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For professional use only

PREP-MB DWP DNA/RNA Extraction Kit

INSTRUCTION FOR USE

EC REP

OBELIS S.A

Registered Address:

Bd. Général Wahis, 53

1030 Brussels, Belgium

Tel: +32.2.732.59.54

Fax: +32.2.732.60.03

E-mail: mail@obelis.net

http://www.obelis.net

"DNA-Technology Research & Production", LLC,

142281, Russia, Moscow Region,

Protvino, Zheleznodorozhnaya Street, 20

Phone/fax: +7(495)640.17.71

E-mail: info@dna-technology.com

https://www.dna-technology.com

Customer service department

E-mail: hotline@dna-technology.ru

REF

P-119-N/9EU

P-119-P/9EU

P-120-P/9EU

P-121-P/9EU

P-119-A/9EU

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1. INTENDED USE

The **PREP-MB DWP DNA/RNA Extraction Kit** is intended for semi-automatic and automatic extraction of respiratory viruses' NA for further analysis by RT-PCR. The **PREP-MB DWP DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal smears.

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 DWP DNA/RNA Extraction Kit.**

The **PREP-MB 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 a 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 the 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 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 DWP DNA/RNA Extraction Kit** with the reagent kit for analysis of nucleic acids by RT-PCR.

3. CONTENT

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

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

Table 1. The **PREP-MB DWP DNA/RNA Extraction Kit** content, package N, for P-119-N/9EU

Reagent	Description	Total volume	Amount
Lysis solution	Slightly foamy blue transparent liquid	28.8 mL	1 vial
Wash solution	Green transparent liquid	48 mL	1 vial
Elution solution	Colorless or slightly pink transparent liquid	9.6 mL	1 vial
Sorbent	Liquid with precipitate forming brown suspension on shaking	4.8 mL	1 vial

Table 2. The **PREP-MB DWP DNA/RNA Extraction Kit** content, package P, Set No. 1, for P-119-P/9EU

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	48 mL (500 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

Table 3. The **PREP-MB DWP DNA/RNA Extraction Kit** content, package P, Set No. 2, for P-120-P/9EU

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	48 mL (500 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
96 Tip Comb	1 pcs		

Table 4. The **PREP-MB DWP DNA/RNA Extraction Kit** content, package P, Set No. 3, for P-121-P/9EU

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	48 mL (500 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
96 Tip Comb	1 pcs		
96 Deep-Well Plate	1 pcs		
PCR Seal Sheet	1 pcs		

Table 5. The **PREP-MB DWP DNA/RNA Extraction Kit** content, package A, for P-119-A/9EU

Number of row		Reagent	Description	Total volume	Number of wells
Cartridge with reagents**	1*	Lysis solution	Slightly foamy blue transparent liquid	14.4 mL (7.2 mL in each well)	2 wells
	2	Wash solution	Green transparent liquid	15 mL (7.5 mL in each well)	2 wells
		Sorbent	Liquid with precipitate forming brown suspension on shaking	2.4 mL	well A
	3	Wash solution	Green transparent liquid	4.8 mL	well B
	4	Wash solution	Green transparent liquid	10.8 mL (5.4 mL in each well)	2 wells
	5	Wash solution	Green transparent liquid	15 mL (7.5 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					

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

The kit is intended for single use and 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), **STOR-M** (REF P-910-1/1EU) or equivalent for the transportation of the sample.

4.2. NA extraction

- Biological safety cabinet class II;
- Refrigerator;
- Vortex mixer;
- 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);
- Tube rack for 1.5 mL tubes;
- Mechanical dispenser 1-10 µL (for example, Eppendorf Multipette M4), (for package N REF P-119-N/9EU);
- 5 mL and 1 mL dispenser tips (for example, Combitips Advanced), (for package N REF P-119-N/9EU);

or

- Eight channel pipettes (dispensers covering 100-1000 µL range) (for example, Biohit Proline), (for package N REF P-119-N/9EU);
- White 60 mL polystyrene (PS) reservoir (cuvette, tray) with a V-shaped bottom (for package N REF P-119-N/9EU);
- System for automatic nucleic acid extraction in 96 Deep-Well Plate (for example, KingFisher Flex 96);
- 96 Deep-Well Plate (for example, Allsheng-AS-17061-02) (except package P, Set No. 3 REF P-121-P/9EU);
- 96 Tip Comb (for example, Allsheng-AS-17061-01) (except package P, Set No. 2 REF P-120-P/9EU, No. 3 REF P-121-P/9EU);
- PCR Seal Sheet (for example, 4titude 4ti-0500) (except package P, Set No. 2 REF P-120-P/9EU, No. 3 REF P-121-P/9EU);
- 1.5 mL RNase and DNase free micro-centrifuge tubes (for DTstream micro-centrifuge tubes SSI-1260 are recommended) (for package A REF P-119-A/9EU);
- Dosing device DTstream 12L4 or 15L4[1] configuration at least 1.1 (for package A REF P-119-A/9EU);
- Exchangeable cone for discharge of waste consumables for DTstream device (for package A REF P-119-A/9EU);
- Container for discharge of waste tips for DTstream device (for package A REF P-119-A/9EU);
- RNase and DNase free filtered pipette tips (volume 1000 µL) for DTstream (for package A REF P-119-A/9EU);
- 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 DWP DNA/RNA Extraction Kit** must be stored at temperatures from 2 °C to 25 °C and out of light during the storage period.

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”.

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

[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.

be stored at temperatures from 2 °C to 25 °C and out of light during the storage period.

The kit must be stored in the upright position in accordance with the handling sign “UP”. The kit stored under undue regime should not be used.

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

Contact our official representative in EU by quality issues of the **PREP-MB DWP 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 the transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When the kit components packaging is breached;
- After the expiry date provided.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

7. SAMPLES

The **PREP-MB DWP DNA/RNA Extraction Kit** is designed to extract DNA/RNA from nasopharyngeal and oropharyngeal smears.

General recommendations

- Use DNAse and RNAse free filter tips;
- 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

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, nasal drops, creams and ointments) less than 24 hours before the assay. When using aerosols and other forms of drugs for inhalation in the treatment of bronchial asthma, biomaterial for the assay should be taken not less than three hours after inhalation.

Sample collection

Smears from the nasal cavity sampling

Take the smear using dry sterile disposable cotton swab with plastic basis. 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. Transfer the swab with the biomaterial into a disposable sterile test tube with transport medium (for example, **STOR-F** (P-901-1/1EU), **STOR-M** (P-910-1/1EU), rinse the swab thoroughly, avoiding splashing of the liquid. Then remove the swab from the solution and, by rotating it against the wall of the test tube above the level of the solution, squeeze out the excess liquid. Dispose the used swab, close the test tube and mark.

Smears from the oropharynx sampling

Take the smear using dry sterile disposable cotton swab with plastic basis by rotationally moving from tonsils surface, faucial pillars and back oropharyngeal wall. Transfer the swab with the biomaterial into a disposable sterile test tube with transport medium (for example, **STOR-F** (P-901-1/1EU), **STOR-M** (P-910-1/1EU)), rinse the swab thoroughly avoiding splashing of the liquid. Then remove the swab from the solution and, by rotating it against the wall of the test tube above the level of the solution, squeeze out the excess liquid. Dispose the used swab, close the test tube and mark.

Preparation of biomaterial for DNA/RNA extraction from nasopharyngeal and oropharyngeal smears

Conduct preparation of biomaterial according to the instruction for the corresponding transport medium. If samples are to be dosed automatically, tubes with samples must not contain remains of swabs for biomaterial taking.

In case of working a reagent kits for acute viral respiratory infection agents' nucleic acids detection by RT-PCR (manufactured by "DNA-Technology", LLC), centrifugation of biomaterial in transport media **STOR-F** and **STOR-M** is not required.

The sample is ready for DNA/RNA extraction.

Transportation and storage of the samples

Type of the sample	Collecting material requirements	Transportation	Storage conditions before transportation	Comments
Nasopharyngeal and oropharyngeal smears	Plastic test tubes and probes for smears**	4 °C	≤5 days: 4 °C >5 days*: minus 70 °C	Nasopharyngeal and oropharyngeal smears 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! Avoid repeated freezing and thawing of samples.

8. PROCEDURE

ATTENTION!

1. The lysis solution can form precipitate. Dissolve it by placing the vial, cartridge or deep-well plate on the 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 within 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 sample should go through all stages of NA extraction. Physiological saline solution 0.9% NaCl Sterile can be used as a negative control sample.

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

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

8.1 Assay procedure for package N

8.1.1 Mark 3 new 96 Deep-Well Plates:

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

ATTENTION! If used in conjunction with a 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.

8.1.2 Add 300 µL of lysis solution into each well of the plate No. 1.

8.1.3 Resuspend the sorbent by pipetting and add 60 µL of the mixture of the sorbent and internal control (if exogenous internal control is required for subsequent PCR testing) or 50 µL of the sorbent (if exogenous IC is not required) into each well of the plate No. 1.

8.1.4 Add 500 µL of wash solution into each well of the plate No. 2.

8.1.5 Add 100 µL of elution solution into each well of the plate No. 3.

8.1.6 Add 100 µL of test sample into the corresponding wells of the plate No. 1 containing lysis solution and sorbent.

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

8.1.8 If positive control is intended for DNA/RNA extraction, add 100 µL of positive control sample (C+) into the corresponding well.

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

8.1.10 Select and run the NA extraction scenario.

8.1.11 Wait for the end of work of the system.

DNA/RNA preparation is ready for RT-PCR (it is contained in the plate No. 3 with elution solution).

8.2 Assay procedure for package P

8.2.1 Mark 3 96 Deep-Well Plates 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 DWP** extraction kit with a reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR (manufactured by "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 (if exogenous internal control is required for subsequent PCR testing) or 50 µL of the sorbent (if exogenous IC is not required) into each well of the plate No. 1.

8.2.5 Add 100 µL of analyzed sample into 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 into the well for negative control sample (C-).

8.2.7 If positive control is intended for DNA/RNA extraction, add 100 µL of positive control sample into the corresponding well.

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

8.2.9 Select and run the NA extraction scenario.

8.2.10 Wait for the end of work of the system.

DNA/RNA preparation is ready for RT-PCR (it is contained in the plate No. 3 with elution solution).

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

8.3.1 Mark 3 new 96 Deep-Well Plates:

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

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

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

8.3.4 If positive control is intended for DNA/RNA extraction, add 100 µL of positive control sample 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 for 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 onto the working table of DTstream.

8.3.7 Remove the protective caps from cartridges with reagents.

ATTENTION! Do not remove or stab protective seal from 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 onto the working table of the dosing unit.

8.3.14 In case of using the **PREP-MB DWP** extraction kit with a reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR (manufactured by "DNA-Technology", LLC) that includes internal control RNA-IC "A", mix on vortex the tube with internal control from the corresponding kit and put the tube onto the working table of the dosing unit.

Dosing unit is ready for work.

8.3.15 Using the buttons on the face panel of the dosing unit, select and run the dosing scenario. The dosing unit will start working.

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

8.3.17 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.

8.3.18 Select and run the NA extraction scenario.

8.3.19 Wait for the end of work of the system.

DNA/RNA preparation is ready for RT-PCR (it is contained in the plate No. 3 with elution solution).

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

8.4.1 Mark 3 new 96 Deep-Well Plates:

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

8.4.2 Prepare dosing unit DTstream for 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 stab protective film from 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 DWP** extraction kit with a reagent kit for acute viral respiratory infection agents' nucleic acids detection by RT-PCR (manufactured by "DNA-Technology", LLC) that includes internal control RNA-IC "A", mix on 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 face panel of the dosing unit, select and run the dosing scenario. The dosing unit will start working.

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

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

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

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

8.4.14 If positive control is intended for DNA/RNA extraction, add 100 µL of positive control sample in the corresponding well.

8.4.15 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.

8.4.16 Select and run the NA extraction scenario.

8.4.17 Wait for the end of work of the system.

DNA/RNA preparation is ready for RT-PCR (it is contained in the 96 Deep-Well Plate No. 3 with elution solution).

It is allowed to store DNA/RNA preparation at temperatures from 2 °C to 8 °C for no more than 2 hours. For long-term storage is required to place the DNA/RNA preparation in the freezing chamber and store at temperatures not exceeding minus 20 °C for no more than 7 days without unfreezing before RT-PCR.

ATTENTION! Only one freezing-thawing of DNA/RNA preparation is allowed.

If DNA/RNA preparation has been stored at temperatures not exceeding minus 20 °C, it is required to unfreeze them at room temperature from 18 °C to 25 °C or at temperatures from 2 °C to 8 °C prior to use.

9. SPECIFICATIONS

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

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

The 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 CI of 95%;

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

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 the **PREP-MB DWP DNA/RNA Extraction Kit**.

Technical support:

hotline@dna-technology.ru

https://www.dna-technology.com

Manufacturer: "DNA-Technology Research & Production", LLC,

142281, Russia, Moscow Region,

Protvino, Zheleznodorozhnaya Street, 20

Phone/fax: +7(495) 640.17.71

E-mail: info@dna-technology.com

https://www.dna-technology.com

Seller: "DNA-Technology" LLC,

117587, Russia, Moscow,

int. ter. Municipal District Chertanovo Severnoye,

Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12;

Phone/fax: +7(495) 640.17.71

E-mail: info@dna-technology.com

https://www.dna-technology.com

Authorized representative in EU:

OBELIS S.A

Registered Address:

Bd. Général Wahis, 53

1030 Brussels, Belgium

Tel: +32.2.732.59.54

Fax: +32.2.732.60.03

E-mail: mail@obelis.net

http://www.obelis.net

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		Keep away from sunlight
	Manufacturer		Caution
EC REP	Authorized representative in the European Community		

REF

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