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For professional use only

PREP-RAPID DNA Extraction Kit

PREP-RAPID Genetics DNA Extraction Kit

INSTRUCTION FOR USE

EC REP

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REF P-001/1EU

P-021/4EU

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1. INTENDED USE

The **PREP-RAPID DNA Extraction Kit** is intended for DNA extraction from biological materials (saliva, urine, prostatic fluid, cerebrospinal fluid, epithelial cells scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) for further analysis by polymerase chain reaction (PCR). The **PREP-RAPID Genetics DNA Extraction Kit** is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.

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-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit.**

The **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction 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 kits only as directed in this instruction for use.

2. METHOD

The **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** offer an express DNA extraction method. The extraction procedure is based on thermal lysis of the cells and intact virus particles followed by PCR inhibitors removal and DNA stabilization preventing its fragmentation.

3. CONTENT

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

Table 1. The **PREP-RAPID DNA Extraction Kit** content, for P-001/1EU

Reagent	Description	Total volume	Amount
«PREP-RAPID» reagent	Blue transparent liquid	50 mL (500 µL in each)	100 tubes

Table 2. The **PREP-RAPID Genetics DNA Extraction Kit** content, for P-021/4EU

Reagent	Description	Total volume	Amount
Lysis buffer	Colorless transparent liquid	28.8 mL	1 vial
«PREP-RAPID» reagent	Blue transparent liquid	14.4 mL	1 vial

WARNING! Tubes with “PREP-RAPID” reagent are recommended to use as a container for collection, storage and transport of biological samples for PCR analysis.

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

The **PREP-RAPID DNA Extraction Kit** is intended for single use and designed for DNA extraction from 100 analyzed samples (including negative controls).

The **PREP-RAPID Genetics DNA Extraction Kit** is designed for DNA extraction from 48 analyzed samples (including negative controls)**.**

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

– Sterile single use swabs and sterile containers to collect clinical material;

- For blood collection: 2.0 or 4.0 mL Vacuette blood collection tubes with anticoagulant, for example, salt of 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

- Biological safety cabinet class II;
- Vortex mixer;
- Refrigerator;
- High speed centrifuge (RCF(g) no less than 16000);
- Solid-state thermostat (temperature range 65-98 °C);
- Tube rack for 1.5 mL tubes;
- 1.5 mL tubes;
- Single channel pipettes (dispensers covering 20-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 200 µL, 1000 µL);
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution;
- Physiological saline solution 0.9% NaCl (Sterile).

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** kit must be transported in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes corresponding to storage conditions of the kit components.

It is allowed to transport the kit in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes from 2 °C to 25 °C, but for no longer than 5 days.

Kits transported with violation of temperature conditions must not be used.

All components of the **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

Shelf-life of the kit following the first opening of the primary container: the components of the kit must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

The kit stored under undue regime must not be used.

An expired **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** must not be used.

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

The conformity of the **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

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. 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.

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-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit** are designed to extract DNA from a wide variety of biological sample types, such urine, prostate fluid, cerebrospinal fluid, scrapes of epithelial cells from the posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, etc. for **PREP-RAPID DNA Extraction Kit** and peripheral whole blood for **PREP-RAPID Genetics DNA Extraction Kit**.

Sample collection recommendations for PREP-RAPID DNA Extraction Kit

- avoid the contact with contaminant material (e.g. blood, purulence, mucus);
- avoid the excess of the sample (add extra 100-200 µL of the "PREP-RAPID" reagent when the excess is observed).

Sample collection and preparation for PREP-RAPID DNA Extraction Kit

Epithelial scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.

WARNING! Remove the mucus from the sampling surface with sterile cotton swab.

Order of taking:

1. Open the 1.5 mL tube, containing the "PREP-RAPID" reagent.
2. Scrape epithelial cells from the corresponding biotope (i.e. posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault etc.) with a sterile sample swab.
3. Put the swab into the tube and rinse it thoroughly. Avoid spraying of solution.
4. Remove swab from solution, press it to the wall of tube and squeeze the rest of the liquid. Throw out the swab.
5. Close the tube tightly and mark it.

Urine

1. Take the portion (approximately 50 mL) of the first-void urine to sterile container and close it tightly.
2. Leave it at room temperature (from 18 °C to 25 °C) for one hour.
3. Pipette the contents of the container.
4. Transfer 1.0 mL of material into 1.5 mL tube.
5. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
6. Remove the supernatant leaving approximately 50 µL (precipitate+ liquid fraction) in the tube.
7. Add 500 µL of the sterile saline to the precipitate.
8. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
9. Remove the supernatant leaving approximately 50 µL (pellet + liquid fraction) in the tube.
10. Add 500 µL of sterile saline to the precipitate.

11. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
12. Remove the supernatant leaving approximately 50 µL (precipitate + liquid fraction) in the tube.
13. Add 500 µL of the "PREP-RAPID" reagent (one reagent tube with "PREP-RAPID" reagent), pipette thoroughly and move back to reagent tube. Close it tightly. Mark the tube.

Saliva, cerebrospinal fluid, synovial fluid

1. Take saliva, cerebrospinal fluid, synovial fluid (approximately 500 µL) to sterile container and close it tightly.
2. Transfer 500 µL of the material into 1.5 mL tube.
3. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
4. Remove the supernatant leaving approximately 50 µL (precipitate + liquid fraction) in the tube.
5. Add 500 µL of sterile saline to the precipitate.
6. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
7. Remove the supernatant leaving approximately 50 µL (precipitate + liquid fraction) in the tube.
8. Add 500 µL of the "PREP-RAPID" reagent (one reagent tube with "PREP-RAPID" reagent), pipette thoroughly and move back to reagent tube. Close it tightly. Mark the tube.

Prostate fluid

1. Take 20-30 µL of the liquid material into 1.5 mL tube with transport medium (or alternatively with 500 µL of sterile buffered saline), vortex the tubes for 5-10 seconds.
2. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).
3. Remove the supernatant leaving approximately 50 µL (precipitate + liquid fraction) in the tube.
4. Add 500 µL of the "PREP-RAPID" reagent (one reagent tube with "PREP-RAPID" reagent), pipette thoroughly and move back to reagent tube. Close it tightly. Mark the tube.

Sample collection and preparation for PREP-RAPID Genetics DNA Extraction Kit

Peripheral whole blood

WARNING! 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 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 longer than 24 hours. 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 stored at temperatures from minus 18 °C to minus 22 °C for no longer than 2 weeks.

Peripheral blood samples should be stored at temperatures from 2 °C to 8 °C for no longer than 24 hours before proceeding with DNA extraction.

8. PROCEDURE

DNA extraction

WARNING! Simultaneously with the extraction of DNA, 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

8.1. PREP-RAPID DNA Extraction Kit

8.1.1 Vortex the tube containing “PREP-RAPID” reagent and analyzed sample for 10 seconds (one reagent tube with “PREP-RAPID” reagent for the negative control sample).

8.1.2 Incubate tubes at 98 °C for 10 minutes. Thermostat must be preheated up to 98 °C. Tubes must be closed tightly.

WARNING! The cap pop up opening is possible while heating. Use the thermostats with hold-down lids (e.g. Gnom Programmable thermostat manufactured by "DNA-Technology Research & Production", LLC) to prevent the tubes opening.

8.1.3 Centrifuge the tubes at RCF(g) 16000 for 3 minutes at room temperature (from 18 °C to 25 °C). Blue pellet could be formed after centrifugation.

Supernatant containing extracted DNA is ready for adding to PCR mix.

WARNING! DNA sample can be stored at temperatures from 2 °C to 8 °C for no longer than 7 days, or at temperatures from minus 18 °C to minus 22 °C for no longer than 6 months**.**

WARNING! When the PCR inhibition is observed (fluorescence signal of the specific product and internal control sample are absent) the DNA extraction procedure must be repeated. For that purpose, transfer 100 µL of supernatant containing extracted DNA into 1.5 mL tube and perform DNA extraction with **PREP-NA DNA/RNA Extraction Kit**.

8.2. PREP-RAPID Genetics DNA Extraction Kit

8.2.1 Mark the required number of 1.5 mL tubes considering the number of samples to be tested and 1 tube for negative control (C-).

8.2.2 Add 600 µL of lysis buffer into each tube avoiding contact of the pipette tip with an edge of the tube.

8.2.3 Add 100 µL of thoroughly mixed peripheral blood to corresponding tubes containing lysis buffer. Add 100 µL of the sterile buffered saline to the tube marked as “C-”. Close the tubes. Vortex the tubes for 3-5 seconds.

8.2.4 Spin the tubes at RCF(g) 16000 for 1 minute.

8.2.5 Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.

8.2.6 Add 300 µL of the “PREP-RAPID” reagent to pellet, close tubes and vortex the tubes for 5-10 seconds.

8.2.7 Incubate the tubes at 98 °C for 10 minutes. Thermostat must be heat up to 98 °C.

WARNING! The cap pop up opening is possible while heating. Use the thermostats with hold-down lids (e.g. Gnom Programable thermostat manufactured by "DNA-Technology Research & Production", LLC) to prevent the tubes opening.

8.2.8 Spin the tubes at RCF(g) 16000 for 3 minutes. After centrifugation blue pellet could be observed.

Supernatant containing extracted DNA is ready for adding to PCR-mix.

WARNING! DNA sample can be stored at temperatures from 2 °C to 8 °C for no longer than 7 days, or at temperatures from minus 18 °C to minus 22 °C for no longer than one month.

9. QUALITY CONTROL

“DNA-Technology Research&Production”, LLC declares that the abovementioned products meet the provision of the Regulation (EU) 2017/746 of the European parliament and of the Council of 5 April 2017. 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 the **PREP-RAPID DNA Extraction Kit** and **PREP-RAPID Genetics DNA Extraction Kit.**

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10. KEY TO SYMBOLS

IVD	*In vitro* diagnostic medical device		Date of manufacture
	Temperature limit		Consult instructions for use
Σ	Contains sufficient for <n> tests	REF	Catalogue number
	Use-by date		Manufacturer
LOT	Batch code	VER	Version
NON STERILE	Non-sterile		Do not re-use
EC REP	Authorized representative in the European Community		

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