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PREP-MB-RAPID DWP DNA/RNA Extraction Kit

INSTRUCTION FOR USE

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REF

P-122-A/9INT
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1. INTENDED USE

The **PREP-MB-RAPID DWP 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 DWP 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 DWP DNA/RNA Extraction Kit.**

The **PREP-MB-RAPID DWP 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 release of nucleic acids under the action of a chaotropic agent (guanidine thiocyanate) with subsequent sorption on paramagnetic nanoparticles and clearing from impurities.

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

3. CONTENT

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

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

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

Number of the row		Reagent	Description	Total volume	Number of wells
Cartridge with reagents**	1*	Lysis solution	Slightly foamy blue transparent 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 on 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 slightly 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 DWP DNA/RNA Extraction Kit** content, package N, for P-122-N/9INT

Reagent	Description	Total volume	Amount
Lysis solution	Slightly foamy blue transparent liquid	28.8 mL	1 vial
Wash solution	Green transparent liquid	57.6 mL (28.8 mL in each vial)	2 vials
Elution solution	Colorless or slightly pink transparent liquid	28.8 mL	1 vial
Sorbent	Liquid with precipitate forming brown suspension on shaking	4.8 mL	1 vial

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

Reagent	Description	Total volume	Amount
Lysis solution	Slightly foamy blue transparent 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 slightly pink transparent liquid	9.6 mL (100 µL in each well)	1 96 Deep-Well Plate
Sorbent	Liquid with precipitate forming brown suspension on shaking	4.8 mL (1.2 mL in each tube)	4 tubes
Elution solution	Colorless or slightly pink transparent liquid	19.2 mL	1 vial

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

Reagent	Description	Total volume	Amount
Lysis solution	Slightly foamy blue transparent 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 slightly pink transparent liquid	9.6 mL (100 µL in each well)	1 96 Deep-Well Plate
Sorbent	Liquid with precipitate forming brown suspension on shaking	4.8 mL (1.2 mL in each tube)	4 tubes
Elution solution	Colorless or slightly 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 bead tips discharge ** for sealing of plates with extracted nucleic acids during storage			

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

The kit is intended for single use and is designed for DNA/RNA extraction from 96 analyzed 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;
- Vortex mixer;
- High speed centrifuge (RCF(g) at least 16000) 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 range 25-95 °C);
- Single channel pipettes (dispensers covering 20-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 200 µL, 1000 µL);
- 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 device DTstream 12L4 or 15L4[1] configuration at least 1.1 (for package A REF P-122-A/9INT);
- Exchangeable cone for discharge of waste consumables for DTstream device (for package A REF P-122-A/9INT);
- Mechanical dispenser 1-10 µL (for example, Eppendorf Multipette M4), (for package N REF P-122-N/9INT);
- Dispenser tips 5 mL and 1 mL, (for example, Combitips Advanced), (for package N REF P-122-N/9INT);
- Eight channel pipettes (dispensers covering 100-1000 µL range) (for example, Biohit Proline), (for package N REF P-122-N/9INT);
- White 60 mL polystyrene (PS) reservoir (cuvette, tray) with a V-shaped bottom (for package N REF P-122-N/9INT);
- Container for discharge of waste tips for DTstream device (for package A REF P-122-A/9INT);
- RNase and DNase free filtered pipette tips (volume 1000 µL) for DTstream (for package A REF P-122-A/9INT);
- System for automatic nucleic acid extraction in 96 Deep-Well Plate (for example, KingFisher Flex 96);

[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.

- 96 Deep-Well Plate (for example, Allsheng-AS-17061-02) (except package P, Set No. 2 REF P-124-P/9INT);
- PCR Seal Sheet (for example, 4titude 4ti-0500) (except package P, No. 2 REF P-124-P/9INT);
- 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-RAPID DWP DNA/RNA Extraction Kit** shall be stored at temperatures from 2 °C to 25 °C and out of light throughout the shelf life of the kit.

The excessive temperature can be detrimental to product performance.

Store in the upright position in accordance with the handling sign “UP”.

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

It is allowed to transport the kit in thermobox with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C during the storage period.

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

Reagent kits transported with violation of temperature conditions shall not be used.

Shelf-life of the kit following the first opening of the primary container: the components of the kit should be stored at temperatures from 2 °C to 25 °C and out of light throughout the shelf life of the kit.

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

The kit stored under undue regime shall not be used.

An expired the **PREP-MB-RAPID DWP DNA/RNA Extraction Kit** shall 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 DWP DNA/RNA Extraction Kit** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

6. WARNINGS AND PRECAUTIONS

Only personnel trained in the methods of molecular diagnostics and the rules of work in the clinical and diagnostic laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the assay as if they were able to transmit infective agents. The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. Avoid direct contact with the biological samples reagents and materials used to carry out the assay. Wear powder-free surgical gloves. Wear protective clothing (work clothes and personal protective equipment) working with microorganisms classified as particularly pathogenic. The protective clothing and personal protective equipment must comply with the work to be performed and health and safety requirements. Avoid producing spills or aerosol. Any material being exposed to biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121 °C before disposal.

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, PCR-amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

All the liquid solutions are designed for single use and can not be used more than once in amplification reactions. Plastic tubes do not contain phthalates. Do not breathe gas/fumes/vapor/spray produced by the components of the kit. Do not eat/drink components of the kit. Avoid contact with eyes. Only use the reagents provided in the kit and those recommended by manufacturer. Do not mix reagents from different batches. Do not use reagents from third party manufacturers' kits. All laboratory equipment, including pipettes, test tube racks, laboratory glassware, lab coats, bouffant caps, etc., as well as reagents should be strictly stationary. It is not allowed to move them from one room to another. Equip separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions. Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions. 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 DWP DNA/RNA Extraction Kit** is designed to extract DNA/RNA from urine, scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.

General recommendations

- Use DNAse and RNAse free filter tips;
- 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, 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.

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

ATTENTION! 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 – probes, cytobrushes, and swabs depending on the source of biological material according to established procedure.

ATTENTION! In case of pregnancy the use of cytobrushes for genitourinary smears sampling is contraindicated.

Sample intake is carried out:

- in tubes with transport medium intended by the manufacturer for transportation and storage of samples for PCR (for example, **STOR-F** (P-901-1/1EU));
- in plastic 1.5 mL tubes with 500 µL of a sterile physiological saline solution.

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

Order of taking:

1. Open the tube.

2. Scrape epithelial cells from the corresponding biotope 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.

Smears from the nasal cavity sampling

Take the smears with a dry sterile disposable swab into 1.5 mL plastic tubes with transport medium (for example, **STOR-F** (P-901-1/1EU)).

Order of taking:

1. Insert the swab carefully along the outer wall of the nose to a depth of 2-3 cm to the lower shell. Then lower the swab down slightly, insert into the lower nasal passage under the lower nasal conch, after a rotational movement remove along the outer wall of the nose.
2. Open the tube.
3. Put the swab into the tube with transport medium, rotate the swab for 10-15 seconds and rinse it thoroughly. Avoid spraying of solution.
4. Remove the swab from solution, press it to the wall of tube and squeeze the rest of the liquid. Throw out the swab. Dispose the used swab.
5. Close the tube tightly and mark it.

Oropharyngeal smears sampling

Take the smear with a dry sterile disposable swab into 1.5 mL plastic tubes with transport medium (for example, **STOR-F** (P-901-1/1EU)).

Order of taking:

1. 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.
2. Open the tube.
3. Put the swab into the tube with transport medium, rotate the swab for 10-15 seconds and rinse it thoroughly. Avoid spraying of solution.
4. Remove the swab from solution, press it to the wall of tube and squeeze the rest of the liquid. Throw out the swab. Dispose of the used swab.

Transportation and storage of the 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.

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

Scrapes/smears of epithelial cells from urogenital tract

In case of using transport media biomaterial samples are transported and stored according to the instruction for the transport medium used intended for subsequent sample PCR analysis.

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).

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

Sample preparation

Urine

1. Transfer 1.0 mL of the sample to the 1.5 mL tube. Close the tube tightly.

2. Centrifuge the tube at RCF(g) 12000-16000 for 10 minutes.

3. Remove supernatant as fully as possible (if a large amount of salt is present in precipitate, sample is ready for extraction, otherwise the next washing stage is necessary).

4. Add 1.0 mL of sterile physiological saline solution. Close the tube tightly.

5. Centrifuge the tube at RCF(g) 12000-16000 for 10 minutes.

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

The sample is ready for NA extraction.

Scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx.

Conduct preparation of biomaterial according the instruction for corresponding transport medium.

ATTENTION! If samples will be dosed automatically, tubes with samples must not contain remains of swab for biomaterial sampling.

The sample is ready for NA extraction.

8. PROCEDURE

ATTENTION!

1. Lysis solution can form precipitate. 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 in the course of 12 hours.

2. 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.

3. Simultaneously with the extraction of NA, a negative control should go through all stages of NA extraction. Physiological saline solution 0.9% NaCl sterile or transport medium can be used as a negative control.

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

5. Change the tip each time when 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.

8.1. Assay procedure for package N

8.1.1. Mark 3 new 96 Deep-Well Plate:

- No. 1 – for analyzed samples, lysis solution and sorbent;
- No. 2 – for wash solution;
- No. 3 – for elution solution.

8.1.2. If used in conjunction 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 and mix by inverting the vial at least 5 times.

8.1.3. Add 300 µL of lysis solution in each well of the plate No. 1.

8.1.4. 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.
It is allowed to compound lysis solution, sorbent and internal control, mix thoroughly and add 360 µL into each plate well (thus, 350 µL without internal control), making sure that sorbent is distributed evenly and shaking the mixture when necessary.

8.1.5. Add 600 µL of wash solution in each well of the plate No. 2.

8.1.6. Add 100 to 300 µL of elution solution in each well of the plate No. 3.

The volume of elution solution depends on:

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

NOTE - The recommended amount of eluate for NA 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
Human acute respiratory viral infections pathogens nucleic acids RT-PCR detection kits ("DNA-Technology"), real-time PCR DNA detection kits ("DNA-Technology")	100
Integrated assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.1.7. Add 100 µL of analyzed sample in the corresponding wells of the plate No. 1 containing lysis solution and sorbent.

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

8.1.9. If positive control is intended for NA extraction, add 100 µL of positive control (C+) in the corresponding well.

8.1.10. Prepare the system for automatic nucleic acid extraction in 96 Deep-Well Plate by putting prepared plates and required consumables in the device according to its user manual.

8.1.11. Choose and run NA extraction scenario.

8.1.12. Wait for the end of work of the system.

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

8.2. Assay procedure for package P

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 usage of the **PREP-MB-RAPID DWP DNA/RNA Extraction Kit** 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 260 µL of internal control into each tube with sorbent, close the tubes and vortex for 3-5 seconds.

8.2.3. Remove the protective sealing from the plates.

8.2.4. 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.

8.2.5. Add 100 µL of analyzed sample in the corresponding wells of the plate No.1 containing lysis solution and sorbent.

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

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

8.2.8. If necessary add 200 µL of elution solution in each well of the plate No. 3.

The volume of elution solution depends on:

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

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

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
Integrated assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.2.9. Prepare the system for automatic nucleic acid extraction in 96 Deep-Well Plate by putting prepared plates and required consumables in the device according to its user manual.

8.2.10. Choose and run NA extraction scenario.

8.2.11. Wait for the end of work of the system.

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

8.3. Assay procedure for package A using automatic adding of analyzed samples

8.3.1. Mark 3 new 96 Deep-Well Plate:

- No. 1 – for analyzed samples, lysis solution and sorbent;
- No. 2 – for wash solution;
- No. 3 – for elution solution.

8.3.2. Mark the required number of 1.5 mL plastic tubes for negative control (C-) and positive control (C+), if positive control is intended for NA extraction.

8.3.3. Add 500 µL of transport medium (for example, **STOR-F**) or sterile physiological saline solution in the tube for negative control (C-).

8.3.4. If positive control is intended for NA extraction, add 100 µL of positive control in the corresponding tube and add 400 µL of transport medium (for example, **STOR-F**) or sterile physiological saline solution. Vortex the tube for 3-5 seconds, then spin for 1-3 seconds to collect the drops.

8.3.5. Prepare dosing unit DTstream to work by putting the reagents and consumables according to the scheme of its working table.

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.

8.3.7. Remove protective caps from cartridges with reagents.

ATTENTION!Do not remove or puncture protective film on cartridges with reagents.

8.3.8. Put cartridge to the corresponding adaptor of DTstream.

8.3.9. Put the 96 Deep-Well Plate in adaptors for microplates.

8.3.10. Prepare the device for discarding according to the user manual for the dosing unit.

8.3.11. Vortex the tubes with samples for 3-5 seconds, then spin for 1-3 seconds to collect the drops.

8.3.12. Put the tubes (including controls) in a rack for 1.5 mL tubes, fix the tubes' caps in the holders.

8.3.13. Put the racks on the working table of the dosing unit.

8.3.14. In case of usage of the **PREP-MB-RAPID DWP DNA/RNA Extraction Kit** 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", vortex the tube with internal control from the corresponding kit and put the tube on the working table of the dosing unit.

8.3.15. Dosing unit is ready to work.

8.3.16. Using the buttons on the front panel of the dosing unit choose the dosing scenario.

8.3.17. Set the dosing parameters:

- the number of samples,
- eluate (dissolved NA sample after extraction) volume from 100 to 300 µL.

The volume of elution solution depends on:

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

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

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
Integrated assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.3.18. Run the dosing scenario.

8.3.19. Wait for the end of work of the dosing unit.

8.3.20. Prepare the system for automatic nucleic acid extraction in 96 Deep-Well Plate by putting prepared plates and required consumables in the device according to its user manual.

8.3.21. Choose and run NA extraction scenario.

8.3.22. Wait for the end of work of the system.

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

8.4. Assay procedure for package A using manual adding of analyzed samples

8.4.1. Mark 3 new 96 Deep-Well Plate:

- No. 1 – for analyzed samples, lysis solution and sorbent;
- No. 2 – for wash solution;
- No. 3 – for elution solution.

8.4.2. Prepare DTstream to work by putting the reagents and consumables according to the scheme of its working table.

8.4.3. 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.

8.4.4. Remove the protective caps from cartridges with reagents.

ATTENTION!Do not remove or puncture protective film on cartridges with reagents.

8.4.5. Put cartridge to the corresponding adaptor of DTstream.

8.4.6. Put the 96 Deep-Well Plate in adaptors for microplates.

8.4.7. Prepare the device for discarding according to the user manual for the dosing unit.

8.4.8. In case of usage of the **PREP-MB-RAPID DWP DNA/RNA Extraction Kit** 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", vortex the tube with internal control from the corresponding kit and put the tube on the working table of the dosing unit.

Dosing unit is ready to work.

8.4.9. Using the buttons on the front panel of the dosing unit choose the dosing scenario.

8.4.10. Set the dosing parameters:

- the number of samples;
- eluate (dissolved NA sample after extraction) volume from 100 to 300 µL.

The volume of elution solution depends on:

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

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

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
Integrated assays (e.g., Femoflor®, Androflor®, HPV-QUANT-21® kits)	300

8.4.11. Run the dosing scenario.

8.4.12. The dosing unit will start working.

8.4.13. Wait for the end of work of the dosing unit.

8.4.14. Vortex the tubes with samples for 3-5 seconds, then spin for 1-3 seconds to collect the drops.

8.4.15. Add 100 µL of sample in the corresponding wells of 96 Deep-Well Plate No. 1 containing lysis solution and sorbent.

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

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

8.4.18. Prepare the system for automatic nucleic acid extraction in 96 Deep-Well Plate by putting prepared plates and required consumables in the device according to its user manual.

8.4.19. Choose and run NA extraction scenario.

8.4.20. Wait for the end of work of the system.

NA preparation is ready for PCR/RT-PCR (it is contained in the 96 Deep-Well Plate No. 3 with elution solution). Use microplate seal for storage of microplate with extracted DNA.

Storage and use of NA preparation

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.

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.

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

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.

NA preparation is ready for introduction to PCR/RT-PCR reaction mixture.

9. SPECIFICATIONS

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

The concentration of nucleic acids in a 100 µL preparation is in the range 5.9-24.4 ng/µL of nucleic acid solution.

Purity of the nucleic acid samples (A260/280) is 1.4-2.0.

b. Effectiveness of the reagent kit

Effectiveness of the reagent kit was

for DNA extraction – 100% (99.05 - 100%) with 95% CI;

for RNA extraction – 100 % (99.78 - 100%) with 95% CI.

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 customer service with quality issues of the **PREP-MB-RAPID DWP DNA/RNA Extraction Kit**:

Technical support:

E-mail: hotline@dna-technology.ru

http://www.dna-technology.com

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11. KEY TO SYMBOLS

	Temperature limit		Version
	Contains sufficient for<n>tests		Date of manufacture
	Use-by date		Consult instructions for use
	Batch code		Catalogue number
	Manufacturer		Caution

P-122-A/9INT
P-122-N/9INT
P-122-P/9INT
P-124-P/9INT

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