InterLabService

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Molecular diagnostics PCR kits

CATALOGUE 2016

Advanced technology
for Molecular Diagnostics

AmpliSens
biotechnologies

InterLabService company profile

InterLabService Ltd. is one of the most experienced molecular diagnostics suppliers. InterLabService company supplies high-quality and professional solutions for infectious disease diagnostics and GMO testing. ILS is an exclusive distributor for **AmpliSens®** reagents and supplies its products to customers in Russia and worldwide. Each product is supported by professional staff.

The principal product distributed by InterLabService is **AmpliSens®** PCR kits that are developed and manufactured by the **Central Research Institute for Epidemiology (Moscow, Russia)**.

Company provides

- regular supply of diagnostic kits, reagents, instruments and laboratory plastics for molecular diagnostics and research market;
- competent information support for the customers on technical and consumable features of the products. Release of newly developed products;
- efficient technical support with instrument installation and engineering service.

Background information

InterLabService Ltd. was founded in 2002 as a privately held company. Now it is a constantly growing Company adding product lines to its portfolio and broadening i ts activity worldwide. InterLabService has subsidiaries in St. Petersburg, Nizhny Novgorod, Rostov-on-Don, and Yekaterinburg and representative offices in the Central Asia (Kazakhstan, Almaty).
The number of its employees has grown from 10 in 2002 to 300 in 2014; until 2008 the Company focused mainly on the Russian and CIS markets. In 2009, we established the foreign sales department to enhance business activity outside of Russia.

Our Resources

R&D and manufacture
R&D department is based in the Central Research Institute for Epidemiology and it includes 10 research groups with over 60 researchers engaged.
PCR kit manufacturing is certified according to DIN EN ISO 13485:2012 and employs up to 200 specialists.

Sales, distribution & technical support

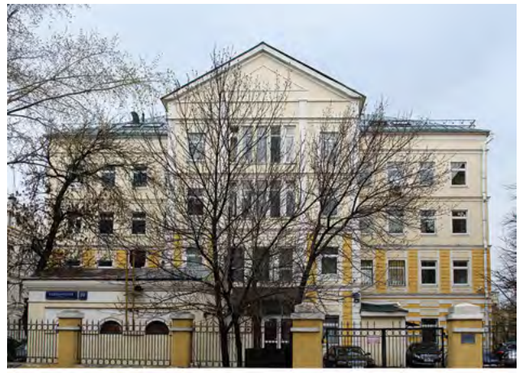
- 32 Sales Representatives in 15 cities of the Russian Federation;
- more than 35 people are involved in office sales support;
- technical & engineering support;
- 26 distributors in the Russian Federation;
- 10 distributors in the CIS countries;
- International partners in 27 countries.

Education & training

We organize a special annual training program for English speaking customers , during which we demonstrate how to work with AmpliSens kits in our laboratory.
We have 3 training centers in Moscow, St. Petersburg and Yekaterinburg.

Storage & transportation

Warehouse total area is 900 m^2, including 100m^2 of coolers for reagent storage. All types of transportation and delivery are photo provided with cooling control.



Located at:

InterLabService, 20/13, b.2, Sadovnicheskaya str., Moscow, Russia, 115035,
Phone: +7 (495) 664 2884, Fax: +7 (495) 664 2889
www.interlabservice.ru, pcr@interlabservice.ru

EC/CE Directive Certificate

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System
No. 11 0040 QS/NB

The quality system of manufacturer

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3A Novogireevskaya Street, Moscow 111123, Russia

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

AmpliSens® PCR kits

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2016-06-17
Valid until: 2021-06-16
First Issued: 2011-01-24
Revision: e

Date: 2016-06-17

RNDr. Radomír Cevelík
Representative of the Notified Body No. 1023

Page 1/1

ISO Certificate

Management Systems Certification Body
Institute for Testing and Certification, Inc.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE
No. 15 0125 SJ

We confirm on the basis of a performed audit that company

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3a, Novogireevskaya, 111123 Moscow, Russian Federation
Headquarters and production plant: 3a, Novogireevskaya str., 111123 Moscow
Production plant: 8, Polymernaya str., 111394 Moscow

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2012

Covering the following activities:

Manufacturing and final control of *in vitro* diagnostic medical devices

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233404056/2015. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.

S 3002

Date of Issue: 20. 05. 2015
Valid until: 20. 05. 2018

Ing. Pavel Vanik
Head of Certification Body

Declarations of Conformity

FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
111123, Moscow, 3A Novogireevskaya Street, Tel.: +7 495 974 96 42; Fax: +7 495 305 54 23,
e-mail: otdk@pcr.ru

CE

EC DECLARATION OF CONFORMITY
Directive 98/79/EC of the European Parliament and of the Council of 27th of October 1998 on In Vitro Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by Institute for testing and certification, Inc. (certificate No. 15 0125 SJ, valid until 2018.05.20).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	Ecoli s.r.o. Studenohorska 12 841 03 Bratislava 47 Slovak Republic tel.: (+421) 02/64 789 336 fax: (+421) 02/64 789 040 email: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
Classification:	Article 9, paragraph 3 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) Full QA System
Notified Body:	Institute for testing and certification, Inc. třída Tomáše Bati 299 Louky, 763 02 Zlín, Czech Republic e-mail: itc@itczlin.cz Notified Body No. 1023
EC Certificate:	No. 11 0040 QS/NB revision e, valid until 2021.06.16
Place, Date of Issue:	Zlín, Czech Republic, 2016.06.17

Signed _____

Valid from 2016.06.17
Valid until 2021.06.16

Full name: Valentin I. Pokrovsky
Title: Director

List B

FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
111123, Moscow, 3A, Novogireevskaya St., Tel.: +7 495 974 96 42, Fax: +7 495 305 54 23,
e-mail: otdk@pcr.ru

CE

EC DECLARATION OF CONFORMITY
Directive 98/79/EC of the European Parliament and of the Council of 27th of October 1998 on In Vitro Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by INSTITUTE FOR TESTING AND CERTIFICATION, a.s. (certificate No. 15 0125 SJ, valid until 2018.05.20).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	Ecoli s.r.o. Studenohorska 12 841 03 Bratislava 47 Slovak Republic Tel.: +421 2 6478 9336 Fax: +421 2 6478 9040
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents
Classification:	Article 9, paragraph 1 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices
Conformity Assessment Route:	Annex III (IVDD)

Signed _____

Valid from 2015.05.29

Full name: Valentin I. Pokrovsky
Title: Director

List C/ others

AmpliSens biotechnologies

AmpliSens® PCR and Real-time PCR kits

We offer a complete solution for Molecular diagnostics, including

- **PCR kits**;
- reverse transcription kit;
- DNA/RNA extraction kits;
- transport and storage media;
- pretreatment reagents.

ADVANTAGE

- More than 200 PCR kits for pathogen detection, genetic markers, GMO.
- Our products comply with EU directives 98/79/EC for medical products and IVD (CE marked; only HCV, HBV, HDV, HIV kits have RUO certificates).
- Extraction kits provide fast and efficient isolation of DNA/RNA from various types of biological material.
- PCR assays with electrophoresis, fluorescent real-time and end-point product detection.
- All our products are clinically validated.

KEY FEATURES

- wide range of pathogen detection;
- high specificity and sensitivity;
- ready-to-use reagents;
- cost-effectiveness;
- application of Taq-F-polymerase («**hot start**»).

TaqF polymerase is used in PCR kits. TaqF polymerase is a thermostable chemically modified Hot Start Taq DNA polymerase. It is inactive until heated. The chemically modified polymerase TaqF is activated by heating at 95 ◦C for 15 min.
Hot-start PCR activation approaches allow users to minimize non-specific amplification while increasing target yield and specificity.

OVERALL CONTROL OF PCR WORKFLOW THROUGH ALL STEPS OF ANALYSIS

AmpliSens® Extraction kits are kits based on different methods and composed of all reagents necessary for extraction: lysis buffer, washing buffers, elution buffer and, depending on a method, solution for precipitation/beads/silica.

AmpliSens® Real-time PCR kits are ready to-use test-systems including buffer, primers, probes, Taq-polymerase, internal control, positive controls (quantification standards for the quantification format).

Sampling	DNA/RNA extraction		Amplification	
Endogenous Internal control Human β-globin gene Exogenous Internal control	**Positive Control**	**Negative Control**	**Positive Control of Amplification**	**Negative Control of Amplification**
MATERIAL'S LOSS	**MATERIAL'S LOSS**	**CONTAMINATION**	**INHIBITION**	**CONTAMINATION**

Quantitation:
Set of calibrators.
High precision measurement of a concentration.

Calibrator Q (for Monitor-kits: HCV-Monitor-FRT, HBV-Monitor-FRT and HBV/HCV/HIV-FRT). Calibrator Q is used to obtain a special coefficient for calculation of a pathogen concentration when non AmpliSens® produced extraction kits are applied.

CONVENIENT PACKAGING

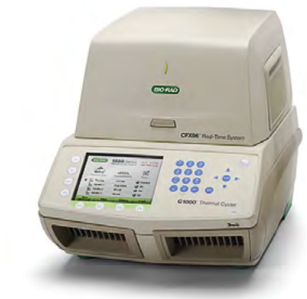
Two packing options:
- aliquoted (pre dispensed into 0,2 ml tubes under wax),
- non-aliquoted.

EQUIPMENT

AmpliSens® kits are adapted for different types of thermal cyclers and can be used with the following equipment.*
***for more detailed information please see a special Instruction Manual and Guidelines**

Smart Cycler
Cepheid (USA)

iCycler iQ
iCycler iQ5
BioRad (USA)



CFX96
BioRad (USA)

Rotor Gene 3000
Rotor Gene 6000
Corbett Life Science (Sydney, Australia)

Rotor Gene Q
QIAGEN (Germany)

Mx
Stratagene (USA)

AmpliSens biotechnologies

CONTENT

SIMBOLS

– a kit contains PCR tubes with pre-dispensed reaction mixture under wax (a reaction mix (primers and probes) is predispensed into individual PCR tubes under wax) - **aliquoted format.**

– a kit contains individual vials with all necessary reagents: Taq-F polymerase («hot start»), mixes with primers and probes, buffers (All reagents are in separate vials (not predispensed into PCR tubes) - **non-aliquoted format.**

– Real-time pcr kit (FRT).

– End-point detection pcr kit (FEP, Eph).

– a kit contains reagents only for the amplification step, it does not include an additional extraction kit.

– a kit contains reagents for both amplification and extraction steps.

FRT – Fluorescent Real-time detection.

FEP – Fluorescent End-point detection, it requires an appropriate thermo-cycler and fluorometer (e.g. ALA-1/4, BioSan) equipment.

Eph – Electrophoresis detection: it requires a camera for gel-electrophoresis, UV transilluminator / complete Gel imaging system with a high resolution CCD camera.

QL – Qualitative detection.

QN – Quantitative detection.

Diff – type / serotype / genotype differentiation.

NoDiff – no type / serotype / genotype differentiation.

GE/ml – Genome equivalents (GE) of a pathogen agent per 1 ml of a sample.

IU/ml – International units (IU) of a pathogen agent per 1 ml of the sample.

Sampling of biological materials for PCR-analysis, transportation, storage and pretreatment is described in the **manufacturer's Handbook "Sampling, Transportation, and Storage of Clinical Material for PCR diagnostics"**, developed by the Federal Budget Institute of Science "Central Research Institute for Epidemiology" of the Federal Service for Surveillance on Consumers' Rights Protection and Human Well-Being, Moscow, 2010.

http://www.interlabservice.ru/upload/medialibrary/af6/sampling_storage-and-transportation-of-clinical-material.pdf

InterLabService

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For more detailed information please refer to relevant instructions and guidelines on our website: www.interlabservice.ru/en/

SEXUALLY TRANSMITTED INFECTIONS

KEY FEATURES

- CE-IVD marked;
- wide range of pathogen detection;
- multiplex detection;
- qualitative and quantitative detection of pathogen agent;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost-effectiveness.

The PCR kit uses **«Hot-start»**, which greatly reduces frequency of nonspecifically primed reactions. **«Hot-start»** is ensured through separation of nucleotides and Taq-polymerase by using chemically modified polymerase (TaqF). Chemically modified polymerase (TaqF) is activated by heating at 95°C for 15 min.

STI KITS ARE INTENDED FOR

- epidemiological screening;
- etiological diagnostics;
- control of treatment;
- detection of reinfection;
- detection of wide range of specimen types.

OVERVIEW

Sexually Transmitted Infections (STIs) are spread worldwide. Early treatment is essential and is conditioned by timely diagnosis of an infection. Delay in diagnosis may result in, e.g. reproductive disorders, complications during pregnancy or neo -natal period, and significantly increases the risk of HIV acquisition. In terms of analytical and/or diagnostic sensitivity and specificity, routine tests employing different microscopy techniques, ELISA, or even culturing might misguide accurate diagnosis of STIs. Nucleic acid amplification testing, particularly PCR, is now considered to be an adequate response to clinical laboratory needs.

SAMPLING, HANDLING AND PRESERVATION

Range of specimen types:

- cervical, vaginal (including self-collected samples);
- urethral swabs;
- urine, prostatic secretion, ejaculate;
- swabs from genital ulcers, rectal swabs;
- conjunctival, throat swabs;
- oral and oropharyngeal swabs (Florocenosis/Candida).

Transport Medium for transport and storage:

- Transport Medium with a Mucolytic Agent, REF 952-CE;
- Transport Medium TM-EDEM, REF 1533-CE.

Examples of recommended urogenital probes

EXTRACTION KITS

For extraction DNA we recommend to use the kit DNA-sorb-AM, REF K1-12-100-CE, REF K1-11-100-CE, which is based on silica sorbtion method.

DNA extraction using express methods (for example, EDEM REF K2-17-100-CE) is prohibited for QUANTITATIVE kits!

Extracted volume of the clinical / biological material is 100 µl.

Each test sample DNA is extracted with non-competitive Internal Control-FL (IC) present.

Internal control is used for quality monitoring at all steps of assay.

Exclusion: it is not required to add an Internal Control sample for AmpliSens® Florocenosis / Bacterial vaginosis-FRT! We strictly recommend to extract DNA according to manufacturer's protocols.

Tube with urogenital probe placed into a transport medium

SEXUALLY TRANSMITTED INFECTIONS PCR KITs

Monoplex sexually transmitted infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples[2]
AmpliSens® *Chlamydia trachomatis*-FRT	R-B1-F(RG,iQ)-CE		5 x 10^2 GE/ml[1], Urogenital swabs[3] 1x10^3 GE/ml, Urine[4]	*Chlamydia trachomatis* DNA	QL	CE	110
AmpliSens® *Neisseria gonorrhoeae*-screen-FRT	R-B51-F(RG,iQ)-CE		5 x 10^2 GE/ml, Urogenital swabs 1x10^3 GE/ml, Urine	*Neisseria gonorrhoeae* DNA	QL	CE	110
AmpliSens® *Neisseria gonorrhoeae*-test-FRT	R-B56-F(RG,iQ)-CE CONFIRMATION TEST		1 x 10^3 GE/ml, Urogenital swabs 2x10^3 GE/ml, Urine	*Neisseria gonorrhoeae* DNA	QL	CE	110
AmpliSens® *Treponema pallidum*-FRT	R-B20-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs	*Treponema pallidum* DNA	QL	CE	110
AmpliSens® *Trichomonas vaginalis*-FRT	R-B6-F(RG,iQ)-CE		5 x 10^2 GE/ml, Urogenital swabs 1 x 10^3 GE/ml, Urine	*Trichomonas vaginalis* DNA	QL	CE	110
AmpliSens® *Mycoplasma genitalium*-screen-titre-FRT	R-B4-100-FT(RG,iQ,Mx)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine (first portion)	*Mycoplasma genitalium* DNA	QL QN	CE	110
AmpliSens® *Mycoplasma genitalium*-FRT	R-B4-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Mycoplasma genitalium* DNA	QL	CE	110
AmpliSens® *Mycoplasma hominis*-screen-titre-FRT	R-B3-100-FT(RG,iQ,Mx)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Mycoplasma hominis* DNA	QL QN	CE	110
AmpliSens® *Mycoplasma hominis*-FRT	R-B3-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Mycoplasma hominis* DNA	QL	CE	110
AmpliSens® *Ureaplasma spp.*-screen-titre-FRT	R-B2-100-FT(RG,iQ,Mx)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Ureaplasma spp. (U.parvum U.urealyticum* DNA*)*	QL QN NoDiff	CE	110
AmpliSens® *Ureaplasma spp.*-FRT	R-B2-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine *Ureaplasma parvum, Ureaplasma urealyticum*	*Ureaplasma spp. (U.parvum, U.urealyticum)* DNA	QL	CE	110
AmpliSens® *U.parvum/ U.urealyticum*-FRT	R-B19-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs 5 x 10^3 GE/ml, Urine *Ureaplasma parvum, Ureaplasma urealyticum*	*Ureaplasma parvum Ureaplasma urealyticum* DNA	QL Diff	CE	110
AmpliSens® *U.parvum/ U.urealyticum*-screen-titre-FRT	R-B19-100-FT(RG,iQ,Mx)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine (first portion)	*Ureaplasma parvum Ureaplasma urealyticum* DNA	QN Diff	CE	110
AmpliSens® *Gardnerella vaginalis*-FRT	R-B7-F(RG,iQ)-CE		1 x 10^4 GE/ml, Urogenital swabs	*Gardnerella vaginalis* DNA	QL	CE	110
AmpliSens® *Candida albicans*-FRT	R-F1-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Candida albicans* DNA	QL	CE	100

1 The quantity of microorganism genome equivalents per 1 ml of a sample placed in a transport medium.

2 Number of tested samples including controls and calibrators.

3 Urogenital swabs are to be placed into a transport Medium for Swabs (RUO 956-CE, RUO 987-CE) or a transport Medium with Mucolytic (RUO 952-CE, RUO 953-CE).

4 For Urine pretreatment is required.

Multiplex sexually transmitted infections PCR kits

OPTIMIZATION OF STI DETECTION

A wide range of microorganisms can cause or be associated with urogenital inflammatory diseases. It is extremely important to identify obligate pathogens, especially those responsible for Sexually Transmitted Infections (STIs) – Neisseria gonorrhoeae, Chlamydia trachomatis, Mycoplasma genitalium, and Trichomonas vaginalis, which play a major role in subsequent reproductive complications even in asymptomatic patients.Moreover, STIs enhance the risk of HIV acquisition.

STI clinical diagnosis is often complicated due to:

- absence of pathognomonic symptoms (innacurate syndromic approach);
- high prevalence of asymptomatic course;
- frequent mixed infections (multiple causative agents).

AmpliSens® N.gonorrhoeae/C.trachomatis / M.genitalium/T.vaginalis-MULTIPRIME-FRT

- First and obligate test for STI screening and identification of abnormal vaginal discharge causes.
- PCR-test for NCMT detection was validated in CDC USA.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *C.trachomatis/ Ureaplasma/ M.genitalium-* MULTIPRIME-FRT[5]	R-B46-F(RG,iQ)-CE		*Chlamydia trachomatis* 5 x 10^2 GE/ml, Urogenital swabs 10^3 GE/ml, Urine *Ureaplasma spp., Mycoplasma genitalium* 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Chlamydia trachomatis, Ureaplasma spp. (U.parvum; U.urealyticum), Mycoplasma genitalium* DNA	QL	CE	110
AmpliSens® *C.trachomatis/ Ureaplasma/ M.genitalium/ M.hominis-* MULTIPRIME-FRT	R-B60-F(RG)-CE		not less than 5 x 10^2 GE/ml	*Chlamydia trachomatis, Ureaplasma spp. (U.parvum; U.urealyticum), Mycoplasma genitalium, Mycoplasma hominis* DNA	QL	CE	110
AmpliSens® *N.gonorrhoeae/ C.trachomatis/ M.genitalium/ T.vaginalis-* MULTIPRIME-FRT	R-B61-F(RG)-CE		not less than 5 x 10^2 GE/ml	*Neisseria gonorrhoeae, Chlamydia trachomatis, Mycoplasma genitalium, Trichomonas vaginalis* DNA	QL	CE	110
AmpliSens® *C.albicans/ C.glabata/ C.krusei-* FRT	R-F3-F(RG,iQ)-CE		10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Candida albicans, Candida glabrata, Candida krusei* DNA	QL	CE	110
AmpliSens® *T.vaginalis/ N.gonorrhoeae-* MULTIPRIME-FRT	R-B65-F(RG,iQ)-CE		5 x 10^2 GE/ml, Urogenital swabs 10^3 GE/ml, Urine	*Trichomonas vaginalis, Neisseria gonorrhoeae* DNA	QL	CE	110
AmpliSens® *C.trachomatis/ Ureaplasma/ M.hominis-* MULTIPRIME-FRT[6]	R-B43-F(RG,iQ)-CE		*Chlamydia trachomatis* 5 x 10^2 GE/ml, Urogenital swabs 10^3 GE/ml, Urine *Ureaplasma spp. Mycoplasma hominis* 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Chlamydia trachomatis, Ureaplasma spp.(U.parvum; U.urealyticum), Mycoplasma hominis* DNA	QL	CE	110
AmpliSens® *C.trachomatis/ Ureaplasma-* MULTIPRIME-FEP	R-B47-100-R0,2-FEP-CE		*Chlamydia trachomatis* 5 x 10^2 GE/ml, Cervical/ urethral swabs 10^3 GE/ml, Urine *Ureaplasma spp.* 10^3 GE/ml, Cervical/ urethral swabs 2 x 10^3 GE/ml, Urine	*Chlamydia trachomatis, Ureaplasma spp. (U.parvum; U.urealyticum)* DNA	QL	CE	110
AmpliSens® *T.vaginalis/ N.gonorrhoeae/ C.trachomatis-* MULTIPRIME-FRT	R-B83-F(RG,iQ)-CE		5 x 10^2 GE/ml, Urogenital swabs 1 x 10^3 GE/ml, Urine	*Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis* DNA	QL	CE	110
AmpliSens® *N.gonorrhoeae/ C.trachomatis/ M.genitalium-* MULTIPRIME-FRT	R-B67-F(RG)-CE		*Neisseria gonorrhoeae Chlamydia trachomatis* 5 x 10^2 GE/ml, Urogenital swabs 1 x 10^3 GE/ml, Urine *Mycoplasma genitalium* 10^3 GE/ml, Urogenital swabs 2 x 10^3 GE/ml, Urine	*Neisseria gonorrhoeae, Chlamydia trachomatis, Mycoplasma genitalium* DNA	QL	CE	110

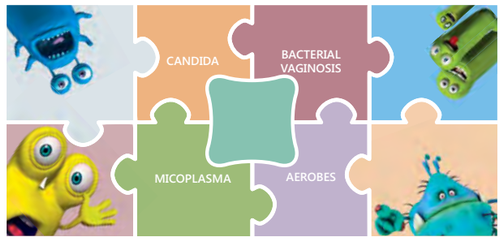
[5] FEP format of kit AmpliSens® C.trachomatis /Ureaplasma / M.genitalium-MULTIPRIME-FEP, R-B46-100-R0,2-FEP-CE, is available on request.

[6] FEP-format of kit AmpliSens® C.trachomatis/Ureaplasma/ M.hominis-MULTIPRIME- FEP R-B43-100-R0,2-FEP-CE, is available on request.

Florocenosis PCR kits

Application of Amplisens Florocenosis kits and a AmpliSens® N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis-MULTIPRIME-FRT kit provides complex diagnostics and allows for:

- simultaneous detection of four obligate STI pathogens;
- screening and confirmatory tests;
- control of treatment;
- investigation of wide range of specimen types.



What is "Florocenosis"?

"Florocenosis" is a group of tests based on multiplex real-time PCR intended for detection of genital infections in women. Each test allows for differentiation and quantitative detection of a respective group of microorganisms:

Important		Required
Different treatment	**is required**	**Differentiation of pathogen**
Clinically significant concentration/ratio	**is required**	**Quantitative detection**

AmpliSens® NCMT	**AmpliSens® Florocenosis / Candida-FRT**	**AmpliSens® Florocenosis / Bacterial vaginosis-FRT**	**AmpliSens® Florocenosis / Mycoplasma-FRT**	**AmpliSens® Florocenosis / Aerobes-FRT**
Neisseria gonorrhoeae *Chlamydia trachomatis* *Mycoplasma genitalium* *Trichomonas vaginalis*	*C.albicans* *C.glabrata* *C.krisei* *C.tropicalis/parapsilosis*	*Bacteriaceae* *Lactobacillus spp* *G.vaginalis* *A.vaginae*	*M.hominis* *U.urealyticum* *U.parvum*	*Enterobacteriaceae spp.* *Staphylococcus spp* *Streptococcus spp*

FLOROCENOSIS KITS ARE INTENDED FOR DETECTION AND DIAGNOSTICS OF:

- Vulvovaginal candidiasis.
- Infections associated with opportunistic mycoplasmas.
- Bacterial vaginosis.
- Aerobic vaginitis.

1 sample
5 kits
5 PCR tubes
19 targets

Basic concept of Florocenosis tests

It should not only identify microorganisms quantitatively/qualitatively, but also contribute to solving a particular problem for a clinician.
Pathological states are not related to either a number of opportunistic pathogens or a ratio of different microorganisms of the urogenital tract.
It is needed to ensure a comprehensive approach to diagnosis.

High technology of new generation

- Test design is based on contemporary science and knowledge of genital infections.
- Combination of microorganisms by nosology and syndromes.
- Wide range of application for differential diagnostics, screening, control of treatment.
- Each test – is an instrument for solution of a specific clinical problem.
- Tests are based on multiplex method Real-time PCR.
- The fastest way to achieve results and a universal approach with minimum laboratory error probability.

Florocenosis-Candida

The Candida family includes many non-pathogenic species for a human being!
For informative diagnostics is reasonably to define only most widespread and clinically significant Candida species.
AmpliSens® Florocenosis / *Candida*-FRT kit is designed for diagnostics of vulvovaginal candidiasis (VVC):

- Detection of clinically significant species only: *C.albicans, C.glabrata, C.krusei, C.parapsilosis / C.tropicalis*.
- Quantitative estimation.
- Differentiation of species (it is important due to differences in antifungal resistance).

Florocenosis-Mycoplasma

AmpliSens® Florocenosis / *Mycoplasma*-FRT kit is designed for diagnostics of infections associated with conditionally pathogenic genital mycoplasmas:

- Detection of three conditionally pathogenic species: *Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis*.
- Species differentiation.
- Quantitative estimation – necessary for estimation of clinical significance.

Florocenosis-Bacterial vaginosis

AmpliSens® Florocenosis / Bacterial vaginosis-FRT kit is designed for diagnostics of bacterial vaginosis (BV):

- Necessary and sufficient markers for BV diagnostics: *Gardnerella vaginalis, Atopobium vaginae, Lactobacillus spp., Bacteria*;
- Unique algorithm for microorganisms ratio analysis.
- Formal conclusion (BV detected / not detected).
- Validation by the gold standard of BV diagnostics (Amsel criteria, Nugent criteria).

Florocenosis-Aerobes

AmpliSens® Florocenosis / Aerobes-FRT kit is designed for diagnostics of aerobic vaginitis:

- Necessary and sufficient markers for Aerobic vaginitis diagnostics: *Enterobacteriaceae (E.coli, Klebsiella spp., Proteus spp. etc.), Staphylococcus spp, Streptococcus spp*.
- Unique algorithm for microorganisms ratio analysis.
- Formal conclusion (Aerobic vaginitis is detected / not detected).

Advantage and benefits of Amplisens® Multiprime and Florocenosis kits

Clinicians

- Diagnostics of urogenital tract microflora disorders.
- Minimum amount of tests for quantitative detection of required range of microorganisms.
- High standard assay procedure (from extraction of DNA to delivery of results).
- Automatic program for evaluation and result generation.
- Differential diagnosis in symptomatic patients.
- Effective screening in asymptomatic patients.

Lab staff

- Decrease in time and labor for pre-PCR steps.
- 1 sample – 1 extraction – 1 amplification – 3-4 targets.

Healthcare providers

- Cutting of reagents and consumables costs.
- Enhancement of laboratory turnover.
- Extension of equipment service life.

AmpliSens biotechnologies

Florocenosis Multiplex PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detec-tion type	CE/ RUO	Number of tested samples
AmpliSens® Florocenosis/ *Bacterial vaginosis*-FRT	R-B74-100-FT(RG)-CE		5×10^3 copies/ml, Epithelial cells scrapes from the lateral walls of vagina; vaginal discharge	*Gardnerella vaginalis, Atopobium vaginae, Lactobacillus spp., total quantity of bacteria*	QN	CE	110
AmpliSens® Florocenosis/ *Mycoplasma*-FRT	R-B75-100-FT(RG,iQ,Mx)-CE		1×10^3 GE/ml, Urogenital swabs 2×10^3 GE/ml, Urine (first portion)	*Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis* DNA	QN	CE	110
AmpliSens® Florocenosis/ *Aerobes*-FRT	R-B88-100-FT-CE		2×10^3 GE/ml, Vaginal swabs	*Enterobacteriaceae, (E.coli, Klebsiella spp., Proteus spp. ect.), Staphylococcus spp Streptococcus spp.* DNA	QN	CE	110
AmpliSens® Florocenosis/ *Candida*-FRT	R-F5-100-FT(RG,CFx)-CE		1×10^2 GE/ml, Urogenital swabs, oral and oropharyngeal swabs 1×10^2 GE/ml, Urine[7]	Candida genus fungi DNA: *C.albicans, C.glabrata, C.krusei, C.parapsilosis C.tropicalis*	QN	CE	110

[7] Urine samples require pretreatment to produce sediment out of 1 ml of urine.

HUMAN PAPILLOMAVIRUS (HPV) INFECTIONS

KEY FEATURES

- CE-IVD marked;
- quantitative and qualitative detection and differentiation of 14 genotypes;
- wide variability of different format kits: Real-time format, FEP, Eph (on request);
- clinically validated.

HPV KITS ARE INTENDED FOR

- detection of a wide range of HCR HPV genotypes;
- genotyping and screening formats;
- viral load monitoring;
- resolving of equivocal results of colposcopy and cytology;
- use with liquid-based cytology medium;
- validity of clinical specimen control;
- option to use material extracted from paraffin blocks.

OVERVIEW

Key facts

- human papillomavirus (HPV) is a group of viruses that are extremely common worldwide;
- there are more than 100 types of HPV, at least 13 of which are cancer-causing (also known as high risk type);
- HPV is mainly transmitted through sexual contact and most people are infected with HPV shortly after the onset of sexual activity;
- cervical cancer is caused by sexually acquired infection with certain types of HPV;
- two HPV types (16 and 18) cause 70% of cervical cancers and precancerous cervical lesions;
- there is also evidence linking HPV with cancers of the anus, vulva, vagina and penis;
- cervical cancer is the second most common cancer in women living in less developed regions with estimated 445,000 new cases in 2012 (84% of new cases worldwide);
- in 2012, approximately 270,000 women died of cervical cancer; more than 85% of those deaths occurring in low- and middle-income countries;
- vaccines against HPV 16 and 18 are approved for use in many countries.

HPV infection can lead to cervical cancer

Human papillomavirus (HPV) is the most common viral infection of the reproductive tract. Most sexually active women and men will be infected at some point in their lives and some may be repeatedly infected.
The peak time for acquiring infection for both women and men is shortly after becoming sexually active. HPV is sexually transmitted, but penetrative sex is not required for transmission. Skin-to-skin genital contact is a well-recognized mode of transmission.
There are many types of HPV, and many do not cause problems. HPV infections usually clear up without any intervention within a few months after acquisition, and about 90% clear within 2 years. A small proportion of infections with certain types of HPV can persist and progress to cancer.
Cervical cancer is by far the most common HPV-related disease. Nearly all cases of cervical cancer can be attributable to HPV infection.
Though data on anogenital cancers other than cancer of the cervix are limited, there is an increasing body of evidence linking HPV with cancers of the anus, vulva, vagina, and penis. Although these cancers are less frequent than cancer of the cervix, their association with HPV make them potentially preventable using similar primary prevention strategies as those for cervical cancer.
Non-cancer causing types of HPV (especially types 6 and 11) can cause genital warts and respiratory papillomatosis (a disease in which tumours grow in the air passages leading from the nose and mouth into the lungs). Although these conditions very rarely result in death, they may cause significant occurrence of disease. Genital warts are very common and highly infectious.

Screening for cervical cancer

There are 3 different types of screening tests currently available:

- conventional (Pap) test and liquid-based cytology (LBC);
- visual inspection with Acetic Acid (VIA);
- **HPV testing for high-risk HPV types.**

SAMPLING, HANDLING AND PRESERVATION

Biological material: cervical swabs, vaginal discharge, epithelial swabs from lateral vaginal walls, urogenital swabs, biopsy material of cervical mucous membrane.
For women: epithelial samples from endocervix and ectocervix are taken in the same way as for cytological analysis.
For men: place the urethral epithelial swab taken with a universal probe.

EXTRACTION KITS

Transport medium for transport and storage: transport medium with Mucolytic Agent REF 952-CE.
Extraction kits recommended for use: extraction from urogenital swabs (epithelium from endo-/exocervix) - DNA-sorb-AM, REF K1-12-100-CE; DNA-sorb-B REF K1-2-50-CE; REF K1-2-100-CE.
Extraction from biopsy material of cervical mucous membrane: DNA-sorb-C, REF K1-6-50-CE.
Extraction of DNA from epithelial cells (cervical swabs) taken into the transport medium for liquid-based cytology (for example, PreservCyt (Hologic Inc., USA)) for subsequent analysis by the polymerase chain reaction (PCR): DNA-sorb-D, REF K1-8-100-CE.

HUMAN PAPILLOMAVIRUS INFECTIONS PCR KITs

High-risk human papillomavirus infections PCR kits

AmpliSens® HPV HCR screen-titre-FRT PCR kit is an *in vitro* nucleic acid amplification test for qualitative and quantitative detection of DNA of *human papillomaviruses (HPV)* of high carcinogenic risk (HCR) in biological material (vaginal swab, scrapes of membrane mucosa of cervix uteri and urethra, endocervical scrapes, biopsy material of cervical mucous membrane) and able to detect (without genotyping) DNA of *HPV* of two main phylogenetic groups, A7 and A9, which include 10 types (16, 18, 31, 33, 35, 39, 45, 52, 58, and 59), as well as DNA of *HPV* type 51 (group A5) and *HPV* type 56 (group A6). These types exhibit a high transforming activity and are responsible for over 94 % of cases of cervical dysplasia and *cervix uteri* cancer – totally 12 genotypes.
New **AmpliSens® HPV HCR screen-titre-FRT** PCR kit allow for detection of the total of 14 genotypes HCR HPV: 18,31,33,35,39, 45,51,52,56,58,59,66,68.
AmpliSens® HPV HCR genotype-titre-FRT and AmpliSens® HPV HCR genotype-titre-FRT allow for differentiation of 12 and 14 genotypes, respectively.
Besides, New AmpliSens® HPV HCR-genotype-titre-FRT allow for the quantitative analysis.
DNA fragment of human β-globin gene is used as an internal endogenous (IC) control.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HPV* HCR-screen-titre-FRT	R-V31-T-4x (RG,iQ,Mx)-CE		no less then 5 x 10^3 GE/ml for *HPV* types: 16, 18, 31, 35, 39, 45, 51, 52, 56, 59 and no less than 2.5 x 10^4 GE/ml for *HPV* types 33 and 58. DNA-sorb-AM; DNA-sorb-B; DNA-sorb-C (for biopsy samples)	HCR ***HPV*** DNA *16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 types*	QL QN NoDiff (only phylo-genetic gruops A7,A9, 51+56 geno-types)	CE	108
NEW AmpliSens® *HPV* HCR screen-titre-FRT	R-V31-F-CE		1 x 10^3 copies/ml DNA-sorb-AM	***Additional genotype of HPV!*** HCR *HPV* DNA *16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59,* ***66, 68*** *types*	QL QN NoDiff (Diff 16,18,45 genotypes)	CE	110

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HPV* HCR genotype-FRT	R-V25(RG,iQ,Mx)-CE		no less than 1 x 10^3 GE/ml DNA-sorb-AM; DNA-sorb-B; DNA-sorb-C (for biopsy material from mucosa)	***HR HPV*** DNA *16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 types*	QL Diff	CE	108
NEW AmpliSens® *HPV* HCR-genotype-titre-FRT	R-V67-F-CE		1 x 10^3 copies/ml DNA-sorb-AM (urogenital swabs), DNA-sorb-C (biopsy material of cervical mucous membrane)	***Additional genotype of HPV!*** *HCR HPV* DNA *16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59,* ***66, 68*** *types*	QL QN Diff	CE	110

Low-risk human papillomavirus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® HPV 6/11-FRT	R-V11(RG,iQ,Mx)-CE		no less than 1 x 10^3 GE/ml DNA-sorb-AM, DNA-sorb-B, DNA-sorb-C	*HPV* DNA *6,11 types*	QL Diff	CE	120

AmpliSens biotechnologies

TORCH-INFECTIONS

KEY FEATURES

- CE-IVD marked;
- real-time format kits for quantitative and qualitative detection of TORCH infections;
- AmpliSens® *Parvovirus* B19-FRT was validated on the 2nd WHO International Standard for *Parvovirus* B19 DNA for Nucleic Acid Amplification (NAT) Assay (version 1.0, dated 04/02/2009, standard sample, NIBSC code 99/802).

TORCH KITS ARE INTENDED FOR

- for qualitative detection of *Toxoplasma gondii* DNA in the biological material by means of real-time hybridization-fluorescence detection;
- for qualitative and quantitative detection of *Parvovirus* B19 DNA in the biological material in case of non-immune fetal hydrops by using real-time hybridization-fluorescence detection of amplified products. This PCR kit can be used for screening donated blood as well as blood products;
- for qualitative detection of *Rubella virus* RNA in biological material. The results of PCR analysis are taken into account in complex diagnostics of disease.

OVERVIEW

Perinatal infections account for 2% to 3% of all congenital anomalies. TORCH, which includes *Toxoplasmosis*, Other *(Syphilis, Varicella-zoster, Parvovirus B19), Rubella, Cytomegalovirus (CMV)*, and *Herpes infections*, are some of the most common infections associated with congenital anomalies. Most of the TORCH infections cause mild maternal morbidity, but have serious fetal consequences, and treatment of maternal infection frequently has no impact on fetal outcome. Therefore, recognition of maternal disease and fetal monitoring once disease is recognized are important for all clinicians. Knowledge of these diseases will help the clinician appropriately counsel mothers on preventive measures to avoid these infections, and will aid in counseling parents on the potential for adverse fetal outcomes when these infections are present.

Toxoplasma gondii / Parvovirus B19 / Rubella virus
SAMPLING, HANDLING AND PRESERVATION

Biological material: peripheral or umbilical blood, plasma or serum of peripheral or umbilical blood, oropharyngeal washes and swabs, saliva, cerebrospinal fluid (CSF), bone marrow biopsy samples, amniotic fluid, chorionic villi, placental biopsy samples, transudate (ascitic fluid) in case of non-immune fetal hydrops.

Handling and Preservation:
Peripheral and umbilical cord blood plasma. Collect blood to a Vacuett tube (lavender cap, 6% EDTA) after overnight fasting or at least 3 h after the patient had a meal.
Whole peripheral and umbilical blood. Blood should be collected to a tube with 6% EDTA solution at a ratio 20:1 (20 portions of blood per 1 portion of EDTA) after overnight fasting. Umbilical cord blood is obtained by cordocentesis.
White blood cells taken from peripheral and/or umbilical cord blood are to be treated with Hemolytic REF 137. To do this, add 1.0 ml of Hemolytic and 0.25 ml of whole blood.
Biopsy and autopsy material is obtained from an expected location of the pathogen, from a damaged tissue or from an area adjoining the damaged tissue. Collect the samples to a 2-ml tube with 0.3 ml of transport medium.
Transfer the sample to a porcelain mortar; add an equal volume of saline or PBS.

Transport Medium for Storage and Transportation of Respiratory Swabs, REF 957-CE.

EXTRACTION KITS

For extraction from whole peripheral and umbilical cord blood, white cells of peripheral or umbilical cord blood, CSF/ cerebrospinal fluid, amniotic fluid: RIBO-prep, REF K2-9-Et-50-CE; REF K2-9-Et-100-CE; RIBO-sorb, REF K2-1-Et-50-CE; REF K2-1-Et-100-CE; NucliSENS easyMAG automated system **(bioMérieux, France)**
From biopsy and autopsy material: DNA-sorb-C, REF K1-6-50-CE.

Toxoplasma gondii / Parvovirus B19 / Rubella virus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Toxoplasma gondii*-FRT	R-P1(RG, iQ, Mx)-CE		400 copies/ml*	*Toxoplasma gondii* DNA	QL	CE	60
AmpliSens® *Parvovirus B19*-FRT	R-V49(RG, iQ, Mx)-CE		360 IU/ml**	*Parvovirus B19* DNA	QL QN	CE	60
AmpliSens® *Rubella virus*-FRT	R-V24-S(RG, iQ, Mx)-CE		400 copies/ml***	*Rubella virus* RNA	QL	CE	60

***Extraction kit and biological material:**
RIBO-prep / whole peripheral and umbilical cord blood, white cells of peripheral or umbilical cord blood, cerebrospinal fluid, amniotic fluid;
DNA-sorb-C, / biopsy and autopsy material.
****Extraction kit and biological material:**
RIBO-prep / peripheral or umbilical blood, plasma or serum of peripheral or umbilical blood, oropharyngeal washes and swabs, saliva, cerebrospinal fluid, bone marrow biopsy samples, amniotic fluid, chorionic villi, placental biopsy samples, transudate (ascitic fluid) in case of non-immune fetal hydrops.
*****Extraction kit and biological material:**
RIBO-prep; RIBO-sorb; NucliSENS easyMAG automated system / plasma of peripheral and umbilical cord blood, saliva, throat swabs, amniotic fluid.

HERPESVIRUS INFECTIONS
SAMPLING, HANDLING AND PRESERVATION

Biological material: peripheral blood plasma, amniotic fluid, bronchoalveolar lavage, whole human blood, white blood cells, and viscera biopsy material, white blood cells, viscera biopsy material, saliva, oropharyngeal swabs, urogenital, rectal, and oral swabs; exudate of blisters and erosive-ulcerative lesions of skin and mucosa; whole blood and cerebrospinal fluid (CSF); pharyngeal, oropharyngeal swabs; urine samples, amniotic fluid.
Whole peripheral and umbilical blood. Before extraction, it is necessary to pretreat blood. Add 1.0 ml of Hemolytic (REF 137-CE, manufactured by the Federal Budget Institute of Science "Central Research Institute for Epidemiology") and 0.25 ml of whole blood to 1.5-ml Eppendorf tube using an individual tip and then handle according to the Instruction Manual.
Transport Medium for transport and storage: transport Medium with Mucolytic, REF 952-CE.

EXTRACTION KITS

DNA-sorb-AM, REF K1-12-100-CE; DNA-sorb-C, REF K1-6-100-CE (for viscera biopsy material); DNA-sorb-B, REF K1-2-100-CE (for blood and cerebrospinal fluid samples); RIBO-prep,REF K2-9-Et-50-CE; REF K2-9-Et-100-CE. Automatic instrument NucliSENS easyMAG can also be used also.

Cytomegalovirus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *CMV*-FRT	R-V7-F(RG,iQ)-CE*		1 x 10^3 GE/ml, Urogenital swabs	*Human cytomegalovirus (CMV)* DNA	QL	CE	110
			2 x 10^3 GE/ml, Urine				
AmpliSens® *CMV*-screen/ monitor-FRT	R-V7-100-S(RG,iQ,Mx)-CE**		400 copies/ml, Peripheral blood plasma, amniotic fluid, CSF, saliva, oropharyngeal swabs, urine samples, bronchoalveolar lavage	*Human cytomegalovirus (CMV)* DNA	QL QN	CE	110
			CMV DNA copies per 10^5 cells, Whole human blood, white blood cells, viscera biopsy material				

***Extraction kit:**
DNA-sorb-AM, Transport Medium with a Mucolytic Agent.
Biological material:
urogenital swabs, urine samples, saliva, whole human blood.
****Extraction kit:**
RIBO-prep, DNA-sorb-B; NucliSENS easyMAG automated system can also be used.
Biological material:
peripheral blood plasma, amniotic fluid, CSF, saliva, oropharyngeal swabs, urine samples, bronchoalveolar lavage, whole human blood, white blood cells, and viscera biopsy material.

Epstein-bar virus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *EBV*-screen/ monitor-FRT	R-V9-100-S(RG,iQ,Mx)-CE*		400 copies/ml , Peripheral blood plasma, amniotic fluid, CSF, saliva, oropharyngeal swabs, bronchoalveolar lavage	*Epstein-Barr virus (EBV)* DNA	QL QN	CE	110
			5 EBV DNA copies per 10^5 cells, Whole human blood, white blood cells, viscera biopsy material				

***Extraction kit and biological material:**
RIBO-prep; Automatic instrument NucliSENS easyMAG can also be used.

Varicella-zoster virus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *VZV*-FRT	R-V61-50-F(RG)-CE		500 copies/ml (RIBO-prep), Peripheral blood plasma, umbilical blood plasma amniotic fluid, CSF, blister content, saliva, oropharyngeal swab and washes*	*Varicella-Zoster virus* DNA	QL	CE	60

***Extraction kit and biological material:**
RIBO-prep; NucliSENS easyMAG automated system.

Human herpesvirus 6 infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HHV6*-screen-titre-FRT	R-V10-T(RG,iQ,Mx)-CE		400 copies/ml CSF, saliva, oropharyngeal swabs, and lavages	*human herpes virus type 6 (HHV6)* DNA	QL QN	CE	110
			5 DNA copies per 10^5 cells Whole human blood, white blood cells, viscera biopsy material*				

***Extraction kits:**
RIBO-prep, DNA-sorb-B, DNA-sorb-C, (for viscera biopsy material).

SAMPLING AND PRESERVATION

AmpliSens® HHV6-screen-titre-FRT PCR kit is designed for the analysis of DNA extracted with DNA extraction kits from whole human blood, white blood cells, viscera biopsy material, saliva, oropharyngeal swabs and CSF.
Whole peripheral and umbilical blood
Before extraction, it is necessary to pretreat blood. Using of Hemolytic (REF 137-CE, manufactured by the Federal Budget Institute of Science “Central Research Institute for Epidemiology”).

Herpes simplex virus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HSV* I, II-FRT	R-V8-F(RG,iQ)-CE		1 x 10^3 GE/ml, Urogenital swabs; DNA-sorb-AM*	*herpes simplex virus* types I and II *(HSV I, HSV II)* DNA	QL NoDiff	CE	110
AmpliSens® *HSV*-typing-FRT	R-V38-F(RG,iQ)-CE		*HSV* type I, *HSV* type II 1 x 10^3 GE/ml, Urogenital swabs DNA-sorb-AM**	*herpes simplex virus* types I and II *(HSV I and HSV II)* DNA	QL Diff	CE	110

***Extraction kits:**
DNA-sorb-B (for blood and cerebrospinal fluid samples); DNA-sorb-AM.
Biological material:
urogenital, rectal, and oral swabs; exudate of blisters and erosive-ulcerative lesions of skin and mucosa; whole blood and CSF.
Transport Medium with a Mucolytic

****Extraction kits:**
DNA-sorb-AM.
Biological material:
urogenital, rectal, and pharyngeal swabs; exudate of blisters and erosive-ulcerative lesions of skin and mucous membranes; whole blood; and CSF.
Transport Medium with a Mucolytic

Multiplex herpesvirus infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *EBV/CMV/-HHV6*-screen-FRT	R-V48(RG,iQ,Mx)-CE		400 copies/ml , CSF, saliva, oropharyngeal swabs, and lavages, RIBO-prep 5 DNA copies per 10^5 cells, Whole human blood, white blood cells, viscera biopsy material, RIBO-prep	*Epstein-Barr virus (EBV)*, DNA *Human Herpes virus type 6 (HHV6)* DNA, *Human cytomegalovirus (CMV)* DNA	QL QN	CE	110

Extraction kits:
RIBO-prep, DNA-sorb-B, DNA-sorb-C (for viscera biopsy material).
Biological material:
whole human blood, white blood cells, viscera biopsy material, saliva, oropharyngeal swabs, and CSF.

RESPIRATORY INFECTIONS

KEY FEATURES

- CE-IVD marked;
- Mono- and multiplex Real-time format;
- Differential diagnostics.

RESPIRATORY KITS ARE INTENDED FOR

- qualitative and quantitative detection;
- subtype identification.

OVERVIEW

Respiratory tract diseases are diseases that affect the air passages, including the nasal passages, the bronchi and the lungs. They range from acute infections, such as pneumonia and bronchitis, to chronic conditions such as asthma and chronic obstructive pulmonary disease.

Respiratory tract infections (RTIs) are any infections of the sinuses, throat, airways or lungs

They are usually caused by viruses, but can be caused by bacteria.
RTIs are thought to be one of the main reasons why people visit their GP or pharmacist. A common cold is the most widespread RTI.
Healthcare professionals generally make a distinction between:
- **upper respiratory tract infections** – which affect the nose, sinuses and throat;
- **lower respiratory tract infections** – which affect the airways and lungs.

Children tend to get more upper RTIs than adults because they have not built up immunity (resistance) to the many viruses that can cause these infections.

Seasonal influenza

Seasonal influenza viruses circulate and cause disease in humans every year. In temperate climates, the disease tends to occur seasonally in winter months, spreading from person-to-person through sneezing, coughing, or touching contaminated surfaces. Seasonal influenza viruses can cause mild to severe illness and even death, particularly in some high-risk individuals. Persons at increased risk for severe disease include pregnant women, the very young and very old, immune-compromised people, and people with chronic underlying medical conditions. Seasonal influenza viruses evolve continuously, which means that people can get infected multiple times throughout their lives. Therefore the components of seasonal influenza vaccines are reviewed frequently (currently biannually) and updated periodically to ensure continued effectiveness of the vaccines.
There are three large groupings or types of seasonal influenza viruses, labeled A, B, and C. Type A influenza viruses are further divided into subtypes according to a specific variety and combinations of two proteins that occur on the surface of the virus, the hemagglutinin or "H" protein and the neuraminidase or "N" protein. Currently, influenza A(H1N1) and A(H3N2) are the circulating seasonal influenza A virus subtypes. This seasonal A(H1N1) virus is the same virus that caused the 2009 influenza pandemic, as it is now circulating seasonally. In addition, there are two type B viruses that are also circulating as seasonal influenza viruses, which are named after the areas where they were first identified, Victoria lineage and Yamagata lineage. Type C influenza causes milder infections and is associated with sporadic cases and minor localized outbreaks. As influenza C poses much less of a disease burden than influenza A and B, only the latter two are included in seasonal influenza vaccines.

Pandemic influenza

A pandemic occurs when an influenza virus which was not previously circulating among humans and to which most people do not have immunity emerges and transmits among humans. These viruses may emerge, circulate and cause large outbreaks outside of the normal influenza season. As the majority of population has no immunity to these viruses, the proportion of persons in a population getting infected may be quite large. Some pandemics may result in large numbers of severe infections while others will result in large numbers of milder infections, but the reasons behind these differences are not completely understood. The most notorious pandemic for which data are available was the "Spanish Flu" in 1918-1919 which caused an estimated 20-50 million deaths worldwide. Subsequent pandemics in 1957 and 1968 resulted in many fewer deaths in spite of large portions of the world's population being susceptible to infection.

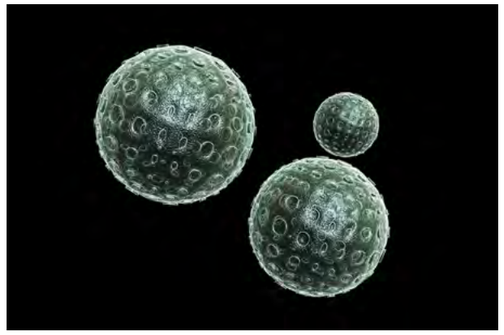
In 2009, a strain of influenza A(H1N1) virus, which had not ever been seen before, emerged, spread across the world and caused the 2009 H1N1 pandemic. This pandemic A(H1N1)2009 virus has been widely circulating across the globe since 2009 and is now established in human populations as a seasonal influenza virus, as described above. Currently there is no longer a pandemic virus circulating in the world.

Zoonotic or variant influenza

Humans can also be infected with influenza viruses that are routinely circulating in animals, such as avian influenza virus subtypes A(H5N1) and A(H9N2) and swine influenza virus subtypes A(H1N1) and (H3N2). Other species including horses and dogs also have their own varieties of influenza viruses. Even though these viruses may be named as the same subtype as viruses found in humans, all of these animal viruses are distinct from human influenza viruses and do not easily transmit between humans. Some may occasionally infect humans, however, and may cause disease ranging from mild conjunctivitis to severe pneumonia and even death. Usually these human infections of zoonotic influenza are acquired through a direct contact with infected animals or contaminated environments, and do not spread very far among humans. If such virus acquired the capacity to spread easily among people either through adaptation or acquisition of certain genes from human viruses, it could start an epidemic or a pandemic.
Over the past decades, there have been multiple instances of sporadic transmission of influenza viruses between animals and humans. When viruses of subtype A(H3N2) circulating in swine, began to infect people in the USA in 2011, they were labeled "variant" (with a "v" placed after the name of the virus) in order to distinguish them from human viruses of the same subtype 1. The variant terminology is also used for other non-seasonal influenza viruses of a subtype shared with human seasonal influenza viruses, particularly viruses of the H1 and H3 subtypes circulating in swine, when these viruses are detected in humans. Other animal viruses, e.g. avian influenza A(H5N1), A(H7N7), A(H7N9), and A(H9N2), infecting people are simply called "avian influenza" or "zoonotic influenza" viruses.
When animal influenza viruses infect their natural animal host, they are named for that host, as in avian influenza viruses, swine influenza viruses, equine influenza viruses, etc. As such, the term "swine flu" refers to swine influenza viruses infecting swine, and is never used when such viruses infect people.

Avian influenza A(H7N9)

Avian influenza A(H7N9) is a subtype of influenza viruses that was detected in birds in the past. This particular A(H7N9) virus had not previously been seen in either animals or people until it was found in March 2013 in China.
However, since then, infections in both humans and birds have been observed. The disease is of concern because most patients have become severely ill. Most of the cases of human infection with this avian H7N9 virus have reported recent exposure to live poultry or potentially contaminated environments, especially markets where live birds have been sold. This virus does not appear to transmit easily from person to person, and sustained human-to-human transmission has not been reported.



Avian influenza in humans

Most avian influenza viruses do not cause disease in humans. However, some are zoonotic, meaning that they can infect humans and cause disease. The most well known example is the avian influenza subtype H5N1 viruses currently circulating in poultry in parts of Asia and northeast Africa, which have caused human disease and deaths since 1997.
Other avian influenza subtypes, including H7N7 and H9N2, have also infected people. Some of these infections have been very severe and some have resulted in deaths, but many infections have been mild or even subclinical in humans.
Because birds play an important role as a source of food and livelihoods in many countries affected by avian influenza viruses, WHO and animal health sector partners are working at the human-animal interface to identify and reduce animal health and public health risks within national contexts.

Swine influenza in humans

Most swine influenza viruses (SIVs) do not cause disease in humans. However, some countries have reported cases of human infection with SIVs. Most of these human infections have been mild and the viruses have not spread further to other people. The H1N1 virus that caused the influenza pandemic in 2009-2010, thought to have originated in swine, is an example of an SIV that was able to spread easily among people and also cause disease.

Because pigs can become infected with influenza viruses from a variety of different hosts (such as birds and humans), they can act as a "mixing vessel," facilitating the reassortment of influenza genes from different viruses and creating a "new" influenza virus. The concern is that such "new" reassortant viruses may be more easily spread from person to person, or may cause more severe disease in humans than the original viruses. WHO and animal health sector partners are working at the human-animal interface to identify and reduce animal health and public health risks within national contexts.

SARS

Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a *coronavirus*, called SARS-associated coronavirus (SARS-CoV). SARS was first reported in Asia in February 2003. The illness spread to more than two dozen countries in North America, South America, Europe, and Asia before the SARS global outbreak of 2003 was contained.
Among the several types of assays used to detect SARS-CoV (http://www.cdc.gov/sars/lab/images.html), RT-PCR and antibody assays are the most commonly used ones.

Real-Time RT-PCR Assays

Many laboratories have developed SARS-CoV real-time RT-PCR assays (http://www.cdc.gov/sars/lab/rtpcr-consent.html). They can also be very sensitive, with consistent detection limits of between 1 and 10 SARS-CoV RNA copies per reaction. Real-time PCR assays can be performed faster than traditional RT-PCR assays and, because they operate as closed systems, with reduced risk of contamination in the laboratory. Finally, real-time RT-PCR assays can give an accurate estimate of the quantity of virus present in a sample.

MERS-CoV

Middle East respiratory syndrome coronavirus (MERS-CoV)
Middle East respiratory syndrome (MERS) is a viral respiratory disease caused by a novel coronavirus (MERS-CoV) that was first identified in Saudi Arabia in 2012. Our understanding of the virus and the disease it causes is continuing to evolve.
Coronaviruses are a large family of viruses that can cause diseases ranging from a common cold to Severe Acute Respiratory Syndrome (SARS).
The last case of MERS-CoV infection in the Republic of Korea as reported to WHO was laboratory confirmed on 4 July 2015.

Tuberculosis

Tuberculosis (TB) is caused by bacteria (*Mycobacterium tuberculosis*) that most often affect the lungs. Tuberculosis is curable and preventable.
Global situation and trends: Tuberculosis (TB) is contagious and airborne. It ranks as the second leading cause of death from a single infectious agent, after the human immunodeficiency virus (HIV). 9 million people fell ill with TB in 2013, including 1.1 million cases among people living with HIV. In 2013, 1.5 million people died from TB, including 360,000 among people who were HIV-positive. 510,000 women died from TB in 2013, including 180,000 among women who were HIV-positive. Of the overall TB deaths among HIV-positive people, 50% were among women. TB is one of the top killers of women of reproductive age. An estimated 550,000 children became ill with TB and 80,000 children who were HIV-negative died of TB in 2013. The TB mortality rate has decreased by 45% since 1990.

KEY FACTS

- Tuberculosis (TB) is second only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent;
- In 2013, 9 million people fell ill with TB and 1.5 million died from the disease;
- Over 95% of TB deaths occur in low- and middle-income countries, and it is among the top 5 causes of death for women aged 15 to 44;
- In 2013, an estimated 550,000 children became ill with TB and 80,000 HIV-negative children died of TB;
- TB is a leading killer of HIV-positive people causing one fourth of all HIV-related deaths;
- Globally in 2013, an estimated 480,000 people developed multidrug resistant TB (MDR-TB);
- The estimated number of people falling ill with TB each year is declining, although very slowly, which means that the world is on track to achieve the Millennium Development Goal to reverse the spread of TB by 2015;
- The TB death rate dropped by 45% between 1990 and 2013;
- An estimated 37 million lives were saved through TB diagnosis and treatment between 2000 and 2013.

SAMPLING AND PRESERVATION

Biological material:
viral respiratory pathogens

- nasal / oropharyngeal and throat swabs or washes;
- feces;
- sputum or nasopharyngeal and tracheal aspirates;
- autopsy material (fragments of affected parts of lungs);
- bronchoalveolar lavage;
- bronchial washing fluid;
- viral culture;
- eye discharge;
- blood plasma;
- swabs, smears from oropharynx and nasopharynx.

Bacterial respiratory pathogens

- tracheal sputum or aspirate;
- nasopharyngeal and oropharyngeal swabs;
- bronchial washes or bronchoalveolar lavage;
- sputum;
- urine;
- autopsy material;
- PBS;
- 10 % homogenate of different tissues (lungs, lymph nodes, kidney, liver, brain, spleen);
- environmental samples (water, washes from environmental objects, biofilms, and soil);
- microorganism cultures.

Preservation: transport Medium for Storage and Transportation of Respiratory Swabs, REF 957-CE.

EXTRACTION KITS

RIBO-prep, REF K2-9-Et-50-CE, REF K2-9-Et-100-CE.
RIBO-sorb, REF K2-1-Et-50-CE, REF K2-1-Et-100-CE.
DNA-sorb-B REF K1-2-50-CE.
DNA-sorb-C, REF K1-6-50-CE.

Viral respiratory infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Influenza virus A* H5N1-FRT	R-V33(SC)-CE		no less than 5 x 10^3 copies/ml (nasal and throat swabs or washes; aspirate of trachea; faeces ; autopsy material) RIBO-sorb	*Influenza virus A* RNA and identifying of H5N1 subtype	QL	CE	55
	R-V33(RG)-CE						
AmpliSens® *Influenza virus* A/H1-swine-FRT	R-V55-F(SC)-CE		1 x 10^3 copies/ml, RIBO-prep 5 x 10^3 copies/ml, RIBO-sorb (nasal/ oropharyngeal swabs[8]) nasal and oropharyngeal swabs, sputum or nasopharyngeal and tracheal aspirates, and autopsy material (fragments of affected parts of lungs)	*Influenza virus* A/H1N1 (sw2009) RNA	QL	CE	55
	R-V55(RG)-CE						

[8] Nasal and oropharyngeal swabs should be placed into the Transport Medium for Storage and Transportation of Respiratory Swabs (REF 957-CE).

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Influenza virus* A-type-FRT	R-V54(RG)-CE		1 x 10^3 copies/ml (nasal and oropharyngeal swabs); nasal and oropharyngeal swabs; sputum or nasopharyngeal or tracheal aspirate; and autopsy material RIBO-prep; RIBO-sorb; Transport Medium for Respiratory Swabs	*Influenza virus A* (identification to subtypes H1N1 and H3N2) RNA	QL Diff	CE	55
NEW AmpliSens® *Influenza virus* type-FRT	R-V54-100-F(RG,iQ,Dt,SC)-CE					CE	100
NEW AmpliSens® *Influenza virus* A-type-H5,H7,H9-FRT	R-V66-F-CE		1 x 10^3 GE/ml Nasal and oropharyngeal swabs, sputum (or tracheal aspirates), bronchoalveolar lavage, autopsy material in which the Influenza virus A RNA was detected RIBO-sorb; RIBO-prep; NucliSENS easyMAG)	typing (identification) of *Influenza virus* A RNA subtypes H5, H7, H9	QL Diff	CE	55
NEW AmpliSens® *Influenza virus* A/B-FRT	R-V36-50-Mod-CE		1 x 10^3 GE/ml Nasopharyngeal and oropharyngeal swabs, RIBO-sorb, RIBO-prep, NucliSENS easyMAG. nasopharyngeal and oropharyngeal swabs; sputum; aspirate of trachea; bronchoalveolar lavage, bronchial washing fluid, autopsy material, viral culture	*Influenza virus* A and *Influenza virus* B RNA	QL	CE	55
	R-V36-100-F-Mod (RG;iQ;Dt;CFX;SC) -CE						100
AmpliSens® *Parainfluenza virus*-FRT	R-V51(RG)-CE		1 x 10^3 GE/ml RIBO-sorb, RIBO-prep, Nasal and oropharyngeal swabs	*Parainfluenza virus* types 1 and 3 (genus *Respirovirus*); *Parainfluenza virus* types 2 and 4 (genus *Rubulavirus*)	QL Diff	CE	55
AmpliSens® *hRSV*-FRT *(human Respiratory-Syncytial virus)*	R-V37(RG)-CE		1 x 10^3 GE/ml RIBO-sorb; RIBO-prep, Nasal and oropharyngeal swabs, nasopharyngeal or tracheal sputum or aspirate, and autopsy material	*Human Respiratory Syncytial virus* RNA	QL	CE	55

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Adenovirus*-Eph[9]	V23-50-R0,2-CE		no less than 5 x 10^3 GE/ml DNA-sorb-B; feces, oropharyngeal swabs (washing fluid), and eye discharge	*Adenovirus* DNA hAdv(462b.p.)	QL	CE	55
AmpliSens® SARS-*Coronavirus*-Eph	TV29-100-R0,2-CE		5 x 10^3 GE/ml RIBO-sorb, blood plasma, swabs, smears from oropharynx and nasopharynx 1 x 10^4 GE/ml feces, RIBO-sorb	SARS-*Coronavirus* RNA; (221 b.p.) ic (400 b.p.)	QL	CE	110
NEW AmpliSens® *CoV*-Bat-FRT (Coronavirus Bat subtype)	R-V65-F-CE		MERS-Cov, SARS-Cov 1 x 10^3 GE/ml - nasopharyngeal and oropharyngeal swabs, blood plasma, sputum, feces – for rotor-type instruments 1 x 10^4 GE/ml – feces - for plate-type instruments RIBO-prep	MERS-Cov, SARS-Cov RNA[10]	QL	CE	55

[9] It is recommended to use the following detection agarose kit: EPh variant 200, REF K5-200-CE.

[10] RNA of coronaviruses causing severe respiratory infections MERS-Cov (Middle East respiratory syndrome coronavirus) and SARS-Cov (Severe acute respiratory syndrome coronavirus).

Bacterial respiratory infections PCR kits

Bordetella

The genus Bordetella comprises Gram-negative beta-proteobacteria including three species which are human pathogens, *Bordetella pertussis, Bordetella parapertussis* and *Bordetella bronchiseptica*. *B. pertussis*, and occasionally *B. parapertussis*, can cause whooping cough in human infants. *B. pertussis* infects only humans while *B. parapertussis* infects both humans and sheep. Phylogenetic analyses have shown that *B. parapertussis* strains isolated from humans are distinct from those isolated from sheep, and there is little or no transmission between the two reservoirs (sheep and human). *B. bronchiseptica* colonize the respiratory tracts of a range of mammals, but can also persist in the environment for extended periods. It causes chronic and often asymptomatic respiratory infections in a wide range of animals, but only occasionally in humans. A related species, *B. avium* causes a disease (bordetellosis) in commercially grown turkeys, but is also found in a variety of healthy wild and domesticated birds.

The strains selected for sequencing included :
B. bronchiseptica strain 253 (ST27), *B. pertussis* strain 18323 (ST24), *B. parapertussis* (ovine) Bpp5 (ST16), *B. bronchiseptica* strain MO149 (ST15), *B. bronchiseptica* strain D445, *B. bronchiseptica* Bbr77, *B. bronchiseptica* strain 1289.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Legionella Pneumophila*-FRT	R-B50(RG)-CE		not less than 1 x 10^3 GE/ml (biological materials; microorganism cultures, and environmental samples) DNA-sorb-B **Biological material***	*Legionella pneumophila* DNA	QL QN	CE	70
AmpliSens® *MBT*-EPh	B15-100-R0,2-CE		1 x 10^3 cells/ml 5 x 10^3 GE/ml, sputum). 1 x 10^3 GE/ml, bronchoalveolar lavage or urine DNA-sorb-B	*M. tuberculosis complex (M. tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. microti)* DNA[11]	QL	CE	110
AmpliSens® *MTC*-FEP	B57-FEP-CE		**Analytical sensitivity, biological material, extraction kits****	*M.tuberculosis, M.bovis, M.africanum, M.microti, M.canetti, M.pinipedii* DNA[12]	QL	CE	55
AmpliSens® *MTC*-FRT	R-B57(RG,iQ,SC,Dt)-CE						

[11] Mycobacterium tuberculosis complex (Mycobacterium tuberculosis, Mycobacterium bovis, Mycobacterium bovis BCG, Mycobacterium africanum, Mycobacterium microti) DNA.

[12] Mycobacterium tuberculosis (MBT) DNA – Mycobacterium tuberculosis complex (MTC), including M.tuberculosis, M.bovis, M.africanum, M.microti, M.canetti, M.pinipedii.

AmpliSens biotechnologies

***AmpliSens®Legionella Pneumophila-FRT**
Biological material:
tracheal sputum or aspirate, nasopharyngeal and oropharyngeal swabs, bronchial washes or bronchoalveolar lavage, and autopsy material, microorganism cultures, and environmental samples (water, washes from environmental objects, biofilms, and soil).

****Analytical sensitivity for kits AmpliSens® MTC-FEP, AmpliSens® MTC-FRT:**

Nucleic extraction kit	Material	Sensitivity, mb/ml
		M.tuberculosis (H37 Ra strain)
RIBO-prep	PBS, sputum, BAL	$5x10^2$
	Urine	$1x10^3$
	Washing fluids from environmental objects[13]	$2.5x10^2$ copy/ml
DNA-sorb-B	PBS, sputum	$5x10^2$
	BAL, urine	$1x10^3$
	Washing fluids from environmental objects	$2.5x10^2$ copy/ml
DNA-sorb-C	10 % homogenate of different tissues (lungs, lymph nodes, kidney, liver, brain, spleen)	$1x10^2$

[13] Analysis can be performed without DNA extraction if washing fluids from environmental objects are added immediately to the reaction mixture for carrying out PCR analysis.

Multiplex respiratory infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FRT	R-B42-4x(RG)-CE		not less than 1×10^3 GE/ml DNA-sorb-B, **Biological material:** sputum, nasopharyngeal and oropharyngeal swabs, bronchial washing fluid or bronchoalveolar lavage, whole blood, and autopsy material	DNA of *Mycoplasma pneumonia, Chlamydophila pneumoniae*	QL	CE	55
AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FRT	R-B42-100-F-CE		1×10^3 GE/ml, RIBO-sorb 5×10^2 GE/ml, RIBO-prep, NucliSENS easyMAG **Biological material:** nasopharyngeal and oropharyngeal mucosa and sputum treated with mucolysin; volume 100µl	DNA of *Mycoplasma pneumoniae and Chlamydophila pneumoniae*	QL	CE	100
NEW AmpliSens® *Bordetella multi*-FRT	R-B84-100-F(RG,iQ,Dt)-CE		1×10^3 GE/ml, RIBO-sorb 5×10^2 GE/ml, RIBO-prep NucliSENS easyMAG **Biological material:** swabs taken from lower nasal passage and back of oropharynx as well as culture of microorganisms	*Bordetella pertussis, Bordetella parapertussis, Bordetella bronchiseptica* DNA	QL Diff	CE	100
AmpliSens® ARVI-screen-FRT	R-V57-100-F(RG,iQ,Dt)-CE		1×10^3 GE/ml (*hRSv, hMpv, hPiv, hBov, hRv*) RIBO-sorb, RIBO-prep, NucliSENS easyMAG 5×10^3 GE/ml (*hAdv*) RIBO-sorb, RIBO-prep, NucliSENS easyMAG 1×10^4 GE/ml (*hCov*) RIBO-sorb, RIBO-prep, NucliSENS easyMAG **Biological material:** nasal and oropharyngeal swabs, sputum, aspirate of trachea, bronchoalveolar lavage, bronchial washing fluid, and autopsy material	*hRSv* RNA; *hMpv* RNA; *hPiv 1-4* RNA; OC43, E229, NL63; HKUI *hCov* RNA; *hRv* RNA; B, C, E *hAdv* DNA; *hBov* DNA[14]	QL Diff	CE	100

[14] Human Respiratory Syncytial virus (hRSv) RNA; human Metapneumovirus (hMpv) RNA; human Parainfluenza virus-1-4 (hPiv) RNA; OC43, E229, NL63; HKUI human Coronavirus (hCov) RNA; human Rhinovirus (hRv) RNA; human B, C, and E Adenovirus (hAdv) DNA; human Bocavirus (hBov) DNA.

Kit type	Catalog number	Format	Analytical sensitivity		Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *MTC*-diff-FRT*	R-B80(RG,iQ,Dt,SC)-CE		AmpliSens® *MTC*-FRT; AmpliSens® *MTC*-diff-FRT		*M.tuberculosis*, *M.bovis*, *M.bovis* BCG strains DNA[15]	QL Diff	CE	55
			M.tuberculosis (H37 Ra strain)	*M.bovis* BCG (*M.bovis* BCG strain)				
			1×10^2-5×10^3 mb/ml**	5×10^2-5×10^3 mb/ml**				

***AmpliSens® MTC-diff-FRT** PCR kit is designed as a supplement test for **AmpliSens® MTC-FRT** PCR kit and is used for analysis of the DNA previously extracted from the clinical material.

**depends on a biological material and extraction method

Amplisens® MTC-diff-FRT, Analytical sensitivity

DNA extraction kit	Biological material	Sensitivity, mb/ml			
		AmpliSens® MTC-FRT	AmpliSens® MTC-diff-FRT	AmpliSens® MTC-FRT	AmpliSens® MTC-diff-FRT
		M.tuberculosis (H37 Ra strain)		*M.bovis* BCG (*M.bovis* BCG strain)	
RIBO-prep	PBS-buffer	5×10^2	1×10^3	1×10^3	1×10^3
	Urine	1×10^3	5×10^3	1×10^3	1×10^3
	Sputum[16], BAL/BWF	5×10^2	1×10^3	1×10^3	1×10^3
DNA-sorb-B	PBS-buffer	5×10^2	1×10^3	1×10^3	1×10^3
	Sputum, BAL/BWF	5×10^2	5×10^3	1×10^3	5×10^3
	Urine	1×10^3	5×10^3	1×10^3	5×10^3
DNA-sorb-C	10 % homogenate of different tissues	1×10^2	1×10^3	5×10^2	1×10^3

15 DNA of M.tuberculosis complex (MTC) including the human (M.tuberculosis), the bovine (M.bovis) and the vaccine (M.bovis BCG) strains.

16 Concentration in 1 ml of sputum, treated with a pre-treatment reagent for mucous material "Mucolysin".

PURULENT SEPTIC INFECTIONS

KEY FEATURES

- CE-IVD marked;
- quantitative detection;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost-effectiveness.

PURULENT SEPTIC INFECTIONS KITS ARE INTENDED FOR

Qualitative and quantitative detection of most frequently spread septic pathogens.

OVERVIEW

Prospective epidemiological observation in an otorhinolaryngological hospital has made it possible to distinguish specific features of pyoseptic nosocomial infections. Such infections, appearing as cross re- and superinfections, are most frequently induced by staphylococci, as well as by Proteus and Pseudomonas aeruginosa. High risk groups include patients with purulent otitis and sinusitis, who have contracted infection through instruments in examination and dressing rooms. The main sources of infection are patients with pyoseptic infections of the ear and sinuses.

As an example, among the causative agents of purulent septic diseases in a surgical hospital, 25 microbial species were isolated; of these, the prevailing species were Staphylococcus aureus (19.86 +/- 1.07%), Escherichia coli (16.5 +/- 0.99%) and Pseudomonas aeruginosa (10.06 +/- 0.8%). From environmental objects in the hospital 14 microbial species were isolated, among them bacteria of the genus Enterobacter (27 +/- 1.7%), E. coli (19.07 +/- 1.48%), S. aureus (14.7 +/- 1.31%), Klebsiella pneumoniae (13.73 +/- 1.31%), P. aeruginosa (7.33 +/- 0.98%). During 3 years of observation the isolation rate of K. pneumoniae from different environmental objects was found to increase threefold to 24.7 +/- 2.7%.

Pseudomonas are ubiquitous organisms distributed widely in the environment, including the soil and water, and in association with various living host organisms. There are representatives such as *Pseudomonas aeruginosa* that are one of the most prevalent causes of opportunistic infections in humans and are the most common cause of eventually fatal, persistent respiratory infections in cystic fibrosis (CF) patients. Others such as *Pseudomonas fluorescens* represent a physiologically diverse species that contribute greatly to turnover of organic matter and, while in soil, are abundant on the surfaces of plant roots and leaves. Of the plant-colonizing strains, some isolates are known to positively affect plant health and nutrition. Mechanistic bases of these effects remain unclear, but are known to include production of plant-growth hormones, suppression of pathogens (especially fungi and oomycetes) detrimental to plant health via competitive and / or allelopathic effects, and direct elicitation of plant defence responses.

Streptococcus pyogenes (Group A Strep) strains are associated with a wide variety of clinical manifestations, including streptococcal toxic-shock syndrome, acute rheumatic fever, scarlet fever, and others.

Group B *Streptococcus* (GBS), also known as ***Streptococcus agalactiae***, is best known as a cause of postpartum infection and as the most common cause of neonatal sepsis. This organism also causes infection in nonpregnant adults. Group B streptococcal infection in healthy adults is extremely uncommon, except in young and middle-aged women, and is almost always associated with underlying abnormalities, with diabetes most commonly associated with infection in some series.

Staphylococcus aureus is an important nosocomial and community-acquired pathogen. *S. aureus* is the most common cause of hospital acquired infection, causing clinical disease in 2% of all patient admissions in the UK. Not only does it cause enormous numbers of infections, but *S. aureus* in hospitals are becoming increasingly resistant to antibiotics. In several industrialised nations including parts of Europe, the US and Japan, 40-60% of all hospital S. aureus are now resistant to methicillin (methicillin-resistant *Staphylococcus aureus*, MRSA).

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a bacteria that is resistant to many antibiotics. In the community, most MRSA infections are skin infections. In medical facilities, MRSA causes life-threatening bloodstream infections, pneumonia and surgical site infections.

SAMPLING AND PRESERVATION

Biological material: ● oropharyngeal swabs, ● sputum, ● throat swabs, ● bronchial washing fluid, ● bronchoalveolar lavage (BAL), ● endotracheal aspirate, ● urine (first portion pellet), ● prostatic secretion, ● epithelial swabs of lateral vaginal walls, ● anorectal swabs, ● blood, ● blood plasma, ● cerebrospinal fluid (CSF), ● aspirate from the lesions of organs and tissues, ● puncture samples from affected organs and tissues, ● biopsies, ● synovial fluid, ● wound discharge, ● washes from healthcare equipment and instruments.

Preservation: transport Medium for Storage and Transportation of Respiratory Swabs, REF 957-CE.

EXTRACTION KITS: RIBO-prep, REF K2-9-Et-50-CE, REF K2-9-Et-100-CE, NucliSENS easyMAG automated system.

AmpliSens biotechnologies

Purulent septic infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Pseudomonas aeruginosa*-screen-titre-FRT	R-B76-50-FT(RG,iQ)-CE		500 copies/ml, RIBO-prep **Biological material***	*Pseudomonas aeruginosa* DNA	QL QN	CE	60
AmpliSens® *Streptococcus agalactiae*-screen-titre-FRT	R-B77-100-FT(RG,iQ)-CE		3 x 10^2 copies/ml, RIBO-prep **Biological material:** blood plasma, CSF, oropharyngeal swabs, epithelial swabs of lateral vaginal walls, anorectal swabs	*Streptococcus agalactiae* DNA	QL QN	CE	110
AmpliSens® *Streptococcus pyogenes*-screen-titre-FRT	R-B82-100-FT(RG,iQ)-CE		3 x 10^2 copies/ml, RIBO-prep **Biological material:** throat swabs, sputum, blood, biopsies, synovial fluid, wound discharge, CSF, urine	*Streptococcus pyogenes* DNA	QL QN	CE	110
AmpliSens® *MRSA*-screen-titre-FRT	R-B78-100-FT(RG,iQ)-CE		400 copies/ml, RIBO-prep **Biological material****	*Staphylococcus aureus* DNA *mecA* gene in *S.aureus* and some other *Staphylococcus spp.* DNA[17]	QL QN	QN	110

***AmpliSens®Pseudomonas aeruginosa-screen-titre-FRT**
Biological material:
blood, blood plasma, oropharyngeal swabs, bronchoalveolar lavage (BAL), sputum, endotracheal aspirate, urine, prostatic secretion, cerebrospinal fluid, aspirate from the lesions of organs and tissues.

****AmpliSens®MRSA-screen-titre-FRT**
Biological material:
oropharyngeal swabs, bronchoalveolar lavage (BAL), sputum, endotracheal aspirate, bronchial washing fluid, urine (first portion pellet)[18] , blood, blood plasma, CSF, puncture samples from affected organs and tissues, washes from healthcare equipment and instruments.

[17] Methicillin-sensitive and methicillin-resistant Staphylococcus aureus DNA and methicillin-resistant coagulase-negative Staphylococcus spp. DNA.

[18] Pretreatment is required.

GENETIC MARKERS OF ANTIBIOTIC-RESISTANCE

KEY FEATURES

- CE-IVD marked;
- quantitative detection;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost-effectiveness.

GENETIC MARKERS OF ANTIBIOTIC-RESISTANCE

Qualitative detection of DNA fragments of KPC-type and OXA-48-like (OXA-48- and OXA-162-type) carbapenemases genes and DNA fragments of carbapenemases genes of metallo-β-lactamases class, types IMP, VIM, and NDM.

OVERVIEW

The WHO has identified antimicrobial resistance as one of the three most important problems for human health (WHO. Antimicrobial Resistance: Global Report on Surveillance, 2014).
A significant increase in incidence of bacteria antibiotic resistance observed in recent years represents a significant challenge to public health microbiology worldwide. Not least among these challenges are extended-spectrum β-lactamases (ESBLs) and carbapenemases among Enterobacteriaceae and other Gram-negative micro-organisms and vancomycin resistance among enterococci.

Usefulness of special tests for carbapenemase detection in routine practice

The European Committee on Antimicrobial Susceptibility Testing - EUCAST - advised recently that, with low breakpoints, susceptibility results for cephalosporins and carbapenems can be reported 'as found', even for strains with extended-spectrum β-lactamases (ESBLs) and carbapenemases. The CLSI (Clinicals Laboratory Standards Institute) has similar advice, but with higher ceftazidime and cefepime breakpoints than those of EUCAST. Pharmacodynamic and animal data are used to support these views, along with some analysis of clinical case series. We contend that such advice is misguided on three counts.
First, whilst there are cases on record where cephalosporins and carbapenems have proved effective against infections due to low-MIC ESBL producers and low-MIC carbapenemase producers, respectively, there are similar numbers of cases where such therapy has failed.
Second, routine susceptibility testing is less precise than in research analyses, meaning that ESBL and carbapenemase producers with 'real' MICs of 1–8 mg/L will oscillate between susceptibility categories according to who tests them and how.
Third, although EUCAST continues to advocate ESBL and carbapenemase detection for epidemiological purposes, the likely consequence of not seeking these enzymes for treatment purposes is that some laboratories will not seek them at all, leading to a loss of critical infection control information. In short, it is prudent to continue to seek ESBLs and carbapenemases directly and, where they are found, generally to avoid substrate drugs as therapy.

(Livermore D., Woodford N. et al., J Antimicrob Chemother 2012; 67:1569-77; "Are susceptibility tests enough, or should laboratories still seek ESBLs and carbapenemases directly?")

Public Health Importance of Antimicrobial Resistance

Infectious diseases were the primary cause of mortality in mankind prior to their discovery and use of antimicrobials. In most of the developing world without access to good quality medicines, infections continue to be major killers, and in all countries healthcare-associated infections with resistant microorganisms are a major cause of death.

Antimicrobial resistance is an unusual public health threat

- Antimicrobial resistance is not a "disease". Typically, there is no difference in severity of disease caused by susceptible strains and resistant ones. Resistance is generally not a problem of disease pathology but one of limited therapy options.
- The core issue is our dependence on antimicrobials for treating infections. If there were alternate methods of treating infections, antimicrobial resistance would persist in the world but would no longer be relevant as a public health concern.
- Antimicrobial resistance is a public health threat driven by healthcare practices, most notably the overuse of antimicrobials in conditions for which they provide no benefit.
- Resistance is a characteristic of many pathogens causing different diseases. Containment strategies thus must be adapted to needs of specific disease control and treatment programs.

Some Leading Resistant Pathogens

Many types of microorganisms cause infection in humans and animals, so disease prevention and treatment strategies must be adapted to reflect infection risk factors and available treatment options. Over the past decades, most pathogenic species have developed resistance to one or more antimicrobials. Some of the species in which resistance is of greatest public health concern are listed below.

Bacteria-Community

- *Escherichica coli*
- *Mybocaterium tuberculosis* (cause of tuberculosis)
- *Neisseria gonorrhoeae* (cause of gonorrhoea)
- *Salmonella* Typhi
- *Staphylococcus aureus,* including community-associated MRSA (Methicillin-Resistant *S. aureus)*
- *Streptococcus pneumoniae*

Bacteria-Hospitals

- *Acinetobacter baumannii*
- *Enterococcus faecium* and *Enterococcus faecalis,* including VRE (Vancomycin-resistant enterococci)
- Multidrug-resistant enteric pathogens, including *Escherichia coli* and *Klebsiella pneumoniae* producing ESBL and KPC enzymes
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus,* including MRSA (Methicillin-Resistant *S. aureus)*
- *Stenotrophomonas maltophilia*

Bacteria-Zoonotic disease

- *Campylobacter species*
- *Salmonella species*

Fungi

- *Candida albicans*

Viruses

- Cytomyegalovirus
- Herpes simplex virus
- HIV

Parasites

- *Leishmania* species
- *Plasmodium* species (cause of malaria)
- *Trypanosoma* species

SAMPLING AND PRESERVATION

Needs the pretreatment: oropharyngeal and rectal swabs should be placed in Transport Medium with Mucolytic Agent, REF 952-CE.

EXTRACTION KITS

DNA-sorb-AM, REF K1-12-100-CE.
RIBO-prep, REF K2-9-Et-100-CE.

Genetic markers of antibiotic-resistance PCR kits

Kit type	Catalog number	Format	Analytical sensitivity, GE/ml	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® MDR KPC/OXA-48-FRT	R-C2(RG,CFX)-CE		Analytical sensitivity* depends of type of biological material, extraction **Biological material and extraction kits****	DNA fragments of KPC-type and OXA-48-like (OXA-48- and OXA-162-type) carbapenemases genes	QL	CE	110
AmpliSens® MDR MBL-FRT	R-C1(RG,CFX)-CE		Analytical sensitivity* depends of type of clinical material, extraction **Biological material and extraction kits****	DNA fragments of carbapenemases genes of metallo-β-lactamases class, types IMP, VIM, and NDM	QL	CE	110

***Sensitivity for AmpliSens® MDR MBL-FRT and MDR KPC/OXA-48-FRT**

Nucleic acid extraction kit	Biological material	Sensitivity	Transport medium
DNA-sorb-AM	Blood cultures, a mixture of bacterial cultures obtained by primary seeding biological material to solid or liquid medium[20]	1 x 10^5 copies/ml[19]	—
DNA-sorb-AM RIBO-prep	Urine	5 x 10^2 copies/ml	—
DNA-sorb-AM	Oropharyngeal and rectal swabs	2 x 10^3 copies/ml	Transport Medium for Swabs or Transport Medium with a Mucolytic Agent

Relevant types of MBL genes were identified by using this reagent kit and then DNA samples of control strains, carrying genes of known MBL of VIM-1, VIM -2, VIM-4, VIM-10, IMP-1, IMP-2, IMP -12, IMP-13 types, were analysed.
Relevant carbapenemase genes were identified using this reagent kit for analysis of control strain DNA samples, carrying genes of known KPC-3- and OXA-48 carbapenemases.

****Biological material for AmpliSens® MDR MBL-FRT and MDR KPC/OXA-48-FRT:**
DNA extracted from samples of pure bacterial culture, positive blood culture, mixture of bacterial cultures obtained by primary seeding of biological material (CSF, bronchoalveolar lavage (BAL), traumatic discharge, etc.) to solid or liquid medium) and in the clinical material (urine, oropharyngeal and rectal swabs).

****Extraction kits for AmpliSens® MDR MBL-FRT and MDR KPC/OXA-48-FRT:**
DNA-sorb-AM – positive blood cultures, a mixture of bacterial cultures obtained by seeding biological material to liquid medium, after pretreatment, according to the Instruction Manual of the reagent kit.
DNA-sorb-AM and RIBO-prep (urine after pretreatment).
DNA-sorb-AM (oropharyngeal and rectal swabs according to the Instruction Manual of the reagent kit).

19 It is necessary to observe pre-treatment rules and recommended volume of a test sample to obtain this sensitivity.

20 Bacterial cultures obtained by primary seeding of biological material onto solid medium have respective sensitivity to bacterial cell suspension lysis solution "DNA-sorb-AM".

NEURO-INFECTIONS

KEY FEATURES

- CE-IVD marked;
- multiplex pathogen detection;
- qualitative and quantitative formats;
- differentiation;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost effectiveness.

NEURO-INFECTIONS KITS ARE INTENDED FOR

- qualitative and quantitative detection of pathogen;
- type identification (AmpliSens® *Poliovirus*-FRT PCR kit).

OVERVIEW

Viruses and microorganisms sometimes invade the body, infecting various organs and causing everything from mild disturbances to serious problems. Bacterial organisms are often to blame, but animal parasites and fungi can also cause infection. Neurological infections occur when these viruses and organisms invade the nervous system.

Symptoms of Infection

Pain, swelling, redness, impaired function and fever are all characteristics of an infection. There may also be heat at a site of the infected area. In case of some viral infections, drowsiness, confusion and convulsions may occur.

Public Health Importance of Antimicrobial Resistance

Infectious diseases were the primary cause of mortality in mankind prior to their discovery and use of antimicrobials. In most of the developing world without access to good quality medicines, infections continue to be major killers, and in all countries healthcare-associated infections with resistant microorganisms are a major cause of death.

Types of Neurological Infections

The most common neurological infections are:

- **Encephalitis**, an inflammation of the brain, which can be caused by either bacteria or virus.
- **Meningitis**, an inflammation of the membranes that cover the brain and spinal cord, which can be caused by either bacteria or virus.
- **HIV**, a viral infection that causes AIDS and gradually destroys the body's immune system.

Other neurological infections include:

- Fungal infections.
- Parasitic infections.
- Prion diseases.
- Bacterial infections such as Lyme disease, tuberculosis, syphilis.
- Brain abscess.

SAMPLING AND PRESERVATION

Samples pretreatment is carried out in accordance with the manufacturer's Handbook "Sampling, Transportation, and Storage of Clinical Material for PCR diagnostics", developed by the Federal Budget Institute of Science "Central Research Institute for Epidemiology" of the Federal Service for Surveillance on Consumers' Rights Protection and Human Well-Being, Moscow, 2010.

http://www.interlabservice.ru/upload/medialibrary/af6/sampling_storage-and-transportation-of-clinical-material.pdf

EXTRACTION KITS

RIBO-prep: REF K2-9-Et-50-CE, REF K2-9-Et-100-CE; RIBO-sorb: REF K2-1-Et-50-CE, REF K2-1-Et-100-CE;
DNA-sorb-B: REF K1-2-50-CE, REF K1-2-100-CE.

Listeria monocytogenes

Listeriosis is a serious infection usually caused by eating food contaminated with the bacterium *Listeria monocytogenes*. Although uncommon as a cause of infection in general population, the bacterium, *Listeria monocytogenes*, is an important foodborne cause of life-threatening bacteremia and central nervous system (CNS) infection in certain high risk groups.
Most often listeriosis occurs in newborns, the elderly, pregnant women, and those with impaired cell-mediated immunity due to disease states, such as hematological malignancy or acquired immune deficiency syndrome (AIDS), or due to corticosteroid or other immunosuppressive therapy, as in case of solid organ transplant recipients. Patients with cancer, particularly that of blood, are also at high risk for listeria infection.
Following ingestion of a large inoculum, *L. monocytogenes* can result in acute, self-limiting, febrile gastroenteritis in otherwise healthy people. An increasing interest in this organism has arisen from concerns about food safety following lethal foodborne outbreaks. It is typically a food-borne organism. **Listeria** is also a common veterinary pathogen, being associated with abortion and encephalitis in sheep and cattle. It can be isolated from soil, water, and decaying vegetation.
The most common clinical manifestation is diarrhea. A mild presentation of fever, nausea, vomiting, and diarrhea may resemble a gastrointestinal illness. The microorganism has gained recognition because of its association with epidemic gastroenteritis. In 1997, an outbreak of noninvasive gastroenteritis occurred in 2 schools in northern Italy, involving more than 1500 children and adults.

Bacteremia and meningitis are more serious manifestations of disease that can affect individuals at high risk. Unless recognized and treated, Listeria infections can result in significant morbidity and mortality.

Listeria monocytogenes infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Listeria monocytogenes* -screen-titre-FRT	R-B14-100-FT(RG,iQ)-CE		500 copies/ml **Biological material*** RIBO-prep	DNA of *Listeria monocytogenes*	QN	CE	110

***Biological material:**
peripheral and umbilical cord blood; cerebro-spinal fluid; node aspirates; naso-pharyngeal swabs; the discharge of the eye conjunctiva; amniotic fluid; placenta; the scrapes of epithelial cells taken from vagina side parietal; urine; breast milk; meconium; feces; autopsy material; primary aliment fortification medium; the medium for primary fortification of environment objects (concentrated (eluated) water samples (discharged water, drinking water taken from land-based bodies of water, etc).

Enteroviruses

While ninety percent of enteroviral infections are asymptomatic or result in a mild illness, counting up the fraction of those with serious illness adds up to a large number of people.
Enteroviruses are small, very contagious viruses made of ribonucleic acid (RNA) and protein. The most well known are polioviruses — the cause of paralytic poliomyelitis, commonly known as polio. While paralytic poliomyelitis is targeted for global eradication through vaccination, the nonpolio enteroviruses continue to be responsible for a wide spectrum of diseases. Infants and young children are hit hardest, however adults are affected as well. (Goldman, 2008).

The unsettling fact about enteroviruses is that they can spread to various organs and persist in the body for years — potentially causing disease long after the initial infection.

Enteroviruses are associated with at least 26 different syndromes and diseases, including coronary heart disease, type 1 diabetes, hand-foot-and-mouth disease, chronic fatigue syndrome/myalgic encephalomyelitis, encephalitis, herpangia, myocarditis, pleurodynia, ADHD, and central nervous system infections such as polio, meningitis, encephalitis, chronic meningoencephalitis, and acute flaccid paralysis. It is possible for an enteroviral infection to result in a multi-organ illness or a series of illnesses in different organs spanning several years.

Picornaviridae Enterovirus - Members of this family have a linear single stranded, positive sense RNA genome of 7.1 to 8.9 kilobases, which is polyadenylated. Their genomes, 12 genera in the Picornaviridae: Enterovirus, Cardiovirus, Aphthovirus, Hepatovirus, Parechovirus, Erbovirus, Kobuvirus, Teschovirus, Sapelovirus, Senecavirus, Tremovirus and Avihepatovirus.
Enteroviruses (EV) frequently infect the central nervous system (CNS) and induce neurological diseases. Although the CNS is composed of many different cell types, the spectrum of tropism for each EV is considerable. These viruses have the ability to completely shut down host translational machinery and are considered highly cytolytic, thereby causing cytopathic effects. Hence, CNS dysfunction following EV infection of neuronal or glial cells might be expected. Perhaps unexpectedly given their cytolytic nature, EVs may establish a persistent infection within the CNS, and the lasting effects on the host might be significant with unanticipated consequences.
Enterovirus (EV) infections are a significant cause of morbidity and mortality throughout the world. The EV genus is part of the picornavirus family and includes such notable members as poliovirus (PV), coxsackievirus (CV), and enterovirus-71 (EV-71). EVs have been associated with many human diseases, including myocarditis **(Klingel et al., 1992)**, pancreatitis **(Ramsingh, 2008)**, and chronic inflammatory myopathy **(Tam and Messner, 1999).** Diseases caused by EV are not restricted to the well-known scourge of mankind throughout history, recognized as poliomyelitis. Many non-polio human EVs are quite common, causing an estimated 10–15 million or more symptomatic infections in the US alone. Non-polio EVs are known to target the central nervous system (CNS) and are responsible for numerous clinical manifestations, including encephalitis, and meningitis **(Michos et al., 2007)**. The long-term consequences of EV infection upon the CNS are largely unknown. However, these viruses are known to persist, and the presence of viral RNA by itself has been shown to be potentially pathogenic in some cases. Also, EVs have been linked to autoimmune-like diseases, including diabetes, chronic inflammatory myopathy, and chronic myocarditis, perhaps in part due to long-term presence of viral material. Therefore, EVs may be able to persist within the CNS potentially causing lasting neuropathology.
The original classification of enteroviruses included the four groups: Polioviruses (PVs), Coxsackie A viruses, Coxsackie B viruses, and ECHO (**E**nteric **C**ytopathic **H**uman **O**rphan) viruses. However, the significant level of phylogenetic overlap among the four groups has led to a new classification system of consecutive numbers for the more recently isolated viruses (such as Enterovirus-71, Enterovirus-72, etc.) **(Oberste et al., 2002).** Our review will cover the most common and more extensively studied types of enteroviruses. However, a large number of circulating strains in human populations alone suggests a potential role for these viruses for unknown or unappreciated human diseases **(Victoria et al., 2009)**. Also, vaccine design against enteroviruses may be difficult based on significant EV genetic variability.

Enteroviruses infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detec-tion type	CE/ RUO	Number of tested samples
NEW AmpliSens® *Enterovirus*-FRT ***ONE STEP***	R-V16-F-CE		5×10^3 GE/ml CSF, concentrated water samples* 1×10^4 GE/ml Fecal samples* RIBO-prep	*Human enterovirus* RNA	QL	CE	55
AmpliSens® *Enterovirus* 71-FRT ***ONE STEP***	R-V64-F-CE		5×10^3 GE/ml CSF, concentrated water samples* 1×10^4 GE/ml fecal samples* RIBO-sorb, RIBO-prep	*Human enterovirus* type 71 RNA	QL	CE	55

***Biological material:**
cerebrospinal fluid, fecal samples, taken from the persons suspected of enteroviral infection without distinction of form and presence of manifestation, and natural environments (concentrated water samples).

Multiplex neuro-infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detec-tion type	CE/ RUO	Number of tested samples
AmpliSens® *Poliovirus*-FRT	R-V58(RG,iQ)-CE		5×10^3 GE/ml - Feces, RIBO-prep 1×10^3 GE/ml - concentrated water samples (environmental samples), RIBO-sorb	*Poliovirus* strains (Sabin 1, Sabin 2, Sabin 3); *Enterovirus* group C (HEV-C) RNA	QL Diff	CE	55
AmpliSens® *N.meningitidis / H.influenzae / S.pneumoniae*-FRT	R-B25(RG,iQ)-CE		*Neisseria meningitides, Haemophilus influenza, Streptococcus pneumonia* 1×10^3 GE/ml, **Clinical material:** CSF RIBO-prep or DNA-sorb-B; RIBO-sorb	*Neisseria meningitidis, Haemophilus influenzae, Streptococcus pneumoniae* DNA	QL	CE	55

INTESTINAL INFECTIONS

KEY FEATURES

- CE-IVD marked;
- wide range of pathogen detection;
- multiplex pathogen detection with type differentiation;
- qualitative format;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost effectiveness.

INTESTINAL KITS ARE INTENDED FOR

- qualitative mono-pathogen detection;
- qualitative multiplex pathogen detection with differentiation.

OVERVIEW

Most infections discussed in this section of the handout include pseudomembranous colitis, bacterial dysentery and parasitic dysentery. Bacterial dysentery includes campylobacteriosis, shigellosis, salmonellosis, and *Escherichia coli* dysentery. Parasitic dysentery is caused by *Entamoeba histolytica*. These infections occur primarily in the large intestine (note some of these organisms can also infect the small intestine) and can invade the surrounding tissues. Invasion of the intestine can result in blood in the feces and cause an inflammatory response with fecal leukocytes.

SAMPLING AND PRESERVATION

Samples pretreatment is carried out in accordance with the manufacturer's Handbook "Sampling, Transportation, and Storage of Clinical Material for PCR diagnostics", developed by the Federal Budget Institute of Science "Central Research Institute for Epidemiology" of the Federal Service for Surveillance on Consumers' Rights Protection and Human Well-Being, Moscow, 2010.

http://www.interlabservice.ru/upload/medialibrary/af6/sampling_storage-and-transportation-of-clinical-material.pdf

EXTRACTION KITS

DNA-sorb-B: REF K1-2-50-CE, REF K1-2-100-CE; RIBO-prep: REF K2-9-Et-50-CE, REF K2-9-Et-100-CE;
RIBO-sorb: REF K2-1-Et-50-CE, REF K2-1-Et-100-CE.

INTESTINAL INFECTIONS PCR KITS

Salmonella spp.. Salmonella typhi

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Salmonella spp.*-FRT	R-B11(RG,iQ)-CE		1 x 10^3 GE/ml, Selenite F Broth[21] DNA-sorb-B, RIBO-prep **Biological material:** food products	*Salmonella spp.* DNA	QL	CE	55
AmpliSens® *Salmonella typhi*-FRT	R-B63(RG,iQ)-CE		1 x 10^3 GE/ml **Biological material:** Feces RIBO-prep; RIBO-sorb or DNA-sorb-B	*S.typhi; S.paratyphi C* and *S.dublin; S.stanley, S.isangi, S.muenchen, S.gaminara, S.utrecht**	QL semi Diff	CE	55

[21] Pretreatment is not required.

*Detection of the genes of Vi antigen and the first phase of flagellar H antigen *d* (phase H1 of *d* flagellar antigen) of *Salmonella spp*. It makes it possible to differentiate *S.typhi* from *S.paratyphi C* and *S.dublin*, which have the Vi antigen, and from *S.stanley, S.isangi, S.muenchen, S.gaminara,* and *S.utrecht*, which have the H1 phase of *d* flagellar antigen.

Correspondence table of detection channels, and pathogens

Channel for fluorophore	PCR-mix-1-FEP/FRT S.typhi / STI
FAM	Internal Control-FL (IC) DNA
JOE	Vi-antigen gene DNA (*S.paratyphi C* and *S.dublin*)
ROX	H1-phase of d flagellant antigen DNA (*S.stanley, S.isangi, S.muenchen, S.gaminara, S.utrecht*)

Yersinia enterocolitica/ Y.pseudotuberculosis

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
NEW AmpliSens® *Yersinia enterocolitica/ Y.pseudo-tuberculosis*-FRT	R-B64(RG,iQ)-CE		*Y.enterocolitica, Y.pseudotuberculosis* 1 x 10^3 GE/ml Feces, RIBO-prep; and RIBO-sorb, DNA-sorb-B	DNA of virulent and avirulent *Yersinia enterocolitica* strains; *Yersinia pseudotuberculosis**	QL Diff	CE	55

*DNA of virulent and avirulent *Yersinia enterocolitica* strains (virulence is assessed by genes encoding enterotoxin (*Yst*), attachment invasion locus (*ail*), and plasmid pYV adhesion (*yadA*)) and *Yersinia pseudotuberculosis* strains.
Clinical material: feces and environmental samples (concentrated water samples).

Helicobacter pylori

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Helicobacter pylori*-FRT	R-B9(RG,iQ)-CE		1 x 10^3 GE/ml **Biological material:** biopsy material of gastric mucosa[22] DNA-sorb-B; RIBO-prep	*Helicobacter pylori* DNA	QL	CE	55

[22] Pretreatment is not required.

Clostridium difficile

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Clostridium difficile*-EPh	B23-50-R0,2-CE		no less than 5 x 10^3 GE/ml **Biological material:** feces and environmental samples (concentrated water samples) DNA-sorb-B	*Clostridium difficile* DNA	QL	CE	55

Multiplex intestinal infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Shigella spp.* and *EIEC/ Salmonella spp./ Campylobacter spp.*-FRT	R-B44(RG,iQ)-CE		*Shigella spp., EIEC, Salmonella spp., Campylobacter spp.* 1 x 10^3 GE/ml - feces, RIBO-prep; or DNA-sorb-B; **Biological material:** feces and environmental samples	*Shigella spp., EIEC, Salmonella spp., thermophilic Campylobacter spp.* DNA[23]	QL Diff	CE	55
AmpliSens® *Rotavirus/ Norovirus/ Astrovirus*-FRT	R-V40(RG,iQ)-CE		1 x 10^4 GE/ml (Rotavirus A, Astrovirus) 5 x 10^3 GE/ml (Norovirus genotype 2) **Biological material:** feces and environmental samples (water sample concentrates) RIBO-prep; RIBO-sorb	*Rotavirus* A, *Norovirus* genotype 2, *Astrovirus* RNA	QL Diff	CE	55
AmpliSens® All screen-FRT	R-B45(RG,iQ)-CE		1 x 10^3 GE/ml *Shigella spp., EIEC*; *Salmonella spp.*, thermophilic *Campylobacter spp.* 1 x 10^4 GE/ml *Adenovirus* F, *Rotavirus* A **Biological material:** feces and environmental samples RIBO-prep; RIBO-sorb	RNA/DNA of *Shigella spp., EIEC, Salmonella spp.,* thermophilic *Campylobacter spp.,* gr F *Adenoviruses* and gr A *Rotaviruses, Norovirus* gt 2, *Astroviruses*[24]	QL Diff	CE	55
AmpliSens® Escherichioses-FRT	R-B62(RG,iQ)-CE		*EPEC, ETEC, EIEC, EHEC, EAgEC* 1 x 10^3 GE/ml – feces, RIBO-prep or RIBO-sorb; DNA-sorb-B; environmental compartments and biological material (feces)	*diarrheagenic E.coli (EPEC, ETEC, EIEC, EHEC* and *EAgEC)* DNA	QL Diff	CE	55

[23] Shigella species (Shigella spp.) and enteroinvasive E.coli (EIEC), Salmonella species (Salmonella spp.), and thermophilic Campylobacter species (Campylobacter spp.) DNA.

[24] RNA/DNA of Shigella spp., enteroinvasive E.coli (EIEC), Salmonella spp., thermophilic Campylobacter spp., group F Adenoviruses and group A Rotaviruses, Norovirus genotype 2, Astroviruses.

ESPECIALLY DANGEROUS AND FERAL HERD INFECTIONS

KEY FEATURES

- CE-IVD marked;
- wide range of pathogen detection;
- mono- and multiplex pathogen detection;
- qualitative format;
- type differentiation;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost effectiveness.

ESPECIALLY DANGEROUS AND FERAL HERD KITS ARE INTENDED FOR

- qualitative pathogen detection;
- qualitative pathogen detection with type differentiation.

OVERVIEW

The continuing emergence and re-emergence of novel and dangerous pathogens of epidemic potential (eg. Ebola, Marburg, Rift Valley fever, Plague, Monkeypox, Lassa Fever, SARS, Tularaemia, MERS-CoV, Nipah, Legionellosis, Borreliosis, Melioidosis, etc.) is a permanent threat to health of populations around the world and a major challenge to global health security. The WHO Emerging and Dangerous Pathogens Laboratory Network (EDPLN) is made up of global and regional EDPLN networks of high security human and veterinary diagnostic laboratories. EDPLN contributes to outbreak response and preparedness as well as rapid development of diagnostic assays for emerging and infectious pathogens globally.
Among especially dangerous (quarantine) infections are highly contagious diseases that spread rapidly, causing serious epidemics and occur and have a greater likelihood of death in the short term.
Currently, the World Health Organization announced four diseases as especially dangerous infections of international importance: plague, cholera, smallpox and yellow fever. In Russia, relevant epidemiological rules also apply to anthrax and tularemia.

Epidemic and pandemic diseases

- **Airborne diseases** – influenza (seasonal, pandemic, avian), severe acute respiratory syndrome (SARS), Middle East respiratory syndrome coronavirus (MERS-CoV) (See paragraph “Respiratory infections”).
- **Vector-borne diseases** – yellow fever, chikungunya, Zika fever, West Nile fever.
- **Water-borne diseases** – cholera, shigellosis, typhoid fever.
- **Epidemic meningitis.**
- **Rodent-borne diseases** – plague, leptospirosis, hantavirus, Lassa fever, rickettsia (murine typhus).
- **Haemorrhagic fevers** – Ebola virus disease, Marburg virus disease, Crimean-Congo haemorrhagic fever, Rift Valley fever.
- **Smallpox, monkeypox.**
- **Other zoonotic diseases** – Nipah virus infection, Hendra virus infection.
- **Any other emerging diseases.**

SAMPLING AND PRESERVATION

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http://www.interlabservice.ru/upload/medialibrary/af6/sampling_storage-and-transportation-of-clinical-material.pdf

EXTRACTION KITS

RIBO-prep, REF K2-9-Et-50-CE; REF K2-9-Et-100-CE
DNA-sorb-B, REF K1-2-100-CE
MAGNO-sorb, REF K2-16-200-CE; REF K2-16-1000-CE
RIBO-sorb, REF K2-1-Et-100-CE,
RIBO-zol-B, REF K2-3-100-CE
RIBO-zol-A, REF K2-2-100-CE
RIBO-zol-C, REF K2-13-50-CE

Vibrio cholerae

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Vibrio cholerae*-FRT	R-B53(RG)-CE		1×10^3 GE/ml[25] 1×10^3 m.c./ml[26] biological material** DNA-sorb-B – for all material types; RIBO-prep – for watery feces	*Vibrio cholerae* DNA and identification of pathogenic strains of *Vibrio cholera**	QL Diff	CE	55

***Vibrio cholerae screen:**
-*CtxA* gene DNA fragment,
-*tcpA* DNA fragment.

Vibrio cholerae type:
-*wbeT* (identifying O1 serogroup),
-*wbfR* (identifying of O139 serogroup),
-*Hly* (all *Vibrio cholerae* serogroups).

****Biological material:**
native feces, rectal swabs, vomit masses, autopsy material, water after preliminary filtration, washing fluids from environmental samples, peptone water after bacterial inoculation or food products, germ cultures.

Dengue virus

Dengue is a fast emerging pandemic-prone viral disease in many parts of the world. Dengue flourishes in urban poor areas, suburbs and the countryside but also affects more affluent neighbourhoods in tropical and subtropical countries.
Dengue is a mosquito-borne viral infection causing a severe flu-like illness and, sometimes causing a potentially lethal complication called severe dengue. Incidence of dengue has increased 30-fold over the last 50 years. Up to 50-100 million infections are now estimated to occur annually in over 100 endemic countries, putting almost half of the world's population at risk.
Severe dengue (previously known as dengue haemorrhagic fever) was first recognized in the 1950s during dengue epidemics in the Philippines and Thailand. Today it affects Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions.

Transmission

The full life cycle of dengue fever virus involves the role of mosquito as a transmitter (or vector) and humans as the main victim and source of infection.
Dengue is transmitted by the bite of a mosquito infected with one of the four dengue virus serotypes. It is a febrile illness that affects infants, young children and adults with symptoms appearing 3-14 days after the infective bite.
Dengue is not transmitted directly from person-to-person and symptoms range from mild fever, to incapacitating high fever, with severe headache, pain behind the eyes, muscle and joint pain, and rash. There is no vaccine or any specific medicine to treat dengue.
Severe dengue (also known as dengue hemorrhagic fever) is characterized by fever, abdominal pain, persistent vomiting, bleeding and breathing difficulty and is a potentially lethal complication, affecting mainly children. Early clinical diagnosis and careful clinical management by trained physicians and nurses increase survival of patients.

The virus

The dengue virus (DEN) comprises four distinct serotypes (DEN-1, DEN-2, DEN-3 and DEN-4) which belong to the genus *Flavivirus*, family Flaviviridae.
Distinct genotypes have been identified within each serotype, highlighting extensive genetic variability of the dengue serotypes. Among them, "Asian" genotypes of DEN-2 and DEN-3 are frequently associated with severe disease accompanying secondary dengue infections.

[25] Genome equivalents of a microorganism per 1 ml of the sample from transport medium.

[26] Microbial cells of a microorganism per 1 ml of the sample.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Dengue virus type*-FRT	R-V63(RG,CFX)-CE		100 µl 5×10^3 copies/ml, blood plasma/blood serum, mosquito suspension RIBO-prep* 1 ml 5×10^2 copies/ml, blood plasma, blood serum MAGNO-sorb**	RNA of *Dengue virus* type 1-4	QL Diff	CE	60
NEW AmpliSens® *Dengue virus-FRT*	R-V68-F-CE		**Analytical sensitivity***** blood plasma, histological (autopsy) material (brain and visceral tissues)) RIBO-prep; MAGNO-sorb	*Dengue virus* RNA	QL NoDiff	CE	55

Biological material:
in human (blood plasma, blood serum and autopsy material (brain, liver, spleen tissues), in animal material (brain, spleen tissues), in mosquitoes.

Material pretreatment:
the claimed sensitivity is achieved only when the material pretreatment is carried out in accordance with chapter *Sampling and Handling* and the recommended volume of test sample is used.

***RIBO-prep** – for RNA extraction from blood plasma and serum, internal and brain tissues homogenates, mosquitoes.

****MAGNO-sorb** – for RNA extraction from 1 ml of blood plasma and serum.

*****Analytical sensitivity**

Nucleic acid extraction kit	Test material	Analytical sensitivity, copies/ml	Sample volume for extraction, µl
RIBO-prep	Blood plasma	10^3	100
	Histological (autopsy) material	$5x10^3$	100
MAGNO-sorb	Blood plasma	10^3	200
		10^2	1,000

Zika virus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Zika virus*-FRT	R-V73-F-CE		2,000 - 10,000 copies/ml (RIBO-prep) 100 - 1,000 copies/ml (MAGNO-sorb) blood plasma, saliva, urine, spermatic fluid, histological material (autopsy/biopsy material, placenta), amniotic fluid, mosquitos, oropharyngeal swabs	RNA of *Zika virus*	QL	RUO	55

Yersinia pestis

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Yersinia pestis*-FRT	R-B79(RG,iQ,Dt)-CE		1 x 10^3 copies/ml* **biological material**** RIBO-prep	*Yersinia pestis* DNA	QL	CE	60

***Biological material (volume of sample):**
fleas (30 specimens homogenized in 500 µl of PBS, sample volume 100 µl); *Dermacentor reticulatus* ticks (pool of 10 specimens, sample volume 50 µl); blood (200 µl); urine (100 µl); sputum (50 µl); feces (100 µl of 10 % suspension); 10 % suspension of liver tissue, lymph nodes (50 µl).

****Biological material:**
human biological material (blood; bubo aspirate, vesicle aspirate, pustule aspirate, carbuncle aspirate; sputum; oropharyngeal swabs; urine; feces; lymph nodes; liver, spleen, lungs, adrenal, and brain tissues; as well as pathologically modified tissues and organs), animal material (blood, feces, parenchymal organs, brain tissues, and pathologically changed tissues and organs), fleas, ticks, bird pellets and soil.

Biological material pretreatment is required!

The claimed sensitivity is achieved only when the material pretreatment is carried out in accordance with chapter Sampling and Handling and the recommended volume of test sample is used.

Bacillus anthracis

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Bacillus anthracis*-FRT	R-B41(RG)-CE		not less than 1 x 10^3 GE/ml spores of *Bacillus anthracis* pXO1+ and pXO2+ per 1 ml, DNA-sorb-B **Biological material and environmental samples***	*pagA* (plasmid pXO1) and *capA* (plasmid pXO2) genes of *Bacillus anthracis*[27]	QL Diff	CE	55

***The following material is used for analysis:**
water (from water bodies, wastewater, and drinking water) – 10-20 ml; soil; washing fluids from air filters; powdery substances (cattle food, meal, etc).

Human material:
Whole blood (5 ml). Blood is taken fasting to a Vacuette® tube with 6 % EDTA (50 µl of EDTA per 1 ml of blood). Close the tube with blood and mix the contents carefully by inverting several times.
Exudate from lesion foci (in case of a skin form) is placed to 200 µl of 0.9 % sterile NaCl solution (it can be used without pretreatment).
Sputum is to be treated with Mucolysin reagent REF 180-CE according to the Mucolysin instruction manual. If the analysis should be repeated, the remaining sputum should be frozen.

Animal material:
Whole blood (5 ml). Blood is taken to a Vacuette® tube with 6 % EDTA (50 µl of EDTA per 1 ml of blood). Close the tube with blood and mix by inverting several times.
Cattle milk (without pretreatment).
Parenchymal organs and lymph nodes.

Material pretreatment is required for water and washing fluids from air filters, soil, powdery substances, parenchymal organs.

[27] DNA of vegetative and cryptogamic forms of Bacillus anthracis;
determination of Bacillus anthracis plasmid composition by identification of pagA (plasmid pXO1) and capA (plasmid pXO2) genes.

Brucella species

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Brucella spp.*-FRT	R-B10(RG)-CE		no less than 1 x 10^3 GE/ml bacterial cells per 1 ml of sample, DNA-sorb-B, **Biological material***	DNA of *B.melitensis, B.abortus, B.suis, B.ovis, B.canis, B.neotomae*	QL	CE	55

***Biological material:**
human (whole blood, synovial fluid, and lymph node aspirate) and animal (blood, milk, placenta, lymph nodes, spleen, aborted fetal liver, hygroma, and parenchymal organs) biological materials and bacterial culture.

For some material the pretreatment is required.

Leptospira species

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Leptospira*-FRT	R-B49(RG,iQ)-CE		not less than 5 x 10^3 copies/ml* RIBO-sorb; RIBO-zol-C; RIBO-prep	16S RNA of pathogenic *Leptospira* genospecies	QL	CE	60

***Biological material:**
blood and cerebrospinal fluid, autopsy material (brain, kidney, liver, lung tissue, and mesenteric lymph nodes), biological material (lung, brain, and kidney tissue), material obtained from dead animals (lung, brain, and kidney tissue), and animals suffering from acute leptospirosis (blood) or Leptospira persisting in kidneys (urine).

For some materials pretreatment is required.

(Leptospira species 16s RNA Reverse Transcription Kit, cDNA Real Time PCR Kit For RNA extraction «RIBO-zol-C» (Cat. No. K2-13-50) and «RIBO-sorb» (Cat. No. K2-1-Et-50) or «RIBO-prep» (Cat. No. K2-9-Et-100) kits are recommended for use).

Crimean-Congo hemorrhagic fever virus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *CCHFV*-FRT	R-V22-50-F(RG,iQ,Mx,Dt)-CE		5 x 10^3 copies/ml* RIBO-prep – for RNA extraction from blood plasma and serum or suspension of non-sated or semi-sated ticks. RIBO-zol-B – for RNA extraction from suspension of sated ticks **Biological material:** blood plasma and serum, ticks	*Crimean-Congo hemorrhagic fever virus (CCHFV)* RNA	QL	CE	60

***Biological material:**
blood serum (100 µl); *H.marginatum* tick pools (50 µl); *H.marginatum* ticks pools (100 µl).

Pretreatment is carried out in accordance with chapter Sampling and Handling and the recommended volume of test sample is used.

AmpliSens biotechnologies

Borrelia burgdorferi sensu lato (B. burgdorferi sensu stricto, B. afzelii, B. garinii)

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Borrelia burgdorferi sensu lato*-FRT	R-B37(RG)-CE		no less than 1×10^4 GE/ml **Biological material:** ticks RIBO-prep	Borrelia burgdorferi sensu lato (B. burgdorferi sensu stricto, B. afzelii, B. garinii) 16S rRNA	QL	CE	60
AmpliSens® *Borrelia* TBE-MULTIPRIME -FRT	COMING SOON! under development NEW		Borellia-Tick-borne encephalitis virus MULTIPRIME Real time PCR Kit				

Tick-borne encephalitis virus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® TBE-FRT	R-V52(RG)-CE		no less than 1×10^3 copies/ml* RIBO-prep	*tick-borne encephalitis virus* RNA	QL	CE	120
AmpliSens® TBE-genotype -FRT	IS COMING SOON! under development NEW		Tick-borne encephalitis virus Reverse Transcription and cDNA Real Time PCR Kit. Genotypic differentiation				

***Biological material:**
blood plasma and serum; leucocytic fraction of blood; cerebrospinal fluid; autopsy material of human and animal (brain tissue); ticks.
RIBO-prep, REF K2-9-Et-50-CE

Coxiella burnetii

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Coxiella burnetii-FRT	R-B85-50-F(RG,iQ,Mx,Dt)-CE		5×10^3 GE/ml* RIBO-prep	DNA of Coxiella burnetii	QL	CE	60

***Biological material:**
ticks, biological human material (blood, sputum, bronchial washing fluid, CSF, autopsy material) and animal material (blood, autopsy material, placenta and abortive material).

*ticks of *Dermacentor* genera (50 µl ticks suspension);
blood (white blood cell fraction of blood, 200 µl);
10 % suspension of tissue of spleen and liver (50 µl).

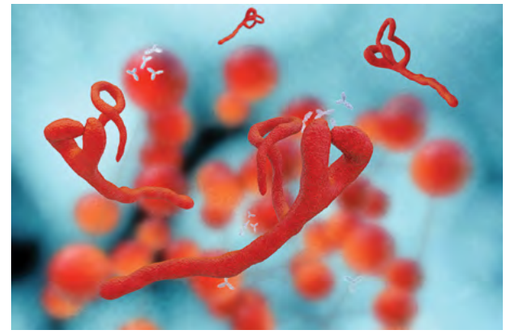
Specified pretreatment is required!

Zaire ebolavirus

Ebola virus disease (EVD) is a rare but severe infection in humans and non-human primates. It is caused by the Ebola virus, a filovirus that:
- was first recognised in 1976;
- has caused sporadic outbreaks since in several African countries.

The first imported case of Ebola virus disease in the UK was reported on 29 December 2014.

Ebola virus disease is a serious illness that originated in Africa, where there is currently an outbreak. But for people living in countries outside Africa, it continues to be a very low threat.



The current outbreak of the Ebola virus mainly affects three countries in West Africa: Guinea, Liberia and Sierra Leone. Around 27,000 cases and more than 11,000 deaths have been reported by the World Health Organization. This is the largest known outbreak of Ebola.
Effective infection control procedures: in recent outbreaks, infection control measures have been very effective in containing Ebola within an immediate area.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *EBOV* Zaire-FRT	R-V69-50-F-CE		Whole blood, saliva, urine, viscera biopsy material 10^4 GE/ml, RIBO-zol-A	Zaire Ebola virus (*EBOV Zaire*) RNA	QL	CE	55
			2×10^3 GE/ml, RIBO-prep; MAGNO-sorb; QIAGEN QIAamp MinElute Virus				

Biological material:
whole blood, saliva, urine, viscera biopsy material, taken from the persons suspected of Ebola fever without distinction of form and presence of manifestation.

West Nile fever virus

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *WNV*-FRT	R-V53(RG,iQ,Mx)-CE		5×10^2 copies/ml*, MAGNO-sorb	*West Nile virus* RNA	QL	CE	60
			5×10^3 copies/ml**, RIBO-sorb; RIBO-prep; RIBO-zol-C				

***Biological material:** blood plasma, blood serum, CSF (1 ml for all).
**** Biological material:**
blood serum (200 µl), CSF (200 µl),
leukocytic fraction of blood (200 µl),
10 % brain tissue homogenate (30 µl), mosquitoes (100 µl),
in the biological material (blood plasma, serum, leukocytic fraction of blood, cerebrospinal fluid, and urine) and human autopsy material (brain, liver, spleen, and lymph node tissue) and animals (brain tissue), mosquitoes and ticks.

AmpliSens biotechnologies

Analytical sensitivity, AmpliSens® WNV-FRT

DNA extraction kit	Biological material	Analytical sensitivity, copies/ml	Pretreatment of biological material
RIBO-prep	blood serum (200 µl), CSF (200 µl), leukocytic fraction of blood (200 µl), 10 % brain tissue homogenate (30 µl), mosquitoes (100 µl)	$5x10^3$	Indicated sensitivity can be reached only if specified pretreatment instructions are followed and specified specimen volume is used
RIBO-prep, RIBO-zol-C	leukocytic fraction of blood (200 µl), 10 % brain tissue homogenate (30 µl), mosquitoes (100 µl)		
RIBO-sorb, RIBO-zol-C	leukocytic fraction of blood (200 µl), 10 % brain tissue homogenate (30 µl), mosquitoes (100 µl)		
MAGNO-sorb	blood plasma, blood serum, CSF (1 ml for all)	$5x10^2$	

For some materials pretreatment is required.

Rickettsia

AmpliSens® *Rickettsia*-screen-MULTIPRIME-FRT	COMING SOON! under development	Rickettsia Real time PCR Kit

Hantavirus

AmpliSens® *Hantavirus*-FRT	COMING SOON! under development	Hantavirus Real time PCR Kit

Malaria

AmpliSens® *Malaria*-FRT	COMING SOON! under development	Malariae Real time PCR Kit

Multiplex pathogen detection kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *TBEV, B.burgdorferi sl, A.phagocytophilum, E.chaffeensis / E.muris*-FRT	R-V59(RG,iQ,Mx,Dt)-CE		5 x 10^3 GE/ml* RIBO-prep	*TBEV* RNA, *A. phagocytophilum* DNA, *E.chaffeensis / E.muris* RNA; *Borrelia burgdorferi sl.* RNA[28]	QL	CE	120

***Biological material:** ticks, blood, cerebrospinal fluid, and autopsy material.

Specified pretreatment is required!

[28] RNA tick-borne encephalitis virus (TBEV), Borrelia burgdorferi sl (Ixodes tick-borne borreliosis (ITB) pathogen), Ehrlichia chaffeensis and Ehrlichia muris (human monocytic ehrlichiosis (HME) pathogens) and DNA of Anaplasma phagocytophilum (human granulocytic anaplasmosis (HGA) pathogen).

ONCOLOGICAL DISEASES PCR KIT FOR QUANTITATIVE DETERMINATION OF CHIMERIC GENE BCR-ABL (p210) mRNA

Kit type	Catalog number	Format	Analytical sensitivity	Detected gene	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Leucosis-Quantum-M-*bcr*-FRT	TR-O1(RG,iQ,Mx,A)-CE		**Biological materials:** peripheral blood, bone marrow RIBO-zol-D variant 100	*bcr-abl* chimeric gene (*M-bcr* variant) mRNA and *abl* gene mRNA	QL QN	CE	180

AmpliSens® Leucosis Quantum M-bcr-FRT PCR kit is produced in a single form

AmpliSens® Leucosis Quantum M-bcr-FRT form 1 consists of RIBO-zol-D variant 100, REVERTA-L variant 100, AmpliSens® Leucosis Quantum M-bcr-FRT PCR kit variant FRT, REF TR-O1(RG,iQ,Mx,A)-CE.

AmpliSens® Leucosis Quantum M-bcr-FRT PCR kit can be used for screening detection of CML (chronic myelogenous leukemia) associated with M-*bcr-abl* chromosomal rearrangement, confirmation of CML diagnosis, and monitoring of minimal residual disease (MRD) and therapy efficiency.

AmpliSens® Leucosis Quantum M-bcr-FRT PCR kit is intended for one of the formats listed below:
● Quantitative analysis: 50 clinical samples in two replicates; ● Qualitative analysis (screening): 100 clinical samples in one repetition (120 RNA extractions, 120 reverse transcription reactions, and 360 PCR, including controls).

!	Results of PCR analysis are taken into account in complex diagnostics of a disease.

Cell lysis

Two variants for lysis can be produced:

- **Variant 1 Blood with EDTA**: Treatment with Hemolytic. Treatment of the leukocyte pellicle (without Hemolytic).
- **Variant 2 Blood with RNA stabilizer.**

Extraction

Volume of clinical material for RNA isolation is 150–200 µl.
For extraction we recommend to use kit RIBO-zol-D variant 100.

Reverse transcription

It is recommended to use the following kit for complementary DNA (cDNA) synthesis on an RNA template:
REVERTA-L containing RT-G-mix, REF K3-4-100-CE.

!	RNA-eluent *brc-abl* contains components required for reverse transcription. RNA diluted in other RNA eluents should not be used.

AmpliSens biotechnologies

Analytical sensitivity

Analytical sensitivity of AmpliSens® Leucosis Quantum *M-bcr*-FRT PCR kit was estimated by using control RNA phage preparations: *b3a2* (contains *bcr* exons 13 and 14 and *abl* exon 2) and *b2a2* (contains *bcr* exon 13 and *abl* exon 2) with given concentrations. RNA extraction and real-time RT-PCR were performed for 2X diluted control phage preparations with 10^7 leukocytes per extraction.

Table

mRNA variant	Sensitivity, mRNA copies per extraction procedure	Sensitivity, mRNA copies per ml
b2a2	24 (19.5 – 28.5)	237 (189 – 282)
b3a2	48 (37.5 – 52.5)	474 (378 – 525)

Sensitivity (mRNA copies per extraction procedure) is the number of control phage particles that should be added during the extraction procedure to ensure 100% positive test result in the presence of 10^7 leukocytes. The sensitivity value is a dilution of the control phage that can be reproducibly detected as positive in 12 of 12 replicates. This value represents the minimum detectable number of mRNA copies in one-half of a peripheral blood leukocyte sample or one-half of a bone marrow sample. Therefore, the detection sensitivity during treatment of a 2.5-ml blood sample is 20–30 mRNA copies per 1 ml (according to the test protocol, analysis is performed in duplicate; therefore, RNA is extracted from leukocytes of 1.25 ml of a whole-blood sample).
Sensitivity expressed as a number of mRNA copies per 1 ml is sensitivity recalculated per 1 ml (assuming that extraction is performed for 0.1 ml of a sample). This sensitivity is valid, for example, for analysis of the whole blood without isolation of leukocytes.

The claimed analytical features of the AmpliSens® Leucosis Quantum *M-bcr*-FRT PCR kit are guaranteed only when additional reagent kits RIBO-zol-D and REVERTA-L (manufactured by the Federal Budget Institute of Science "Central Research Institute for Epidemiology") are used.

HIV AND HIV-ASSOCIATED OPPORTUNISTIC INFECTIONS

KEY FEATURES

- qualitative detection of *HIV-1* and *HIV-2* and quantitative detection of *HIV-1*;
- quantitative kits are provided with Q-calibrator for calculation of B-coefficient if different extraction platforms are used;
- multiplex pathogen detection including *HCV, HBV, HIV-1, HIV-2*;
- possibility to work with dried blood spots (DNA-*HIV*-FRT);
- detection of *HIV*-associated infections;
- each kit contains Internal Control and Positive Control of Extraction;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost effectiveness.

HIV INFECTIONS KITS ARE INTENDED FOR

The RNA HIV qualitative detection test is better to be used in the following cases, when nearest infection is suspected, for example: ● in blood banks (together with serological analysis); ● for verification of discordant ELISA results and immune-blotting (ELISA "+",immune-blotting "-").

The DNA HIV qualitative detection test is better to be used when the infection is assumed to have been contracted a long time ago and for early HIV diagnostics in children, which were born from HIV-infected mothers.

The HIV-monitor kit allows for quantitative detection of *human immunodeficiency virus* type 1 (*HIV*-1) RNA in a biological material (blood plasma).

OVERVIEW

Human immunodeficiency virus (HIV) is a retrovirus that infects cells of the immune system, destroying or impairing their function. As the infection progresses, the immune system becomes weaker, and the person becomes more susceptible to infections. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS). It can take 10-15 years for an HIV-infected person to develop AIDS; antiretroviral drugs can slow down the process even further.
HIV is transmitted through unprotected sexual intercourse (anal or vaginal), transfusion of contaminated blood, sharing of contaminated needles, and between a mother and her infant during pregnancy, childbirth and breastfeeding.

SAMPLING AND PRESERVATION

Samples pretreatment is carried out in accordance with the manufacturer's Handbook "Sampling, Transportation, and Storage of Clinical Material for PCR diagnostics", developed by the Federal Budget Institute of Science "Central Research Institute for Epidemiology" of the Federal Service for Surveillance on Consumers' Rights Protection and Human Well-Being, Moscow, 2010.

http://www.interlabservice.ru/upload/medialibrary/af6/sampling_storage-and-transportation-of-clinical-material.pdf

Peripheral blood plasma
Collect a blood sample in a tube with 3% EDTA solution a t a ratio of 20:1 (20 p ortions of blood per 1 p ortion of EDTA). Invert the closed tube several times to ensure adequate mixing. Remove and transfer the plasma specimen in a new tube within 6 h from the time of blood taking. To do this, centrifuge the tube with blood at 800 – 1600 g for 20 min.

Oropharyngeal swabs
For AmpliSens® Genoscreen HLA B*5701-FRT PCR kit – *Oropharyngeal swabs* are taken with a sterile probe with a cotton tip. After swabbing, the probe is placed into a tube with 0.5 ml of the "Transport Medium for Storage and Transportation of Respiratory Swabs" (REF 957-CE).

Sputum
For AmpliSens® *Pneumocystis jirovecii (carinii)*-FRT PCR kit – *Sputum.* is collected into a sterile disposable container after preliminarily rinsing of mouth with water. Add Mucolysin reagent REF 180-CE to the sputum sample at a ratio of 5:1 (5 volume of Mucolysin per 1 volume of sputum) using graduation on the container.

Biopsy and autopsy material samples
Tissue samples are excised from areas of presumable pathogen location, from damaged tissue, or from areas adjacent to damaged areas. Tissue fragments not more than 5 mm in diameter are placed in a sterile disposable 2-ml Eppendorf tube containing 0.5 ml of the Transport Medium with a Mucolytic Agent (manufactured by the FBIS CRIE).

Oropharyngeal washing fluid and swabs
Oropharyngeal washing fluid and swabs are obtained with a sterile probe and placed in a tube with the Transport Medium for Storage and Transportation of Respiratory Swabs manufactured by the FBIS CRIE.

EXTRACTION KITS

RIBO-prep, REF K2-9-Et-50-CE; REF K2-9-Et-100-CE.
RIBO-sorb REF K2-1-Et-50-CE, REF K2-1-Et-100-CE.
MAGNO-sorb, REF K2-16-200-CE, REF K2-16-1000-CE.
NucliSENS easyMAG automated nucleic acid extraction system (bioMérieux, France) can also be used.

IDENTIFICATION OF HLA-B*5701 ALLELE WHICH IS ASSOCIATED WITH ABACAVIR HYPERSENSITIVITY

AmpliSens® Genoscreen HLA B*5701-FRT PCR kit is an *in vitro* nucleic acid amplification test for qualitative detection of B locus 5701 allele of human major histocompatibility complex (HLA B*5701) in a biological material (whole blood and oropharyngeal swabs) by means of real-time hybridization-fluorescence detection.
Hypersensitivity reaction to abacavir is strongly associated with the presence of the HLA-B*5701 allele. This study was designed to establish effectiveness of prospective HLA-B*5701 screening in order to prevent the hypersensitivity reaction to abacavir.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Genoscreen HLA B*5701-FRT	R-O2(RG,iQ)-CE		not less than 1×10^3 cells/ml RIBO-prep **Biological materials:** whole blood, oropharyngeal swabs	HLA B*5701 DNA	QL	CE	110

HIV-infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® DNA-*HIV*-FRT[28]	TR-V0-G(RG,iQ)-CE		500 GE/ml **Biological material:** whole blood	*human immunodeficiency virus type 1 (HIV-1) proviral* DNA	QL	RUO	120
AmpliSens® RNA-*HIV*-FRT	R-V0-R(RG,iQ,Mx)-CE		not less than 100 *HIV* RNA copies/ml. RIBO-sorb; NucliSENS easyMAG **Biological material:** blood plasma	*human immunodeficiency virus (HIV-1)* RNA	QL	RUO	76

[28] AmpliSens® DNA-HIV-FRT includes Gem-sorb reagent kit and PCR kit variant FRT.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® HIV-Monitor-FRT	R-V0-M(RG,iQ,Mx,Dt)-CE		The linear measurement range is 5×10^2 - 5×10^6 copies/ml (extraction volume is 100 µl). NucliSENS easyMAG **Biological material:** blood plasma	*human immunodeficiency virus* type 1 (*HIV-1*) RNA	QN	RUO	76
AmpliSens® *HIV*-Monitor-FRT*	R-V0-MC(RG,iQ,Mx,Dt)-CE		Sensitivity** **Biological material:** blood plasma	*human immunodeficiency virus* type 1 *(HIV-1)* RNA	QN	RUO	80

* the kit is released in Form 4 and contains PCR kit var. FRT and HIV-Q calibration kit, REF R-V0-MC(RG,iQ,Mx,Dt)-CE.
Includes additional Calibrator HIV-Q

**** Analytical Sensitivity**

RNA extraction kit	Biological material	Volume of sample for extraction, µl	Linear measurement range of HIV-1 RNA, copies/ml
RIBO-prep NucliSENS easyMAG	Blood plasma	100	500 - 10,000,000
MAGNO-sorb	Blood plasma	200	250 - 10,000,000
RIBO-sorb-12 RIBO-prep	Blood plasma (*ultracentrifuged*)	1,000	50 - 10,000,000
MAGNO-sorb NucliSENS easyMAG	Blood plasma	1,000	50 - 10,000,000

HIV-associated opportunistic infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *Cryptococcus neoformans*-FRT	R-F4-F(RG,iQ)-CE		400 copies/ml RIBO-prep **Biological material:** CSF, bronchoalveolar lavage, sputum, blood, skin lesions aspirate, viscera biopsy, autopsy material	*Cryptococcus neoformans* DNA	QL	CE	110
AmpliSens® *Pneumocystis jirovecii (carinii)* -FRT	R-F2-Mod(RG,iQ,Mx)-CE		500 copies/ml RIBO-prep **Biological material:** bronchoalveolar lavage, sputum, oropharyngeal and tracheal aspirates, lung biopsy material, oropharyngeal washes and swabs	*Pneumocystis jirovecii (carinii)* DNA	QL	CE	60

MULTIPLEX HCV/HBV/HIV PCR KITs

These kits were developed by the Russian Central Research Institute for Epidemiology to provide safety control tests during blood transfusions, transplantations, and preparation of blood products. Investigation of plasma samples combined into mini-pools is also possible.
These kits are intended for simultaneous detection of hepatitis C virus RNA (HCV), hepatitis B virus DNA (HBV), and human immunodeficiency virus RNA (HIV-1 and HIV-1+HIV-2) in blood plasma samples with Real-Time PCR.

Kit provides

- simultaneous detection of HCV, HBV and HIV-1 (or HIV-1+HIV-2);
- enhanced sensitivity compared to serum analysis;
- testing of both individual samples and mini-pools;
- compatibility with various nucleic acid extraction solutions.

Plasma pooling

«**AmpliSens HCV/HBV/HIV®-FRT**» reagent kit can be used for analysis of individual samples as well as for several plasma samples combined into a mini-pool. Plasma pooling allows for cutting the analysis cost and increasing laboratory throughput. The number of plasma samples recommended for mini-pools is 4-10 with total volume of 1,000 µl.

Advantages of «AmpliSens® HCV/HBV/HIV-FRT» Real-Time PCR kit

- Multiplex reaction in one tube saves time and costs.
- Analytical sensitivity and specificity is up to the highest worldwide standards.
- Mini-pools (up to 10 samples in each pool) can be tested along with individual samples.
- Combination of reverse transcription and amplification reactions simplifies the protocol and reduces the error rate.
- Automatic or manual extraction from 1,000 µl of blood plasma ensures maximal sensitivity.
- The test reveals infected persons even if ELISA-results are negative and serves as a confirmatory study for ELISA-positive samples.
- RNA extraction and DNA amplification controls allow monitoring of every step of analysis.
- Automated soft-hardware complex was developed to analyze samples and interpret results.
- Real-Time PCR kit was approved upon state acceptance tests and evaluated at large blood transfusion stations and in transplantation centers.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detec-tion type	CE/ RUO	Number of tested samples
NEW AmpliSens® *HCV/HBV/HIV*-FRT	R-V62(RG,Dt)-CE		**Sensitivity** Biological material:** peripheral blood plasma	hepatitis C virus RNA (*HCV*), hepatitis B virus DNA (*HBV*), human immunodeficiency virus RNA (*HIV*-1,*HIV*-2)	QL	RUO	100
	R-V62-Q(RG,Dt)-CE*						
AmpliSens® *HCV/HBV/HIV*-FRT	R-V50-4x (RG,iQ,Mx,Dt)-CE		**Sensitivity** Biological material:** peripheral blood plasma	hepatitis C virus RNA (*HCV*), hepatitis B virus DNA (*HBV*), human immunodeficiency virus RNA (*HIV-1*)	QL	RUO	100

* R-V62-Q(RG,Dt)-CE is a special kit for **QIAsymphony (QIAGEN)**

**** Analytical Sensitivity**

Method of extraction	Volume of sample for extraction, µl	Analytical sensitivity			
		HCV, IU/ml	HBV, IU/ml	HIV-1, copies/ml	HIV-2***,copies/ml
RIBO-sorb; RIBO-prep; NucliSENS easyMAG	100	100	50	200	600
MAGNO-sorb	200	50	25	100	300
MAGNO-sorb NucliSENS easyMAG QIAsymphony Virus/Bacteria Midi Kit	1,000	10	5	20	60

*** PCR kit variant FRT-4x does not detect HIV-2 RNA.

AmpliSens® HCV/HBV/HIV-FRT PCR Kit recommended extraction kits

Kit	Cat. №	Description	Number of tests
MAGNO-sorb	REF K2-16-1000-CE	Kit for DNA/RNA extraction from 1,000 µl of human plasma and blood serum. Magnetic bead-based method. For manual or automated extraction using Neon 100-1-8 (Xiril's Robotic Workstation)	100 tests
MAGNO-sorb	REF K2-16-200-CE	Kit for DNA/RNA extraction from 200 µl of human plasma and blood serum. Magnetic bead-based method. For manual or automated extraction using Neon 100-1-8 (Xiril's Robotic Workstation	100 tests
RIBO-prep	REF K2-9-Et-100-CE	Kit for RNA/DNA extraction from blood plasma, CSF, saliva, amniotic fluid, and swabs. Precipitation method	100 tests
RIBO-sorb	REF K2-1-Et-100-CE	Kit for RNA/DNA extraction, universal. Silica sorbtion method	100 tests

AmpliSens biotechnologies

HEPATITIS VIRUSES INFECTIONS

KEY FEATURES

- wide range of pathogen detection (*HAV, HBV, HCV, HDV, HGV*);
- multiplex pathogen detection;
- qualitative, quantitative formats;
- genotyping;
- high specificity and sensitivity;
- clinically validated;
- ready-to-use reagents;
- cost effectiveness.

HEPATITIS KITS ARE INTENDED FOR

- direct method for detection of viruses in clinical samples;
- early diagnostics within the «serological window» period;
- blood testing;
- diagnostics of occult infection. Measurement of the viral load;
- genotyping;
- selection of an optimal treatment mode (based on results of genotyping and quantitative assays);
- monitoring of treatment efficiency.

OVERVIEW

Hepatitis is an inflammation of the liver. The condition can be self-limiting or can progress to fibrosis (scarring), cirrhosis or liver cancer. Hepatitis viruses are the most common cause of hepatitis in the world but other infections, toxic substances (e.g. alcohol, certain drugs), and autoimmune diseases can also cause hepatitis.

There are 5 main hepatitis viruses, referred to as types A, B, C, D and E. These 5 types are of greatest concern because of the burden of illness and death they cause and the potential for outbreaks and epidemic spread. In particular, types B and C lead to chronic diseases in hundreds of millions of people and, together, are the most common cause of liver cirrhosis and cancer. Hepatitis A and E are typically caused by ingestion of contaminated food or water. Hepatitis B, C and D usually occur as a result of parenteral contact with infected body fluids. Common modes of transmission for these viruses include receipt of contaminated blood or blood products, invasive medical procedures using contaminated equipment and for hepatitis B transmission from mother to baby at birth, from family member to child, and also by sexual contact.

Acute infection may occur with limited or no symptoms, or may include symptoms such as jaundice (yellowing of the skin and eyes), dark urine, extreme fatigue, nausea, vomiting and abdominal pain.

SAMPLING AND PRESERVATION

Biological material:

- blood plasma;
- feces and environmental objects (concentrated water samples) – for detection of HAV.

Peripheral blood plasma

Take a blood sample in a tube with 3% EDTA solution (1 : 20) after overnight fasting. Invert closed tube several times to ensure adequate mixing. Remove and transfer plasma specimen in a new tube within 6 h from the time of blood taking. To do this, centrifuge the tube with blood at 800-1600 rpm for 20 min.

Whole blood

Whole blood samples should be treated with a "Hemolytic" (REF 137-CE) before adding the lysis solution – for AmpliSens® Genoscreen-IL28B-FRT PCR kit.

Swabs from the internal cheek surface (buccal epithelium)

Swabs from the internal cheek surface (buccal epithelium) are taken with a sterile probe with a cotton tip. After swabbing, the probe should be placed to a 1.5-2.0 ml capped tube with 0.5 ml of the "Transport Medium for Storage and Transportation of Respiratory Swabs" (REF 957-CE). The probe should be broken off at the score mark so that the tube is tightly closed. The sample is allowed for storage at 2–8 °C for up to 3 days – for AmpliSens® Genoscreen-IL28B-FRT kit.

WORKFLOW

Sampling	DNA/RNA extraction		Amplification	
Exogenous Control	**Positive Control**	**Negative Control**	**Positive Control**	**Negative Control**
MATERIAL'S LOSS *Exclude kits* HBV-genotype HCV-123	**MATERIAL LOSS** *Exclude kits* HBV-genotype HCV- genotype	**CONTAMINATION**	**INHIBITION**	**CONTAMINATION**

Note

In HBV-genotype kits, HCV-123 does not use Internal control.

In HBV-genotype kits, HCV-genotype (1-6) does not use Positive control of Extraction.

Calibration and calculation of coefficient B using an *HIV-Q* calibration kit (if extraction is carried out with nucleic acid extraction kits, which are not included in this PCR kit - for forms 4 and 5).

In this case Calibrator Q is used – only for kits requiring precision measurement of the amount (Monitor - format):
AmpliSens® *HCV*-Monitor-FRT, AmpliSens® *HDV*-Monitor-FRT, AmpliSens® *HBV*-Monitor-FRT.

EXTRACTION KITS

RIBO-sorb, REF K2-1-Et-50-CE; REF K2-1-Et-100-CE;
RIBO-prep, REF K2-9-Et-50-CE; REF K2-9-Et-100-CE;
MAGNO-sorb, REF K2-16-200-CE, REF K2-16-1000-CE.

HEPATITIS PCR KITs

Hepatitis A virus detection

Hepatitis A virus (*HAV*) is present in the faeces of infected persons and is most often transmitted through consumption of contaminated water or food. Certain sex practices can also spread *HAV*. Infections are in many cases mild with most people making full recovery and remaining immune to further *HAV* infections. However, *HAV* infections can also be severe and life threatening. Most people in poorly sanitised areas of the world have been infected with this virus. Safe and effective vaccines are available to prevent *HAV*.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HAV*-FRT*	R-V4(RG,iQ)-CE		**Analytical sensitivity**** **Biological material:** blood plasma, feces and environmental objects (concentrated water samples)	*Hepatitis A* virus (*HAV*) RNA	QL	CE	55

* AmpliSens® *HAV*-FEP, Cat.No. V4-FEP-CE is available on request

**** AmpliSens® HAV-FRT, analytical sensitivity**

Nucleic extraction kit	Material	Volume, µl	Sensitivity, copies/ml
RIBO-prep	Blood plasma (serum), clarified fecal extracts, concentrated water samples (eluates)	100	500
NucliSENS easyMAG	Blood plasma (serum), concentrated water samples (eluates)	100	500
MAGNO-sorb		200	250
MAGNO-sorb		1,000	50

Hepatitis B virus

Hepatitis B virus (*HBV*) is transmitted through exposure to infective blood, semen, and other body fluids. HBV can be transmitted from infected mothers to infants at the time of birth or from family member to infant in early childhood. Transmission may also occur through transfusions of *HBV*-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. *HBV* also poses a risk to healthcare workers who sustain accidental needle stick injuries while caring for infected-*HBV* patients. Safe and effective vaccines are available to prevent *HBV*.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HBV*-FRT*	R-V5-Mod(RG,iQ,Mx,Dt)-CE		**Analytical sensitivity**** **Biological material:** blood plasma	*Hepatitis B virus (HBV)* DNA	QL	RUO	112
AmpliSens® *HBV*-Monitor -FRT	R-V5-MC(RG,iQ,Mx,Dt)-CE		**Analytical sensitivity***** **Biological material:** blood plasma	*Hepatitis B virus (HBV)* DNA	QN	RUO	80
NEW AmpliSens® *HBV*-genotype -FRT	R-V5-G-F-CE		500 IU/ml (extraction volume100 µl) RIBO-prep **Biological material:** blood plasma	*Hepatitis B virus (HBV)* genotypes A, B, C and D	QL Diff	RUO	55

* AmpliSens® *HBV*-FEP, Cat.No. V5-FEP-CE is available on request

**** AmpliSens® HBV-FRT, analytical sensitivity**

DNA extraction kit	Volume of sample for extraction, µl	Analytical sensitivity, IU/ml
RIBO-sorb	100	100
RIBO-prep NucliSENS easyMAG	100	50
MAGNO-sorb	200	50
MAGNO-sorb	1,000	10
NucliSENS easyMAG	1,000	5

*****AmpliSens® HBV-Monitor-FRT, analytical sensitivity**

DNA/RNA extraction kit	Volume of sample for extraction, µl	Linear measurement range, IU/ml
RIBO-prep NucliSENS easyMAG	100	150 - 100,000,000
MAGNO-sorb	200	75 - 100,000,000
MAGNO-sorb NucliSENS easyMAG	1,000	15 - 100,000,000

Hepatitis C virus

Hepatitis C virus (*HCV*) is mostly transmitted through exposure to infective blood. This may happen through transfusions of *HCV*-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible, but is much less common. There is no vaccine for *HCV*.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HCV*-FRT*	R-V1-Mod(RG,iQ,Mx,Dt)-CE		**Analytical sensitivity***** RIBO-sorb; RIBO-prep; MAGNO-sorb; NucliSENS easyMAG automated nucleic acid extraction system (bioMérieux, France) **Biological materials:** blood plasma	*Hepatitis C virus (HCV)* RNA	QL	RUO	112
AmpliSens® *HCV*-1/2/3-FRT**	R-V1-G-4x (RG,iQ,Mx)-CEE		**Analytical sensitivity****** RIBO-sorb; RIBO-prep; NucliSENS easyMAG automated nucleic acid extraction system (bioMérieux, France) can also be used **Biological materials:** blood plasma	*Hepatitis C virus (HCV)* RNA, genotypes 1, 2, 3	QL Diff	RUO	55
AmpliSens® *HCV*-genotype-FRT	R-V1-G(1-6)-2x(RG,iQ,Mx,Dt,SC)-CE		**Analytical sensitivity******* RIBO-sorb; RIBO-prep; **Biological materials:** peripheral blood plasma	*Hepatitis C virus (HCV)* RNA genotypes 1a, 1b, 2, 3a, 4, 5a, 6	QL Diff	RUO	55
AmpliSens® *HCV*-Monitor-FRT	R-V1-MC(RG,iQ,Mx,Dt)-CE		**Analytical sensitivity******** RIBO-prep; MAGNO-sorb; NucliSENS easyMAG, automated nucleic acid extraction system (bioMérieux, France) **Biological materials:** blood plasma	*Hepatitis C virus (HCV)* RNA	QN	RUO	80
	TR-V1-P-M(RG,iQ,Mx,Dt)-CE						

*AmpliSens® *HCV*-FEP, Cat.No. V1-FEP-CE is available on request
**AmpliSens® HCV-1/2/3-FRT, Cat.No. V1-G-FEP-CE is available on request

*****AmpliSens® HCV-FRT, analytical sensitivity**

RNA/DNA extraction kit	Volume of sample for extraction, µl	Analytical sensitivity, IU/ml
RIBO-sorb RIBO-prep NucliSENS easyMAG	100	100
MAGNO-sorb	200	50
MAGNO-sorb NucliSENS easyMAG	1,000	10

AmpliSens biotechnologies

****AmpliSens® HCV-1/2/3-FRT, analytical sensitivity

Nucleic acid extraction kit	Volume of sample for extraction, µl	Sensitivity, IU/ml
RIBO-sorb RIBO-prep NucliSENS easyMAG	100	500
NucliSENS easyMAG	1,000	50

*****AmpliSens® HCV-genotype -FRT, analytical sensitivity

Nucleic acid extraction kit	Volume of sample for extraction, µl	Analytical sensitivity, IU/ml
RIBO-sorb	100	2.5×10^3
RIBO-prep	100	5×10^3

******AmpliSens® HCV-Monitor-FRT, analytical sensitivity

DNA/RNA extraction kit	Volume of sample for extraction, µl	Linear measurement range, IU/ml
RIBO-prep NucliSENS easyMAG	100	300 - 100,000,000
MAGNO-sorb	200	150 - 100,000,000
MAGNO-sorb NucliSENS easyMAG	1,000	30 - 100,000,000

**AmpliSens® HDV-FRT, analytical sensitivity

RNA/DNA extraction kit	Volume of sample for extraction, µl	Analytical sensitivity, copies/ml
RIBO-sorb RIBO-prep NucliSENS easyMAG automated nucleic acid extraction system (bioMérieux, France)	100	100
MAGNO-sorb	200	50
MAGNO-sorb NucliSENS easyMAG automated nucleic acid extraction system (bioMérieux, France)	1,000	10

***AmpliSens® HDV- Monitor-FRT, analytical sensitivity

DNA/RNA extraction kit	Volume of sample for extraction, µl	Linear measurement range, IU/ml
RIBO-prep NucliSENS easyMAG	100	40 - 100,000,000
MAGNO-sorb	200	20 - 100,000,000
MAGNO-sorb NucliSENS easyMAG	1,000	4 - 100,000,000

Hepatitis D virus

Hepatitis D virus (*HDV*) infections occur only in those who are infected with *HBV*. The dual infection of *HDV* and *HBV* can result in a more serious disease and worse outcome. Hepatitis B vaccines provide protection from *HDV* infection.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HDV*-FRT	R-V3 (RG,iQ,Mx,Dt)-CE*		**Analytical sensitivity**** RIBO-sorb, RIBO-prep, MAGNO-sorb, NucliSENS easyMAG **Biological materials:** blood plasma	*hepatitis D virus (HDV)* RNA	QL	RUO	112
AmpliSens® *HDV*-Monitor-FRT	R-V3-MC (RG,iQ,Mx,Dt)-CE		**Analytical sensitivity***** RIBO-prep, MAGNO-sorb, NucliSENS easyMAG **Biological materials:** blood plasma	*hepatitis D virus (HDV)* RNA	QN	RUO	80

*AmpliSens® *HDV*-FEP, Cat.No. V3-FEP-CE is available on request

Hepatitis G virus

The clinical significance of GBV-C (hepatitis G) infection with respect to acute or chronic hepatitis is not well understood, but the preponderance of other evidence suggests that GBV-C does not cause hepatitis in humans.
GBV-C RNA has been detected in patients with acute non-A to non-E viral hepatitis, in patients with chronic hepatitis of presumed viral etiology, in patients with cryptogenic cirrhosis, and in some patients with primary hepatocellular carcinoma. However, it is often difficult to tease out the direct role of GBV-C in these settings since coinfection with HCV is so common. Studies in patients with apparently isolated GBV-C infection show that the acute liver injury is similar to and may be less severe than in those with HCV. On the other hand, in patients with post-transfusion hepatitis where GBV-C presence can be documented, the plasma ALT peak and the peak viral titers may be discordant, which means that GBV-C may not be responsible for a rise in ALT levels.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
NEW AmpliSens® *HGV*-FRT*	R-V2-50-F(RG,iQ,Mx,Dt)-CE		**Analytical sensitivity**** RIBO-prep, NucliSENS easyMAG **Biological materials:** blood plasma	*Hepatitis G virus (HGV)* RNA	QL	CE	55

*AmpliSens® HGV-FEP, Cat.No. V2-50F-FEP-CE is available on request

****AmpliSens® HGV–FRT-FRT, analytical sensitivity**

RNA/DNA extraction kit	Volume of sample for extraction, µl	Analytical sensitivity, copies/ml
RIBO-prep, NucliSENS easyMAG	100	500
NucliSENS easyMAG	1,000	50

Multiplex hepatitis infections PCR kits

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® *HBV / HDV*-FRT	R-V56 (RG,iQ,Mx,Dt)-CE		**Analytical sensitivity*** RIBO-sorb, RIBO-prep, MAGNO-sorb, NucliSENS easyMAG **Biological materials:** blood plasma	*hepatitis B virus (HBV)* DNA and *hepatitis D virus (HDV)* RNA	QL	RUO	112
AmpliSens® *HCV / HBV / HIV* -FRT	Please find information in a relevant “HIV-infection” paragraph						

***AmpliSens® HBV / HDV-FRT, analytical sensitivity**

RNA/DNA extraction kit	Volume of sample for extraction, µl	Analytical sensitivity	
		HBV, IU/ml	HDV, copies/ml
RIBO-sorb, RIBO-prep NucliSENS easyMAG	100	100	100
MAGNO-sorb	200	50	50
MAGNO-sorb, NucliSENS easyMAG	1,000	10	10

Identification of single-nucleotide polymorphisms in the Interleukin-28B gene (IL28B) as a pre-treatment predictor of HCV treatment response

AmpliSens® Genoscreen-IL28B-FRT PCR kit is an *in vitro* nucleic acid amplification test for qualitative detection of the single-nucleotide polymorphism (SNP) rs8099917 and rs12979860 in the Interleukin-28B gene (IL28B) in a biological material (whole blood or swabs collected from the internal cheek surface (buccal epithelium)) by using real-time hybridization-fluorescence detection of amplified products.
Identification of the Interleukin 28B gene polymorphisms plays a role in prediction of effective antiviral therapy for Chronic Hepatitis C.

Kit type	Catalog number	Format	Analytical sensitivity	Detected pathogen	Detection type	CE/ RUO	Number of tested samples
AmpliSens® Genoscreen-IL28B-FRT	R-O5-100-F(RG,iQ,Dt,CFX)-CE		5×10^3 copies/ml (extraction volume 100 µl) RIBO-prep **Biological material:** whole blood or swabs collected from the internal cheek surface (buccal epithelium)	DNA single-nucleotide polymorphism (SNP) rs8099917 and rs12979860 in the Interleukin-28B gene (*IL*28B)	QL	CE	110

Note:
Whole blood samples must be treated with a “Hemolytic” (REF 137-CE) before adding the lysis solution.
Swabs from the internal cheek surface (buccal epithelium) are taken with a sterile probe with a cotton tip. After swabbing, the probe should be placed to a 1.5-2.0 ml capped tube with 0.5 ml of the “Transport Medium for Storage and Transportation of Respiratory Swabs” (REF 957-CE). The probe should be broken off at the score mark so that the tube is tightly closed. The sample can be stored is allowed for storage at 2–8 °C for up to 3 days. Then extract the DNA according to the manufacturer’s protocol.

EXTRACTION KITS
DNA extraction kits

Sorbtion method-based kits / PRINCIPLE of nucleic acid extraction

DNA-sorb-AM, DNA-sorb-B nucleic acid extraction kits are reagent kits for rapid and efficient manual extraction and purification of DNA from various biological materials.
Lysis solution contains a chaotropic agent (guanidine chloride) that lyses cells and denaturates cell proteins. The nucleic acids are then sorbed on silica particles. DNA extracted from clinical samples may be used for PCR diagnostic tests.
DNA-sorb-C nucleic acid extraction kit is a reagent kit for rapid and efficient manual extraction and purification of DNA from various biological materials.
Lysis Reagent Buffer and Washing Solution 1 contain chaotropic agents (guanidine chloride and guanidine thiocyanate), which lyse cells and denature cell proteins, respectively. The nucleic acids are then sorbed on silica particles. DNA extracted from biological samples may be used for PCR diagnostic tests.

DNA-sorb-AM

This kit is intended for extraction and purification of DNA from a biological material (scrapes and discharges of urogenital tract, throat, rectum, conjunctiva, erosions, ulcers; urine).
DNA-sorb-AM nucleic acid extraction kit is recommended for DNA extraction and purification from scrapes and discharges of urogenital tract mucous membranes, throat, rectum, conjunctiva, erosions, ulcers; urine.

Note:
Depending on a configuration form the extraction kit can have Internal control samples with electrophoretic detection and hybridization-fluorescent detection, respectively.

DNA-sorb-B

This kit is intended for extraction and purification of DNA from a biological material (whole blood, plasma, urine sediment, saliva, cerebrospinal fluid, sputum, biopsy material, bronchoalveolar lavage, feces).
DNA-sorb-B nucleic acid extraction kit is recommended for DNA extraction and purification from: whole blood, blood plasma, urine sediment, saliva, cerebrospinal fluid, sputum, biopsy material, bronchoalveolar lavage, feces.

DNA-sorb-C

This kit is intended for extraction and purification of DNA from a biological material, food and animal feeding stuff: microbiopsy material of skin, mucous membrane (urogenital system, gastrointestinal tract, bronchi), and parenchymal organs (liver or spleen aspirate), as well as homogenized tissue. DNA-sorb-C nucleic acid extraction kit is suitable for extraction from 50 biopsy specimens (10-25 mm^3) or 50% tissue homogenates (not exceeding 50 µl in terms of the volume). Food, bioactive food additives, animal feeding stuff, plant stock.

Microbiopsy material
Skin, mucous, or parenchymal organ biopsy specimen of 10–25 mm^3 should be placed into a tube which contains 0.2 ml of saline solution (PBS-buffer) or transport medium.

Macrobiopsy material
Parenchymal organ biopsy specimen of more than 50 mm^3 should be placed into a container or a tube which contains 0.2 ml of saline solution (PBS-buffer) or transport medium.
Food, bioactive food additives, animal feeding stuff, and plant stock should be treated as described in the “PLANT-SCREEN” PCR kit instruction manual (produced by the FBIS CRIE).

DNA-sorb-D

DNA-sorb-D kit is intended for extraction of DNA from epithelial cells (cervical swabs) taken into the transport medium for liquid-based cytology (for example, PreservCyt (Hologic Inc., USA)) for subsequent analysis by the polymerase chain reaction (PCR).
Test samples are treated using mucolysin to dissolve cervical mucus. Then the cells are washed out off the transport medium using phosphate buffer solution (PBS-buffer) and cell membranes are destructed by lysis with detergent (cytolysin). As a result the nucleic acids are released and the proteins are degradated by protease. DNA without proteins is purified by sorption on silica gel.

The dissolved nucleic acids bind to sorbent particles while other components of the lysed biological material stay in the solution and are removed by sorbent centrifugal sedimentation and subsequent washings. The nucleic acids are transferred from the silica surface to the solution after adding the buffer for elution to the sorbent. Then the solution is separated from the sorbent by centrifugation.
The obtained nucleic acid sample is highly purified and free from inhibitors of amplification, which provides high analytical sensitivity of a PCR assay.

Express method kits / PRINCIPLE of nucleic acid extraction

A biological material obtained from a patient is transferred into the transport medium TM-EDEM and in such way is stored and transported to a laboratory. For DNA extraction, a clinical sample aliquot is transferred into a tube with “IC-diluent”, then it is treated thermally with destruction of cell membranes, viral coats and other biopolymer complexes and DNA release. Insoluble components are pelleted on the tube bottom by centrifuging; the supernatant with DNA is used for PCR. The internal control sample (IC) contained in “IC-diluent” is isolated from a biological material simultaneously with DNA and, thereby, is a quality marker for laboratory analysis of clinical samples.

EDEM

The reagent kit for Extraction of DNA by Express Method (EDEM) is intended for treatment of different types of a biological material (urogenital swabs, throat swabs, conjunctiva swabs, erosive and ulcerative elements of mucous membranes and skin and first portions of human urine samples) with subsequent tests for STIs and other reproductive tract infections by using hybridization-fluorescence detection and PCR kits manufactured by the FBIS CRIE.
EDEM reagent kit is intended for DNA isolation from 100 samples of urogenital swabs, throat swabs, conjunctiva swabs, erosive and ulcerative elements of mucous membranes and skin, including controls.
Clinical samples are to be collected into the Transport Medium TM-EDEM, which the EDEM kit is completed with. Biological material sampling for PCR-analysis, transportation and storage is described in the manufacturer’s handbook [1].
It is recommended that this handbook is studied before the work begins.
Each EDEM kit includes 0,5 ml of the Transport MediumTM-EDEM aliquoted into tubes.

EDEM express extraction kit is not recommended for use with QUANTITATIVE kits!

Kit type	Catalog number	Description	CE/ RUO	Number of tested samples
DNA-sorb-AM	K1-11-100-CE K1-12-100-CE*	**Volume of extracted sample is 100 µl**	CE	100
DNA-sorb-B	K1-2-100-CE		CE	100
DNA-sorb-C	K1-6-50-CE		CE	50
EDEM	K2-17-100-CE		CE	100
DNA-sorb-D	K1-8-100-CE		RUO	100
Citolizin	K1-3-100-CE	Citolizin nucleic acid extraction kit is intended for DNA extraction from whole blood leukocytes	CE	100

* without internal controls (IC)

Citolizin nucleic acid extraction kit is produced in a single form and includes:

Reagent	Description	Volume (ml)	Amount
Hemolytic	colorless clear liquid	100	2 vials
Citolisin	colorless clear liquid	5.0	2 vials

AmpliSens biotechnologies

DNA/RNA extraction kits

Precipitation method-based kits / PRINCIPLE of nucleic acid extraction

RIBO-prep nucleic acid extraction kit is a reagent kit for rapid and efficient manual extraction and purification of RNA from various biological materials. The lysis solution contains a chaotropic agent (guanidine thiocyanate), which lyses cells and denatures cell proteins. Nucleic acids are then precipitated in isopropanol. RNA or DNA extracted from biological samples may be used for PCR diagnostic tests.
RIBO-sorb nucleic acid extraction kit is a reagent kit for rapid and efficient manual extraction and purification of RNA from various biological materials. The lysis solution contains a chaotropic agent (guanidine thiocyanate) that lyses cells and denaturates cell proteins. The nucleic acids are then sorbed on silica particles. RNA or DNA extracted from biological samples may be used for PCR diagnostic tests.

RIBO-prep

The kit is intended for extraction and purification of the entire RNA/DNA from a biological material (peripheral blood plasma, cerebrospinal and amniotic fluid, nasal and oropharyngeal swabs, and saliva).
RIBO-prep nucleic acid extraction kit is recommended for RNA and DNA extraction and purification from: ● blood plasma; ● cerebrospinal fluid; ● amniotic fluid; ● saliva; ● nasal or feces swabs.

Sorbtion method-based kits
RIBO-sorb

The kit is intended for extraction and purification of RNA and DNA from a biological material.
RIBO-sorb nucleic acid extraction kit is recommended for RNA and DNA extraction and purification from: ● plasma; ● serum; ● fecal extract; ● cervical or urethral scrapes (swabs); ● urine; ● saliva; ● secret of the prostate gland; ● throat or nasopharynx or fauces swabs (lavages); ● biopsy and autopsy materials after getting of the water phase; ● ticks, mosquitoes and ectoparasites (lice and fleas) after getting of the water phase.

Kit type	Catalog number	Description	CE/ RUO	Number of tested samples
RIBO-prep	K2-9-Et-100-CE	**Volume of extracted sample is 100 µl**	CE	100
	K2-9-Et-50-CE		CE	50
RIBO-sorb	K2-1-Et-100-CE		CE	100

Phenol method-based kits (modification of Chomczynski extraction method) / PRINCIPLE of nucleic acid extraction

RIBO-zol-A

RIBO-zol-A nucleic acid extraction kit is a reagent kit for rapid and efficient manual extraction and purification of RNA from various biological materials. RNA extraction is based on separation of phenolic and hydrous phases. The hydrous phase obtained after Ribozol and Solution B are added contains RNA. Sediment, containing purified RNA, is formed after Solution C and Washing Solution 3 are added. RNA extracted from clinical samples may be used for PCR diagnostic tests.
RIBO-zol-A is intended for extraction of the entire RNA from a biological material for further analysis by using the reverse transcription and polymerase chain reaction method.

RIBO-zol-B

RIBO-zol-B nucleic acid extraction kit is a reagent kit for rapid and efficient manual extraction and purification of RNA from various biological materials. Solution D contains a chaotropic agent (guanidine thiocyanate) that lyses cells and denaturates cell proteins. RNA extracted from clinical samples may be used for PCR diagnostic tests.

RIBO-zol-B nucleic acid extraction kit is intended for extraction of the entire RNA from a biological material for further analysis using the reverse transcription and polymerase chain reaction method.
RIBO-zol-B nucleic acid extraction kit is recommended for RNA extraction and purification from 30 mg (or 30 µl) of a biological material.

RIBO-zol-C

RIBO-zol-C nucleic acid extraction kit is a reagent kit for rapid and efficient first stage RNA manual extraction from various biological materials. Solution D contains a chaotropic agent (guanidine thiocyanate) that lyses cells and denaturates cell proteins. The hydrous phase, obtained after Solution A, Solution B and Solution E are added contains RNA. After further purification and concentration it can be used in PCR diagnostic tests.
RIBO-zol-C nucleic acid extraction kit is intended for the first stage extraction of the entire RNA from a biological material. Further RNA purification and concentration using sorbtion or precipitation methods are required.

Kit type	Catalog number	Description	CE/ RUO	Number of tested samples
RIBO-zol-A	K2-2-100-CE	**Volume of extracted sample is 100 µl**	CE	100
RIBO-zol-B	K2-3-100-CE	Transfer 30 mg (or 30 µl) of a biopsy material (brain, liver, spleen or lymph nodes tissues) into porcelain mortar and homogenize it using a teflon pestle	CE	100
RIBO-zol-C	K2-13-50-CE	Continue RNA extraction using the second stage nucleic acid extraction kit. Follow the instruction manual. Start extraction from the lysis step taking into account that an Internal Control sample has already been added. Use with «RIBO-sorp» version 50 Cat. No. K2-1-Et-50 for nucleic acids extraction and Cat. No. R-B49(RG) «AmpliSens Leptospira-FRT **Volume of extracted sample is 100 µl»**	CE	50

Magnetic beads method-based kits / PRINCIPLE of nucleic acid extraction

A clinical sample is treated by the lysis solution with magnetic silica particles (magnetic sorbent). As a result the cell membranes, viral envelopes and other biopolymer complexes are destructed and the nucleic acids are released. The dissolved nucleic acids bind to the sorbent particles while other components of the lysed biological material stay in the solution and are removed by sorbent precipitation on a magnetic rack and subsequent washings. The nucleic acids are transferred from the sorbent surface to the solution after adding the buffer for elution to the magnetic sorbent. Then the solution is separated from the sorbent by magnetic force.
The resulting nucleic acid sample is highly purified and free from inhibitors of amplification, which provides high analytical sensitivity of the PCR assay.

MAGNO-sorb

MAGNO-sorb nucleic acid extraction kit is intended for extraction of DNA/RNA from human blood plasma for subsequent detection of *hepatitis B virus, hepatitis C virus, human immunodeficiency virus,* and other pathogens by the polymerase chain reaction (PCR).
MAGNO-sorb nucleic acid extraction kit is recommended for DNA and RNA extraction from blood plasma.

RNA/DNA Extraction kit. Magnetic beads sorbtion method.

Kit type	Catalog number	Description	CE/ RUO	Number of tested samples
MAGNO-sorb Nucleic Acid Extraction Kit	K2-16-200-CE	NEW **Volume of extracted sample is 200 µl**	CE	100
MAGNO-sorb Nucleic Acid Extraction Kit	K2-16-1000-CE	NEW **Volume of extracted sample is 1,000 µl**	CE	100

SAMPLE PRETREATMENT

Sample pretreatment is necessary for different types of biological materials
(blood, urine, viscous kind material and so on)

Kit type	Catalog number	Description	CE/ RUO	Volume
Mucolysin	180-CE	Medium for sputum preliminary treatment	CE	100 ml (2 vials)
Hemolytic	137-CE	Reagent for pretreatment of whole peripheral and umbilical cord blood, in stock	CE	100 ml (1 vials)

REVERSE TRANSCRIPTION KITS

REVERTA-L RT reagent kit is intended for complementary DNA (cDNA) synthesis from RNA extracted from biological samples.

PRINCIPLE

The procedure provides for reverse transcription reaction using random sequence hexamers (random primers) as polymerization primers. The reverse transcription reaction generates cDNAs from all the different RNA molecules in RNA extracted from the sample under testing. cDNAs can be used in diagnostic tests based on amplification reactions. With an amplification assay it is possible to verify whether the reverse transcription reaction product contains specific cDNA target molecules originating, for example, from genomic regions of microorganisms with an RNA genome.

Kit type	Catalog number	Description	CE/ RUO	Number of tested samples
Reverta-L	K3-4-100-CE	Reverse transcription kit	CE	120
Reverta-L	K3-4-50-CE	Reverse transcription kit	CE	60

TRANSPORT AND STORAGE MEDIA

Transport Medium for Storage and transportation of Respiratory Swabs

It is intended for sampling, transportation, and storage of the following biological materials:
Nasal swabs. If the nasal cavity of a patient is full of mucosa, make him blow his nose prior to taking a swab. Insert the cotton bud end of a dry sterile swab into a nostril and rub firmly against the turbinate (to ensure that the swab contains cells as well as mucus).
Throat swabs. Make a patient rinse his mouth with water prior to sampling. Use a sterile cotton swab to swab both tonsils, palatine arches, and the posterior nasopharynx, without touching the sides of the mouth.
Storage and transportation of a test material placed in the Transport Medium for Storage and Transportation of Respiratory Swabs.

PRINCIPLE
Transport Medium for Storage and Transportation of Respiratory Swabs is a phosphate buffer solution supplemented with preservative and cryopreservative agents. The salt composition and pH of the medium prevent premature lysis of cell in swabs, the preservative agent prevents growth of foreign microflora, and the cryopreservative agent stabilizes microorganisms during freeze-thaw transitions.

Transport Medium with Mucolytic Agent

It is a reagent intended for transportation and storage of swabs and discharges collected from the urogenital tract, throat, rectum, eye conjunctiva, and erosive-ulcerative lesions of human skin and mucous membranes for subsequent analysis of the material for STIs and other reproductive tract infections by polymerase chain reaction (PCR) and nucleic acid sequence-based amplification (NASBA) with the use of reagent kits manufactured by the FBIS CRIE.

PRINCIPLE
Transport Medium with Mucolytic Agent is a ready-to-use sterile pink buffer-salt solution supplemented with mucolytic, preservative, and stabilizing agents. The mucolytic agent ensures liquefaction of mucus, provides effective and homogenous mixing of a biological material with the transport medium. The preservative and stabilizing agents prevent growth of nonspecific microflora and premature lysis of cells, providing long-term stability of RNA/DNA of microorganisms and viruses in a wide temperature range.
Transport Medium with Mucolytic Agent is intended for transportation and storage of the following biological materials: swabs and discharges collected from the urogenital tract, throat, rectum, eye conjunctiva, and erosive-ulcerative lesions of human skin and mucous membranes.

RNA-medium

It is a medium intended for sampling, transportation, and storage of whole blood samples with simultaneous stabilization of cell mRNA and subsequent extraction of the entire RNA. Phenol extraction of RNA according to Chomczynski or its modifications using RIBO-zol-A and RIBO-zol-D nucleic acid extraction kits manufactured by the FBIS CRIE are recommended.

PRINCIPLE
The first step of many molecular studies of mRNA is collecting whole blood. The main problem of these studies is the instability of the RNA cell that degrades rapidly within a few hours. Moreover, the amount of some RNA types in collected blood increases *in vitro* due to gene induction. Both degradation and induction may lead to inadequate estimation of the RNA level *in vivo*.
RNA-medium contains an agent that ensures *in vitro* stabilization of the *in vivo* expression profile by suppressing RNA degradation and minimizing gene induction *in vitro*.

Transport media for swabs

Is intended for transportation and storage of scraping material and discharge of the mucous membranes of the urogenital tract, of the oropharynx, rectum, and the erosive and ulcerative mucosal cells and human skin for further research of the pathogens of sexually transmitted infections (STIs) and other reproductive organs infections.

PRINCIPLE
Transport media for swabs is a ready to use sterile isotonic water-buffered saline with preserving agent. Preserving agent prevents the growth of non-specific microflora.

Kit type	Catalog number	Description	CE/ RUO	Volume
Transport Medium for Storage and Transportation of Respiratory Swabs	957-CE	Transport Medium for Storage and Transportation of Respiratory Swabs is a reagent intended for sampling, transportation, and storage of upper respiratory tract swabs	CE	50 ml (1 vial)
Transport Medium with Mucolytic Agent	952-CE	Reagent for transportation and storage of clinical material Transport media for biological materials from male and female urogenital tract with mucolytic and stabilizator (pink color), in stock	CE	50 ml (1 vial)
Transport Medium for swabs	987-CE	Transport medium for transportation and storage of different types of biological material taken with swabs	RUO	0,3 ml (100 tubes)
RNA-medium	981-CE	Transport medium for storage, stabilization and preservation of the entire RNA in blood	CE	100 ml (1 vial)

AmpliSens biotechnologies

Reagent kits «Amplisens Peeroscreen» series for detection of genetic polymorphisms by sequencing method applying PyroMark system instruments

Name	Association with disease	Analyzed genes	Polymorphism	Catalogue number
«TONO-screen»	Arterial hypertension	ARDB2 AGT AGT AGTR1 NOS3	rs1042713 rs4762 rs699 rs5186 rs1799983	PMQ-004-50-F
«IHD-screen»	Ischemic heart disease	AMPD1 CDKN2A/2B HIF1A MMP3 APOE APOE	rs17602729 rs1333049 rs11549465 rs3025058 rs429358 rs7412	PMQ-018-50-F
«LIPO-screen-B»	Disorders of lipid metabolism, cardiovascular disease: myocardial infarction, atherosclerosis and coronary heart disease; Familial dysbetalipoproteinemia hyperlipoproteinemia type III and V, xanthomatosis, Alzheimer's disease, diabetes mellitus, ischemic stroke	APOE APOE APOB APOB PCSK9	rs429358 rs7412 rs5742904 rs754523 rs11206510	PMQ-019-50-F
«LIPO-screen-D»		ABCA1 APOC3 APOC3 APOC3 LPL LPL PON1 PON1	rs2230806 rs2854116 rs2854117 rs5128 rs268 rs328 rs854560 rs662	PMQ-013-50-F
«PLASMO-screen»	Abnormality of plasma factors of blood coagulation	F2 F5 F7 FGB SERPINE1	rs1799963 rs6025 rs6046 rs1800790 rs1799768	PMQ-001-50-F
«FOLATE-screen»	Abnormality of folate metabolism, hyperhomocysteinemia	MTHFR MTHFR MTR MTRR SLC19A1	rs1801133 rs1801131 rs1805087 rs1801394 rs1051266	PMQ-002-50-F
«THROMBO-screen»	Abnormality of blood aggregation and coagulation factors, thrombophilia	GP1BA GP1BA ITGB3 JAK2 SELPLG	rs2243093 rs6065 rs5918 rs77375493 rs2228315	PMQ-003-50-F
«BRCA-screen»	Breast cancer, ovarian cancer	BRCA1 BRCA1 BRCA1 BRCA1 BRCA1 BRCA2	185delAG 300T>G (C61G) 2080delA 4153delA 5382insC 6174delT	PMQ-005-50-F
«OSTEO-screen»	Osteoporosis	COL1A1 ESR1 ESR1 LCT LRP5 VDR	rs1800012 rs2234693 rs9340799 rs4988235 rs3736228 rs1544410	PMQ-008-50-F

Name	Association with disease	Analyzed genes	Polymorphism	Catalogue number
«DIABETES-1-screen»	Diabetes mellitus type 1	C12ORF30 CLEC16A rs2544677 INS PTPN22	rs17696736 rs12708716 rs2544677 rs689 rs2476601	PMQ-009-50-F
«DIABETES-2-screen»	Diabetes mellitus type 2	KCNJ11 PPARG TCF7L2 TCF7L2	rs5219 rs1801282 rs7903146 rs12255372	PMQ-015-50-F
«DIABETES-2D-screen»	Diabetes mellitus type 2	CDKAL1 CDKN2A/2B HHEX IGF2BP2 SLC30A8	rs7756992 rs10811661 rs1111875 rs4402960 rs13266634	PMQ-017-50-F
«ADIPO-screen»	Examining of susceptibility to obesity	FTO PPARD PPARGC1A PPARGC1B	rs9939609 rs6902123 rs8192678 rs7732671	PMQ-006-50-F
«COLO-screen»	Crohn's disease, colorectal cancer	NOD2 NOD2 NKX2-3 PTPN2	rs2066844 rs2066845 rs10883365 rs2542151	PMQ-007-50-F
«PHARMA-screen-1»	Determination of the individual patient's sensitivity to the action of various drugs, establishing the causes of various pharmacological response, optimization of strategy of applied drug therapy	CYP1A1 CYP1A1 CYP1A1 CYP1A2 CYP3A4 CYP2C9 CYP2C9	rs1048943 rs1799814 rs4646903 rs762551 rs2740574 rs1799853 rs1057910	PMQ-010-50-F
«PHARMA-screen-16»		CYP2C19 CYP2C19 CYP2C19 CYP2D6 CYP2D6	rs4244285 rs4986893 rs12248560 rs35742686 rs3892097	PMQ-024-50-F
«PHARMA-screen-2a»		NAT2 NAT2 NAT2 NAT2 NAT2 NAT2	rs1041983 rs1801280 rs1799929 rs1799930 rs1208 rs1799931	PMQ-011-50-F
«PHARMA-screen-2b»		EPHX1 EPHX1 GSTP1 GSTP1 TPMT TPMT TPMT	rs1051740 rs2234922 rs1695 rs1138272 rs1800462 rs1800460 rs1142345	PMQ-012-50-F
«PHARMA-screen-transport»		ABCB1 ABCB1 ABCB1 ABCG2 ABCG2	1236T>C 2677T>A, G 3435T>A, C 421C>A 376C>T	PMQ-020-50-F

Name	Association with disease	Analyzed genes	Polymorphism	Catalogue number
«PHARMA-screen-Warfarin»	Determination of individual dose Warfarin	VKORC1 CYP4F2 GGCX CYP2C9 CYP2C9 CYP2C9 CYP2C9	rs9923231 rs2108622 rs11676382 rs1799853 rs1057910 rs28371686 rs9332131	PMQ-014-50-F
«PHARMA-screen-Imatinib»	Determining individual sensitivity to Imatinib	ULK3 KDR KDR VEGFA VEGFA VEGFA VEGFA	rs2290573 rs1531289 rs1870377 rs699947 rs833061 rs3025039 rs2010963	PMQ-021-50-F
«CCR5del32-screen»	Evaluation of individual intolerance to HIV	CCR5	rs333	PMQ-016-50-F
«SPORT-myo-screen»	Evaluation of energy metabolism, evaluation of the type and activity of muscle energy metabolism	ACTN3 MSTN AGT HIF1A	rs1815739 rs1805086 rs699 rs11549465	PMQ-022-50-F
«SPORT-energy-screen»		PPARA PPARD PPARG PPARGC1A PPARGC1B AMPD	rs4253778 rs2016520 rs1801282 rs8192678 rs7732671 rs17602729	PMQ-023-50-F
«VEGFA / NOS3-screen»	Disorders of blood clotting, retinopathy, angiogenic disorders	VEGFA VEGFA VEGFA NOS3 NOS3	rs3025039 rs2010963 rs1570360 rs2070744 rs1799983	PMQ-025-50-F
«IL28B-screen»	Evaluation of the immune response: analysis of IL-28B gene	IL28B	rs8099917 rs12979860	PMQ-026-50-F
«UGT1A1-screen»	Gilbert's syndrome, the risk forecast of irinotecan toxicity (upon chemotherapy of ovarian cancer/ lung cancer)	UGT1A1	rs8175347	PMQ-027-50-F

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