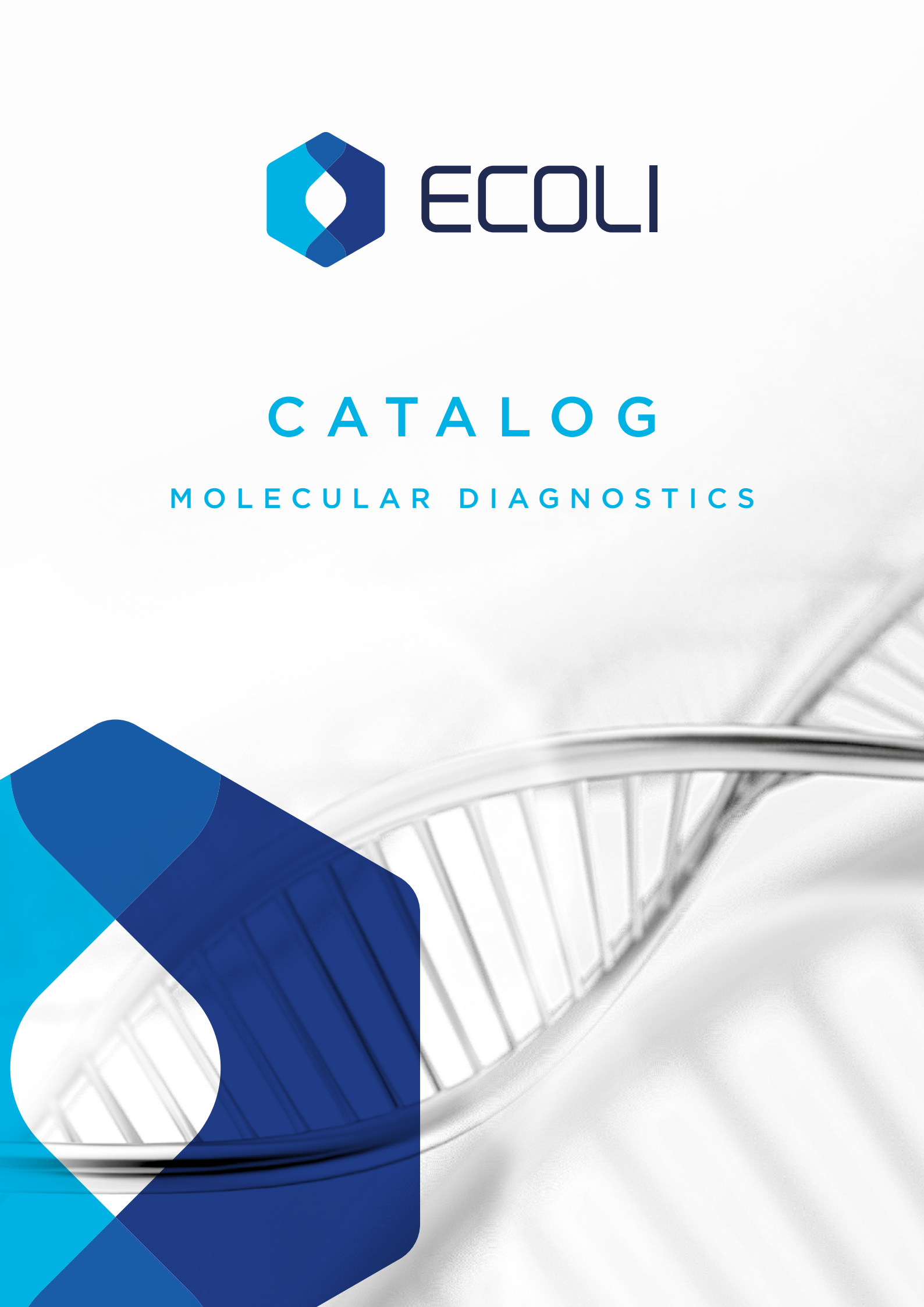
ECOLI

CATALOG

MOLECULAR DIAGNOSTICS



CATALOG CONTENT

CATALOG CONTENT

COMPANY PROFILE

Ecoli Dx, s.r.o. is an European company situated in the Czech Republic with the worldwide distribution network.

Ecoli Dx, s.r.o. provides about 200 different types of AmpliSens® PCR kits for clinical diagnostics and human genome testing developed and produced by CRIE (Central Research Institute for Epidemiology, Moscow). Kits are designed according to laboratory facilities for PCR and Real-Time PCR detection.

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 a 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.

We organize distributors meetings and workshops that help our partners grow their knowledge base of AmpliSens® products to ensure the best possible service to the customers.

ORDERING

When ordering our PCR diagnostic kits, please keep on mind, that we have a schedule of regular order deadlines. We work in 2 weeks cycles; it means we order the goods at the manufacturer twice a month.

Concrete ordering deadlines are listed on our web page below: *https://www.pcrdiagnostics.eu/ordering/*

Till these dates it is essential to place an order on our email address. Your order is confirmed by Order Acknowledgement, every time please check if it is correct. If you do not receive confirmation of your order, please contact us as by return. Once our order is processed and accepted by the production, it takes about 4-6 weeks to ship ordered products out to you.

Required Information

Following data are required by ordering

- Product name
- Catalog numbers
- Quantity
- Billing and shipping address
- VAT number (EU only)
- Contact person (name, phone number, email)

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 each shipment separately, because every box has different dimensions and weight. We do our best to minimalize the shipping costs and because of that you pay for real shipping costs. This system is customer-friendly!

Terms of Payment

Ecoli s.r.o. accepts payments by wire transfer. For other payment methods please contact us.

Be informed about deadlines!

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

LEGEND

Explanation of Symbols in the Catalog

Real-Time detection

WHAT CYCLERS CAN BE USED?

Cycler type abbreviation in the catalog number determines the intended qPCR cyclers (or an equivalent qPCR cyclers can be used):

- **RG** Rotor-Gene Q/3000/6000 (QIAGEN/Corbett),
- **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.

Reverse transcription required

Reverse transcription kit (REVERTA-L) is not included in PCR kit (has to be ordered separately)

Availability

available

on request

Fluorescent End-Point detection

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

Certification

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

RUO Research use only

Kit reagents are non-aliquoted

The reagents are supplied in reagent stock tubes ready to perform PCR setup.

Kit reagents are aliquoted

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

Fluorescent channels

- G FAM/Green
- Y JOE/HEX/Yellow
- O ROX/Orange
- R Cy5/Red
- C Cy5.5/Crimson

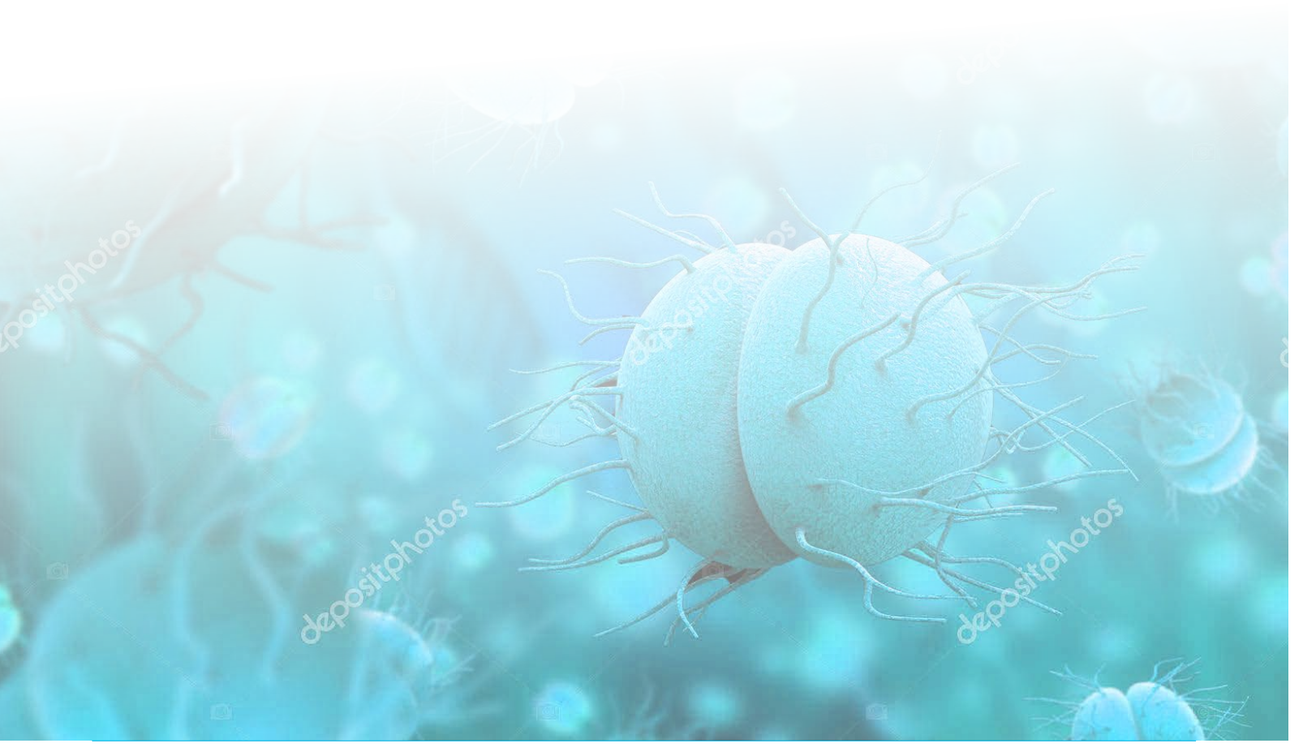
1. SEXUALLY TRANSMITTED INFECTIONS

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

Some STIs can also be transmitted via the use of IV drug needles after its use by an infected person, as well as through childbirth or breastfeeding. STI is a broader term than STD. Infection is 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 using 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.

The sensitivity of these tests is not affected by changing the number of infections. Each mono- and multiplex PCR kit contains independent Internal Control (IC) for the determination of DNA extraction efficiency and PCR process. Presence of the Internal Control signal/band shows, that the DNA extraction process and amplification steps were sufficient for significant results interpretation.



1.1.1. *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 symptomatic, with dysuria and a discharge from the penis. Untreated chlamydial infection in men can spread to the epididymis. Most women with chlamydial infection have minimal or no symptoms, but some develop. Chlamydial infection in newborns can cause ophthalmia neonatorum.

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B1-F (RG,iQ)-CE	AmpliSens® *Chlamydia trachomatis*-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	12 months	G Y	✔
R-B1(RG)-CE	AmpliSens® *Chlamydia trachomatis*-FRT (aliquoted in 0,2 ml tubes)	Real-Time	Ready-to-use PCR tubes	110	CE IVD	qualitative	12 months	G Y	✔
B1-100-R0, 2-FEP-CE	AmpliSens® *Chlamydia trachomatis*-FEP	Fluorescent End-Point	Ready-to-use PCR tubes	110	CE IVD	qualitative	12 months	G Y	▲

1.1.2. *Neisseria gonorrhoeae*

Gonorrhea is a common STD caused by the bacterium *N. gonorrhoeae*. The usual symptoms in men are burning with urination and penile discharge. Women are asymptomatic half the time or have vaginal discharge and pelvic pain. Infection of the genitals in females can result in pelvic inflammatory disease if left untreated, which can result in infertility. If left untreated, gonorrhea may spread locally causing epididymitis, disseminated infections can result in endocarditis, meningitis, or gonococcal dermatitis-arthritis syndrome. Neonatal gonorrheal conjunctivitis can lead to corneal scarring or perforation, resulting in blindness in the neonate.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B51-F (RG,iQ)-CE	AmpliSens® *Neisseria gonorrhoeae*-screen-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	9 months	G Y	✔
R-B51(RG)-CE	AmpliSens® *Neisseria gonorrhoeae*-screen-FRT (aliquoted in 0,2 ml tubes)	Real-Time	Ready-to-use PCR tubes	110	CE IVD	qualitative	9 months	G Y	▲

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
▲ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

1.1.3. *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*-FRT PCR kits are amplification tests for the qualitative detection of T. pallidum DNA in the clinical materials (scrapes/swabs of urogenital tract mucous membranes; serous exudate of vesicles, ulcers or erosions). Kit contains Internal Control that allows detection of DNA extraction efficiency, as well as amplification process.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B20-F (RG,iQ)-CE	AmpliSens® *Treponema pallidum*-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y	✔

1.1.4. *Trichomonas vaginalis*

T. vaginalis is a parasitic protozoan flagellate, generally restricted to the genitourinary tract by the host's immune system and is the etiological agent of human trichomoniasis. In women symptoms of infection include vaginal secretion that is scanty and mixed with mucus; malodorous discharge that is frothy, yellow or green, mycopurulent and copious. Complications may result in cervical erosion, cervical cancer, infertility, adnexitis, pyosalpinx and endometritis. Premature rupture of the placental membranes can occur in pregnant women, resulting in premature birth and low-birth-weight. In men is the prevalence lower and infection is often asymptomatic. Infection in men can be present in the prostate, seminal vesicles and epididymis. Complications are rare, but can potentially lead to genitourinary inflammation disease, sterility, scanty, clear to mucopurulent discharge, dysuria, non-gonococcal urethritis, prostatitis and urethral disease.

AmpliSens® *Trichomonas vaginalis*-FRT 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 the amplification process.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B6-F (RG,iQ)-CE	AmpliSens® *Trichomonas vaginalis*-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y	✔

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B4-F(RG,iQ)-CE	AmpliSens® *Mycoplasma genitalium*-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y	✔
R-B4(RG)-CE	AmpliSens® *Mycoplasma genitalium*-FRT (aliquoted in 0,2ml tubes)	●	▮▮▮	110	CE IVD	qualitative	9 months	G Y	▲

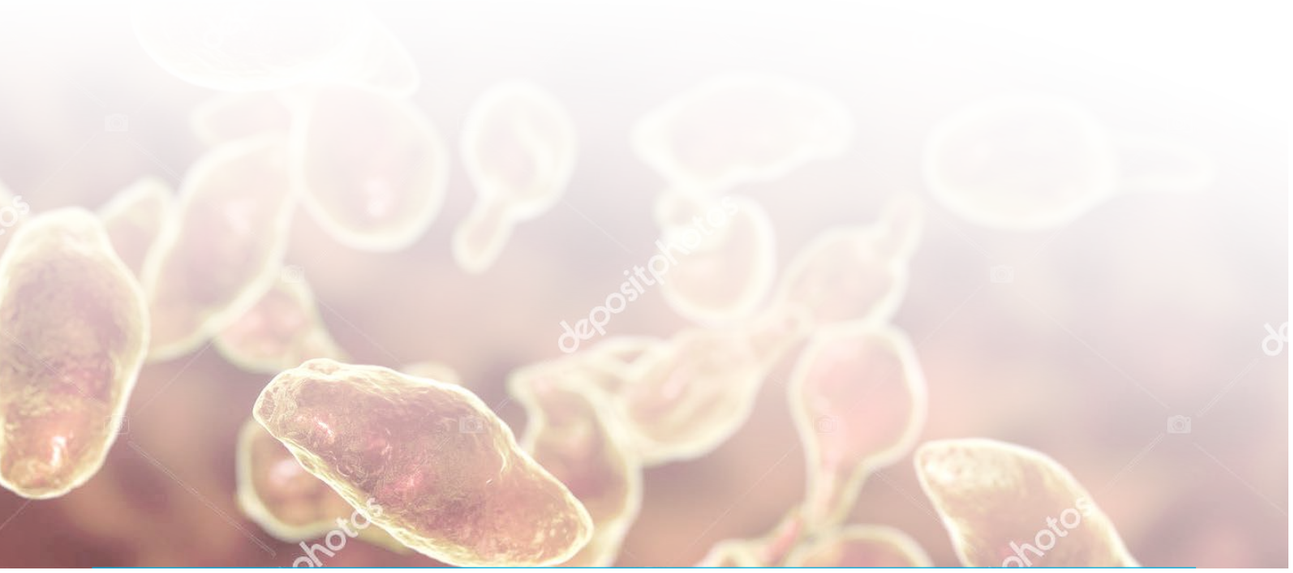
● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

1.1.6. *Mycoplasma hominis*

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

AmpliSens® *Mycoplasma hominis*-FRT PCR kits contain Internal Control for detection of DNA extraction efficiency, as well as for control of amplification process.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B3-F(RG,iQ)-CE	AmpliSens® *Mycoplasma hominis*-FRT	Real-Time	1 tube	110	CE IVD	qualitative	9 months	G Y	✔
R-B3(RG)-CE	AmpliSens® *Mycoplasma hominis*-FRT (aliquoted in 0,2 ml tubes)	Real-Time	8 tubes	110	CE IVD	qualitative	9 months	G Y	▲
B3-100-R0, 2-FEP-CE	AmpliSens® *Mycoplasma hominis*-FEP	Fluorescent End-Point	8 tubes	110	CE IVD	qualitative	9 months	–	▲



Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
▲ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

1.1.7. *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 the case of syndromes, described by *Mycoplasma* kits.

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B2-F(RG,iQ)-CE	AmpliSens® *Ureaplasma* spp.-FRT	Real-Time	1 tube	110	CE IVD	qualitative	9 months	G Y	✔
R-B2-100-FT (RG,iQ,Mx)-CE	AmpliSens® *Ureaplasma* spp.-screen-titre-FRT PCR kit	Real-Time	1 tube	110	CE IVD	quantitative	9 months	G Y	✔

1.1.8. *Ureaplasma* spp. Differentiation

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B19-F(RG,iQ)-CE	AmpliSens® *U.parvum/ U.urealyticum*-FRT	Real-Time	1 tube	110	CE IVD	qualitative	9 months	G Y O	✔
R-B19(RG)-CE	AmpliSens® *U.parvum/ U.urealyticum*-FRT (aliquoted in 0,2 ml tubes)	Real-Time	8 tubes	110	CE IVD	qualitative	9 months	G Y O	▲

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
▲ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

1.1.9. *Gardnerella vaginalis*

Gardnerella vaginalis is just one of many causes of bacterial vaginosis caused by 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® *Gardnerella vaginalis*-FRT 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 the amplification process.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B7-F(RG,iQ)-CE	AmpliSens® Gardnerella vaginalis-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	9 months	G Y	available

1.1.10. *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, septicemia or endocarditis in severely immunocompromised patients. There does not appear to be a significant difference in pathogenic the 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*-FRT PCR kits are qualitative tests and contain Internal Control which must be used in the extraction procedure in order to control the extraction process of each specimen and to identify possible PCR reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-F1-F(RG,iQ)-CE	AmpliSens® *Candida albicans*-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	9 months	G Y	available
F1-100-R0, 2-FEP-CE	AmpliSens® *Candida albicans*-FEP	Fluorescent End-Point	Ready-to-use PCR tubes	110	CE IVD	qualitative	9 months	G Y	on request

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
on request · available; for detailed explanations and usable PCR cyclers see page 9

1.2. MULTIPLEX PCR DETECTION KITS

1.2.1. *Trichomonas vaginalis / Neisseria gonorrhoeae*

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B65-F(RG,iQ)-CE	AmpliSens® *T.vaginalis/ N.gonorrhoeae-Multiprime*-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	9 months	G Y O	available

1.2.2. *Chlamydia trachomatis / Ureaplasma / Mycoplasma genitalium / Mycoplasma hominis*

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B60-F(RG)-CE	AmpliSens® *C.trachomatis/ Ureaplasma/ M.genitalium/ M.hominis*-Multiprime-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	12 months	G Y O R C	available

1.2.3. *Candida albicans / Candida glabrata / Candida krusei*

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-F3-F(RG,iQ)-CE	AmpliSens® *C.albicans/ C.glabrata/C.krusei*-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	9 months	G Y O R	available

1.2.4. *Chlamydia trachomatis / Ureaplasma / Mycoplasma genitalium*

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B46-F(RG,iQ)-CE	AmpliSens® *C.trachomatis/ Ureaplasma/ M.genitalium*-FRT	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative	12 months	G Y O R	available

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
on request · available; for detailed explanations and usable PCR cyclers see page 9

1.2.5. *Trichomonas vaginalis / Neisseria gonorrhoeae / Chlamydia trachomatis*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B83-F(RG,iQ)-CE	AmpliSens® *T.vaginalis/ N.gonorrhoeae/ C.trachomatis*-Multiprime-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y O R	✔

1.2.6. *Neisseria gonorrhoeae / Chlamydia trachomatis / Mycoplasma genitalium / Trichomonas vaginalis*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B61-F(RG)-CE	AmpliSens® *N.gonorrhoeae/ C.trachomatis/ M.genitalium/ T.vaginalis*-Multiprime-FRT	●	▮	110	CE IVD	qualitative	12 months	G Y O R C	✔

1.2.7. *Gardnerella vaginalis / Lactobacillus species*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B7-FT (RG,iQ,Mx)-CE	AmpliSens® *Gardnerella vaginalis/Lactobacillus* spp.-titre-FRT	●	▮▮▮	110	RUO	quantitative	9 months	G Y	✔

1.2.8. *Chlamydia trachomatis / Ureaplasma / Mycoplasma hominis*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B43-F(RG,iQ)-CE	AmpliSens® *C.trachomatis/ Ureaplasma/ M.hominis*-FRT	●	▮	110	CE IVD	qualitative	12 months	G Y O R	✔

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

1.2.9. *Neisseria gonorrhoeae / Chlamydia trachomatis / Mycoplasma genitalium*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B67-F(RG,iQ)-CE	AmpliSens® *N.gonorrhoeae/ C.trachomatis/ M.genitalium*-Multiprime-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y O R	✔

1.2.10. Florocenosis / Bacterial vaginosis

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B74-100-FT (RG)-CE	AmpliSens® Florocenosis/ Bacterial Vaginosis-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y O R	✔

1.2.11. Florocenosis / *Mycoplasma*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B75-100-FT(RG,iQ,Mx)-CE	AmpliSens® Florocenosis/ Mycoplasmas (*M. hominis, U.parvum, U.urealyticum*)-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y O R	✔

1.2.12. Florocenosis / *Candida*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-F5-100-FT(RG,CFX)-CE	AmpliSens® Florocenosis/ Candida-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y O R C	✔

1.2.13. Florocenosis / Aerobes

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B88-100-FT-CE	AmpliSens® Florocenosis/ Aerobes-FRT	●	▮	110	CE IVD	quantitative	12 months	G Y O R	✔

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

2. HUMAN PAPILLOMAVIRUS INFECTIONS

Human papillomaviruses (HPVs) are a group of more than 150 related viruses. They are called papillomaviruses because certain types may cause warts, or papillomas, which are benign (noncancerous) tumors. Some HPVs, such as those that cause common warts that grow on hands and feet, do not spread easily. However, more than 40 *HPV* types are sexually transmitted and these *HPV*s spread very easily through genital contact.

Some types of sexually transmitted *HPV*s cause cervical cancer and other types of cancer. These are called high-risk, oncogenic, or carcinogenic *HCR HPV*s - (about 13 types) (about 13 types). Other sexually transmitted types of *HPV* do not appear to cause cancer and are called low-risk *HPV*s (LCR *HPV*s).

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 *HPV*s 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 PCR kit (R-V67-F-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 detection but also differentiation and quantification of the virus genotype. For detection FAM/Green, JOE/HEX/Yellow, ROX/Orange and RED/Cy5 channels are needed. Analytical sensitivity is 1 x 10^3 copies/ml.

AmpliSens® *HPV HCR* genotype-FRT kit (R-V25 (RG,iQ,Mx)-CE) - the detection and differentiation of 12 *HPV HCR* types - 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58 nad 59 is carried in four tubes. For detection FAM/Green, JOE/Yellow/HEX, ROX/Orange and RED/Cy5 channels are needed.

AmpliSens *HPV HCR* screen-titre-FRT PCR kits (R-V31-T-2x-CE; R-V31-T-4x-CE) are capable to detect and quantify the *HPV* DNA of the following types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59. The method is based on simultaneous amplification and detection of E1-E2 *HPV* genes and fragment of beta-globine gene, which is used as an endogenous internal control (detected in the channel for the FAM fluorophore). PCR analysis for the presence of DNA of 12 *HPV* types is carried out in two tubes (PCR kit variant screen-titre-FRT 2x) or in a single tube (PCR kit variant screen-titre-FRT 4x).

PCR kit variant screen-titre-FRT 2x: *HPV* DNA is detected in the channel for the JOE/HEX/Yellow fluorophore. The genotypes belonging to phylogenetic group A9 (16, 31, 33, 35, 52, and 58) are detected in one tube, whereas the genotypes belonging to phylogenetic group A7 (18, 39, 45, and 59) as well as genotypes 51 and 56 are detected in the other tube.

PCR kit variant screen-titre-FRT 4x: *HPV* DNA of each *HPV* phylogenetic group is detected in separate fluorescent channels (group A9 HPV, in the channel for the JOE/HEX/Yellow fluorophore; group A7 *HPV*, in the channel for the ROX fluorophore; and *HPV* types 51 and 56, in the channel for the Cy5 fluorophore).

Analytical sensitivity is no less then 5x 10^3 copies/ml.
AmpliSens® *HPV HCR* screen-titre-14 FRT PCR kit (H-2311-1-13-CE) 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 the internal endogenous control. For detection - JOE/HEX/Yellow, FAM/Green, ROX/Orange and Cy5.5/Crimson channels are needed. Analytical sensitivity is no less then 1 x 10^3 copies/ml. Endogenous Internal Control, present in all our *HPV* kits, allows not only control stages of PCR (DNA extraction and amplification) but also evaluate sample quality and storage adequacy. If epithelial swab quality is not sufficient (number of epithelial cells in the clinical sample is insufficient), signal of β--globin gene will be significantly lowered. Such β-globin based Internal Control significantly reduces false negative results, caused by a poor clinical sample quality.

2.1.1. High-Risk *HPV* Infections

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V12-F-CE	AmpliSens® *HPV* 16/18-FRT PCR kit. variant FRT-100 F	●	▮	110	CE IVD	genotyping + quantitative	12 months	G Y O	✔
R-V67-F-CE	AmpliSens® *HPV HCR* genotype-titre-FRT PCR kit	●	▮	110	CE IVD	genotyping + quantitative	12 months	G Y O R	✔
R-V25 (RG,iQ,Mx)-CE	AmpliSens® *HPV* HCR genotype-FRT	●	▮	108	CE IVD	genotyping	6 months	G Y O R	▲
R-V31-T-2x (RG,iQ,SC)-CE	AmpliSens® *HPV* HCR screen-titre-FRT	●	▮	108	CE IVD	quantitative	9 months	G Y	✔
R-V31-T-4x (RG,iQ,Mx)-CE	AmpliSens® *HPV* HCR screen-titre-FRT	●	▮	108	CE IVD	quantitative	6 months	G Y O R	▲
H-2311-1-13-CE	AmpliSens® *HPV* HCR screen-titre-14 FRT PCR kit variant FRT-100 FN	●	▮	110	CE IVD	genotyping + quantitative	12 months	G Y O R C	✔
V31-3x-FEP-CE	AmpliSens® *HPV* HCR screen -FEP	★	▮	120	RUO	qualitative	6 months	–	▲

2.1.2. Low-Risk *HPV* Infections

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V11-Mod(RG,iQ,Mx)-CE	AmpliSens® *HPV* 6/11-FRT PCR kit. variant FRT-100F	●	▮	110	CE IVD	genotyping	12 months	G Y O	✔

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

3. HEPATITIS VIRUSES INFECTIONS

3.1.1. *Hepatitis A virus*

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

AmpliSens® *HAV*-FRT PCR kit is One-Step RT-PCR test for the qualitative detection of Hepatitis A virus RNA in clinical material (blood plasma, feces) and environmental objects (water samples). Kit contains Internal Control in order to check the extraction and reverse transcription process of individual sample and to identify possible reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V4(RG,iQ)-CE	AmpliSens® *HAV*-FRT	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G Y	✔

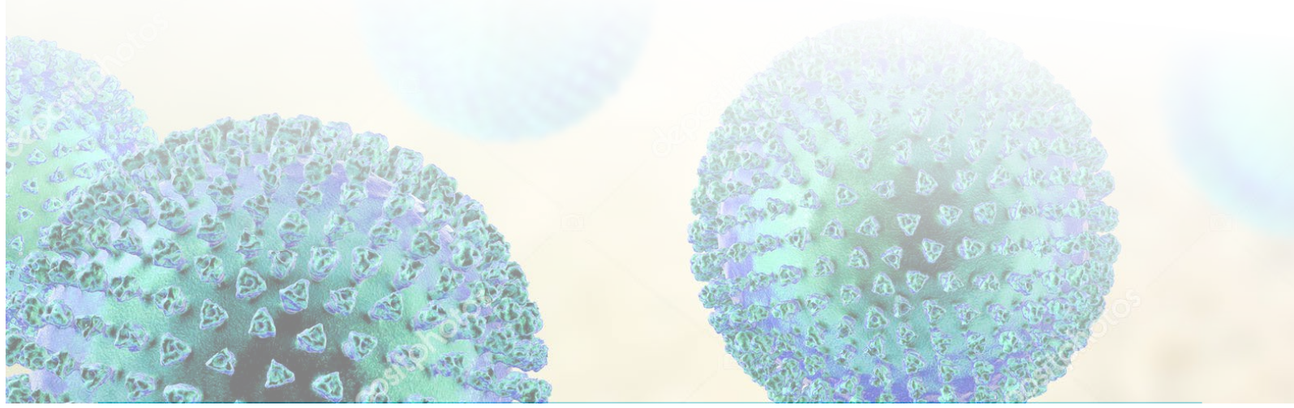
3.1.2. *Hepatitis B virus*

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 that infects the liver and causes an inflammation called hepatitis. Transmission of *HBV* results from exposure to infectious blood or body fluids such as semen and vaginal fluids, while viral DNA has been detected in the saliva, tears and urine of chronic carriers with high titer DNA in serum. Perinatal infection is a major route of infection in endemic countries. Other risk factors for developing *HBV* infection includes working in a health care setting, transfusions and dialysis. Acute infection with *HBV* is associated with acute viral hepatitis - an illness that begins with general ill-health, loss of appetite, nausea, vomiting, body aches, mild fever, dark urine and then progresses to the development of jaundice. It has been noted that itchy skin has been an indication of 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 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 the 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 the sample volume is 100 µl, 5 IU/ml if the sample volume is 1 ml). AmpliSens® HBV-Monitor-FRT PCR kit is a test for the 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 us to differentiate A, B, C and D genotypes of *HBV*.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V5-Mod (RG,iQ,Mx,Dt)-CE	AmpliSens® *HBV*-FRT	Real-Time	Reagents in stock tubes	112	RUO	qualitative	12 months	G Y	✔
R-V5-MC(R-G,iQ,Mx,Dt)-CE	AmpliSens® *HBV*-Monitor-FRT	Real-Time	Reagents in stock tubes	80	RUO	quantitative	12 months	G Y	✔
R-V5-G-F-CE	AmpliSens® *HBV*-genotype-FRT	Real-Time	Reagents in stock tubes	55	RUO	genotyping	9 months	G Y O R	✔
NEW H-4021-1-14-CE	AmpliSens® *HBV*-Monitor-L PCR kit. Variant FRT-L	Real-Time	Ready-to-use PCR tubes	480	RUO	quantitative	12 months	G Y	✔
NEW H-4021-1-14-100-CE	AmpliSens® *HBV*-Monitor-L PCR kit. Variant FRT-L	Real-Time	Ready-to-use PCR tubes	96	RUO	quantitative	12 months	G Y	✔



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

3.1.3. *Hepatitis C virus*

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

Hepatitis C is an infectious disease primarily affecting the liver, caused by the *HCV*. *HCV* is transmitted by blood-to-blood contact. In developed countries, it is estimated that 90 % of persons with chronic *HCV* infection were infected through transfusion of unscreened blood or blood products or via injecting drug use or sexual exposure. The infection is often asymptomatic, but chronic infection can lead to scarring of the liver and ultimately to cirrhosis, which is generally apparent after many years. In some cases, those with cirrhosis will go on to develop liver failure or other complications, including liver cancer or life-threatening esophageal varices and gastric varices. During the first 12 weeks after infection with *HCV*, most people suffer no symptoms. For those who do, the main manifestations of acute infection are generally mild and vague and rarely point to a specific diagnosis of hepatitis C. Symptoms of acute *HCV* infection include decreased appetite, fatigue, abdominal pain, jaundice, itching and flulike symptoms.

HCV is usually detectable in the blood by PCR within one to three weeks after infection and antibodies to the virus are generally detectable within 3 to 15 weeks. Liver enzyme tests show variable ALT/ALS elevation. Periodically, they might show normal results. Usually, prothrombin and albumin results are normal, but may become abnormal, once cirrhosis has developed. The levels of elevation of liver tests do not correlate well with the amount of liver injury on biopsy. Viral genotype and viral load also do not correlate with the amount of liver injury. Liver biopsy is the best test to determine the amount of scarring and inflammation. The natural course of chronic hepatitis C varies considerably from one person to another. Although almost all people infected with *HCV* have evidence of inflammation on liver biopsy, the rate of progression of liver scarring (fibrosis) shows significant variability among individuals. Once chronic hepatitis C has progressed to cirrhosis, signs and symptoms may appear that are generally caused by either decreased liver function or increased pressure in the liver circulation, a condition known as portal hypertension. Possible signs and symptoms of liver cirrhosis include accumulation of fluid in the abdomen, bruising and bleeding tendency, varices (especially in the stomach and esophagus), jaundice and syndrome of cognitive impairment known as hepatic encephalo pathy (HE). HE is due to the accumulation of ammonia and other substances normally cleared by a healthy liver.

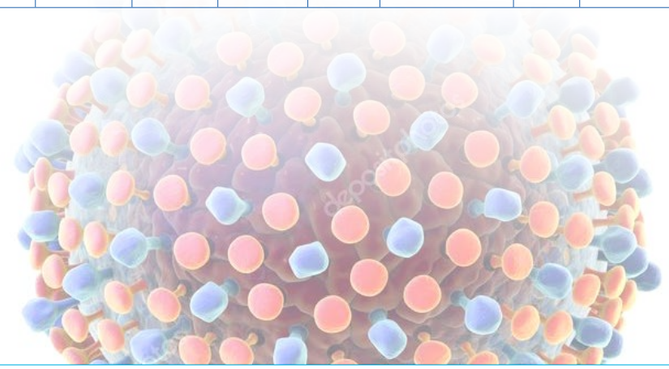
AmpliSens® *HCV*-FRT PCR kit is a qualitative One-Step RTPCR test for detection of *HCV* RNA in the clinical material (blood plasma). Internal Control allows to determine the RNA extraction efficiency, reverse transcription and cDNA amplification steps. The analytical sensitivity depends on the clinical sample volume and is 100 IU/ml (if the sample volume is 100 ul) or 10 IU/ml (if the sample volume is 1 ml). Detection channels: FAM/Green and JOE/Yellow/HEX.

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

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

AmpliSens® *HCV*-genotype-FRT (R-V1-G(1-4)-2x) PCR kit allows detection and differentiation of *HCV* genotypes 1a, 1b, 2, 3a and 4. Analytical sensitivity is not less than 2.5 x 10^3 copies/ml. Detection channels: FAM/Green and JOE/HEX/Yellow. AmpliSens® *HCV*-genotype-FRT R-V1-G(1-6)-2x PCR kit allows detection and differentiation of *HCV* genotypes 1a, 1b, 2, 3a, 4, 5a and 6. Detection channels: FAM/Green and JOE/HEX/Yellow/Cy3. A reverse transcription kit in AmpliSens® *HCV*-genotype-FRT kits is not included.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V1-Mod (RG,iQ,Mx,Dt)-CE	AmpliSens® *HCV*-FRT	Real-Time	Reagents in stock tubes	112	RUO	qualitative	12 months	G Y	✓
R-V1-MC (RG,iQ,Mx,Dt)-CE	AmpliSens® *HCV*-Monitor-FRT	Real-Time	Reagents in stock tubes	80	RUO	quantitative	12 months	G Y	✓
R-V1-G-4x (RG,iQ,Mx)-CE	AmpliSens® *HCV*-1/2/3-FRT	Real-Time	Reagents in stock tubes	55	RUO	genotyping	9 months	G Y O R	✓
R-V1-G(1-4)-2x (RG,iQ,Mx,Dt,SC)--CE	AmpliSens® *HCV*-genotype-FRT	Real-Time, Reverse transcription	Reagents in stock tubes	55	RUO	genotyping	12 months	G Y	✓
R-V1-G(1-6)-2x (RG,iQ,Mx,Dt,SC)--CE	AmpliSens® *HCV*-genotype-FRT	Real-Time, Reverse transcription	Reagents in stock tubes	55	RUO	genotyping	12 months	G Y	✓
NEW H-4001-1-14-CE	AmpliSens® *HCV*-Monitor-L PCR kit. Variant FRT-L	Real-Time	Ready-to-use PCR tubes	480	RUO	quantitative	12 months	G Y	✓
NEW H-4001-1-14-100-CE	AmpliSens® *HCV*-Monitor-L PCR kit. Variant FRT-L	Real-Time	Ready-to-use PCR tubes	96	RUO	quantitative	12 months	G Y	✓



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

3.1.4. *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*-FRT 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 extraction, reverse transcription and amplification process and to identify possible reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V3-MC (RG,iQ,Mx,Dt)-CE	AmpliSens® *HDV*-Monitor-FRT			80	RUO	quantitative	12 months	G Y	✓
R-V3 (RG,iQ,Mx,Dt)-CE	AmpliSens® *HDV*-FRT			112	RUO	qualitative	12 months	G Y	⚠

3.1.5. *Hepatitis G virus*

Hepatitis G is a form of liver inflammation caused by *HGV* from the *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*-FRT PCR kit is One-Step RT-PCR qualitative test for the detection of *HGV* in clinical samples. FRT kit contains Internal Control for the detection of RNA extraction, reverse transcription and cDNA amplification.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V2-50-F (RG,iQ,Mx,Dt)-CE	AmpliSens® *HGV*-FRT PCR kit			55	CE IVD	qualitative	12 months	G Y	✓

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✓ available; for detailed explanations and usable PCR cyclers see page 9

3.2. MULTIPLEX PCR DETECTION KITS

3.2.1. *HCV/HBV/HIV*

AmpliSens® *HCV/HBV/HIV* FRT PCR kits are multiplex PCR tests for qualitative detection and differentiation of HCV/HBV/HIV-1/HIV-2(R-V62-CE) or *HCV/HBV/HIV*-1 (R-V50-4x-CE). The analytical sensitivity of the kits depend on the clinical sample volume and is for: *HCV* 100 IU/ml (100 ul sample) or 10 IU/ml (1 ml sample), for *HBV* 50 IU/ml (100 ul sample) or 5 IU/ml (1 ml sample), for *HIV*-1 200 copies/ml (100 ul sample) or 20 copies/ml (1 ml sample). For *HIV*-2 600 copies/ml (100 ul sample) or 60 copies/ml (1 ml sample).

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V62(RG,Dt)-CE	AmpliSens® *HCV/HBV/HIV*-FRT			100	RUO	qualitative	12 months	G Y O R C	✓
R-V50-4x (RG,iQ,Mx,Dt)-CE	AmpliSens® *HCV/HBV/HIV*-FRT			100	RUO	qualitative	12 months	G Y O R	⚠

3.2.2. *HBV/HDV*

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V56 (RG,iQ,Mx,Dt)-CE	AmpliSens® *HBV/HDV*-FRT			112	RUO	qualitative	12 months	G Y O	✓

3.2.3. 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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-O5-100-F (RG,iQ,Dt,CFX)-CE	AmpliSens® Genoscreen-IL28B-FRT PCR kit			110	CE IVD	genotyping	12 months	G Y O	✓

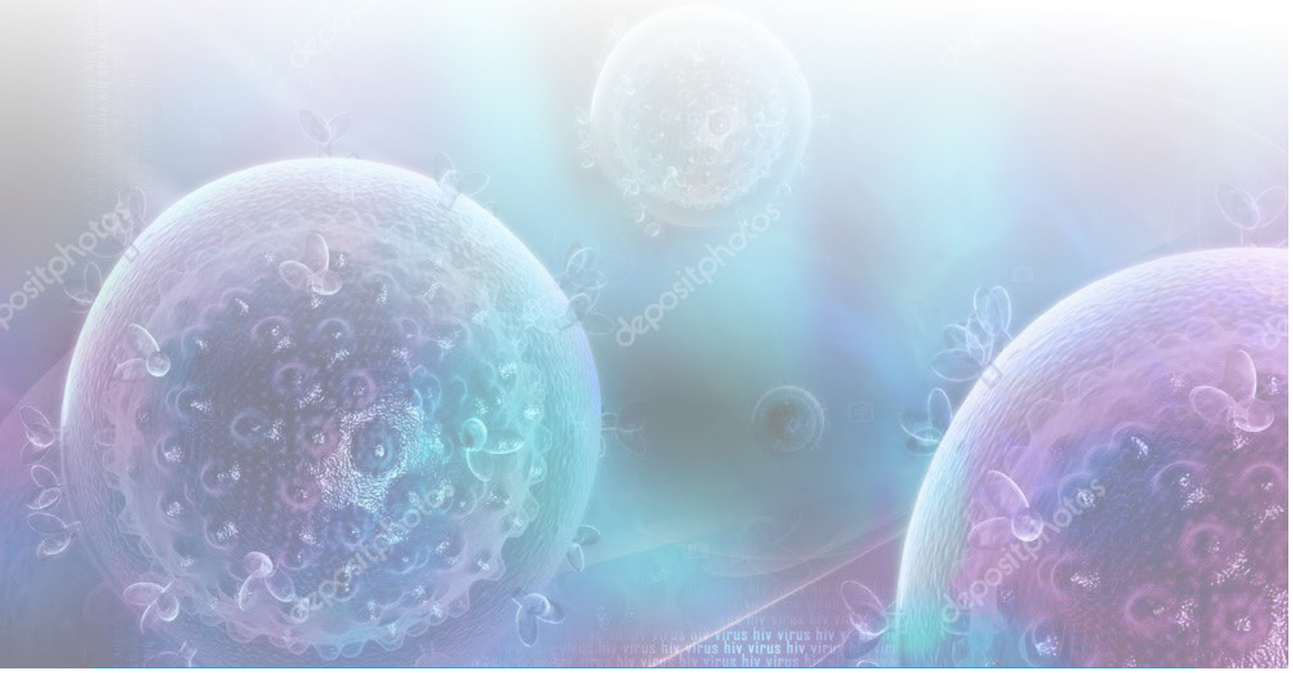
Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✓ available; for detailed explanations and usable PCR cyclers see page 9

4. *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 a 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 people with clinical stage 3 have AIDS. Clinical stage 4 - includes 22 opportunistic infections or cancers related to *HIV*. All people with clinical stage 4 have AIDS.



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

4.1.1. *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 - the direct viral killing of infected cells; second - increased rates of apoptosis in infected cells and third - the 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® *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 us to determine the quality of RNA extraction, reverse transcription and amplification processes. Analytical sensitivity is 500 copies/ml *HIV*-1 (100µl sample) or 50 copies/ml *HIV*-1 (1 ml sample).

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 us to determine the quality of DNA extraction and amplification processes. Analytical sensitivity is 500 GE/ml DNA (250 µl sample).

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V0-MC (RG,iQ,Mx,Dt)-CE	AmpliSens® *HIV*-Monitor-FRT PCR kit	●	▮	80	RUO	quantitative	12 months	G Y	✔
TR-V0-G (RG,iQ)-CE	AmpliSens® DNA-*HIV*-FRT	●	▮	120	RUO	qualitative	12 months	G Y	✔
NEW H-4011-1-14-CE	AmpliSens® *HIV*-Monitor-L PCR kit. Variant FRT-L	●	▮▮▮	480	RUO	quantitative	12 months	G Y	✔
NEW H-4011-1-14-100-CE	AmpliSens® *HIV*-Monitor-L PCR kit. Variant FRT-L	●	▮▮▮	96	RUO	quantitative	12 months	G Y	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

4.1.2. *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 people 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 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 are typical of pneumothorax.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-F2-Mod (RG,iQ,Mx)-CE	AmpliSens *Pneumocystis jirovecii (carinii)*-FRT PCR kit	●	▮	60	CE IVD	qualitative	9 months	G Y	✔

4.1.3. *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.

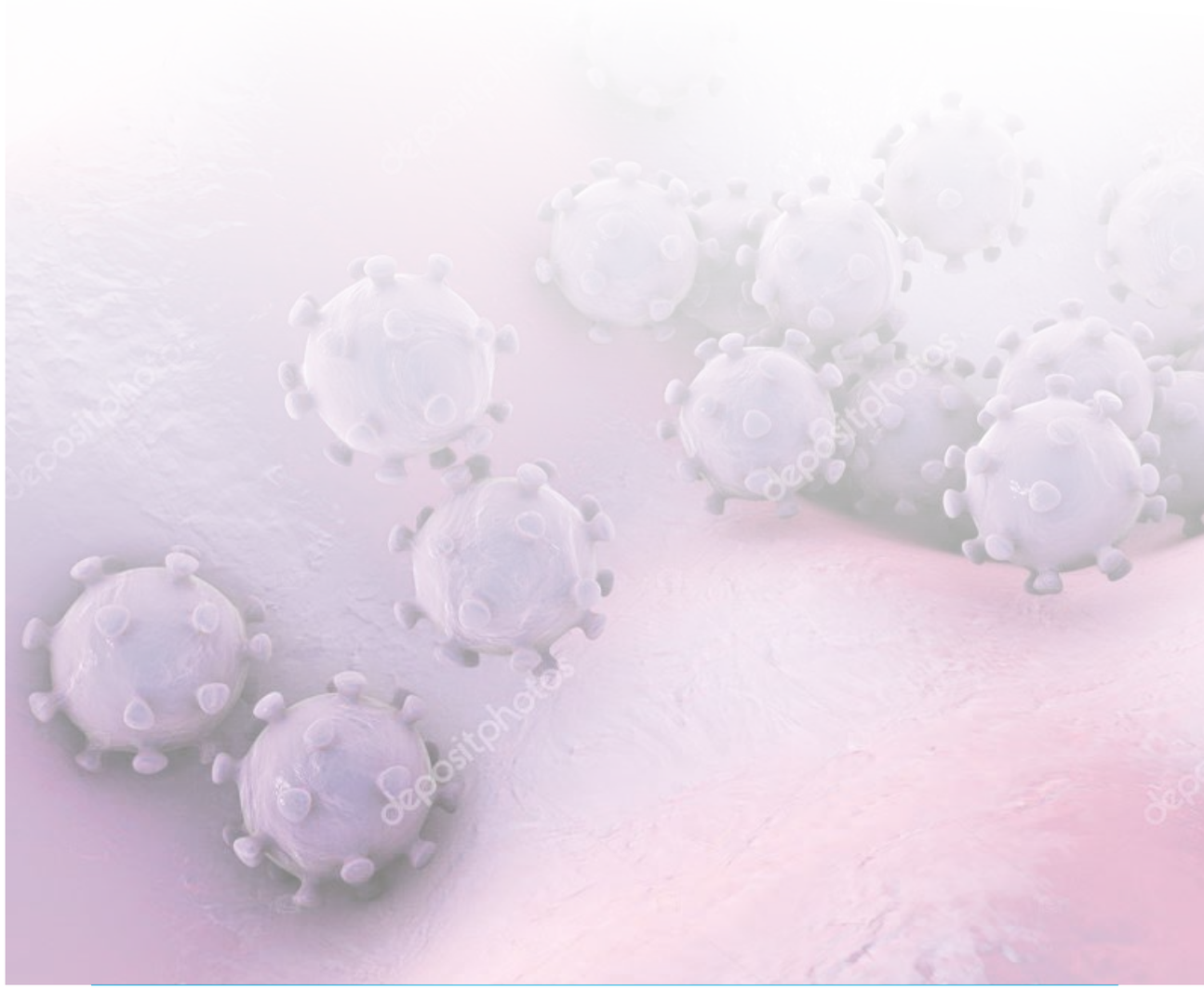
Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-F4-F(RG,iQ)-CE	AmpliSens® *Cryptococcus neoformans*-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y	✔

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

4.1.4. Identification of Drug Resistant Mutations: GenoScreen HLA B*5701

AmpliSens® Genoscreen HLA B*5701 - FRT is a PCR test for the qualitative detection of B locus 57:01 allele of HLA B*57:01 in clinical material (whole blood and oropharyngeal swabs).

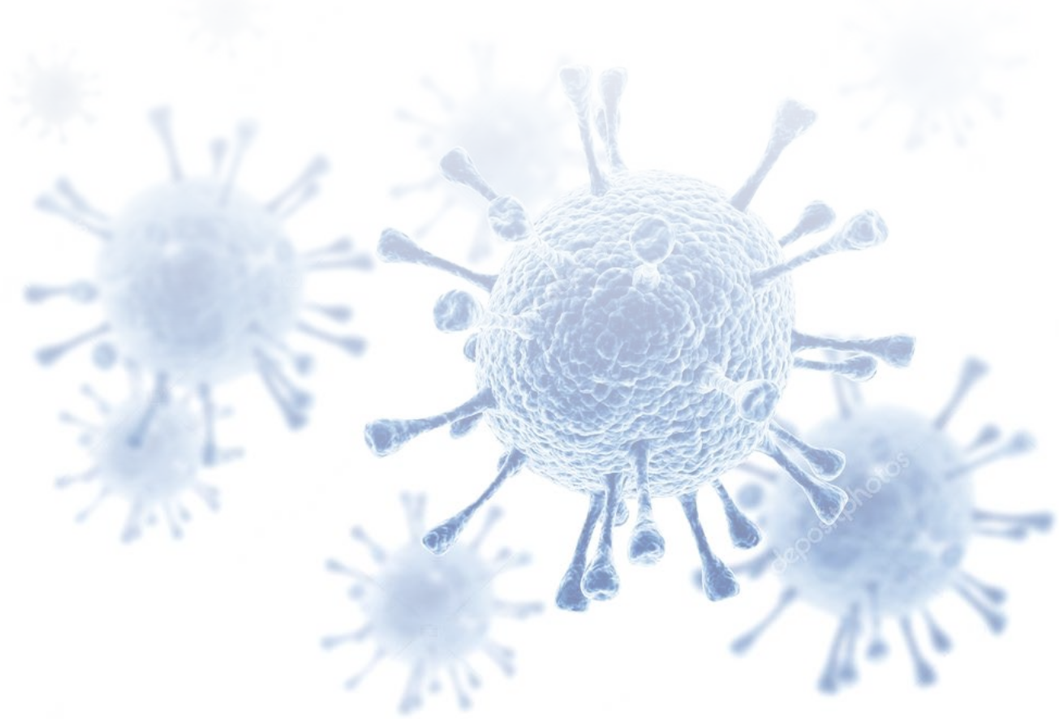
Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-O2(RG,iQ)-CE	AmpliSens® Genoscreen HLA B*5701-FRT	●	▮	110	CE IVD	qualitative	12 months	G Y	✔



● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

5. RESPIRATORY INFECTIONS

Respiratory tract infection refers to any of a number of infectious diseases involving the respiratory tract. An infection of this type is normally further classified as an upper respiratory tract infection (URI) or a lower respiratory tract infection (LRI). Lower respiratory infections, such as pneumonia, 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 tends to bind to receptors deep in the lungs. Viruses cause most URIs, with rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, coxsackievirus and influenza virus. Human metapneumovirus is a newly discovered agent causing URIs. Group A beta-hemolytic streptococci (GABHS) cause 5 % to 10 % of cases of pharyngitis in adults. Other less common causes of bacterial pharyngitis include group *C beta-hemolytic streptococci*, *Corynebacterium diphtheriae*, *Neisseria gonorrhoeae*, *Arcanobacterium haemolyticum*, *Chlamydia pneumoniae*, *Mycoplasma pneumoniae and Herpes simplex virus*. *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* are the most common organisms that cause the bacterial superinfection of viral acute sinusitis. Less than 10 % of cases of acute tracheobronchitis are caused by *Bordetella pertussis*, *B. parapertussis*, *M. pneumoniae* or *C. pneumoniae*.



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

5.1.1. *Influenza virus* A/B

Influenza A and B viruses routinely spread in people are responsible for seasonal flu epidemics. The emergence of a new influenza virus causing illness in people can result in a pandemic influenza. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: hemagglutinin (H) and neuraminidase (N) and are constantly changing through a process called „antigenic drift".
Influenza B viruses naturally infect humans and seals. In comparison to influenza A viruses, influenza B viruses generally change more slowly.
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-FRT 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).

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V36-100-F-Mod (RG,iQ,Dt,CFX,SC)--CE	AmpliSens® *Influenza virus* A/B-FRT PCR kit			100	CE IVD	qualitative	12 months	G Y O	

5.1.2. *Influenza virus* A/H1N1 & H3N2

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V54-100-F (RG,iQ,Dt,SC)-CE	AmpliSens® *Influenza virus* A-type-FRT			100	CE IVD	qualitative	12 months	G Y O	

5.1.3. *Influenza virus* A-type H5, H7, H9

AmpliSens® *Influenza virus* A-type-H5, H7, H9-FRT 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).

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V66-F-CE	AmpliSens® *Influenza virus* A-type-H5, H7, H9-FRT PCR kit			55	CE IVD	qualitative	9 months	G Y O	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

5.1.4. 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 subtypes.

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-FRT PCR kits are qualitative tests, containing the Internal Control in order to control the RNA extraction process and to identify PCR reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V33(SC)-CE	AmpliSens® *Influenza virus A* H5N1-FRT	Real-Time, Reverse transcription	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G, Y	✔ available

5.1.5. *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-FRT 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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V55(RG)-CE	AmpliSens® *Influenza virus* A/H1-swine-FRT (aliquoted in 0,2 ml tubes)	Real-Time, Reverse transcription	Ready-to-use PCR tubes	55	CE IVD	qualitative	9 months	G, Y	✔ available
R-V55-F(SC)-CE	AmpliSens® *Influenza virus* A/H1-swine-FRT	Real-Time, Reverse transcription	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G, Y	⚠ on request
V55-50-R0, 2-FEP-CE	AmpliSens® *Influenza virus* A/H1-swine-FEP PCR kit	Real-Time, Reverse transcription, Fluorescent End-Point	Ready-to-use PCR tubes	55	CE IVD	–	9 months	–	⚠ on request

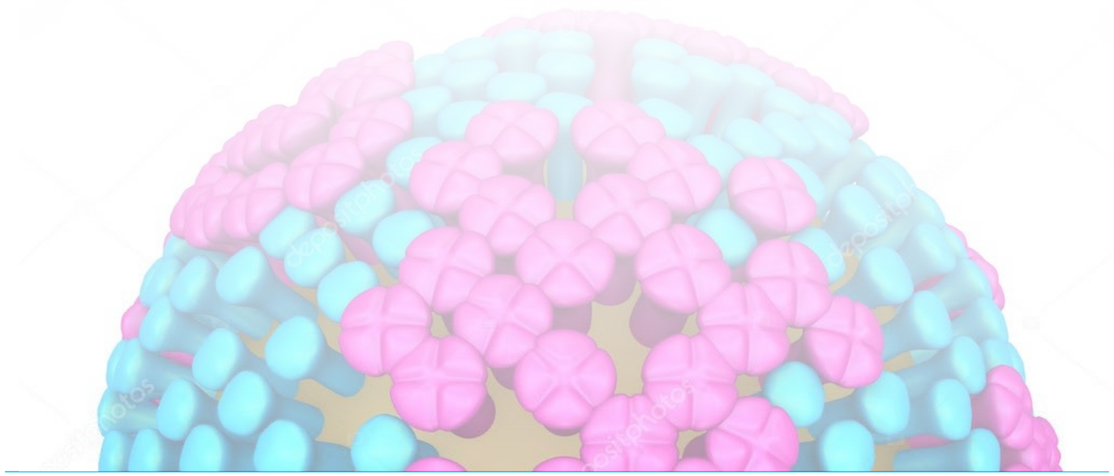
Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

5.1.6. *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 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, paraffin blocks and environmental samples can be used. For DNA extraction from synovial fluid Mukolysin reagent is necessary to use. AmpliSens® *MTC*-FRT kit 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/HEX/Yellow.

AmpliSens® MTC-diff-FRT PCR kit detects and differentiates *M. tuberculosis*, *M. bovis* and *M. bovis* BCG strains. UDG is used in all kits for preventing contamination.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B57 (RG,iQ,SC,Dt)-CE	AmpliSens® *MTC*-FRT	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G, Y	✔ available
R-B80 (RG,iQ,Dt,SC)-CE	AmpliSens® *MTC*-diff-FRT PCR kit	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	12 months	G, Y, O, R	⚠ on request
H-3611-1-CE	AmpliSens® *MTC*-MDR-FRT PCR kit. variant FRT-50 F	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	12 months	G, Y, O, R	✔ available
H-3612-1-4-CE	AmpliSens® *MTC*-MDR-FRT PCR kit. variant FRT-L	Real-Time	Ready-to-use PCR tubes	48	CE IVD	qualitative	12 months	G, Y, O, R	✔ available
B57-FEP-CE	AmpliSens® *MTC*-FEP	Real-Time, Reverse transcription, Fluorescent End-Point	Reagents in stock tubes	55	CE IVD	qualitative	9 months	–	⚠ on request



Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

5.1.7. *Legionella pneumophila*

L. pneumophila infection can cause Legionnaire´s disease, a severe form of pneumonia. The symptoms of Legionnaire's disease include confusion, headache, diarrhoea, abdominal pain, fever, chills and myalgia as well as 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 the qualitative detection of *L. pneumophila* DNA in the clinical materials (sputum or aspirate from the trachea, nasopharyngeal swabs, throat swabs, bronchi scourage or bronchoalveolar lavage, autopsy material), microorganism cultures and qualitative detection and also quantitation of *L. pneumophila* DNA in environmental samples (water, washes from environmental objects, biofilms scrapes, ground).

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B50(RG)-CE	AmpliSens® *Legionella pneumophila*-FRT	Real-Time	Ready-to-use PCR tubes	70	CE IVD	quantitative	9 months	G Y	available
B50-R0,2-FEP-CE	AmpliSens® *Legionella pneumophila*-FEP	Fluorescent End-Point	Ready-to-use PCR tubes	55	CE IVD	–	9 months	–	on request

5.1.8. *Corynebacterium diphteriae*

Corynebacterium is a genus of bacteria that are widely distributed in nature in the microbiota of animals. Toxin producing *C. diphtheriae* infects the respiratory tract and causes most notably diphtheria. Diphtheria spreads from person to person, usually through respiratory droplets.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2842-1-CE	AmpliSens® *Corynebacterium diphtheriae* / tox-genes-FRT PCR kit variant FRT-100 F	Real-Time	Reagents in stock tubes	110	CE IVD	qualitative + toxins	12 months	G Y O R	on request

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

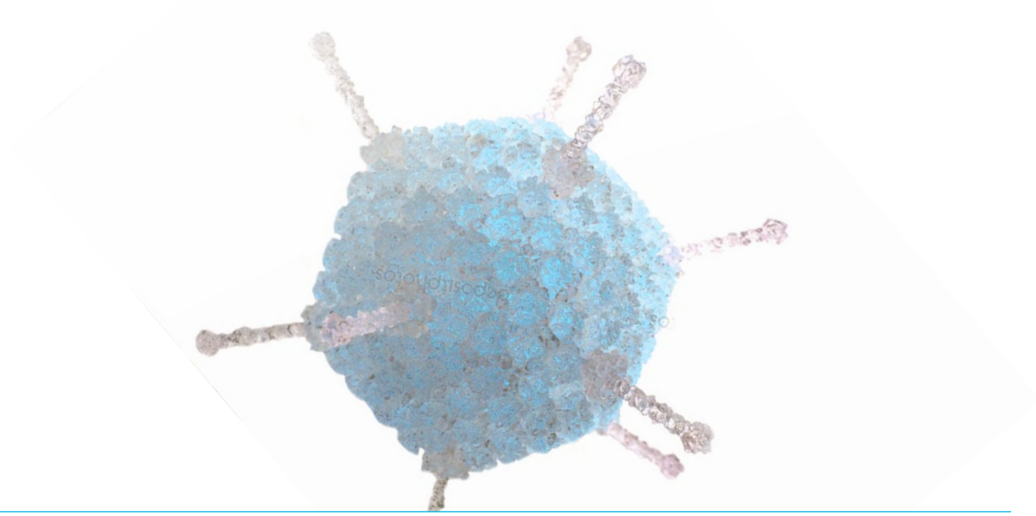
5.2. MULTIPLEX PCR DETECTION KITS

5.2.1. Acute Respiratory Viral Infections (ARVI)

Acute respiratory viral infections (ARVI) belong to the most frequent illnesses. There is a wide spectrum of DNA and RNA viruses, responsible for ARVI. To the most important viruses belong: rhinoviruses, coronaviruses, parainfluenza viruses, respiratory syncytial virus, adenoviruses and metapneumoviruses. Rhinoviruses and coronaviruses are the most frequent cause of the common cold. There are min. 99 recognized types of Human rhinoviruses that differ according to their surface proteins and four to five different currently known strains of coronaviruses that infect humans. Parainfluenza viruses and RSVs show high similarities while four types of parainfluenza viruses are known. Parainfluenza type 4 is rare and causes only very light cold. In contrast, whenever young children are studied, parainfluenza types 1, 2 and 3 and RSV lead to respiratory illnesses with hospitalization. Types 1 and 2 most typically cause laryngotracheobronchitis, parainfluenza type 3 produces pneumonia, often with of obstruction. For most people, RSV produces only mild symptoms, often indistinguishable from common colds and minor illnesses. The typical syndrome is usually bronchiolitis, but pneumonia is sometimes diagnosed as well.

AmpliSens® ARVI-screen-FRT 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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V57-100-F(R-G,iQ,Dt)-CE	AmpliSens® ARVI-screen-FRT PCR kit	Real-Time Reverse transcription	Reagents in stock tubes	100	CE IVD	qualitative	12 months	G Y O	available



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

ECOLI

5.2.2. *Bordetella* multiplex

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.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B84-100-F(R-G,iQ,Dt)-CE	AmpliSens® *Bordetella multi*-FRT	●	▮	100	CE IVD	qualitative	12 months	G Y O R	✔

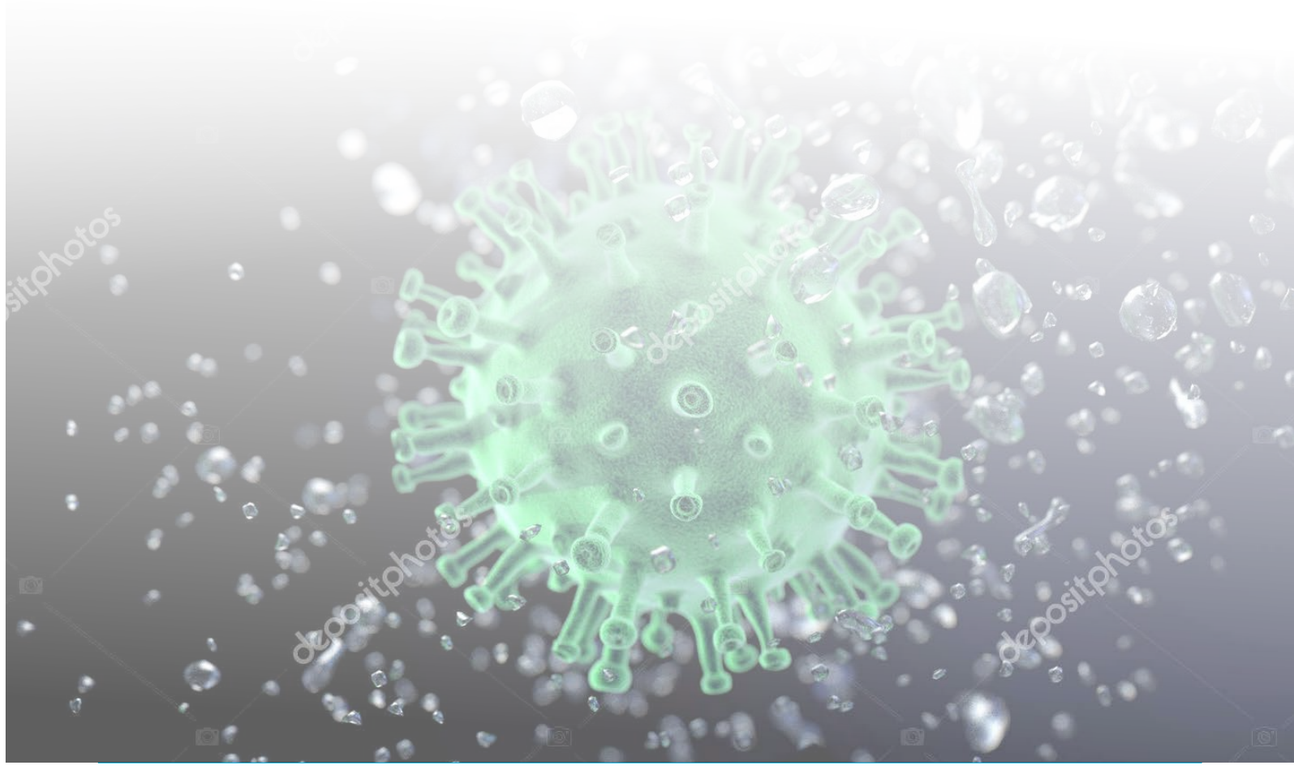
5.2.3. *Mycoplasma pneumoniae / Chlamydophila pneumoniae*

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B42-100-F-CE	AmpliSens® *Mycoplasma pneumoniae/ Chlamydophila pneumoniae*-FRT PCR kit	●	▮	100	CE IVD	qualitative	9 months	G Y O	✔
B42-50-R0, 2-FEP-CE	AmpliSens® *Mycoplasma pneumoniae/ Chlamydophila pneumoniae*-FEP	★	▮▮▮	55	CE IVD	–	9 months	–	▲

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

6. 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 viral particle contacts a cell. Following binding, the virion is internalized and dismantled, allowing viral DNA to migrate to the cell nucleus, where replication of viral DNA and transcription of viral genes occurs. During symptomatic infection, infected cells transcribe lytic viral genes. In some host cells, a small number of viral genes termed latency-associated transcript (LAT) accumulate instead. In this fashion, the virus can persist in the cell (and thus the host) indefinitely. While the primary infection is often accompanied by a self-limited period of clinical illness, long-term latency is symptom-free. Reactivation of latent viruses has been implicated in a number of diseases. Following activation, transcription from latency-associated LAT to multiple lytic genes lead to enhanced replication and virus production. Clinically, lytic activation is often accompanied by the 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 and 2, *VZV*, *EBV*, *CMV*, *HHV-6*, *HHV-7*, *HHV-8*.



● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

6.1.1. *Cytomegalovirus*

CMV infection is common and usually asymptomatic in healthy children and adults, but can cause severe disease in newborns and immunocompromised patients. Infections are often recurrent, caused by reactivation of latent virus (especially in transplant recipients), but reinfection may also occur due to the antigenic diversity of the virus. Infection may cause a mononucleosis-like-syndrome with prolonged fever (lasting 2-3 weeks), malaise, atypical lymphocytosis, cervical lymphadenitis, mild hepatitis and encephalitis. *CMV* can persist in body fluids such as urine, saliva and seminal fluids for many years, or can remain dormant until reactivation of the latent infection. Transmission occurs through direct contact with body fluids from people excreting the virus, thus the infection may be transmitted between humans and from adults to children through childbirth and breastfeeding.

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V7-100-S (RG,iQ,Mx)-CE	AmpliSens® *CMV*-screen/ Monitor-FRT	●	▮	110	CE IVD	quantitative	12 months	G Y O	✓
R-V7-F(RG,iQ)-CE	AmpliSens® *CMV*-FRT PCR kit	●	▮	110	CE IVD	qualitative	12 months	G Y	✓

6.1.2. *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 periorbital edema, 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-FRT kit can determine quantity of *EBV* in 1 ml of the liquid sample or *EBV* DNA concentration in copies per the human cell quantity. The linear range of AmpliSens *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 cells.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V9-100-S(R-G,iQ,Mx)-CE	AmpliSens® *EBV*-screen/ Monitor-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y O	✓

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

6.1.3. *Varicella zoster virus*

Varicella-zoster virus (*VZV*) is closely related to the *herpes simplex viruses* (*HSV*), sharing much genome homology. The known envelope glycoproteins (gB, gC, gE, gH, gI, gK, gL) correspond with those in HSV, however, there is no equivalent of HSV gD. VZV also fails to produce the LAT (latency-associated transcripts) that play an important role in establishing HSV latency (herpes simplex virus). VZV is known by many names such as chicken pox virus, varicella virus, zoster virus and human herpes virus type 3 or HHV-3. Varicella is chicken pox and zoster is shingles.

These are two different types of illnesses that manifest themselves through lesions, fever, and overall not feeling well. After having the chicken pox typically as a child, the virus lies dormant in the body before reoccurring into a viral infection. Only about twenty-five percent of adults are affected by the reactivation known as shingles. Both chicken pox and shingles are caused by the Varicella zoster igg which is a type of a herpes virus. Chicken pox is spread by human contact through the rash, sneezing, coughing or breathing. The contagious period appears two days before the rash appears to the day when the last lesion has crusted over. After the chicken pox the virus hibernates in the body's nerve cells along the spine. When the virus in an adult decides to wake up due to stress, aging or a weaken immune system, it reappears as pain and a rash. The rash will usually last up to thirty days.

AmpliSens® *VZV*-FRT PCR 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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V61-50-F(RG)-CE	AmpliSens® *VZV*-FRT	●	▮	60	CE IVD	qualitative	9 months	G Y	✓

6.1.4. *Human Herpes virus 6*

HHV-6 is an immunosuppressive and neurotropic virus that can cause encephalitis and seizures during a primary infection or when it is reactivated from latency in immunosuppressed patients. *HHV*-6 may play a role in several chronic neurological conditions including mesial temporal lobe epilepsy, status epilepticus and chronic fatigue syndrome. Primary *HHV*-6 infection usually occurs in infants and is the most common cause of fever-induced seizures in children aged 6-24 months. Acute *HHV*-6 infection is rare in immunocompetent adults but may manifest as a mononucleosis like illness with fever, lymphadenopathy and hepatitis or encephalitis, with negative test results for *CMV* or *EBV*.

AmpliSens® *HHV6*-screen-titre-FRT is a quantitative PCR kit with calculation of *HHV*-6 per ml or number of human cells. This 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/10^5 cells.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V10-T(RG,iQ,Mx)--CE	AmpliSens® *HHV6*-screen-titre-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y	✓

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

6.1.5. *Human Herpes virus 7*

HHV-7 is one of nine known members of the *Herpesviridae* family that infects humans. *HHV-7* is a member of *Betaherpesvirinae*, a subfamily of the *Herpesviridae* that also includes *HHV-6* and *Cytomegalovirus* (*HHV-5* or *HCMV*). *HHV-7* often acts together with *HHV-6*, and the viruses together are sometimes referred to by their genus, Roseolovirus.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2431-1-1-CE	AmpliSens® *HHV7*-screen/monitor-FRT PCR kit	●	▮	110	CE IVD	quantitative	12 months	G Y O	✔

6.1.6. *Herpes Simplex virus HSV-1, 2*

The primary difference between the two viral types is in the location 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.

AmpliSens® *HSV I,II*-FRT PCR kit is qualitative test and contains the Internal Control to control the extraction process of each sample and to identify possible reaction inhibition. Analytical sensitivity is 1 x 10^3 copies/ml.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V8-F(RG,iQ)-CE	AmpliSens® *HSV I,II*-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y	✔

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

6.1.7. *Herpes Simplex virus* Genotyping

AmpliSens® *HSV*-typing-FRT PCR kits are *in vitro* nucleic acid amplification tests for qualitative detection and differentiation of *Herpes Simplex virus* types 1 and 2 (*HSV-1* a *HSV-2*). In the biological material (scrapes, swabs of urogenital tract mucous membranes; papules, vesicles, or ulcers fluid; urine sediment) by using of Real-Time PCR. Kits contain the Internal Control, used in the extraction procedure in order to control the extraction process of each sample and to identify possible reaction inhibition. Analytical sensitivity is 10^3 copies/ml.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V38-F(RG,iQ)-CE	AmpliSens® *HSV*-typing-FRT	●	▮	110	CE IVD	qualitative	9 months	G Y O	✔

6.2. 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 is not affected by changing number of infections.

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V48 (RG,iQ,Mx)-CE	AmpliSens® *EBV/CMV/HHV6*-screen-FRT	●	▮	110	CE IVD	quantitative	12 months	G Y O R	✔

6.2.2. *Herpes Simplex virus / Cytomegalovirus*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V60-F(RG,iQ)-CE	AmpliSens® *HSV/CMV*-Multiprime-FRT	●	▮	110	CE IVD	quantitative	9 months	G Y O	▲

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

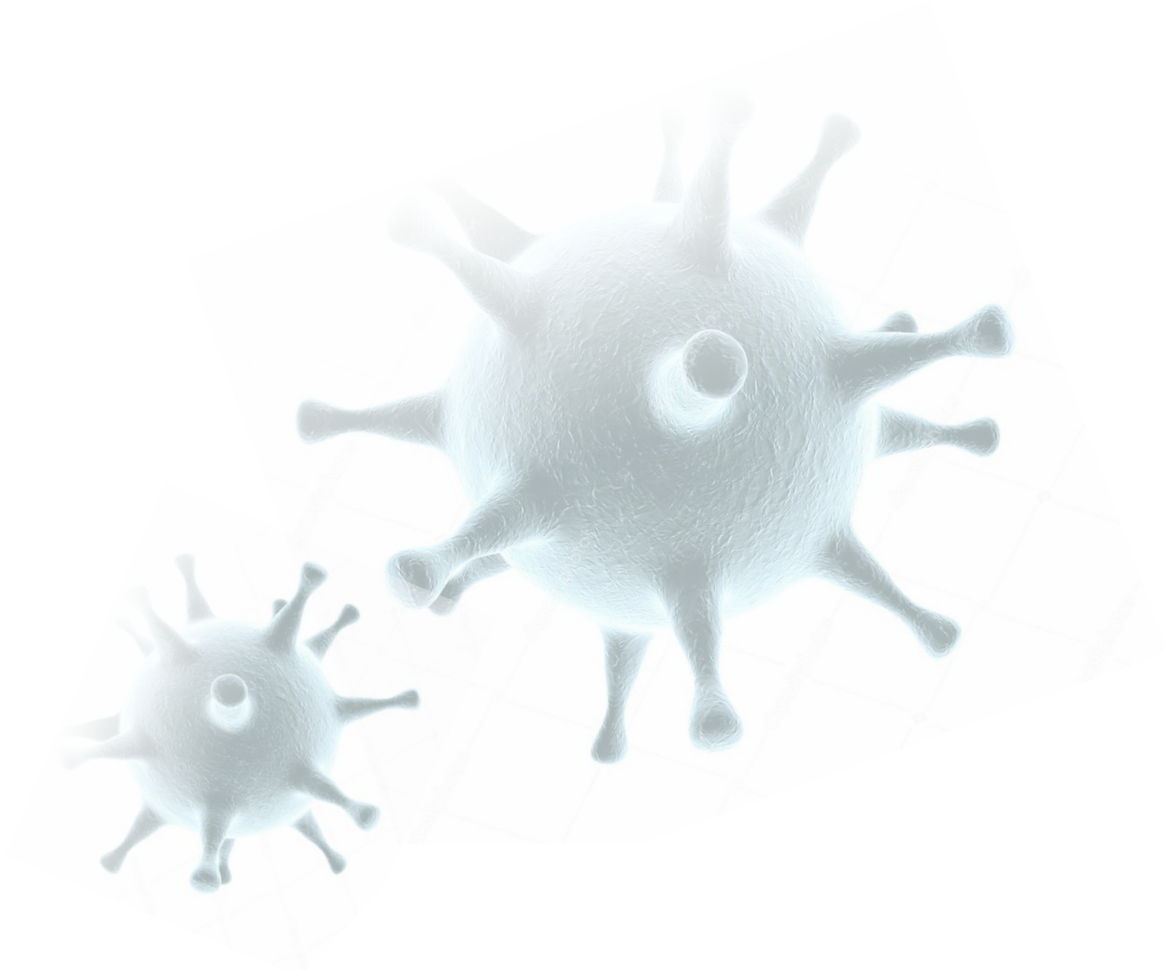
7. TORCH INFECTIONS

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

The TORCH complex was originally considered to consist of four conditions, with the „TO“ referring to „Toxoplasma“. The four-term form is still used in many modern references, and the capitalization „TORCH“ is sometimes used in these contexts. Alternatively, the „O“ is redefined as „other“, and the acronym is spelled out as follows:

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

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



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

7.1.1. *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 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, myocarditis and encephalitis. Congenital cases can result in the abortion and stillbirth, live births may result in the severe central nervous system involvement along with chorioretinitis.

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-P1(RG,iQ,Mx)-CE	AmpliSens® *Toxoplasma gondii*-FRT PCR kit	●	▮	60	CE IVD	qualitative	12 months	G Y	✔

7.1.2. *Parvovirus* B19

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

AmpliSens® *Parvovirus B19*-FRT Real Time PCR kit is a quantitative kit based on DNA extraction from the plasma of peripheral or umbilical blood, amniotic fluid, throat washes and swabs, saliva along with Internal Control.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V49 (RG,iQ,Mx)-CE	AmpliSens® *Parvovirus B19*-FRT	●	▮	60	CE IVD	quantitative	9 months	G Y	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

7.1.3. *Rubella virus*

Rubella virus belongs to the family *Togaviridae*. It causes a mild infection characterized by a 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*-FRT 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.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V24-S(R-G,iQ,Mx)-CE	AmpliSens® *Rubella virus*-FRT PCR kit	●	▮	60	CE IVD	qualitative	12 months	G Y	✓

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

8. 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 the 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 infections are very often resistant to antibiotics.

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

8.1.1. *MRSA*

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

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B78-100-FT (RG,iQ)-CE	AmpliSens® *MRSA*-screen-titre-FRT			110	CE IVD	quantitative	9 months	G Y O	

8.1.2. *Streptococcus agalactiae*

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

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B77-100-FT (RG,iQ)-CE	AmpliSens® *Streptococcus agalactiae*-screen-titre-FRT			110	CE IVD	quantitative	9 months	G Y O	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

8.1.3. *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/monitor-FRT PCR kit can detect and quantify *S. pyogenes* DNA.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2171-1-1-CE	AmpliSens® *Streptococcus pyogenes*-screen/monitor-FRT PCR kit variant FRT-100 FN			110	CE IVD	quantitative	12 months	G Y	

8.1.4. Genetic markers of antibiotic resistence

Kits are designed for the 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).

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-C1(RG,CFX)-CE	AmpliSens® MDR MBL-FRT PCR kit			110	CE IVD	qualitative	9 months	G Y O R	
R-C2(RG,CFX)-CE	AmpliSens® MDR KPC/OXA-48-FRT PCR kit			110	CE IVD	qualitative	9 months	G Y O	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

9. NEURO INFECTIONS

9.1.1. *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 people who become ill usually develop either mild upper respiratory symptoms, a flu-like illness with fever and muscle aches, or illness with rash. Less commonly, some people have aseptic or viral meningitis. Rarely, a person may develop an illness that affects the heart or the brain or causes paralysis. *Enterovirus* infections are suspected to play a role in the development of juvenile-onset diabetes mellitus.

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2773-1-CE	AmpliSens® *Human enterovirus*-FRT PCR kit variant FRT-50 F	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	12 months	G Y	✔
R-V64-F-CE	AmpliSens® *Enterovirus* 71-FRT PCR kit	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G Y	✔
H-2771-2-2-CE	AmpliSens® *Human enterovirus*-FEP PCR kit	Fluorescent End-Point	Ready-to-use PCR tubes	55	CE IVD	qualitative	12 months	G Y	✔

9.1.2. *Poliovirus*

Poliovirus is a human enterovirus and a member of the family of *Picornaviridae*. The genome is a single-stranded RNA genome and because of its short genome and its simple composition is poliovirus widely regarded as the simplest significant virus. There are 3 serotypes of *Poliovirus*, PV1, PV2 and PV3. PV1 is the most common form encountered in nature, however, all three forms are extremely infectious. Poliovirus infection occurs via the fecal-oral route. The virus is shed in the feces of infected individuals.

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

AmpliSens® *Poliovirus*-FRT PCR kit is an amplification test for the 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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V58(RG,iQ)-CE	AmpliSens® *Poliovirus*-FRT	Real-Time	Reagents in stock tubes	55	CE IVD	qualitative	9 months	G Y O	✔

9.1.3. *Listeria monocytogenes*

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2161-1-1-CE	AmpliSens® *Listeria monocytogenes*-screen/monitor-FRT PCR kit variant FRT-50 FN	Real-Time	Reagents in stock tubes	55	CE IVD	quantitative	12 months	G Y O	✔

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

Real-Time · Reverse transcription · Fluorescent End-Point · Reagents in stock tubes · Ready-to-use PCR tubes
⚠ on request · ✔ available; for detailed explanations and usable PCR cyclers see page 9

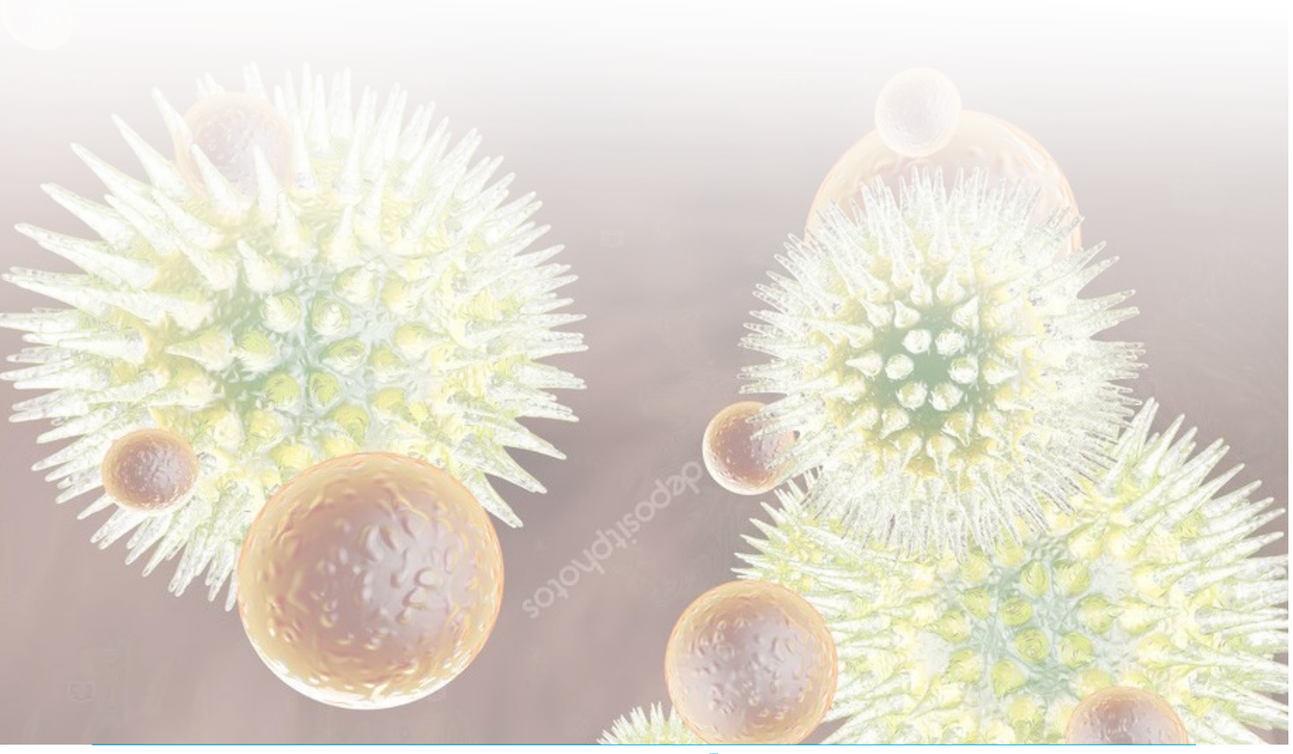
9.2. MULTIPLEX PCR DETECTION KITS

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B25(RG,iQ)-CE	AmpliSens® *N. meningitidis/ H. influenzae/ S. pneumoniae*-FRT			55	CE IVD	qualitative	9 months	G Y	

9.2.2. *JC Virus/BK Virus*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2441-1-1-CE	AmpliSens® *JCV-BKV* screen/monitor-FRT PCR kit			110	CE IVD	quantitative	12 months	G Y O	



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

10. INTESTINAL INFECTIONS

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B9(RG,iQ)-CE	AmpliSens® *Helicobacter pylori*-FRT			55	CE IVD	qualitative	9 months	G Y	

10.1.2. *Norovirus*

Norovirus, sometimes referred to as the winter vomiting bug, is the most common cause of gastroenteritis. Infection is characterized by non-bloody diarrhea, vomiting, and stomach pain. Fever or headaches may also occur. Symptoms usually develop 12 to 48 hours after being exposed, and recovery typically occurs within 1 to 3 days. Complications are uncommon, but may include dehydration, especially in the young, the old, and those with other health problems.

The virus is usually spread by the fecal–oral route. This may be through contaminated food or water or person-to-person contact. It may also spread via contaminated surfaces or through the air from the vomit of an infected person. Risk factors include unsanitary food preparation and sharing close quarters.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
H-2751-1-3-CE	AmpliSens® *Norovirus GI/ GII*-FRT PCR kit variant FRT-50 F			55	CE IVD	qualitative	12 months	G Y O	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

ECOLI

10.2. MULTIPLEX PCR DETECTION KITS

10.2.1. *Rotavirus / Norovirus / Astrovirus*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V40(RG,iQ)-CE	AmpliSens® *Rotavirus/ Norovirus/Astrovirus*-FRT			55	CE IVD	qualitative	9 months	G Y	

10.2.2. All screen *Shigella + EIEC / Salmonella / Campylobacter/ Rotavirus / Norovirus / Astrovirus / Adenovirus*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B45(RG,iQ)-CE	AmpliSens® All-screen-FRT			55	CE IVD	qualitative + genotyping	9 months	G Y	

10.2.3. *Shigella* and *EIEC / Salmonella / Campylobacter*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B44(RG,iQ)-CE	AmpliSens® *Shigella spp.* and *EIEC/Salmonella spp./Campylobacter spp.*-FRT PCR kit			55	CE IVD	qualitative	9 months	G Y	

10.2.4. *Yersinia enterolytica / Yersinia pseudotuberculosis*

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B64(RG,iQ)-CE	AmpliSens® *Y.enterocolitica/ Y. pseudotuberculosis* -FRT			55	CE IVD	qualitative	9 months	G Y O	

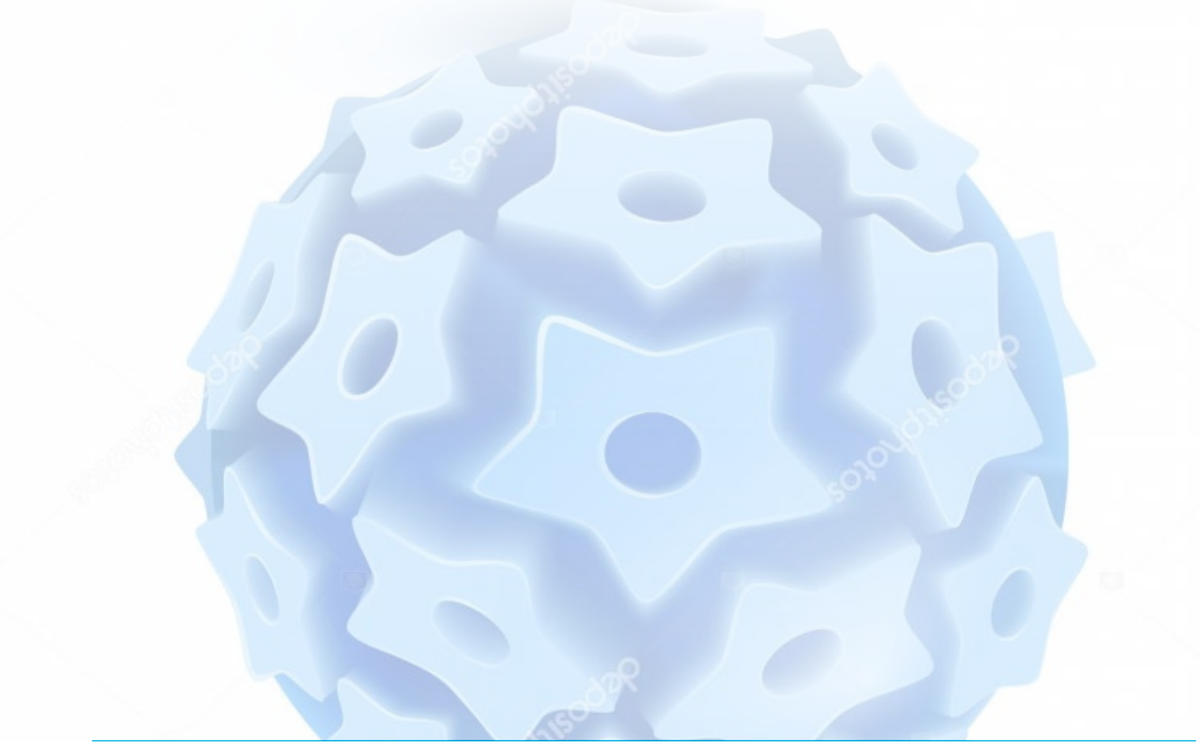
Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

10.2.5. Escherichiose

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 (enterotoxigenic *E. coli*), hemorrhagic colitis and hemolytic-uremic syndrome (enterohemorrhagic *E. coli*), persistent diarrhea (enteroaggregative *E. coli*) and watery diarrhea of infants (enteropathogenic *E. coli*).

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B62(RG,iQ)-CE	AmpliSens® Escherichioses-FRT PCR kit			55	CE IVD	qualitative	9 months	G Y O	



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

11. ESPECIALLY DANGEROUS AND FERAL HERD INFECTIONS

11.1.1. *Vibrio cholerae*

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

AmpliSens® *Vibrio cholerae*-FRT PCR kit enables to detect *V. cholerae* DNA (if Hly sequence is present) and identification of pathogen V. cholerae strains (if main virulence factors - CtxA, tcpA are present), belonging to serogroups O1 (if amplification target wbeT is present), or O139 (if amplification target wbf is present). Analytical sensitivity is 1 x 10^3 copies/ml.

Amplisens® *Vibrio cholerae*-FRT PCR kit contains two mastermixes: PCR-mix-1-FRT screen for amplification of CtxA target, tcpA and Internal Control, and the PCR-mix-1-FRT type for amplification of Hly target (cholera germs of all group), wbeT (serogroup O1) and wbf (serogroup O139). It is necessary to carry out both "Screen" and "Type" reactions for valid results interpretation.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B53(RG)-CE	AmpliSens® *Vibrio cholerae*-FRT (aliquoted in 0,2 ml tubes)	●	▮▮▮	55	CE IVD	screen + genotyping	9 months	G Y O	✔

11.1.2. *Bacillus anthracis*

Bacillus anthracis is typically a disease of herbivores, although it can affect other animals as well. Infection in humans traditionally have 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 the qualitative detection of vegetative and cryptogamic forms of *B. anthracis* DNA in biological material and environmental compartments as well as for determination of *B. anthracis* plasmid composition by identification of pagA (plasmid pXO1) and capA (plasmid pXO2) genes.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B41(RG)-CE	AmpliSens® *Bacillus anthracis*-FRT (aliquoted in 0,2 ml tubes)	●	▮▮▮	55	CE IVD	qualitative	9 months	G Y O	✔

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

11.1.3. *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 to check the efficiency of DNA extraction process and identify possible reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B10(RG)-CE	AmpliSens® *Brucella spp.*-FRT (aliquoted in 0,2 ml tubes)	●	▮▮▮	55	CE IVD	qualitative	9 months	G Y	✔

11.1.4. *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 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. Analytical sensitivity is 5 x 10^2 copies/ml. AmpliSens® *Dengue virus*-FRT (H-2391-1-CE) is One-Step RTPCR test for detection of *Dengue virus* types 1-4 (without differentiation).

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V63(RG,CFX)-CE	AmpliSens® *Dengue virus* type-FRT	●	▮	60	CE IVD	qualitative	9 months	G Y O R C	✔
H-2391-1-CE	AmpliSens® *Dengue virus*-FRT PCR kit variant FRT-50 F	●	▮	55	CE IVD	qualitative	12 months	G Y	✔

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

11.1.5. *Leptospira species*

Leptospirosis is a bacterial disease caused by bacteria of the genus *Leptospira*, that affects humans and animals. In humans, it can cause a wide range of symptoms, some of which may be mistaken for other diseases. Some infected people, 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 a One-Step RT-PCR amplification test for the 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 the brain, lung, kidney) and animals suffering from acute infection (blood) or persistence of *Leptospira* microorganisms in the kidney (urine). PCR kit contains Internal Control to check RNA extraction and reverse transcription efficiency of each sample and to identify possible amplification reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B49(RG,iQ)-CE	AmpliSens® *Leptospira*-FRT			60	CE IVD	qualitative	9 months	G Y	

11.1.6. *Borrelia burgdorferi sensu lato*

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

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-B37(RG)-CE	AmpliSens® *Borrelia burgdorferi sensu lato*-FRT			60	CE IVD	qualitative	9 months	G Y	
H-2791-1-CE	AmpliSens® *Borrelia miyamotoi*-FRT PCR kit variant FRT-50 FN			55	CE IVD	qualitative	12 months	G O	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

11.1.7. *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 meningoencephalitis. 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 has 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).

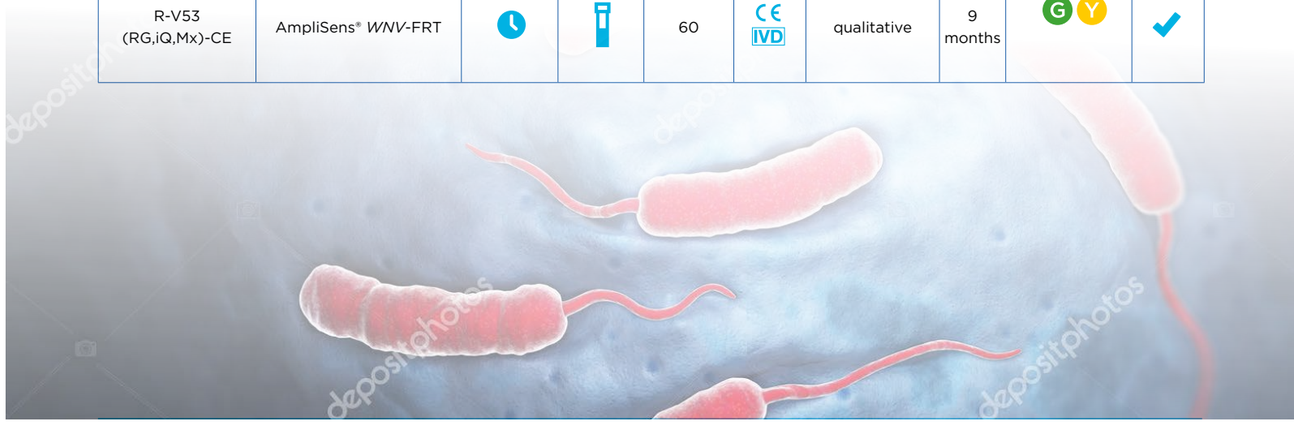
Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V52(RG)-CE	AmpliSens® TBE-FRT			120	CE IVD	qualitative	9 months	G Y	

11.1.8. *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 the 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 to check RNA extraction and reverse transcription processes of each sample and to identify possible cDNA amplification reaction inhibition.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V53 (RG,iQ,Mx)-CE	AmpliSens® *WNV*-FRT			60	CE IVD	qualitative	9 months	G Y	



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V22-50-F (RG,iQ,Mx,Dt)-CE	AmpliSens® CCHFV-FRT	●	▮	60	CE IVD	qualitative	9 months	G Y	✓

11.1.10. *Yersinia pestis*

Yersinia pestis (formerly *Pasteurella pestis*) is a Gramnegative rod-shaped coccobacillus, a facultative anaerobic bacterium that can infect humans and other animals. Human Y. pestis infection takes three main forms: pneumonic, septicemic and bubonic plagues. All three forms were responsible for a number of high-mortality epidemics throughout human history, including the Justinianic plague of the 6h century and the Black Death that accounted for the death of at least one-third of the European population between 1347 and 1353. It has now been shown that these plagues probably originated in rodent populations in China.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B79(RG,iQ,D-t)-CE	AmpliSens® *Yersinia pestis*-FRT PCR kit	●	▮	60	CE IVD	qualitative	9 months	G Y	✓

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

11.1.11. *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.

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-B85-50-F (RG,iQ,Mx,Dt)-CE	AmpliSens® *Coxiella burnetii*-FRT	●	▮	60	CE IVD	qualitative	9 months	G Y	✓

11.1.12. *Ebola Zaire virus*

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

Catalog number	Description	Detection	Format	# of reactions	Certification	Assay detail	Shelf life	Fluorescent channels	Availability
R-V69-50-F-CE	AmpliSens *EBOV* Zaire 1-FRT PCR kit	●	▮	55	CE IVD	qualitative	12 months	G Y	✓
H-2781-1-4-CE	AmpliSens® FiloA-screen-FRT PCR kit variant FRT-L	●	▮▮▮	96	CE IVD	qualitative	12 months	G Y O R	✓

● Real-Time ● Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✓ available; for detailed explanations and usable PCR cyclers see page 9

11.1.13. *Zika virus*

Zika virus (ZIKV) is a member of the virus family Flaviridae. 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 dengue, yellow fever, Japanese encephalitis, and West Nile viruses. Since the 1950s, it has been known to occur within a narrow equatorial belt from Africa to Asia. From 2007 to 2016, the virus spread eastward, across the Pacific Ocean to the Americas, leading to the 2015– 16 Zika virus epidemic.

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
H-2411-1-CE	AmpliSens® *Zika virus*-FRT			55	CE IVD	qualitative	12 months	G Y	

11.1.14. *Yellow fever virus*

Yellow fever is caused by an RNA virus of the genus *Flavivirus*. It infects only humans and other primates. It is spread by the bite of an infected female mosquito, mainly by *Aedes aegypti*, a type of mosquito found throughout the tropics and subtropics. The disease may be difficult to tell apart from other illnesses, especially in the early stages. To confirm a suspected case, blood-sample testing by PCR is required.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
H-2461-1-CE	AmpliSens® *Yellow fever virus*-FRT PCR kit variant FRT-50 F			55	CE IVD	qualitative	12 months	G Y	

11.1.15. *Rickettsia*

Rickettsia bacterias are obligate intracellular parasites of living eukaryotic host cells. *Rickettsia* species cannot grow in artificial nutrient culture; they must be grown either in tissue or embryo cultures. *Rickettsia* species are transmitted by numerous types of arthropod, including chigger, ticks, fleas, and lice, and are associated with both human and plant diseases. Most notably, *Rickettsia* species are the pathogens responsible for typhus, rickettsialpox, boutonneuse fever, African tick-bite fever, Rocky Mountain spotted fever, Flinders Island spotted fever, and Queensland tick typhus (Australian tick typhus).

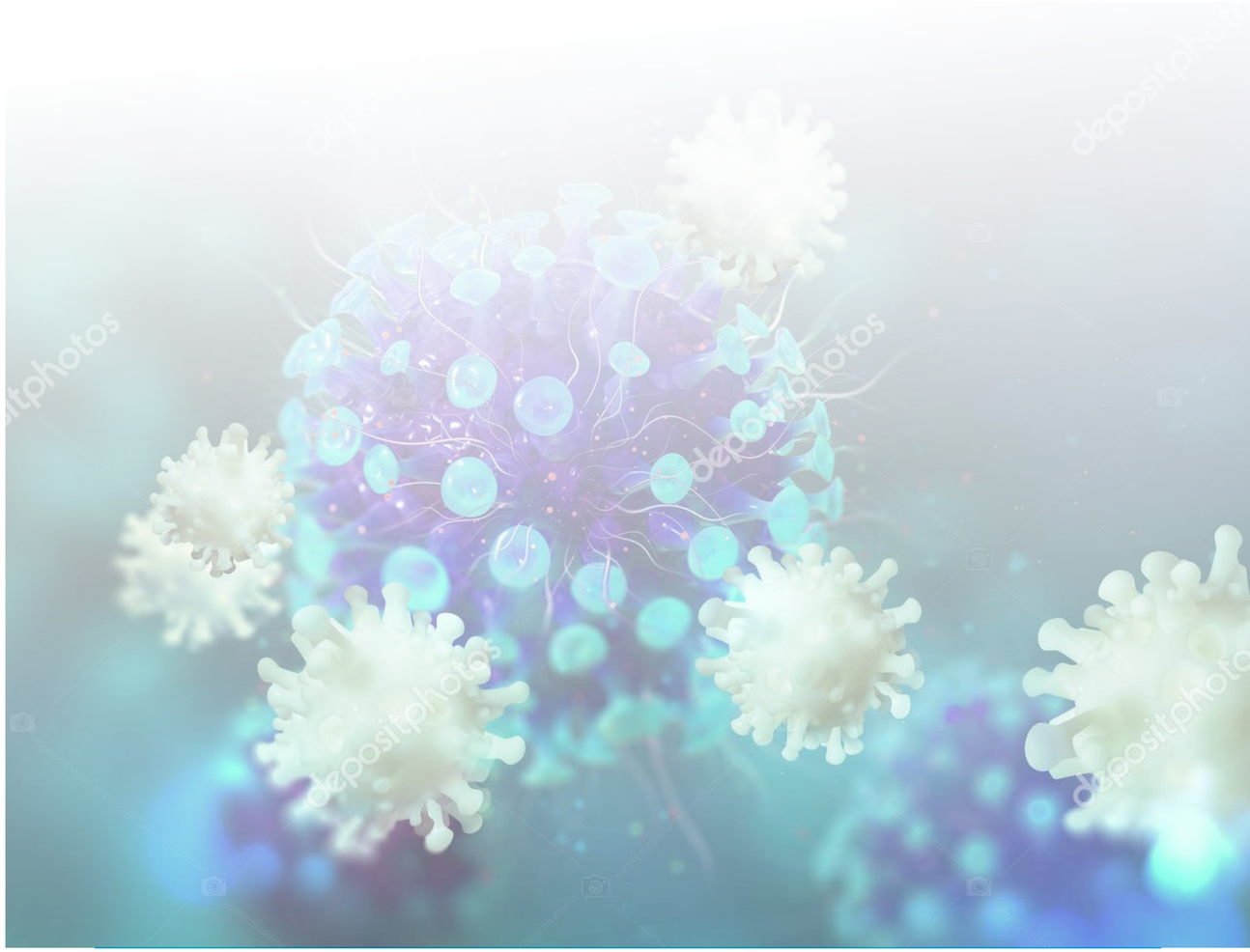
Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
H-2741-1-CE	AmpliSens® *Rickettsia conorii*-FRT PCR kit variant FRT-50 FN			55	CE IVD	qualitative	12 months	G Y	

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

11.2. MULTIPLEX PCR DETECTION KITS

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

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
R-V59(RG,iQ, Mx,Dt)-CE	AmpliSens® *TBEV, B.burgdorferi sl, A.phagocytophillum, E.chaffeensis/E.muris*-FRT			120	CE IVD	qualitative	9 months	G Y O	



Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

12. HUMAN GENETICS

12.1.1. Leukosis Quantum M-bcr

Chronic myelogenous (or myeloid) leukemia (CML), also known as chronic granulocytic leukemia (CGL), is a cancer of the white blood cells. It is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood. CML is a clonal bone marrow stem cell disorder in which proliferation of mature granulocytes (neutrophils, eosinophils, and basophils) and their precursors are 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 has 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-ABLprotein 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® Leucosis-Quant *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 in one repetition (120 RNA extractions, 120 reverse transcription reactions and 360 PCR reactions, including controls).

The principle of detection is based on amplification with Real -Time detection (two oligonucleotide mixes are used): amplification of mRNA fragment of the chimeric M-bcrabl (p210) gene, that conforms 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.

Catalog number	Description	Detection	Format	# of reactions	Certifi-cation	Assay detail	Shelf life	Fluorescent channels	Availa-bility
TR-O1 (RG,iQ,Mx,A)-CE	AmpliSens® Leucosis-Quant *M-bcr*-FRT	●	▮	50	CE IVD	quantitative	12 months	Y	✔

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

● Real-Time ◷ Reverse transcription ★ Fluorescent End-Point ▮ Reagents in stock tubes ▮▮▮ Ready-to-use PCR tubes
▲ on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

13. ADDITIONAL KITS

13.1. NUCLEIC ACID EXTRACTION KITS

13.1.1. DNA-sorb-AM

Kit for DNA extraction from clinical material (smears, scrapes, urine, etc.). K1-11-100-CE includes Internal Control for sexually transmitted diseases detection. Kit K1-12-100-CE is without STD Internal Control, but such Control is always included in all STD amplification kits.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K1-12-100-CE	DNA-sorb-AM	100	CE IVD	12 months	✔
K1-11-100-CE	DNA-sorb-AM	100	CE IVD	12 months	✔

13.1.2. DNA-sorb-B

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K1-2-100-CE	DNA-sorb-B	100	CE IVD	12 months	✔

13.1.3. DNA-sorb-C

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K1-6-50-CE	DNA-sorb-C	50	CE IVD	9 months	✔

13.1.4. DNA-sorb-D

DNA extraction kit for extraction of DNA from epithelial cells (cervical swabs) taken into the transport medium for liquid-based cytology

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K8-2331-100-CE	DNA-sorb-D	100	CE IVD	12 months	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

13.1.5. RIBO-prep

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K2-9-Et-100-CE	RIBO-prep	100	CE IVD	9 months	✔

13.1.6. RIBO-sorb

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K2-1-Et-100-CE	RIBO-sorb	100	CE IVD	9 months	✔

13.1.7. RIBO-zol-B

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K2-3-100-CE	RIBO-zol-B	100	CE IVD	9 months	✔

13.1.8. MAGNO-sorb

Kit for DNA/RNA extraction with magnetic beads.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K2-16-200-CE	MAGNO-sorb	100	CE IVD	15 months	✔
K2-16-1000-CE	MAGNO-sorb	100	CE IVD	15 months	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

13.1.9. MAGNO-sorb-URO

DNA extraction kit for extraction from biological material (vaginal, cervical, urethral discharge; urine) for detection of DNA of pathogens which causes STIs, other infections of reproductive organs and urinary tract.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K4-2181-100-CE	MAGNO-sorb-URO	100	CE IVD	15 months	✔

13.1.10. EDEM reagents kit for extraction of DNA by express method

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K11-1581-100-CE	EDEM reagents kit for extraction of DNA by express method	100	CE IVD	12 months	✔

13.1.11. AmpliSens® PEERO-prep kit

Reagent kit for sample preparation is intended for product preparation for pyrosequencing using the Vacuum Prep Workstation.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K15-1611-40-CE	AmpliSens® PEERO-prep kit	1000	CE IVD	9 months	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

13.2. REVERSE TRANSCRIPTION

13.2.1. Reverta-L

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
K3-4-100-CE	REVERTA-L	120	CE IVD	9 months	✔
K3-4-50-CE	REVERTA-L	60	CE IVD	9 months	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request ✔ available; for detailed explanations and usable PCR cyclers see page 9

13.3. TRANSPORT AND STORAGE MEDIA

13.3.1. Hemolytic

Reagent for pretreatment of whole peripheral and umbilical cord blood.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
137-CE	Hemolytic	100 ml	CE IVD	18 months	✔

13.3.2. Mucolysin

Medium for sputum preliminary treatment.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
180-CE	Mucolysin	200 ml	CE IVD	12 months	✔

13.3.3. Transport media with mucolysin

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

Catalog number	Description	# of preps	Certification	Shelf life	Availability
952-CE	Transport media with mucolytic	50 ml	CE IVD	12 months	✔

13.3.4. Transport Medium for Storage and Transportation of Respiratory Swabs

Transport medium for storage and transporting of respiratory swabs.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
958-CE	Transport Medium for Storage and Transportation of Respiratory Swabs	100 ml	CE IVD	12 months	✔

13.3.5. Transport medium for Swabs

Transport medium for transporting of respiratory swabs.

Catalog number	Description	# of preps	Certification	Shelf life	Availability
987-CE	Transport medium for Swabs	0,3 ml	RUO	12 months	✔

13.4. OTHER

13.4.1. Internal Control-FL (IC)

Catalog number	Description	# of preps	Certification	Shelf life	Availability
4625-CE	Internal Control-FL (IC)	1 ml	RUO	12 months	✔

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

Real-Time Reverse transcription Fluorescent End-Point Reagents in stock tubes Ready-to-use PCR tubes
on request available; for detailed explanations and usable PCR cyclers see page 9

HEADQUARTERS

Ecoli Dx, s.r.o.
Purkyňova 74/2
110 00 PRAHA 1
Czech Republic

ID: 107 07 409
Phone: +420 325 209 912
Cell: +420 739 802 523
Email: ecoli@ecoli.sk
www.pcrdiagnostics.eu

www.pcrdiagnostics.eu

ECOLI

Ver.01_06/2021