For professional use only

AZF Microdeletions REAL-TIME PCR Genotyping Kit

USER MANUAL

EC REP

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1. INTENDED USE

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** is intended for research and diagnostic applications. The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** is an *in vitro* Nucleic Acid Test (NAT) – human genotyping-based product. The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** is designed to detect AZF locus deletions which are the common cause of male infertility defined by loss of spermatozoids motion ability with an aid of Polymerase Chain Reaction (PCR) method.

The application of the kit does not depend on population and demographic aspects. The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** can be used only for men. There are no other contradictions for use the **AZF Microdeletions REAL-TIME PCR Genotyping Kit.**

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** can be used in clinical and diagnostic laboratories of medical institutions and research practice.

Potential users: personnel qualified in molecular diagnostics methods and working in the clinical and diagnostic laboratory.

It is necessary to apply the kit only as directed in this user manual.

2. METHOD

The implemented PCR method is based on amplification of a target DNA sequence. To increase the sensitivity and specificity of the amplification reaction, the use of a hot-start is provided. Hot-start is provided by reaction mixture preparation consisting of two layers separated by a layer of paraffin or the use of Taq-polymerase blocked by antibodies. The polymerase chain reaction starts only when paraffin is melted or thermal dissociation of a complex of Taq polymerase and antibodies is happened. It excludes non-specific annealing of primers to targets DNA in the initial heating of the tube.

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** is based on fluorescent modification of the PCR method. The PCR-mix contains three target-specific probes bearing reporter fluorescent dyes (Fam, Hex and Rox) and quencher molecules. Once hybridized to a target sequence, the probes become activated. As a result of activation fluorescence increases proportionally to target sequence amplification. The intensity of fluorescence is measured at every cycle of reaction with a Real-time PCR thermal cycler data collection unit and analyzed with the software provided.

AZF Microdeletions REAL-TIME PCR Genotyping Kit contains oligonucleotides capable for detection of Y chromosome deletions which are associated with azoospermia (sY84, sY86, sY127, sY134, sY142, sY242, sY254, sY255, sY615, sY1125, sY1197, sY1206 и sY1291), sex-determining region Y protein (SRY gene) indicating the gender and additional genomic target serving as sample intake control (SIC). SIC is intended for sample quality assurance. If the amount of collected material is insufficient for the analysis, it is necessary to repeat sampling procedure.

The fluorescent dyes are assigned to individual types of sequences. The Fam and Hex dye labels are used to detect specific sequences. The Fam dye label also is used to detect SRY gene. The Hex dye label also is used to detect SIC. The Rox dye label is used to detect “Marker”. It tags the strip orientation. Upon completion of run, software defines actual position of the strip (by means of “marker” position) relative to the position preset by the operator. If it mismatches, the software suggests rearrangement of the tubes by default. In accordance with the operator, order can be rearranged and saved in new file.

The application of several fluorescent dyes makes it possible to determine two alleles and estimate the amount of genomic DNA simultaneously in one tube. Table 1 shows the detection channels of PCR-mix.

Table 1. Detection channels of amplification products

№ tube in strip	Day label/Detection channel					Color labeling of the buffer/paraffin
	Fam	Hex	Rox	Cy5	Cy5.5	
1	sY134	sY242	-	-	-	Blue/White
2	sY142	sY255	-	-	-	Colorless/ White
3	sY615	sY254	-	-	-	
4	sY1125	sY84	-	-	-	
5	sY1197	sY86	Marker	-	-	
6	sY1206	sY127	-	-	-	
7	sY1291	-	-	-	-	
8	SRY	SIC	-	-	-	

The automatic analysis is available on “DNA-Technology” made instruments: DTlite or DTprime REAL-TIME Thermal Cyclers for **AZF Microdeletions REAL-TIME PCR Genotyping Kit** (see the catalogue at www.dna-technology.com to see available supply options).
The current version of the software is available for download at http://dna-technology.com/software .

3. CONTENT

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** contains PCR-mix, Taq-polymerase solution, mineral oil and positive control sample. The detailed description of content is represented in Table 2.

Table 2. The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** content, for R1-H801-S3/5EU

Reagent	Description	Total volume	Amount
Paraffin sealed PCR-mix	Colorless or blue transparent liquid under waxy white fraction	3480 µL (20 µL per tube)	24 8-tube strips
Taq-polymerase solution	Colorless transparent liquid	2000 µL (500 µL per tube)	4 tubes
Mineral oil	Colorless transparent viscous oily liquid	4.0 mL (1.0 mL per tube)	4 tubes
Positive control	Colorless transparent liquid	150 µL	1 tube
Strip’s caps	24 8-caps		

All components are ready to use and do not require additional preparation for operation.

The kit is intended for single use and designed for 24 tests for **AZF Microdeletions REAL-TIME PCR Genotyping Kit.**

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

Blood sampling equipment is required:

– For blood collection: 2.0 or 4.0 mL Vacuette blood collection tubes with anticoagulant, for example, salt of ethylenediaminetetraacetate (EDTA) at a final concentration of 2.0 mg/mL or sodium citrate anticoagulant.

Please use only salt of EDTA or sodium citrate as an anticoagulant, since other substances can provide PCR inhibition.

4.2. DNA extraction and PCR

Preamplification-specimen and control preparation area

– Biological safety cabinet class II;
– Vortex mixer;
– Refrigerator;
– Nucleic acid extraction kit ("DNA-Technology" made **PREP-GS Genetics** (REF P-023/4EU) or **PREP-RAPID Genetics** (REF P-021/4EU) **DNA Extraction Kits** are recommended**;**
– High speed centrifuge (RCF 16000 x g);
– Solid-state thermostat (temperature range 50-98 °C);
– Tube rack for 1.5 mL tubes;
– 1.5 mL tubes;
– Physiological saline solution 0.9% NaCl (Sterile) for the preparation of negative control sample (if needed);
– Container for used pipette tips;
– Single channel pipettes (dispensers covering 20 -1000 µL volume range);
– RNase and DNase free filtered pipette tips (volume 200 µL, 1000 µL);
– Powder-free surgical gloves;
– Disinfectant solution.

Preamplification-reagent preparation area

– UV PCR cabinet;
– Vortex mixer;
– Vortex rotor for strips;
– Refrigerator;
– PCR tube rack for 0.2 mL tubes in strips;
– Single channel pipettes (dispensers covering 2.0-1000 µL volume range);
– RNase and DNase free filtered pipette tips (volume 20 µL, 200 µL, 1000 µL);
– Powder-free surgical gloves;

– Disinfectant solution;

– Container for used pipette tips.

Post-Amplification – Amplification detection area

– Real-time PCR thermal cycler.

Software:

The most recent version of the DT thermal cyclers software can be downloaded from http://dna-technology.com/software.

The OS supported: all versions of Windows starting from 7.

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

All components of the **AZF Microdeletions REAL-TIME PCR Genotyping Kit** must be stored at temperatures from 2 °C to 8 °C over the storage period. PCR-mix must be stored at temperatures from 2 °C to 8 °C and out of light during the storage period. The excessive temperature and light can be detrimental to product performance.

Transportation is allowed in thermal containers with icepacks by all types of covered transport at temperatures from 2 °C to 8 °C inside the container, but for no longer than 5 days.

Shelf-life of the kit following the first opening of the primary container:

– components of the kit should be stored at temperatures from 2 °C to 8 °C during the storage period;

– PCR-mix for amplification should be stored at temperatures from 2 °C to 8 °C and out of light during the storage period.

The kit stored in under undue regime should not be used.

An expired the **AZF Microdeletions REAL-TIME PCR Genotyping Kit** should not be used.

We strongly recommend to follow the given instructions in order to obtain accurate and reliable results.

The conformity of the **AZF Microdeletions REAL-TIME PCR Genotyping Kit** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

Contact our official representative in EU by quality issues of the **AZF Microdeletions REAL-TIME PCR Genotyping Kit**.

6. WARNINGS AND PRECAUTIONS

Only personnel trained in the methods of molecular diagnostics and the rules of work in the clinical and diagnostic laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the assay as if they were able to transmit infective agents. The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. Avoid direct contact with the biological samples reagents and materials used to carry out the assay. Use powder-free surgical gloves. Use protective clothing (work clothes and personal protective equipment) working with microorganisms classified as particularly pathogenic. The protective clothing and personal protective equipment must comply with the work to be performed and health and safety requirements. Avoid producing spills or aerosol. Any material being exposed to biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121 °C before disposal.

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

All oligonucleotide components are produced by artificial synthesis technology according to internal quality control protocol and do not contain blood or products of blood processing.

Positive control is produced by artificial DNA synthesis technology. Positive control does not include parts of infectious agents.

All the liquid solutions are designed for single use and can not be used more than once in amplification reactions. Plastic tubes do not contain phthalates. Do not breathe gas/fumes/vapor/spray produced by the components of the kit. Do not eat/drink components of the kit. Avoid contact with eyes. Only use the reagents provided in the kit and those recommended by manufacturer. Do not mix reagents from different batches. Do not use reagents from third party manufacturers' kits. All laboratory equipment, including pipettes, test tube racks, laboratory glassware, lab coats, bouffant caps, etc., as well as reagents should be strictly stationary. It is not allowed to move them from one room to another. Equip separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions. Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions. Amplification products must be handled in such a way as to reduce dispersion into the environment as much as possible, in order to avoid the possibility of contamination. Pipettes used to handle amplification products must be exclusively employed for this specific purpose. Remove PCR waste only in a closed form. Remove waste materials (tubes, tips) only in a special closed container containing a disinfectant solution. Work surfaces, as well as rooms where NA extraction and PCR are performed, must be irradiated with bactericidal irradiators for 30 minutes before and after the work.

Do not open the tubes after amplification. Waste materials are disposed of in accordance with local and national standards. All surfaces in the laboratory (work tables, test tube racks, equipment, etc.) must be treated daily with disinfecting solution.

Emergency actions

Inhalation: Inhalation of the Master Mix contained within this kit is unlikely, however care should be taken.

Eye Contact: If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Skin Contact: If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

Ingestion: If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

Do not use the kit:

- When the transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When the kit components packaging is breached;
- After the expiry date provided.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

7. SAMPLES

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** is designed to detect DNA extracted from the peripheral blood.

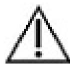
Sampling, sample processing procedures and storage are carried out in accordance with the instructions to the DNA extraction kit from biological material.

Peripheral blood sampling is carried out in vacuum plastic tube. It may be 2.0 or 4.0 mL Vacuette blood collection tubes with anticoagulant, for example salt of ethylenediaminetetraacetate (EDTA) at a final concentration of 2.0 mg/mL or sodium citrate anticoagulant. After taking the material, it is necessary to mix the blood with anticoagulant turning the tube 2 – 3 times.

It is not allowed to use heparin as an anticoagulant.

Transportation and storage of the samples

Samples may be stored at temperatures from 2 °C to 8 °C for no more than 24 h. When it is impossible to deliver the material in the laboratory during the day, a one-time freezing of the material is allowed. The frozen material is allowed to be store at a temperature of minus 20 °C for one month.



The detailed description of sampling and sample processing procedures as well as sample storage and transportation requirements cited in **PREP-GS Genetics** and **PREP-RAPID Genetics Extraction Kit** user manuals.

8. PROCEDURE

DNA extracting from biological material

DNA extraction is carried out according to the extraction kit instructions. **PREP-GS GENETICS** and **PREP-RAPID GENETICS Extraction Kit** are recommended. The **PREP-GS GENETICS Extraction Kit** is intended for long-term storage of the extracted DNA (up to 6 months). The DNA extracted with aid of **PREP-RAPID GENETICS Extraction Kit** should be stored no more than one month. It is allowed to use any kits of reagents registered as a medical device and recommended by manufacturers for the extraction of DNA from the corresponding types of biomaterial.

Independently of DNA extraction kit used, a negative control sample should go through all stages of DNA extraction. Physiological saline solution can be used as a negative control in volumes as indicated.

Assay procedure

The reagents and tubes should be kept away from direct sun light.

Strictly observe the completeness of the strips and caps for them. Do not use the caps for the strips of the other kits!

8.1 Mark one strip with paraffin sealed PCR-mix for each test sample, positive control (C+) and negative control (C-).

One strip contains PCR-mixes for one sample testing.

Example: to test 2 samples, mark 2 strips for test samples, 1 strip for “C+” and 1 strip for “C-“. The resulting number of strips is 4.

Sample 1	Tubes 1-8 (first strip)
Sample 2	Tubes 1-8 (second strip)
“C-”	Tubes 1-8 (third strip)
“C+”	Tubes 1-8 (fourth strip)

8.2 Vortex the Taq-polymerase solution for 3-5 seconds, then spin for 1-3 seconds to collect the drops.

8.3 Add 10 µL of Taq-polymerase solution into each tube. Avoid paraffin layer break.

8.4 Add one drop (~20 µL) of mineral oil into each tube of the strip. Close strips tightly.

8.5 Vortex the tubes with samples, “C+” and “C-“ and for 3-5 seconds and spin down drops for 1-3 seconds.

In case of using **PREP-GS GENETICS DNA extraction kit**. After vortexing centrifuge the tubes with the DNA preparation at 16000 x g for one minute to precipitate the sorbent. If, after isolation, the supernatant containing the isolated DNA was transferred to new tubes, centrifugation is carried out for 1-3 seconds in a vortex mixer.

Open the strip, add DNA sample (or control sample), then close the strip before proceeding to the next DNA sample to prevent contamination. Use filter tips.

8.6 Add 5.0 µL of DNA sample into corresponding strips. Do not add DNA into the "C+", "C-" strips. Avoid paraffin layer break. Close the strips tightly.

8.7 Add 5.0 µL of negative control (C-) which passed whole DNA extraction procedure into corresponding strip. Add 5.0 µL of positive control sample (C+) into corresponding strip. Avoid paraffin layer break. Close the strips tightly.

8.8 Spin strips for 3-5 seconds.

8.9 Set the tubes into the Real-time Thermal Cycler.

8.10 Launch the RealTime_PCR application in "Device operation" mode. Upload the .ini file supplied with the kit before first run. Please refer to DTlite or DTprime thermal cycler's user manual for details on working with .ini files. In subsequent runs add corresponding test to the protocol, specify the number and ID's of the samples, specify the position of the tubes in the thermal unit (p. 8.9) and run PCR. See table 3.

The type of control strips must be specified as "Sample".

Selecting a test, Table 3 should be displayed in the "Start run" window.

Table 3. The PCR program for DTlite and DTprime Thermal Cyclers

Step	Temperature, °C	Min.	Sec.	Number of cycles	Optical measurement	Type of the step
1	80	0	30	1		Cycle
	94	1	30			
2	94	0	30	5		Cycle
	64	0	15		v	
3	94	0	10	45		Cycle
	64	0	15		v	
4	94	0	5	1		Cycle
5	10	…	…	Holding		Holding

9. CONTROLS

The **AZF Microdeletions REAL-TIME PCR Genotyping Kit** contains positive control sample. Positive control is a cloned part of the gene detected by the aid of the kit. It is produced with genetic engineering techniques and characterized by automatic DNA sequencing. The PCR-Mix contains amplification system for human genomic DNA intended to sample intake control (SIC). SIC allows to determine sufficiency of the extracted DNA for analysis. To reveal possible contamination a negative control is required.

A negative control sample should go through all stages of DNA extraction. Physiological saline solution can be used as a negative control sample in volumes indicated in supplied instructions.

The test result is considered valid when the software represents a graph with the fluorescence dependence of the cycle number for each tube in the thermoblock. The table will show the sample ID and the Cp values.

The test result is considered invalid when the Cp of Hex (SIC dye label) is more than 32 or absent.

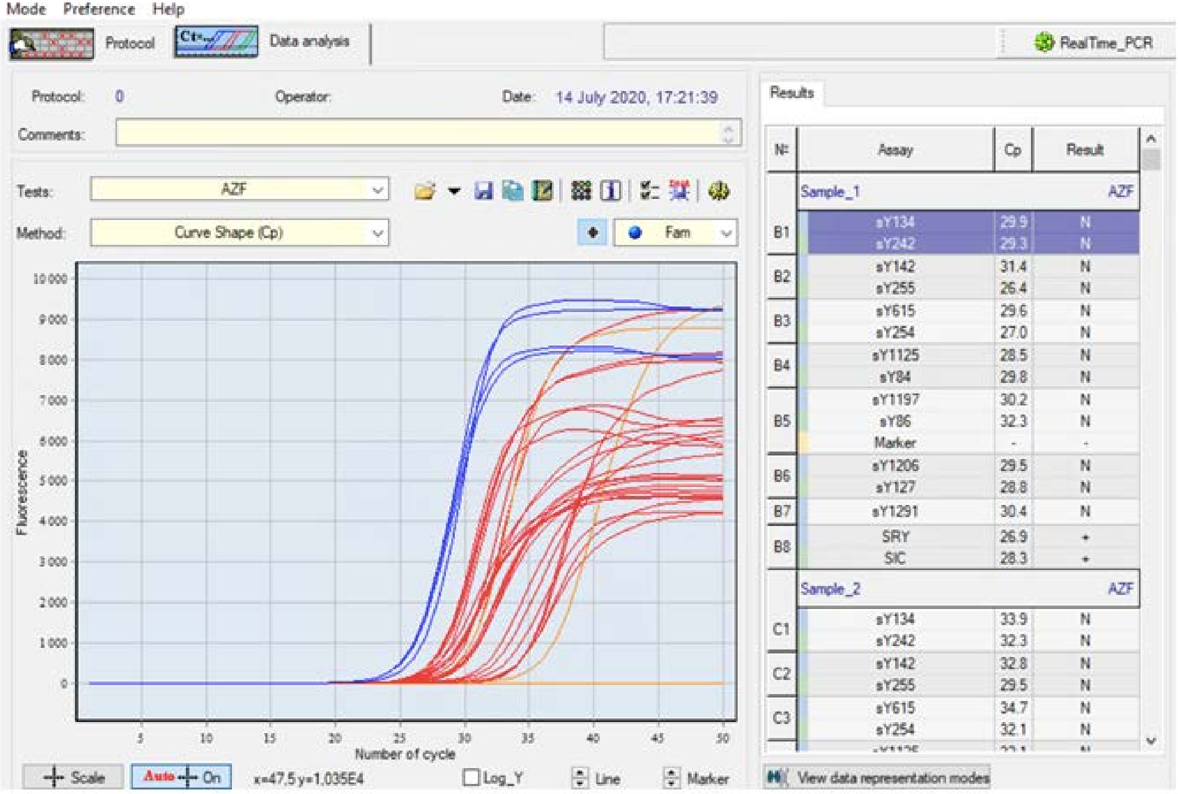
If positive control (C+) does **not** have the signal, it is necessary to repeat the whole test. It may be caused by inhibitors, operation error or violation of storage and handling requirements.

If the signal for negative control (C-) is present, all results of current PCR run are considered false. Decontamination is required.

10. DATA ANALYSIS

Registration and interpretation of the PCR results are held in automatic mode. The graph will show the fluorescence dependence of the cycle number for each tube in the thermoblock. The table will show the sample ID, the name of the deletion being detected, the Cp values and the genotyping result of each sample. It is possible to create and print a report based on the analysis results. Please refer to DTlite or DTprime thermal cycler’s user manual for details on working with software.

For samples containing a sufficient quantity of DNA for correct analysis, the software defines the genotype. The samples containing an insufficient quantity of DNA (less than 1.0 ng per reaction or Cp>32) will be analyzed as invalid.



The interpretation of the result for each sample is carried out automatically with respect to Cp values for Fam and Hex (specific dye label) and Hex (SIC dye label) channels.

Genetics of inherited diseases.

Detection of AZF loci deletions by real-time PCR.

Date 14 July 2020, 17:21:39
Number of tube ...
Patient name ...
Sex ...
Age ...
Organization ...
Clinician name ...
Comments ...

Logotype

Information about laboratory

Sample ID: Sample_3

№	Name of marker	Loci	Result
1	sY86	AZFa	Norm
2	sY84	AZFa	Norm
3	sY615	AZFa	Norm
4	sY127	AZFb	Norm
5	sY134	AZFb	Norm
6	sY142	AZFb	Norm
7	sY1197	AZFc	Norm
8	sY254	AZFc	Norm
9	sY255	AZFc	Norm
10	sY1291	AZFc	Deletion
11	sY1125	AZFc	Norm
12	sY1206	AZFc	Norm
13	sY242	AZFc	Norm

Conclusion:

Study was carried out by

Date
Signature

Table 4. Cp values for Fam and Hex channels used for interpretation of PCR results (only for DTlite or DTprime instruments)

Result (Cp)	Indication	Interpretation
Detection of deletions sY134 - sY1291		
Cp≤37	“N”	No deletion
Cp>37	“invalid”	Uncertain result
Cp is undefined	“DEL”	Deletion
Detection of gender (SRY gene)		
Cp≤37	“+”	SRY gene is defined (the sample was taken from male)
Cp>37	“invalid”	Uncertain result
Cp is undefined	“-“	No SRY gene
Detection of SIC		
Cp≤32	“+”	Positive result
Cp>32	“invalid”	Uncertain result

Table 5. Results of the assay of negative and positive control samples

	Detection	Cp	Result
“C-“	sY134 - sY1291	Cp is undefined	“DEL”
	SRY		
	SIC		
“C+”	sY134 - sY1291	Cp is defined	“N”
	SRY		
	SIC		
N — norma, DEL — deletion			

When negative result in positive control (C+) is obtained, the results of whole series are considered false. It is necessary to repeat the assay.

When positive result in negative control (C-) is obtained, the results of whole series are considered false. It is required to eliminate contamination.

When the result of amplification is considered as uncertain, amplification, or DNA extraction, or collecting of clinical material are required to be repeated.

11. SPECIFICATIONS

a. The analytical specificity of the **AZF Microdeletions REAL-TIME PCR Genotyping Kit** was assessed by bioinformatics analysis using available on-line databases with up-to-date comprehensive genetic information. The specific oligonucleotides used in the test were checked against GenBank database sequences. None of the sequences showed sufficient similarity for unspecific detection.

The samples with detected Y-specific markers are to be registered positive for specific product (Y-specific chromosome). The samples free of detected Y-specific markers are to be registered negative for specific product.

b. In a determination of analytical sensitivity, the **AZF Microdeletions REAL-TIME PCR Genotyping** Kit demonstrated the ability to reproducibly detect 1 or more genome equivalents per PCR reaction.

The lower limit of detection is not less than 1.0 ng of human DNA per amplification tube, which corresponds to Cp≤32 on the SIC detection channel (Hex) in corresponding tube after amplification. When the amount of DNA is smaller (Cp>32 on the SIC detection channel (Hex)), the manufacturer does not guarantee the correct result of the kit.

After the amplification reaction for samples with insufficient quantity of DNA (less than 1.0 ng per amplification tube), the result is defined as unreliable.

c. SRY gene

The samples belonging to a male biological material are to be registered as an exponential increase in the level of fluorescence in the corresponding test tube (SRY). The samples belonging to a woman biological material are not to be registered as an exponential increase in the level of fluorescence in the corresponding test tube (SRY) during amplification.

d. Sample Intake Control

During amplification of biological samples containing human genomic DNA the Real-Time PCR instrument should record the exponential growth of the fluorescence level in the corresponding tube.

During amplification of biological samples that do not contain the human genomic DNA the Real-Time PCR instrument should record the absence of exponential growth of the fluorescence level in the corresponding tube.

The claimed specifications are guaranteed when DNA extraction is performed with **PREP-GS Genetics** REF P-023/4EU or **PREP-RAPID Genetics** REF P-021/4EU **Extraction Kits**.

12. TROUBLESHOOTING

Table 4. Troubleshooting

	Result	Possible cause	Solution
C+	-	Operation error PCR inhibition Violation of storage and handling requirements	Repeat whole test Dispose current batch
C-	+	Contamination	Dispose current batch Perform decontamination procedures
SIC	-	PCR inhibition Insufficient amount of DNA	Repeat whole test Resample

If you face to any undescribed issues contact our customer service department regarding quality issues with the kit:

Phone: +7(495)640.16.93,

Phone/Fax: +7(495)640.17.71.

E-mail: hotline@dna-technology.ru, http://dna-technology.com/support.

13. QUALITY CONTROL

“DNA-Technology Research&Production”, LLC declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In vitro Diagnostic Medical Devices. The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of IVDD products;
- creation of values for customers;
- maintenance of the best service quality and customer management.

Contact our customer service with quality issues of **AZF Microdeletions REAL-TIME PCR Genotyping Kit**:

Technical support: hotline@dna-technology.ru,

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http://www.dna-technology.com

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14. KEY TO SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	*In vitro* diagnostic medical device		Date of manufacture
	Temperature limitation		Consult instructions for use
	Sufficient for	REF	Catalogue number
	Use by		Manufacturer
LOT	Batch code		Keep away from sunlight
	Caution	VER	Version
CONTROL −	Negative control	CONTROL +	Positive control
EC REP	Authorized representative in the European Community		Do not reuse
NON STERILE	Non-sterile		