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For professional use only

PREP-MB MAX DNA Extraction Kit

INSTRUCTION FOR USE

EC REP

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P-103-A/8EU

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1. INTENDED USE

The **PREP-MB MAX DNA Extraction Kit** is intended for human, bacterial, viral, and fungal DNA extraction from human biological material (whole peripheral blood; smears/scrapings from urogenital tract and rectum; urine; ejaculate; milk; faeces) for further PCR analysis.

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

The application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **PREP-MB MAX DNA Extraction Kit.**

The **PREP-MB MAX 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 kit only as directed in this instruction for use.

2. METHOD

Method: lysis and release of nucleic acids induced by a chaotropic agent (guanidine thiocyanate), followed by sorption on paramagnetic nanoparticles and washing out the impurities.

3. CONTENT

The **PREP-MB MAX DNA Extraction Kit** is produced in the following packages: package N, package A.

The **PREP-MB MAX DNA Extraction Kit** content is represented in Tables 1-2.

Table 1. The **PREP-MB MAX DNA Extraction Kit** content, package N, for P-103-N/4EU

Reagent	Description	Total volume	Amount
Lysis solution	Colorless transparent foamy liquid	7.2 mL	1 vial
Sorbent	Brown suspension	2.88 mL (1.44 mL in each tube)	2 tubes
Binding solution	Colorless transparent liquid	12 mL	1 vial
Wash solution №1	Colorless transparent liquid	24 mL	1 vial
Wash solution №2	Colorless transparent liquid	24 mL	1 vial
Elution solution	Colorless transparent liquid	14.4 mL	1 vial
Negative control	Colorless transparent liquid	2.4 mL (1.2 mL in each tube)	2 tubes
Magnetic rods	Dark rods in polypropylene blister	48 rods (16 rods in each blister)	3 blisters

Table 2. The **PREP-MB MAX DNA Extraction Kit** content, package A, for P-103-A/8EU

Number of row		Reagent	Description	Total volume	Amount
Cartridge with reagents**	1*	Sorbent	Brown suspension	480 µL (240 µL in each well)	2 wells
	2	Binding solution	Colorless transparent liquid	4.00 mL (2.0 mL in each well)	2 wells
	3	Wash solution №2	Colorless transparent liquid	8.8 mL (4.4 mL in each well)	2 wells
	4	Lysis solution	Colorless transparent foamy liquid	2.4 mL (1.2 mL in each well)	2 wells
	5	Elution solution	Colorless transparent liquid	4.8 mL (2.4 mL in each well)	2 wells
	6	Wash solution №1	Colorless transparent liquid	8.8 mL (4.4 mL in each well)	2 wells
Negative control			Colorless transparent liquid	1.2 mL	1 tube
Magnetic rods			Dark rods in polypropylene blister	32 rods (16 rods in each blister)	2 blisters
* The row 1 of cartridge with reagents has a lateral skew ** The kit includes 2 cartridges with reagents					

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

The reagent kit in package N is intended for single use and is designed for DNA extraction from 48 test samples (including control samples).

The reagent kit in package A is intended for single use and is designed for DNA extraction from 32 test samples (optimal: one run of 32 samples, or two runs of 16 samples), including control samples.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

- Sterile single-use swabs, single-use sterile containers to collect clinical material;
- Sterile tubes containing transport media: “DNA-Technology” made **STOR-F** (REF P-901-1/1EU), or equivalent for the transportation of the sample;
- 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.

4.2. NA extraction

- Biological safety cabinet class II-III;
- Refrigerator;
- High speed centrifuge (RCF(g) at least 16000);
- Vortex mixer;
- Solid-state thermostat (temperature range 25-98 °C);
- Magnetic homogenizer;
- 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);

- 1.5 mL tubes (SSI-1260 are recommended);
- Tube rack for 1.5 mL tubes;
- Electric laboratory aspirator with trap flask for the removal of supernatant (for package N);
- RNase and DNase free non-filtered pipette tips for aspirator with trap flask (for package N);
- Specialized forceps or plastic forceps for arranging the magnetic rods (for package N);
- Dosing device DTstream *L4 (for package A);
- RNase and DNase free filtered pipette tips (volume 1000 µL) for DTstream (for package A);
- Physiological saline solution 0.9% NaCl (sterile);
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution.

5. STORAGE AND HANDLING REQUIREMENTS

Expiry date – 12 months from the date of production.

All components of the **PREP-MB MAX DNA Extraction Kit** must be stored at temperatures from 2 °C to 8 °C and out of light over the storage period.

A small amount of precipitate is allowed in the lysis solution, binding solution and wash solution № 1 during storage.

NOTE. The precipitate is dissolved by heating at 65 °C.

Cartridges as well as vials with lysis solution, binding solution and wash solution №1 must be kept out from sunlight and stored at 2 °C to 8 °C for the entire shelf life of the kit.

Blisters with magnetic rods can be stored at 2 °C to 25 °C for the entire shelf life of the kit.

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 is allowed in thermobox 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.

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;
- cartridges as well as vials with lysis solution, binding solution and wash solution №1 must be kept out from sunlight and stored at 2 °C to 8 °C for the entire shelf life of the kit;
- blisters with magnetic rods can be stored at 2 °C to 25 °C for the entire shelf life of the kit.

The kit stored under undue regime should not be used.

An expired the **PREP-MB MAX DNA Extraction 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-MB MAX DNA Extraction 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-MB MAX DNA Extraction 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 transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When 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-MB MAX DNA Extraction Kit** is designed to extract DNA from whole peripheral blood; smears/scrapings from urogenital tract and rectum; urine; ejaculate; milk; faeces.

General recommendations

- Use DNAse and RNAse free filter tips.
- When adding a solution to a sample containing biological material, be careful not to touch the walls of the tubes. If you touch the wall of the tube, change the tip. The tip should be changed each time the solution is removed from the sample.
- When transferring biological material into the extraction tube, rest the tip on the bottom of the tube. Avoid dripping from the tip onto the walls and cap of the tube.
- Open only the cap of the tube which is in work, then close the tube before proceeding to the next tube to prevent contamination.

Interfering substances

Maximum concentrations of interfering substances in biomaterial samples that do not affect the PCR assay: chlorhexidine (0.05% aqueous solution) – 10% v/v, high viscosity ultrasound gel – 5% v/v.

Sample collection

Smears/scrapes of epithelial cells

Sample taking is made with special sterile single-use tools – probes, cytobrushes, and swabs depending on the source of biological material according to established procedure.

ATTENTION! Remove mucus with sterile cotton swab before taking scrape from cervical channel.

The taking of the sample is carried out:

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

Order of taking:

1. Open the tube.

2. Scrape epithelial cells from the corresponding biotope (urogenital tracts, rectum) with a sterile swab.

3. Put the swab into the tube with solution 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.

Blood sampling

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.

ATTENTION! It is not allowed to use heparin as an anticoagulant.

The sample is ready for DNA extraction.

Ejaculate sampling

The ejaculate is obtained by masturbation and collected in a sterile container. The container with ejaculate is hermetically closed and marked.

Urine sampling

The portion of urine in the amount of 20–30 mL is selected for the analysis. The urine is taken into a special dry sterile container with volume of up to 60 mL, equipped with a hermetic screw-cap.

After the urine collection, container is tightly screwed and marked.

Milk sampling

1. Collect the sample into the sterile container and close it tightly.

2. Mix thoroughly and put 1.0 mL of the sample into the 1.5 mL tube.

3. Centrifuge the tube at RCF(g) 12000-16000 for 3 minutes.

4. Remove the supernatant, leaving approximately 100 µL in the tube.

3. Close the tube tightly and mark it.

The sample is ready for DNA extraction.

Faeces sampling

Samples of faeces with mass (volume) 1.0-3.0 g (1.0-3.0 mL) are transferred to a special sterile dry flask by a single-use filtered pipette tip or single-use shovel. After sample collection the flask is tightly closed and marked.

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 hours prior to analysis. When it is impossible to deliver the material in the laboratory during the day, a one-time freezing of the material is allowed. Frozen material is allowed to be stored at temperatures from minus 18 °C to minus 22 °C for up to 3 months.

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.

NOTE. If samples were stored at minus 18 °C to minus 22 °C, thaw them at room temperature (from 18 °C to 25 °C) or at 2 °C to 8 °C before DNA extraction.

Sample preparation

Smears/scrapes of epithelial cells

1. Centrifuge the tube at RCF(g) 16000 for 10 minutes at room temperature (from 18 °C to 25 °C).

2. Remove supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Sample is ready for DNA extraction.

Ejaculate

1. Transfer 100 µL of liquid sample into 1.5 mL tube with 500 µL of sterile physiological saline solution.

Sample is ready for DNA extraction.

Urine

1. Transfer 1.0 mL of sample to 1.5 mL tube.

2. Centrifuge the tube at RCF(g) 16000 for 10 minutes.

3. Remove supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Samples are ready for DNA extraction.

Faeces

1. Transfer approximately 50-100 mg (µL) of faeces into 1.5 mL tube with 1.0 mL of sterile physiological saline solution.

2. Mix samples by vortexing for 10-15 seconds.

3. Spin the tubes with samples for 30 seconds in vortex mixer.

4. Transfer 100 µL of supernatant into the 1.5 mL tube.

Samples are ready for DNA extraction.

To examine samples for the presence of **bacteria** – acute intestinal infections pathogens, further DNA extraction shall be carried out according to the **PREP-MB MAX** kit instruction.

To examine samples for the presence of **RNA-viruses** – acute intestinal infections pathogens, the **PREP-MB MAX** kit **IS NOT APPLICABLE!**

To extract DNA of Gram-negative bacteria or to conduct a study of the **intestinal biocenosis**, it is necessary to pretreat the sample (faeces) with lysozyme solution:

- add 20 µL of 100 mg/mL lysozyme solution to each tube with biomaterial (faeces), vortex for 5-10 seconds and centrifuge for 1-3 seconds in vortex mixer;
- leave the tubes at room temperature between 18 °C and 25 °C for one hour;

NOTE. If necessary, samples with lysozyme can be stored at 2 °C to 8 °C for no more than 14 hours.

- extract DNA using the **PREP-MB MAX** kit.

8. PROCEDURE

General requirements

1. Sorbent contains very light paramagnetic particles. It is recommended to use 1.0 mL tips to remove solutions from the samples using a single-channel pipette. When using a laboratory aspirator, set the aspiration rate to minimum and do not use large cross-sectional tips.

2. For sample preparation and extraction use DNAse and RNAse free filter tips.

3. Change the tip each time while removing, transferring or adding liquid into the tube. Do not touch the tube walls while adding liquid in the tube. If touching the wall, change the tip.

4. Always open the tube that you are working with, and close it after handling. It is not allowed to work simultaneously with several tubes with open caps.

5. Simultaneously with the extraction of DNA, a negative control should go through all stages of DNA extraction.

6. For information on the necessity of using an internal control, refer to the relevant user manual for PCR kits for the detection of pathogen DNA.

8.1. Assay procedure for package N

1. A magnetic homogenizer[1] is used.

2. Precipitate is allowed in lysis solution, binding solution and wash solution №1 when stored in the refrigerator (from 2 °C to 8 °C).

Prior to work:

- check the lysis solution, binding solution, and wash solution № 1 for the absence of precipitate. If precipitate occurs, place the vial(s) on a thermostat preheated to 65 °C and warm until the precipitate is dissolved. Cool solutions to room temperature (from 18 °C to 25 °C) before use. The precipitate can also be dissolved at room temperature (from 18 °C to 25 °C) for approximately 12 hours;
- stir the contents of the vial(s) by turning them upside down 5-10 times, avoiding foaming.

ATTENTION! When dispensing, use individual tips for each sample. Avoid sorbent loss during supernatant withdrawal.

8.1.1. Mark one 1.5 mL tube for each test sample and for negative control “C-”.

NOTE. For pretreated samples with precipitate and supernatant obtained (epithelial cell scrapings, ejaculate, urine, etc.), mark test tubes with 100 µL of material prepared for assay.

8.1.2. Carefully remove protective foil from the required number of blister wells with magnetic rods.

8.1.3. Add a magnetic rod into each test tube using a forceps, without touching the edge of the test tube.

8.1.4. When using internal control, add 10 µL of the corresponding internal control to each tube.

8.1.5. Stir all solutions thoroughly by inverting at least 20 times.

8.1.6. Add 150 µL of lysis solution to each tube without touching the edge of the tube.

ATTENTION! The solution should be applied to the bottom of the test tube, avoiding the formation of drops. If splashing occurs, it is necessary to spin down the drops on a vortex mixer.

8.1.7. Add 100 µL of the test sample into each test tube.

8.1.8. Add 100 µL of negative control from the kit to the tube labeled “C-”.

[1] - magnetic homogenizer provides sorbent precipitation (paramagnetic particles) and mixing of reagents in the test tube (when adding a magnetic rod). The sorbent precipitation is performed with the homogenizer turned off.

8.1.9. Close the caps tightly and place the tubes in the magnetic homogenizer. Start the homogenizer in pulse mode for 10 minutes.

ATTENTION! Each test tube should be positioned relative to the magnet so that the rod is always covered with solution, and uniform homogenization of suspension throughout the volume of liquid is ensured.

8.1.10. Add 250 µL of binding solution into each tube. Start the homogenizer in pulse mode for 30 seconds.

8.1.11. Carefully resuspend the sorbent in a vortex mixer. Turn the tube upside down and make sure that the sorbent does not stick to the bottom of the tube. If necessary, repeat stirring.

8.1.12. Add 60 µL of sorbent into each tube.

ATTENTION! Add the sorbent into each tube with a separate tip.

8.1.13. Place the tubes in the magnetic homogenizer. Start the homogenizer in pulse mode for 5 minutes.

ATTENTION! If the magnetic particles (sorbent) have partially deposited above and/or below the magnetic rod on the wall of the test tube during mixing in pulse mode, shake these test tubes for 3-5 seconds and centrifuge for 3-5 seconds in a vortex mixer, then return the test tubes to the magnetic homogenizer.

8.1.14. Without removing the tubes from the homogenizer, precipitate the sorbent on the walls of the tubes for 3 minutes (homogenizer off).

8.1.15. Collect as much as possible of the supernatant without removing the tubes from the magnetic homogenizer (with a separate tip from each tube). Avoid taking the sorbent.

8.1.16. Add 250 µL of wash solution №1 to the precipitate. Close the caps of the tubes. Start the homogenizer in pulse mode for 30 seconds.

8.1.17. Without removing the tubes from the homogenizer, precipitate the sorbent onto the walls of the tubes for 3 minutes (homogenizer off).

8.1.18. Collect the supernatant without removing the tubes from the magnetic homogenizer (with a separate tip from each tube). Avoid taking the sorbent.

8.1.19. Repeat p. 8.1.16 – 8.1.18.

8.1.20. Add 500 µL of wash solution №2 to the precipitate. Start the homogenizer in pulse mode for 30 seconds.

8.1.21. Without removing the tubes from the homogenizer, precipitate the sorbent onto the walls of the tubes for 3 minutes (homogenizer off).

8.1.22. Collect as much supernatant as possible without removing the tubes from the magnetic homogenizer (with a separate tip from each tube). Avoid taking the sorbent.

8.1.23. Add 50 to 300 µL of elution solution into each tube. Shake the tubes in a vortex mixer so that all particles from the walls are transferred to the solution.

The volume of elution solution depends on:

- type of assay;
- number of assay parameters;
- number of assays carried out from one DNA sample.

NOTE. The recommended amount of eluate for DNA extraction is given in the instructions for the PCR assays kits.

E x a m p l e :

Type of assay	Amount of elution solution, µL
Virus DNA from whole blood	50
Integrated assays (e.g., Femoflor® kits, Immunoquantex C/V, HPV-QUANT-21, genetic polymorphisms kits)	300

8.1.24. Spin down the particles and the rod to the bottom of the tube in a vortex mixer.

8.1.25. Spin down the drops by centrifugation at RCF(g) 1000-3000 for 3-5 seconds.

8.1.26. Place the tubes in the magnetic homogenizer. Start the homogenizer in pulse mode for 15 minutes.

8.1.27. Without removing the tubes from the homogenizer, precipitate the sorbent onto the walls of the tubes for 3 minutes (homogenizer off).

Supernatant containing the extracted DNA is ready to be added to the reaction mixture for PCR amplification.

ATTENTION! When taking the supernatant containing DNA, do not remove the tubes from the magnetic homogenizer and do not touch the sorbent (magnetic particles).

The obtained DNA preparation can be stored at temperatures from 2 °C to 8 °C for up to 7 days or at temperatures from minus 18 °C to minus 22 °C for up to 1 year.

NOTE. If the DNA preparation is to be stored for more than 7 days, the supernatant must be transferred to a new tube.

8.2. Assay procedure for package A

NOTE. In case of precipitation in the cartridge, place it upside down (protective foil down) without removing the cap, on a thermostat preheated to 65 °C and warm until the precipitate is completely dissolved. Allow solutions to cool to room temperature (from 18 °C to 25 °C) before use. The precipitate can also be dissolved at room temperature (from 18 °C to 25 °C) for approximately 12 hours.

ATTENTION! If the cartridge has been stored after using some of the reagents in previous runs, the precipitate in the cells with binding solution, lysis solution and wash solution № 1 should be dissolved at room temperature (from 18 °C to 25 °C) for at least 12 hours without removing the protective lid avoiding the inversion of the cartridge.

8.2.1. Place the tip racks, having previously removed their cap, on the working table of the DTstream dosing device.

8.2.2. Place the rod blisters in the magnetic rod dispenser.

8.2.3. Carefully remove the protective foil from the blisters.

ATTENTION! Only remove the protective foil once the blisters are installed into the adapter. Otherwise accident scattering of the rods may occur.

8.2.4. Remove the caps from the reagent cartridges. Shake the cartridge thoroughly before inserting it into the adapter so that all the sorbent is at the bottom of the well.

ATTENTION! Do not remove or puncture the reagent cartridges' protective foil.

8.2.5. Place the reagent cartridges into the cartridge adapter.

8.2.6. Install the protective cap for the magnetic forceps and prepare the resetting device according to the dosing device manual.

8.2.7. Mark one 1.5 mL tube for each test sample (16 or 32 including a "C-" negative control tube).

NOTE. For pretreated samples with precipitate and supernatant obtained (epithelial cell scrapings, ejaculate, urine, etc.), mark test tubes with 100 µL of material prepared for assay.

8.2.8. When using internal control, add 10 µL of the corresponding internal control to each tube.

8.2.9. Add 100 µL of the test sample into each test tube.

8.2.10. Add 100 µL of negative control from the kit to the tube labeled "C-". Prepare the system for automatic nucleic acid extraction in deep-well trays by putting prepared trays and required consumables in the device according to its user manual.

ATTENTION! Place the samples in the rack from left to right, top to bottom.

8.2.11. Set up the sample tubes (including the "C-" tube) on the extraction rack, and secure the tube caps in the holders. Place the rack in the magnetic homogenizer.

8.2.12. Using the DTstream start menu or the control computer (see the operating instructions), select the "PREP-MB MAX" scenario.

8.2.13. Set the dosing parameters:

- the number of samples multiple of eight (see p. 8.2.7),
- eluate (dissolved NA sample after extraction) volume from 50 to 300 µL.

The volume of elution solution depends on:

- type of assay;
- number of assay parameters;
- number of assays carried out from one DNA sample.

NOTE. The recommended amount of eluate for DNA extraction is given in the instructions for the PCR assays kits.

Example:

Type of assay	Amount of elution solution, µL
Virus DNA from whole blood	50
Integrated assays (e.g., Femoflor® kits, Immunoquantex C/V, HPV-QUANT-21, genetic polymorphisms kits)	300

8.2.14. Run the reagents dosing.

ATTENTION! After running the scenario, be sure to visually check the placement of magnetic rods at the beginning of the program! If any of the tubes is missing a rod, pause the DTstream program and manually add a rod from an additional blister to the missing tube.

8.2.15. Close the tube caps after running the program.

The supernatant containing the extracted DNA is ready to be added to the reaction mixture for PCR amplification. The obtained DNA preparation can be stored at 2 °C to 8 °C for up to 7 days, or at minus 18 °C to minus 22 °C for up to one year.

NOTE.

1. If the DNA preparation is to be stored for more than 7 days, the supernatant must be transferred to a new tube.
2. If the cartridge is to be stored after running the DTstream program, it must be sealed with a protective lid and stored in accordance with the reagent kit storage conditions, avoiding the inversion of the cartridge.

9. SPECIFICATIONS

a. The minimum amount of biomaterial for nucleic acids extraction is 100 µL.

DNA yield from 100 µL sample: 5-50 ng.

b. Nucleic acid isolation purity: 1.6-2.0 OD260/280 nm.

c. Maximum sorbent capacity: at least 100 ng per extraction per DNA.

Table 3– Functional indicators by type of biomaterial.

Type of biomaterial	**Nucleic acid isolation purity OD260/280, nm**	**DNA yield from 100 µL sample**
Whole peripheral blood (n=45)	1.6 -2.0	6-50
Epithelial cell smears/scrapings from urogenital tract (n=40)	1.6 -2.0	6-50
Epithelial cell smears/scrapings from rectum (n=10)	1.6 -2.0	7-40
Urine (n=36)	1.6 -2.0	8-49
Ejaculate (n=27)	1.6 -2.0	11-50
Milk (n=5)	1.6 -1.8	13-49
Faeces (n=17)	1.6 -2.0	8-42

d. Effectiveness of the reagent kit

The effectiveness of the **PREP-MB MAX** kit was established during clinical trials with the use of additional amplification reagent kits (produced by «DNA-Technology Research&Production», LLC) in the biomaterial samples assay.

Type of biomaterial	**Number of test samples**	**Amplification reagent kit (abbreviated name)**	**The PREP-MB MAX reagent kit efficiency**
Whole peripheral blood	36	CMV	100% (91.65 - 100)
	43	SIC*	100% (92.92 - 100)
Epithelial cell smears/scrapings from urogenital tract	41	Mycoplasma hominis	100% (92.60 - 100)
Epithelial cell smears/scrapings from rectum	27	Candida albicans	100% (89.15 - 100)
Urine	35	CMV	100% (91.40 - 100)
Ejaculate	38	Mycoplasma hominis	100% (92.06 - 100)
	31	SIC*	100% (90.43 - 100)
Milk	32	CMV	100% (90.70 - 100
Faeces	23	Candida albicans	100% (87.49 - 100)
The PREP-MB MAX reagent kit overall efficiency	306	**100% (98.94 – 100)**	
* The amount of extracted genomic DNA was sufficient for further PCR assays.			

10. QUALITY CONTROL

"DNA-Technology Research&Production", LLC declares that the abovementioned 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-MB MAX DNA Extraction Kit**.

Technical support:

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11. KEY TO SYMBOLS

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

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