	::	110	⑨
R-B4-100-FT(RG,iQ,Mx)-CE	***QUANTITATIVE***	110	⑨
B4-100-R0,2-FEP-CE	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE *Mycoplasma hominis*

Mycoplasma species are the smallest free-living organisms without cell wall, capable of self-replication. *M. hominis* exists in parasitic and saprophytic state. There is evidence, that *M. hominis* may be implicated in pelvic inflammatory disease, which may cause ectopic pregnancy. This bacterium prospers in the environment created by other G- bacteria implicated in bacterial vaginosis and may be a cause of preterm delivery or miscarriage. It may also be implicated in postpartum fever, because it may be a cause of endometritis. *M. hominis* is also suspected to be the cause of neonatal infections, including conjunctivis, respiratory distress, fever, meningitis, abscesses and congenital pneumonia, which occurs a few hours after birth. In adults, *M. hominis* may be implicated in pharyngitis, septicaemia, lung, as well as joint and wound infections.

AmpliSens® ***Mycoplasma hominis*** **PCR** kits contain Internal Control for DNA extraction and amplification processes. control

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow.**

R-B3-F(RG,iQ)-CE		110	⑨
R-B3(RG)-CE	::	110	⑨
R-B3-100-FT(RG, iQ, Mx)-CE	***QUANTITATIVE***	110	⑨
B3-100-R0,2-FEP-CE	::	110	⑨
B3-100-R0,2-CE	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

PCR Diagnostics Kits

Sexually Transmitted Infections

CE *Ureaplasma species*

Ureaplasma spp. causes bacterial infection, generally asymptomatic in nature, that is sexually transmitted. The bacteria can survive in the reproductive tract for many years undetected, until a patient is specifically tested for the infection. Infection is very similar to *Mycoplasma*, so it is recommended to test both bacteria in case of syndroms, described by Mycoplasma kits.

AmpliSens® ***Ureaplasma spp.*** **PCR kits** are built for fast detection (without differentiation) of the pathogen in clinical material (cervical, urethral scrapes/swabs, urine sediment, prostate gland secrete). Kits contain Internal Control for detection of DNA extraction efficiency and control of amplification.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-B2-F(RG,iQ)-CE		110	⑨
R-B2(RG)-CE	::	110	⑨
R-B2-100FT(RG,iQ,Mx)-CE	***QUANTITATIVE***	110	⑨
B2-100-R0,2-CE	::	110	⑨

For ***DNA isolation*** *use* ***DNA-sorb-AM***

CE *Ureaplasma spp. differentiation*

U. parvum/U. urealyticum **PCR kits** are *in vitro* nucleic acid amplification tests for qualitative detection and **differentiation** of *U. parvum* and *U. urealyticum* DNA in clinical materials (scrapes/swabs of urogenital tract mucous membranes; urine sediment; secret of the prostate gland). Kits contain Internal Control for detection of DNA extraction efficiency, as well as for control of amplification pro-cess.

Analytical sensitivity is 1 x 10^3 copies/ml.

In AmpliSens® ***Ureaplasma spp.*** **differentiation** PCR kits, *U. parvum* DNA is detected on the **FAM/Green** channel, *U. urealyticum* DNA is detected on **JOE/Yellow/HEX** channel and Internal Control is detected on the **ROX/Orange** channel.

R-B19-F(RG,iQ)-CE		110	⑨
R-B19(RG)-CE	::	110	⑨
R-B19-100-FT(RG,iQ,Mx)-CE	***QUANTITATIVE***	110	⑨
B19-100-R0,2-FEP-CE	::	110	⑨
B19-100-R0,2-CE	::	110	⑨

For ***DNA isolation*** *use* ***DNA-sorb-AM***

CE *Gardnerella vaginalis*

Gardnerella vaginalis is just one of many causes of bacterial vaginosis caused by an increased production of the naturally occurring bacteria *G. vaginalis*. It is presumed to be a sexually transmitted disease and is often found in conjunction with a variety of other anaerobic bacteria. The most common symptom of *G. vaginalis* infection is a "fishy" smelling discharge and gray-white secretions.

AmpliSens® ***G. vaginalis*** **PCR kits** are built for fast and accurate detection of the pathogen. PCR kits contain Internal Control for detection of DNA extraction efficiency, as well as control of amplification process.

Analytical sensitivity is 1 x 10^4 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-B7-F(RG,iQ)-CE		110	⑨
B7-100-R0,2-FEP-CE	::	110	⑨

For ***DNA isolation*** *use* ***DNA-sorb-AM***

CE *Candida albicans*

Candida sp. cause a wide spectrum of diseases, ranging from superficial mucocutaneous disease to invasive illnesses, such as hepatosplenic candidiasis, *Candida* peritonitis and systemic candidiasis. Local and systemic disease caused by *Candida spp.* has resulted in numerous new clinical syndromes, the expression of which depends primarily on the immune status of the host. Although *Candida* most frequently infects the skin and mucosal surfaces, it can cause systemic infections manifesting as pneumonia, septicaemia or endocarditis in severely immunocompromised patients. There does not appear to be significant difference in pathogenic potential of different *Candida* strains, therefore establishment of infection appears to be determined by host factors and not by the organism itself. However, the ability to assume various forms may be related to the pathogenicity of the organism.

AmpliSens® ***Candida albicans*** **PCR kits** are qualitative tests and contain Internal Control which must be used in the isolation procedure in order to control the isolation process of each individual specimen and to identify possible PCR reaction inhibition.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-F1-F(RG,iQ)-CE		110	⑨
F1-100-R0,2-FEP-CE	::	110	⑨

For ***DNA isolation*** *use* ***DNA-sorb-AM***

PCR Diagnostics Kits

Sexually Transmitted Infections

1

CE MultiPlex PCR Detection Kits

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX
- ROX/Orange
- Cy5/Red
- Cy5.5/Crimson

Neisseria gonorrhoeae / Trichomonas vaginalis

R-B65-F(RG,iQ)-CE ***NEW*** 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Chlamydia trachomatis / Ureaplasma / Mycoplasma genitalium / Mycoplasma hominis

R-B60-F(RG)-CE 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Candida albicans / Candida glabrata / Candida krusei

R-F3-F(RG,iQ)-CE 110 ⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Chlamydia trachomatis / Ureaplasma / Mycoplasma genitalium

R-B46-F(RG,iQ)-CE 110 ⑨
B46-100-R0,2-FEP-CE :: 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml – *C. trachomatis*
Analytical sensitivity is 1 x 10^3 copies/ml – *Ureaplasma spp.*
Analytical sensitivity is 1 x 10^3 copies/ml – *M. genitalium*
*For **DNA isolation** use **DNA-sorb-AM***

Chlamydia trachomatis / Ureaplasma

B47-100-R0,2-FEP-CE :: 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml – *C. trachomatis*
Analytical sensitivity is 1 x 10^3 copies/ml – *Ureaplasma spp.*
*For **DNA isolation** use **DNA-sorb-AM***

Mycoplasma hominis / Gardnerella vaginalis

B48-100-R0,2-FEP-CE :: 110 ⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Trichomonas vaginalis/Neisseria gonorrhoeae / Chlamydia trachomatis

R-B83-F(RG,iQ)-CE 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Neisseria gonorrhoeae /Chlamydia trachomatis Mycoplasma genitalium /Trichomonas vaginalis

R-B61-F(RG) 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Gardnerella vaginalis / Lactobacillus species

R-B7-FT(RG,iQ,Mx)-CE ***QUANTITATIVE*** ***RUO*** 110 ⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-AM***

Chlamydia trachomatis / Ureaplasma / Mycoplasma hominis

R-B43-F(RG,iQ)-CE 110 ⑨
R-B43(RG)-CE :: 110 ⑨
B43-100-R0,2-FEP-CE :: 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml – *C. trachomatis*
Analytical sensitivity is 1 x 10^3 copies/ml – *Ureaplasma spp.*
Analytical sensitivity is 1 x 10^3 copies/ml – *M. hominis*
*For **DNA isolation** use **DNA-sorb-AM***

Neisseria gonorrhoeae /Chlamydia trachomatis Mycoplasma genitalium

R-B67-F(RG,iQ)-CE 110 ⑨
R-B67(RG)-CE :: 110 ⑨

Analytical sensitivity is 5 x 10^2 copies/ml – *N. gonorrhoeae*
Analytical sensitivity is 5 x 10^5 copies/ml – *Ch. trachomatis*
Analytical sensitivity is 1 x 10^3 copies/ml – *M. genitalium*
*For **DNA isolation** use **DNA-sorb-AM***

Ⓡ - Real-Time; ✷ - FEP; ▤ - Elfo; :: - aliquoted form; ♦ - non-aliquoted form (usable cyclers see page 7)

PCR Diagnostics Kits

Sexually Transmitted Infections

CE Florocenosis / Bacterial vaginosis

AmpliSens® ***Florocenosis / Bacterial vaginosis*** **PCR kit** allows to estimate the **ratio of total bacteria**, lactobacilli and opportu-nistic pathogens associated with bacterial vaginosis (*Gardnerella vaginalis, Atopobium vaginae*) in the vaginal biotope as well as total number of bacteria to evaluate the adequacy of the clinical material - vaginal secretions and scrapings of the epithelial cells from the lateral vaginal walls.

Ratio of the logarithms of the concentrations of *Lactobacillus spp.* and the total number of bacteria (KC1) and the ratio of the logarithms of the concentrations of *Lactobacillus spp.* and pathogenic microflora - *G. vaginalis* and *A. vaginae* - (COP 2) enables to diagnose bacterial vaginosis - a disease caused by the suppression of the normal vaginal microflora (*Lactobacillus spp.*) and its replacement by opportunistic (including *G. vaginalis, A. vaginae*) one with high accuracy.

DNA calibrators allow to determine the exact DNA copies of *G. vaginalis, A. vaginae, Lactobacillus spp.* and the total number of bacteria in analyzed sample.

Analytical sensitivity is 5 x 10^3 copies/ml.

For detection of *G. vaginalis* **FAM/Green,** *A. vaginae* **JOE/Yellow/HEX**, *Lactobacillus spp.* **Orange/ROX** and total bacteria DNA **Cy5/Red** channels are needed.

R-B74-100-FT(RG)-CE	***QUANTITATIVE***	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE Florocenosis / Mycoplasma

AmpliSens® ***Florocenosis / Mycoplasma*** **PCR kit** allows to estimate the **quantity** of *Ureaplasma parvum*, *Ureaplasma urealyticum* and *Mycoplasma hominis* in a clinical material in 2 different ways - as 1. absolute quantity of described bacteria per ml of sample or 2. DNA copies of mentioned bacteria per number of human cells. For that, 2 independent Internal Controls are used - an artificial DNA fragment as well as human β-globin gene DNA. This kit allows to determine the status quo of vaginal microflora and the treatment efficiency.

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*

Detection channels: **FAM/Green, JOE/Yellow, ROX/Orange** and **Red/Cy5**.

R-B75-100-FT(RG,iQ,Mx)-CE	***QUANTITATIVE***	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE Florocenosis / Candida

AmpliSens® ***Florocenosis/Candida-FRT*** **PCR kit** is a Real-Time PCR test for simultaneous detection and **quantitation** of fungi DNA of *Candida* class (*C. albicans, C. glabrata, C. krusei, C. parapsilosis* and *C. tropicalis*) in the clinical material - scrape of urogenital tract mucous membrane, oral swabs and urine samples.

The amplification results of *C. albicans, C. glabrata* and *C. krusei* DNA are registered separately for each type through three different channels. Results of amplification of *C. parapsilosis* and *C. tropicalis* DNA are registered together through the fourth channel. Cy5.5/Crimson channel detects the amplification product of IC (Internal Control).

Analytical sensitivity is 1 x 10^2 copies/ml *(all pathogens)*

Detection channels: **FAM/Green, JOE/Yellow/HEX**, **Orange/ROX, Cy5/Red** and **Cy5.5/Crimson**.

R-F5-100-FT(RG,CFx)-CE	***NEW*** ***QUANTITATIVE***	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

CE Florocenosis / Aerobes

AmpliSens® ***Florocenosis/Aerobes FRT*** **PCR kit** is a Real-Time PCR test for simultaneous detection and **quantitation** of enterobacteria DNA (genus *Enterobacteriaceae* DNA including *E. coli, Klebsiella spp., Proteus spp.),* staphylococci (*Staphylococcus* spp.) and streptococci (*Streptococcus* spp.*)* in the clinical material - scrape of urogenital tract mucous membrane.

Analytical sensitivity is 2 x 10^3 copies/ml *(all pathogens)*

Detection channels: **FAM/Green** (genus *Enterobacteriaceae)*, **JOE/Yellow/HEX** (*Staphylococcus spp.),* **Orange/ROX** (*Streptococcus spp.*), **Cy5/Red** (Internal Control).

R-B88-FT-CE	***NEW*** ***QUANTITATIVE***	110	⑨

*For **DNA isolation** use **DNA-sorb-AM***

PCR Diagnostics Kits

Human HPV Infections

Human Papilloma virus Infections

Human papillomaviruses (HPVs) are a group of more than 150 related viruses. They are called papillomaviruses because certain types may cause warts, or papillomas, which are benign (noncancerous) tumors. Some HPVs, such as those that cause the common warts that grow on hands and feet, do not spread easily. However, more than 40 HPV types are sexually transmitted and these HPVs spread very easily through genital contact. Some types of sexually transmitted HPVs cause cervical cancer and other types of cancer. These are called **high-risk** (about 13 types), oncogenic, or carcinogenic HPVs. Other sexually transmitted types of HPV do not appear to cause cancer and are called **low-risk** HPVs.

Although genital HPV infections are very common, most occur without any symptoms and go away without any treatment within a few years. However, some HPV infections can persist for many years. Persistent infections with high-risk HPV types can cause cell abnormalities. If untreated, areas of abnormal cells (lesions) can in some cases develop into cancer.

Some types of sexually transmitted low-risk HPVs cause warts to appear on or around the genitals or anus. Most genital warts are caused by two HPV types, HPV-6 and HPV-11. Warts may appear within several weeks after sexual contact with a person who is infected with HPV, or they may take months or years to appear, or they may never appear.

AmpliSens® ***HPV*** **HCR Genotype titre FRT** (R-V67-CE) - the detection, exact **differentiation** and **quantitation** of **14 HPV HCR types** - 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 is carried out in four tubes. Each HPV type is registered on its own channel that allows not only to detect, but also to **differentiate** the virus genotype and **quantify** it.
For detection - **FAM/Green, JOE/Yellow/HEX, ROX/Orange and RED/Cy5** channels are needed.
Analytical sensitivity is 1 x 10^3 copies/ml.

AmpliSens® ***HPV*** **HCR screen-titre-FRT** (R-V31-T-2x-CE) PCR kit is capable to detect and **quantify** (without exact genotype detecting) the *HPV* DNA of two main phylogenetic groups – A7, A9, which include the following 10 types: 16, 18, 31, 33, 35, 39, 45, 52, 58, 59 – as well as the HPV DNA 51 (A5 group) and 56 (A6 group) types.

The method is based on simultaneous Real-time multiplex PCR and detection of E1-E2 *HPV* genes DNA fragments and a fragment of β-globin gene DNA which is used as internal endogenous control. For detection - **JOE/Yellow** and **FAM/Green** channels are needed.
Analytical sensitivity is no less then 5 x 10^3 copies/ml.

AmpliSens® ***HPV*** **HCR screen-titre-FRT** (R-V31-F-CE) PCR kit is capable to detect and **quantify** (without exact genotype differentiation) the *HPV* DNA of the following types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 and detect, **exactly differentiate** and **quantify** the HPV DNA types: 16, 18 and 45.

The method is based on simultaneous Real-time multiplex PCR and detection of *HPV* genes DNA fragments and a fragment of β-globin gene DNA which is used as internal endogenous control. For detection - **JOE, FAM, ROX, Orange and Cy5.5** channels are needed.
Analytical sensitivity is no less then 1 x 10^3 copies/ml.

Endogenous Internal Control, present in all our HPV kits, allows not only control stages of PCR (DNA isolation and amplification) but also evaluate sample quality and storage adequacy. If epithelial swab quality is not sufficient (number of epithelial cells in the clinical sample is insufficient), signal of β-globin gene will be significantly lowered. Such β-globin based Internal Control significantly reduces false negative results, caused by a poor clinical sample quality.

CE *High-Risk HPV Infections*

R-V31-T-2x(RG,iQ,SC)-CE	***QUANTITATIVE***	108	⑨
R-V31-F-CE ***NEW***	***QUANTITATIVE***	110	⑫
R-V12(RG,iQ,Mx)-CE	16/18	108	⑨
R-V67-F-CE	**Genotyping + *QUANTITATIVE***	110	⑫
V31-FEP-CE	screen	120	⑨
V31-3x-FEP-CE	screen	120	⑨
V31-100F-CE	screen	110	⑥
V25-50F-CE	**Genotyping**	55	⑥

*For **DNA isolation** use **DNA-sorb-AM***

CE *Low-Risk HPV Infections*

R-V11(RG,iQ,Mx)-CE	6/11	120	⑨
V11-100-R0,2-CE	6/11	:: 110	⑨

Analytical sensitivity is 1 x 10^3 copies/ml

*For **DNA isolation** use **DNA-sorb-AM***

Ⓡ - Real-Time; ✶ - FEP; ▤ - Elfo; :: - aliquoted form; ♦ - non-aliquoted form (usable cyclers see page 7)

PCR Diagnostics Kits

TORCH Infections

TORCH complex (also known as **STORCH**, **TORCHES** or the **TORCH infections**) is a medical acronym for a set of perinatal infections (i.e. infections that are passed from a pregnant woman to her fetus). The TORCH infections can lead to severe fetal anomalies or even fetal loss. They are a group of viral, bacterial, and protozoan infections that gain access to the fetal bloodstream transplacentally via the chronic villi. Hematogenous transmission may occur at any time during gestation or occasionally at the time of delivery via maternal-to-fetal transfusion.

The TORCH complex was originally considered to consist of four conditions, with the "TO" referring to "*Toxoplasma*". The four-term form is still used in many modern references, and the capitalization "TORCH" is sometimes used in these contexts.

Alternatively, the "O" is redefined as "other", and the acronym is spelled out as follows:

1. **T** – Toxoplasmosis/ *Toxoplasma gondii*
2. **O** – Other infections (see below)
3. **R** – *Rubella*
4. **C** – *Cytomegalovirus*
5. **H** – *Herpes simplex virus*

The "other agents" included under **O** are *Hepatitis B, Coxackievirus, Syphilis, Varicella-Zoster virus, HIV* and *Parvovirus B19*.

CE *Toxoplasma gondii*

T. gondii is an obligate intracellular sporozoan; both sexual (enteroepithelial) and asexual (extraintestinal) reproductive cycles occur in felines, other species only undergo extraintestinal infection.

Most infections are asymptomatic; mild cases with a localized lymphadenopathy accompanied with fever, sore throat, rash, mimicking infectious mononucleosis in some individuals. Immunocompromised host suffers from widespread dessimination of the infection with pneumonitis, myocarditis and encephalitis. Congenital cases can result in abortion and stillbirth, live births may result in severe central nervous system involvement along with chorioretinitis.

AmpliSens® ***T. gondii*** **kit** is based on total DNA isolation from white blood cells of peripheral and umbilical cord blood, biopsy and autopsy material, cerebrospinal and amniotic fluid with the exogenous Internal Control.

Analytical sensitivity is 400 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-P1(RG,iQ,Mx)-CE 60 ⑨

*For **DNA isolation** use **Ribo-prep** or **DNA-sorb-C** (biopsy)*

CE *Parvovirus B19*

Parvovirus B19 is a member of the family *Parvoviridae*. It is classified into three genotypes: genotype 1 (classical B19 strains), genotype 2 (prototype K71- and A6-like strains) and genotype 3 (prototype V9 virus). The clinical conditions associated with the infection include erythema infectiosum (Fifth Disease), arthropathy, transient aplastic crisis, chronic red cell aplasia, hydrops foetalis and papular, purpuric eruptions on the hands and feet ("gloves and socks" syndrome). Complications thought to be associated with *Parvovirus B19* infection include encephalopathy, epilepsy, meningitis, myocarditis, dilated cardiomyopathy and autoimmune hepatitis.

AmpliSens® ***Parvovirus B19*** **Real-Time PCR kit** is a **quantitative** kit based on DNA isolation from plasma of peripheral or umbilical blood, amniotic fluid, throat washes and swabs, saliva along with Internal Control. Simultaneous multiplex PCR detects DNA fragment of structural gene, coding for *Parvovirus B19* VP1 protein and DNA fragment, which is used as exogenous noncompetitive Internal Control.

Analytical sensitivity is 360 IU/ml.

Linear range is 720 – 9,000,000 IU/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-V49(RG,iQ,Mx)-CE ***QUANTITATIVE*** 60 ⑨

*For **DNA isolation** use **DNA-sorb-B** (blood) **or Ribo-prep** (swabs)*

3

Rubella virus

Rubella virus belongs to the family *Togaviridae*. It causes mild infection characterized by rash starting on the face and gradually spreading to the feet, fever, lymphadenopathy and other flu-like symptoms such as coughing, sore throat and sneezing. Older children and adults may experience joint involvement and purpuric rash. Women in their first trimester who contract rubella have an increased risk of passing the infection to the developing foetus. When contracted during the first trimester the effects on the child are most marked. Ocular, cardiovascular and central nervous system defects are common, along with deafness and intrauterine growth retardation. Second trimester infections are associated with deafness, retinopathy, microcephaly and mental retardation, while third trimester infections are associated with intrauterine growth retardation.

AmpliSens® ***Rubella virus PCR*** **kit** is One-Step RT-PCR kit based on RNA extraction (plasma, saliva, throat swabs, amniotic fluid), followed with reverse transcription (RT kit is included) and cDNA amplification. Internal Control allows to control RNA extraction efficiency, as well as RT and PCR processes.

Analytical sensitivity is 400 copies/ml.

Detection channels: **JOE/Yellow/HEX** and **FAM/Green**.

R-V24-S(RG,iQ,Mx)-CE	♦	60	⑨

*For **RNA isolation** use **Ribo-prep.***
***Reverse transcription** kit is included.*

Herpes-virus Infections

The ***Herpesviridae*** are a large family of DNA viruses, that cause diseases in humans. The family name is derived from the Greek word *herpein* ("to creep"), referring to the latent, recurring infections typical of this group of viruses. Herpesviruses all share a common structure - all herpes viruses are composed of relatively large ds linear DNA encoding 100-200 genes and all herpes viruses are *nuclear-replicating* - the viral DNA is transcibed to RNA within the infected cell's nucleus.

Infection is initiated when a viral particle contacts a cell. Following binding, the virion is internalized and dismantled, allowing viral DNA to migrate to the cell nucleus, where replication of viral DNA and transcription of viral genes occurs. During symptomatic infection, infected cells transcribe ***lytic*** viral genes. In some host cells, a small number of viral genes termed **latency associated transcript** (LAT) accumulate instead. In this fashion the virus can persist in the cell (and thus the host) indefinitely. While primary infection is often accompanied by a self-limited period of clinical illness, long-term latency is symptom-free.

Reactivation of latent viruses has been implicated in a number of diseases. Following activation, transcription from latency-associated LAT to multiple *lytic* genes lead to enhanced replication and virus production. Clinically, lytic activation is often accompanied by emergence of non-specific symptoms such as low grade fever, headache, sore throat, malaise and rash as well as clinical signs such as swollen or tender lymph nodes and immunological findings such as reduced levels of natural killer cells. In this family, there are **eight human herpes-viruses:** *Herpes Simplex virus* type 1, type 2, *CMV*, *EBV* and *HSV* 6, 7 and 8.

CE Cytomegalovirus

CMV infection is common and usually asymptomatic in healthy children and adults, but can cause severe disease in newborns and immunocompromised patients. Infections are often recurrent, caused by reactivation of latent virus (especially in transplant recipients), but reinfection may also occur due to the antigenic diversity of the virus. Infection may cause a mononucleosis-like-syndrome with prolonged fever (lasting 2-3 weeks), malaise, atypical lymphocytosis, cervical lymphadenitis, mild hepatitis and encephalitis.

CMV can persist in body fluids such as urine, saliva and seminal fluids for many years, or can remain dormant until reactivation of latent infection. Transmission occurs through direct contact with body fluids from persons excreting the virus, thus infection may be transmitted between humans and from adults to children through childbirth and breastfeeding.

AmpliSens® ***CMV* Screen Monitor** Real-Time PCR kit (R-V7-100-S) can determine **quantity** of CMV in **1 ml of liquid sample** or *CMV* DNA concentration **in copies per the human cell quantity**.

Linear range of CMV-screen/monitor-FRT PCR kit is 500–10,000,000 copies/ml, analytical sensitivity is 400 copies/ml or 5 *CMV* DNA copies per 10^5 cells.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

R-V7-F(RG,iQ)-CE			110	⑨
R-V7-100-S(RG,iQ,Mx)-CE	***QUANTITATIVE***		110	⑨
V7-100-R0,2-FEP-CE		::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM** (qualitative kit) or **Ribo-Prep** (quanitative kit)*

CE Epstein-Barr virus

Most *EBV* infections are acquired during childhood and are asymptomatic. Symptoms, when produced, are undistinguishable from other acute viral syndromes. Many benign and malignant diseases, however, have been associated with *EBV* in immunocompromised patients. *EBV* causes Infectious mononucleosis - an acute, self limiting febrile illness in young adults, characterized by fever, sore throat, abdominal discomfort, pharyngitis, tonsillitis, tender generalized lymphadenopathy, palatal petechaie and periorbital oedema, as well as with Burkitt's lymphoma. In transplant patients, early and late onset lymphoproliferative diseases are often caused by *EBV*.

AmpliSens® ***EBV* screen/monitor** qPCR kit can determine **quantity** of EBV in **1 ml of liquid sample** or *EBV* DNA concentration **in copies per the human cell quantity**.

Linear range of *EBV*-screen/monitor-FRT PCR kit is 500–10,000,000 copies/ml, analytical sensitivity is 400 copies/ml or 5 *EBV* DNA copies per 10^5 cells.

Detection channels: **FAM/Green**, **JOE/Yellow** and **ROX/Orange**.

R-V9-100-S(RG,iQ,Mx)-CE	***QUANTITATIVE***		110	⑨
V9-100-R0,2-CE		::	110	⑥

*For **DNA isolation** use **Ribo-prep***

CE Varicella zoster virus

Varicella zoster virus (*VZV*) is closely related to the herpes simplex viruses (*HSV*), sharing much genome homology. The known envelope glycoproteins (gB, gC, gE, gH, gI, gK, gL) correspond with those in *HSV*, however there is no equivalent of HSV gD. *VZV* also fails to produce the LAT (latency-associated transcripts) that play an important role in establishing *HSV* latency (*herpes simplex virus*).

VZV is known by many names such as *chicken pox virus, varicella virus, zoster virus* and *human herpes virus type 3* or *HHV-3*. Varicella is chicken pox and zoster is shingles. These are two different types of illnesses that manifest themselves through lesions, fever, and overall not feeling well. After having the chicken pox typically as a child, the virus lies dormant in the body before reoccurring into a viral infection. Only about twenty five percent of adults are affected by the reactivation known as shingles.

Both chicken pox and shingles are caused by the *Varicella zoster* igg which is a type of a herpes virus. Chicken pox is spread by human contact through the rash, sneezing, coughing or breathing. The contagious period appears two days before the rash appears to the day when the last lesion has crusted over. After the chicken pox the virus hibernates in the body's nerve cells along spine. When the virus in an adult decides to wake up due to stress, aging or a weaken immune system, it reappears as pain and a rash. The rash will usually last up to thirty days.

AmpliSens® ***Varicella zoster*** **FRT Kit** is a **qualitative** test, containing Internal Control for detection of DNA extraction efficiency as well as amplification process.

Analytical sensitivity is 500 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

⏲ R-V61-50-F(RG)-CE		60	⑨

*For **DNA isolation** use **Ribo-prep***

CE Human Herpes virus 6

HHV-6 is an immunosuppressive and neurotropic virus that can cause encephalitis and seizures during a primary infection or when it is reactivated from latency in immunosuppressed patients. *HHV-6* may play a role in several chronic neurological conditions including mesial temporal lobe epilepsy, status epilepticus and chronic fatigue syndrome.

Primary *HHV-6* infection usually occurs in infants and is the most common cause of fever-induced seizures in children aged 6-24 months. Acute *HHV-6* infection is rare in immunocompetent adults but may manifest as a mononucleosis like illness with fever, lymphadenopathy and hepatitis or encephalitis, with negative test results for *CMV* or *EBV*.

AmpliSens® ***HHV6-screen-titre-FRT*** is a **quantitative** PCR kit with calculation of *HHV-6* per ml or number of human cells. Such multiplex PCR kit is based on analyzis of *HHV-6* pol-gene fragment and β-globin gene fragment, used as endogenous Internal Control.

Analytical sensitivity is 400 copies/ml or 5 HHV-6 copies/10^5 cells.

Detection channels: **FAM/Green** and **JOE/Yellow**.

⏲ R-V10-T(RG,iQ,Mx)-CE	***QUANTITATIVE***	110	⑨

*For **DNA isolation** use **Ribo Prep** or **DNA-sorb-C** (biopsy material)*

CE Herpes Simplex virus HSV-1, 2

The primary difference between the two viral types is in where they typically establish latency in the body- their "site of preference." HSV-1 usually establishes latency in the trigeminal ganglion and produces most cold sores. HSV-2 usually sets up residence in the sacral ganglion at the base of the spine. From there, it recurs in the genital area. Symptoms of HSV infection include watery blisters in the skin or mucous membranes of the mouth, lips or genitals. Lesions heal with a scab characteristic of herpetic disease. Sometimes the viruses cause very mild or atypical symptoms during outbreaks. *HSV-1* and *-2* persist in the body by becoming latent and hiding from the immune system in the cell bodies of nerves. After the initial infection some infected people experience sporadic episodes of viral reactivation. In an outbreak, the virus in a nerve cell becomes active and is transported via the nerve axon to the skin, where virus replication and shedding occur and cause sores.

Analytical sensitivity is 1 x 10^3 copies/ml.

AmpliSens® ***HSV I, II*** **PCR kits** are **qualitative** tests, and contain the Internal Control in order to control the isolation process of each individual sample and to identify possible reaction inhibition.

Detection channels: **FAM/Green** and **JOE/Yellow**.

⏲ R-V8-F(RG,iQ)-CE		110	⑨
✷ V8-100-R0,2-FEP-CE		:: 110	⑨

*For **DNA isolation** use **DNA-sorb-AM** (smears) or **DNA-sorb-B** (blood, liquor)*

PCR Diagnostics Kits

Herpes-virus Infections

CE *Herpes Simplex virus Genotyping*

AmpliSens® ***HSV*-typing PCR kits** are *in vitro* nucleic acid amplification tests for qualitative detection and **differentiation** of *Herpes Simplex virus* types I and II ***(HSV* I** and ***HSV* II)** DNA in the biological material (scrapes, swabs of urogenital tract mucous membranes; papules, vesicles, or ulcers fluid; urine sediment) by using of Real-Time or FEP technology.

Kits contain the Internal Control, used in the isolation procedure in order to control the isolation process of each individual sample and to identify possible reaction inhibition.

Analytical sensitivity is 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

R-V38-F(RG,iQ)-CE	♦	110	⑨
R-V38(RG)-CE	::	110	⑨
V38-100-R0,2-FEP-CE	::	110	⑨

*For **DNA isolation** use **DNA-sorb-AM** (smears) or **DNA-sorb-B** (blood, liquor)*

CE MultiPlex PCR Detection Kits

AmpliSens® **MultiPlex line kits** are based on dual labeled fluorescent probes technology. This technology uses primers and probes for several DNA targets. Amplification products identification for each DNA target runs on a different optical channel. It allows to identify simultaneously for up to 4 infections + Internal Control in one tube.

The sensitivity of these tests are not affected by changing number of infections.

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX
- ROX/Orange
- Cy5/Red

Epstein-Barr virus / Cytomegalovirus / Human Herpes virus 6

R-V48(RG,iQ,Mx)-CE	***QUANTITATIVE***	♦	110	⑨

Analytical sensitivity is 400 copies/ml or 5 copies/10^5 cells

Each virus is quantified separately.

*For **DNA isolation** use **Ribo Prep** (blood, smears) or **DNA-sorb-C** (biopsy)*

Herpes Simplex virus / Cytomegalovirus

R-V60-F(RG,iQ)-CE	♦	110	⑨

Analytical sensitivity is 10^3 copies/ml

*For **DNA isolation** use **DNA-sorb-AM** or **DNA-sorb-B** (blood, cerebrospinal fluid)*

4

Purulent Septic Infections

Purulent infections are characterized by purulent inflammation of tissues that arise in the implementation of pyogenic bacteria, most commonly *Streptococcus, Staphylococcus*, more rarely *Pseudomonas* or *E. coli*. For some common infections local centers of suppuration (glanders, bubonic plague, cutaneous anthrax) are typical. Purulent infection can develop in form of the disease (furuncle, carbuncle, erysipelas, osteomyelitis, etc.), or as a complication of the wound. In some cases, purulent focus can disappear spontaneously or may be disposed of after a simple intervention, in others requires a complex operation. Generalization of the purulent process may lead to the development of general purulent infection, ie, sepsis. Purulent infection are very often resistant to antibiotics.

CE MRSA

Methicillin-resistant *Staphylococcus aureus* (MRSA) is responsible for several difficult-to-treat infections in humans. It is also called multidrug-resistant *S. aureus* and oxacillin-resistant *S. aureus* (ORSA). MRSA is any strain of *S. aureus* that has developed resistance to beta-lactam antibiotics, which include the penicillins and the cephalosporins. MRSA is especially troublesome in hospitals and nursing homes, where patients with open wounds, invasive devices and weakened immune systems are at greater risk of infection than the general public.

AmpliSens® **MRSA-screen-titre-FRT kit** can detect and **quantify** methicillin-susceptible and methicillin-resistant *S. aureus* DNA, methicillin-resistant coagulase-negative *Staphylococcus spp*. in oropharyngeal swab, BAL fluid, sputum, endotracheal aspirate, bronchial washings, urine, blood, plasma, CS fluid, punctates, tissues, wipes from medical equipment.

Analytical sensitivity is 400 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

R-B78-100-FT(RG,iQ)-CE **QUANTITATIVE** 110 ⑨

*For **DNA isolation** use **Ribo-Prep***

CE Streptococcus agalactiae

S. agalactiae is a member of normal flora that can be transferred to a neonate passing through the birth canal and can cause serious group B streptococcal infection. In the western world, *S. agalactiae* is the major cause of bacterial septicemia of the newborn, which can lead to death or long-term sequelae. Early-onset septicemia is more prone to be accompanied by pneumonia, while late-onset septicemia is more often accompanied by meningitis. Hearing loss can be a long-term sequela of GBS-meningitis. Infection with GBS is the cause of some instances of stillbirth.

AmpliSens® ***Streptococcus agalactiae*-screen-titre-FRT kit** can detect and **quantify** DNA of *S. agalactieae*.

Analytical sensitivity is 3 x 10^2 copies/ml.

Detection channels: **FAM**, **JOE and ROX**.

R-B77-100-FT(RG,iQ)-CE **QUANTITATIVE** 110 ⑨

*For **DNA isolation** use **Ribo-prep***

CE Pseudomonas aeruginosa

Pseudomonas aeruginosa is a common bacterium that can cause disease in animals and humans. The symptoms of infections are generalized inflammation and sepsis. If such colonizations occur in critical body organs, the results can be fatal. This bacterium is also found on/in medical equipment, including catheters, causing cross-infections in hospitals.

AmpliSens® ***Pseudomonas aeruginosa*-screen-titre-FRT kit** can detect and **quantify** *P. aeruginosa* DNA.

Analytical sensitivity is 500 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B76-50-FT(RG,iQ)-CE **QUANTITATIVE** 60 ⑨

*For **DNA isolation** use **Ribo-prep***

CE Streptococcus pyogenes

S. pyogenes causes mild superficial skin infections to life-threatening systemic diseases. Mild infections include pharyngitis and localized skin infection (impetigo). Erysipelas and cellulitis are characterized by multiplication and lateral spread of *S. pyogenes* in deep layers of the skin. Other toxigenic *S. pyogenes* infections may lead to life-threatening toxic shock syndrome.

AmpliSens® ***Streptococcus pyogenes*-screen-titre-FRT kit** can detect and **quantify** *S. pyogenes* DNA.

Analytical sensitivity is 3 x 10^2 copies/ml.

Detection channels: **FAM, JOE** and **ROX** .

R-B82-100-FT(RG,iQ)-CE **QUANTITATIVE** 110 ⑨

*For **DNA isolation** use **Ribo-prep***

CE Genetic markers of antibiotic resistance

Kits are designed for detection of metallo-β-lactamases genes VIM, IMP and NDM groups *(kit R-C1)* and for carbapenemase genes KPC and OXA-48 groups *(kit R-C2)*.

Analytical sensitivity is 5 x 10^2 copies/ml.

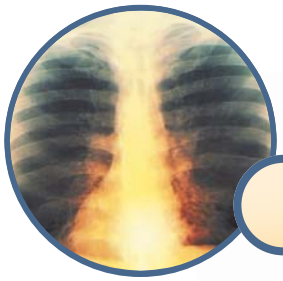
Detection channels **FAM**, **JOE**, **ROX** (kit R-C2)+ **Cy5** (kit R-C1).

R-C1(RG,CFX)-CE ***VIM, IMP, NDM*** 110 ⑨

R-C2(RG,CFX)-CE ***KPC, OXA-48*** 110 ⑨

*For **DNA isolation** use **DNA-sorb-AM** or **Ribo-prep** (urine)*

PCR Diagnostics Kits



Respiratory Infections

Respiratory tract infection refers to any of a number of infectious diseases involving the respiratory tract. An infection of this type is normally further classified as an upper respiratory tract infection (URI) or a lower respiratory tract infection (LRI). Lower respiratory infections, such as pneumoniae, tend to be far more serious conditions than upper respiratory infections, such as the common cold.

URIs represents the most common acute illness evaluated in the outpatient setting and is a nonspecific term used to describe acute infections involving the nose, paranasal sinuses, pharynx, larynx, trachea and bronchi. URIs range from the common cold - typically a mild, self-limited, catarrhal syndrome of the nasopharynx - to life-threatening illnesses such as epiglottitis. Symptoms of URIs can include cough, sore throat, runny nose, nasal congestion, headache, low grade fever, facial pressure and sneezing. Influenza is a systemic illness that involves the upper respiratory tract and should be differentiated from other URIs.

LRIs are generally more serious than URIs. LRIs are the leading cause of death among all infectious diseases. The two most common LRIs are bronchitis and pneumonia. *Influenza* affects both the upper and lower respiratory tracts, but more dangerous strains such as the highly pernicious H5N1 tend to bind to receptors deep in the lungs. Viruses cause most URIs, with rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, coxsackievirus and influenza virus. Human metapneumovirus is a newly discovered agent causing URIs. Group A beta-hemolytic streptococci (GABHS) cause 5% to 10% of cases of pharyngitis in adults. Other less common causes of bacterial pharyngitis include group C beta-hemolytic streptococci, *Corynebacterium diphtheriae*, *Neisseria gonorrhoeae*, *Arcanobacterium haemolyticum*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae* and *Herpes simplex virus*. *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* are the most common organisms that cause the bacterial superinfection of viral acute sinusitis. Less than 10% of cases of acute tracheobronchitis are caused by *Bordetella pertussis*, *B. parapertussis*, *M. pneumoniae* or *C. pneumoniae*.

CE Avian Influenza (bird flu), sub. H5N1

Avian influenza is an infection caused by avian (bird) influenza (flu) A viruses. These *influenza A* viruses occur naturally among birds. Wild birds worldwide get flu A infections in their intestines, but usually do not get sick from flu infections.

Subtypes differ are based on differences in two main proteins on the surface of the influenza A virus (hemagglutinin [HA], neuraminidase [NA] proteins). There are 16 known HA subtypes and 9 known NA subtypes of influenza A. Each combination represents different subtype. Highly pathogenic *Influenza A* (H5N1) virus occurs mainly in birds and can be deadly to them. HPAI H5N1 virus does not usually infect people, but infections with these viruses have occurred in humans.

AmpliSens® ***Influenza virus*** **A H5N1** PCR kits are **qualitative** tests, containing the Internal Control in order to control the RNA isolation process and to identify PCR reaction inhibition.

Analytical sensitivity is no less than 5 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX/Cy3**.

R-V33(RG)-CE	::	55	⑨
R-V33(SC)-CE	♦	55	⑨
✷ V33-50-R0,2-FEP-CE	::	55	⑨

*For **RNA isolation** use **Ribo-sorb***
*For **reverse transcription** use **Reverta-L***

CE Influenza virus A/H1 (swine flu)

Swine influenza (swine flu) is a respiratory disease of pigs caused by type A influenza viruses that regularly cause outbreaks of influenza in pigs. Swine flu viruses do not normally infect humans, but sporadic human infections with swine flu have occurred.

AmpliSens® ***Influenza virus*** **A/H1-swine** PCR kits allow identification of *Influenza virus* A/H1-swine RNA in clinical material. Detection is based on RNA extraction, cDNA preparing and cDNA amplification. The presence of the Internal Control determines RNA extraction and reverse transcription efficiency, as well as cDNA amplification process.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX/Cy3**.

R-V55(RG)-CE	::	55	⑨
R-V55-F(SC)-CE	♦	55	⑨
✷ V55-50-R0,2-FEP-CE	::	55	⑨

*For **RNA isolation** use **Ribo-sorb** or **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

CE Influenza virus A/B

Influenza A and *B viruses* routinely spread in people are responsible for seasonal flu epidemics. The emergence of a new *influenza virus* causing illness in people can result in an influenza pandemic. *Influenza A viruses* can be broken down into sub-types. *influenza viruses* are constantly changing through a process called "antigenic drift." *Influenza B viruses* are only known to infect humans and seals.

AmpliSens® ***Influenza virus A/B*** **PCR kits are** tests for **qualitative** detection and **differentiation** of *Influenza virus A* and *Influenza virus B* RNA in the clinical material (nasal, throat swabs; sputum or aspirate of nasopharynx or trachea).

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX/Cy3** and **Orange/ROX/Texas Red**.

R-V36-50-Mod-CE	NEW	::	55	⑨
R-V36-100-F-Mod (RG,iQ,Dt,CFX,SC)-CE	NEW	♦	100	⑫
V36-Mod-50-R0,2-FEP-CE		::	55	⑨

*For **RNA isolation** use **Ribo-sorb** or **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

CE Mycobacterium tuberculosis complex (MBTC)

Tuberculosis is a common and potentially lethal infectious disease caused by various mycobacteria strains, usually *M. tuberculosis* in humans. Most infections in humans result in an asymptomatic, latent infection and about one in ten latent infections eventually progresses to active disease.

As samples, BAL and BAL fluid, liquor, sputum, urine, whole blood, pleural fluid, tissue, paraffine blocks and environmental samples can be used. For DNA extraction from synovial fluid **Mukolysin** reagent is necessary to use.

AmpliSens® ***M. tuberculosis*** **complex PCR kits** detects in qualitative format also other TB-causing mycobacteria: *M. bovis, M. pinnipedii, M. africanum, M. microti* and *M. canetti.* Detection channels: **FAM/Green** and **JOE/Yellow**.

AmpliSens® ***MTB differentiation*** **kit** detects and **differentiates** *M. tuberculosis, M. bovis* and *M. bovis* BCG strains.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM**, **JOE**, **ROX** and **Cy5**.

UDG is used in all kits for preventing of contamination.

R-B57(RG,iQ,SC,Dt)-CE	MTB complex	♦	55	⑨
R-B80(RG,iQ,Dt,SC)-CE	MTB differentiation	♦	55	⑨
B57-FEP-CE	MTB complex	♦	55	⑨

*For **DNA isolation** use **Ribo-prep** (BAL, urine, cultures, enviro samples) or **DNA-Sorb-C** (biopsy material)*

CE Influenza virus A-type H5, H7, H9

AmpliSens® ***Influenza virus A type H5,H7,H9*** **PCR kit** is a PCR test for **qualitative** detection and **differentiation** of *Influenza virus A* type H5,H7 and H9 in the clinical material (nasal, throat swabs; sputum or aspirate of nasopharynx or trachea; autopsy).

Analytical sensitivity is no less than 1 x 10^3 GE/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX/Cy3** and **Orange/ROX/Texas Red**.

R-V66-F-CE	NEW	♦	55	⑨

*For **RNA isolation** use **Ribo-sorb** or **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

CE Influenza virus A/H1N1 & H3N2

AmpliSens® ***Influenza virus A*** **type H1N1 & H3N2 kits** allow identification and **differentiation** of *Influenza virus A H1N1* and *H2N3* cDNA in the clinical material (nasal, throat swabs; sputum or aspirate of nasopharynx or trachea; autopsy).

Analytical sensitivity is no less than 1 x 10^3 GE/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX/Cy3** and **Orange/ROX/Texas Red**.

R-V54-100-F(RG,iQ,Dt,SC)-CE	NEW	♦	100	⑨
R-V54(RG)-CE	NEW	::	55	⑫

*For **RNA isolation** use **Ribo-sorb** or **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

CE Adenovirus

Adenoviruses most commonly cause respiratory illness; however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis (bladder infection) and rash illness. Although epidemiologic characteristics of the adenoviruses vary by type, all are transmitted by direct contact, fecal-oral transmission and occasionally waterborne transmission

AmpliSens® ***Adenovirus*** **PCR kit** is a test for **qualitative** detection of *Adenovirus* DNA in the clinical material (feces, feces washes/swabs, eye discharge) by using electrophoretic detection method.

Analytical sensitivity is no less than 5 x 10^3 copies/ml.

V23-50-R0,2-CE		::	55	⑥

*For **DNA isolation** use **DNA-sorb-B***

PCR Diagnostics Kits

Respiratory Infections

CE *Respiratory-Syncytial virus*

Human *Respiratory-Syncytial virus* (*hRSV)* primarily infects human epithelial cells within the nasopharynx, but it can also infect, with much lower efficacy, other types of cells, including cell lines. Infection may lead to the formation of syncytia within the infected cell. Primary infection with h*RSV* is generaly exhibited as lower respiratory tract disease, pneumonia, bronchiolitis, tracheobronchitis, or upper respiratory tract illness. Common clinical symptoms include rhinorrhea, sneezing, cough, pharyngitis, bronchitis, headache, fatigue and fever. Severe infection (involving pneumonia) may develop among elderly patients with underlying respiratory conditions.

AmpliSens® ***hRSV*-FRT PCR kits** are **qualitative** tests, which contain the Internal Control, used in the isolation procedure in order to control the isolation process of each individual sample and to identify possible reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-V37(RG)-CE		::	55	⑨
V37-50-R0,2-FEP-CE		::	55	⑨

*For **RNA isolation** use **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

CE *Legionella pneumophila*

L. pneumophila infection can cause Legionnaire´s disease, a severe form of pneumonia. The symptoms of Legionnaire's disease include confusion, headache, diarrhoea, abdominal pain, fever, chills and myalgia as well as a non-productive cough. Pontiac fever is a non-pneumonic form of *L. pneumophila* infection. Symptoms are flu-like, including fever, tiredness, myalgia, headache, sore throat, nausea and cough may or may not be present. Pontiac fever is self limited and requires no hospitalization or antibiotic therapies.

AmpliSens® ***Legionella pneumophila*-FRT PCR kits** are *in vitro* nucleic acid amplification tests for **qualitative** detection of *L. pneumophila* DNA in the clinical materials (sputum or aspirate from trachea, nasopharyngeal swabs, throat swabs, bronchi scourage or bronchoalveolar lavage, autopsy material), microorganism cultures and qualitative detection and also **quantitation** of *L. pneumophila* DNA in environmental samples (water, washes from environmental objects, biofilms scrapes, ground).

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

The *L. pneumophila mip*-gene is analyzed in **JOE/Yellow** and prothrombin gene is analyzed in **FAM/Green** channel.

R-B50(RG)-CE	***QUANTITATIVE***	::	70	⑨
B50-50-R0,2-FEP-CE		::	55	⑨

*For **DNA isolation** use **DNA-sorb-B***

CE *MERS and SARS – Coronavirus*

The SARS *Coronavirus* (SARS-CoV) causes severe acute respiratory syndrome (SARS). SARS-CoV causes often severe illness marked initially by systemic symptoms of muscle pain, headache and fever, followed in 2–10 days by the onset of respiratory symptoms, mainly cough, dyspnea and pneumonia. Another common finding in SARS patients is a decrease in the number of blood circulating lymphocytes. In the SARS outbreak of 2003, about 9% of patients with confirmed SARS infection died.

AmpliSens® **MERS-CoV/SARS-CoV PCR kit (**R-V65-F-CE) is a qualitative Real-Time PCR test for detection and **differentiation** of MERS-CoV and SARS-CoV RNA in a clinical sample.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM**, **JOE** and **ROX**.

AmpliSens® **SARS-*Coronavirus* PCR kit (**TV29-100-R0,2-CE) is a **qualitative** test, based on RNA extraction, reverse transcription and cDNA amplification.

Kits contain Internal Control to check RNA extraction, reverse transcription as well as cDNA amplification steps.

Analytical sensitivity is no less than 5 x 10^3 copies/ml.

R-V65-F-CE		♦	55	⑫
TV29-100-R0,2-CE		::	110	⑨

*For **RNA isolation** use **Ribo-prep**.* TV29-100-R0,2-CE contains **RNA extraction** and ***reverse transcription** kits.*

CE *Parainfluenza virus*

One in a group of four RNA viruses that rank second only to *respiratory syncytial virus* (RSV) as a common cause of lower respiratory tract disease in young children.

There are four serotypes types of *HPIV.* Each of the four *HPIV* has different clinical and epidemiologic features. The most distinctive clinical feature of HPIV-1 and HPIV-2 is croup; HPIV-1 is the leading cause of croup in children, whereas HPIV -2 is less frequently detected. HPIV-3 is more often associated with bronchiolitis and pneumonia. HPIV-4 is less likely to cause severe disease.

AmpliSens® ***Parainfluenza virus* qPCR kit** is for **qualitative** detection and **genotyping** of all *Parainfluenza virus* types 1, 2, 3 and 4 RNA in the clinical material (swabs, sputum, autopsy material).

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/HEX/Yellow** and **ROX/Orange**.

R-V51(RG)-CE		::	55	⑨

*For **RNA isolation** use **Ribo-sorb** or **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

6

MultiPlex PCR Detection Kits

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX
- ROX/Orange
- Cy5/Red

CE *Acute Respiratory Viral Infections (ARVI)*

Acute respiratory viral infections (ARVI) belong to the most frequent illnesses. There is a wide spectrum of DNA and RNA viruses, responsible for ARVI. To the most important viruses belong: rhinoviruses, coronaviruses, parainfluenza viruses, respiratory syncytial virus, adenoviruses and metapneumoviruses.

Rhinoviruses and coronaviruses are the most frequent cause of the common cold. There are min. 99 recognized types of Human rhinoviruses that differ according to their surface proteins and four to five different currently known strains of coronaviruses that infect humans.

Parainfluenza viruses and RSVs show high similarities while four types of parainfluenza viruses are known. *Parainfluenza* type 4 is rare and causes only very light cold. In contrast, whenever young children are studied, parainfluenza types 1, 2 and 3 and RSV lead to respiratory illnesses with hospitalization. Types 1 and 2 most typically cause laryngotracheobronchitis, parainfluenza type 3 produces pneumonia, often with of obstruction.

For most people, RSV produces only mild symptoms, often indistinguishable from common colds and minor illnesses. The typical syndrome is usually bronchiolitis, but pneumonia is sometimes diagnosed as well.

AmpliSens® **ARVI screen PCR kit** is a **qualitative** nucleic acid amplification test for multiplex **detection** and **differentiation** of specific nucleic acid fragments of pathogens that cause acute respiratory viral infections:

- human *Respiratory Syncytial virus* (hRSV) RNA,
- human *Metapneumovirus* (hMpv) RNA,
- human *Parainfluenza virus*-1-4 (hPiv) RNA,
- human *Coronavirus* (hCov) RNA - OC43, E229, NL63, HKUI,
- human *Rhinovirus* (hRv) RNA,
- human B, C and E *Adenovirus* (hAdv) DNA,
- human *Bocavirus* (hBov) DNA

in the clinical material. Internal Control allows to check the DNA/RNA extraction, reverse transcription and amplification efficiency.

Analytical sensitivity is:

- 1 x 10^3 copies/ml – *hRSv, hMpv, hPiv, hBov, hRv,*
- 1 x 10^4 copies/ml – *hCov,*
- 5 x 10^3 copies/ml – *hAdv.*

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

ⓣ	R-V57-100-F(RG,iQ,Dt)-CE	screen	100	⑫

*For **RNA isolation** use **Ribo-Prep***
*For **reverse transcription** use **Reverta-L.***

NOTE: 1 x ARVI screen kit requires 2 x Reverta L (120 Rx) kits.

CE *Bordetella multi*

Bordetella pertussis, B. bronchiseptica, B. parapertussis are closely related respiratory pathogens that infect mammalian species. B. *pertussis and B. parapertussis* are exclusively human pathogens and cause whooping cough, or pertussis, a disease that has resurged despite vaccination. Although it most often infects animals, infrequently *B. bronchiseptica* is isolated from humans and these infections are thought to be zoonotic.

AmpliSens® ***Bordetella multi-FRT* PCR kit** is a qPCR test for **qualitative** detection and **differentiation** of *Bordetella pertussis, B. bronchiseptica* and *B. parapertussis* in the clinical material.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX**, **ROX/Orange** and **Red/Cy5.**

ⓣ	R-B84-100-F(RG,iQ,Dt)-CE	♦	100	⑫

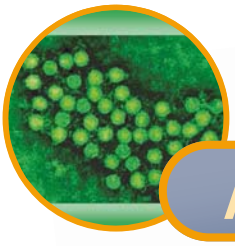
*For **DNA isolation** use **Ribo-prep***

CE *Mycoplasma pneumoniae / Chlamydophila pneumoniae*

ⓣ	R-B42-4x(RG)-CE	::	55	⑨
ⓣ	R-B42-100-F-CE	♦	100	⑫
✶	B42-50-R0,2-FEP-CE	::	55	⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*
*For **DNA isolation** use **DNA-sorb-B***

PCR Diagnostics Kits



Neuro Infections

Enterovirus

Enterovirus enters the body through the gastrointestinal tract and thrives there, often moving on to attack the nervous system. Enteroviruses can be found in the respiratory secretions or stool of an infected person. Most people infected with *Enterovirus* have no disease at all. Infected persons who become ill usually develop either mild upper respiratory symptoms, a flu-like illness with fever and muscle aches, or an illness with rash. Less commonly, some persons have aseptic or viral meningitis. Rarely, a person may develop an illness that affects the heart or the brain or causes paralysis. *Enterovirus* infections are suspected to play a role in the development of juvenile-onset diabetes mellitus.

AmpliSens® ***Enterovirus*** **PCR kits** are built for **qualitative** detection of *Enterovirus* RNA in the clinical material (CS fluid) and environmental samples (water samples). Tests are based on RNA detection and contain the Internal Control in order to control the RNA extraction and to identify possible reaction inhibition.

Analytical sensitivity is no less than 5 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow**.

R-V16(RG)-CE		::	55	⑨
R-V16-F-CE *NEW*	One-Step RT-PCR	♦	55	⑨
R-V64-F-CE **Enterovirus 71**	One-Step RT-PCR	♦	55	⑨
✶ V16-50-R0,2-FEP-CE		::	55	⑨

*For **RNA isolation** use **Ribo-prep**, for **reverse transcription** use **Reverta-L**, One-Step RT-PCR **kits** contains **already Reverta kit.***

Poliovirus

Poliovirus is a human enterovirus and member of the family of Picornaviridae. The genome is a single-stranded RNA genome and because of its short genome and its simple composition is poliovirus widely regarded as the simplest significant virus.

There are 3 serotypes of *Poliovirus*, PV1, PV2 and PV3. PV1 is the most common form encountered in nature, however all three forms are extremely infectious.

Poliovirus infection occurs via the fecal-oral route. Virus is shed in the feces of infected individuals. In 95% of cases only a primary, transient presence of viremia occurs and the poliovirus infection is asymptomatic. In about 5% of cases, the virus spreads and replicates in other sites such as brown fat, reticuloendothelial tissue and muscle. The sustained viral replication causes secondary viremia and leads to the development of minor symptoms such as fever, headache and sore throat. Paralytic poliomyelitis occurs in less than 1 % of poliovirus infections. Paralytic disease occurs when the virus enters the central nervous system and replicates in motor neurons within the spinal cord, brain stem, or motor cortex, resulting in the selective destruction of motor neurons leading to temporary or permanent paralysis. In rare cases, paralytic poliomyelitis leads to respiratory arrest and death. In cases of paralytic disease, muscle pain and spasms are frequently observed prior to weakness and paralysis.

AmpliSens® ***Poliovirus*****-FRT PCR kit** is amplification test for **qualitative detection** of *Poliovirus* and *Enterovirus* group C (HEV-C) RNA with *Poliovirus* **differentiation** (Sabin 1, Sabin 2, Sabin 3) in clinical materials and environmental samples.

Sensitivity of the kit is 1 x 10^3 copies/ml (water samples) or 5 x 10^3 copies/ml (feces).

Detection channels: Internal Control - **JOE/Yellow/HEX**l, Sabin 1 cDNA - **ROX/Orange**, Sabin 2 cDNA - **FAM/Green**, Sabin 3 cDNA - **JOE/Yellow/HEX**.

R-V58(RG,iQ)-CE	♦	55	⑨

*For **RNA isolation** use **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

Listeria monocytogenes

L. monocytogenes is one of the most virulent food-borne pathogens. It is the third-most-common cause of meningitis in newborns. When the infection is not invasive, any illness as a consequence of infection is termed febrile gastroenteritis. The manifestations of listeriosis include septicaemia, meningitis, encephalitis, corneal ulcer, pneumonia and intrauterine infections in pregnant women, which may result in abortion or stillbirth. Surviving neonates of fetomaternal listeriosis may suffer granulomatosis infantiseptica and may suffer from physical retardation. Influenza-like symptoms, including persistent fever, usually precede the onset of the disorders.

Analytical sensitivity is 500 copies/ml.

Linear range is 800 - 1 x 10^7 copies/ml.

Detection channels: **FAM**, **JOE** and **ROX**.

R-B14-100-FT(RG,iQ)-CE	*QUANTITATIVE*	♦	110	⑨

*For **DNA isolation** use **Ribo-prep***

MultiPlex PCR Detection Kits

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX

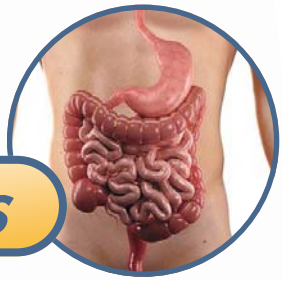
Neisseria meningitidis / Haemophilus influenzae / Streptococcus pneumoniae 🟡🟢

R-B25(RG,iQ)-CE	♦	55	⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*
*For **DNA isolation** use **Ribo Prep***

7

PCR Diagnostics Kits



Intestinal Infections

Campylobacter species

Campylobacteriosis is an infectious disease caused by bacteria of the genus *Campylobacter*. Most people who become ill with campylobacteriosis get diarrhea, cramping, abdominal pain and fever within two to five days after exposure to the microorganism. The diarrhea may be bloody and can be accompanied by nausea and vomiting. Some infected persons do not have any symptoms. In persons with compromised immune systems, *Campylobacter* occasionally spreads to the bloodstream and causes a serious life-threatening infection.

AmpliSens® ***Campylobacter spp.*** **PCR kit** is *in vitro* nucleic acid amplification test for **qualitative** detection of DNA of the **thermophilic group** of *Campylobacter spp.* Presence of Internal Control allows to control DNA extraction procedure as well as to identify possible reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B35(RG,iQ)-CE	55	⑨	

For ***DNA isolation*** *use* ***Ribo –prep***

Helicobacter pylori

Helicobacter pylori is a bacterium that causes chronic inflammation of the inner lining of the stomach (gastritis) in humans. It causes a chronic low-level inflammation of the stomach lining and is strongly linked to the development of duodenal and gastric ulcers, stomach cancer. *H. pylori* infection is most likely acquired by ingesting contaminated food and water and through person to person contact. Over 80 percent of individuals infected with the bacterium are asymptomatic.

AmpliSens® ***Helicobacter pylori*** **PCR kits** are *in vitro* nucleic acid amplification test for **qualitative** detection of *Helicobacter pylori* DNA in clinical material (biopsy material of gastric mucosa). Kits contain the Internal Control which is used in the extraction procedure in order to control the extraction process of each sample and to identify possible amplification reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B9(RG,iQ)-CE	55	⑨	
B9-FEP-CE	55	⑨	

For ***DNA isolation*** *use* ***Ribo-prep***

Clostridium difficile

Clostridium difficile as a bacteria that causes severe diarrhea and other intestinal disease when competing bacteria in the gut flora have been wiped out by antibiotics. It is the most serious cause of antibiotic-associated diarrhea and can lead to pseudomembranous colitis, a severe inflammation of the colon. Overpopulation of *C. difficile* in colon is harmful because the bacteria release toxins that can cause bloating and diarrhea with abdominal pain. In rare cases this can progress to toxic megacolon, which can be life-threatening.

Latent symptoms of *C. difficile* infection often mimic some flu-like symptoms and can mimic disease flare in patients with inflammatory bowel disease-associated colitis.

AmpliSens® ***Clostridium difficile*** **PCR kit** is an *in vitro* nucleic acid amplification test for **qualitative** detection of *C. difficile* DNA in clinical material. Kit contains the Internal Control which is used in the extraction procedure in order to control the extraction process of each sample and to identify possible PCR reaction inhibition.

Analytical sensitivity is no less than 5 x 10^3 copies/ml.

B23-50-R0,2-CE	::	55	⑨

For ***DNA isolation*** *use* ***DNA Sorb B***

Salmonella typhi

This bacterium is the causative agent of typhoid fever. It is very common in under-developed countries and causes a serious, often fatal disease. The symptoms of typhoid fever include nausea, vomiting, fever and death. Unlike the other *Salmonella*, *S.* typhi can only infect humans. The main source of *S. typhi* infection is from swallowing infected water.

AmpliSens® ***Salmonella typhi*****-FL PCR** kit is designed to detect DNA *Salmonella typhi* (detection is performed by Vi-antigen genes and the first phase of flagellar H-antigen d (H1-phase flagellar antigen d), *Salmonella* spp.). That allows to differentiate *S. typhi* of Vi-antigen having *S. paratyphi C, S. dublin* and having H1-phase flagellar antigen d *S. stanley, S. isangi, S. muenchen, S. gaminara, S. utrecht*) in environmental and clinical samples.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

R-B63(RG,iQ)-CE	55	⑨	

For ***DNA isolation*** *use* ***Ribo–prep***

PCR Diagnostics Kits

Intestinal Infections

Food Pathogen Detection Kits

CE Cronobacter sakazakii

Cronobacter sakazakii is a bacterium that causes a rare but often fatal infection of the bloodstream and central nervous system that can also lead to meningitis, an inflammation of the membranes surrounding the brain and spinal cord. Infants with weakened immune system, particularly premature infants, are most likely to contract *Cronobacter* infection, although the bacteria have caused illnesses in all age groups. Most cases of *C. sakazakii* come from contaminated powdered infant formula.

AmpliSens® ***Cronobacter sakazakii*** **PCR kits** is intended for **qualitative** analysis of DNA extracted from samples of primary enrichment media or selective liquid media used for detection of *C. sakazakii*, such as Kessler's medium with glucose, Glucose broth with brilliant green and Bile or MacConkey broth). Kit contains the Internal Control in order to control the extraction process and to identify possible reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels:, **FAM/Green** and **JOE/Yellow/HEX**.

R-B58(RG,iQ)-CE	55	⑨

*For **DNA isolation** use **Ribo-prep***

CE Shigella spp. and EIEC

Enteroinvasive Escherichia coli (EIEC) infection causes a syndrome that is identical to Shigellosis, with profuse diarrhea and high fever. *EIEC* are highly invasive and they utilize adhesin proteins to bind to and enter intestinal cells. They do not produce toxins, but damage the intestinal wall through mechanical cell destruction. After ingesting the organisms of *EIEC*, there is an invasion and adhesion of the epithelial cells of the intestine. The invasion of the cells can trigger a mild form of diarrhea or dysentery, often mistaken for dysentery caused by *Shigella* species. The illness is characterized by the appearance of blood and mucus in the stool of infected individuals or by a condition called colitis. Dysentery caused by *EIEC* usually occurs within 12 to 72 hours following the ingestion of contaminated food.

AmpliSens® ***Shigella spp.*** **and** ***EIEC*** **FRT PCR kits** are amplification tests for **qualitative** detection of *Shigella spp.* and *Enteroinvasive E. coli* DNA in clinical material. PCR kits contain the Internal Control in order to control the extraction process and to identify possible PCR reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B12(RG,iQ)-CE	55	⑨
B12-FEP-CE	55	⑨

*For **DNA isolation** use **Ribo-prep***

CE EHEC

*Enterohaemorrhagic E. coli (*EHEC) can cause severe food-borne diseases. It is transmitted to humans primarily through consumption of contaminated food. *EHEC*-FRT PCR kits is intended for amplification of DNA of the genes encoding **Shiga toxins 1 and 2** (Stx1/2) in *EHEC* and *Shigella spp*. Both microorganisms can cause diseases complicated by the hemorrhagic colitis and the hemolytic-uremic syndrome.

AmpliSens® ***EHEC PCR kit*** is **qualitative** test containing Internal Control in order to control the extraction process of each individual sample and to identify possible reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B59(RG,iQ)-CE	55	⑨

*For **DNA isolation** use **Ribo-prep***

CE Salmonella spp.

Salmonellosis is an infection with bacteria called *Salmonella*. *Salmonella* bacteria are known to cause disease in humans, animals and birds (especially poultry) worldwide. The two major human diseases caused by *Salmonella spp.* are gastroenteritis and typhoid fever (typhoid and paratyphoid fevers). Most persons infected with *Salmonella* develop diarrhea, fever and abdominal cramps 12 to 72 hours after infection. Typhoid fever occurs when some of the *Salmonella* organisms are not killed by the normal human immune defenses after they enter the gastrointestinal tract. *Salmonella* then survive and grow in the human spleen, liver and other organs and may reach the blood. *Salmonella* can be spread from the liver to the gallbladder, where they can continue to survive and be secreted into the patient's feces for up to a year.

AmpliSens® ***Salmonella spp.*** **PCR kits** are intended for **qualitative** analyzis of samples of primary enrichment media (selective liquid media such as Selenite F broth, Magnesium medium). Kits contain Internal Control in order to control the extraction process of each individual sample and to identify possible reaction inhibition.

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B11(RG,iQ)-CE	55	⑨
B11-FEP-CE	55	⑨

*For **DNA isolation** use **Ribo-prep***

PCR Diagnostics Kits

Intestinal Infections

CE MultiPlex PCR Detection Kits

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX
- ROX/Orange

Rotavirus / Norovirus /Astrovirus

R-V40(RG,iQ)-CE	*One-Step RT-PCR kit*	55	⑥

Analytical sensitivity is 1 x 10^4 copies/ml – *Rotavirus, Astrov.*
Analytical sensitivity is 5 x 10^3 copies/ml – *Norovirus*

*For **RNA isolation** use **Ribo-prep***
***Reverse transcription** kit is included*

ALL SCREEN

Shigella + EIEC / Salmonella / Campylobacter/ Rotavirus / Norovirus / Astrovirus / Adenovirus

R-B45(RG,iQ)-CE	*One-Step RT-PCR kit*	55	⑥

Analytical sensitivity is 1 x 10^3 copies/ml – *Shigella, EIEC, Salmonella, Campylobacter*
Analytical sensitivity is 5 x 10^3 copies/ml – *Norovirus*
Analytical sensitivity is 1 x 10^4 copies/ml – *Adenovirus, Rotavirus, Astrovirus*

*For **RNA isolation** use **Ribo-prep***
***Reverse transcription** kit is included*

Shigella and EIEC / Salmonella / Campylobacter

R-B44(RG,iQ)-CE		55	⑨
B44-FEP-CE		55	⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*

*For **DNA isolation** use **Ribo-prep***

Yersinia enterolytica / Yersinia pseudotuberculosis

R-B64(RG,iQ)-CE		55	⑨

Analytical sensitivity is 1 x 10^3 copies/ml *(all pathogens)*

*For **DNA isolation** use **Ribo-prep***

CE *Escherichioses*

Escherichia coli is the predominant nonpathogenic facultative flora of the human intestine. Some *E. coli* strains, however, have developed the ability to cause disease of the gastrointestinal, urinary or central nervous system in even the most robust human hosts. Diarrheagenic strains of *E. coli* can be divided into at least six different categories with corresponding distinct pathogenic schemes.

In general, these organisms probably represent the most common cause of pediatric diarrhea worldwide. Several distinct clinical syndromes accompany infection with diarrheagenic *E. coli* categories, including traveler's diarrhea (*entero-toxigenic E. coli*), hemorrhagic colitis and hemolytic-uremic syndrome (*enterohemorrhagic E. coli*), persistent diarrhea (*entero-aggregative E. coli*) and watery diarrhea of infants (*entero-pathogenic E. coli*)

AmpliSens® **Escherichioses PCR test** allows **qualitative** detection and **differentiation** of *diarrheagenic E. coli* (*EPEC, ETEC, EIEC, EHEC and EAgEC*) DNA (including E. coli O157:H7 without differentiation) in environmental and clinical samples. Kit contains Internal Control that allows to check DNA extraction and amplification processes.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green, JOE/Yellow/HEX** and **ROX/Orange**.

R-B62(RG,iQ)-CE		55	⑨

*For **DNA isolation** use **Ribo-prep***

8

Ⓡ - Real-Time; ✷ - FEP; ▤ - Elfo; **::** - aliquoted form; ♦ - non-aliquoted form (usable cyclers see page 7)

PCR Diagnostics Kits

Especially Dangerous and Feral Herd Infections

Vibrio cholerae

Vibrio cholerae can cause syndromes from asymptomatic to cholera gravis. Symptoms include abrupt onset of watery diarrhoea, occasional vomiting and abdominal cramps. Dehydration ensues with symptoms and signs such as thirst, dry mucous membranes, decreased skin turgor, sunken eyes, hypotension, weak pulse, tachycardia, tachypnea, hoarse voice, oliguria, cramps, renal failure, seizures, somnolence, coma and death.

AmpliSens® ***Vibrio cholerae*** **PCR kit** enables to detect *V. cholerae* DNA (if Hly sequence is present) and identification of pathogen *V. cholerae* strains (if main virulence factors - CtxA, tcpA are present), belonging to serogroups O1 (if amplification target wbeT is present), or O139 (if amplification target wbf is present).

Analytical sensitivity is 1 x 10^3 copies/ml.

Each PCR kit contains two detection forms - **Screen kit form** - enables amplification of *CtxA* target (**FAM/Green**), *tcpA* target (**ROX/Orange**) and IC target (**JOE/Yellow/HEX**), form **Type kit form** enables amplification of *Hly* target (**JOE/Yellow/HEX**) - cholera germs of all groups, *wbeT* (**FAM/Green**) - belonging to serogroup O1 and *wbf* (**ROX/Orange**) - belonging to serogroup O139. It is necessary to carry out both "**Screen**" and "**Type**" reactions for valid results interpretation.

R-B53(RG)-CE		::	55	⑨

*For **DNA isolation** use **Ribo-prep***

Bacillus anthracis

Bacillus anthracis is typically a disease of herbivores, although it can affect other animals as well. Infection in humans traditionally has been much rarer than infection in animals. Humans can become infected with anthrax by handling products from infected animals or by breathing in anthrax spores from infected animal products. In humans, there are three possible forms of the disease anthrax - cutaneous anthrax, inhalation anthrax and intestinal anthrax.

AmpliSens® ***Bacillus anthracis*** **FRT PCR kit** is a nucleic acid amplification test for **qualitative** detection of vegetative and cryptogamic forms of *B. anthracis* DNA in biological material and environmental compartments as well as for determination of *B. anthracis* plasmid composition by identification of ***pagA*** (plasmid pXO1) and ***capA*** (plasmid pXO2) genes.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** and **ROX/Orange**.

R-B41(RG)-CE		::	55	⑥

*For **DNA isolation** use **DNA-sorb-B***

Brucella species

Brucellosis is an infectious disease caused by the bacteria of the genus *Brucella*. These bacteria are primarily passed among animals and they cause disease in many different vertebrates. Humans become infected by coming in contact with animals or their contaminated products. In humans, brucellosis can cause a range of symptoms similar to the flu and may include fever, sweats, headaches, back pains and physical weakness. Severe infections of the central nervous system or lining of the heart may occur. Brucellosis can also cause long-lasting or chronic symptoms that include recurrent fevers, joint pain and fatigue.

AmpliSens® ***Brucella spp.*** **PCR kits** are amplification tests for **qualitative** detection of *Brucella* species (*B. melitensis, B. abortus, B. suis, B. ovis, B. canis, B. neotomae*) DNA in the human (whole blood, synovial fluid, lymph node punctate) and animal (blood, milk, placenta, lymph nodes, spleen, liver of aborted fetus, parenchymal organs) samples and bacterial culture. Kits contain Internal Control in order to check the efficiency of DNA isolation process and identify possible reaction inhibition.

Analytical sensitivity is 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B10(RG)-CE			::	55	⑥
B10-R0,2-FEP-CE	**RUO**		::	55	⑨

*For **DNA isolation** use **DNA-sorb-B***

Dengue fever virus

Dengue fever is an infectious tropical disease caused by the *Dengue virus*. Symptoms include fever, headache, muscle and joint pains and a characteristic skin rash that is similar to measles. In a some cases the disease develops into the life-threatening dengue hemorrhagic fever, resulting in bleeding, low levels of blood platelets and blood plasma leakage, or into dengue shock syndrome, where dangerously low blood pressure occurs.

AmpliSens® ***Dengue virus*** **type FRT (R-V63-CE)** is ***One-Step RT-PCR*** test for **detection** and **differentiation** of *Dengue virus* types 1-4. **FAM**, **JOE**, **ROX**, **Cy5** and **Cy5,5 (Crimson)** channels are needed. Analytical sensitivity is 5 x 10^2 copies/ml.

AmpliSens® ***Dengue virus*** **FRT (R-V68-CE)** is ***One-Step RT-PCR*** test for **detection** of *Dengue virus* types 1-4 (without differentiation). Detection channels: **FAM/Green** and **JOE/Yellow/HEX** .

R-V63(RG,CFX)-CE	***differentiation of 1-4 types***	♦	60	⑨
R-V68-F-CE ***NEW***	***1-4 types screening***	♦	55	⑨

*For **RNA isolation** use **Ribo-prep. Reverse transcription** kit is included*

9

PCR Diagnostics Kits

Especially Dangerous and Feral Herd Infections

Leptospira species

Leptospirosis is a bacterial disease caused by bacteria of the genus *Leptospira,* that affects humans and animals. In humans, it can cause a wide range of symptoms, some of which may be mistaken for other diseases. Some infected persons, however, may have no symptoms at all. Without treatment, leptospirosis can lead to kidney damage, meningitis, liver failure, respiratory distress and even death.

AmpliSens® ***Leptospira*** - **FRT PCR kit** is *One-Step RT-PCR* amplification test for **qualitative** detection of *Leptospira* pathogenic genospecies 16S rRNA in the a clinical material (blood, cerebrospinal fluid), autopsy material (brain, kidney, liver, lung tissues, mesenterial lymph nodes) and biological material (tissue of lung, brain, kidney of animals), materials from dead animals (tissue of brain, lung, kidney) and animals suffering from acute infection (blood) or persistence of *Leptospira* microorganisms in kidney (urine).

PCR kit contains Internal Control in order to check RNA isolation and reverse transcription efficiency of each individual sample and to identify possible amplification reaction inhibition.

Analytical sensitivity is 5 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B49(RG)-CE	♦	60	⑨

*For **RNA isolation** use **Ribo-prep** (tissue) or **Ribo-zol-C** (blood, cerebrospinal fluid)*
***Reverse transcription** kit is included*

Borrelia burgdorferi sensu lato

Lyme disease is caused by the bacterium *Borrelia burgdorferi* and is transmitted to humans through the bite of infected black-legged ticks. Typical symptoms include fever, headache, fatigue and a skin rash called erythema migrans. If left untreated, infection can spread to joints, heart and nervous system. Lyme disease diagnostics is based on symptoms, physical findings (e.g. rash) and the possibility of exposure to infected ticks.

AmpliSens® ***Borrelia burgdorferi sensu lato - FRT*PCR kit** is amplification test for **qualitative** detection of *Borrelia burgdorferi* sensu lato (*B. burgdorferi sensu stricto, B. afzelii, B. garinii*) **16S rRNA** in the biological material. Kit is based on RNA extraction, reverse transcription and amplification of target RNA region. Such **RNA detection is much effective** and **much sensitive** than if detection is based only on DNA analyzis.

Analytical sensitivity is no less than 1 x 10^4 copies/1 ml.

Detection channels. **FAM/Green** and **JOE/Yellow/HEX**.

R-B37(RG)-CE	♦	60	⑨

*For **RNA isolation** use **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

Tick-borne encephalitis virus

Tick-borne encephalitis (TBE) is a human viral infectious disease involving the central nervous system. The disease is most often manifested as meningitis, encephalitis or meningo-encephalitis. Although TBE is most commonly recognized as a neurologic disease, mild febrile illnesses can also occur. Person-to-person transmission has not been reported, but vertical transmission from an infected mother to fetus was occurred.

AmpliSens® ***TBE*** **- FRT PCR kit** is *One-Step RT-PCR* test for **qualitative** detection of *Tick-borne encephalitis virus* RNA in the biological material (blood plasma and serum, leucocytic fraction of blood, CS fluid, autopsy human and animal material, ticks).

Analytical sensitivity is no less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V52(RG)-CE	♦	120	⑨

*For **RNA isolation** use **Ribo-prep***
***Reverse transcription** kit is included*

West Nile fever virus

West Nile virus (*WNV*) mainly infects birds, but is known to infect humans, horses, dogs and other domestic animals. The main route of human infection is through the bite of an infected mosquito. Approximately 90% of *West Nile virus* infections in humans are without any symptoms. *WNV* produces three different outcomes in humans. The first is an asymptomatic infection; the second is a mild febrile syndrome termed West Nile Fever; the third is a neuroinvasive disease termed West Nile meningitis or encephalitis. The population proportion of these three states is roughly 110:30:1.

AmpliSens® ***WNV*** **- FRT** PCR kit is *One-Step RT-PCR* test for **qualitative** detection of *West Nile virus* RNA in the clinical material (blood plasma, serum; white blood cells; cerebrospinal fluid), autopsy material of human and animals (brain tissue) and biological material (mosquitoes and ticks).

Kit contains Internal Control in order to check RNA isolation and reverse transcription processes of each individual sample and to identify possible cDNA amplification reaction inhibition.

Analytical sensitivity is not less than 5 x 10^2 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V53(RG,iQ,Mx)-CE	♦	60	⑨

*For **RNA isolation** use **Ribo-prep***
***Reverse transcription** kit is included*

PCR Diagnostics Kits

Especially Dangerous and Feral Herd Infections

CE *Crimean-Congo hemorrhagic fever virus*

Crimean–Congo hemorrhagic fever (CCHF) is a widespread tick-borne viral disease, a zoonosis of domestic animals and wild animals, that may affect humans. The pathogenic virus, especially common in East and West Africa, is a member of the *Bunyaviridae* family of RNA viruses. Clinical disease is rare in infected mammals, but it is commonly severe in infected humans, with a 30% mortality rate.

Ixodid (hard) ticks, especially those of the genus, Hyalomma, are both a reservoir and a vector for the *CCHF virus*. Numerous wild and domestic animals, such as cattle, goats, sheep and hares, serve as amplifying hosts for the virus. Transmission to humans occurs through contact with infected animal blood or ticks or from one infected human to another by contact with infectious blood or body fluids. Documented spread of *CCHF* has also occurred in hospitals due to improper sterilization of medical equipment or contamination of medical supplies.

AmpliSens® ***CCHF*** **RNA - FRT kit** is *One-Step RT-PCR* **qualitative** test for detection of virus RNA in clinical samples.

Analytical sensitivity is not less than 5 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V22-50F(RG,iQ,Mx,Dt)-CE — 60 — ⑨

*For **RNA isolation** use **Ribo-Prep***
Reverse transcription** kit **is included

CE *Yersinia pestis*

Yersinia pestis (formerly *Pasteurella pestis*) is a Gram-negative rod-shaped coccobacillus, a facultative anaerobic bacterium that can infect humans and other animals.

Human *Y. pestis* infection takes three main forms: pneumonic, septicemic and bubonic plagues. All three forms were responsible for a number of high-mortality epidemics throughout human history, including the Justinianic plague of the 6h century and the Black Death that accounted for the death of at least one-third of the European population between 1347 and 1353. It has now been shown that these plagues probably originated in rodent populations in China.

AmpliSens® ***Yersinia pestis*** **- FRT** is a qualitative qPCR kit for detection of *Y. pestis* in clinical sample - fleas, ticks, blood, urine, stool, biopsy.

Analytical sensitivity is not less than 1 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B79(RG,iQ,Dt)-CE — 60 — ⑨

*For **DNA isolation** use **Ribo-prep***

CE *Coxiella burnetii*

Coxiella burnetii is an obligate intracellular bacterial pathogen and is the causative agent of Q fever. The genus *Coxiella* is morphologically similar to *Rickettsia*, but with a variety of genetic and physiological differences. *C. burnetii* is a small Gram-negative bacterium that is highly resistant to environmental stresses such as high temperature, osmotic pressure and ultraviolet light. These characteristics are attributed to a small cell variant form of the organism that is part of a biphasic developmental cycle, including a more metabolically and replicatively active large cell variant form. It can survive standard disinfectants and is resistant to many other environmental changes like those presented in the phagolysosome.

AmpliSens® ***Coxiella burnetii*** **- FRT** is amplification test for qualitative detection of *C. burnetii* in clinical material.

Analytical sensitivity is 5 x 10^3 copies/ml of clinical sample.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-B85-50-F(RG,iQ,MX,Dt)-CE — 60 — ⑨

*For **DNA isolation** use **Ribo-prep***

CE *Ebola Zaire virus*

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.

AmpliSens® ***EBOV Zaire*** **- FRT kit** is *One-Step RT-PCR* **qualitative** test for detection of virus RNA in clinical samples.

Analytical sensitivity is 1 x 10^4 copies/ml of clinical sample.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V69-50-F-CE *NEW* — 55 — ⑫

*For **DNA isolation** use **Ribo-prep***
Reverse transcription** kit **is included

9

RUO

Zika virus

Zika virus (**ZIKV**) is a member of the virus family *Flaviviridae* It is spread by daytime-active Aedes mosquitoes, such as *A. aegypti* and *A. albopictus*. Its name comes from the Zika Forest of Uganda, where the virus was first isolated in 1947 Zika virus is related to the dengue, yellow fever, Japanese encephalitis, and West Nile viruses. Since the 1950s, it has been known to occur within a narrow equatorial belt from Africa to Asia. From 2007 to 2016, the virus spread eastward, across the Pacific Ocean to the Americas, leading to the 2015–16 Zika virus epidemic.

The infection, known as Zika fever or Zika virus disease, often causes no or only mild symptoms, similar to a very mild form of dengue fever. Zika can also spread from a pregnant woman to her fetus. This can result in microcephaly, severe brain malformations, and other birth defects. Zika infections in adults may result rarely in Guillain–Barré syndrome.

AmpliSens® ***Zika virus-FRT*** **kit** is *One-Step RT-PCR* **qualitative** test for detection of virus RNA in clinical samples.

Analytical sensitivity is not less than 2 x 10^3 copies/ml.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

ⓣ R-V73-F-CE	♦	55	⑫

*For **RNA isolation** use **Ribo-Prep***
Reverse transcription** kit **is included

9

CE MultiPlex PCR detection kits

Detecting channels:
- **FAM/Green**
- **JOE/Yellow/HEX**
- **ROX/Orange**

TBEV / B. burgdorferi sensu lato / A. phagocytophillum / E. chaffeensis / E. muris

ⓣ R-V59(RG,iQ,Mx,Dt)-CE	♦	120	⑨

Analytical sensitivity is 5 x 10^3 copies/ml *(all pathogens)*

*For **RNA isolation** use **Ribo-prep***
*For **reverse transcription** use **Reverta-L***

PCR Diagnostics Kits

HIV and HIV-associated Infections

HIV stands for 'human immunodeficiency virus'. *HIV* is a virus (of the type called retrovirus) that infects cells of the human immune system (mainly CD4 positive T cells and macrophages), and destroys or impairs their function. Infection with this virus results in the progressive deterioration of the immune system. Within the retrovirus family, *HIV* belongs to a subgroup known as lentiviruses, or "slow" viruses. Lentiviruses are known for having a long time period between initial infection and the beginning of se-rious symptoms. Similar versions of *HIV* infect other nonhuman species, such as *feline immunodeficiency virus* (*FIV*) in cats and *simian immunodeficiency virus* (*SIV*) in monkeys and other nonhuman primates.

The immune system is considered deficient when it can no longer fulfill its role of fighting off infections and diseases. Immunodeficient people are more susceptible to a wide range of infections, most of which are rare among people without immune deficiency.

Infections associated with severe immunodeficiency are known as 'opportunistic infections', because they take advantage of a weakened immune system. Some people at the time of seroconversion develop "Acute retroviral syndrome" which is a glandular fever-like illness with fever, rash, joint pains and enlarged lymph nodes.

Seroconversion refers to the development of antibodies to *HIV* and usually takes place between 1 and 6 weeks after *HIV* infection has happened.

Whether *HIV* infection causes initial symptoms or not, an *HIV* infected person is highly infectious during this initial period and can transmit the virus to another person. The only way to determine whether *HIV* is present in a person's body is by testing for HIV antibodies, DNA or RNA.

After *HIV* has caused progressive deterioration of the immune system, increased susceptibility to infections may lead to symptoms. Primary *HIV* infection - may be asymptomatic or experienced as Acute retroviral syndrome.

Clinical stage 1 - asymptomatic or generalized swelling of the lymph nodes
Clinical stage 2 - minor weight loss, mucocutaneous manifestations and recurrent upper respiratory tract infections
Clinical stage 3 - includes unexplained chronic diarrhoea, unexplained persistent fever, oral candidiasis or leukoplakia, severe bacterial infections, pulmonary tuberculosis, and acute necrotizing inflammation in the mouth. Some persons with clinical stage 3 have AIDS.
Clinical stage 4 - includes 22 opportunistic infections or cancers related to HIV. All persons with clinical stage 4 have AIDS.

RUO

HIV Infection

Human immunodeficiency virus (*HIV*) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS), a condition in humans, in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. Infection with *HIV* occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate or breast milk. Within these bodily fluids, *HIV* is present as both free virus particles and virus within infected immune cells.

There are two types of *HIV* - *HIV-1* and *HIV-2*. Ususally, unless otherwise noted, the term *HIV* primarily refers to *HIV-1*.

Both types of *HIV* damage a person's body by destroying specific blood helper T cells (CD4+) *HIV* infects also other vital cells in the human immune system such as macrophages and dendritic cells. *HIV* infection leads to low levels of CD4+ T cells through three main mechanisms: first - direct viral killing of infected cells; second - increased rates of apoptosis in infected cells and third - killing of infected CD4+ T cells by CD8 cytotoxic lymphocytes that recognize infected cells. When CD4+ T cell numbers decline below a critical level, cell-mediated immunity is lost and the body becomes progressively more susceptible to opportunistic infections.

Most untreated people infected with HIV-1 develop AIDS. These individuals mostly die from opportunistic infections or malignancies associated with the progressive failure of the immune system.

AmpliSens® **DNA *HIV* FRT** PCR kit is a **qualitative DNA test** based on the amplification of *HIV* DNA target region and Internal Control. Such Internal Control allows to determine quality of DNA extraction and amplification processes.

Analytical sensitivity is 500 GE/ml DNA (250 µl sample).

AmpliSens® ***HIV* Monitor FRT** PCR kit is ***One-Step RT-PCR* test** for **qualitative detection** and **quantitation** of *HIV* type 1 RNA in the clinical material (plasma). The RNA based kits contain Internal Control that allows to determine quality of RNA extraction, reverse transcription and amplification processes.

Analytical sensitivity is 500 copies/ml HIV-1 (100 µl sample) or 50 copies/ml HIV-1 (1 ml sample).

The linear range of **HIV Monitor - FRT** PCR kit is 500 – 10.000.000 copies/1 ml (100 µl sample) or 50 – 10.000.000 copies/1 ml (1 ml sample).

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

HIV DNA detection

TR-V0-G(RG,iQ)-CE		100	⑫

DNA extraction** kit is **included

HIV RNA detection

R-V0-M(RG,iQ,Mx,Dt)-CE	***QUANTITATIVE***	76	⑫
R-V0-MC(RG,iQ,Mx,Dt)-CE ***NEW***	***QUANTITATIVE + IC calculation coefficient***	80	⑫
R-V0-R(RG,iQ,Mx)-CE	***QUALITATIVE***	76	⑨

*For **RNA isolation** use **Ribo-prep***
Reverse transcription** kit is **included

CE *Identification of Drug Resistant Mutations: GenoScreen HLA B*5701*

AmpliSens® **Genoscreen HLA B*5701 - FRT** is a PCR test for qualitative detection of B locus 5701 allele of HLA B*5701 in clinical material (whole blood and oropharyngeal swabs).

R-O2(RG,iQ)-CE		110	⑫

Analytical sensitivity is 1 x 10^3 copies/ml

*For **DNA isolation** use **Ribo-prep** + **Hemolytic***

HIV-associated Infections

CE *Pneumocystis jirovecii (carinii)*

Pneumocystis pneumonia (PCP) or pneumocystosis is a form of pneumonia, caused by the yeast-like fungus, which had previously been classified as a protozoan, *Pneumocystis jirovecii*. This pathogen is specific to humans; it has not been shown to infect other animals, while other species of *Pneumocystis* that parasitize other animals have not been shown to infect humans.

Pneumocystis is commonly found in the lungs of healthy people. The PCP disease is relatively rare in people with normal immune systems, but being a source of opportunistic infection it can cause a lung infection of people with a weak immune system, such as premature or severely malnourished children, the elderly and especially persons with HIV/AIDS, in whom it is most commonly observed. PCP can also develop in patients who are taking immunosuppressive medications (patients after solid organ or bone marrow transplantation and after a surgery). Infections with *Pneumocystis* are also common in infants with hyper IgM syndrome.

Symptoms of PCP include fever, non-productive cough (because sputum is too viscous to become productive), shortness of breath (especially on exertion), weight loss and night sweats. There is usually not a large amount of sputum with PCP unless the patient has an additional bacterial infection. The fungus can invade other visceral organs, such as the liver, spleen and kidney, but only in a minority of cases. Pneumothorax is a well-known complication of PCP. An acute history of chest pain with breathlessness and diminished breath sounds is typical of pneumothorax.

AmpliSens® ***Pneumocystis jirovecii (carinii)* - FRT PCR kit** is an *i*nucleic acid amplification test for **qualitative** detection of *Pneumocystis jirovecii (carinii)* in the clinical material (bronchoalveolar lavage, sputum, biopsy material, throat washes and swabs) by Real-Time technology.

Analytical sensitivity is 500 copies/ml of sample.

Detection channels: **FAM/Green** and **JOE/HEX/Yellow**.

R-F2-Mod(RG,iQ,Mx)-CE	***NEW***	60	⑨

*For **DNA isolation** use **Ribo-prep***

CE *Cryptococcus neoformans*

Infection with *C. neoformans* is termed cryptococcosis and most infections consist of a lung infection. However, fungal meningitis and encephalitis, especially as a secondary infection for AIDS patients, are often caused by *C. neoformans* making it a particularly dangerous fungus. Infections with this fungus are rare in those with fully functioning immune systems. For this reason, *C. neoformans* is sometimes referred to as an opportunistic fungus. It is a facultative intracellular pathogen.

AmpliSens® ***Cryptococcus neoformans* - FRT** kit is amplification test for **qualitative** detection of *C. neoformans* in the clinical material (bronchoalveolar lavage, sputum, biopsy material, throat washes and swabs) by Real-Time technology.

Analytical sensitivity is 400 copies/1 ml of sample.

Detection channels: **FAM/Green** and **JOE/HEX/Yellow**.

R-F4-F(RG,iQ)-CE	***NEW***	110	⑨

*For **DNA isolation** use **Ribo-prep***

PCR Diagnostics Kits

Hepatitis viruses Infections

Hepatitis A virus

Hepatitis A is an acute infectious disease of the liver caused by the *hepatitis A virus* (*HAV*), an RNA virus, usually spread the fecal-oral route, transmitted person-to-person, by ingestion of contaminated food or water or through direct contact with an infectious person. *HAV* only causes acute hepatitis and is not associated with chronic liver disease. Most individuals infected with *HAV* develop non-specific constitutional signs and symptoms followed by gastrointestinal symptoms. Symptoms include fever, malaise, anorexia, nausea, abdominal discomfort, dark urine and jaundice. The disease course typically lasts less than 2 months. In rare cases, *HAV* can cause severe cases of fulminant hepatitis with fatal outcomes in otherwise healthy adults.

AmpliSens® ***HAV* PCR kits** are *One-Step RT-PCR* tests for **qualitative** detection of *Hepatitis A virus* RNA in clinical material (blood plasma, feces) and environmental objects (water samples).

Kits contain Internal Control in order to check the isolation and reverse transcription process of each individual sample and to identify possible reaction inhibition.

Analytical sensitivity is 500 copies/ml of sample.

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V4(RG,iQ)-CE		55	⑨
V4-FEP-CE		55	⑨

*For **RNA isolation** use **Ribo-prep***
Reverse transcription** kit is **included

Hepatitis B virus

Hepatitis B virus (*HBV*) is divided into **four major serotypes** (adr, adw, ayr, ayw) based on antigenic epitopes present on its envelope proteins and into eight genotypes (labeled A through H) according to overall nucleotide sequence variation of the genome. The genotypes have a distinct geographical distribution and are used in tracing the evolution and transmission of the virus. Differences between genotypes affect the disease severity, course and likelihood of complications and response to treatment and possibly vaccination. A possible new "I" genotype has been described, but acceptance of this notation is not universal. Different genotypes may respond to treatment in different ways. *HBV* is one of a few known non-retroviral viruses which use reverse transcription as a part of its replication process.

Hepatitis B is an infectious illness which infects the liver and causes an inflammation called hepatitis. Transmission of *HBV* results from exposure to infectious blood or body fluids such as semen and vaginal fluids, while viral DNA has been detected in the saliva, tears and urine of chronic carriers with high titer DNA in serum. Perinatal infection is a major route of infection in endemic countries. Other risk factors for developing *HBV* infection include working in a health care setting, transfusions and dialysis.

Acute infection with *HBV* is associated with acute viral hepatitis - an illness that begins with general ill-health, loss of appetite, nausea, vomiting, body aches, mild fever, dark urine and then progresses to development of jaundice. It has been noted that itchy skin has been an indication as a possible symptom of all *hepatitis virus* types. The illness lasts for a few weeks and then gradually improves in most affected people. A few patients may have more severe liver disease (fulminant hepatic failure) and may die as a result. The infection may be entirely asymptomatic and may go unrecognized.

Chronic infection with *HBV* may be either asymptomatic or may be associated with a chronic inflammation of the liver, leading to cirrhosis over a period of several years. This type of infection dramatically increases the incidence of hepatocellular carcinoma.

AmpliSens® ***HBV* FRT PCR kit** is an amplification test for **qualitative** detection of HBV DNA in the clinical materials (blood plasma). The Internal Control is present in order to check all detection steps - DNA extraction and amplification.

The analytical **sensitivity** depends on the DNA extraction kit as well as on the initial sample volume (50 IU/ml if sample volume is 100 µl, 5 IU/ml if sample volume is 1 ml).

AmpliSens® ***HBV* Monitor FRT PCR kit** is a test for **quantitative** detection of *HBV* DNA in clinical material (blood plasma).

The **linear measurement range** of kit is 15–100.000.000 IU/ml (1 ml sample), or 150–100.000.000 IU/ml (100 µl sample).

In both kits, Internal Control amplification product is detected on the **FAM/Green** channel and *HBV* amplification product is detected on the **JOE/Yellow/HEX** channel.

***HBV* Genotype FRT PCR** kit allows to **differentiate** A, B, C and D genotypes of HBV.

Analytical sensitivity is 500 IU/ml of sample.

Detection channels: **FAM**, **JOE**, **ROX** and **Cy5**.

R-V5-Mod(RG,iQ,Mx,Dt)-CE	***QUALITATIVE***		112	⑫
R-V5-MC(RG,iQ,Mx,Dt)-CE	***QUANTITATIVE ****		52/100	⑫
R-V5-G-F-CE ***NEW***	***Genotypes A, B, C, D***		55	⑫
V5-FEP-CE			110	⑫

*For **DNA isolation** use **Ribo-prep***
* The quantity of Rx is 100 if half reaction volume is used

RUO

Hepatitis C virus

The *hepatitis C virus* is a small, enveloped, single-stranded, positive sense RNA virus. It is the only known member of the hepacivirus genus in the family Flaviviridae. There are six major genotypes of the hepatitis C virus, which are indicated numerically - genotype 1 etc.). Based on the NS5 gene there are three major and eleven minor genotypes. *HCV* genotype matters because it can affect how successful a person's hepatitis C treatment will likely be and how long the hepatitis C medication will need to be taken.

Hepatitis C is an infectious disease primarily affecting the liver, caused by the HCV. *HCV* is transmitted by blood-to-blood contact. In developed countries, it is estimated that 90% of persons with chronic *HCV* infection were infected through transfusion of unscreened blood or blood products or via injecting drug use or sexual exposure.

The infection is often asymptomatic, but chronic infection can lead to scarring of the liver and ultimately to cirrhosis, which is generally apparent after many years. In some cases, those with cirrhosis will go on to develop liver failure or other complications, including liver cancer or life-threatening esophageal varices and gastric varices. During the first 12 weeks after infection with HCV, most people suffer no symptoms. For those who do, the main manifestations of acute infection are generally mild and vague and rarely point to a specific diagnosis of hepatitis C. Symptoms of acute *HCV* infection include decreased appetite, fatigue, abdominal pain, jaundice, itching and flu-like symptoms.

HCV is usually detectable in the blood by PCR within one to three weeks after infection and antibodies to the virus are generally detectable within 3 to 15 weeks. Liver enzyme tests show variable ALT/ALS elevation. Periodically, they might show normal results. Usually prothrombin and albumin results are normal, but may become abnormal, once cirrhosis has developed. The levels of elevation of liver tests do not correlate well with the amount of liver injury on biopsy. Viral genotype and viral load also do not correlate with the amount of liver injury. Liver biopsy is the best test to determine the amount of scarring and inflammation.

The natural course of chronic hepatitis C varies considerably from one person to another. Although almost all people infected with *HCV* have evidence of inflammation on liver biopsy, the rate of progression of liver scarring (fibrosis) shows significant variability among individuals.

Once chronic hepatitis C has progressed to cirrhosis, signs and symptoms may appear that are generally caused by either decreased liver function or increased pressure in the liver circulation, a condition known as portal hypertension. Possible signs and symptoms of liver cirrhosis include accumulation of fluid in the abdomen, bruising and bleeding tendency, varices (especially in the stomach and esophagus), jaundice and syndrome of cognitive impairment known as hepatic encephalopathy (HE). HE is due to the accumulation of ammonia and other substances normally cleared by a healthy liver.

AmpliSens® ***HCV* FRT PCR kit** is a **qualitative *One-Step RT-PCR*** test for detection of *HCV* RNA in the clinical material (blood plasma). Internal Control allows to determine the RNA extraction efficiency, reverse transcription and cDNA amplification steps.

The **analytical sensitivity** depends on the clinical sample volume and is 100 IU/ml (if the sample volume is 100 ul) or 10 IU/ml (if the sample volume is 1 ml).

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

AmpliSens® ***HCV*-1/2/3-FRT** PCR kit allows detection and **differentiation** of HCV genotypes 1, 2, and 3 in one tube. The **analytical sensitivity** depends on the clinical sample volume and is 500 IU/ml (100 ul sample) or 50 IU/ml (1 ml sample). **FAM/Green** (genotype 1), **JOE/Yellow/HEX** (genotype 2), **ROX/Orange** (genotype 3), **Red/Cy5** (IC) channels are needed.

AmpliSens® ***HCV* genotype FRT 1-4** PCR kit (RNA extraction is included) allows detection and **differentiation** of HCV genotypes 1a, 1b, 2, 3a and 4. Analytical sensitivity is not less than 2.5 x 10^3 copies/ml. Detection channels: **FAM/Green** and **JOE/Yellow/HEX/Cy3**.

AmpliSens® ***HCV* genotype FRT 1-6** PCR kit allows detection and **differentiation** of HCV genotypes 1a, 1b, 2, 3a, 4, 5a and 6. Detection channels: **FAM/Green** and **JOE/Yellow/HEX/Cy3**. Reverse transcription kit is **not included**.

AmpliSens® ***HCV* Monitor FRT** PCR kit is **quantitative *One-Step RT-PCR*** test for detection of *HCV* RNA. The **linear range** depends on the clinical sample volume and is 300-100,000,000 IU/ml (100 ul sample) or 150-100,000,000 IU/ml (200 µl sample) or 30-100,000,000 IU/ml (1 ml sample).

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V1-Mod(RG,iQ,Mx,Dt)-CE	***QUALITATIVE***	♦	112	⑫
R-V1-G-4x(RG,iQ,Mx)-CE	***Genotypes 1/2/3***	♦	55	⑨
R-V1-G(1-6)-2x(RG,iQ,Mx,Dt,SC)-CE	***Genotypes 1-6***	♦	55	⑨
TR-V1-G-2x(RG,iQ,SC)-CE	***Genotypes 1-4***	♦	48	⑨
R-V1-G(1-4)-2x(RG,iQ,Dt,SC)-CE	***Genotypes 1-4***	♦	55	⑫
R-V1-MC(RG,iQ,Mx,Dt)-CE	***QUANTITATIVE****	♦	50/100	⑫
V1-FEP-CE	***QUALITATIVE***	♦	110	⑫
V1-G-FEP-CE	***Genotypes 1/2/3***	♦	55	⑨

*For **RNA isolation** use **Ribo-prep***

***Reverse transcription** kit is **included** (ex* R-V1-G(1-6)2x(RG,iQ,Mx,Dt,SC)-CE and R-V1-G(1-4)2x(RG,iQ,Dt,SC)-CE)

***RNA extraction** kit is **included** only in TR-V1-G-2x(RG,iQ,SC)-CE*

* The quantity of Rx is 100 if half reaction volume is used

PCR Diagnostics Kits

Hepatitis viruses Infections + HIV

RUO

Hepatitis D virus

Hepatitis D is caused by a small circular enveloped RNA virus. *HDV* is considered to be a subviral satellite because it can propagate only in the presence of the *HBV*. Transmission of *HDV* can occur via simultaneous infection with *HBV* (coinfection) or superimposed on chronic hepatitis B or hepatitis B carrier state (superinfection). Both superinfection and coinfection with *HDV* results in more severe complications than with *HBV* alone. AmpliSens® ***HDV*** **PCR kits** are *One-Step RT-PCR* tests for **qualitative** or **quantitative** detection of *HDV* RNA in the clinical material (blood plasma). Kits contain Internal Control in order to check the RNA solation, reverse transcription and amplification proces and to identify possible reaction inhibition.

The **analytical sensitivity** depends on the sample volume and is 100 copies/ml (100 ul sample), 50 copies (200 ul sample), 10 Icopies (1 ml sample). Linear **measurement range** of ***HDV*** **Monitor FRT** depends on the clinical sample volume and is 40 – 100.000.000 IU/ml (100 ul sample) or 20 – 100.000.000 IU/ml (200 µl sample) or 4 – 100.000.000 IU/ml (1 ml sample).

Detection channels: **FAM/Green** and **JOE/Yellow/HEX**.

R-V3-MC(RG,iQ,Mx,Dt)-CE	***QUANTITATIVE***	80	⑫
R-V3(RG,iQ,Mx,Dt)-CE	***QUALITATIVE***	110	⑫
V3-FEP-CE		110	⑫

*For **RNA isolation** use **Ribo-prep***
Reverse transcription** kit is **included

CE

Hepatitis G virus

Hepatitis G is a form of liver inflammation caused by *HGV* from *Flaviviridae* family. It is known that transfused blood containing *HGV* has caused some cases of hepatitis. For this reason, patients with hemophilia and other bleeding conditions who require large amounts of blood products are at risk of hepatitis G. Also at risk are patients with kidney disease with blood exchange by hemodialysis.

AmpliSens® ***HGV*** **PCR FRT Kit** is *One-Step RT-PCR* **qualitative** test for detection of *HGV* in clinical samples. FRT kit contains IC for detection of RNA extraction, reverse transcription and cDNA amplification.

The analytical sensitivity depends on the sample volume and is 500 IU/ml (sample volume 100 ul) or 50 IU/ml (sample volume 1 ml).

Detection channels: **FAM/Green** and **JOE/HEX/Yellow**.

R-V2-50-F(RG,iQ,Mx,Dt)-CE	55	⑫

*For **RNA isolation** use **Ribo-prep***
Reverse transcription** kit is **included

MultiPlex PCR Detection Kits

Detecting channels:
- FAM/Green
- JOE/Yellow/HEX
- ROX/Orange
- Cy5/Red

RUO

HCV/HBV/HIV

AmpliSens® ***HCV/HBV/HIV*** **FRT PCR kit** is a multiplex PCR test for qualitative detection and **differentiation** of *HCV/HBV/HIV-1 or HCV/HBV/HIV-1/HIV-2* in one reaction.

The **analytical sensitivity** of the kits depend on the clinical sample volume and is for: **HCV** 100 IU/ml (100 ul sample) or 10 IU/ml (1 ml sample), for **HBV** 50 IU/ml (100 ul sample) or 5 IU/ml (1 ml sample), for **HIV-1** 200 copies/ml (100 ul sample) or 20 copies/ml (1 ml sample). For **HIV-2** 600 copies/ml (100 ul sample) 60 copes/ml (1 ml sample)

Detection channels for ***HCV/HBV/HIV-1 FRT*** kit are*:* **FAM/Green**, **JOE/Yellow/HEX, ROX/Orange** and **Cy5/Red**.

Detection channels for ***HCV/HBV/HIV-1/HIV-2 FRT*** *kit are:* **FAM/Green**, **JOE/Yellow/HEX, ROX/Orange** , **Cy5/Red** and **Cy5.5/Crimson/Quasar705**.

R-V50-4x(RG,iQ,Mx,Dt)-CE	100	⑨
R-V62(RG,Dt)-CE	***NEW***	100	⑫

*For **DNA/RNA isolation** use **Ribo-prep***
Reverse transcription** kit is **included

RUO

HBV/HDV

R-V56(RG,iQ,Mx,Dt)-CE	112	⑫

Analytical sensitivity for **HBV** is 100 IU/ml (100 ul sample) or 50 IU/ml (200 ul sample) or 10 IU/ml (1 ml sample), for **HDV** 100 copies/ml (100 ul sample) or 50 copies/ml (200 ul sample) or 10 copies/ml (1 ml sample).

*For **DNA/RNA isolation** use **Ribo-prep***
One-Step RT-PCR kit** - **Reverse transcription** kit is **included

CE

Genoscreen IL 28B

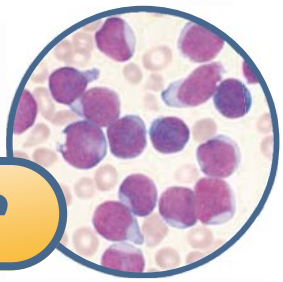
PCR test for detection of SNP rs8099917 and rs12979860 in Interleukin 28B gene. Analytical sensitivity is no less than 5 x 10^3 copies/ml.

Detection channels: **FAM/Green**, **JOE/Yellow/HEX** , **ROX/Orange**.

R-O5-100-F(RG,iQ,Dt,CFX)-CE	110	⑫

*For **DNA isolation** use **Ribo-prep** + **Hemolytic***

11



Oncological Disease

CE Leukosis Quantum M-bcr

Chronic myelogenous (or myeloid) leukemia (CML), also known as chronic granulocytic leukemia (CGL), is a cancer of the white blood cells. It is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood. CML is a clonal bone marrow stem cell disorder in which proliferation of mature granulocytes (neutrophils, eosinophils, and basophils) and their precursors is the main finding. It is a type of myeloproliferative disease associated with a characteristic chromosomal translocation called the Philadelphia chromosome. CML is now largely treated with tyrosine kinase inhibitors (TKIs), such as imatinib, dasatinib or nilotinib, which have led to dramatically improved survival rates since their introduction in the last decade.

CML was the first malignancy to be linked to a clear genetic abnormality, the chromosomal translocation known as the Philadelphia chromosome. In this translocation, parts of two chromosomes (the 9th and 22nd by conventional karyotypic numbering) switch places. As a result, part of the BCR ("breakpoint cluster region") gene from chromosome 22 is fused with the ABL gene on chromosome 9. This abnormal "fusion" gene generates a protein of p210 or sometimes p185 weight (p210 is short for 210 kDa protein, a shorthand used for characterizing proteins based solely on size). Because *abl* carries a domain that can add phosphate groups to tyrosine residues (a tyrosine kinase), the *bcr-abl* fusion gene product is also a tyrosine kinase.

The fused BCR-ABL protein interacts with the interleukin 3 beta (c) receptor subunit. The *bcr-abl* transcript is continuously active and does not require activation by other cellular messaging proteins. In turn, BCR-ABL activates a cascade of proteins that control the cell cycle, speeding up cell division. Moreover, the BCR-ABL protein inhibits DNA repair, causing genomic instability and making the cell more susceptible to developing further genetic abnormalities. The action of the BCR-ABL protein is the pathophysiologic cause of chronic myelogenous leukemia.

With improved understanding of the nature of the BCR-ABL protein and its action as a tyrosine kinase, targeted therapies (the first of them was imatinib mesylate) that specifically inhibit the activity of the BCR-ABL protein, have been developed. These tyrosine kinase inhibitors can induce complete remissions in CML, confirming the central importance of *bcr-abl* as the cause of CML.

Clinically, leukemia is manifested in three distinct phases: chronic, accelerated, and blast. Most patients present in the chronic phase, a stage that is typically indolent in nature. Mature granulocytes are found, but patients typically have an increase in the number of myeloid progenitor cells found in the blood. Left untreated, the disease progresses to an accelerated phase followed by blast crisis, which is inevitably fatal. During blast phase, hematopoietic differentiation is blocked and blast cells accumulate in the bone marrow and peripheral blood. Expression of BCR-ABL onco-proteins in hematopoietic cells induces resistance to apoptosis, growth factor independence and leukomogenesis.

AmpliSens® **Leukosis Quantum M-*bcr*-FRT PCR kit** is an in vitro nucleic acid amplification test for **qualitative** and **quantitative detection** of the ***bcr-abl* chimeric gene** (M-bcr variant) **mRNA** and ***abl* gene mRNA** in the clinical materials (peripheral blood, bone marrow) by using Real-Time PCR method. Kit can be used for screening and detection of CML associated with M-*bcr-abl* chromosomal rearrangement, for confirmation of CML diagnosis, monitoring of the minimal residual disease (MRD) and therapy efficiency.

Leukosis Quantum M-bcr-FRT PCR kit **is intended for one of the formats**:

1. Quantitative analysis: 50 clinical samples in two replicates.
2. Qualitative analysis (screening): 100 clinical samples (120 RNA extractions, 120 reverse transcription reactions and 360 PCR reactions, including controls).

PCR Diagnostics Kits

Oncology Disease

Principle of detection is based on amplification with Real -Time detection (two oligonucleotide mixes are used):

amplification of mRNA fragment of the chimeric M-*bcr-abl* (p210) gene, that conform to fragment of *bcr* and *abl* (b2a2 and b3a2) genes linkage and mRNA fragment of *abl* gene splicing site (recommended by Europe Against Cancer (EAC) group) as an endogenous Internal Control and gene normalizer.

The **detection sensitivity** by treatment of 2.5 ml blood sample is 20 – 30 mRNA copies/ml.

Detection channel: **JOE/Yellow/HEX**

TR-O1(RG,iQ,Mx,A)-CE ***QUANTITATIVE*** 50/100 ⑫

RNA extraction *and* ***Reverse transcri ption*** *kits are included*

Additional Kits

DNA and RNA Extraction Kits

DNA-sorb-AM

Kit for **DNA** extraction from clinical material (smears, scrapes, urine...). K1-11 includes Internal Control for sexually transmitted diseases detection.

Kit K1-12 is without STD Internal Control, but such Control is always included in all STD amplification kits.

K1-11-100-CE	**with** STD Internal Control	100	⑫
K1-12-100-CE	**without** STD Internal Control	100	⑫

DNA-sorb-B

Kit for **DNA** extraction from whole blood, bioptats, fecal extract.

K1-2-50-CE	50	⑫
K1-2-100-CE	100	⑫

DNA-sorb-C

Kit for **DNA** extraction from bioptats, human tissues, food samples, supplements and plants material.

K1-6-50-CE	50	⑨

CYTOLYSIN

Kit for **DNA** extraction from white blood cells.

K1-3-100-CE	100	⑥

EDEM

Kit for **DNA** extraction by EXPRESS method from urogenital, throat and conjunctiva swabs, erosive and ulcerative elements of mucous membranes and skin, urine.

K2-17-100-CE	100	⑫

AUTO-sorb

Kit for **DNA/RNA** extraction, silica sorbtion based method using X-Tractor Gene (Corbett Robotics) automated system.

K2-14-96-CE	96	⑨

RIBO-prep

Kit for **RNA/DNA** extraction by precipitation method from blood plasma, liquor, saliva, amniotic fluid and smears.

K2-9-Et-50-CE	50	⑨
K2-9-Et-100-CE	100	⑨

RIBO-sorb

Kit for **RNA/DNA** extraction by affine sorption on silicagel.

K2-1-Et-50-CE	50	⑨
K2-1-Et-100-CE	100	⑨

RIBO-zol-A

Kit for **RNA** extraction from clinical material (white blood cells) by shortened Guanidine/Phenol/Chloroform method.

K2-2-50-CE	50	⑥
K2-2-100-CE	100	⑥

RIBO-zol-B

Kit for **RNA** extraction from clinical material (white blood cells, cells suspensions and homogenate bioptat) by Guanidine/Phenol/Chloroform method (classical).

K2-3-100-CE	100	⑥

RIBO-zol-C

Kit for **DNA/RNA** extraction intended for the first stage of extraction of total RNA from clinical biological materials. Following purification and concentration of RNA performed by sorption or precipitation methods are required. Kit is used for *Leptospira* and *Flavivirus* nucleic acid extraction by using RIBO-sorb or RIBO-prep.

K2-13-50-CE	50	⑥

MAGNO-sorb

Kit for **DNA/RNA** extraction with magnetic beads.

K2-16-200-CE	200 ml of material	100	⑮
K2-16-1000-CE	1,000 ml of material	100	⑮

Additional Kits

Reverse Transcription
Electrophoretic Detection
Transport and Storage Media

CE *Reverta-L*

Reverse transcription kit including RT-G-mix-1.

K3-4-50-CE	60	⑨
K3-4-100-CE	120	⑨

CE *EPh*

Qualitative electrophoretic detection of the amplified products in agarose gel. EPh detection agarose kit is based on electrophoretic separation of amplified DNA fragments in agarose gel with following UV-detection. Concentrated TBE buffer with EtBr stain and agarose are included.

K5-200-CE		240	⑨
K5-300-CE		360	⑨
K6-200-CE	*for genotyping*	144	⑨
K6-300-CE	*for genotyping*	216	⑨

CE *Transport media with mucolysin*

Transport media for clinical material from male and female urogenital tract with mucolytic and stabilizator (pink color).

952-CE	50 ml	⑫

CE *Transport media for storage and transportation of respiratory swabs*

Transport medium for storage and transporting of respiratory swabs.

957-CE	50 ml	⑫

CE *Transport medium TM-EDEM*

Transport medium for use with EDEM nucleic acid extraction kit.

1533-CE	50 ml	⑫

CE *RNA-media*

Transport media for storage and stabilization of whole blood RNA.

981-CE	100 ml	⑫

CE *Mucolysin*

Medium for sputum preliminary treatment.

180-CE	200 ml	⑥

CE *Hemolytic*

Reagent for pretreatment of whole peripheral and umbilical cord blood.

137-CE	100 ml	⑥

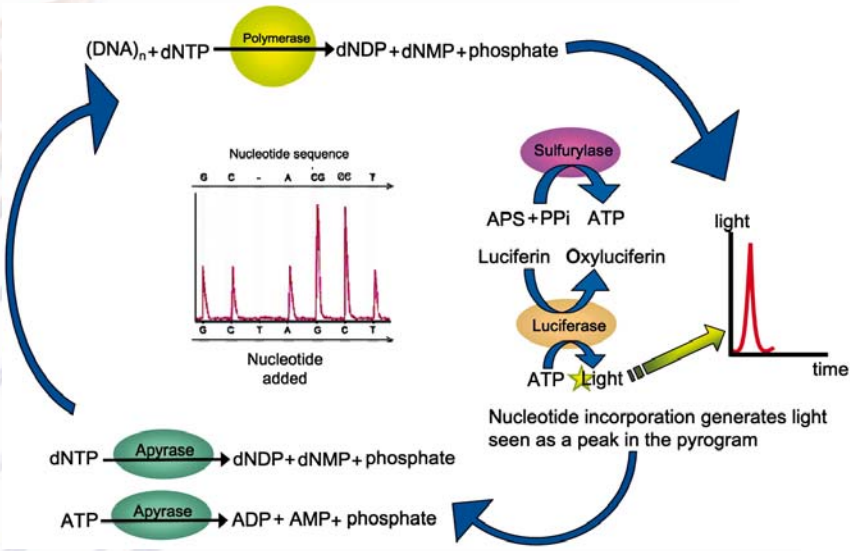
13

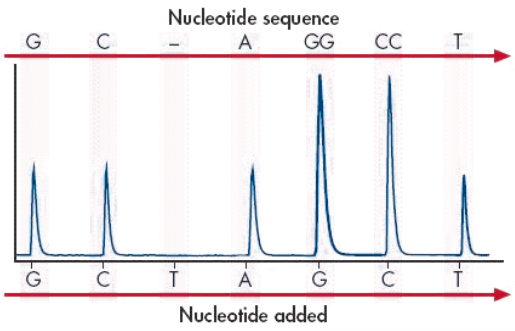
Ecoli s.r.o. *offers wide range of SNP kits, based on pyrosequencing technology, for rapid and cost-effective analyzis of human DNA in clinical samples.*

Pyrosequencing technology is a unique method for short-read DNA sequencing and mutation or SNP analysis. It is suitable for applied genomics including molecular applications for disease diagnosis, clinical prognosis and pharmacogenomics testing.

Principle

Pyrosequencing is based on the detection of released pyrophosphate (PPi) during DNA synthesis. In a cascade of enzymatic reactions, visible light is generated that is proportional to the number of incorporated nucleotides. The cascade starts with a nucleic acid polymerization reaction in which inorganic PPi is released as a result of nucleotide incorporation by polymerase. The released PPi is subsequently converted to ATP by ATP sulfurylase, which provides the energy to luciferase to oxidize luciferin and generates light. Because the added nucleotide is known, the sequence of the template can be determined. When the light signal is detected, the base is registered and the next nucleotide is added. If the added nucleotide is not complementary to the next base in the template, no light is generated.





There are two different pyrosequencing strategies that are currently available: solid-phase pyrosequencing and liquid-phase pyrosequencing. Solid-phase pyrosequencing utilizes immobilized DNA in the three-enzyme system described previously. In this system, a washing step is performed to remove the excess substrate after each nucleotide addition. In liquid-phase pyrosequencing apyrase, a nucleotide-degrading enzyme from potato, is introduced to make a four-enzyme system. Addition of this enzyme eliminates the need for solid support and intermediate washing thereby enabling the pyrosequencing reaction to be performed in a single tube.

The combination of instrumentation, dedicated software and reagent kits make pyrosequencing technology ideal for analysis of

Human SNP Kits

Description

all genetic diversities such as bi-tri- and tetra-allelic polymorphisms, multiple SNPs, mutations and insertions/deletions (InDels).

Pyrosequencing is unique among genotyping methods in that the measurement of every allele is fully quantitative. This property has made pyrosequencing a primary choice for SNP screening in DNA pools, quantification of the degree of DNA /CpG methylation in epigenetic research, the analysis of hematopoeitic chimerism and discriminating between mixed genotypes in heterogeneous samples (e.g. tumor and normal cells). Because both alleles are extracted and measured in a single sample, this method is insensitive to differences in extraction efficiency and eliminates the need for control genes or quantification of total RNA recovery. Samples for pyrosequencing detection can be blood, tissue or cells collected on a swab.

Methodology of Human SNP Kits

Pyrosequencing detection human SNP kits in offered list belong to the solid-phase form and are fully optimized for ***PyroMark Q24*** or ***PyroMark Q96*** (Qiagen) analyzers.

The principle of SNP analyzis using PYRO-Screen kits is universal:

1. Upon DNA extraction, PCR of studied genetic locus is performed with the use of specific primers.

2. A biotinylated primer is used for subsequent immobilization of amplification product and sample preparation. The direction of sequencing determines the type of analysis (forward or reverse). Reverse biotinylated primers are used in forward analysis and forward biotinylated primers are used in reverse analysis.

3. A PCR product binds to streptavidin-coated Sepharose beads and then is used for subsequent purification of reaction mixture to obtain a single-stranded DNA fragment by serial washes performed with a Vacuum Prep Workstation. Streptavidin Sepharose High Performance reagent (GE Healthcare) is used for amplicon binding. When purification and immobilization of a single-stranded PCR product are completed, relevant genetic locus is sequenced using pyrosequencing technology.

4. At the PCR stage, the reagent kit uses "hot-start", which greatly reduces the frequency of nonspecifically primed reactions. "Hot-start" is guaranteed by separation of nucleotides and Taq-polymerase by using a chemically modified polymerase. PCR and sequencing are performed by PyroMark machine and sequences are analyzed by PyroMark software.

Cardiovascular Diseases

Arterial Hypertension (AH) Profile

Cat. no.	Profile	No. of Rx
PMQ-004-50-F	**Arterial hypertension («AH») profile**	55

Description:

Product	Gene	Polymorphism	rs
1. Adrenoreceptor β 2 «AH-1»	ADRB2	G16R G>A	rs1042713
2. Angiotensionogene «AH-2»	AGT	T207M C>T	rs4762
3. Angiotensionogene «AH-3»	AGT	M268T T>C	rs699
4. Receptor 1 angiotensin II type «AH-4»	AGTR1	A1666C	rs5186
5. Nitric oxide synthase «AH-5»	NOS3	D298E T>G	rs1799983

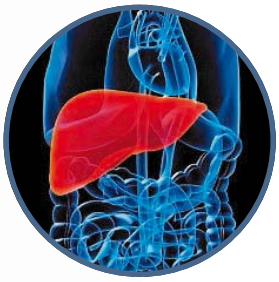
Ischemic Heart Disease (IHD)

Cat. no.	Profile	No. of Rx
PMQ-018-50-F	**Ischemic heart disease profile**	55

Description:

Product	Gene	Polymorphism	rs
1. Adenosinmonophosphate-desaminase 1 «IHD-1»	AMPD1	Q12X G>A	rs17602729
2. Inhibitors of cyclin-dependent kinase «IHD-2»	CDKN2A/2B	G>C	rs1333049
3. Hypoxia induced factor 1 alfa «IHD-3»	HIF1A	P582S C>T	rs11549465
4. Matrix metalloproteinase 3 «IHD-4»	MMP3	5A>6A	rs3025058
5. Apolipoprotein E (*4) «LM-1»	APOE	C112R T>C	rs429358
6. Apolipoprotein E (*2) «LM-2»	APOE	R158C C>T	rs7412

Lipid Metabolism



Basic Profile

Cat. no.	Profile	No. of Rx
PMQ-019-50-F	**Lipid metabolism, basic profile**	55

Description:

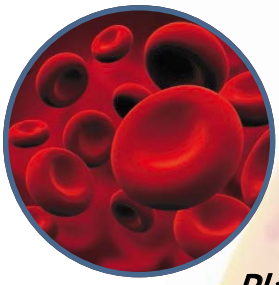
Product	Gene	Polymorphism	rs
1. Apolipoprotein E (*4) «LM-1»	APOE	C112R T>C	rs429358
2. Apolipoprotein E (*2) «LM-2»	APOE	R158C C>T	rs7412
3. Apolipoprotein B «LM-3»	APOB	R3527Q G>A	rs5742904
4. Apolipoprotein B «LM -4»	APOB	G>A	rs754523
5. Serin protease «LM -5»	PCSK9	T>C	rs11206510

Supplementary Profile (LMBP)

Cat. no.	Profile	No. of Rx
PMQ-013-50-F	**Lipid metabolism, supplementary profile**	55

Description:

Product	Gene	Polymorphism	rs
1. ABCA1 transporter «LM-6»	ABCA1	R219K G>A	rs2230806
2. Apolipoprotein C3 «LM-7,8»	APOC3	-455 C>T	rs2854116
3. Apolipoprotein C3 «LM-7,8»	APOC3	-482 C>T	rs2854117
4. Apolipoprotein C3 «LM-9»	APOC3	G>C	rs5128
5. Lipoprotein lipase «LM -10»	LPL	N318S A>G	rs268
6. Lipoprotein lipase «LM -11»	LPL	S447X C>G	rs328
7. Paraoxonase-1 «LM -12»	PON1	L55M A>T	rs854560
8. Paraoxonase-1 «LM -13»	PON1	Q192R A>G	rs662



Pathology of Blood Coagulation System

Plasma Factors of Blood Coagulation System (PFBC)

Cat. no.	Profile	No. of Rx
PMQ-001-50-F	**Plasma factors of blood coagulation system**	55

Description:

Product	Gene	Polymorphism	rs
1. Prothrombin (FII) «PF-1»	F2	G>A	rs1799963
2. Leiden's factor (FV) «PF-2»	F5	R534Q A>G	rs6025
3. Coagulation factor VII «PF-3»	F7	R353Q	rs6046
4. Fibrinogen «PF-4»	FGB	–455 G>A	rs1800790
5. Inhibitor of plasminogen activator «PF-5»	SERPINE1	–675 (5G/4G)	rs1799768

Folate Cycle (CSFC)

Cat. no.	Profile	No. of Rx
PMQ-002-50-F	**Folate cycle**	55

Description:

Product	Gene	Polymorphism	rs
1. Methylentetrahydrofolat reductase «FC-1»	MTHFR	A222V C>T	rs1801133
2. Methylentetrahydrofolat reductase «FC-2»	MTHFR	E429A A>C	rs1801131
3. Methionine synthase «FC-3»	MTR	D919G A>G	rs1805087
4. Methionine synthase reductase «FC-4»	MTRR	I22M A>G	rs1801394
5. Folate's transporter «FC-5»	SLC19A1	H27R A>G	rs1051266

Aggregation Factors of Blood Coagulation System (AFBC)

Cat. no.	Profile	No. of Rx
PMQ-003-50-F	**Aggregation factors of blood coagulation system**	55

Description:

Product	Gene	Polymorphism	rs
1. Platelet glycoprotein 1B «AF-1»	GP1BA	T-5C	rs2243093
2. Platelet glycoprotein 1B «AF-2»	GP1BA	T145M C>T	rs6065
3. Platelet fibrinogen receptor «AF-3»	ITGB3	L33P (A1/A2)	rs5918
4. Janus kinase 2 «AF-4»	JAK 2	V617F G>T	rs77375493
5. Selectin P ligand of glycoprotein «AF-5»	SELPLG	M62I A>G	rs2228315

Human SNP Kits

Breast/Ovarian Cancer

Cat. no.	Profile	No. of Rx
PMQ-005-50-F	**Breast/ovarian cancer**	55

Description:

Product	Gene	Polymorphism	rs
1. Breast cancer gene 1 «B1-AG»	BRCA1	185delAG	
2. Breast cancer gene 1 «B1-61»	BRCA1	300T>G (C61G)	rs28897672
3. Breast cancer gene 1 «B1-7A»	BRCA1	2080delA	
4. Breast cancer gene 1 «B1-A»	BRCA1	4153delA	
5. Breast cancer gene 1 «B1-C»	BRCA1	5382insC	
6. Breast cancer gene 2 «B2-T»	BRCA2	6174delT	

Osteoporosis (OST)

Cat. no.	Profile	No. of Rx
PMQ-008-50-F	**Osteoporosis**	55

Description:

Product	Gene	Polymorphism	rs
1. Collagen, type 1 «OST-1»	COL1A1	IVS1, 2046G>T	rs1800012
2. Estrogene receptor «OST-2»	ESR1	T>C (PvuII)	rs2234693
3. Estrogene receptor «OST-3»	ESR1	A>G (XbaI)	rs9340799
4. Lactase «OST-4»	LCT	-13910 C>T	rs4988235
5. Low density lipoprotein receptor «OST-5»	LRP5	A1330V	rs3736228
6. Vitamin D receptor «OST-6»	VDR	C>T (G>A) BsmI	rs1544410

Diabetes mellitus

Diabetes mellitus 1 type (DM1)

Cat. no.	Profile	No. of Rx
PMQ-009-50-F	**Diabetes mellitus 1 type**	55

Description:

Product	Gene	Polymorphism	rs
1. NatB subunit «DM1-1»	C12ORF30	A>G	rs17696736
2. C-type lectin domain family 16 «DM1-2»	CLEC16A	A>G	rs12708716
3. rs2544677 «DM1-3»	–	G>C	rs2544677
4. Insulin «DM1-4»	INS	A>T	rs689
5. Tyrosin phosphotase «DM1-5»	PTPN22	G>A	rs2476601

Diabetes mellitus 2 type (DM2) - Basic Profile

Cat. no.	Profile	No. of Rx
PMQ-015-50-F	**Diabetes mellitus 2 type, basic profile**	55

Description:

Product	Gene	Polymorphism	rs
1. ATP-sensitive inward rectifier potassium channel «DM2-1»	KCNJ11	E23K C>T	rs5219
2. Trascription factor PPAR gamma «DM 2-2»	PPARG	P12A C>G	rs1801282
3. Trascription factor 7 «DM 2-3»	TCF7L2	IVS3C>T	rs7903146
4. Trascription factor 7 «DM 2-4»	TCF7L2	IVS4G>T	rs12255372

Human SNP Kits

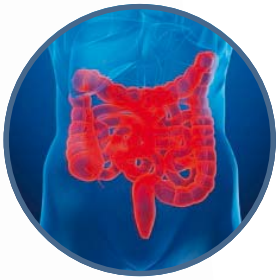
Obesity

Cat. no.	Profile	No. of Rx
PMQ-006-50-F	**Obesity**	55

Description:

Product	Gene	Polymorphism	rs
1. FTO-gene (Fat mass and obesity -associated gene) «OB-1»	FTO	IVS1 A>T	rs9939609
2. Transcription factor PPAR delta «OB-2»	PPARD	–87 T>C	rs6902123
3. Coactivator 1a PPARG «OB-3»	PPARGC1A	S482G A>G	rs8192678
4. Coactivator 1b PPARG «OB-4»	PPARGC1B	A203P G>C	rs7732671

Crohn's Disease



Cat. no.	Profile	No. of Rx
PMQ-007-50-F	**Crohn's disease**	55

Product	Gene	Polymorphism	rs
1. Caspase activator «CD-1»	NOD2	R702W	rs2066844
2. Caspase activator «CD-2»	NOD2	G908R	rs2066845
3. Transcription factor «CD-3»	NKX2-3	A>G	rs10883365
4. Thyrosin phosphotase «CD-4»	PTPN2	T>G	rs2542151

PYRO-prep

Cat. no.	Description
PMQ-P	Binding of PCR-product, purification of reaction mixture and amplicons' denaturation with «PyroMark Q24 Vacuum Prep Workstation».
ATTENTION !	Additional eagents needed for pyrosequencing analyzis: Streptavidin Sepharose High Performance (GE Healthcare) PyroMark Plate and PyroMark Gold Reagents (Qiagen)

Ordering

How to Order

Orders can be sent to us by:

- email: ecoli@ecoli.sk
- fax: +421 2 6478 9040
- address:

Ecoli s.r.o.
Studenohorská 12
841 03 Bratislava
Slovak Republic

Ordered products will be sent out to you within app. 4 weeks after the deadline. If you do not receive confirmation of your order, please contact us as by return.

The ordering dates are listed on our web page www.pcrdiagnostics.eu

Required Information

Following informations are required by ordering:

- Product names
- Catalog numbers
- Specification (like number of reactions)
- Shipping address
- Billing address
- VAT number (EU only)
- Contact person
- Phone or cell number

Customer Care

We are committed to provide supreme services for our customers. All inquiries are answered and to all technical questions is given high priority and our full attention.

Shipping

Shipping costs are calculated for every shipment separately, because every box has different dimensions and weight. This system is customer-friendly because you pay for real shipping costs.

Terms of Payment

Ecoli s.r.o. accepts payments by wire transfer. Other payment methods are allowed after discussion.

Be Informed About DEADLINES!

Ask for regular sending of info about our orders deadlines. Sending of your order before deadline reduces delivery time to the minimum (approx. 4 weeks). If you send your order after deadline, it will be processed in the next deadline.

Ecoli s.r.o.

Studenohorská 12, 841 03 Bratislava

Slovak Republic

tel.: +421 2 64 789 336 • fax: +421 2 64 789 040

ecoli@ecoli.sk • www.ecoli.sk • www.pcrdiagnostics.eu