TestGene

New generation
of genetics

PRODUCT CATALOG

NEW GENERATION OF GENETICS

Contents

«TestGene»

is one of the leaders of the Russian molecular diagnostics, biotechnologies and bioinformatics markets

- TestGene offers a wide range of reagents and test-kits based on cutting-edge innovative biotechnologies in molecular biology, oncology, prenatal diagnostics, virology and epidemiology.
- TestGene's products enable laboratory diagnostics specialists and doctors to introduce advanced biotechnologies into their daily practice and make correct and informed decisions promptly, saving people's lives and restoring their health.
- TestGene's solutions are widely used by laboratory diagnostics specialists in Russia, the CIS and the European Union countries.

KEY TECHNOLOGIES

PCR	Real-time PCR
NGS	Next-generation sequencing
LAMP	Loop-mediated isothermal amplification
LFT	Lateral flow test

Scientific and technical potential

TestGene started back in 2012 by introducing the first molecular genetics test-kits for non-invasive prenatal testing on the Russian market.

TestGene has brought together international-level professionals sharing desire to develop and produce innovative diagnostic products. Today our R&D team is formed by three research groups located in Moscow, Novosibirsk and Ulyanovsk. Many of the team members are PhDs in medicne and biology with hundreds of scientific publications and high level of citation.

Constant development and advanced training of the personnel, improvement of diagnostic methods and keeping track of the latest technological innovations combined with prompt reaction to market requests and fast product development have made TestGene one of the key players on the Russian molecular genetic diagnostics market.

Directions of R&D activity

- Determination of predisposition to hereditary cancers
- Diagnostics of oncological diseases
- Detection of mutations for prescribing targeted therapy in oncology
- Diagnostics in obstetrics and gynecology
- Detection of bacterial and viral infections
- Development of tests for scientific research (more than 2000 in the portfolio)
- Bioinformatics
- CRISPR (genome editing)

Product quality

One of the company's priorities is to develop and produce safe and reliable products of consistently high quality

TestGene has established 5 high-tech production sites. Cutting-edge technological equipment, constant modernization and automation of the manufacturing process combined with top-level team's proficiency ensure high quality of the products and outstanding operational performance.

The company's quality management system is certified according to the ISO 13485:2016 international standard ("Production of medical evices"). Most test-kits have been CE-marked providing compliance with the European production safety and quality standards.

TestGene's products are registered as medical devices in Russia and many of the CIS and the European Union countries.

Personalized approach combined with solid experience in development of universal solutions lets us create test-kits that fully meet the requirements of the leading diagnostic centers and laboratories.

Fast and top-level technical support is provided by our Support Team at any time when necessary.

The main advantages of the products:

- ✓ Stable high quality
- ✓ Reliability
- ✓ High sensitivity and specificity
- ✓ High assay speed
- ✓ Ease of use
- ✓ Standardized assay procedure
- ✓ Versatility (PCR kits are compatible with all amplifiers of open type)
- ✓ Flexibility of use

Some of the developments are unique and protected by copyright certificates and patents.

Polymerase chain reaction (PCR)

PCR is a method of molecular genetic diagnostics which has become widespread in clinical practice due to its accuracy, reliability, simplicity and fast assay.

PCR is the main diagnostic method in modern oncology, including the cases of choosing tactics for the treatment of malignant tumors, use of targeted drugs, and evaluating effectiveness of the therapy. Detection of hereditary forms of cancer is especially important for determining the risk of development of diseases and possible prevention.

PCR is one of the most accurate and sensitive methods for diagnostics of infectious diseases due to its main advantages:

- High specificity

Detection of the specific region of the pathogen DNA eliminates the possibility of obtaining false results. PCR can be used for genotyping.

- High sensitivity

Even single cells of the pathogen are detected, which makes it possible to detect the causative agent of the disease before the first symptoms of the disease appear and in cases when it is impossible to implement other methods (immunological, bacteriological, microscopic).

- Universality

Most types of biomaterial are suitable for analysis. It is possible to diagnose several pathogens from one biological sample.

- Diagnostics of not only acute but also latent infections
- Fast result of the analysis

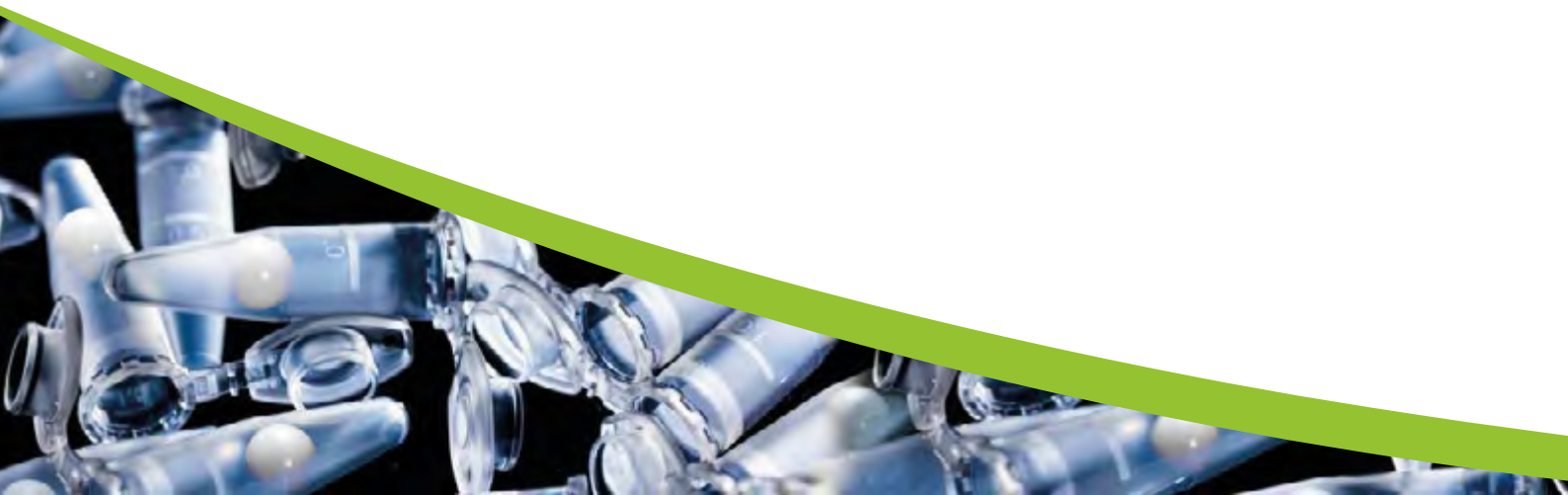
TestGene has significantly expanded its product line over the past year. All the new products are developed with regard to the latest trends in PCR diagnostics and the requests from the laboratories.

Lyophilized PCR kits

Manufacturing of PCR test-kits in the form of lyophilized dispensed ready-made mixes is a recent trend in PCR diagnostics.

- Lyophilization solves the "cold chain" problem, which involves transportation and storage of kits refrigerated or frozen. It is especially important for long-term transportation and for places where there is no suitable infrastructure and appropriate storage conditions cannot be secured.
- Water is removed as a participant of the reaction during the lyophilization process providing increased stability and extended reagents' shelf life along with reduced transportation costs.
- Inintial activity of the components is completely preserved due to the absence of freeze-thaw cycles.
- Test-kits are represented by ready-made mixes dispensed into reaction tubes, strips or plates and containing all the reaction components. This type of design increases the kit's usability, reduces the complexity of preparation and time for analysis. Since the mixes do not need to be prepared and dispensed into tubes reproducibility is increased and the risk of contamination is lowered.

TestGene has started migration to the lyophilized kit format for most of its products.



Next generation sequencing (NGS)

The most informative method of molecular genetic diagnostics is next generation sequencing (NGS). TestGene also has profound experience in this area. Domestic developments will solve the problem of import substitution and significantly reduce the cost of an assay, making it more affordable.

New NGS kits are developed to be used in clinical diagnostics of oncological diseases, as well as for conducting selective screening assays to identify risk groups.

- The NGS method has high sensitivity and specificity and allows to detect all possible mutations in the tested genes.
- The assay procedure is simplified to the level of standard PCR.
- The report is prepared using TestGene's in-house **XplainBio** bioinformatics platform, which performs all stages of the analysis automatically.

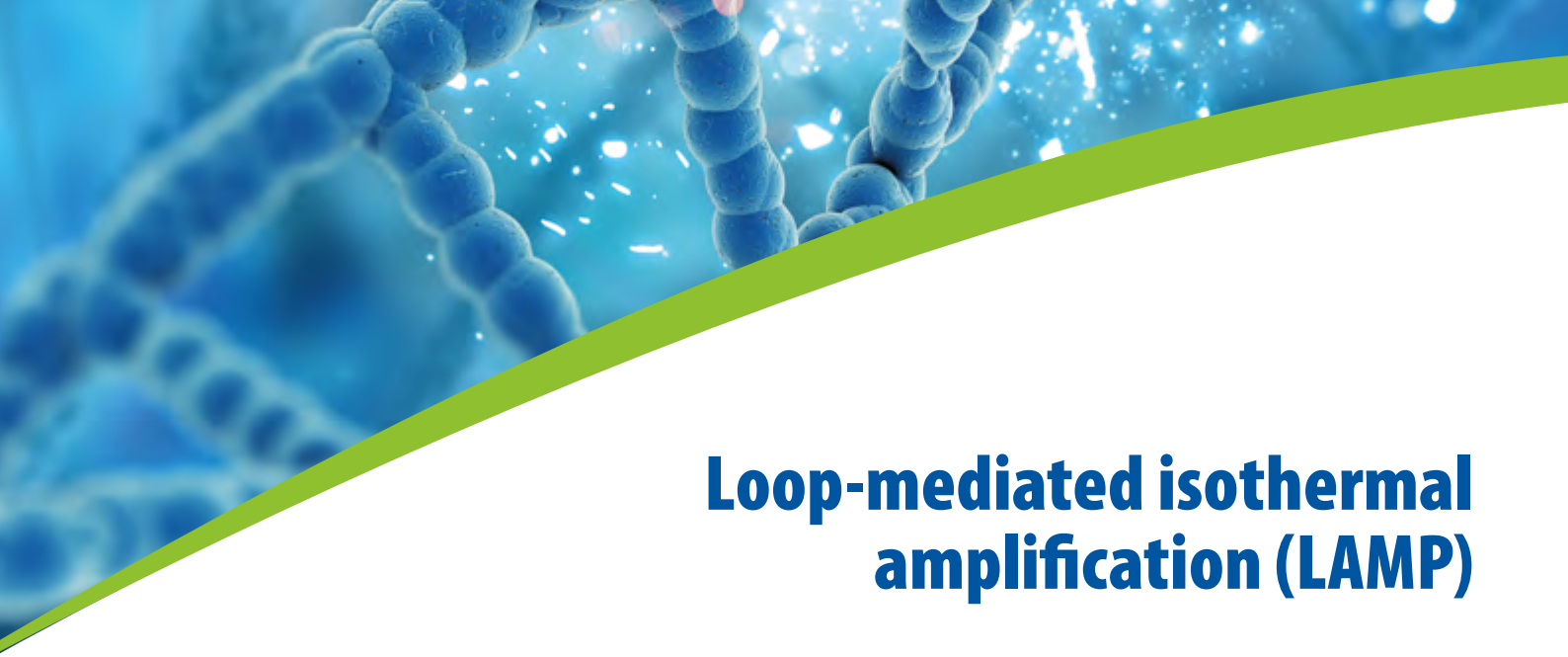
Bioinformatics in NGS: interpretation of results with automation of all stages of the assay

TestGene has developed a flexible and secure **XplainBio** cloud platform based on artificial intelligence technologies. The platform is designed to interpret the results of the NGS analysis. The support module helps doctors make reasonable decisions on treatment tactics.

- Modern bioinformatic algorithms are used to search for the pathogenic gene variants in whole genome sequencing data.
- Automatic processing of genomes, exomes and targeted panels is performed.
- International databases of genetic variants and more than 80 different sources of information are used for the most complete description of genes and mutations.
- The result is represented in the form of a clear report and does not require knowledge of bioinformatics.
- Result in less than 30 minutes.

Storage and processing of the uploaded data is perdormed in Russian data centers that comply with the requirements of 152-FZ "On personal data" Federal Law of the Russian Federation.

More than 30,000 samples have been processed using the platform.



Loop-mediated isothermal amplification (LAMP)

Molecular genetic assays based on loop-mediated isothermal amplification are becoming increasingly common in clinical practice.

The LAMP method makes it possible to conduct the same assay as the PCR-based one but faster and more specific with no expensive equipment or qualified personnel required.

- In contrast to PCR, LAMP-based amplification is performed at a constant temperature without the thermal cycling step making it possible to replace the thermal cycler with a common thermostat. Thus the assay is more affordable, including the cases of diagnostics with limited resources.
- Reverse transcription is performed at the same temperature as amplification during LAMP reaction.
- LAMP is not affected by the presence of biological components. The sample can be added to the reaction mix without purification.

TestGene has developed and successfully brought to the market a high-precision LAMP-base test-kit for diagnostics of SARS-CoV-2. With sample-to-result in just 25 minutes and easy result identification (with the unaided eye due to colorimetric detection) the kit significantly increases the capacity of laboratories. The kit features internal control sample, it is also possible to directly add the transport medium with a respiratory swab into the reaction mix skipping the nucleic acid extraction stage.

LAMP is promising to be an excellent nucleic acids detection instrument. The company is working on more LAMP-based kits.

Lateral flow test (LFT)

Express testing by the LFT method is actively used in medical practice globally. The COVID-19 pandemic has demostrated high availability and effectiveness of the method during screening assays, including the "field" ones. The use of rapid tests has made it possible to reduce the speed of spread of the novel coronavirus infection by quick isolation of the patients with positive test results.

High sensitivity and specificity, fast and reliable results without the use of specialized equipment and the possibility of conducting an assay on the spot make LFT testing one of the most popular methods.

Rapid tests have a wide range of applications and are used to diagnose diseases and life-threatening conditions. They are used at the patient's bedside, in the emergency rooms in hospitals, in outpatient practice, as part of medical examinations. Rapid testing makes it possible to reduce the number of labor-intensive laboratory tests, quickly and efficiently exclude or confirm the presence of a disease, and take the necessary measures in a timely manner, which is especially important for asymptomatic diseases.

TestGene is expanding its product line of LFT kits. In-house high-tech production line guarantees high product quality and ensures uninterrupted supply.

Detection of genes and identification of polymorphisms and mutations

TestGene develops test-kits for molecular genetic assays in the field of monogenic and multifactorial hereditary diseases, oncology and prenatal diagnostics by real-time PCR and PCR followed by sequencing, which makes it possible to assess the degree of genetic predisposition to development of a genetic disease.

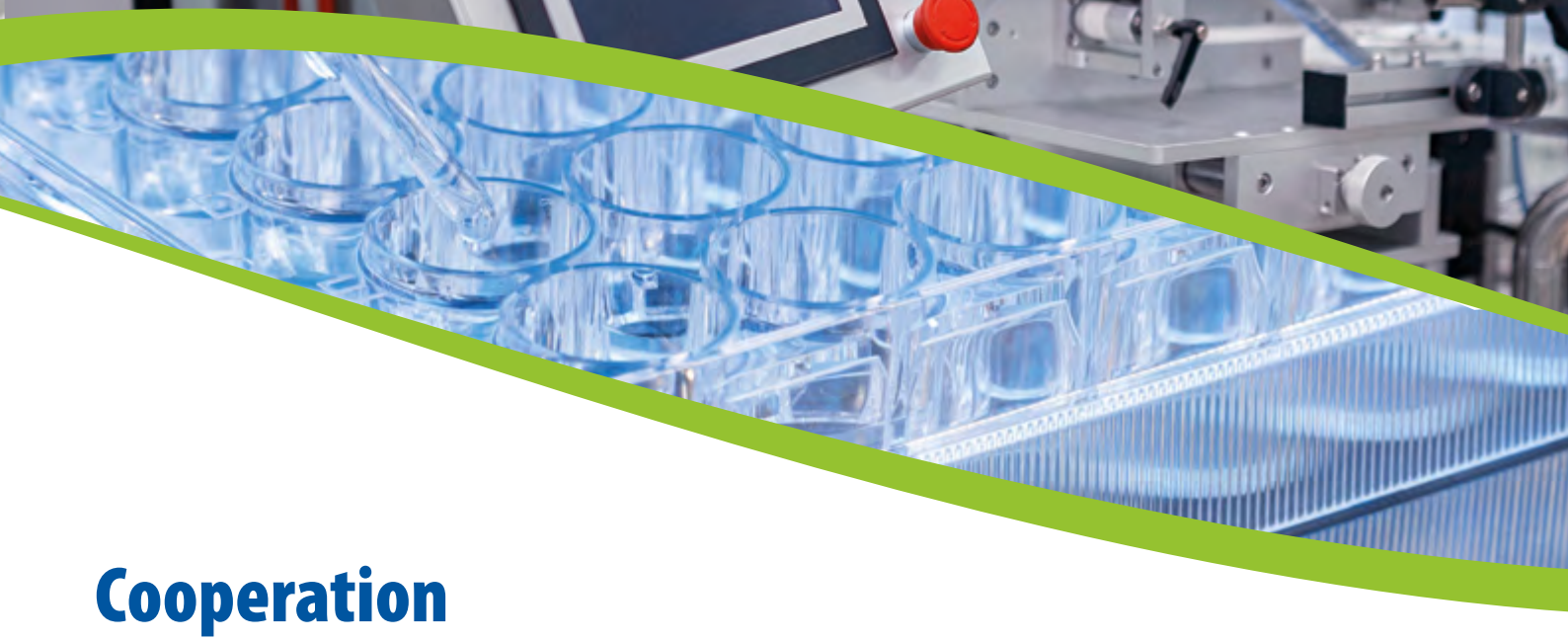
Human genomic DNA isolated from saliva, blood or other biological material is used for the assay.

The company's portfolio includes more than 2000 developments.

Production of mixes of reagents and enzymes for PCR

Full cycle of development and production from enzymes to test-kits guarantees the quality of absolutely all the components used in the kits. Enzymes and mixes for PCR diagnostics developed in-house make it possible to set new trends and create unique products for the market.

TestGene has launched an in-house production of enzymes, among other reasons, following the market's request for high-quality reagents. Nowadays when the trend is set for import substitution this request has become stronger than ever. With practical knowledge of the optimal characteristics of the PCR diagnostics reagens, TestGene is ready to develop and produce mixes and enzymes that meet the requirements of the most signficant participants of the maket.

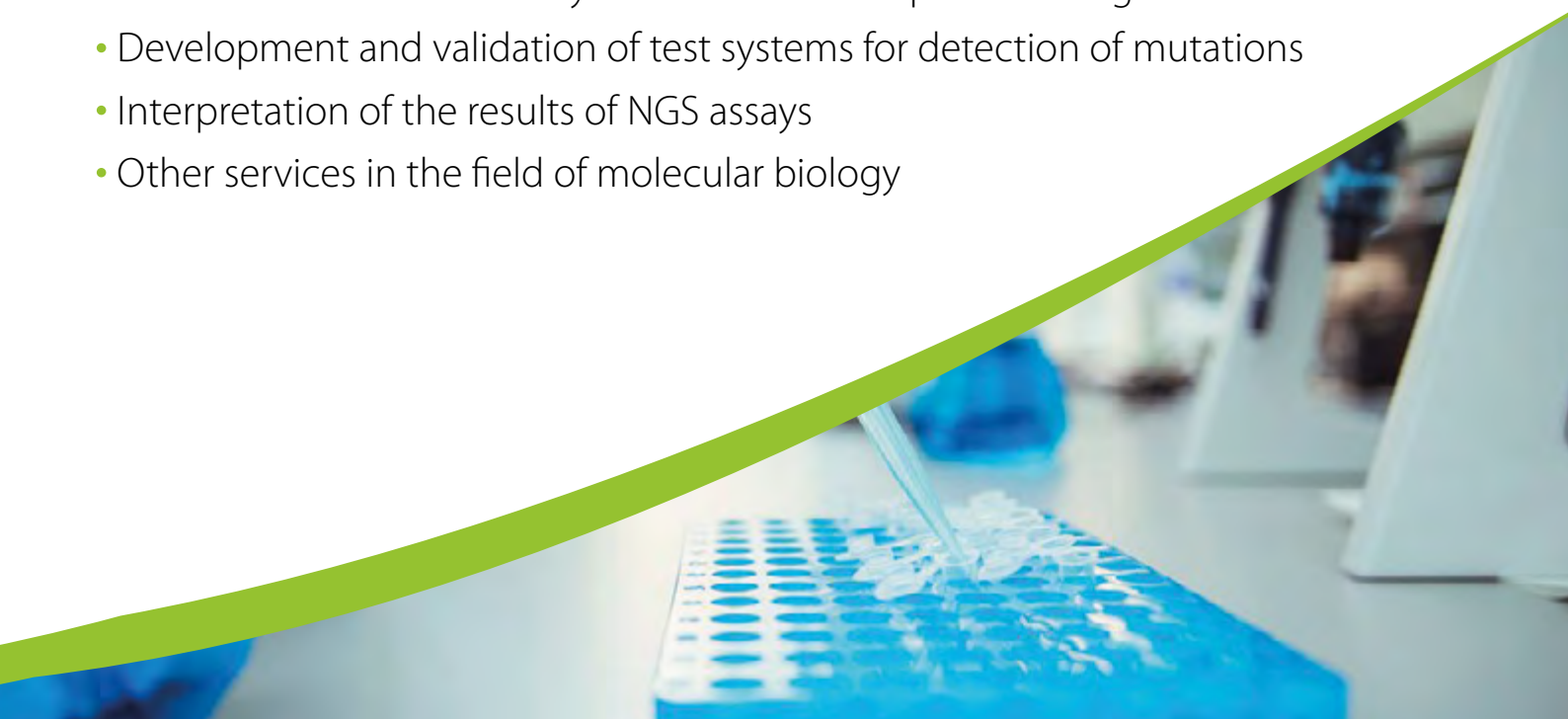


Cooperation

TestGene has profound experience in and in-depth understanding of molecular-genetic R&D process for laboratory diagnostics. We are ready to cooperate with commercial companies and research organizations and participate in projects of any level of complexity.

Services in the field of genetic engineering and molecular biology

- Genotyping of patients' samples (SNP analysis)
- Detection of mutations
- Determination of the degree of heteroplasmy
- Measurement of gene expression
- Detection of translocations, deletions, insertions and duplications
- DNA and RNA sequencing services
- Determination of the methylation status of the promoter regions
- Development and validation of test systems for detection of mutations
- Interpretation of the results of NGS assays
- Other services in the field of molecular biology



TestGene
New generation of genetics

Diagnostics in oncology

Determination of hereditary cancer predisposition

HRR-SCREENING
QUASAR-BRCA1/2

Determination of the medical treatment strategy for oncological diseases

BRCA1,2-DIAGNOSTICS
BRCA1,2-TISSUE

Detection of mutations for prescribing of targeted therapy

TEST-BRAF-TISSUE
TEST-BRAF-TISSUE-MULTI
TEST-EGFR-PLASMA
TEST-EGFR-TISSUE
TEST-EGFR-TISSUE-MULTI
TEST-NRAS-TISSUE
TEST-KRAS-TISSUE

Diagnostics of oncological diseases

PROSTA-TEST
PROSTA-TEST-2.0

Diagnostics and treatment of oncological diseases is impossible to imagine without molecular genetic assays. Detection of mutations in oncogenes makes it possible:

- to diagnose oncological diseases;
- to determine hereditary cancer predisposition;
- to determine the treatment strategy and the expediency of prescribing targeted drugs;
- to predict the rate of development and the course of certain oncological diseases.

TestGene is one of the market leaders in oncology test systems. Successfully proven and unique kits are used by specialists from Russia's leading cancer centres.

HRR-SCREENING

The kit is designed for detection of **16 germline mutations in the HRR** genes and is used in screening for predisposition to breast, ovarian, prostate, pancreatic and stomach cancer.

- In addition to the **8 common mutations**, 8 additional mutations are detected, the most relevant for the Eurasian region.*
- High specificity of the assay.

CHARACTERISTICS	
Method of detection	Real-time PCR (melting curves)
Devices	CFX96, DTprime, DTlight, Rotor-Gene Q, Rotor-Gene 3000 or 6000, QuantStudio 5
Format	Qualitative multiplex
Material	Peripheral blood, buccal scraping
Detection of mutations	**BRCA1** c.5266dupC, c.181T>G, c.5251C>T, c.4035delA, c.5161C>T, c.4675G>A, c.68_69del, c.3700_3704del, c.1961delA **BRCA2** c.3749dupA, c.961_962insAA **CHEK2** c.470T>C, c.1100delC, c.444+1G>A, c.893_897del **PALB2** c.1592delT
Number of reactions	48
Storage and transportation conditions	-16 . . .-24 °C, 12 months + 2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 5 times
Analytical sensitivity	10 copies of the BRCA1, BRCA2, CHEK2, PALB2 genes in 1 µl of DNA solution
Sensitivity	100 % (with a confidence level of 95 %)
Specificity	100 % (with a confidence level of 95 %)
Time for 1 analysis	90 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

* *information on the frequency of hereditary mutations in the genes of the DNA repair system (homologous recombination repair, HRR) is contained in the oncoBRCA database obtained as part of the Hereditary syndromes in the Russian Federation project, https://oncobrca.ru/*

QUASAR-BRCA1/2

The kit is designed for detection of **germline and somatic mutations in the BRCA1, BRCA2** genes and is recommended for screening for hereditary forms of **breast cancer, ovarian cancer** in potentially healthy women and for examining patients diagnosed with breast and ovarian cancer in order to determine an effective treatment strategy and predict the effectiveness of the treatment.

- All mutations in the coding regions of the BRCA1 and BRCA2 genes, as well as in adjacent intron regions, are determined.
- Easy to prepare libraries.
- High specificity and sensitivity of the assay.
- A free automated bioinformatics analysis system that makes interpretation of the obtained data easier.

CHARACTERISTICS		
Method of detection	Real-time PCR + mass parallel sequencing (NGS)	
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio, Illumina MiSeq with GenerateFastq module, Illumina NextSeq. Device for measuring the concentration and purity of NA. *It's necessary to use Illumina MiSeq Reagent Kit v3 (600-cycles) MS-102-3003 (Illumina, USA)*	
Type of analysis	Qualitative	
Material	Whole blood / Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)	
Detection of mutations	BRCA1, BRCA2: all mutations of coding exons and adjacent intron regions	
Number of reactions	48 / 96 / 192 with simultaneous testing by Quasar-BRCA1/2-96A and Quasar-BRCA1/2-96B kits	
Storage and transportation conditions	Packing №1 -15 . . .-25 °C, 12 months + 2 . . .+8 °C, up to 5 days freezing / thawing is allowed for up to 5 times	Packing №2 + 2 . . .+8 °C, 12 months + 2 . . .+30 °C, up to 5 days
Analytical sensitivity	300 copies of the BRCA1, BRCA2 genes in 1 µl of DNA solution	
Sensitivity	Whole blood 94,22-100 %	Tissue 90,75-100 %
Specificity	Whole blood 91,78-100 %	Tissue 88,06-100 %
Time for preparing analyses for sequencing	4-5 hours	
Presence of RC	✓	

Assay stages


Primary amplification


Cleaning libraries


Secondary amplification


Sequencing

BRCA1,2-DIAGNOSTICS

The kit is designed for detection of **16 germline mutations in the BRCA1 and BRCA2** genes and is used in diagnostics of hereditary forms of breast, ovarian, pancreatic and stomach cancer to determine an effective treatment strategy.

- In addition to the **8 common mutations**, **8 additional** mutations are detected, the most relevant for the Eurasian region.*
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR (melting curves)
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Peripheral blood, buccal smear
Detection of mutations	**BRCA1** c.5266dupC, c.181T>G, c.5251C>T, c.5161C>T, c.4035delA, c.1961delA, c.4675G>A, c.68_69del, c.3700_3704del, c.4689C>G, c.3756_3759del **BRCA2** c.3749dupA, c.961_962insAA, c.2897_2898del, c.8754+1G>A, 6174delT
Number of reactions	48
Storage and transportation conditions	-16 . . . -24 °C, 12 months +2 . . . +8 °C, up to 30 days +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the BRCA1, BRCA2 gene in 1 µl of DNA solution
Sensitivity	100 % (with a confidence level of 95 %)
Specificity	100 % (with a confidence level of 95 %)
Time for 1 analysis	90 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

* *information on the frequency of hereditary mutations in the genes of the DNA repair system (homologous recombination repair, HRR) is contained in the oncoBRCA database obtained as part of the Hereditary syndromes in the Russian Federation project, https://oncobrca.ru/*

BRCA1,2-TISSUE

The kit is designed for detection of **16 somatic mutations in the BRCA1, BRCA2** genes and is used in the examination of patients with hereditary forms of breast, ovarian, pancreatic and stomach cancer. The assay allows for prediction of the course of the disease and determination of an effective treatment strategy both with targeted drugs and various chemotherapy regimens.

- In addition to the **8 common mutations, 8 additional mutations** are detected, the most relevant for the Eurasian region.*
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR (melting curves)
Devices	CFX96, ДТпрайм, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	**BRCA1** c.5266dupC, c.181T>G, c.5251C>T, c.5161C>T, c.4035delA, c.1961delA, c.4675G>A, c.68_69del, c.3700_3704del, c.4689C>G, c.3756_3759del **BRCA2** c.3749dupA, c.961_962insAA, c.2897_2898del, c.8754+1G>A, 6174delT
Number of reactions	48
Storage and transportation conditions	-16…-24 °C, 12 months +2 …+8 °C, up to 30 days +15 …+25 °C, up to 5 days
Analytical sensitivity	10 copies of the BRCA1, BRCA2 genes in 1 µl of DNA solution
Sensitivity	100 % (with a confidence level of 95 %)
Specificity	100 % (with a confidence level of 95 %)
Time for 1 analysis	90 min.
Presence of RC	✓

Assay stages

* *information on the frequency of hereditary mutations in the genes of the DNA repair system (homologous recombination repair, HRR) is contained in the oncoBRCA database obtained as part of the Hereditary syndromes in the Russian Federation project, https://oncobrca.ru/*

TEST-BRAF-TISSUE

The kit is used in the examination of patients diagnosed with stage III-IV **metastatic melanoma** to determine indications for targeted therapy.

- Detection of **3 mutations** in the BRAF gene.
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LC96, Abbot m2000rt
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	V600E и V600E complex, V600K
Number of tests	5 / 24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days freezing during transportation up to 5 days
Analytical sensitivity	10 copies of the BRAF gene in 1 µl of DNA solution
Sensitivity	89,1 %
Sensitivity	94,4 %
Time for 1 analysis	60 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

The reagent kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the BRAF gene mutations to determine indications for targeted therapy.

TEST-BRAF-TISSUE-MULTI

The kit is used in the examination of patients diagnosed with **melanoma, papillary thyroid cancer, ovarian, colorectal and prostate cancer** to determine indications for targeted therapy.

- Detection of **7 mutations** in the BRAF gene.
- High specificity and sensitivity of the assay.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	V600E, V600E complex, V600K, V600R, V600D, V600Dc, V600M
Number of tests	24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the BRAF gene in 1 µl of DNA solution
Sensitivity	100 % (with a confidence level of 95 %)
Specificity	100 % (with a confidence level of 95 %)
Time for 1 analysis	60 min.
Presence of RC	✓

Assay stages

The kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the BRAF gene mutations to determine indications for targeted therapy.

TEST-EGFR-PLASMA

The kit is used in the examination of patients diagnosed **with non-small cell lung cancer (NSCLC)** to determine indications for targeted therapy with the EGFR tyrosine kinase inhibitors and monitor the response to them.

- Detection of **29 mutations** in the EGFR gene.
- The liquid biopsy method allows for continuous monitoring of the patient's condition and making prompt changes to the treatment program.
- Can be used when adequate tumor material is not available.
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative monoplex
Material	Blood plasma
Detection of mutations	L858R, T790M, 27 deletions (del) in exon 19
Number of tests	12 / 24
Storage and transportation conditions	-18 . . .-25 °C, 12 months +2 . . .+8 °C, up to 3 days
Analytical sensitivity	1 copy of the EGFR gene in 1 µl of DNA solution
Sensitivity	90,75 %
Specificity	96,52 %
Time for 1 analysis	from 120 min.
Presence of RC	✓

Assay stages

Collection of biomaterial

DNA isolation

Amplification of specific targets

Hybridization fluorescence detection

The reagent kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the EGFR gene mutations to determine indications for targeted therapy.

TEST-EGFR-TISSUE

The kit is used in the examination of patients diagnosed with **non-small cell lung cancer (NSCLC)** to determine indications for targeted therapy with the EGFR tyrosine kinase inhibitors and monitor response to them.

- Detection of **28 mutations** in the EGFR gene.
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LC96, Abbot m2000rt
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	L858R, 27 deletions (del) in exon 19
Number of tests	5 / 24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the EGFR gene in 1 µl of DNA solution
Sensitivity	90,9 %
Specificity	94,3 %
Time for 1 analysis	60 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

The reagent kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the EGFR gene mutations to determine indications for targeted therapy.

TEST-EGFR-TISSUE-MULTI

The kit is used in the examination of patients diagnosed with **non-small cell lung cancer stage** IB–IIIA and IV of the disease to determine indications for targeted therapy with the EGFR tyrosine kinase inhibitors and monitor response to them.

- Detection of **48 mutations** in the EGFR gene.
- High specificity and sensitivity of the assay.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	**Exon 18** detects the G719S, G719C, G719D, G719A mutations but does not differentiate them **Exon 19** detects 35 mutations but does not differentiate them **Exon 20** detects the S768I, T790M mutations but does not differentiate them **Exon 21** detects the L858R and L861Q mutations but does not differentiate them
Number of tests	24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the EGFR gene in 1 µl of DNA solution
Sensitivity	100 % (with a confidence level of 95 %)
Specificity	100 % (with a confidence level of 95 %)
Time for 1 analysis	60 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

The kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the EGFR gene mutations to determine indications for targeted therapy.

TEST-NRAS-TISSUE

The kit is used in the examination of patients diagnosed with **colorectal cancer** to determine indications for targeted therapy.

- Detection of **8 mutations** in the NRAS gene.
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LC96, Abbot m2000rt
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	**Codon 12** Gly12Asp, Gly12Cys, Gly12Ser **Codon 13** Gly13Asp, Gly13Arg **Codon 61** Gln61Lys, Gln61Leu, Gln61Arg
Number of tests	5 / 24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the NRAS gene in 1 µl of DNA solution
Sensitivity	94,1 % (with a confidence level of 90 %)
Specificity	89,1 % (with a confidence level of 90 %)
Time for 1 analysis	60-80 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

The reagent kits cannot be used to diagnose any pathology and are designed only for qualitative determination of the status of the NRAS gene mutations to determine indications for targeted therapy.

TEST-KRAS-TISSUE

The kit is used in the examination of patients diagnosed with **colorectal cancer** to determine indications for targeted therapy.

- Detection of **7 mutations** in the KRAS gene.
- High specificity and sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LC96, Abbot m2000rt
Format	Qualitative multiplex
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)
Detection of mutations	**Codon 12** Gly12Asp, Gly12Ala, Gly12Arg, Gly12Val, Gly12Ser, Gly12Cys **Codon 13** Gly13Asp
Number of tests	5 / 24
Storage and transportation conditions	+2 . . . +8 °C, 12 months +15 . . . +25 °C, up to 5 days
Analytical sensitivity	10 copies of the KRAS gene in 1 µl of DNA solution
Sensitivity	90,9 %
Specificity	95 %
Time for 1 analysis	60 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

The kits cannot be used in diagnostics of any pathology and are designed only for qualitative determination of the KRAS gene mutation status to determine indications for targeted therapy.

PROSTA-TEST

The kit is designed for non-invasive diagnostics **of prostate cancer**. The assay determines the level of expression of the **PCA3 gene, specific for prostate cancer**, in relation to the level of the KLK3 gene, characteristic only for prostate tissue.

- High specificity and sensitivity of the assay.
- Material for the assay can be collected without special preparation of the patient.

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Semi-quantitative monoplex
Material	Urine
Detection of mutations	The ratio of the amount of the PCA3 gene mRNA relative to the level of the KLK3 gene mRNA
Number of tests	12 / 24
Storage and transportation conditions	-20 . . . -40 °C, 12 months -18 . . . -25 °C, up to 30 days +2 . . . +8 °C, up to 3 days
Analytical sensitivity	100 RNA copies
Sensitivity	78,3 %
Specificity	81,5 %
Time for 1 analysis	about 180 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

PROSTA-TEST-2.0

The kit is designed for early non-invasive diagnosis of **prostate cancer** by detection of the **TMPRSS2-ERG chimeric gene** and determination of the level of expression of the **PCA3 gene**, specific for prostate cancer, in relation to the level of the KLK3 gene, characteristic only for prostate tissue.

- Use of **2 targets**.
- High specificity and sensitivity of the assay.
- It is an additional criterion when prescribing a primary or repeated prostate biopsy to a patient.
- Material for the assay can be collected without special preparation of the patient.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative / semi-quantitative multiplex
Material	Urine
Detection of mutations	Chimeric gene TMPRSS2-ERG The amount of mRNA of the PCA3 gene in relation to the KLK3(PSA) gene
Number of tests	12 / 24
Storage and transportation conditions	-16 . . .-24 °C, 12 months freezing / thawing is allowed up to 10 times
Analytical sensitivity	10 copies/µl
Sensitivity	87,5-100 %
Specificity	100 %
Time for 1 analysis	180 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

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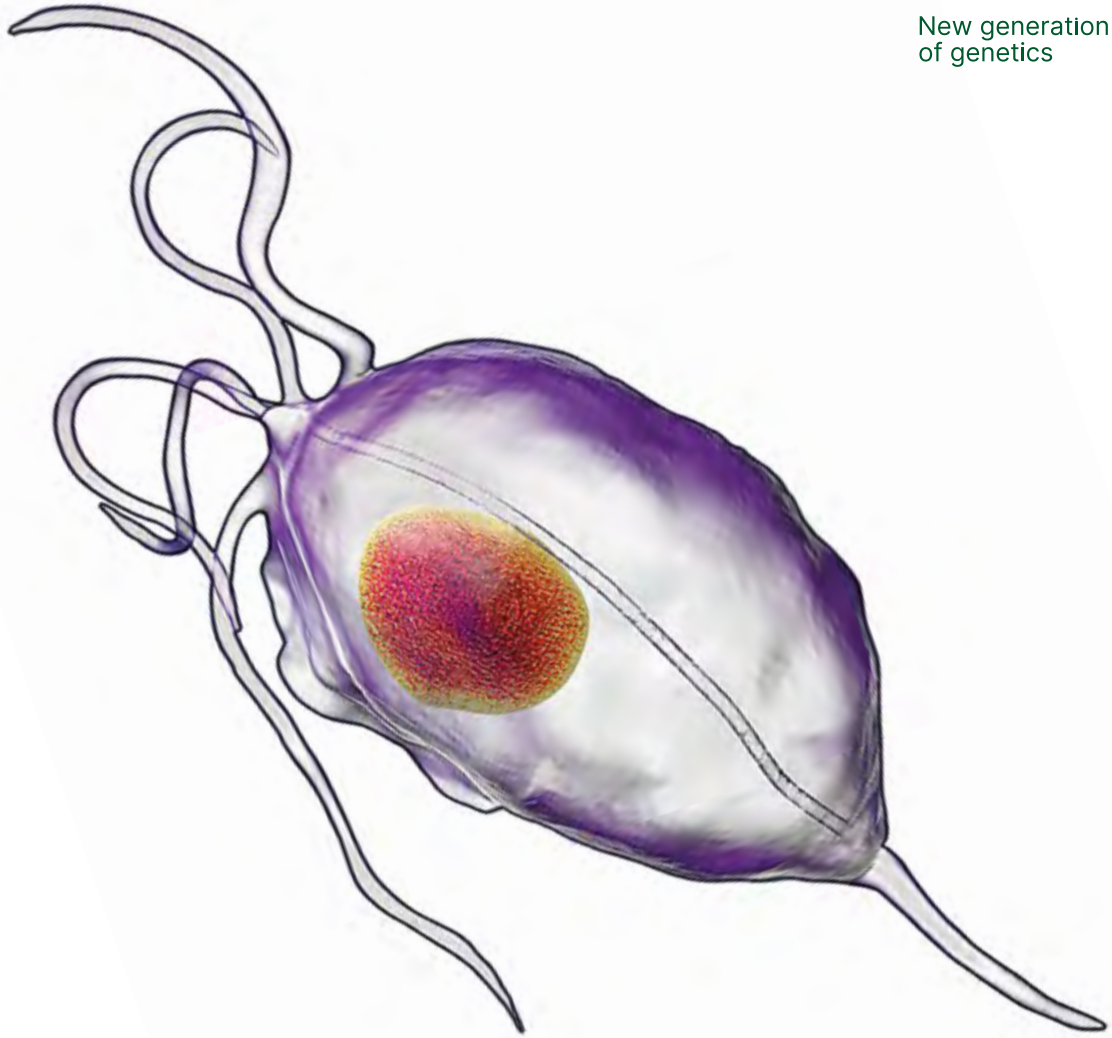
TestGene
New generation
of genetics



Diagnostics of urogenital infections

Test systems for detection
of STI pathogens

UROGEN-TEST-5
UROGEN

Urogenital infections are one of the most common infections. In many cases there are no symptoms or a characteristic clinical picture. Mixed infections caused by several pathogens are common. The asymptomatic course often leads to late visits to the doctor and the development of serious complications, such as infertility, as well as congenital fetal diseases in case of intrauterine transmission.

The speed of obtaining the result, high sensitivity and specificity determine the clinical significance and convenience of the PCR method.

The UROGEN-TEST-5 and UROGEN kits allow for detection of causative agents of the most common urogenital infections.

UROGEN-TEST-5

The kit is designed for detection of DNA of 5 pathogens of urogenital infections.

- Multiple targets in a test tube reduce the chance of mistakes during the test.
- The speed of obtaining results increases the productivity of the laboratory.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Vaginal swabs, cervical/urethral scraping, cell sediment from the first portion of freely voided urine, prostate secretion
Detection	Mycoplasma genitalium, Ureaplasma urealyticum, Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis
Number of reactions	96
Storage and transportation conditions	-20 °C, 12 months +2 . . . +8 °C, up to 30 days at room temperature but not exceeding +30 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	500 copies/ml
Sensitivity	90-100 %
Specificity	100 %
Time for 1 analysis	60 min.
Variants	5 infections / Mycoplasma genitalium, Ureaplasma urealyticum / Trichomonas vaginalis, Neisseria gonorrhoeae / Chlamydia trachomatis
Presence of RC	✓

Assay stages

UROGEN

The kit is designed for detection of DNA of 12 pathogens of urogenital infections.

- 5 tubes for analysis of 12 infections.
- The kit contains sampling volume control.
- The speed of obtaining results increases the productivity of the laboratory.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, FLUORITE
Format	Qualitative multiplex
Material	Swabs from the mucous membrane of the vagina, scraping from the cervical canal, scraping from the urethra, the first portion of freely released urine, prostate secretion.
Detection	Chlamydia trachomatis, Mycoplasma genitalium, Neisseria gonorrhoeae, Ureaplasma urealyticum, Trichomonas vaginalis, Mycoplasma hominis, Ureaplasma parvum, Gardnerella vaginalis, Candida albicans, CMV (Human betaherpesvirus 5), HSV1 (Human alphaherpesvirus 1), HSV2 (Human alphaherpesvirus 2)
Number of reactions	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months / +2 . . .+8 °C, up to 90 days / +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	500 copies/ml
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	60-80 min.
Variants	12 infections / Chlamydia trachomatis, Mycoplasma genitalium / Neisseria gonorrhoeae, Trichomonas vaginalis / Human betaherpesvirus 5 (CMV), Human alphaherpesvirus 1 (HSV1), Human alphaherpesvirus 2 (HSV2) / Mycoplasma hominis, Ureaplasma urealyticum, Ureaplasma parvum / Candida albicans, Gardnerella vaginalis
Presence of RC	Check with the sales department

Assay stages

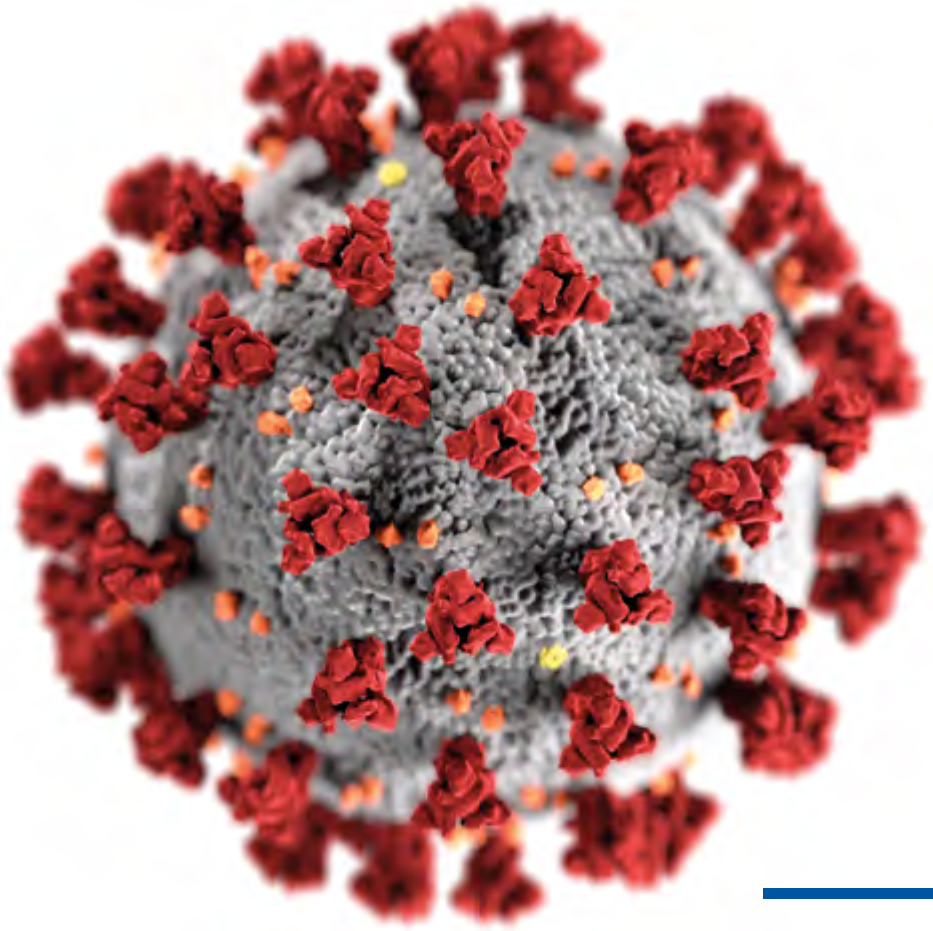

Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

TestGene
New generation of genetics



Diagnostics of respiratory infections

Test systems for high-precision detection of the coronavirus infection

GT ANTIGEN COVID-19
SARS-COV-2 ANTIGEN HOME TEST
GT COV-INFLU ANTIGEN TEST
COV-INFLU-TEST
COV-2-FAST-TEST
COV-2-TEST
COV-2-TEST-DIF-O
COV-2-COLOR-TEST

It is important to diagnose acute respiratory viral infections accurately and quickly. One of the reasons for the development of serious complications is the late seeking medical help and diagnosis without laboratory diagnostics. TestGene offers a comprehensive solution:

• PCR tests make it possible to determine the presence/absence of RNA of the influenza A and B viruses and SARS-CoV-2 in biomaterial, as well as to differentiate the Omicron strain.

• The loop-mediated isothermal amplification (LAMP) diagnostic kit provides accurate results without the use of a thermal cycler.

• The rapid test is used to quickly detect the influenza A and B viruses and SARS-CoV-2 in the acute phase of infection. It is possible to use the kit at the bedside of the patient and in conditions of limited access to laboratory diagnostics.

GT ANTIGEN COVID-19

The rapid test is designed to diagnose a respiratory viral infection caused by the SARS-CoV-2 coronavirus.

- A fast alternative to PCR diagnostics.
- No equipment is required.
- Infection is detected in the early stages.
- Wide storage temperature range.

CHARACTERISTICS	
Detection method	LFT (lateral flow test)
Analysis type	Qualitative
Material	Oropharyngeal / nasopharyngeal swabs
Detection of	Protein N
Number of detections	1 / 25
Storage and transportation conditions	-30 . . . +30 °C, 20 months keep test cassettes sealed until use
Sensitivity	Oropharyngeal swab 98,15 % Nasopharyngeal swab 95,83 %
Specificity	100 %
Obtaining of the result	within 10 min.
Packaging options	Bulk / in individual zip bags / individually packed
Presence of RC	✓

Assay stages


Collection of biomaterial


Proceeding of the sample in a tube with buffer


Applying the sample to the test cassette

Interpretation of the results

Rapid tests have high specificity, constantly undergo detection tests and detect all known strains of SARS-COV-2.

SARS-COV-2 ANTIGEN HOME TEST

The rapid test is designed to diagnose a respiratory viral infection caused by the SARS-CoV-2 coronavirus.

- A fast alternative to PCR diagnostics.
- No equipment is required.
- **Used at home.**
- Infection is detected in the early stages.
- Wide storage temperature range.

CHARACTERISTICS	
Detection method	LFT (lateral flow test)
Analysis type	Qualitative
Material	Nasopharyngeal swabs
Detection of	Protein N
Number of detections	1 / 5 / 25
Storage and transportation conditions	-30 . . . +30 °C, 24 months keep test cassettes sealed until use
Analytical sensitivity	0,4 ng/ml
Sensitivity	92,73 %
Specificity	100 %
Obtaining of the result	within 10 min.
Packaging options	Bulk / individually packed
Presence of RC	✓

Assay stages


Collection of biomaterial


Processing of the sample in a test tube with buffer


Applying the sample to the test cassette

Interpretation of the results

✓ *Rapid tests have high specificity, constantly undergo detection tests and detect all known strains of SARS-COV-2.*

GT COV-INFLU ANTIGEN TEST

The rapid test is designed for diagnostics and differentiation of the most dangerous respiratory viral infections: **coronavirus and influenza A and B.**

- Fast alternative to PCR diagnostics.
- No equipment is required.
- Infections are detected at early stages.
- Wide range of storage temperatures.

CHARACTERISTICS	
Detection method	LFT (lateral flow test)
Type of analysis	Qualitative
Material	Oropharyngeal / nasopharyngeal swabs
Detection of	**SARS-CoV-2** N protein **Influenza A** M1 protein **Influenza B** NP protein
Number of tests	25
Storage and transportation conditions	-30 . . . +30 °C, 24 months keep test cassettes sealed until use
Sensitivity	Oropharyngeal swab 89,66-92 % Nasopharyngeal swab 92-96 %
Specificity	100 %
Obtaining of the result	within 10 min.
Packaging options	Bulk / in individual zip bags
Presence of RC	✓

Assay stages


Collection of biomaterial


Proceeding of the sample in a tube with buffer


Applying the sample to the test cassette


Interpretation of the results

The rapid tests have a high level of specificity, constantly pass detection tests and detect all known SARS-CoV-2 strains.

COV-INFLU-TEST

The kit is designed for diagnostics of the respiratory viral infection caused by the SARS-CoV-2 coronavirus and influenza A and B viruses.

- Detection of the SARS-CoV-2 virus using **2 targets.**
- Detection of all known strains of the **influenza A and B.**
- High sensitivity and specificity of the assay.
- One test tube per patient.

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Oropharyngeal / nasopharyngeal swabs, sputum
Revealed	**SARS-CoV-2 -** N and RdRp gene fragments **Influenza A -** M1 gene fragment **Influenza B -** NP gene fragment
Number of reactions	96
Storage and transportation conditions	-18 . . . -22 °C, 12 months +2 . . . +8 °C, up to 30 days +15 . . . +25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	~1000 copies/ml
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	100-125 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

The test systems are highly specific, constantly undergo detection tests and detect all known strains of SARS-CoV-2.

COV-2-FAST-TEST

The kit is designed for diagnostics of the respiratory viral infection caused by the SARS-CoV-2 coronavirus.

Isolation of RNA from clinical material is not required.

- Reliable result in 80-100 minutes.
- Possibility of performing the assay in one test tube.
- Detection of conservative regions of the gene that are not susceptible to mutations.
- High sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time RT-PCR without the isolation step
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Oropharyngeal / nasopharyngeal swabs
Detection of	N gene fragment
Number of reactions	94
Storage and transportation conditions	-16 . . .-24 °C, 18 months at +4 °C, up to 3 days
Analytical sensitivity	~600 copies/ml
Sensitivity	94,0-100 %
Specificity	91,2-100 %
Time for 1 analysis	80-100 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RT-amplification of specific targets


Hybridization fluorescence detection

The test systems are highly specific, constantly undergo detection tests and detect all known strains of SARS-CoV-2.

COV-2-TEST

The kit is intended for diagnostics of the respiratory viral infection caused by the SARS-CoV-2 coronavirus.

- Possibility of performing the assay in one test tube.
- Detection of conservative regions of the gene that are not susceptible to mutations.
- High sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, DTlite, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Oropharyngeal / nasopharyngeal swabs
Revealed	N gene fragment
Number of reactions	96
Storage and transportation conditions	not exceeding -20 °C, 18 months at +4 °C, up to 10 days +15 . . .+25 °C, up to 2 days
Analytical sensitivity	500 copies/ml
Sensitivity	96-100 %
Specificity	96-100 %
Time for 1 analysis	120 min.
Variants	With a kit for RNA extraction / without a kit for RNA extraction
Presence of RC	✓

Assay stages

The test systems are highly specific, constantly undergo detection tests and detect all known strains of SARS-CoV-2.

COV-2-TEST-DIF-0

The kit is designed for diagnostics of the respiratory viral infection caused by the SARS-CoV-2 coronavirus with differentiation of the B.1.1.529 variant (Omicron). The study is important for making a differentiated diagnosis and solving epidemiological problems.

- The use of the kit without the stage of RNA isolation greatly increases laboratory productivity.
- Performing the assay in one test tube.
- High sensitivity of the assay.

CHARACTERISTICS	
Detection method	Real-time RT-PCR with RNA isolation / without the isolation step
Devices	CFX96, DTprime, DTlite, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Oropharyngeal / nasopharyngeal swabs
Revealed	Gene N, including mutations Δ31-33 in the "Omicron" gene N
Number of tests	94
Storage and transportation conditions	-18 . . . -22 °C, 18 months / +2 . . . +6 °C, up to 30 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	~600 copies/ml - complete with RNA isolation ~1000 copies/ml - complete without RNA isolation
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	80-100 min.
Variants	Without the stage of RNA isolation / with a kit for RNA extraction / without a kit for RNA extraction
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation / without isolation


RT-amplification of specific targets


Hybridization fluorescence detection

The test systems are highly specific, constantly undergo detection tests and detect all known strains of SARS-CoV-2.

COV-2-COLOR-TEST

The kit is designed for diagnostics of the respiratory viral infection caused by the SARS-CoV-2 coronavirus.

- The assay is performed with the use of a thermostat or a cycler.
- RNA isolation is not required.
- The IC sample is included in the kit to control false negative results.
- Visual interpretation of the test results.
- Reliable result in 25 minutes.

CHARACTERISTICS	
Detection method	LAMP
Devices	Thermostat TDB-120 / CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Oropharyngeal / nasopharyngeal swabs
Revealed	N gene fragment
Number of reactions	92
Storage and transportation conditions	-15 . . .-25 °C, 12 months freezing / thawing is allowed up to 10 times
Analytical sensitivity	$2,5x10^4$ copies/ml with RNA isolation 10^5 copies/ml without RNA isolation
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	25 min.
Presence of RC	✓

Assay stages

The test systems are highly specific, constantly undergo detection tests and detect all known strains of SARS-CoV-2.

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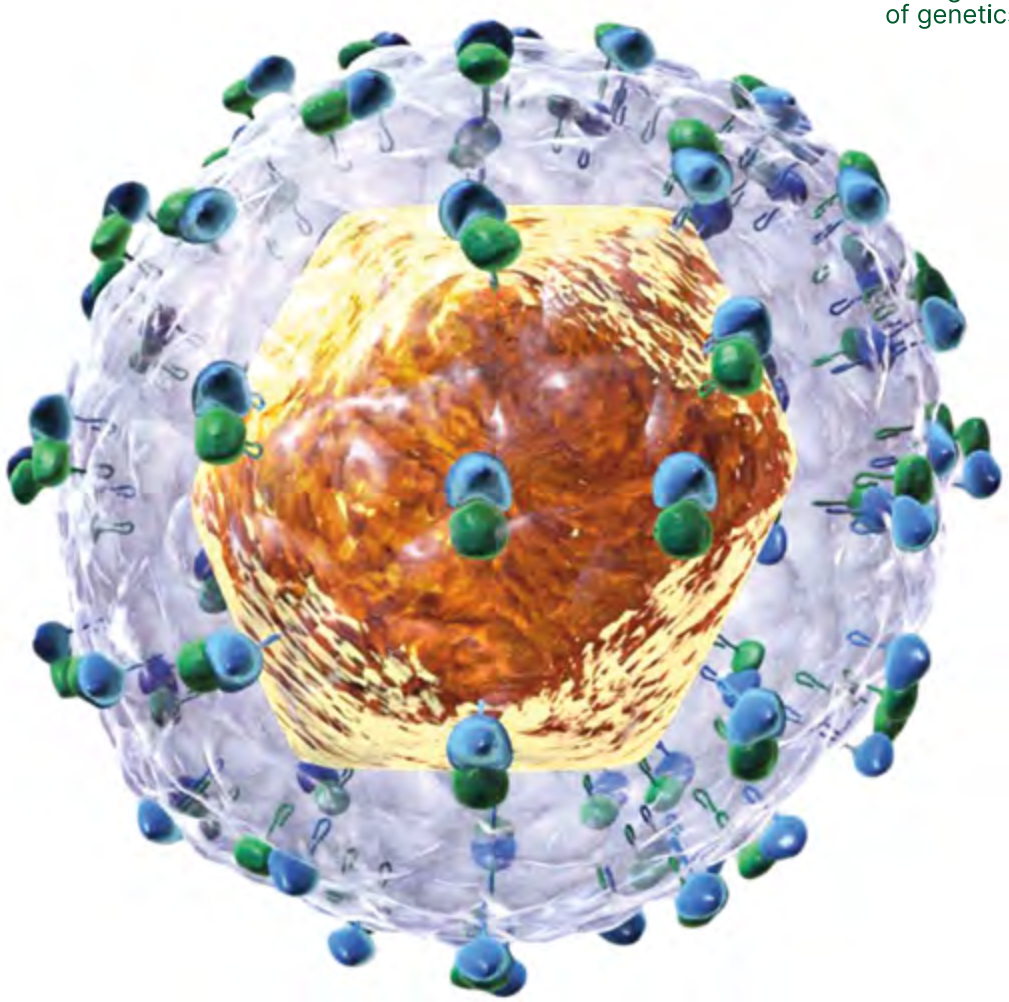
New generation of genetics



Diagnostics of hepatitis

Test systems for detection of the hepatitis B, C and D viruses

HEPA-BCD-TEST
HEPA-B-TEST-Q
HEPA-C-TEST-Q
HEPA-D-TEST-Q
HEPA-C-GENE-TEST

Hepatitis B, C, D are the most significant among viral hepatitis. In their diagnostics PCR tests makes it possible:

- to diagnose the disease, to determine its form and phase;
- to determine the viral load;
- to decide on the start of the therapy and monitor its effectiveness. The assay is extremely important for the analysis of donor blood.

Diagnostics of hepatitis D is of particular importance. In the case of co-infection with hepatitis B, acute hepatitis develops which is characterized by a severe course and high fatality. In the case of superinfection (infection with the hepatitis D virus in HBV-positive patients), chronic hepatitis develops with a more severe course of the disease than in patients with chronic hepatitis B.

HEPA-BCD-TEST

The kit is designed for detection and differentiation of the **hepatitis B, C and D** viruses in patients with suspected infection.

- Qualitative detection of specific regions of the hepatitis B virus genomic DNA and the hepatitis C and D virus RNA in one test tube.
- One test tube per patient.
- Possible joint testing with the kits "HEPA-B-TEST-Q", "HEPA-C-TEST-Q", "HEPA-D-TEST-Q", "HEPA-C-GENE-TEST", "HIV-TEST and "HIV-1-TEST-Q".

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Blood plasma
Number of tests	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	Hepatitis B: ~48 IU/ml and hepatitis C: ~100 IU/ml when isolating from 100 µl of plasma
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	120-145 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA / RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

HEPA-B-TEST-Q

The kit is designed for **quantitative** detection of the **hepatitis B** virus DNA in patients with suspected infection and determination of viral load in patients with the detected hepatitis B virus to choose an appropriate therapy and evaluate its effectiveness.

- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.
- Possible joint testing with the kits "HEPA-BCD-TEST", 'HEPA-C-TEST-Q", 'HEPA-D-TEST-Q", "HEPA-C-GENE-TEST", "HIV-TEST" and "HIV-1-TEST-Q".

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Quantitative multiplex
Material	Blood plasma
Number of tests	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	47 IU/ml when isolating from 100 µl of plasma 4,7 IU/ml when isolating from 1000 µl of plasma
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	80-100 min.
Presence of RC	✓

Assay stages

HEPA-C-TEST-Q

The kit is designed for **quantitative** detection of the hepatitis C virus RNA in patients with suspected infection and patients with the detected **hepatitis C** virus in order to choose an appropriate therapy and evaluate its effectiveness.

- Possible joint testing with the kits "HEPA-BCD-TEST", "HEPA-B-TEST-Q", "HEPA-D-TEST-Q", "HEPA-C-GENE-TEST", "HIV-TEST" and "HIV-1-TEST-Q".

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Quantitative multiplex
Material	Blood plasma
Number of tests	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	48 IU/ml when isolating from 100 µl of plasma 7 IU/ml when isolating from 1000 µl of plasma
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	120-145 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation / without isolation


RT-amplification of specific targets


Hybridization fluorescence detection

HEPA-D-TEST-Q

The kit is designed for qualitative and quantitative detection of hepatitis D virus RNA in patients with suspected infection and determination of viral load in patients with detected hepatitis D virus to choose the correct therapy and evaluate its effectiveness.

- Possible joint testing with the kits "HEPA-BCD-TEST", "HEPA-B-TEST-Q", "HEPA-C-TEST-Q", "HEPA-C-GENE-TEST", "HIV-TEST" and "HIV-1-TEST-Q".

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX 96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative / quantitative multiplex
Material	Blood plasma
Number of tests	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	Qualitative detection ~40 IU/ml when isolated from 100 µl of plasma ~9 IU/ml when isolated from 1000 µl of plasma Quantitative detection ~113 IU/ml when isolated from 100 µl of plasma ~13 IU/ml when isolated from 1000 µl of plasma
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	120-145 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

HEPA-C-GENE-TEST

The kit is designed for detection of the hepatitis C virus and its **genotypes (1a, 1b, 2, 3, 4, 5a, 6)** in patients with the detected virus to choose an appropriate antiviral therapy, to predict and evaluate the course of the disease and possible complications.

- Possible joint testing with the kits "HEPA-BCD-TEST", "HEPA-B-TEST-Q", "HEPA-C-TEST-Q", "HEPA-D-TEST-Q", "HIV-TEST" and "HIV-1-TEST-Q".

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Quantitative multiplex
Material	Blood plasma
Number of tests	94 (HEPA-C-GENE-test-A) / 92 (HEPA-C-GENE-test-AB)
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 30 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	~ 77 copies/ml when isolating from 1 000 µl of plasma ~ 1500 IU/ml when isolating from 100 µl of plasma
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	120-145 min.
Configuration forms	HEPA-C-GENE-test-A (detection of genotypes 1a, 1b, 2 and 3) / HEPA-C-GENE-test-AB (detection of genotypes 1a, 1b, 2, 3, 4, 5a and 6)
Presence of RC	✓

Assay stages

TestGene
New generation of genetics

Diagnostics of the human immunodeficiency virus

Test systems for detection of the HIV-1 and HIV-2 viruses

HIV-TEST
HIV-1-TEST-Q

The HIV infection, caused by the HIV-1, HIV-2 viruses, has a devastating effect on the human immune system. Without timely diagnostics and treatment, HIV leads to death due to the activation of opportunistic infections or the development of tumors. The PCR test makes it possible to detect even single viral particles and is used in clinical practice in the following cases:

- early diagnostics of the HIV infection before the appearance of antibodies;
- diagnostics of the HIV status in children born to HIV-infected mothers;
- selection of treatment tactics and assessment of the effectiveness of the antiretroviral therapy;
- additional assay to exclude a misdiagnosis;
- operational examination of donor blood.

HIV-TEST

The kit is designed for detection and differentiation of human immunodeficiency viruses type 1 and 2 (HIV-1 and HIV-2) in order to diagnose the HIV infection and choose an antiretroviral therapy regimen.

Possible joint testing with the kits "HIV-1-TEST-Q", "HEPA-BCD-TEST", "HEPA-B-TEST-Q", "HEPA-C-TEST-Q", "HEPA-D-TEST-Q" and "HEPA-C-GENE-TEST".

CHARACTERISTICS	
Method of detection	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, Quant Studio 5
Format	Qualitative multiplex
Material	Blood plasma
Detection of	HIV-1 – pol gene fragment HIV-2 – 5` and 3` LTR fragments
Number of tests	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 10 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	at least 20 copies/ml of plasma when isolated from 1000 µl of plasma and 50 µl elution volume
Sensitivity	HIV-1: 98,70-100 % HIV-2: 95,49-100 %
Specificity	95,14-100 %
Time for 1 analysis	85-120 min.
Presence of RC	✓

Assay stages

HIV-1-TEST-Q

The kit is designed for quantitative detection of the human immunodeficiency virus (HIV-1) in order to diagnose the HIV infection, choose an antiretroviral therapy regimen, monitor the progression of the HIV infection and/or the effectiveness of the antiretroviral therapy, and is also recommended for dispensary registration.

Possible joint testing with the kits "HIV-TEST", "HEPA-BCD-TEST", "HEPA-B-TEST-Q", "HEPA-C-TEST-Q", "HEPA-D-TEST-Q" and "HEPA-C-GENE-TEST".

CHARACTERISTICS	
Method of detection	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, Quant Studio 5
Format	Quantitative multiplex
Material	Blood plasma
Detection of	pol gene fragment
Number of tests	88
Storage and transportation conditions	-18 . . .-22 °C, 12 months +2 . . .+8 °C, up to 10 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	at least 20 copies/ml of plasma when isolated from 1000 µl of plasma and 50 µl elution volume
Sensitivity	98,70-100 %
Specificity	95,14-100 %
Time for 1 analysis	85-120 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


RNA isolation


RT-amplification of specific targets


Hybridization fluorescence detection

TestGene
New generation of genetics

MTB-TEST
MTB-RESIST-I-TEST
MTB-RESIST-II-TEST

Diagnostics of tuberculosis and determination of antimicrobial resistance

Tuberculosis is one of the most common causes of death in the world.

The MTB-TEST kit for PCR diagnostics allows to quickly obtain the result for prediction of the course and outcome of the disease, is characterized by maximum sensitivity, specificity and informativeness of the analysis. Tuberculosis and non-tuberculous complex mycobacteria are detected in any material in accordance with the localization of the process.

At least three different classes of antibiotics are required to treat tuberculosis. Multidrug resistance significantly complicates and lengthens the treatment process. Timely detection of drug resistance is an important element in the choice of an appropriate therapy. The MTB-RESIST-I-test kit allows to determine drug resistance to rifampicin and isoniazid.

MTB-TEST

The kit is designed for detection of the **tuberculosis and non-tuberculosis complex mycobacteria** and their differentiation in patients with suspected pulmonary and extrapulmonary tuberculosis, mycobacteriosis.

- High sensitivity and specificity of the assay.
- One test tube per patient.
- Detection of the tuberculosis complex mycobacteria using two targets simultaneously, both targets are recorded via one channel (FAM).
- The IC sample is included.
- Fast result.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mix.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Sputum, bronchoalveolar lavage, bronchial washing, gastric washing, pleural fluid, blood, urine, microbiological cultures, prostate secretion, tissue (biopsy and surgical) material, synovial fluid, pericardial fluid and cerebrospinal fluid, washings from environmental objects
Detection and differentiation of	Mycobacterium tuberculosis complex (M. tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. canettii, M. caprae, M. microti) and nontuberculous mycobacteria (M. avium, M. abscessus, M. septicum, M. fortuitum, M. gordonae, M. intracellulare, M. kansasii, M. marinum, M. smegmatis, M. xenopi, M. ulcerans, M. terrae), Mycolicibacterium spp., and Mycobacteroides spp.
Number of reactions	96
Storage and transportation conditions	-18 . . .-22 °C, 12 months / +2 . . .+8 °C, up to 30 days / +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	from 100 copies/ml
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	90-110 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

MTB-RESIST-I-TEST

The kit is designed for detection of mutations associated with drug resistance in the tuberculosis complex mycobacteria DNA with determination of sensitivity to the first-line chemotherapy drugs and their analogues.

The result of the assay allows for choosing of an appropriate therapy for patients with the confirmed diagnosis **of pulmonary and extrapulmonary tuberculosis.**

- The resistance of the tuberculosis complex mycobacteria to **rifampicin** (rpoB), **isoniazid** (katG and inhA) and their analogues is determined.
- High sensitivity and specificity of the assay.
- Three test tubes per patient.
- The IC sample is included.
- Fast result.

CHARACTERISTICS	
Detection method	Real-time PCR (melting curves)
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Sputum, bronchoalveolar lavage, bronchial washing, gastric washing, pleural fluid, blood, urine, microbiological cultures, prostate secretion, tissue (biopsy and surgical) material, synovial fluid, pericardial fluid and cerebrospinal fluid
Targets	**rpoB** polymorphisms of codons 510–533, D516V, D516Y, codon 526, L533R, L533P, S531L **katG** S315T, S315N, S315R, S315I polymorphisms **inhA** C-15T polymorphism, and polymorphisms of the region -20 – +6 are also detected, but not differentiated
Number of reactions	96
Storage and transportation conditions	-18 . . . -22 °C, 12 months / +2 . . . +8 °C, up to 5 days freezing / thawing is allowed up to 5 times
Analytical sensitivity	at least 5000 copies of genomic DNA per 1 ml of biomaterial
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	125-165 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

MTB-RESIST-II-TEST

The kit is designed to detect polymorphisms associated with drug resistance to second-line chemotherapy drugs (aminoglycosides and fluoroquinolones) and their analogues.
The result of the assay makes it possible to choose the appropriate therapy for patients with a confirmed diagnosis of **pulmonary** and **extrapulmonary tuberculosis.**

- The resistance of the Mycobacterium tuberculosis complex to **aminoglycosides** (*rrs* and *eis* gene polymorphisms) and **fluoroquinolones** (*gyrA* and *gyrB* gene polymorphisms) and their analogs is detected.
- High sensitivity and specificity of the assay.
- The IC is available.

CHARACTERISTICS	
Detection method	Real-time PCR (melting curves)
Devices	CFX 96, ДТпрайм, QuantStudio 5
Format	Qualitative multiplex
Material	Sputum, bronchoalveolar lavage, bronchial lavage, gastric lavage, pleural fluid, blood, urine, cultures of microorganisms, prostate secretion, tissue (biopsy and surgical) material, synovial fluid, pericardial fluid and cerebrospinal fluid
Targets	**rrs:** 1401A>G, 1402C>T and 1484G>T; **eis:** C-14G, C-14T, C-12T, G-10C, G-10A and G-37T; **gyrA:** p.G88C, p.A90V, p.S91P, p.D94G, p.D94N, p.D94H, p.D94A and p.D94Y; **gyrB:** p.D461H, p.D461N, p.N499D, p.E501V and p.A504V
Number of reactions	12 / 96
Storage and transportation conditions	-18 . . .-22 °C, 12 months / +2 . . .+8 °C, up to 30 days freezing / thawing is allowed up to 5 times
Analytical sensitivity	at least 2000 copies of genomic DNA per 1 ml of biomaterial
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	120-165 min.
Presence of RC	✓

Assay stages

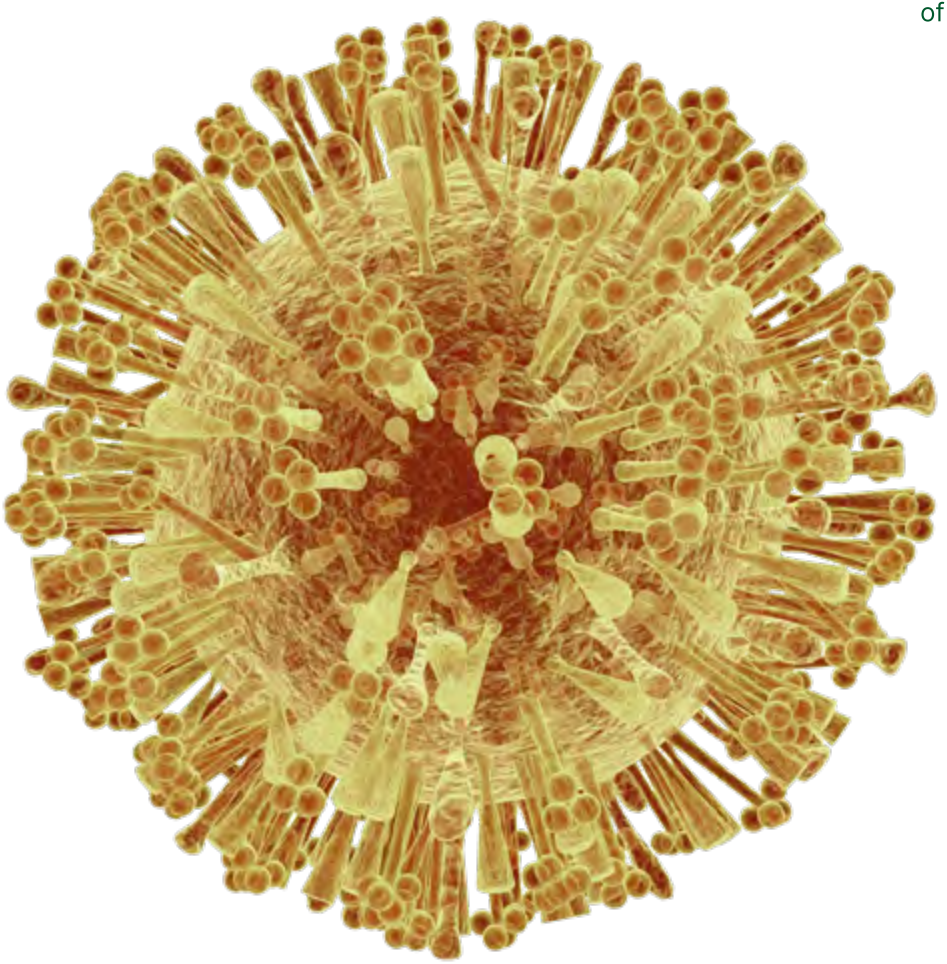

Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

TestGene
New generation
of genetics



Diagnostics of tropical diseases

PLASMODIUM-TEST-Q
PLASMODIUM-SPECIES-TEST
DENV-TEST
ZIK-TEST
CHIK-TEST
TROPIC-TEST

Malaria, Dengue fever, Zika fever and Chikungunya are diseases with a transmissible passing mechanism. All of these diseases are quite serious and characterized by development of severe symptoms. At the same time, the symptoms of these diseases are similar, so it can be difficult or impossible to differentiate between them without laboratory tests. It is necessary to differentiate between them to prescribe the correct treatment. An infection is to be suspected in patients with typical clinical manifestations and an epidemiological history (living or traveling to regions of the habitat of mosquitoes, unprotected sexual contact with a person living in an endemic area). The diagnosis is made on the basis of PCR tests with detection of the virus RNA.

PLASMODIUM-TEST-Q

The kit is recommended for use in patients with clinical symptoms of malaria with a suspected infection caused by representatives of the Plasmodium genus.

- The use of the enzyme uracil-DNA-glycosidase prevents obtaining false-positive results in case of contamination with amplification products.
- High sensitivity and specificity of the assay.
- The IC is available.
- Fast result.

CHARACTERISTICS	
Method of detection	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Quantitative multiplex
Material	Whole blood
Detection of	*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale curtisi*, *P. ovale wallikeri* and *P. knowlesi*
Number of tests	96
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing / thawing is allowed up to 10 times
Analytical sensitivity	500 IU/ml
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	55-75 min.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

PLASMODIUM-SPECIES-TEST

The kit is recommended for use in patients with clinical symptoms of malaria with a suspected infection caused by representatives of the *Plasmodium* genus.

- Detects highly specific DNA/RNA regions – a fragment of the gene encoding **18S rRNA or 18S rRNA.**
- Configuration form 1: DNA isolated from human whole blood.
- Configuration form 2: RNA isolated from human whole blood.
- The IC is available.
- High sensitivity and specificity of the assay.
- Fast result.

CHARACTERISTICS		
	PLASMODIUM-SPECIES-TEST- DNA	**PLASMODIUM-SPECIES-TEST- RNA**
Detection method	Real-time PCR	Real-time RT-PCR
Devices	FAM/Green, HEX/Yellow, ROX/Orange, Cy5/Red, Cy5.5/Crimson, DTprime, Rotor-Gene Q, QuantStudio 5, CFX96	
Format	Qualitative multiplex	Qualitative monoplex
Material	Whole blood	
Number of exons for the analysis	P. falciparum, P. vivax, P. malariae and P. ovale (including P. ovale curtisi and P. ovale wallikeri)	
Number of tests	96	
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing/thawing is allowed up to 10 times	
Analytical sensitivity	500 IU of DNA	500 IU of RNA
Sensitivity	100 %	
Specificity	100 %	
Time for 1 analysis	55-75 min.	80-100 min.
Presence of RC	✓	

Assay stages


Collection of biomaterial


DNA / RNA isolation


Amplification / RT-amplification of specific targets


Hybridization fluorescence detection

DENV-TEST

It is intended for use in patients with clinical symptoms of a viral disease with a suspected infection caused by Dengue virus.

- Two configuration forms: with RNA isolation and without RNA isolation.
- Specific in relation to RNA of Dengue virus (types 1-4).
- The IC is available.
- High sensitivity and specificity of the assay.

CHARACTERISTICS		
	DENV-TEST-CLASSIC	**DENV-TEST-CITO**
Detection method	Real-time RT-PCR	
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5	
Format	Qualitative multiplex	
Material	Blood plasma	
Detection of	RNA of Dengue virus	
Number of tests	96	
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing/thawing is allowed up to 10 times	
Analytical sensitivity	500 copies/ml – with RNA isolation 1000 copies/ml – without RNA isolation	
Sensitivity	100 %	
Specificity	100 %	
Time for 1 analysis	80-100 min.	
Presence of RC	✓	

Assay stages

ZIK-TEST

It is intended for use in patients with clinical symptoms of a viral disease with a suspected infection caused by Zika virus.

- Two configuration forms: with RNA isolation and without RNA isolation.
- Specific in relation to RNA of Zika virus.
- The IC is available.
- Possibility of carrying out a test in one test tube.
- High sensitivity and specificity of the assay.

CHARACTERISTICS		
	ZIK-TEST-CLASSIC	**ZIK-TEST-CITO**
Detection method	Real-time RT-PCR	
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5	
Format	Qualitative multiplex	
Material	Blood plasma	
Detection of	RNA of Zika virus	
Number of tests	96	
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing/thawing is allowed up to 10 times	
Analytical sensitivity	500 copies/ml – with RNA isolation 1000 copies/ml – without RNA isolation	
Sensitivity	100 %	
Specificity	100 %	
Time for 1 analysis	80-100 min.	
Presence of RC	✓	

Assay stages


Collection of biomaterial


RNA isolation / without solation


Amplification of specific targets


Hybridization fluorescence detection

CHIK-TEST

It is intended for use in patients with clinical symptoms of a viral disease with a suspected infection caused by Chikungunya virus.

- Detection of Chikungunya virus.
- Two configuration forms: with RNA isolation and without RNA isolation.
- The IC is available.
- Possibility of carrying out a test in one test tube.
- High sensitivity and specificity of the assay.

CHARACTERISTICS		
	CHIK-TEST-CLASSIC	**CHIK-TEST-CITO**
Detection method	Real-time RT-PCR	
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5	
Format	Qualitative multiplex	
Material	Blood plasma	
Detection of	RNA of Chikungunya virus	
Number of tests	96	
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing/thawing is allowed up to 10 times	
Analytical sensitivity	500 copies/ml – with RNA isolation 1000 copies/ml – without RNA isolation	
Sensitivity	100 %	
Specificity	100 %	
Time for 1 analysis	80-100 min.	
Presence of RC	✓	

Assay stages

TROPIC-TEST

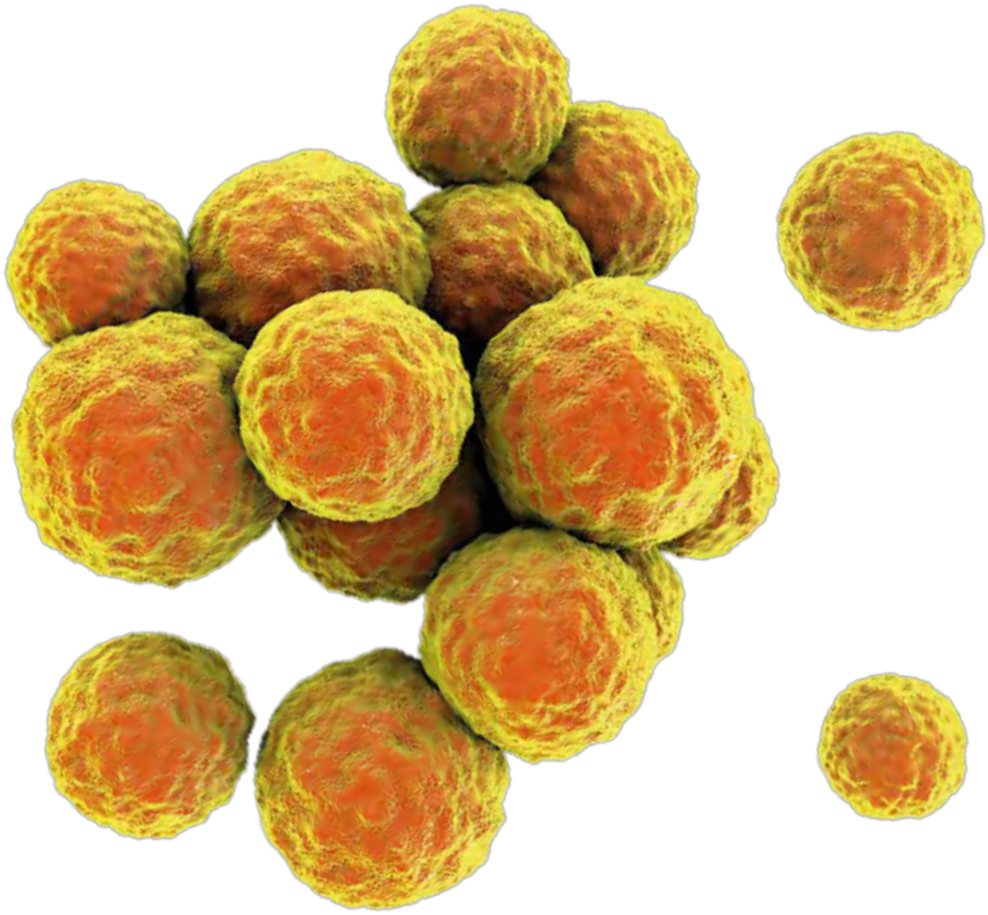
It is intended for use in patients with clinical symptoms of a viral disease with a suspected infection caused by Chikungunya, Zika, Dengue viruses.

- Detection of three viruses (Chikungunya, Zika, Dengue).
- Two configuration forms: with RNA isolation and without RNA isolation.
- The IC is available.
- Possibility of carrying out a test in one test tube.
- High sensitivity and specificity of the assay.

CHARACTERISTICS	
Detection method	Real-time RT-PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	Blood plasma
Detection of	RNA of Chikungunya, Zika, Dengue viruses
Number of tests	96
Storage and transportation conditions	From -18 °C to -22 °C, up to 12 months From +2 °C to +6 °C, up to 30 days Freezing/thawing is allowed up to 10 times
Analytical sensitivity	500 copies/ml – with RNA isolation 1000 copies/ml – without RNA isolation
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	80-100 min.
Presence of RC	✓

Assay stages

TestGene
New generation of genetics



LAMP-STAPH-TEST

Diagnostics of infections caused by staphylococci

Staphylococcal infection is a group of purulent-inflammatory diseases caused by pathogenic strains of staphylococci. Four types of staphylococci are pathogenic: golden, epidermal, saprophytic and hemolytic. They produce toxic substances and enzymes that disrupt the functioning and vitality of the cells of the internal tissues and layers of the skin.

Risk groups include patients with immunodeficiencies, endocrine, oncological, chronic bronchopulmonary diseases, pregnant women, newborns, etc.

Staphylococcus aureus (S. aureus) is the most dangerous of all staphylococci; with a decrease in human immunity, it can cause infections of the genitourinary system, pneumonia, purulent-septic infections and other diseases.

LAMP-STAPH-TEST

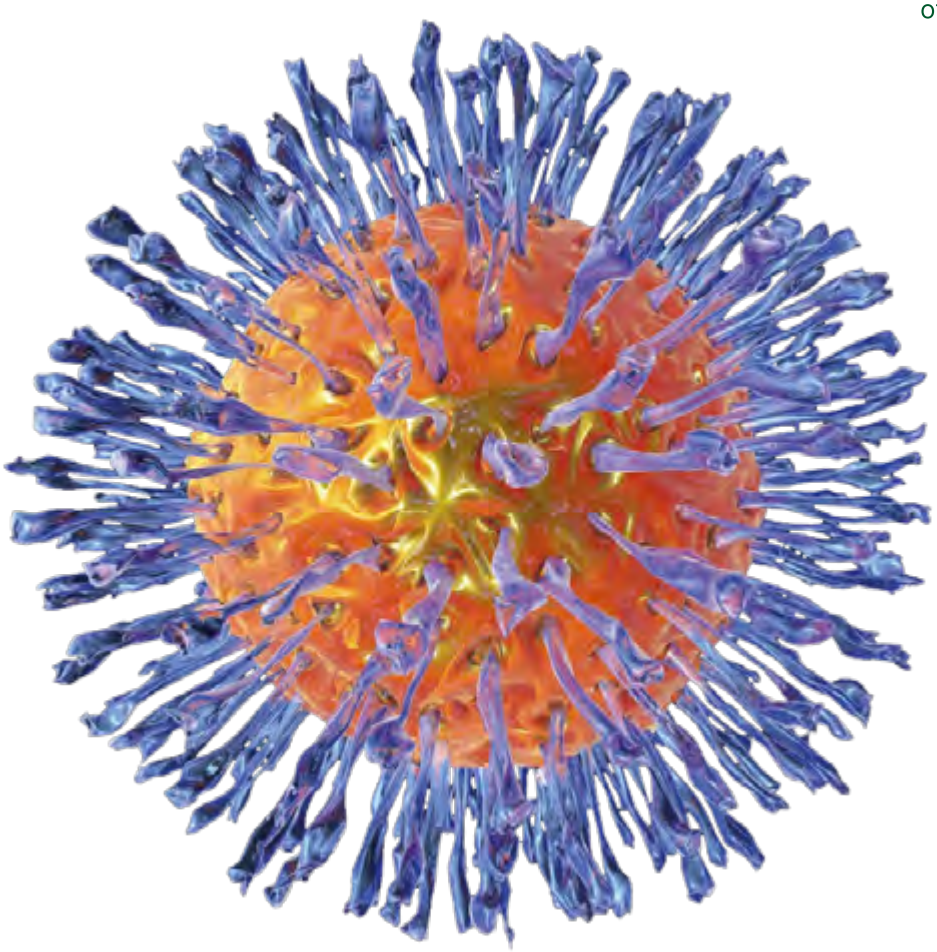
The kit is designed for qualitative detection *Staphylococcus aureus*.

- Optional DNA isolation.
- High sensitivity and specificity of the assay.
- The IC is available.
- Reliable result in 35 minutes.

CHARACTERISTICS	
Detection method	LAMP
Devices	CFX 96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative multiplex
Material	DNA preparations isolated from oropharyngeal swabs, urine, sputum, blood, punctates from lesions of organs and tissues), environmental objects (washings from medical equipment and tools), as well as native clinical material — oropharyngeal swabs, washings from medical equipment and tools
Number of reactions	96
Storage and transportation conditions	-15 . . .-25 °C, 12 months +2 . . .+6 °C, up to 7 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	$2,5*10^3$ copies/ml with DNA isolation $2,5*10^4$ copies/ml without DNA isolation
Sensitivity	100 %
Specificity	100 %
Time for 1 analysis	35-40 min.
Presence of RC	✓

Assay stages

TestGene
New generation
of genetics



Diagnostics of herpes simplex virus infections

HHV6-TEST

Infections caused by herpes simplex viruses affect various human organs and are characterized by a wide variety of clinical forms.

Herpes simplex virus 6 (HHV-6) is a common infection that has been cited as the cause of many serious diseases and aggravates other viral and bacterial infections. Infectious mononucleosis, sudden onset eczema, serous meningitis, encephalitis, and some cancers, such as cervical carcinoma, are associated with human herpes simplex virus 6. HHV-6 can lead to complications and organ rejection after transplantation.

Active HHV6-6 can promote the transition of HIV infection to AIDS, so regular monitoring of HHV-6 activity in HIV-positive patients is important for the timely initiation of antiviral therapy.

HHV6-TEST

The kit is designed for qualitative and quantitative detection of **human herpes simplex virus type 6 (HHV-6)** DNA. It is used when examining patients with suspected herpes simplex virus infection and a confirmed diagnosis to assess viral load and evaluate the effectiveness of treatment.

- Identification of herpes simplex virus infection caused by HHV-6 is possible in any form and stage of the disease.
- High sensitivity and specificity of the assay.
- The risk of contamination is reduced due to the inclusion of uracil-DNA-glycosylase (UDG) and 2'-deoxyuridine-5'-triphosphate (dUTP) in the reaction mixture.
- High speed of the assay.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX 96, DTprime, Rotor-Gene Q, QuantStudio 5
Format	Qualitative / quantitative multiplex
Material	Whole blood, white blood cells, oropharyngeal swabs, saliva, visceral biopsies, cerebrospinal fluid, urine
Number of reactions	96
Storage and transportation conditions	-18 . . .-20 °C, 12 months +2 . . .+8 °C, up to 90 days +15 . . .+25 °C, up to 5 days freezing / thawing is allowed up to 10 times
Analytical sensitivity	~400 IU/ml
Чувствительность	100 %
Специфичность	100 %
Time for 1 analysis	65 min.
Presence of RC	✓

Assay stages

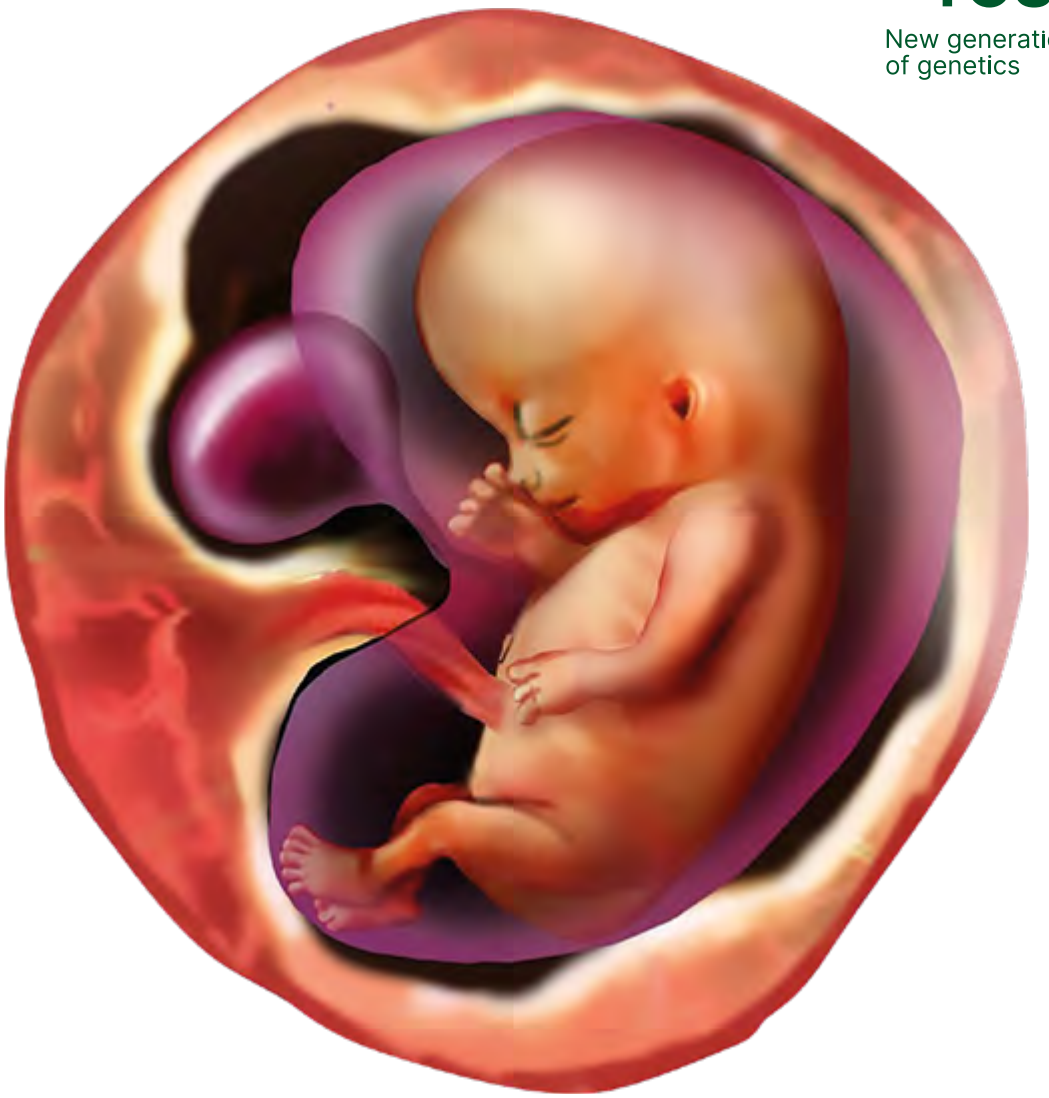

Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

TestGene
New generation of genetics



Prenatal diagnostics

Determination of the Rh factor and the sex of the fetus

TEST-RHD PLUS
TEST-SRY PLUS

Early non-invasive determination of the sex of the fetus and timely prevention of hemolytic disease of the fetus and newborn (HDFN) in Rh-negative women and assessing the risk of genetic diseases are very important for reducing prenatal morbidity and mortality.

Determination of the sex and Rh factor of the fetus is carried out using blood of a pregnant woman and possible already starting from the 10th week of pregnancy.

TestGene's test systems have proven to be high-precision test kits and are successfully used in Russian clinics.

TEST-RHD PLUS

The kit is designed for non-invasive detection of the fetal **Rh factor (RHD)** gene in blood plasma of an Rh-negative mother to predict the risk of developing Rh incompatibility and HDFN.

- The method is based on determination of fetal DNA in the mother's blood plasma.
- The test can be performed starting already from the **10th embryological week**.
- Use of **3 targets.**

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LineGene, Gentier, LC96
Format	Qualitative monoplex
Material	Blood plasma
Number of exons for the analysis	3 exons (6, 7, 10)
Number of tests	50 / 100
Storage and transportation conditions	-18 . . .-25 °C, 12 months +2 . . .+8 °C, up to 3 days freezing / thawing is allowed up to 50 times
Analytical sensitivity	10 genomic equivalents/µl
Sensitivity	99,8 %
Specificity	97,5 %
Time for 1 analysis	100 min.
Presence of RC	✓

Assay stages

TEST-SRY PLUS

The kit is designed for non-invasive diagnostics of the sex of a child by detecting the sex-determining gene (SRY) of the fetus in blood plasma of a pregnant woman.

- The method is based on determination of the fetal DNA in the mother's blood plasma.
- The test can be performed starting already from the **10th embryological week.**

Detection of the SRY gene indicates pregnancy with a male fetus, if this gene was not detected – a female fetus.

CHARACTERISTICS	
Detection method	Real-time PCR
Devices	CFX96, DTprime, Rotor-Gene Q, QuantStudio 5, LineGene, Gentier, LC96
Format	Qualitative monoplex
Material	Blood plasma
Number of exons for the analysis	the presence of the SRY gene
Number of tests	50 / 100
Storage and transportation conditions	-18 . . .-25 °C, 12 months +2 . . .+8 °C, up to 3 days freezing / thawing is allowed up to 50 times
Analytical sensitivity	10 genomic equivalents/µl
Sensitivity	98,76 %
Specificity	99,88 %
Time for 1 analysis	100 мин.
Presence of RC	✓

Assay stages


Collection of biomaterial


DNA isolation


Amplification of specific targets


Hybridization fluorescence detection

TestGene
New generation
of genetics

DNA / RNA isolation

NA-EXTRA
NA-EXTRA-PLATE
DNA-PLASMA-M
DNA-PLASMA-M-RT
DNA-TISSUE-M
DNA-TISSUE-F
DNA-FAST
DNA-PLANT

TestGene's NA isolation kits are suitable for use with analytical stations from various manufacturers and provide consistent high yields of DNA/RNA. Isolation takes place on the basis of spin-column, magnetic particle and thermal lysis technologies.

Isolation kits are designed according to the needs of different laboratories. The range includes kits for isolation of human and plant NA:

- kits for manual and automated isolation;
- dispensed and not dispensed versions of the kits;
- versatile kits for various biological materials and kits for isolation of NA from blood plasma and tissue.

NA-EXTRA

The kit is designed for isolation of DNA/RNA from human clinical material by the method based on magnetic particles for subsequent PCR tests.

CHARACTERISTICS	
Basic technology	Magnetic particles
Material	Venous blood, venous blood plasma, sputum, nasopharyngeal swabs, oropharyngeal swabs, vaginal swabs, cervical scraping, urethral scraping, urine cell sediment, prostate secretion
Number of isolation procedures	96
Input volume of material	100 µl
Storage and transportation conditions	+2 . . .+30 °C, 12 months
Efficiency of DNA isolation	from 25 %
Purity of the isolated NA, A260/280	from 1,7
Time of isolation from 1 sample	40 min.
Variants	For manual isolation and isolation using automated sample preparation stations. Not poured kit for automated isolation. Poured kit for automated isolation.
Presence of RC	✓

Used for the kits: COV-2-TEST, COV-2-DIF-O, COV-2-COLOR-TEST, COV-INFLU-TEST, HRR-SCREENING, BRCA-DIAGNOSTICS, PROSTA-TEST , PROSTA-TEST-2.0, UROGEN-TEST-5, UROGEN-TEST-12, HEPA-BCD-TEST, HEPA-C-TEST-Q, HEPA-B-TEST-Q, HEPA-C-GENE-TEST, MTB-TEST, MTB-RESIST-I-TEST.

NA-EXTRA-PLATE

The kit is designed for semi-automatic simultaneous extraction of DNA/RNA from human clinical material by the method based on magnetic particles for the subsequent PCR test. Recommended for use in laboratories with a large flow of analyzes in the absence of automated stations for DNA/RNA extraction.

CHARACTERISTICS	
Basic technology	Magnetic particles
Material	Venous blood, venous plasma, sputum, nasopharyngeal swabs, oropharyngeal swabs, vaginal swabs, cervical scrapings, urethral scrapings, urine cell sediment, prostate secretion
Number of extraction procedures	96
Material input volume	100 mg
Storage and transportation conditions	+2 . . .+30 °C, 12 months
Efficiency of NA extraction	from 25 %
Purity of the isolated DNA, A260/280	from 1,7
Time of extraction from 1 sample	40 min.
Presence of RC	✓

Used for the kits: COV-2-TEST, COV-2-DIF-O, COV-2-COLOR-TEST, COV-INFLU-TEST, PROSTA-TEST, PROSTA-TEST-2.0, UROGEN-TEST-5, UROGEN-TEST-12, HEPA-BCD-TEST, HEPA-C-TEST-Q, HEPA-B-TEST-Q, HEPA-C-GENE-TEST, MTB-TEST, MTB-RESIST-I-TEST.

DNA-PLASMA-M
DNA-PLASMA-M-RT

The kits are designed for isolation of human DNA from plasma samples by the method based on the reversible binding of nucleic acids on the surface of magnetic particles for subsequent analysis.

The assay can be performed using automatic stations from various manufacturers.

CHARACTERISTICS		
	DNA-PLASMA-M	**DNA-PLASMA-M-RT**
Basic technology	Magnetic particles	
Equipment	Magnetic rack, centrifuge, thermostat	Magnetic rack, centrifuge
Material	Blood plasma	
Number of isolation procedures	50 / 100	25 / 50
Input volume of material	1 ml	2-5 ml
Storage and transportation conditions	up to +25 °C, 12 months «Proteinase K» – up to -18°C, 12 months wash solutions after adding ethanol – 6 months	up to +30 °C, 12 months wash solutions after adding ethanol – 6 months
Efficiency of DNA isolation	from 25 %	
Purity of the isolated DNA, a260/280	from 1,6	
Time of isolation from 1 sample	90 min.	70 min.
Presence of RC	✓	

Used for the kits: TEST-EGFR-PLASMA, TEST-RHD PLUS, TEST-SRY PLUS.

DNA-TISSUE-M
DNA-TISSUE-F

The kits are designed for isolation of human DNA from formalin-fixed paraffin-embedded tissues (FFPE blocks).

- Method based on sample lysis, binding of nucleic acids on the surface of magnetic particles.
- Method based on binding of nucleic acids to a silicate membrane in a spin column for subsequent analysis.

CHARACTERISTICS		
	DNA-TISSUE-M	**DNA-TISSUE-F**
Basic technology	Magnetic particles	Spin columns
Equipment	Magnetic rack, centrifuge, thermostat	Centrifuge, thermostat
Material	Formalin-fixed, paraffin-embedded tissue (FFPE-blocks)	
Number of isolation procedures	50 / 100	
Input volume of material	30 mg	
Amount of isolated DNA	up to 5 ng/µl	
Storage and transportation conditions	up to +25 °C, 12 months «Proteinase K» – up to -18°C, 12 months wash solutions after adding ethanol – 6 months	
Efficiency of DNA isolation	from 20 %	
Purity of the isolated DNA, a260/280	from 1,7	from 1,6
Time of isolation from 1 sample	120 min., not including incubation time	
Presence of RC	✓	

Used for the kits: TEST-BRAF-TISSUE, TEST-BRAF-TISSUE-MULTI, TEST-EGFR-TISSUE, TEST-EGFR- TISSUE-MULTI, TEST-KRAS-TISSUE, TEST-KRAS-TISSUE-MULTI, TEST-NRAS-TISSUE, TEST-NRAS-TISSUE-MULTI, BRCA1,2-TISSUE

DNA-FAST

The kit is designed for collection, transportation and isolation of DNA from clinical material.

It is recommended to transfer the test tubes with the DNA-FAST reagent included in the kit to the treatment rooms of clinics as a container for collection, storage and transportation of biological material for PCR analysis.

CHARACTERISTICS	
Basic technology	Thermal lysis
Equipment	Centrifuge, thermostat
Number of isolation procedures	100
Material	Nasopharyngeal swabs, oropharyngeal swabs, vaginal swabs, cervical scraping, urethral scraping, urine cell sediment, saliva, cerebrospinal fluid, synovial fluid, prostate secretion
Input volume of material	from 5 ng/µl
Storage and transportation conditions	+2 . . . +8 °C, 12 months +18 . . . +25 °C, up to 5 days
Efficiency of DNA isolation	from 20 %
Time of isolation from 1 sample	15 min.
Presence of RC	✓

Used for the kits: UROGEN-TEST-5, UROGEN-TEST-12.

DNA-PLANT

The reagent kit is designed for isolation of nucleic acids from plant products and raw materials of plant origin.

CHARACTERISTICS	
Basic technology	Magnetic particles
Equipment	Magnetic rack, centrifuge, ther-mostat
Number of isolation procedures	50 /100
Material	Vegetable raw materials, feed and food products of plant origin
Input volume of material	30 mg
Storage and transportation conditions	up to +30 °C, 12 months wash solutions after adding ethanol – 6 months
Efficiency of DNA isolation	from 20 %
Purity of the isolated DNA, a260/280	from 1,7
Time of isolation from 1 sample	60 min.
Presence of RC	Check with the sales department


TestGene
THE FUTURE
STARTS
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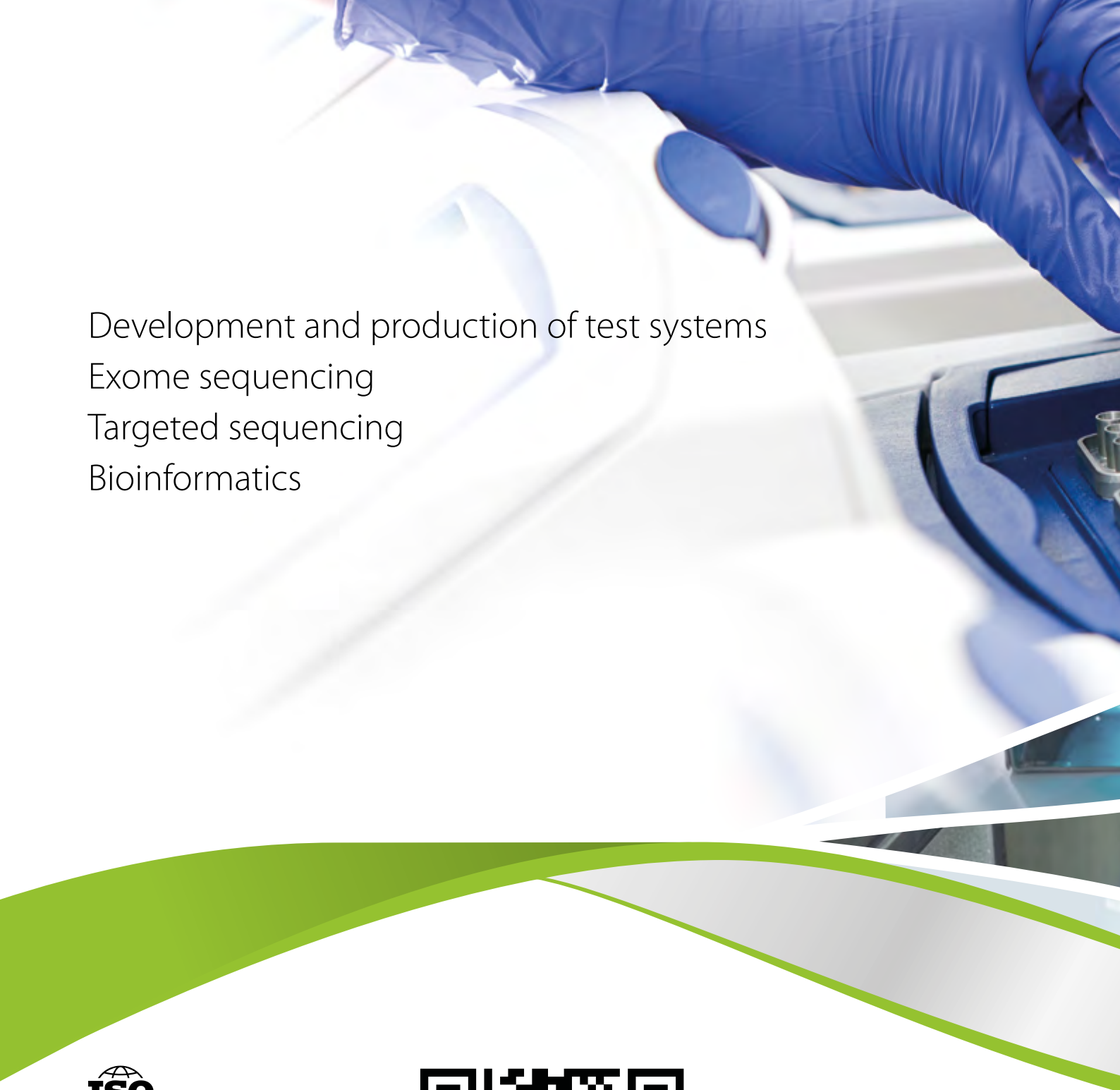

Development and production of test systems
Exome sequencing
Targeted sequencing
Bioinformatics

ISO 13485

Always the current version of the catalog

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