DNA-TECHNOLOGY

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CE IVD

For professional use only

PREP-PK

Kit for sample pretreatment while processing of nucleic acid isolation

INSTRUCTION FOR USE

EC REP

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REF P-028-N/2EU

P-030-N/2EU

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1. INTENDED USE

The **PREP-PK** kit is intended for the removal of inhibiting effects causing by fixation and proteolysis by proteinase K in human biomaterial (formalin-fixed paraffin-embedded (FFPE) tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology) before nucleic acid extraction for molecular-genetic analysis by PCR method.

PREP-PK kit is manufactured in the following variants: Set № 1 and Set № 2.

Set № 1 is intended for the preprocessing of FFPE tissues, native tissues, cervical swabs taken in fixing transport medium for liquid-based cytology.
Set № 2 is a shortened of Set № 1 and is intended for the pretreatment of FFPE tissues and cervical swabs taken in fixing transport medium for liquid-based cytology.

This medical device is an auxiliary agent in clinical laboratory diagnostics.

The application of the kits does not depend on population and demographic aspects. There are no contradictions for use of the **PREP-PK** kit**.**

The **PREP-PK** 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 instruction for use.

2. METHOD

The method is based on proteolysis by Proteinase K and removal of inhibiting effects caused by cross-linking of nucleic acids under action of fixation agents in order to increase the effectiveness of nucleic acids extraction in subsequent DNA and/or RNA extraction.

3. CONTENT

The detailed description of content is represented in Tables 1-2.

Table 1. The **PREP-PK** kit content, Set № 1 for P-028-N/2EU

Reagent	Description	Total volume	Amount
PK buffer	Colorless transparent liquid	15 mL	1 vial
PK-NT buffer	Colorless transparent liquid	20 mL	1 vial
Proteinase K	Colorless transparent viscous liquid	250 µL	1 tube

Table 2. The **PREP-PK** kit content, Set № 2 for P-030-N/2EU

Reagent	Description	Total volume	Amount
PK buffer	Colorless transparent liquid	15 mL	1 vial
Proteinase K	Colorless transparent viscous liquid	250 µL	1 tube

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

The **PREP-PK** kit is designed for 50 samples (including negative controls).

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

- Biological safety cabinet class II;
- Vortex mixer;
- Refrigerator;
- Freezing chamber;
- High speed centrifuge (RCF(g) no less than 16000);
- Solid-state thermostat (temperature range 25-98 °C) (for example, TT-1 made by "DNA-Technology", LLC);
- Tube rack for 1.5 mL tubes;
- 1.5 mL tubes;
- 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);
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution;
- Beads for homogenization with diameter 2.0-5.0 mm (when working with native tissues);
- D-limonene (when working with FFPE tissues samples and depending on the way of paraffin removal);
- 96% distilled ethyl alcohol (when working with FFPE tissues samples and depending on the way of paraffin removal);
- Nucleic acid extraction kit.

«DNA technology» production kits are recommended for NA extraction/isolation

Analytes	**Taxonomy group**	**PREP-PK in combination with NA extraction kit**
Cervical swabs collect in BD ShuePath		
DNA	Viruses	PREP-NA PLUS
		PREP-MB RAPID
	Viruses, bacteria, fungi, protozoa	PREP-GS PLUS
		PREP-MB-NA
FFPE tissue samples		
DNA	Human (genomic DNA)	PREP-NA PLUS
RNA	Human (mRNA of human genes)	PREP-NA
		PREP-MB-NA
Native tissue samples		
RNA and DNA	Human (mRNA of human genes)	PREP-NA
	Human (genomic DNA)	PREP-MB-NA

5. STORAGE AND HANDLING REQUIREMENTS

Expiry date – 12 months from the date of production.

PK buffer, PK-NT buffer must be stored at temperatures from 2 °C to 8 °C over the storage period.

Proteinase K must be stored at temperatures from minus 18 °C to minus 22 °C over the storage period.

The excessive temperature can be detrimental to product performance.

The kit has to be transported in thermoboxes with ice packs by all types of roofed transport at temperatures corresponding to storage conditions of the kit components.

Transportation of the kit, except the Proteinase K, is allowed in termobox with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C but no more than 5 days and should be stored at temperatures from 2 °C to 8 °C immediately on receipt.

It is allowed to transport the Proteinase K in termobox with ice packs by all types of roofed transport at temperatures up to 25 °C but no more than 5 days and should be stored at temperatures from minus 18 °C to minus 22 °C immediately on receipt.

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

- PK buffer, PK-NT buffer must be stored at temperatures from 2 °C to 8 °C over the storage period;
- Proteinase K must be stored at temperatures from minus 18 °C to minus 22 °C over the storage period.

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

An expired **PREP-PK** 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 **PREP-PK** 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 **PREP-PK** 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. Wear powder-free surgical gloves. Wear 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, PCR-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 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. 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.

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

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 **PREP-PK** kit is designed for the analysis of FFPE tissues samples, native tissues samples, cervical swabs taken in fixing transport medium for liquid-based cytology.

For RNA extraction it is recommended to fix native tissue samples in special transport media intended for transportation and stabilization of RNA.

ATTENTION! PREP-PK kit cannot be used for RNA extraction from biomaterial fixed in BD SurePath transport medium. Isolation of DNA can be performed from biomaterial in BD SurePath transport medium.

Extraction of RNA can be performed from cervical swabs collected in transport medium Thin Prep (Hologic, USA) or Cell Prep (Biodyne, Korea) directly without using **PREP-PK** kit.

Amount of biomaterial for preprocessing

FFPE tissues

2-4 FFPE tissue sections 5.0 µm depth (average square of section 0.5-1.5 sm^2) are placed into dry single-use 1.5 mL tubes.

Native tissues (including bioptates)

50-100 mg in transport medium or medium for RNA stabilization. Native tissue samples can be fragments 3.0-5.0 mm.

Swabs in fixing transport medium for liquid-based cytology

From 1 mL.

8. PROCEDURE

ATTENTION!

1. Use DNAse and RNAse filter tips
2. Change the tip each time while removing, transferring or adding liquid to the tube. Do not touch the tubes walls while adding liquid in the tube. If touching the wall, change the tip.
3. Open only the cap of the tube which is in work, then close the tube before proceeding to the next tube to prevent contamination.
4. Proceed the tubes with samples and negative control equally.

Assay procedure:

8.1 FFPE tissue sections, without special paraffin removal (without usage of d-limonene)

8.1.1 Centrifuge tubes with samples at RCF(g) 13000 for 30-60 seconds at room temperature (from 18 °C to 25 °C) to spin down the biomaterial.

8.1.2 Add 300 µL of PK buffer into marked tubes with samples and an empty 1.5 mL tube marked for “C-”.

8.1.3 Mix the samples by vortexing for 3-5 seconds.

8.1.4 Spin the tubes with samples in vortex mixer for 60 seconds to drop sections into liquid.

8.1.5 Incubate the tubes with samples at 72 °C for 10 minutes. Mix the samples by vortexing for 3-5 seconds 2-3 times for incubation. The tissue shouldn’t be left on the walls of the tubes.

8.1.6 Spin the tubes with samples in vortex mixer for 60 seconds.

8.1.7 Vortex the tube with Proteinase K for 3-5 seconds and spin down the drops in vortex mixer for 3-5 seconds.

8.1.8 Add 5.0 µL of Proteinase K into each tube with samples, breaking the paraffin layer. Add Proteinase K under paraffin into reaction mixture containing PK buffer and mix by pipetting.

8.1.9 Incubate the tubes:

8.1.9.1 **To obtain RNA** incubate the tubes with samples at temperature 60 °C for 30 minutes and then at temperature 80 °C for 10 minutes.

8.1.9.2 **To obtain DNA** incubate the tubes with samples at temperature 60 °C for 2 hours. In case of excessive amount of biomaterial the time of incubation can be increased to 24 hours, for example, samples can be left in thermostat overnight. In case of increasing the time of incubation additional volume (5.0 µL) of Proteinase K can be added after 2-3 hours of incubation. After the end of incubation at 60 °C, incubate at temperature 95 °C of 10 minutes.

ATTENTION! For the incubation at 60 °C it is required to vortex the samples 1-2 times for 3-5 seconds. The tissue shouldn't be left on the tubes walls. During warming the tubes, cap opening can happen. It is recommended to use tubes with safety lock caps and/or thermostats with clamping lid. Warming the thermostat prior to work is not required. Both temperature regimes can be programmed in one thermostat.

8.1.10 Centrifuge the tubes with samples at RCF(g) 16000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.1.11 Take out the required volume of the lysate from under the paraffin layer without touching precipitate to use for nucleic acids (NA) extraction. Transfer it into the new marked tube.

A paraffin layer will be formed on top of the liquid. On the bottom of the tube remainings of debris can form precipitate.

8.1.12 Conduct NA extraction according to NA extraction kit user manual. Considering sample preprocessing, time of lysis can be shorten to 5 minutes.

It is allowed to store the remaining of the sample at minus 20°C for one month for subsequent use

8.2 FFPE tissue sections with usage of d-limonene

8.2.1 Centrifuge tubes with samples at RCF(g) 13000 for 30-60 seconds at room temperature (from 18 °C to 25 °C) to spin down the biomaterial.

8.2.2 Add into marked tubes with samples 1.0 mL of d-limonene, vortex the tubes for 3-5 seconds.

8.2.3 Incubate the tubes at temperature 50 °C for 5 minutes. Mix the samples by vortexing 3-5 seconds 1-2 times during incubation.

8.2.4 Centrifuge tubes with samples at RCF(g) 13000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.2.5 Remove supernatant.

8.2.6 Add in the tubes with samples 1.0 mL of 96% distilled ethanol, vortex the tubes for 3-5 seconds.

8.2.7 Centrifuge tubes with samples at RCF(g) 13000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.2.8 Remove supernatant.

8.2.9 Add in the tubes with samples 1.0 mL of 96% distilled ethanol, vortex the tubes for 3-5 seconds.

8.2.10 Centrifuge tubes with samples at RCF(g) 13000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.2.11 Remove supernatant.

8.2.12 Leave the tubes opened and dry the precipitate for 30-45 minutes at room temperature (from 18 °C to 25 °C).

8.2.13 Add 200 µL of PK buffer into marked tubes with samples and a new 1.5 mL tube marked "C-".

8.2.14 Mix the samples by vortexing for 3-5 seconds.

8.2.15 Spin the tubes with samples in vortex mixer for 60 seconds to drop biomaterial into liquid.

8.2.16 Vortex the tube with Proteinase K for 3-5 seconds and spin down the drops in vortex mixer for 3-5 seconds.

8.2.17 Add 5.0 µL of Proteinase K into each tube with samples. Add Proteinase K directly into reaction mixture containing PK buffer and mix by pipetting.

8.2.18 Incubate the tubes:

8.2.18.1 **To obtain RNA** incubate the tubes with samples at temperature 60 °C for 30 minutes and then at temperature 80 °C for 10 minutes.

8.2.18.2 **To obtain DNA** incubate the tubes with samples at temperature 60 °C for 2 hours. In case of excessive amount of biomaterial the time of incubation can be increased to 24 hours, for example, samples can be left in thermostat overnight. In case of increasing the time of incubation additional volume (5.0 µL) of Proteinase K can be added after 2-3 hours of incubation. After the end of incubation at 60 °C, incubate at temperature 95 °C for 10 minutes.

ATTENTION! For the incubation at 60 °C it is required to vortex the samples 1-2 times for 3-5 seconds. The tissue shouldn't be left on the tubes walls. On warming the tubes, cap opening can happen. It is recommended to use tubes with safety lock caps and/or thermostats with clamping lid. Warming the thermostat prior to work is not required. Both temperature regimes can be programmed in one thermostat.

8.2.19 Centrifuge tubes with samples at RCF(g)16000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.2.20 Take out the required volume of the lysate from under the paraffin layer without touching precipitate to use for NA extraction. Transfer it to the new marked tube.

8.2.21 Conduct NA extraction according to NA extraction kit user manual. Considering sample preprocessing, time of lysis can be shorten to 5 minutes.

8.3 Native tissue samples

8.3.1 Spin in vortex mixer the marked tubes with native tissue samples for 60 seconds. Completely remove transport medium.

8.3.2 Add into tubes with samples 400 µL of buffer PK-NT and 3-5 beads for homogenization. Conduct homogenization.

8.3.3 Centrifuge the tubes with samples at RCF(g) 16000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.3.4 Transfer into new marked 1.5 mL tubes 200 µL of homogenate.

8.3.5 Add 200 µL of buffer PK-NT into a new 1.5 mL tube marked "C-".

8.3.6 Vortex the tube with Proteinase K for 3-5 seconds and spin down the drops in vortex mixer for 3-5 seconds.

8.3.7 Add 5.0 µL of Proteinase K into each tube with samples.

8.3.8 Carefully vortex the tubes for 1-2 seconds without liquid splitting.

8.3.9 Incubate the samples at 60°C for 30 minutes, then at 95°C for 10 minutes.

ATTENTION! On warming the tubes, cap opening can happen. It is recommended to use tubes with safety lock caps and/or thermostats with clamping lid. Warming the thermostat prior to work is not required. Both temperature regimes can be programmed in one thermostat.

8.3.10 Centrifuge the tubes with samples at RCF(g) 16000 for 60 seconds at room temperature (from 18 °C to 25 °C).

8.3.11 Take out the required volume of the lysate from under the paraffin layer without touching precipitate to use for NA extraction. Transfer it to the new marked tube. Conduct NA extraction according to NA extraction kit user manual.

It is allowed to store the remaining of the sample at minus 20°C for one month for subsequent use.

8.4 Cervical swabs taken in fixing transport medium for liquid-based cytology for subsequent DNA extraction

8.4.1. Mark new single-use 1.5 mL tube for each sample and negative control sample “C-”.

8.4.2. Mix by pipetting the sample with biomaterial in preservative liquid. Transfer into marked tube 1.0-1.4 mL of biomaterial in preservative liquid.

8.4.3. Centrifuge the tubes with samples at RCF(g) 16000 for 5 minutes at room temperature (from 18 °C to 25 °C).

8.4.4. Without touching the precipitate, completely remove the supernatant. Use new tip for each tube.

8.4.5. Vortex the tubes with buffer PK and Proteinase K for 3-5 seconds and spin down the drops in vortex mixer for 3-5 seconds.

8.4.6. Prepare lysis mixture. Mix in one tube:

- 100 × (N+1) µL of PK buffer,
- 3,0 × (N+1) µL of Proteinase K,

N is the number of marked tubes.

8.4.7. Add to each tubes with samples and “C-” tube 100 µL of lysis mixture. Vortex the tubes for 3-5 seconds.

8.4.8. Thermostate the tubes at 55 °C for 1 hour, after that thermostate at 95 °C for 10 minutes.

ATTENTION! For the incubation at 60 °C it is required to vortex the samples 1-2 times for 3-5 seconds. The tissue shouldn’t be left on the tubes walls. On warming the tubes, cap opening can happen. It is recommended to use tubes with safety lock caps and/or thermostats with clamping lid. Warming the thermostat prior to work is not required. Both temperature regimes can be programmed in one thermostat.

8.4.9. Spin down the drops in vortex mixer for 3-5 seconds.

8.4.10. Take the required for extraction volume of the lysate and transfer it to the new marked tubes.

If the volume of sample corresponds to 100 µL, in case of absence of precipitate it is allowed to conduct NA extraction without transferring the sample into a new tube.

8.4.11. Conduct NA extraction according to NA extraction kit user manual. Considering sample preprocessing, time of lysis can be shorten to 5 minutes.

It is allowed to store the remaining of the sample at minus 20 °C for one month for subsequent use.

9. SPECIFICATIONS

Effectiveness characteristics

Effectiveness of biomaterial preprocessing is estimated after nucleic acid extraction, so the quality and quantity of NA depends on the extraction system used. For the quality and quantity of NA estimation the following parameters can be used: concentration of nucleic acids, proportion of optical density A260/A230 (presence of admixtures of organic compounds), proportion of optical density A260/A280 (presence of protein admixtures), estimation of PCR results.

Nucleic acids can be poorly amplified while having good optical characteristics due to partly degradation or modification during biomaterial fixation that can decrease the effectiveness of PCR. Estimation of the quality and quantity of NA can be conducted using Cp of analyzed and control analytes/parameters (sample intake control (SIC), reference genes on gene transcript analysis (mRNA) and internal controls (IC) of reaction).

On conducting laboratory clinical trials of **PREP-PK** kit in combination with different NA extraction kits the following characteristics have been obtained:

<table>
<tr><th>Analyte</th><th>Taxonomy group</th><th>PREP-PK in combination with NA extraction kit</th><th>Amount of nucleic acid, µg</th><th>A260/ A280</th><th>A260/ A230</th><th>Effectiveness[1]</th></tr>
<tr><td colspan="7">Cervical swabs taken in fixing transport medium for liquid-based cytology
n = 54 samples</td></tr>
<tr><td rowspan="4">DNA</td><td rowspan="2">Viruses</td><td>PREP-NA PLUS</td><td>0.8 – 6.4</td><td>1.6 – 1.9</td><td>0.1 – 0.9</td><td rowspan="4">100 %
(Ptrue = 99.7)</td></tr>
<tr><td>PREP-MB RAPID</td><td>2.7 – 10.7</td><td>1.2 – 1.5</td><td>0.1 – 0.3</td></tr>
<tr><td rowspan="2">Viruses, bacteria, fungi, protozoa</td><td>PREP-GS PLUS</td><td>2.5 – 5.1</td><td>2.0 – 2.0</td><td>0.1 – 0.1</td></tr>
<tr><td>PREP-MB-NA</td><td>1.4 – 7.0</td><td>1.6 – 2.0</td><td>0.1 – 0.6</td></tr>
<tr><td colspan="7">FFPE tissue sections
(mammal gland tissue n = 30 samples;
lung tissue n = 30 samples)</td></tr>
<tr><td>DNA</td><td>Human (genomic DNA)</td><td>PREP-NA PLUS</td><td>1.1 – 26.5</td><td>1.6 – 1.8</td><td>0.05 – 0.6</td><td>100 %
(Ptrue = 99.1)</td></tr>
<tr><td rowspan="2">RNA</td><td rowspan="2">Human (mRNA of human genes)</td><td>PREP-NA</td><td>1.2 – 10.5</td><td>1.8 – 2.0</td><td>0.1 – 1.7</td><td rowspan="2">100 %
(Ptrue = 96.2)</td></tr>
<tr><td>PREP-MB-NA</td><td>1.2 – 6.9</td><td>1.7 – 2.0</td><td>0.1 – 0.1</td></tr>
<tr><td colspan="7">Native tissue
(mammal gland tissue n = 28 samples)</td></tr>
<tr><td rowspan="2">RNA and DNA</td><td>Human (mRNA of human genes)</td><td>PREP-NA</td><td>2.1 – 40.3 (DNA)
1.0 – 30.5 (RNA)</td><td>1.7–1.9</td><td>0.1–1.9</td><td>DNA 100 %
(Ptrue = 96.0)</td></tr>
<tr><td>Human (genomic DNA)</td><td>PREP-MB-NA</td><td>3.0 – 4.8 (DNA)
2.3 – 3.7 (RNA)</td><td>1.8–1.9</td><td>0.04–0.1</td><td>RNA 100 %
(Ptrue = 92.1)</td></tr>
<tr><td>Note:</td><td colspan="6">[1] Effectiveness was calculated based on the estimation of number of identical PCR results on the detection of microorganisms, genomic DNA or human mRNA considering statistical uncertainty with confidence interval 90% by the formula: $Ptrue=0.1^{1/N}$, where N is the number of tests.</td></tr>
</table>

10. 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 official representative in EU by quality issues of **PREP-PK** kit.

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11. KEY TO SYMBOLS

IVD	*In vitro* diagnostic medical device		Manufacturer
	Temperature limit		Date of manufacture
	Contains sufficient for <n> tests		Consult instructions for use
	Use-by date	REF	Catalogue number
LOT	Batch code	VER	Version
	Non-sterile		Caution
EC REP	Authorized representative in the European Community		

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