DNA-TECHNOLOGY

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CE IVD

**For professional use only**

***PREP-GS DNA Extraction Kit***

***PREP-GS PLUS DNA Extraction Kit***

***PREP-GS Genetics DNA Extraction Kit***

**USER MANUAL**


EC REP

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REF P-003/1EU
P-003/2EU
P-023/4EU

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## 1. INTENDED USE

The ***PREP-GS*** and ***PREP-GS PLUS*** **DNA Extraction Kits** are intended for DNA extraction from biological materials (see Table 1) for further analysis by polymerase chain reaction (PCR). In the ***PREP-GS PLUS*** **DNA Extraction Kit** the total volume of purified DNA is larger (300 µL) comparing to standard ***PREP-GS*** **DNA Extraction Kit** (100 µL) for more PCR tests. The ***PREP-GS Genetics*** **DNA Extraction Kit** is intended for DNA extraction from whole peripheral blood for further DNA genetic testing by PCR.

Table 1. Biological material for DNA/RNA extraction by PREP-GS, PREP-GS PLUS and PREP-GS Genetics DNA Extraction Kits

| Extraction Kit | PREP-GS DNA Extraction Kit | PREP-GS PLUS DNA Extraction Kit | PREP-GS Genetics DNA Extraction Kit |
|---|---|---|---|
| Biological material | Phlegm, blood plasma, saliva, urine, ejaculate, prostate fluid, cerebrospinal fluid, milk serum, minced tissue, epithelial scrapes from posterior pharyngeal wall, uretra, cervical canal, posterior vaginal vault, biological samples with PCR inhibitors | | Peripheral blood |

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 the ***PREP-GS, PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits**.

The ***PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** 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 ***PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** are based on nucleic acids release under the action of a chaotropic agent, followed by precipitation and purification of nucleic acids from impurities.

## 3. CONTENT

The ***PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits**' content is represented in Tables 2-4.

Table 2. The PREP-GS DNA Extraction Kit content, for P-003/1EU

| Reagent | Description | Total volume | Amount |
|---|---|---|---|
| Lysis buffer | Light blue slightly foaming liquid | 15 mL | 1 vial |
| Sorbent | Brown suspension | 2 mL (1 mL per tube) | 2 tubes |
| Washout solution №1 | Colorless transparent liquid | 20 mL | 1 vial |
| Washout solution №2 | Colorless transparent liquid | 20 mL | 1 vial |
| Washout solution №3 | Colorless transparent liquid | 20 mL | 1 vial |
| Elution buffer | Colorless transparent liquid | 10 mL | 1 vial |

Table 3. The PREP-GS PLUS DNA Extraction Kit content, for P-003/2EU

| Reagent | Description | Total volume | Amount |
|---|---|---|---|
| Lysis buffer | Light blue slightly foaming liquid | 7,5 mL | 1 vial |
| Sorbent | Brown suspension | 1 mL | 1 tube |
| Washout solution №1 | Colorless transparent liquid | 10 mL | 1 vial |
| Washout solution №2 | Colorless transparent liquid | 10 mL | 1 vial |
| Washout solution №3 | Colorless transparent liquid | 10 mL | 1 vial |
| Elution buffer | Colorless transparent liquid | 15 mL | 1 vial |

Table 4. The PREP-GS Genetics DNA Extraction Kit content, for P-023/4EU

| Reagent | Description | Total volume | Amount |
|---|---|---|---|
| Lysis buffer | Light blue slightly foaming liquid | 7,2 mL | 1 vial |
| Sorbent | Brown suspension | 960 µL | 1 tube |
| Washout solution №1 | Colorless transparent liquid | 19,2 mL | 1 vial |
| Washout solution №2 | Colorless transparent liquid | 9,6 mL | 1 vial |
| Washout solution №3 | Colorless transparent liquid | 9,6 mL | 1 vial |
| Elution buffer | Colorless transparent liquid | 14,4 mL | 1 vial |

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

The kits are intended for single use and designed for 100 tests for ***PREP-GS*** **DNA Extraction Kit**, 50 tests for ***PREP-GS PLUS*** **DNA Extraction Kit** and 48 tests for ***PREP-GS Genetics*** **DNA Extraction Kit.**

## 4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

### 4.1. Specimen collection

- Specimen collection swabs: sterile single use swabs, cytobrushes, cotton swabs e.t.c for sampling of biomaterial;
- Sterile tubes containing transport media: “DNA-Technology” made STOR-M ( REF P-910-1/1EU) or STOR-F ( REF P-901-1/1EU, P-901-N/1EU, P-901-R/1EU) or equivalent or physiological saline solution or sterile PBS for the transportation of the sample;
- For phlegm, prostate fluid, ejaculate, urine, saliva, cerebrospinal fluid, synovial fluid: sterile containers with a volume of up to 60 mL;
- 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 16000 x g);
- Solid-state thermostat (temperature range 65-98 °C);
- 1.5 mL tubes;

- Tube rack for 1.5 mL tubes;
- Electric laboratory aspirator with trap flask for the removal of supernatant;
- RNase and DNase free pipette tips for aspirator with trap flask;
- 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;
- Container for used pipette tips, tubes and other consumables;
- Physiological saline solution 0.9% NaCl (Sterile).

When extracting DNA from phlegm (method 1):

- 10% trisodium phosphate x $12H_2O$;
- 1M HCl solution;
- 5% chloramines solution;
- distilled water.

When extracting DNA from phlegm (method 2): mucolysin.

## 5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

All components of the ***PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** must be stored at temperatures from 2 °C to 8 °C during the storage period. The excessive temperature can be detrimental to product performance.

Transportation of the kits is allowed in thermal containers with icepacks by all types of covered transport at temperatures from 2 °C to 8 °C inside the container.

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

- Sorbent, washout solution №2, washout solution №3 and elution buffer should be stored at temperatures of 2°C to 8 °C during the storage period;
- Lysis buffer and washout solution №1 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 ***PREP PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** 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-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** to the prescribed technical requirements is subject to compliance of storage, carriage and handling conditions recommended by manufacturer.

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

Technical support E-mail: hotline@dna-technology.ru, www.dna-technology.com.

## 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. 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 a 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 coming in contact with the biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121ºC 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 the liquid solutions are designed for single use and can not be used more than once. 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 dispensers, 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 breach;
- 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-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits** is designed to extract DNA from a wide variety of biological sample types, such as blood plasma, saliva, phlegm, milk, urine, ejaculate, prostate fluid, cerebrospinal fluid, scrapes of epithelial cells from the posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, etc. for ***PREP-GS*** and ***PREP-GS PLUS*** **DNA Extraction Kits** and peripheral whole blood for ***PREP-GS Genetics*** **DNA Extraction Kit**.

**Sample collection and preparation**

**Blood plasma**

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.

**Preparation of the blood (only for *PREP-GS* and *PREP-GS PLUS* DNA Extraction Kits):**

1. Centrifuge the tubes with blood at 900 x g for 20 min at the room temperature (from 18 °C to 25 °C);
2. Take the upper fraction (plasma) with a semi-automatic pipette and put it into new 1.5 mL tube.

The samples are ready for DNA extraction.

**Phlegm sampling**

Put approximately 500 µL of biological sample into sterile container, close it tightly and mark it.

**Preparation of the phlegm:**

Method 1:

1. Add to the sample an equal volume of 10% triple-substituted sodium phosphate x12$H_2O$ and mix intensively.
2. Incubate the mixture at 37 °C for 18–24 hours, then neutralize with 1M HCl (down to pH 6.8–7.4).
3. Centrifuge at 100 x g for 20 min.
4. Take out the supernatant into the 5% solution of chloramine for disinfection.
5. Add 500 µL of distilled water to precipitate, mix by pipetting and put to the new 1.5 mL tube.
6. Centrifuge the tube at 16000 x g for 10 min.
7. Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Method 2:

1. Add mucolysin to the sampling container in the 5:1 ratio (5 parts of mucolysin to 1 part of phlegm), referring to container calibrations.
2. Close the lid of the container, mix the content and incubate for 20–30 min at room temperature, shake the container every 2-3 min.

The samples are ready for DNA extraction.

**Epithelial swabs sampling**

Procedural limitations for genitourinary swabs sampling - local application of medicines, vaginal ultrasound less than 24 hours before the procedure.

Sampling procedure is carried out using special sterile disposable instruments – urogenital swabs, cytobrushes or tampons, depending on the source of clinical material in accordance with established procedures.

In case of pregnancy the use of cytobrushes for genitourinary swabs sampling is contraindicated.

The taking of the swabs is carried out:

- in plastic 1.5 mL tubes with 500 µL of a sterile physiological solution;
- in tubes with transport medium intended by the manufacturer for transportation and storage of samples for PCR.

Order of taking:

1. Open the tube.
2. Scrape epithelial cells from the corresponding biotope (posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, etc.) with a sterile swab.
3. Put the swab into the tube with transport medium 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.

**Preparation of the epithelial swabs:**

1. Centrifuge the tube at 16000 x g for 10 min.
2. Remove the supernatant, leaving approximately 50 µL (precipitate+liquid fraction) in the tube.

The samples are ready for DNA extraction.

**Urine sampling**

Take the portion (approximately 50 mL) of the first-void urine to sterile container and close it tightly.

**Preparation of the urine:**

1. Transfer 1.0 mL of the sample to the 1.5 mL tube.
2. Centrifuge the tube at 16000 x g for 10 min.
3. Remove the supernatant completely.
4. Add 1.0 mL of sterile buffered saline to the precipitate.
5. Centrifuge the tube at 16000 x g for 10 min.
6. Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

The samples are ready for DNA extraction.

**Saliva, cerebrospinal fluid, synovial fluid sampling**

Collect the saliva, cerebrospinal fluid, synovial fluid (approximately 500 µL) to the sterile container and close it tightly.

**Preparation of the saliva, cerebrospinal fluid, synovial fluid:**

1. Transfer 500 µL of the sample to the 1.5 mL tube.
2. Centrifuge the tube at 16000 x g for 10 min.
3. Remove the supernatant, leaving approximately 50 µL (precipitate+liquid fraction).
4. Add 500 µL of sterile buffered saline to the precipitate.
5. Centrifuge the tube at 16000 x g for 10 min.
6. Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction).

The samples are ready for DNA extraction.

**Ejaculate, prostate fluid sampling**

Put 100 µL of the liquid sample into the 1.5 mL tube with transport medium (or alternatively with 500 µL of sterile buffered saline).

**Preparation of the ejaculate, prostate fluid:**

1. Centrifuge the tube at 16000 x g for 10 min.
2. Remove the supernatant, leaving approximately 50 µL (precipitate+liquid fraction) in the tube.

The samples are ready for DNA extraction.

**Transportation and storage of the samples**

Samples may be transported and 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 stored at temperatures from minus 18 °C to minus 22 °C for one month.

In case of usage transport media, biological material samples are transported and stored according to the instruction for the transport medium used intended for subsequent sample analysis by PCR.

Storage of processed phlegm in a container is accepted at temperatures from 2 °C to 8 °C for one day or at temperatures not above minus 16 °C for along time (in case of repeated DNA extraction necessity).

## 8. PROCEDURE

**DNA extraction from biological material**

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 lysis buffer and washout solution №1 can form the precipitate. Dissolve it at 50 °C for 15-20 min prior to use.

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

Example**:** to test 5 samples, mark 5 tubes for samples and 1 tube for “C-”. The resulting number of tubes is 6.

For pre-processed samples with obtaining pellet and supernatant (phegm method 1, saliva, cerebrospinal fluid, urine, ejaculate, prostatic fluid and epithelial scrapes) tubes with 50 µL of material prepared for testing must be marked.

2. Prepare the mixture of lysis buffer and sorbent. Add into the one tube::
   - 150 x (N+1) µL of lysis buffer,
   - 20 x (N+1) µL of preliminarily resuspended sorbent,

   N is a quantity of the samples to be tested taking to account “C-”
3. Add 170 µL of prepared mix to marked tubes.
4. Add 50 µL of prepared sample (PREP-GS, PREP-GS PLUS formats) or 100 µL of peripheral blood (PREP-GS Genetics format) into the marked tubes. Do not add samples to the “C-” tube and tubes with pre-processed samples with obtaining pellet and supernatant (phegm method 1, saliva, cerebrospinal fluid, urine, ejaculate, prostatic fluid and epithelial scrapes) (see Table 5)
5. Add 50 µL (PREP-GS, PREP-GS-PLUS formats) or 100 µL (PREP-GS-GENETICS format) of specimen transport medium or sterile buffered saline to “C-” tube (see Table 5)
6. Close the tubes tightly and vortex them for 3–5 sec.
7. Incubate the tubes at 50 °C for 20 min (PREP-GS, PREP-GS PLUS formats) or 10 min (PREP-GS Genetics format) (see Table 5).
8. Centrifuge the tubes at 16000 x g for 1 min.
9. Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.

10. Add 200 µL (PREP-GS, PREP-GS PLUS formats) or 400 µL (PREP-GS Genetics format) of washout solution №1, close tubes and vortex them for 3–5 sec (see Table 5).
11. Centrifuge the tubes at 16000 x g for 1 min.
12. Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
13. Add 200 µL of washout solution №2, close tubes and vortex them for 3–5 sec.
14. Centrifuge the tubes at 16000 x g for 1 min.
15. Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
16. Add 200 µL of washout solution №3, close tubes and vortex them for 3–5 sec.
17. Centrifuge the tubes at 16000 x g for 1 min.
18. Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
19. Open the tubes and dry precipitate by incubation at 50 °C for 5 min.
20. Add to precipitate 100 µL (PREP-GS format) or 300 µL (PREP-GS PLUS or PREP-GS Genetics formats) of elution buffer, close the tubes, and vortex them for 5-10 sec.
21. Incubate tubes at 50 °C for 5 min (see Table 5).
22. Centrifuge the tubes at 16000 x g for 1 min. Transfer the supernatant into the new tube if sample is to be stored for more than 7 days.

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

The obtained DNA sample can be stored at temperatures from 2 °C to 8 °C for no longer than 7 days. Before using the DNA sample for PCR steps, incubate tubes at 50 °C for 5 min and then centrifuge the tubes at 16000 x g for 1 min. DNA preparation can be stored at temperatures from minus 18 °C to minus 22 °C for no longer than 6 months for PREP-GS, PREP-GS PLUS formats and no longer than 1 year for PREP-GS Genetics format (see Table 5).

Table 5.

| Format | **PREP-GS** | **PREP-GS PLUS** | **PREP-GS Genetics** |
|---|---|---|---|
| Volume of analyzed sample and negative control sample required for DNA extraction procedure | 50 µL | | 100 µL |
| Time of incubation in lysis buffer | 20 min | | 10 min |
| Volume of washout solution №1 required for 1 sample extraction | 200 µL | | 400 µL |
| Volume of elution buffer required for 1 sample extraction | 100 µL | 300 µL | |
| Storage period of purified DNA at temperatures from minus 18 °C to minus 22 °C | up to 6 months | | up to 1 year |

## 9. 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 by quality issues of ***PREP-GS***, ***PREP-GS PLUS*** and ***PREP-GS Genetics*** **DNA Extraction Kits**:

Technical support E-mail: hotline@dna-technology.ru,

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## 10. KEY TO SYMBOLS

| | | | |
|---|---|---|---|
|  | In vitro diagnostic medical device |  | Date of manufacture |
|  | Temperature limitation |  | Consult instructions for use |
|  | Sufficient for |  | Catalogue number |
|  | Use by |  | Manufacturer |
|  | Batch code |  | Keep away from sunlight |
|  | Caution |  | Version |
|  | Authorized representative in the European Community |  | Do not reuse |
|  | Non-sterile | | |