CATALOG

PCR diagnostics kits
Molecular biology products
Human SNP kits
CATALOG

PCR Diagnostics Kits

Molecular Biology Reagents

Human SNP Kits

www.pcrdiagnostics.eu
1. Sexually Transmitted Infections

Chlamydia trachomatis ......................................................... 11
Neisseria gonorrhoeae .......................................................... 11
Treponema pallidum ............................................................... 12
Trichomonas vaginalis ............................................................ 12
Mycoplasma genitalium ......................................................... 12
Mycoplasma hominis .............................................................. 12
Ureaplasma species .............................................................. 13
Ureaplasma species differentiation ........................................ 13
Gardnerella vaginalis ............................................................. 13
Candida albicans ................................................................. 13

MultiPlex PCR Detection Kits ................................................. 14
N. gonorrhoeae / T. vaginalis .................................................. 14
C. trachomatis / Ureaplasma / M. genitalium / M. hominis ........ 14
C. albicans / C. glabrata / C. krusei ........................................ 14
C. trachomatis / Ureaplasma / M. genitalium ......................... 14
C. trachomatis / Ureaplasma .................................................. 14
M. hominis / G. vaginalis ....................................................... 14
T. vaginalis / N. gonorrhoeae / C. trachomatis ....................... 14
N. gonorrhoeae /C. trachomatis / M. genitalium / T. vaginalis ... 14
G. vaginalis / Lactobacillus species ........................................ 14
C. trachomatis / Ureaplasma / M. hominis .............................. 14
N. gonorrhoeae /C. trachomatis / M. genitalium .................... 14
Florocenosis / Bacterial vaginosis ......................................... 15
Florocenosis / Candida .......................................................... 15
Florocenosis / Mycoplasma ................................................... 15
Florocenosis / Aerobes .......................................................... 15

2. Human Papilloma virus Infections

High-Risk Human Papilloma virus Infections .......................... 16
Low-Risk Human Papilloma virus Infections .......................... 16

3. TORCH Infections

Toxoplasma gondii ................................................................. 17
Parvovirus B19 ................................................................. 17
Rubella virus ........................................................................ 18

4. Herpes-virus Infections

Cytomegalovirus ................................................................. 19
Epstein-Barr virus ............................................................... 19
Varicella zoster virus ........................................................... 20
Human Herpes virus 6 .......................................................... 20
Herpes Simplex virus HSV-1, HSV-2 .................................... 20
Herpes Simplex virus Genotyping ........................................ 21
5. Purulent Septic Infections
- MRSA
- Streptococcus agalactiae
- Pseudomonas aeruginosa
- Streptococcus pyogenes
- Genetic Markers of Antibiotic Resistance
  - VIM, IMP and NDM
  - KPC and OXA-48

6. Respiratory Infections
- Avian Influenza (bird flu), Subtype H5N1
- Influenza virus A/H1 (swine flu)
- Influenza virus A/B
- Influenza virus A-type H5, H7, H9
- Influenza virus A/H1N1 & H3N2
- Adenovirus
- Parainfluenza virus
- Mycobacterium tuberculosis complex
- Respiratory-Syncytial virus (hRSV)
- Legionella pneumophila
- MERS and SARS – Coronavirus
- MultiPlex PCR Detection Kits
  - Acute Respiratory Viral Infections (ARVI)
  - Bordetella multi
  - Mycoplasma pneumoniae / Chlamydia pneumoniae

7. Neuro Infections
- Enterovirus
- Poliovirus
- Listeria monocytogenes
- MultiPlex PCR Detection Kits
  - Neisseria meningitidis / Haemophilus influenzae / Streptococcus pneumoniae

8. Intestinal Infections
- Campylobacter species
- Helicobacter pylori
- Clostridium difficile
- Salmonella typhi
- Food Pathogen Detection Kits
  - Cronobacter sakazakii
  - Shigella spp. and EIEC
  - EHEC
  - Salmonella spp.
- MultiPlex PCR Detection Kits
  - Rotavirus / Norovirus /Astrovirus
ALL SCREEN (Shigella + EIEC / Salmonella / Campylobacter / Rotavirus / Norovirus / Astrovirus / Adenovirus) ................................................................. 30
Shigella and EIEC / Salmonella / Campylobacter ............................................................... 30
Yersinia enterolytica / Yersinia pseudotuberculosis
Escherichioses .................................................................................................................. 30

9. Especially Dangerous and Feral Herd Infections
Vibrio cholerae .................................................................................................................. 31
Bacillus anthracis ................................................................................................................. 31
Brucella species .................................................................................................................. 31
Dengue fever virus ............................................................................................................. 31
Leptospira species .............................................................................................................. 32
Borrelia burgdorferi sensu lato (B. burgdorferi sensu stricto, B. afzelii, B. garinii) .......... 32
Tick-borne encephalitis virus .......................................................................................... 32
West Nile fever virus ........................................................................................................ 32
Crimean-Congo hemorrhagic fever virus ........................................................................ 33
Yersinia pestis ................................................................................................................... 33
Coxiella burnetii ............................................................................................................... 33
Ebola Zaire virus .............................................................................................................. 33
Zika virus .......................................................................................................................... 34
MultiPlex PCR Detection Kits .......................................................................................... 34
TBEV / B. burgdorferi sensu lato / A. phagocytophilum / E. chaffeensis / E. muris... 34

10. HIV and HIV-associated Infections
HIV ................................................................................................................................... 35
Identification of Drug Resistant Mutations HLA B*5701 .................................................. 36
Pneumocystis jirovecii ........................................................................................................ 36
Cryptococcus neoformans ................................................................................................. 36

11. Hepatitis Viruses Infections
Hepatitis A virus .............................................................................................................. 37
Hepatitis B virus ................................................................................................................. 37
Hepatitis C virus ................................................................................................................ 38
Hepatitis D virus ............................................................................................................... 39
Hepatitis G virus ............................................................................................................... 39
MultiPlex PCR Detection Kits .......................................................................................... 39
HCV/HBV/HIV-1 differentiation ...................................................................................... 39
HCV/HBV/HIV-1/HIV-2 differentiation ........................................................................... 39
HBV/HDV ........................................................................................................................... 39
Genoscreen IL28B .............................................................................................................. 39

12. Oncological Disease
Leukosis Quantum M-bcr ................................................................................................. 40

13. Additional Kits
DNA and RNA Extraction Kits .......................................................................................... 42
Reverse Transcription Kits ................................................................................................. 43
Electrophoretic Detection .................................................................................................. 43
Transport and Storage Media ............................................................................................ 43

14. Human SNP Kits
Description
Principle ............................................................................................................................. 44
Methodology of Human SNP Kits .................................................................................... 45
<table>
<thead>
<tr>
<th>Disease</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Diseases</td>
<td>46</td>
</tr>
<tr>
<td>Lipid Metabolism</td>
<td>47</td>
</tr>
<tr>
<td>Pathology of Blood Coagulation System</td>
<td>48</td>
</tr>
<tr>
<td>Breast/Ovarian Cancer</td>
<td>49</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>49</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>50</td>
</tr>
<tr>
<td>Obesity</td>
<td>51</td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>51</td>
</tr>
<tr>
<td>PYRO-prep</td>
<td>51</td>
</tr>
<tr>
<td>Ordering</td>
<td>52</td>
</tr>
</tbody>
</table>
### Legend

**Explanation of Symbols in Catalog**

<table>
<thead>
<tr>
<th>Kit reagents are</th>
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<tbody>
<tr>
<td>non-aliquoted</td>
<td>aliquoted</td>
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**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.

**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.

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

**IVD** *In vitro* diagnostics
**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.

---

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

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PCR Diagnostics Kits

Index of Catalog

1. Sexually Transmitted Infections .......................................................... 11
2. Human Papilloma Virus Infections ..................................................... 16
3. TORCH Infections .................................................................................. 17
4. Herpes-virus Infections ........................................................................ 19
5. Purulent Septic Infections ..................................................................... 22
6. Respiratory Infections ........................................................................... 23
7. Neuro Infections .................................................................................... 27
8. Intestinal Infections ................................................................................ 28
9. Especially Dangerous and Feral Herd Infections .................................. 31
10. HIV and HIV-associated infections ...................................................... 35
11. Hepatitis viruses Infections ................................................................. 37
12. Oncological Disease .............................................................................. 40
13. Additional Kits ...................................................................................... 42
14. Human SNP Kits .................................................................................... 44
Ordering

How to Order

Orders can be sent to us by:

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

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.

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 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.

---

### **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 occur, like pelvic inflammatory disease or irreversible damage, including infertility. In men, the infection is usually asymptomatic, 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 $5 \times 10^2$ copies/ml (qPCR).

Detection channels: FAM/Green and JOE/Yellow.

---

### **Neisseria gonorrhoeae**

Gonorrhoeae 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: $5 \times 10^2$ copies/ml (Screen), $1 \times 10^3$ copies/ml (Test).

Detection channels: FAM/Green and JOE/Yellow.


**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 $1 \times 10^3$ copies/ml.
Detection channels: FAM/Green and JOE/Yellow.

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For DNA isolation use DNA-sorb-AM

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**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, mucopurulent and copious. Complications may result in cervical erosion, cervical cancer, infertility, adenexitis, 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 genital inflammatory infection 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 $5 \times 10^2$ copies/ml.
Detection channels: FAM/Green and JOE/Yellow.

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For DNA isolation use DNA-sorb-AM

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**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 secretes). Kits contain Internal Control for detection of DNA extraction efficiency, as well as for control of amplification process.

Analytical sensitivity is $1 \times 10^3$ copies/ml.
Detection channels FAM/Green and JOE/Yellow.

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</table>

For DNA isolation use DNA-sorb-AM

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**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 thrives 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 conjunctivitis, respiratory distress, fever, meningitis, abscesses and congenital pneumonia, which occurs a few hours after birth. In adults, *M. hominis* may be implicated in pharyngitis, septicemia, 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 $1 \times 10^3$ copies/ml.
Detection channels: FAM/Green and JOE/Yellow.

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</table>

For DNA isolation use DNA-sorb-AM

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1. - Real-Time; 6 - FEP; 3 - Elfo; :: - aliquoted form; ♣ - non-aliquoted form (usable cyclers see page 7)
PCR Diagnostics Kits

Sexually Transmitted Infections

**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 secretes). Kits contain Internal Control for detection of DNA extraction efficiency and control of amplification process.

Analytical sensitivity is 1 x 10^4 copies/ml.
Detection channels: FAM/Green and JOE/Yellow.

**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 10^3 copies/ml.
Detection channels: FAM/Green and JOE/Yellow.

**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, sepsisemia 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.
## PCR Diagnostics Kits

### Sexually Transmitted Infections

### MultiPlex PCR Detection Kits

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

<table>
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<td>For DNA isolation use DNA-sorb-AM</td>
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<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
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<tr>
<td>R-861-F(RG)-CE</td>
<td>Neisseria gonorrhoeae / Chlamydia trachomatis / Mycoplasma genitalium / Trichomonas vaginalis</td>
<td>Analytical sensitivity is $5 \times 10^2$ copies/ml (all pathogens)</td>
<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Description</th>
<th>Sensitivity</th>
<th>DNA Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-F3-F(RG, IQ)-CE</td>
<td>Candida albicans / Candida glabrata / Candida kruiser</td>
<td>Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)</td>
<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Description</th>
<th>Sensitivity</th>
<th>DNA Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-846-F(RG, IQ)-CE</td>
<td>Chlamydia trachomatis / Ureaplasma / Mycoplasma genitalium</td>
<td>Analytical sensitivity is $5 \times 10^2$ copies/ml – C. trachomatis Analytical sensitivity is $1 \times 10^3$ copies/ml – Ureaplasma spp. Analytical sensitivity is $1 \times 10^3$ copies/ml – M. genitalium</td>
<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Kit Code</th>
<th>Description</th>
<th>Sensitivity</th>
<th>DNA Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-847-F(RG)-CE</td>
<td>Chlamydia trachomatis / Ureaplasma</td>
<td>Analytical sensitivity is $5 \times 10^2$ copies/ml – C. trachomatis Analytical sensitivity is $1 \times 10^3$ copies/ml – Ureaplasma spp.</td>
<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Description</th>
<th>Sensitivity</th>
<th>DNA Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-848-F(RG)-CE</td>
<td>Mycoplasma hominis / Gardnerella vaginalis</td>
<td>Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)</td>
<td>For DNA isolation use DNA-sorb-AM</td>
</tr>
</tbody>
</table>

14 - Real-Time; ♦ - FEP; ♂ - Elfo; ☐ - aliquoted form; ♡ - non-aliquoted form (usable cyclers see page 7)
PCR Diagnostics Kits

Sexually Transmitted Infections

Florocenosis / Bacterial vaginosis

AmpliSens® Florocenosis / Bacterial vaginosis PCR kit allows to estimate the ratio of total bacteria, lactobacilli and opportunistic pathogens associated with bacterial vaginosis (Gardnerella vaginalis, Atopobium vaginae) in the vaginal bio- tope 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 10^5 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.

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

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.

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 Enterobacteri- aceae), JOE/Yellow/HEX (Staphylococcus spp.), Orange/ROX (Streptococcus spp.), Cy5/Red (Internal Control).

For DNA isolation use DNA-sorb-AM

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 10^5 copies/ml (all pathogens)

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

For DNA isolation use DNA-sorb-AM
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 10^2 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 10^2 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 based Internal Control significantly reduces false negative results, caused by a poor clinical sample quality.

**Human Papilloma virus Infections**

**High-Risk HPV Infections**

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

**Low-Risk HPV Infections**

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

Analytical sensitivity is 1 x 10^2 copies/ml

For DNA isolation use DNA-sorb-AM

16 - Real-Time; ♦ - FEP; Ⓗ - Elfo; :: - aliquoted form; ♠ - non-aliquoted form (usable cyclers see page 7)
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, Coackievirus, Syphilis, Varicella-Zoster virus, HIV and Parvovirus B19.

**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 dissemination of the infection with pneumonitis, myocardiitis and encephalitis. Congenital cases can result in abortion and stillbirth, live births may result in severe central nervous system involvement along with choreoarthritis.

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.

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

**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 popular, 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.

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

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 transcribed to RNA within the infected cell's nucleus.

Infection is initiated when a virion 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-limiting 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 leads 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.

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**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 semenal 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.**

<table>
<thead>
<tr>
<th>R-V7-F(RG,iQ)-CE</th>
<th>110</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-V7-100-S(RG,iQ)-CE</td>
<td>110</td>
</tr>
<tr>
<td>V7-100-RO,2-FEP-CE</td>
<td>110</td>
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</tbody>
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* For **DNA isolation** use DNA-sorb-AM (qualitative kit) or Ribo-Prep (quantitative kit)

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**Epstein-Barr virus**

Most *EBV* infections are acquired during childhood and are asymptomatic. Symptoms, when produced, are indistinguishable 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 petechiae and peri orbital 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.**

<table>
<thead>
<tr>
<th>R-V9-100-S(RG,iQ,Mx)-CE</th>
<th>QUANTITATIVE</th>
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</thead>
<tbody>
<tr>
<td>V9-100-RO,2-CE</td>
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<td>110</td>
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* For **DNA isolation** use Ribo-Prep
### 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. 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 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 virus, the virus lies dormant in the body before reoccurring into a viral infection. 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**.

<table>
<thead>
<tr>
<th>R-V61-S0-F(RG)-CE</th>
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</thead>
<tbody>
<tr>
<td>For DNA isolation use Ribo-prep</td>
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</tbody>
</table>

### 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® HHV-6-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 analysis 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/10⁵ cells.

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

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

### 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 10⁵ copies/ml.

**AmpliSens® HSV I, II PCR kits** are quantitative 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**.

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

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.

**Epstein-Barr virus / Cytomegalovirus / Human Herpes virus 6**

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

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

Each virus is quantified separately.

**Herpes Simplex virus / Cytomegalovirus**

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

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 with GBS is the cause of some instances of stillbirth.

Hearing loss can be a long-term sequela of GBS-meningitis. Infection with GBS is more often accompanied by meningitis. 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.

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.

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.

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).

PCR Diagnostics Kits
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, 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, Moraxella catarrhalis and Chlamydia pneumoniae 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.

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 10³ copies/ml. Detection channels: FAM/Green and JOE/Yellow/HEX/Cy3.

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 10² copies/ml. Detection channels: FAM/Green and JOE/Yellow/HEX/Cy3.
**Influenza virus A/B**

Influenza A and B viruses routinely spread in people and 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.

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Format</th>
<th>Analytical Sensitivity</th>
<th>Detection Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-V36-50-Mod-CE</td>
<td>NEW</td>
<td>55</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
<tr>
<td>R-V36-100-F-Mod(RG,iQ,DFX,SC)-CE</td>
<td>NEW</td>
<td>100</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
<tr>
<td>V-36-50-RO.2-FEP-CE</td>
<td>NEW</td>
<td>55</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
</tbody>
</table>

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

**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.

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Format</th>
<th>Analytical Sensitivity</th>
<th>Detection Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-B57(RG,iQ,SC,DT)-CE</td>
<td>Mtb complex</td>
<td>55</td>
<td>FAM, JOE, ROX and Cy5</td>
</tr>
<tr>
<td>R-B80(RG,iQ,DT,SC)-CE</td>
<td>Mtb differentiation</td>
<td>55</td>
<td>FAM, JOE, ROX and Cy5</td>
</tr>
<tr>
<td>B57-FEP-CE</td>
<td>Mtb complex</td>
<td>55</td>
<td>FAM, JOE, ROX and Cy5</td>
</tr>
</tbody>
</table>

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

**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.

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Format</th>
<th>Analytical Sensitivity</th>
<th>Detection Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-V66-F-CE</td>
<td>NEW</td>
<td>55</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Format</th>
<th>Analytical Sensitivity</th>
<th>Detection Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-V54-100-F(RG,iQ,DT,SC)-CE</td>
<td>NEW</td>
<td>55</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
<tr>
<td>R-V54(RG)-CE</td>
<td>NEW</td>
<td>55</td>
<td>FAM/Green, JOE/Yellow/HEX/Cy3 and Orange/ROX/Texas Red</td>
</tr>
</tbody>
</table>

**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 PCR 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.

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Format</th>
<th>Analytical Sensitivity</th>
<th>Detection Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>V23-50-RO.2-CE</td>
<td>NEW</td>
<td>55</td>
<td>Adenovirus DNA isolation using DNA-sorb-B</td>
</tr>
</tbody>
</table>

- **- Real-Time;  - FEP;  - Elfo;  - aliquoted form;  - non-aliquoted form (usable cyclers see page 7)
**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 hRSV is generally 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 $1 \times 10^3$ copies/ml.

Detection channels: FAM/Green and JOE/Yellow.

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**Legionella pneumophila**

*L. pneumophila* infection can cause Legionnaire’s disease, a severe form of pneumonia. The symptoms of Legionnaire’s disease include confusion, headache, diarrhea, 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 trachae, 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 $1 \times 10^3$ copies/ml.

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

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**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 $1 \times 10^3$ 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.

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

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**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 $1 \times 10^3$ copies/ml.

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

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$\text{①}$ R-B35(RO)-CE  \text{QUANTITATIVE}  $\text{②}$  \text{R-V51(RG)-CE}  \text{non-aliquoted form (usable cyclers see page 7)}
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 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:

- $1 \times 10^3$ copies/ml – hRSV, hMpv, hPiv, hBov, hRv,
- $1 \times 10^4$ copies/ml – hCov,
- $5 \times 10^3$ copies/ml – hAdv.

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

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

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 $1 \times 10^3$ copies/ml.

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

Mycoplasma pneumoniae / Chlamydia pneumoniae

Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)

For DNA isolation use DNA-sorb-B

- Real-Time; FEP; Elfo; aliquoted form; non-aliquoted form (usable cyclers see page 7)
PCR Diagnostics Kits

**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 is the main cause of viral meningitis. 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 virus 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 spreads and replicates in other sites such as brown fat, reticuloendothelial tissue and muscle. The sustained viral replication 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 (HEVC) RNA with Poliovirus differentiation (Sabin 1, Sabin 2, Sabin 3) in clinical materials and environmental samples.

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

For RNA isolation use Ribo-prep, for reverse transcription use Reverta-L.

**Listeria monocytoogenes**

*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, and meningitis, encephalitis, and encephalitis. 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 10^9 copies/ml.

Detection channels: FAM, JOE and ROX.

**MultiPlex PCR Detection Kits**

**Neisseria meningitidis / Haemophilus influenzae / Streptococcus pneumoniae**

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

For DNA isolation use Ribo-prep
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 an 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 10³ copies/ml.
Detection channels: FAM/Green and JOE/Yellow/HEX.

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 PCR reaction inhibition.

Analytical sensitivity is no less than 1 x 10³ copies/ml.
Detection channels: FAM/Green and JOE/Yellow/HEX.

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 10³ copies/ml.
Detection channels: FAM/Green and JOE/Yellow/HEX.

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 10³ copies/ml.
Detection channels: FAM/Green, JOE/Yellow/HEX and ROX/Orange.

For DNA isolation use Ribo-prep
**PCR Diagnostics Kits**

**Intestinal Infections**

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**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 broths). 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.

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**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 adhesins and enteropathogenicity 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.

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**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 analysis 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.
### PCR Diagnostics Kits

**Intestinal Infections**

#### MultiPlex PCR Detection Kits

**Rotavirus / Norovirus / Astrovirus**
- **R-V40(RG,iQ)-CE** One-Step RT-PCR kit
- Analytical sensitivity is $1 \times 10^3$ copies/ml – Rotavirus, Astrov.
- Analytical sensitivity is $5 \times 10^3$ copies/ml – Norovirus

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

#### 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 hemorrhagic-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 **quantitative 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 $1 \times 10^3$ copies/ml.
Detection channels: **FAM/Green, JOE/Yellow/HEX** and **ROX/Orange**.

For **DNA isolation** use Ribo-prep

#### ALL SCREEN

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

- **R-B45(RG,iQ)-CE** One-Step RT-PCR kit
- Analytical sensitivity is $1 \times 10^3$ copies/ml – Shigella, EIEC, Salmonella, Campylobacter
- Analytical sensitivity is $5 \times 10^3$ copies/ml – Norovirus
- Analytical sensitivity is $1 \times 10^3$ 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** One-Step RT-PCR kit
- Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)

For **DNA isolation** use Ribo-prep

- **B44-FEP-CE**
- Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)

For **DNA isolation** use Ribo-prep

#### Yersinia enterolytica / Yersinia pseudotuberculosis

- **R-B64(RG,iQ)-CE** One-Step RT-PCR kit
- Analytical sensitivity is $1 \times 10^3$ copies/ml (all pathogens)

For **DNA isolation** use Ribo-prep
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 diarrhea, 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 $1 \times 10^3$ 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.

1. **R-853(RG)-CE** :: 55 0
   
   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 *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 $1 \times 10^2$ copies/ml.

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

1. **R-841(RG)-CE** :: 55 0
   
   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 to identify possible reaction inhibition.

Analytical sensitivity is $1 \times 10^2$ copies/ml.

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

**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 $5 \times 10^2$ 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.

1. **R-V63(RG,CFX)-CE** differentiation of 1-4 types :: 60 0
2. **R-V68-F-CE** NEW 1-4 types screening :: 55 0

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

- Real-Time; • - FEP; III - Elfo; :: - aliquoted form; ♦ - non-aliquoted form (usable cyclers see page 7)
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.

**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.

**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.

**Especially Dangerous and Feral Herd Infections**

- **Leptospirosis**
  - *Leptospira species*
  - 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* in clinical material (blood, cerebrospinal fluid, autopsy 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 analysis.
  - Analytical sensitivity is no less than 1 x 10^6 copies/1 ml.
  - Detection channels: FAM/Green and JOE/Yellow/HEX.

- **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.

- **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.

* F - Real-Time; #: FEP; # - Elfo; :: - aliquoted form; * - non-aliquoted form (usable cyclers see page 7)
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 10³ copies/ml. Detection channels: FAM/Green and JOE/Yellow/HEX.

For DNA isolation use Ribo-Prep Reverse transcription kit is included

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 10³ copies/ml of clinical sample. Detection channels: FAM/Green and JOE/Yellow/HEX.

For DNA isolation use Ribo-prep

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: pneumatic, 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 6th 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 10³ copies/ml. Detection channels: FAM/Green and JOE/Yellow/HEX.

For DNA isolation use Ribo-prep

Ebola Zaire virus

Ebola virus disease (EVD), formerly known as Ebola hemorrhagic 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 10⁴ copies/ml of clinical sample. Detection channels: FAM/Green and JOE/Yellow/HEX.

For DNA isolation use Ribo-prep Reverse transcription kit is included
**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 Guillian–Barré syndrome.

AmpliSens® _Zika virus-FRT kit_ is a 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.

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**MultiPlex PCR detection kits**

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

_TBEV / B. burgdorferi sensu lato / A. phagocytophilum / E. chaffeensis / E. muris_

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 serious 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 diarrhea, 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.

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. Usually, 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).
PCR Diagnostics Kits

HIV and HIV-associated Infections

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

For DNA extraction kit is included

HIV RNA detection

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

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).

Analytical sensitivity is 1 x 10³ copies/ml
For DNA isolation use Ribo-prep + Hemolytic

HIV-associated Infections

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 a 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.

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 Cryptococcus neoformans in the clinical material (bronchoalveolar lavage, sputum, biopsy material, throat washes and swabs) by Real-Time technology.
Analytical sensitivity is 400 copies/ml of sample.
Detection channels: FAM/Green and JOE/HEX/Yellow.

For DNA isolation use Ribo-prep
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 through 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 fulminating 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.

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 titers of 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 healthcare 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.

For DNA isolation use Ribo-prep
The quantity of Rx is 100 if half reaction volume is used.
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 contact. In developed countries, it is estimated that 90% of persons with chronic HCV infection were infected through contact. In developed countries, it is estimated that 90% of persons with chronic HCV infection were infected through contact.

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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 isolation, reverse transcription and amplification processes 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 copies (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 ul sample) or 4 – 100.000.000 IU/ml (1 ml sample).

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

MultiPlex PCR Detection Kits

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/Yellow/HEX.

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.

HIV 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-U50-4x(RG,iQ,Mx,Dt)-CE NEW

R-V56(RG,iQ,Mx,Dt)-CE

R-V3-MC(RG,iQ,Dt,CFX)-CE

R-V62-2x(RG,iQ,Dt)-CE

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

RNA extraction and Reverse transcription kits are included
### Additional Kits

#### DNA and RNA Extraction Kits

<table>
<thead>
<tr>
<th>Kit Code</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DNA-sorb-AM</strong></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>K1-11-100-CE with STD Internal Control</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>K1-12-100-CE without STD Internal Control</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>DNA-sorb-B</strong></td>
<td>Kit for DNA extraction from whole blood, bioptats, fecal extract.</td>
<td></td>
</tr>
<tr>
<td>K1-2-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>K1-2-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>DNA-sorb-C</strong></td>
<td>Kit for DNA extraction from bioptats, human tissues, food samples, supplements and plants material.</td>
<td></td>
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<tr>
<td>K1-6-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td><strong>CYTOLYSIN</strong></td>
<td>Kit for DNA extraction from white blood cells.</td>
<td></td>
</tr>
<tr>
<td>K1-3-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>EDEM</strong></td>
<td>Kit for DNA extraction by EXPRESS method from urogenital, throat and conjunctiva swabs, erosive and ulcerative elements of mucous membranes and skin, urine.</td>
<td></td>
</tr>
<tr>
<td>K2-17-100-CE</td>
<td>100</td>
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</tr>
<tr>
<td><strong>AUTO-sorb</strong></td>
<td>Kit for DNA/RNA extraction, silica sorbtion based method using X-Tractor Gene (Corbett Robotics) automated system.</td>
<td></td>
</tr>
<tr>
<td>K2-14-96-CE</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td><strong>RIBO-prep</strong></td>
<td>Kit for RNA/DNA extraction by precipitation method from blood plasma, liquor, saliva, amniotic fluid and smears.</td>
<td></td>
</tr>
<tr>
<td>K2-9-Et-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>K2-9-Et-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>RIBO-sorb</strong></td>
<td>Kit for RNA/DNA extraction by affine sorption on silicagel.</td>
<td></td>
</tr>
<tr>
<td>K2-1-Et-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>K2-1-Et-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>RIBO-zol-A</strong></td>
<td>Kit for RNA extraction from clinical material (white blood cells) by shortened Guanidine/Phenol/Chloroform method.</td>
<td></td>
</tr>
<tr>
<td>K2-2-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>K2-2-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>RIBO-zol-B</strong></td>
<td>Kit for RNA extraction from clinical material (white blood cells, cells suspensions and homogenate bioptat) by Guanidine/Phenol/Chloroform method (classical).</td>
<td></td>
</tr>
<tr>
<td>K2-3-100-CE</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>RIBO-zol-C</strong></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>K2-13-50-CE</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td><strong>MAGNO-sorb</strong></td>
<td>Kit for DNA/RNA extraction with magnetic beads.</td>
<td></td>
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<tr>
<td>K2-16-200-CE</td>
<td>200 ml of material 100</td>
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<tr>
<td>K2-16-1000-CE</td>
<td>1,000 ml of material 100</td>
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</tr>
</tbody>
</table>

- Real-Time; FEP; Elfo; aliquoted form; non-aliquoted form (usable cyclers see page 7)
Additional Kits

Reverse Transcription

Electrophoretic Detection

Transport and Storage Media

Reverta-L

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

- K3-4-50-CE: 60 ml
- K3-4-100-CE: 120 ml

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 ml
- K5-300-CE: 360 ml
- K6-200-CE: 144 ml
- K6-300-CE: 216 ml

RNA-media

Transport media for storage and stabilization of whole blood RNA.

- 981-CE: 100 ml

Mucolysin

Medium for sputum preliminary treatment.

- 180-CE: 200 ml

Hemolytic

Reagent for pretreatment of whole peripheral and umbilical cord blood.

- 137-CE: 100 ml

Transport media with mucolysin

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

- 952-CE: 50 ml

Transport media for storage and transportation of respiratory swabs

Transport medium for storage and transporting of respiratory swabs.

- 957-CE: 50 ml

Transport medium TM-EDEM

Transport medium for use with EDEM nucleic acid extraction kit.

- 1533-CE: 50 ml
Ecoli s.r.o. offers wide range of SNP kits, based on pyrosequencing technology, for rapid and cost-effective analysis 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, 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
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 hematopoietic 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 analysis 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.
Human SNP Kits

Cardiovascular Diseases

Arterial Hypertension (AH) Profile

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-004-50-F</td>
<td>Arterial hypertension («AH») profile</td>
<td>55</td>
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Description:

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Adrenoreceptor β 2 «AH-1»</td>
<td>ADRB2</td>
<td>G16R G&gt;A</td>
<td>rs1042713</td>
</tr>
<tr>
<td>2. Angiotensionogene «AH-2»</td>
<td>AGT</td>
<td>T207M C&gt;T</td>
<td>rs4762</td>
</tr>
<tr>
<td>3. Angiotensionogene «AH-3»</td>
<td>AGT</td>
<td>M268T T&gt;C</td>
<td>rs699</td>
</tr>
<tr>
<td>4. Receptor 1 angiotensin II type «AH-4»</td>
<td>AGTR1</td>
<td>A1666C</td>
<td>rs5186</td>
</tr>
<tr>
<td>5. Nitric oxide synthase «AH-5»</td>
<td>NOS3</td>
<td>D298E T&gt;G</td>
<td>rs1799983</td>
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Ischemic Heart Disease (IHD)

<table>
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<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
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<tbody>
<tr>
<td>PMQ-018-50-F</td>
<td>Ischemic heart disease profile</td>
<td>55</td>
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Description:

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

**Lipid Metabolism**

### Basic Profile

**Description:**

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<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
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</thead>
<tbody>
<tr>
<td>PMQ-019-50-F</td>
<td>Lipid metabolism, basic profile</td>
<td>55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Apolipoprotein E (&quot;E4&quot;) «LM-1»</td>
<td>APOE</td>
<td>C112R T&gt;C</td>
<td>rs429358</td>
</tr>
<tr>
<td>2. Apolipoprotein E (&quot;E2&quot;) «LM-2»</td>
<td>APOE</td>
<td>R158C C&gt;T</td>
<td>rs7412</td>
</tr>
<tr>
<td>3. Apolipoprotein B «LM-3»</td>
<td>APOB</td>
<td>R3527Q G&gt;A</td>
<td>rs5742904</td>
</tr>
<tr>
<td>4. Apolipoprotein B «LM-4»</td>
<td>APOB</td>
<td>G&gt;A</td>
<td>rs754523</td>
</tr>
<tr>
<td>5. Serin protease «LM-5»</td>
<td>PCSK9</td>
<td>T&gt;C</td>
<td>rs11206510</td>
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### Supplementary Profile (LMBP)

**Description:**

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<th>Cat. no.</th>
<th>Profile</th>
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</thead>
<tbody>
<tr>
<td>PMQ-013-50-F</td>
<td>Lipid metabolism, supplementary profile</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ABCA1 transporter «LM-6»</td>
<td>ABCA1</td>
<td>R219K G&gt;A</td>
<td>rs2230806</td>
</tr>
<tr>
<td>2. Apolipoprotein C3 «LM-7,8»</td>
<td>APOC3</td>
<td>-455 C&gt;T</td>
<td>rs2854116</td>
</tr>
<tr>
<td>3. Apolipoprotein C3 «LM-7,8»</td>
<td>APOC3</td>
<td>-482 C&gt;T</td>
<td>rs2854117</td>
</tr>
<tr>
<td>4. Apolipoprotein C3 «LM-9»</td>
<td>APOC3</td>
<td>G&gt;C</td>
<td>rs5128</td>
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<tr>
<td>5. Lipoprotein lipase «LM-10»</td>
<td>LPL</td>
<td>N318S A&gt;G</td>
<td>rs268</td>
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<tr>
<td>7. Paraoxonase-1 «LM-12»</td>
<td>PON1</td>
<td>L55M A&gt;T</td>
<td>rs854560</td>
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<tr>
<td>8. Paraoxonase-1 «LM-13»</td>
<td>PON1</td>
<td>Q192R A&gt;G</td>
<td>rs662</td>
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Human SNP Kits

Pathology of Blood Coagulation System

Plasma Factors of Blood Coagulation System (PFBC)

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

Folate Cycle (CSFC)

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Methylentetrahydrofolat reductase «FC-1»</td>
<td>MTHFR</td>
<td>A222V C&gt;T</td>
<td>rs1801133</td>
</tr>
<tr>
<td>2. Methylentetrahydrofolat reductase «FC-2»</td>
<td>MTHFR</td>
<td>E429A A&gt;C</td>
<td>rs1801131</td>
</tr>
<tr>
<td>3. Methionine synthase «FC-3»</td>
<td>MTR</td>
<td>D919G A&gt;G</td>
<td>rs1805087</td>
</tr>
<tr>
<td>4. Methionine synthase reductase «FC-4»</td>
<td>MTRR</td>
<td>I22M A&gt;G</td>
<td>rs1801394</td>
</tr>
<tr>
<td>5. Folate’s transporter «FC-5»</td>
<td>SLC19A1</td>
<td>H27R A&gt;G</td>
<td>rs1051266</td>
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Aggregation Factors of Blood Coagulation System (AFBC)

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
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</thead>
<tbody>
<tr>
<td>1. Platelet glycoprotein 1B «AF-1»</td>
<td>GP1BA</td>
<td>T-5C</td>
<td>rs2243093</td>
</tr>
<tr>
<td>2. Platelet glycoprotein 1B «AF-2»</td>
<td>GP1BA</td>
<td>T145M C&gt;T</td>
<td>rs6065</td>
</tr>
<tr>
<td>3. Platelet fibrinogen receptor «AF-3»</td>
<td>ITGB3</td>
<td>L33P (A1/A2)</td>
<td>rs5918</td>
</tr>
<tr>
<td>4. Janus kinase 2 «AF-4»</td>
<td>JAK 2</td>
<td>V617F G&gt;T</td>
<td>rs77375493</td>
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<tr>
<td>5. Selectin P ligand of glycoprotein «AF-5»</td>
<td>SELPLG</td>
<td>M62I A&gt;G</td>
<td>rs2228315</td>
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# Human SNP Kits

## Breast/Ovarian Cancer

**Description:**

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<th>Profile</th>
<th>No. of Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-005-50-F</td>
<td>Breast/ovarian cancer</td>
<td>55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Breast cancer gene 1 «B1-AG»</td>
<td>BRCA1</td>
<td>185delAG</td>
</tr>
<tr>
<td>2.</td>
<td>Breast cancer gene 1 «B1-61»</td>
<td>BRCA1</td>
<td>300T&gt;G (C61G)</td>
</tr>
<tr>
<td>3.</td>
<td>Breast cancer gene 1 «B1-7A»</td>
<td>BRCA1</td>
<td>2080delA</td>
</tr>
<tr>
<td>4.</td>
<td>Breast cancer gene 1 «B1-A»</td>
<td>BRCA1</td>
<td>4153delA</td>
</tr>
<tr>
<td>5.</td>
<td>Breast cancer gene 1 «B1-C»</td>
<td>BRCA1</td>
<td>5382insC</td>
</tr>
</tbody>
</table>

## Osteoporosis (OST)

**Description:**

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-008-50-F</td>
<td>Osteoporosis</td>
<td>55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Collagen, type 1 «OST-1»</td>
<td>COL1A1</td>
<td>IVS1, 2046G&gt;T</td>
</tr>
<tr>
<td>2.</td>
<td>Estrogen receptor «OST-2»</td>
<td>ESR1</td>
<td>T&gt;C (PvuII)</td>
</tr>
<tr>
<td>3.</td>
<td>Estrogen receptor «OST-3»</td>
<td>ESR1</td>
<td>A&gt;G (XbaI)</td>
</tr>
<tr>
<td>4.</td>
<td>Lactase «OST-4»</td>
<td>LCT</td>
<td>-13910 C&gt;T</td>
</tr>
<tr>
<td>5.</td>
<td>Low density lipoprotein receptor «OST-5»</td>
<td>LRP5</td>
<td>A1330V</td>
</tr>
<tr>
<td>6.</td>
<td>Vitamin D receptor «OST-6»</td>
<td>VDR</td>
<td>C&gt;T (G&gt;A) BsmI</td>
</tr>
</tbody>
</table>
## Human SNP Kits

### Diabetes mellitus (DM1)

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NatB subunit «DM1-1»</td>
<td>C12ORF30</td>
<td>A&gt;G</td>
<td>rs17696736</td>
</tr>
<tr>
<td>2. C-type lectin domain family 16 «DM1-2»</td>
<td>CLEC16A</td>
<td>A&gt;G</td>
<td>rs12708716</td>
</tr>
<tr>
<td>3. rs2544677 «DM1-3»</td>
<td>–</td>
<td>G&gt;C</td>
<td>rs2544677</td>
</tr>
<tr>
<td>4. Insulin «DM1-4»</td>
<td>INS</td>
<td>A&gt;T</td>
<td>rs689</td>
</tr>
<tr>
<td>5. Tyrosin phosphatase «DM1-5»</td>
<td>PTPN22</td>
<td>G&gt;A</td>
<td>rs2476601</td>
</tr>
</tbody>
</table>

### Diabetes mellitus 2 type (DM2) - Basic Profile

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Gene</th>
<th>Polymorphism</th>
<th>rs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ATP-sensitive inward rectifier potassium channel «DM2-1»</td>
<td>KCNJ11</td>
<td>E23K C&gt;T</td>
<td>rs5219</td>
</tr>
<tr>
<td>2. Trascrption factor PPAR gamma «DM 2-2»</td>
<td>PPARG</td>
<td>P12A C&gt;G</td>
<td>rs1801282</td>
</tr>
<tr>
<td>3. Trascrption factor 7 «DM 2-3»</td>
<td>TCF7L2</td>
<td>IVS3C&gt;T</td>
<td>rs7903146</td>
</tr>
<tr>
<td>4. Trascrption factor 7 «DM 2-4»</td>
<td>TCF7L2</td>
<td>IVS4G&gt;T</td>
<td>rs12255372</td>
</tr>
</tbody>
</table>
### Human SNP Kits

#### Obesity

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-006-50-F</td>
<td>Obesity</td>
<td>55</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Profile</th>
<th>No. of Rx</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-007-50-F</td>
<td>Crohn’s disease</td>
<td>55</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Cat. no.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMQ-P</td>
<td>Binding of PCR-product, purification of reaction mixture and amplicons’ denaturation with «PyroMark Q24 Vacuum Prep Workstation».</td>
</tr>
</tbody>
</table>

**ATTENTION !**

- Additional eagents needed for pyrosequencing analyzis:
  - Streptavidin Sepharose High Performance (GE Healthcare)
  - PyroMark Plate and PyroMark Gold Reagents (Qiagen)
**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

**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.

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**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

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**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.
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Slovak Republic
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ecoli@ecoli.sk • www.ecoli.sk • www.pcrdiagnostics.eu