AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit

IVD

For Professional Use Only

Instruction Manual

KEY TO SYMBOLS USED

REF	Catalogue number		Caution
LOT	Batch code		Consult instructions for use
IVD	*In vitro* diagnostic medical device	Σ	Contains sufficient for <n> tests
VER	Version		Use-by-date
	Temperature limit		Keep away from sunlight
	Manufacturer	IC	Internal control
	Date of manufacture	C1, C2	DNA-calibrators
EC REP	Authorized representative in the European Community	NCA	Negative control of amplification
FBIS CRIE	Federal Budget Institute of Science "Central Research Institute for Epidemiology"		

1. INTENDED USE

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit is an *in vitro* nucleic acid amplification test for detection of mutations in *M.genitalium* DNA associated with resistance to macrolides (in domain V of the 23S rRNA gene) and fluoroquinolones (in QRDR of the ParC gene) in DNA samples extracted from biological material (urethral, cervical, vaginal swabs and urine samples), using real-time hybridization-fluorescence detection of amplified products.

The PCR kit is recommended for use after the detection of *M.genitalium* DNA in the test samples using PCR kits manufactured by FBIS CRIE. The material for PCR is DNA samples extracted from test material.

Indications and contra-indications for use of the reagent kit

The reagent kit is used in clinical laboratory diagnostics for the analysis of biological material taken from the persons infected with *M.genitalium* in order to prescribe the correct and timely therapy of the infection caused by *M.genitalium*.

There are no contra-indications with the exception of cases when the material cannot be taken for medical reasons.

NOTE: The results of PCR analysis are taken into account in complex diagnostics of disease.

2. PRINCIPLE OF PCR DETECTION

Principle of testing is based on simultaneous amplification of *M.genitalium* DNA fragments, including the location of the mutations associated with *M.genitalium* resistance to macrolides and fluoroquinolones, and DNA of the exogenous internal control sample (Internal Control (IC)[1]) with real-time hybridization-fluorescence detection. IC allows to control all PCR-analysis stages of each individual sample and to identify possible reaction inhibition.

Amplification of DNA fragments with the use of specific primers and Taq-polymerase enzyme are performed with the DNA samples obtained at the extraction stage. In the real-time PCR, the amplified product is detected with the use of fluorescent dyes. These dyes are linked to oligonucleotide probes, which bind specifically to the amplified product during thermocycling. The real-time monitoring of fluorescence intensities during the real-time PCR allows the detection of accumulating product without re-opening the reaction tubes after the PCR run.

Oligonucleotide probes complementary to wild type *M.genitalium* DNA are used for mutation detection. The maximum range of target mutations can be detected with this approach.

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit uses "hot-start", which greatly reduces the frequency of nonspecifically primed reactions. "Hot-start" is guaranteed by using chemically modified polymerase (TaqF). The chemically modified polymerase (TaqF) is activated by heating at 95 °C for 15 min.

Detection of mutations associated with *M.genitalium* resistance to macrolides and fluoroquinolones for one sample is performed in two tubes. In the first tube, *M.genitalium* DNA (gyrB gene) and the presence (or absence) of macrolide resistance mutations (in domain V of the 23S rRNA gene) are detected; in the second tube, IC DNA and the presence (or absence) of fluoroquinolone resistance mutations (in QRDR of the ParC gene) are detected.

The results of amplification are registered in the following fluorescence channels:

Table 1

Channel for fluorophore	FAM	JOE	ROX
Name of PCR-mix-FL	**DNA-target**		
PCR-mix-FL *Mg*ML	domain V of 23S rRNA gene (wild type)	-	gyrB gene
PCR-mix-FL *Mg*FQ	-	QRDR of ParC gene (wild type)	IC DNA (artificially synthesized sequence)

[1] IC is added at the stage of *M.genitalium* DNA extraction when analyzing samples with PCR kits for *M.genitalium* DNA detection manufactured by FBIS CRIE.

3. CONTENT

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit is produced in 1 form:
variant FRT-50 F, REF H-3971-1-CE
Variant FRT-50 F includes:

Reagent	Description	Volume, ml	Quantity
PCR-mix-FL *Mg*ML	clear liquid from colorless to light lilac colour	0.6	1 tube
PCR-mix-FL *Mg*FQ	clear liquid from colorless to light lilac colour	0.6	1 tube
PCR-buffer-B	colorless clear liquid	0.6	1 tube
Polymerase (TaqF)	colorless clear liquid	0.06	1 tube
TE-buffer	colorless clear liquid	0.2	1 tube
C1 *Mg*ML	colorless clear liquid	0.2	1 tube
C2 *Mg*ML	colorless clear liquid	0.2	1 tube
C1 *Mg*FQ	colorless clear liquid	0.2	1 tube
C2 *Mg*FQ	colorless clear liquid	0.2	1 tube

Variant FRT-50 F is intended for 55 reactions (including controls).
AmpliSens® *M.genitalium*-ML/FQ-Resist software (version 1.0) in Microsoft® Excel format for automated data processing and Operator manual.

4. ADDITIONAL REQUIREMENTS

- Sterile pipette tips with aerosol filters (up to 10, 100, 200 and 1,000 µl).
- Tube racks.
- Vortex mixer.
- PCR box.
- Real-time instruments (for example, Rotor-Gene Q (QIAGEN, Germany)).
- Disposable polypropylene tubes:
  a) screwed or tightly closed 1.5-ml tubes for reaction mixture preparation.
  b) thin-walled 0.2-ml PCR tubes with flat caps or strips of four 0.1-ml Rotor-Gene PCR tubes.
- Pipettes (adjustable).
- Refrigerator for 2–8 °C.
- Deep-freezer at the temperature from minus 24 to minus 16 °C.
- Reservoir for used tips.
- Disposable powder-free gloves and a laboratory coat.

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile pipette tips with aerosol filters and use a new tip for every procedure.
- Store all extracted positive material (specimens, controls and amplicons) away from all other reagents and add it to the reaction mix in a distantly separated facility.
- Thaw all components thoroughly at room temperature before starting an assay.
- When thawed, mix the components and centrifuge briefly.
- Use disposable protective gloves and laboratory cloths, and protect eyes while samples and reagents handling. Thoroughly wash hands afterwards.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
- Do not use the PCR kit if the internal packaging was damaged or its appearance was changed.
- Do not use the PCR kit if the transportation and storage conditions according to the Instruction Manual were not observed.
- Do not use a kit after its expiration date.
- Dispose of all specimens and unused reagents in accordance with local regulations.
- Samples should be considered potentially infectious and handled in biological cabinet in compliance with appropriate biosafety practices.
- Clean and disinfect all samples or reagents spills using a disinfectant, such as 0.5 % sodium hypochlorite or another suitable disinfectant.
- Avoid inhalation of vapors, samples and reagents contact with the skin, eyes, and mucous membranes. Harmful if swallowed. If these solutions come into contact, rinse the injured area immediately with water and seek medical advice if necessary.
- While observing the conditions of transportation, operation and storage, there are no risks of explosion and ignition.
- Safety Data Sheets (SDS) are available on request.
- The PCR kit is intended for single use for PCR analysis of specified number of samples (see the section "Content").
- The PCR kit is ready for use in accordance with the Instruction Manual. Use the PCR kit strictly for intended purpose.
- Use of this product should be limited to personnel trained in DNA amplification techniques.
- Workflow in the laboratory must be one-directional, beginning in the Extraction Area and moving to the Amplification and Detection Area. Do not return samples, equipment and reagents in the area where the previous step was performed.

⚠ Some components of this kit contain sodium azide as a preservative. Do not use metal tubing for reagent transfer.

6. SAMPLING AND HANDLING

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit is intended for analysis of the DNA samples obtained earlier at the extraction stage from the test material in which *M.genitalium* DNA was detected.

M.genitalium DNA samples can be stored before PCR-analysis:
- at the temperature from 2 to 8 °C – for 1 week,
- at the temperature from minus 24 to minus 16 °C – for 1 year.

Only one freeze-thawing cycle is required.

Samples can be transported at the temperature from 2 to 8 °C for 1 day.

Interfering substances and limitations of using test material samples

In the course of the risk analysis, the following features of PCR kit content and analysis configuration which allow to exclude the influence of potentially interfering substances on the PCR method were determined:
- the DNA samples obtained earlier at the extraction stage from the test material and in which *M.genitalium* DNA has already been detected are used as test samples;
- use of specific primers and fluorescent-labeled oligonucleotides complementary to detected DNA targets;
- detection of IC DNA artificially synthesized sequence as exogenous internal control.

If the signal of IC DNA and *M.genitalium* DNA is absent, the result of this analysis is invalid.

Due to the indicated features of the PCR kit content and analysis configuration, it is not necessary to study the interfering properties of individual components of a biological sample.

7. WORKING CONDITIONS

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit should be used at the temperature from 20 to 28 °C and relative humidity from 15 to 75 %.

8. PROTOCOL

8.1. Preparing PCR

8.3.1 Preparing tubes for PCR

The total reaction volume is **25 µl**, the volume of the **DNA** sample is **10 µl**.

Use disposable filter tips for adding reagents, DNA and control samples into tubes.

1. Calculate the required quantity of each reagent for reaction mixture preparation. For one reaction:
   - **10 µl** of **PCR-mix-FL *Mg*ML** or **PCR-mix-FL *Mg*FQ**,
   - **5 µl** of **PCR-buffer-B**,
   - **0.5 µl** of **polymerase (TaqF)**.

Prepare the reaction mixture for the total number of test and control samples plus some extra reaction. See numbers of control samples in item 7.

NOTE: Prepare the reaction mixture just before use.

2. Mix the content of the tubes with **PCR-mixes-FL**, **PCR-buffer-B** and **polymerase (TaqF)**. Sediment the drops by vortex.
3. In the two new tubes prepare two reaction mixtures. Mix the required quantities of **PCR-mix-FL *Mg*ML** or **PCR-mix-FL *Mg*FQ, PCR-buffer-B** and **polymerase (TaqF)**. Sediment the drops by vortex.
4. Take the required (twofold) number of the tubes or strips for PCR of DNA of test and control samples, place them in two rows.
5. Transfer **15 µl** per sample of one of the two prepared reaction mixtures to each row of tubes. Discard the unused reaction mixture.
6. Add **10 µl** of **DNA samples** obtained by extraction of the test samples to the two tubes with different reaction mixtures.

NOTE: The volume of the extracted *M.genitalium* DNA sample for the study should be at least **20 µl**.

NOTE: Avoid transferring the sorbent together with the DNA samples extracted with the reagent kits for extraction on silica gel or magnetic separation.

7. Carry out the control amplification reactions:

For **PCR-mix-FL *Mg*ML**:

DNA-calibrator C1 – Add **10 µl** of **C1 *Mg*ML** to the tube labeled **DNA-calibrator C1**.

DNA-calibrator C2 – Add **10 µl** of **C2 *Mg*ML** to the tube labeled **DNA-calibrator C2**.

NCA – Add **10 µl** of **TE-buffer** to the tube labeled **NCA** (Negative Control of Amplification).

For **PCR-mix-FL *Mg*FQ**:

DNA-calibrator C1 – Add **10 µl** of **C1 *Mg*FQ** to the tube labeled **DNA-calibrator C1**.

DNA-calibrator C2 – Add **10 µl** of **C2 *Mg*FQ** to the tube labeled **DNA-calibrator C2**.

NCA – Add **10 µl** of **TE-buffer** to the tube labeled **NCA** (Negative Control of Amplification).

8.3.2. Amplification

1. Create a temperature profile on your instrument as follows:

Table 2

AmpliSens-1 amplification and detection program of fluorescent signal for rotor-type instruments

Step	Temperature, °C	Time	Fluorescent signal detection	Cycles
1	95	15 min	-	1
2	95	5 s	-	5
	60	20 s	-	
	72	15 s	-	
3	95	5 s	-	40
	60	20 s	FAM, JOE, ROX	
	72	15 s	-	

NOTE: If several tests are carried out simultaneously, the detection is enabled in other used channels except for the specified ones.

Fluorescent signal is detected in the channels for the **FAM**, **JOE** and **ROX** fluorophores.

2. Adjust the fluorescence channel sensitivity according to the *Important Product Information Bulletin*.
3. Insert tubes into the reaction module of the device.
4. Run the amplification program with fluorescence detection.
5. Analyze results after the amplification program is completed.

9. DATA ANALYSIS

NOTE: Data analysis is performed automatically by AmpliSens® *M.genitalium*-ML/FQ-Resist software (version 1.0). The operation procedure for AmpliSens® *M.genitalium*-ML/FQ-Resist software (version 1.0) is described in the Operator manual.

The curves of fluorescent signal accumulation are analyzed in three channels:

Table 3

Name of PCR-mix-FL	Channel for fluorophore		
	FAM	JOE	ROX
PCR-mix-FL *Mg*ML	domain V of 23S rRNA gene (wild type)	-	gyrB gene
PCR-mix-FL *Mg*FQ	-	QRDR of ParC gene (wild type)	IC DNA (artificially synthesized sequence)

Results are interpreted by the crossing (or not-crossing) the fluorescence curve with the threshold line set at the specific level, as well as using F, K, d Lg(C) coefficients calculated automatically by AmpliSens® *M.genitalium*-ML/FQ-Resist software (version 1.0).

Principle of interpretation is the following:

Table 4

Results interpretation

Name of PCR-mix-FL	*Ct* values and values for F, K, d Lg(C) coefficients in the channel for fluorophore			Result
	FAM	JOE	ROX	
Variant 1				
***Mg*ML**	absent	not taken into account	absent	***M.genitalium* DNA is NOT detected**
***Mg*FQ**	not taken into account	absent	< boundary value	
Variant 2				
***Mg*ML**	determined or absent	not taken into account	determined or absent*	**Low concentration of *M.genitalium* DNA. No mutations could be detected**
***Mg*FQ**	not taken into account	determined or absent	determined or absent	
Variant 3				
***Mg*ML**	1. absent 2. determined and at least one of the conditions is fulfilled: F < boundary value and/or d Lg(C) > boundary value and/or K < boundary value	not taken into account	determined**	**Mutations ARE DETECTED in the region associated with MACROLID resistance**
***Mg*FQ**	not taken into account	determined or absent	determined or absent	
Variant 4				
***Mg*ML**	determined or absent	not taken into account	determined**	**Mutations ARE DETECTED in the region associated with FLUOROQUINOLONES resistance**
***Mg*FQ**	not taken into account	1. absent 2. determined and at least one of the conditions is fulfilled: F < boundary value and/or d Lg(C) > boundary value and/or K < boundary value	determined or absent	
Variant 5				
***Mg*ML**	determined and the conditions are fulfilled: F ≥ boundary value and d Lg(C) ≤ boundary value and K ≥ boundary value	not taken into account	determined**	**Mutations ARE NOT DETECTED in the regions associated with MACROLID and FLUOROQUINOLONES resistance**
***Mg*FQ**	not taken into account	determined and the conditions are fulfilled: F ≥ boundary value and d Lg(C) ≤ boundary value and K ≥ boundary value	determined or absent	
Variant 6				
***Mg*ML**	absent	not taken into account	absent	**Invalid*** **
***Mg*FQ**	not taken into account	absent	absent or > boundary value	

* *M.genitalium* concentration is < $1x10^3$ GE/ml.

** *M.genitalium* concentration is ≥ $1x10^3$ GE/ml.

*** In case of **invalid result**, the PCR analysis should be repeated for the corresponding test sample starting from the DNA extraction stage.

NOTE: Boundary *Ct* values are specified in the *Important Product Information Bulletin* enclosed to the PCR kit.

The result of the analysis is considered reliable only if the results obtained for the controls of amplification are correct (according to Table 5 and the *Important Product Information Bulletin* enclosed to the PCR kit).

Table 5

Results for controls

Control	Name of PCR-mix-FL	*Ct* value in the channel for fluorophore		
		FAM	JOE	ROX
NCA	*Mg*ML	absent	not taken into account	absent
	*Mg*FQ	not taken into account	absent	absent
C1	*Mg*ML	< boundary value	not taken into account	< boundary value
	*Mg*FQ	not taken into account	< boundary value	< boundary value
C2	*Mg*ML	determined	not taken into account	determined
	*Mg*FQ	not taken into account	determined	determined

10. TROUBLESHOOTING

Results of analysis are not taken into account in the following cases:

1. For the Negative Control of amplification (NCA):
   a) The *Ct* value (*Ct*-1) is determined in the channels for the FAM and/or ROX fluorophores when using PCR-mix-FL *Mg*/ML and in the channels for the JOE and/or ROX fluorophores when using PCR-mix-FL *Mg*/FQ. The contamination of laboratory with amplification products or contamination of reagents, test samples is probable at any stage of PCR analysis. Measures for detecting and elimination of contamination source must be taken. The amplification and detection should be repeated for all samples in which specific DNA was detected;
   b) The *Ct* value (*Ct*-2) is determined in the channel for the FAM fluorophore when using PCR-mix-FL *Mg*/ML and in the channel for the JOE fluorophore when using PCR-mix-FL *Mg*/FQ. The contamination of laboratory with amplification products or contamination of reagents, test samples is probable at any stage of PCR analysis. Measures for detecting and elimination of contamination source must be taken. The amplification and detection should be repeated for all samples in which specific DNA was detected.
2. The *Ct* value (*Ct*-1 and/or *Ct*-2) is absent for the DNA-calibrators C1, C2 *Mg*/ML in any of the specified detection channels (see Table 5). The amplification and detection should be repeated for all the samples.
3. The *Ct* value (*Ct*-1 and/or *Ct*-2) is absent for the DNA-calibrators C1, C2 *Mg*/FQ in any of the specified detection channels (see Table 5). The amplification and detection should be repeated for all the samples.
4. The correlation coefficient R^2 is less than 0.9 when plotting the calibration line. Check the correctness of set concentrations of DNA-calibrators in accordance with the *Important Product Information Bulletin* enclosed to the PCR kit. If the improper result has been obtained again the amplification and detection should be repeated for all the samples.
5. The efficiency is less than 70 % or greater than 120 % when plotting the calibration line. Check the correctness of set concentrations of DNA-calibrators in accordance with the *Important Product Information Bulletin* enclosed to the PCR kit and the correctness of selected level of the threshold line. If set concentrations of DNA-calibrators and the threshold line level are correct but the efficiency does not fit in the required range, then the amplification and detection should be repeated for all the samples.

If you have any further questions or if you encounter problems, please contact our Authorized representative in the European Community.

11. TRANSPORTATION

AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit should be transported at 2–8 °C for no longer than 5 days. PCR kit can be transported at 2–25 °C for no longer than 3 days.

12. STABILITY AND STORAGE

All components of the **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit are to be stored at 2–8 °C when not in use (except for PCR-buffer-B and polymerase (TaqF)).

All components of the **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit are stable until the expiry date stated on the label. The shelf life of reagents before and after the first use is the same, unless otherwise stated.

NOTE: PCR-buffer-B and polymerase (TaqF) are to be stored at the temperature from minus 24 to minus 16 °C.

NOTE: PCR-mix-FL *Mg*/ML and PCR-mix-FL *Mg*/FQ are to be kept away from light.

13. SPECIFICATIONS

13.1. Analytical sensitivity (limit of detection)

Table 6

Test material	PCR kit	Analytical sensitivity (limit of detection), GE/ml
DNA sample extracted from biological material	variant FRT-50 F	$1x10^3$

NOTE: The detection of mutations in *M.genitalium* DNA associated with resistance to macrolides (in domain V of the 23S rRNA gene) and fluoroquinolones (in QRDR of the ParC gene) is possible when *M.genitalium* DNA concentration in the sample is no less than $1x10^3$ GE/ml.

13.2. Analytical specificity

The analytical specificity of **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit is ensured by the selection of specific primers and probes as well as stringent reaction conditions. The primers and probes have been checked for possible homologies to all sequences published in gene banks by sequence comparison analysis.

The PCR kit detects *M.genitalium* DNA fragments. The analytical specificity was proved when investigating the DNA of the following microorganisms/strains in concentration no less than $1x10^7$ GE/ml: *Lactobacillus* spp., *Gardnerella vaginalis*, *Enterococcus faecium*, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma hominis*, *Ureaplasma parvum*, *Ureaplasma urealyticum*, *Trichomonas vaginalis*, *Candida albicans*, *HSV* type 1 and 2, *CMV*, *Atopobium vaginae*, *Staphylococcus aureus*, *Staphylococcus saprophyticus*, *Staphylococcus epidermidis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Neisseria lactamica*, *Neisseria meningitidis*, *Enterobacter cloacae*, as well as human DNA in concentration no less than $1x10^7$ GE/ml.

The nonspecific reactions were not observed while testing the DNA samples of the above mentioned microorganisms, as well as human DNA. The specificity of testing was confirmed by sequencing of the detected amplification products.

The clinical specificity of **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit was confirmed in laboratory clinical trials.

The information about known interfering substances is specified in the *Interfering substances and limitations of using test material samples*.

13.3. Repeatability and reproducibility

Repeatability and reproducibility were determined by testing of positive and negative model samples. Positive samples were a mixture of quality control samples (QCS) containing *M.genitalium* DNA fragments with macrolide and fluoroquinolone resistance mutations at concentrations of $1x10^5$ copies/ml. Quality control samples (QCS) containing wild type *M.genitalium* DNA fragments at concentrations of $1x10^5$ copies/ml were used as samples with no target mutations.

Repeatability conditions included testing in the same laboratory, by the same operator, using the same equipment within a short period of time. Reproducibility conditions included testing in different laboratories, by different operators, using different equipment. The results are presented in Table 9.

Table 7

Sample type	Repeatability		Reproducibility	
	Number of samples	Agreement of results, %	Number of samples	Agreement of results, %
Positive	20	100	40	100
Negative	20	100	40	100

13.4. Diagnostic characteristics

300 DNA samples containing *M.genitalium* DNA extracted from the urogenital tract and urine were tested to determine the diagnostic sensitivity of **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit. The samples were separately tested with **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit and by Sanger sequencing as a reference assay.

Table 8

The results of testing AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit in comparison with the reference assay

Samples type	Antibiotic group	The results of application of AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit		Results of using the reference assay[2]	
				Antibiotic resistance mutations are detected (positive)	Antibiotic resistance mutations are not detected (negative)
DNA samples extracted from biological material	Macrolides	300 samples were tested	Mutations are detected (positive)	25	0
			Mutations are not detected (negative)	0	275
	Fluoroquinolones	300 samples were tested	Mutations are detected (positive)	15	0
			Mutations are not detected (negative)	0	285

Table 9

Diagnostic characteristics of AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT PCR kit

Samples type	Antibiotic group	Diagnostic sensitivity[3] (with a confidence level of 95 %)	Diagnostic specificity[4] (with a confidence level of 95 %)
DNA samples extracted from biological material	Macrolides	100 (88.7-100) %	100 (98.9-100) %
	Fluoroquinolones	100 (81.9-100) %	100 (99-100) %

14. REFERENCES

1. Murray G.L., Bradshaw C.S., Bissessor M., Danielewski J., Garland S.M., Jensen J.S., Fairley C.K., Tabrizi S.N. Increasing Macrolide and Fluoroquinolone Resistance in Mycoplasma genitalium. Emerg Infect Dis. 2017;23(5):809-812.
2. Shedko E. D., Khayrullina G. A., Goloveshkina E. N., Akimkin V. G. Clinical evaluation of commercial PCR assays for antimicrobal resistance in Mycoplasma genitalium and estimation of resistance-mediated mutation prevalence in Moscow and Moscow region // Eur J Clin Microbiol Infect Dis – 2021. – V.40. – №7. – P.1413-1418. DOI: 10.1007 / s10096-021-04170-0.

15. QUALITY CONTROL

In compliance with Federal Budget Institute of Science "Central Research Institute for Epidemiology" ISO 13485-Certified Quality Management System, each lot of the **AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit has been tested against predetermined specifications to ensure consistent product quality.

AmpliSens®

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[2] Sanger sequencing method was used as a reference assay.
[3] Relative sensitivity in comparison with applied reference assay.
[4] Relative specificity in comparison with applied reference assay.