DNA-TECHNOLOGY

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CE IVD

For professional use only

PREP-MB-RAPID II

DNA/RNA Extraction Kit

INSTRUCTION FOR USE

EC REP

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REF

P-122-A/9EU

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P-124-P/9EU

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1. INTENDED USE

The **PREP-MB-RAPID II DNA/RNA Extraction Kit** is intended for semi-automatic and automatic extraction of human, bacterial, viral, and fungal NA for further analysis by PCR/ RT-PCR.

The **PREP-MB-RAPID II DNA/RNA Extraction Kit** is designed to extract NA from biological materials: urine, scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.

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

Application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **PREP-MB-RAPID II DNA/RNA Extraction Kit.**

The **PREP-MB-RAPID II DNA/RNA 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 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 lysis and release of nucleic acids under the action of a chaotropic agent (guanidine thiocyanate) with subsequent sorption on paramagnetic nanoparticles and washing to get rid of impurities.

The **PREP-MB-RAPID II DNA/RNA Extraction Kit** can be used in conjunction with medical devices designed for the PCR/RT-PCR analysis of nucleic acids. It is recommended to validate the **PREP-MB-RAPID II DNA/RNA Extraction Kit** with the reagent kit for PCR/RT-PCR analysis of nucleic acids.

3. CONTENT

The **PREP-MB-RAPID II DNA/RNA Extraction Kit** is produced in the following packages: package A, package N, package P.

The **PREP-MB-RAPID II DNA/RNA Extraction Kit** content is represented in Tables 1-5.

Table 1. The **PREP-MB-RAPID II DNA/RNA Extraction Kit** content, package A, for P-122-A/9EU

Number of the row		Reagent	Description	Total volume	Number of wells
Cartridge with reagents**	1*	Lysis solution	Blue transparent foamy liquid	14.2 mL (7.1 mL in each well)	2 wells
	2	Wash solution	Green transparent liquid	14.4 mL (7.2 mL in each well)	2 wells
	3	Sorbent	Liquid with precipitate forming brown suspension upon shaking	2.4 mL (1.2 mL in each well)	2 wells
	4	-	-	-	-
	5	Wash solution	Green transparent liquid	14.4 mL (7.2 mL in each well)	2 wells
	6	Elution solution	Colorless or pink transparent liquid	14.4 mL (7.2 mL in each well)	2 wells
* The row 1 of cartridge with reagents has a lateral skew ** The kit includes 2 cartridges with reagents					

Table 2. The **PREP-MB-RAPID II DNA/RNA Extraction Kit** content, package N, for P-122-N/9EU

Reagent	Description	Total volume	Amount
Lysis solution	Blue transparent foamy liquid	28.8 mL	1 vial
Wash solution	Green transparent liquid	57.6 mL (28.8 mL in each)	2 vials
Elution solution	Colorless or pink transparent liquid	28.8 mL	1 vial
Sorbent	Liquid with precipitate forming brown suspension upon shaking	4.8 mL	1 vial
Magnetic rods	Dark rods in polypropylene blister	6 16-rod blisters	6 blisters

Table 3. The **PREP-MB-RAPID II DNA/RNA Extraction Kit** content, package P, Set No. 1, for P-122-P/9EU

Reagent	Description	Total volume	Amount
Lysis solution	Blue transparent foamy liquid	28.8 mL (300 µL in each well)	1 96 deep-well plate
Wash solution	Green transparent liquid	57.6 mL (600 µL in each well)	1 96 deep-well plate
Elution solution	Colorless or pink transparent liquid	9.6 mL (100 µL in each well)	1 96 deep-well plate
Sorbent	Liquid with precipitate forming brown suspension upon shaking	4.8 mL (1.2 mL in each tube)	4 tubes
Elution solution	Colorless or pink transparent liquid	19.2 mL	1 vial

Table 4. The **PREP-MB-RAPID II DNA/RNA Extraction Kit** content, package P, Set No. 2, for P-124-P/9EU

Reagent	Description	Total volume	Amount
Lysis solution	Blue transparent foamy liquid	28.8 mL (300 µL in each well)	1 96 deep-well plate
Wash solution	Green transparent liquid	57.6 mL (600 µL in each well)	1 96 deep-well plate
Elution solution	Colorless or pink transparent liquid	9.6 mL (100 µL in each well)	1 96 deep-well plate
Sorbent	Liquid with precipitate forming brown suspension upon shaking	4.8 mL (1.2 mL in each tube)	4 tubes
Elution solution	Colorless or pink transparent liquid	19.2 mL	1 vial
96 tip comb	1 pc		
96 deep-well plate*	1 pc		
PCR seal sheet**	1 pc		
* for magnetic rod tips discharge ** to seal plates with extracted nucleic acids during storage			

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

Reagent kit in package A is single-use and designed for NA extraction from 96 test samples (one run of 96 samples or 2 runs of 48 samples each), including controls.

Reagent kit in package N is designed for NA extraction from 96 test samples (no more than 48 runs), including controls.

Reagent kit in package P is single-use and is designed for NA extraction from 96 test samples (one run of 96 samples), including controls.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

- Sterile single use swabs, cotton swabs e.t.c for sampling of biomaterial;
- Sterile tubes containing transport media: “DNA-Technology” made **STOR-F** (REF P-901-1/1EU) or equivalent for the transportation of the sample.

4.2. NA extraction

- Biological safety cabinet class II;
- Refrigerator with freezer;
- Vortex mixer;
- High speed centrifuge (RCF(g) at least 12,000) for 1.5 mL tubes;
- Laboratory aspirator with trap flask for the removal of supernatant;
- RNase and DNase free non-filtered pipette tips for aspirator with trap flask;
- Solid-state thermostat (temperature from 65 °C);
- Single channel pipettes (dispensers covering 20-1,000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 200 µL; 1,000 µL);
- Pipette stand;
- Magnetic rack;
- Magnetic pick-up tool or plastic pick-up tool for magnetic rods;
- 1.5 mL RNase and DNase free micro-centrifuge tubes (for DTstream micro-centrifuge tubes SSI-1260 are recommended);
- Tube rack for 1.5 mL tubes;
- Dosing instrument DTstream 12L4 or 15L4[1] configuration at least 1.1 (for packages A REF P-122-A/9EU, P REF P-124-P/9EU);
- RNase and DNase free filtered pipette tips (volume 1000 µL) for DTstream (for packages A REF P-122-A/9EU, P REF P-124-P/9EU);
- System for automatic nucleic acid extraction in 96 deep-well plate (Allsheng Auto-Pure 96, KingFisher Flex);
- 96 deep-well plate (for example, Allsheng-AS-17061-02) (except package P, Set No. 2 REF P-124-P/9EU);
- Adhesive seal sheet (for example, 4titude 4ti-0500) (except package P, No. 2 REF P-124-P/9EU);
- 96 tip comb;
- Physiological saline solution 0.9% NaCl sterile;
- Transport medium for transport and storage of PCR biomaterial (DNA-Technology STOR-F is recommended)
- Container for used pipette tips, tubes and other consumables;
- Container for used pipette tips for DTstream;
- Powder-free surgical gloves;
- Disinfectant solution.

[1] - On the first run of dosing device and in case of 1.5 mL tubes type changing calibration is required in consultation with service engineer.

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **PREP-MB-RAPID II DNA/RNA Extraction 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.

The kit must be transported in the upright position in accordance with the handling sign “TOP”.

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

All components of the **PREP-MB-RAPID II DNA/RNA Extraction Kit** must be stored at temperatures from 2 °C to 25 °C and out of light over the storage period.

When stored in refrigerator (from 2 °C to 8 °C), a minor precipitate is allowed in lysis solution.

The excessive temperature and light can be detrimental to product performance.

Shelf-life of the kit following the first opening of the primary container: the components of the kit must be stored at temperatures from 2 °C to 25 °C and out of light over the storage period.

The kit must be stored in the upright position in accordance with the handling sign “TOP”.

The kit stored under undue regime shall not be used.

An expired **PREP-MB-RAPID II DNA/RNA Extraction Kit** must not be used.

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

Conformity of the **PREP-MB-RAPID II DNA/RNA 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-RAPID II DNA/RNA 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-RAPID II DNA/RNA Extraction Kit** is designed to extract DNA/RNA from urine, scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.

General requirements

- During biomaterial preparation and NA extraction use DNAse and RNAse free tips (filter tips, except for supernatant collection using aspirator);
- When adding solution to the tube containing biomaterial, introduce it carefully, without touching the walls of the tube. If touching occurred, change the tip. Change the tip after each solution removal from the sample.
- Only open the cap of the tube you are working with, then close the tube before proceeding to the next tube to prevent contamination.

Interfering substances

Concentrations of interfering compounds that do not influence subsequent reverse transcription and polymerase chain reaction:

Whole blood 5.0% v/v, mucus (mucin), chlorhexidine (water solution 0.05%), Lasolvan Rhino (nasal spray), Rhinofluimucil (nasal spray), Tysine (nasal spray), Oxoline (nasal ointment), Pinosol (nasal spray), Tantum Verde (spray), Hexoral (aerosol), Berodual (aerosol), Salbutamol-Teva (aerosol), Grippferon (nasal spray) – 10% v/v.

Biomaterial	Interfering substance	Examined concentration in the sample
Endogenous substances		
Urine, smears/scrapes of epithelial cells from urogenital tract, oropharynx, nasopharynx	Hemoglobin	0.35 mg/ml
Smears/scrapes of epithelial cells from urogenital tract, oropharynx, nasopharynx	Mucus (mucin)	10% v/v
Exogenous substances		
Urine, smears/scrapes of epithelial cells oropharynx, nasopharynx	Chlorhexidine (water solution 0.05%)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Lasolvan Rhino (nasal spray)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Rhinofluimucil	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Tysine (nasal spray)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Oxoline (nasal ointment)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Pinosol (nasal spray)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Tantum Verde (spray)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Hexoral (aerosol)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Berodual (aerosol)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Salbutamol-Teva (aerosol)	10% v/v
Smears/scrapes of epithelial cells oropharynx, nasopharynx	Grippferon (nasal spray)	10% v/v

Method limitations: local use of medications (sprays, drops, creams and ointments), vaginal ultrasound less than 24 hours before the assay. When using aerosols and other forms of drugs for inhalation in the treatment of bronchial asthma, material for assay should be taken at least three hours after inhalation.

Sample collection

WARNING! Before NA extraction pre-processing of biomaterial samples is required.

Urine

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

After urine collection, container is tightly screwed and marked.

Scrapes/smears of epithelial cells from urogenital tract

Sample intake is made with special sterile single-use tools (e.g., probes).

Method limitations: Local application of medications, use of lubricants, vaginal ultrasound less than 24 hours before the assay.

Sample intake is carried out in accordance with the instruction to the used transport medium.

Taking urogenital scrapes

On the eve of the examination, women should not perform vaginal douching or sprays. In order to obtain

an accurate result, it is necessary that biomaterial contains as many epithelial cells as possible and a minimum amount of mucus and blood. Incorrect biomaterial sampling may lead to an unreliable result and, thus, to the need to repeat the biomaterial collection.

WARNING! Before obtaining a scrape of epithelial cells from the urethra, posterolateral vaginal vault and cervical canal, remove free-flowing secretion with a sterile cotton swab.

Vaginal sampling

The sample must be taken prior to manual examination. Speculum can be treated with hot water before examination. Antiseptics must not be used for speculum treatment. The sample must be taken from the posterolateral vaginal vault. For girls, the material is taken from the mucous membrane of the vaginal vestibule, and in some cases from the posterior vaginal vault through the hymenal rings.

Urethral sampling

Patient must not urinate within 1.5-2 hours prior to sampling procedure. The external urethral orifice must be treated with a swab moistened with sterile physiological saline solution just prior to the sampling procedure.

In the case of purulent discharge, the sample must be taken 15-20 minutes after urinating. In the absence of discharge, it is necessary to massage urethra with sampling swab or brush. Carefully insert the swab into the woman's urethra to a depth of 1-1.5 cm. A child's sample must be taken from the external urethral orifice.

Cervical sampling

Remove mucus with a swab prior to sampling, and treat the cervix with sterile physiological saline solution. Carefully insert sampling swab into the cervix to a depth of 0.5-1.5 cm. Avoid contact with vaginal wall when removing the swab.

Oropharyngeal smears

Take the smear with a swab with a rotational movement from the surface of the tonsils, palatine arches and the back wall of the pharynx.

Nasopharyngeal smears

Smears/scrapes are taken with a dry sterile probe, the probe is inserted with a slight movement along the outer wall of the nose to a depth of 2-3 cm to the lower nasal shell. Then the probe is slightly lowered to the bottom, inserted into the lower nasal passage under the lower nasal shell, and removed along the outer nasal wall after a rotating movement.

Transport and storage of samples

Urine

Urine samples must be transported and stored:

- at temperature from 2 °C to 8 °C for no longer than 1 day.
- at temperature from minus 18 °C to minus 22 °C for no longer than one week.

WARNING! Only one freezing-thawing of material is allowed.

Scrapes/smears of epithelial cells from urogenital tract

Transport and storage conditions for urogenital scrapes are determined by instructions for use for the

transport media used for transport and storage of samples.

Oropharyngeal, nasopharyngeal smears

Type of the sample	Collecting material requirements	Transportation	Storage conditions before transportation	Comments
Nasopharyngeal and oropharyngeal smears	Plastic test tubes and swab for smears**	4 °C	≤5 days: 4 °C >5 days*: minus 70 °C	Nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load

* - If it is not possible to store samples at minus 70 °C, store samples at minus 20 °C.
** - Use a transport medium for storage and transportation of respiratory smears, or saline solution (if the sample is transported to the laboratory no more than 24 hours after sample taking), or a dry swab (if the sample is transported to the laboratory no more than 4 hours after sample taking).

WARNING! Only one freezing-thawing unfreezing of the material is allowed.

Sample preparation

Biomaterial preparation (if necessary) is performed in accordance with instructions for use for the transport media used for transport and storage of samples.

Preparation of epithelial smears/scrapes in STOR-F transport media, PreservCyt transport media (solution) (Hologic Inc, USA), Cellprep LBC Solution (Biodyne, South Korea) (if necessary), and urine is performed in accordance with Table 5.

Table 5. Biomaterial preparation

Biomaterial	**NA extraction using reagent kit**	
	Package N Package A Package P (biomaterial introduced manually into plate No. 1)	**Package P (biomaterial introduced automatically into plate No. 1)**
Scrapes of epithelial cells from urogenital tract in STOR-F transport medium	Centrifuge the tube with biomaterial at RCF(g) 12,000-16,000 for 3 minutes at room temperature (from 18 °C to 25 °C), then remove supernatant leaving ~100 µL (precipitate + liquid fraction)	Biomaterial centrifugation in STOR-F transport medium before NA extraction <u>is not required</u>
Scrapes of epithelial cells from urogenital tract in PreservCyt transport medium (solution) (Hologic Inc, USA), Cellprep LBC Solution (Biodyne, South Korea)	1. Mix thoroughly the sample in the transport medium (solution) by shaking the vial intensively. 2. Transfer 1.0 mL of biomaterial into 1.5 mL plastic tube. Close the cap tightly. 3. Centrifuge the tube at RCF(g) 12,000-16,000 for 3 minutes. 4. Remove supernatant as fully as possible.	
	5. Add 100 µL of STOR-F transport medium or sterile physiological saline solution to precipitate and resuspend the precipitate by pipetting.	5. Add 200 µL of STOR-F transport medium or sterile physiological saline solution to precipitate and resuspend the precipitate by pipetting.
Urine	1. Transfer 1.0 mL of urine into 1.5 mL plastic tube. Close the tube tightly. 2. Centrifuge the tube at RCF(g) 12,000-16,000 for 3 minutes. 3. If after centrifugation the volume of salts precipitate exceeds 100 µL (more than 1/3 of the tube), remove supernatant as fully as possible and do 4-6. If precipitate volume does not exceed 100 µL, remove supernatant leaving up to 100 µL in the tube (precipitate + liquid fraction). The sample is ready for NA extraction. 4. Add 1.0 mL of sterile physiological saline solution to precipitate. Close the tube tightly. 5. Centrifuge the tube at RCF(g) 12,000-16,000 for 3 minutes.	

	6. Remove supernatant leaving up to 100 µL in the tube (precipitate + liquid fraction).	6. Remove supernatant leaving up to 100 µL in the tube (precipitate + liquid fraction). 7. Add 100 µL of STOR-F transport medium or sterile physiological saline solution to precipitate and resuspend the precipitate by pipetting.
Smears of epithelial cells from oropharynx, nasopharynx in STOR-F transport medium	Biomaterial centrifugation in STOR-F transport medium before NA extraction is not required	

The sample is ready for NA extraction.

8. PROCEDURE

WARNING!

1. To introduce and add reagents and samples use RNase and DNase free filter tips.
2. Change the tips after each solution removal from the tube.
3. To prevent contamination only open the tube that you are working with (adding sample/reagent, removing supernatant), and close it after handling. It is not allowed to work simultaneously with several tubes with open caps.
4. Add solution to the tube/well containing biomaterial carefully, without touching the walls of the tube/well. If touching occurred, change the tip.
5. If samples are introduced automatically, make sure that tubes with samples do not contain probe residues.
6. Treat test samples and controls the same way and simultaneously according to this instruction.
7. Lysis solution can form precipitate if stored in the refrigerator (from 2 °C to 8 °C). Dissolve it by placing vial, cartridge or plate onto a thermostat warmed to 65 °C and warm until full precipitate dissolution. Cool the solution to room temperature (from 18 °C to 25 °C) before work. Alternatively, the precipitate can be dissolved at room temperature (from 18 °C to 25 °C) in the course of 12 hours.
8. Cap opening may occur during tube heating! Use tubes with locking caps (Eppendorf Safe-Lock Tubes) or programmable thermostat with clamp cover (solid-state programmable thermostat TT-1-DNA-Tech manufactured by DNA-Technology R&P, LLC).

8.1. Assay procedure for package P (sets No. 1 and 2)

8.2.1. Mark 3 96 deep-well plate from the reagent kit:
- No. 1 with lysis solution
- No. 2 with wash solution
- No. 3 with elution solution

8.2.2. In case of using the **PREP-MB-RAPID II** with reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR ("DNA-Technology", LLC) that includes internal control RNA-IC "A", add 250 µL of internal control into each tube with sorbent, close the tubes and vortex for 3-5 seconds.

8.2.3. Spin down the drops and condensate from the walls of deep-well plates on vortex at RCF(g) 800 for 1-3 minutes, if necessary.

Note. Use dee-well plates with distilled water sealed with adhesive seal as a counterbalance.

8.2.4. Remove the protective sealing from the plates.

8.2.5. Resuspend the sorbent by pipetting and add 60 µL of the mixture of the sorbent and internal control or 50 µL of the sorbent in each well of the plate No. 1.

8.2.6. Add 100 µL of test samples in the corresponding wells of the plate No.1 containing lysis solution and sorbent.

Note. For samples pretreated with obtaining precipitate, resuspend the sample by pipetting and add into the corresponding plate well.

8.2.7. Add 100 µL of transport medium (for example, **STOR-F**) or sterile physiological saline solution into the well for negative control (C-).

8.2.8. If positive control is intended for NA extraction, add 100 µL of positive control into the corresponding well.

8.2.9. Prepare the automatic NA extraction system by setting the prepared deep-well plates and the necessary consumables (tip comb, empty 96 deep-well plate for disposing of the tip comb) according to the operation manual.

8.2.10. Select and run the NA extraction script.

8.2.11. Wait until the system finishes operation.

NA preparation is ready for PCR/RT-PCR (it is in plate No. 3 with elution solution). Use adhesive plate seal for storage of the plate with the extracted NA.

If necessary add 200 µL of elution solution in each well of the plate No. 3 (see example below). When adding the solution into the well with NA, add liquid carefully, without touching the walls of the well. If touching occurred, change the tip.

The final volume of elution solution depends on:

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

Example:

Type of assay	Amount of elution solution, µL
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits (“DNA-Technology”), real-time PCR DNA detection kits (“DNA-Technology”)	100 (default volume of solution in deep-well plates, no adding required)
Multiplex assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.2. Assay procedure for package P (sets No. 1 and 2) using DTstream

8.2.1. Mark 3 new 96 deep-well plates:

- No. 1 with lysis solution
- No. 2 with wash solution
- No. 3 with elution solution

8.2.2. In case of using the **PREP-MB-RAPID II** with reagent kit for acute viral respiratory infection agents’ nucleic acids detection by RT-PCR (“DNA-Technology”, LLC) that includes internal control RNA-IC “A”, add 250 µL of internal control into each tube with sorbent, close the tubes and vortex for 3-5 seconds.

8.2.3. Spin down the drops and condensate from the walls of deep-well plates on vortex at RCF(g) 800 for 1-3 minutes, if necessary.

Note. Use deep-well plates with distilled water sealed with adhesive seal as a counterbalance.

8.2.4. Remove the protective sealing from the plates.

8.2.5. Resuspend the sorbent by pipetting and add 60 µL of the mixture of the sorbent and internal control or 50 µL of the sorbent in each well of the plate No. 1.

8.2.6. Prepare dosing instrument; install all the necessary consumables and reagents according to the dosing instrument working table scheme.

8.2.7. Install plate No. 1 containing lysis solution and sorbent onto the working table of the dosing instrument.

8.2.8. Unpack the rack with RNase and DNase free 1,000 µL filter tips, open the lid.

8.2.9. Install the tips onto the onto the working table of the dosing instrument.

8.2.10. Install the tubes with samples, negative and positive controls into the magnetic homogenizer rack.

WARNING! Tubes with samples must not contain probe residues. The volume of the sample must be at least 200 µL. Samples that were pretreated with precipitate obtaining must be resuspended by pipetting.

8.2.11. Fix the tube caps in the rack holders. Install the rack onto the magnetic homogenizer.

8.2.12. Prepare the disposal container according to the dosing instrument operation manual.

DTstream is ready for operation.

8.2.13. Select and run the dosing script using buttons on the front panel.

8.2.14. Wait for the end of operation (the word "Finished" will appear on the screen).

8.2.15. Prepare the NA automatic extraction system by installing the prepared deep-well plates and the necessary consumables (tip comb, empty 96 deep-well plate for tip comb disposal) according to the system operation manual.

8.2.16. Select and run the NA extraction script.

8.2.17. Wait for the end of system operation for automatic NA extraction in the deep-well plates.

NA preparation is ready for PCR/RT-PCR (it is in plate No. 3 with elution solution). Use adhesive plate seal for storage of the plate with the extracted NA.

If necessary, add 200 µL of elution solution in each well of the plate No. 3 (see example below). When adding the solution into the well with NA, add liquid carefully, without touching the walls of the well. If touching occurred, change the tip.

The final volume of elution solution depends on:

- type of assay (one-tube or multiplex);
- number of assays carried out from one NA sample.

E x a m p l e :

Type of assay	Amount of elution solution, µL
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits ("DNA-Technology"), real-time PCR DNA detection kits ("DNA-Technology")	100 (default volume of solution in deep-well plates, no adding required)
Multiplex assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.3. Assay procedure for package A using using DTstream

WARNING! Before starting the assay, switch on thermostat and heat it to 65 °C. If NA preparation is only to be used for PCR (DNA assay), thermostat is not required.

8.3.1. Mark 1.5 mL plastic tube for each test sample and negative control (C-).

N o t e – For pretreated samples with precipitate and supernatant (urine, scrapes of epithelial cells from urogenital tract) mark the tubes with 100 µL of material prepared for the assay. Mark an additional empty 1.5 mL plastic tube for negative control (C-).

8.3.2. In case of using the **PREP-MB-RAPID II** with reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR ("DNA-Technology", LLC) that includes internal control RNA-IC "A", add 10 µL of internal control previously mixed on vortex into the corresponding tubes. Close the tubes.

8.3.3. Add 100 µL of test sample into marked tubes. Do not add sample into the C- tube.

N o t e – For pretreated samples with precipitate this point shall not be fulfilled.

8.3.4. Add 100 µL of STOR-F transport medium or sterile physiological saline solution into the tube for negative control (C-). Close the tube.

8.3.5. Prepare dosing instrument; install all the necessary consumables and reagents according to the dosing instrument working table scheme.

8.3.6. Unpack the racks with single use DNAse and RNAse free pipette tips (volume 1000 µL), remove the caps and put them on the working table of DTstream. Unpack the racks with RNase and DNase free 1000 µL filter tips (two for NA extraction from 48 samples, four for NA extraction from 96 samples), take off the caps.

8.3.7. Install the tips onto the onto the working table of the dosing instrument.

8.3.8. Install the blisters with magnetic rods into the rod distribution unit. For NA extraction from 48 samples install 3 blisters, from 96 samples – 6 blisters.

8.3.9. Remove protective foil from blisters.

WARNING! Only take off the protective foil when the blister is installed into the adapter, otherwise scattering of magnetic rods may occur.

8.3.10. Remove the protective sealing from the reagent cartridges.

WARNING! Do not take off or puncture the foil from the cartridges.

8.3.11. Install reagent cartridges into the cartridge adapter. To extract NA from 48 samples, install 1 cartridge on the left half of the adapter, to extract NA from 96 samples install 2 cartridges.

8.3.12. Install the protective cap for magnetic pick-up tool and prepare the disposal unit according to the dosing instrument operation manual.

8.3.13. Install the tubes with samples prepared in accordance with 8.3.1-8.3.4 into the magnetic homogenizer racks.

8.3.14. Fix the tube caps in the rack holders. Install the rack onto the magnetic homogenizer.

8.3.15. Prepare the disposal container according to the dosing instrument operation manual.

DTstream is ready for operation.

8.3.16. Select and the dosing script using buttons on the front panel. Set the eluate volume (dissolved NA sample after extraction) of 100 or 300 µL and run the dosing script.

The volume of elution solution depends on:

- type of assay (one-tube or multiplex);
- number of assays carried out from one NA sample.

Example:

Type of assay	Amount of elution solution, µL
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits (“DNA-Technology”), real-time PCR DNA detection kits (“DNA-Technology”)	100 (default volume of solution in deep-well plates, no adding required)
Multiplex assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.3.17. Wait for the end of operation (the word “Finished” will appear on the screen). Close the tubes with samples.

WARNING! If NA preparation is only to be used for PCR (DNA assay), fulfillment of 8.3.18-8.3.21 is not required, the NA preparation is ready for PCR.

8.3.18. Put tubes with samples into the thermostat preheated to 65 °C. Incubate the tubes at 65 °C for

5 minutes.

8.3.19. Carefully shake the tubes on vortex for 1-3 seconds. Avoid splashing of sorbent on the cap.

8.3.20. Vortex the tubes for 1-3 seconds.

8.3.21. Set the tubes into the magnetic rack for 1-3 minutes for sorbent precipitation on the walls of the tubes.

NA preparation is ready for PCR/RT-PCR. If NA is to be used for PCR/RT-PCR, do not take out the tubes from the magnetic rack to avoid the sorbent getting in the PCR-mix.

8.4. NA extraction in 1.5 mL tubes using package N and magnetic rack[2]

WARNING! Before starting the assay, switch on thermostat and heat it to 65 °C. If NA preparation is only to be used for PCR (DNA assay), thermostat is not required.

8.4.1 Mark 1.5 mL plastic tube for each test sample and negative control (C-).

N o t e – For pretreated samples with precipitate and supernatant (urine, scrapes of epithelial cells from urogenital tract) mark the tubes with 100 µL of material prepared for the assay. Mark an additional empty 1.5 mL plastic tube for negative control (C-).

8.4.2 Carefully take off protecting foil from the required wells of blister with magnetic rods.

8.4.3 Using a magnetic pick-up tool or a plastic forceps, add a magnetic rod into each tube. Avoid touching walls of the tube.

8.4.4 In case of using the **PREP-MB-RAPID II** with reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR ("DNA-Technology", LLC) that includes internal control RNA-IC "A", add 10 µL of internal control previously mixed on vortex into the corresponding tubes. Close the tubes.

8.4.5 Mix the contents of lysis solution vial by turning it upside down at least 7 times.

8.4.6 Add 300 µL of lysis solution into each tube. Avoid touching walls of the tube.

8.4.7 Mix thoroughly the contents of sorbent vial by turning it upside down at least 20 times.

8.4.8 Add 50 µL of sorbent into each tube. Avoid touching walls of the tube and lysis solution. Close the tubes.

8.4.9 Shake the tubes on vortex for 3-5 seconds and spin on vortex for 1-3 seconds.

8.4.10 Add 100 µL of test sample into the marked tubes. Do not add samples into the C- tube.

N o t e – For pretreated samples with precipitate this point shall not be fulfilled.

8.4.11 Add 100 µL of STOR-F transport medium or sterile physiological saline solution into the tube for negative control (C-).

8.4.12 Close the tubes tightly and shake on vortex for 3-5 seconds (or place the tubes into homogenizer and set it into impulse mode for 3 minutes, then proceed to 8.4.15).

8.4.13 Incubate the tubes at room temperature (from 18 °C to 25 °C) for 3 minutes without using the magnetic rack.

8.4.14 Shake the tubes on vortex for 3-5 seconds and spin on vortex for 1-3 seconds.

8.4.15 Place the tubes onto the magnetic rack (or leave them in the homogenizer) and incubate at room

[2] - it is allowed to use magnetic rack instead of magnetic homogenizer

temperature (from 18 °C to 25 °C) for 3 minutes (the homogenizer is off).

8.4.16 Remove the supernatant fully without touching the sorbent. Use new tip for each tube.

8.4.17 Add 600 µL of wash solution into each tube, close the tubes tightly and turn them upside down to wash the caps and tube edges. Do not shake the tubes. If using homogenizer, proceed to 8.4.19 without taking out and turning the tubes.

8.4.18 Vortex the tubes for 1-3 seconds.

8.4.19 Place the tubes onto the magnetic rack (or leave them in the homogenizer) and incubate at room temperature (from 18 °C to 25 °C) for 3 minutes (or 1 minute if using homogenizer; the homogenizer is off).

8.4.20 Remove the supernatant fully without touching the sorbent. Use new tip for each tube.

8.4.21 Add 100 or 300 µL of elution solution into each tube. Close the tubes.

The volume of elution solution depends on:

- type of assay (one-tube or multiplex);
- number of assays carried out from one NA sample.

E x a m p l e :

Type of assay	Amount of elution solution, µL
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits (“DNA-Technology”), real-time PCR DNA detection kits (“DNA-Technology”)	100
Multiplex assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® package S kits)	300

8.4.22 If using homogenizer, set it into impulse mode for 3 minutes.

WARNING! If NA preparation is only to be used for PCR (DNA assay), heating sample tubes at 65 °C is not required. Proceed to 8.4.24 – 8.4.25.

8.4.23 Place the tube into the thermostat preheated to 65 °C. Incubate the tubes at 65 °C for 5 minutes.

8.4.24 Shake the tubes on vortex for 3-5 seconds and spin on vortex for 1-3 seconds.

8.4.25 Place the tubes onto the magnetic rack or homogenizer and incubate at room temperature (from 18 °C to 25 °C) for 3 minutes (the homogenizer is off).

NA preparation is ready for PCR/RT-PCR. If NA is to be used for PCR/RT-PCR, do not take out the tubes from the magnetic rack to avoid the sorbent getting in the PCR-mix.

8.5. NA extraction on 96 deep-well plates using package N

8.5.1. Mark three new 96 deep-well plates:

- No. 1 for test samples, lysis solution and sorbent
- No. 2 for wash solution,
- No. 3 for elution solution.

8.5.2. In case of using the **PREP-MB-RAPID II** with reagent kit for acute viral respiratory infection agents’ nucleic acids detection by RT-PCR (“DNA-Technology”, LLC) that includes internal control RNA-IC “A”, add 1.0 mL of internal control into the vial with sorbent. Close the vial cap.

8.5.3. Mix the contents of lysis solution vial by turning it upside down at least 7 times.

8.5.4. Add 300 µL of lysis solution into each plate well.

8.5.5. Resuspend the sorbent by pipetting and add 60 µL of sorbent and internal control mixture or 50 µL of sorbent into each well plate. It is allowed to mix lysis solution, sorbent and internal control thoroughly and add 360 µL into each plate well (or 350 µL without internal control) making sure that the sorbent is distributed evenly and stirring the mixture if necessary.

8.5.6. Add 600 µL of wash solution into each well of the plate No. 2.

8.5.7. Enter 100 or 300 µL of elution solution into each well of the plate No. 3.

The volume of elution solution depends on:

- type of assay (one-tube or multiplex);
- number of assays carried out from one NA sample.

Example:

Type of assay	Amount of elution solution, µL
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits ("DNA-Technology"), real-time PCR DNA detection kits ("DNA-Technology")	100
Multiplex assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® package S kits)	300

8.5.8. Add 100 µL of test sample into each well of plate No. 1 containing lysis solution and sorbent.

Note – For pretreated samples with precipitate, resuspend the sample by pipetting and add into the corresponding plate well.

8.5.9. Add 100 µL of STOR-F transport medium or sterile physiological saline solution into the well for negative control (C-).

8.5.10. In case positive control must go through NA extraction, enter 100 µL of the corresponding positive control into the well for positive control (C+).

8.5.11. Prepare the NA automatic extraction system by installing the prepared deep-well plates and the necessary consumables (tip comb, empty 96 deep-well plate for tip comb disposal) according to the system operation manual.

8.5.12. Select and run the NA extraction script.

8.5.13. Wait for the end of system operation for automatic NA extraction in the deep-well plates.

NA preparation is ready for PCR/RT-PCR (in the plate No. 3 with elution solution). If you need to store the plate with the extracted NA, use adhesive film for plate sealing.

8.6. Storage and use of NA preparation

8.6.1 It is allowed to store NA preparation at temperatures from 2 °C to 8 °C for no longer than 2 hours. For long-term storage it is required to place the NA preparation into the freezing chamber and store at temperatures no more than minus 20 °C for no longer than 7 days without unfreezing before PCR/RT-PCR.

8.6.2 If only PCR DNA detection is intended, it is allowed to store NA preparation at temperature from 2 °C to 8 °C for no longer than 7 days or at temperature no lower than minus 20 °C for no longer than 1 year with thawing just prior to the run.

WARNING! Only one freezing-thawing of NA preparation is allowed.

8.6.3 If NA preparation has been stored at temperatures no more than minus 20 °C, it is required to unfreeze it at room temperature from 18 °C to 25 °C or at temperatures from 2 °C to 8 °C prior to use.

8.6.4 Before using NA preparation for PCR/RT-PCR after storage:

- Packages P, N (NA extraction in 96 deep-well plates):
  Vortex the plate with NA preparation at RCF(g) 100 for 30 seconds to spin down the condensate, take off the adhesive film.
- Packages A, N (NA extraction in 1.5 mL plastic tubes):
  Place the tubes with NA preparation into the magnetic rack.

NA preparation is ready to be introduced into the PCR/RT-PCR mix.

9. SPECIFICATIONS

a. The minimum amount of biomaterial for nucleic acids extraction:

- Transport medium STOR-F containing smears/scrapes of epithelial cells from urogenital tract, oropharynx, nasopharynx: 100 µL;
- Transport medium (solution) PreservCyt (Hologic Inc, USA), Cellprep LBC Solution (Biodyne, South Korea) containing smears/scrapes of epithelial cells from urogenital tract: 1.0 mL;
- urine: 1.0 mL.

b. Functional characteristics of the reagent kit:

- Purity of nucleic acid samples (A260/280) – 1.5-2.4;
- Concentration of nucleic acids in 100 µL of preparation is at 5.9-92.8 ng/µL of nucleic acid solution.

c. Effectiveness of the reagent kit

The effectiveness of the reagent kit was confirmed during clinical trials using additional reagent kits in for study of biological material samples:

Biomaterial	Test samples, pcs	Amplification kit (short name)	Effectiveness of PREP-MB-RAPID II
Scrapes/smears of epithelial cells from oropharynx, nasopharynx	26	AVRI Multiplex	100 % (P_{true} = 91.52)
	32	Candida albicans	100 % (P_{true} = 93.06)
	32	HSV	100 % (P_{true} = 93.06)
	30	BacScreen OM	100 % (P_{true} = 92.62)
Scrapes/smears of epithelial cells from urogenital tract	24	Femoflor® Screen	100 % (P_{true} = 90.85)
	23	HPV-Quant	100 % (P_{true} = 90.47)
urine	30	Androflor® Screen	100 % (P_{true} = 92.62)
	32	HSV1/HSV2/CMV Multiplex	100 % (P_{true} = 93.06)
	32	Candida albicans	100 % (P_{true} = 93.06)
General effectiveness of PREP-MB-RAPID II	261	-	100 % (P_{true} = 99.12)

d. Within-batch and between-batch precision

Within-batch precision – 100 % (88.43% - 100%).

Between-batch precision – 100 % (88.43-% - 100%).

10. 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 IVDR 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-MB-RAPID II DNA/RNA Extraction Kit**:

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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
EC REP	Authorized representative in the European Community		Caution
	Non-sterile		Do not re-use

REF

P-122-A/9EU

P-122-N/9EU

P-122-P/9EU

P-124-P/9EU

VER

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