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For professional use only

PREP-NA-S DNA/RNA Extraction Kit

INSTRUCTION FOR USE

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1. INTENDED USE

The **PREP-NA-S DNA/RNA Extraction Kit** is intended for fast NA extraction from biological materials for further analysis by PCR (polymerase chain reaction)/RT-PCR (PCR with reverse transcription). The **PREP-NA-S DNA/RNA Extraction Kit** is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal smears.

Indications for the use: the kit is an auxiliary agent for *in vitro* diagnostics (nucleic acids extraction for further RT-PCR/PCR analysis) in clinical and diagnostic laboratory.

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

The **PREP-NA-S 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 the clinical and diagnostic laboratory.

It is necessary to apply the kit only as directed in this instruction for use.

2. METHOD

The **PREP-NA-S DNA/RNA Extraction Kit** offers an express DNA/RNA extraction method. The method is based on the release of nucleic acids under the action of a chaotropic agent (guanidine thiocyanate) with subsequent precipitation and clearing from impurities.

The **PREP-NA-S DNA/RNA Extraction Kit** can be used in conjunction with medical devices designed for the analysis of nucleic acids by RT-PCR/PCR. The obtained NA preparation is ready for further analysis with RT-PCR/PCR.

3. CONTENT

The **PREP-NA-S DNA/RNA Extraction Kit** content is represented in Table 1.

Table 1. The **PREP-NA-S DNA/RNA Extraction Kit** content for P-007-N/1EU

Reagent	Description	Total volume	Amount
Lysis solution	Slightly foamy light blue or colorless transparent liquid	30 mL	1 vial
Precipitation buffer	Colorless transparent liquid	40 mL	1 vial
Wash solution	Colorless transparent liquid	50 mL	1 vial
Dilution buffer	Colorless transparent liquid	5.0 mL	1 vial

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

The kit is designed for DNA/RNA extraction from 100 analyzed samples (including negative 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, P-901-N/1EU, P-901-R/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;
- High speed centrifuge (RCF(g) 16000[1]);
- Solid-state thermostat that supports temperatures from 65 °C;
- Single channel pipettes (dispensers covering 20-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 20 µL, 200 µL, 1000 µL);
- Electric laboratory aspirator with trap flask for the removal of supernatant;
- RNase and DNase free non-filtered pipette tips for aspirator with trap flask;
- 1.5 mL RNase and DNase free tubes (Eppendorf Safe-Lock Tubes are recommended);
- Tube rack for 1.5 mL tubes;
- Physiological saline solution 0.9% NaCl Sterile.
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution;

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **PREP-NA-S 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.

It is allowed to transport the kit in thermoboxes with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C inside the thermoboxes, but for no longer than 5 days.

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

All components of the **PREP-NA-S DNA/RNA Extraction Kit** must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period. Lysis solution must be stored out of light.

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 in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

[1] If used in conjunction with RT-PCR kits for detection of nucleic acids of human acute respiratory viral infections’ pathogens produced by “DNA-Technology”, LLC, a centrifuge with RCF(g) no less than 12000 is allowed.

- lysis solution must be stored at temperatures from 2 °C to 8 °C and out of light over the storage period.

A little precipitate is allowed in lysis solution during storage.

The kit stored under undue regime must not be used.

An expired **PREP-NA-S DNA/RNA Extraction Kit** must not be used.

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

The conformity of the **PREP-NA-S 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-NA-S 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-NA-S DNA/RNA Extraction Kit** is designed to extract DNA/RNA from nasopharyngeal and oropharyngeal smears.

General recommendations

- Use DNAse and RNAse free filter tips;
- Do not touch the tube walls while adding a liquid in the tube. If touching the wall, change the tip. Change the tip each time while removing liquid from the tube;
- Open only the cap of the tube which is in work, then close the tube before proceeding to the next tube to prevent contamination.

Method limitations – Local medicine application (sprays, drops, creams and ointments) earlier than 24 hours before the assay. If using aerosols and other medications for inhalation in the treatment of bronchial asthma, the material for research should be taken not earlier than three hours after inhalation.

Sample collection

Smears from the nasal cavity sampling

Take the smear with a dry sterile disposable swab into 1.5 mL plastic tubes with 300 mL of sterile physiological saline solution or a transport medium.

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 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.
5. Close the tube tightly and mark it.

Smears from the oropharynx sampling

Take the smears with a dry sterile disposable swab into 1.5 mL plastic tubes with 300 mL of sterile physiological saline solution or a transport medium.

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 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.
5. Close the tube tightly and mark it.

Transportation and storage of the samples

Samples may be transported and stored in physiological saline at temperatures from 2 °C to 8° C for no more than 24 hours prior to analysis. When it is impossible to deliver the material in the laboratory during the day, a one-time freezing of the material is allowed. The frozen material is allowed to be stored at temperatures from minus 18 °C to minus 22 °C for no longer than 3 months.

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

8. PROCEDURE

WARNING!

1. The lysis buffer can form the precipitate. Dissolve it at 65 °C for 10 minutes prior to use.
2. Mix the contents of vial with washing solution before use by turning the vial intensively 5-7 times.
3. 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.
4. When performing centrifugation, always place the tubes in the centrifuge in the same orientation for easy visualization of the precipitate.
5. After centrifugation, remove supernatant by gradually dipping the tip into the liquid (i.e. lowering it as the liquid is removed). To avoid loss of precipitate with NA, it is necessary to remove supernatant, leaning the tip to the opposite wall of the tube from the precipitate.
6. When using a solid-state thermostat with a pressure lid during incubation of tubes, the thermostat lid must be open to avoid overheating of the tubes and their spontaneous opening when removing the tubes from the thermostat.
7. When working with the RT-PCR kits for detection of nucleic acids of human acute respiratory viral infections' pathogens ("DNA-Technology", LLC, Russia), the centrifugation of the biomaterial in the transport media **STOR-F**, **STOR-M** before RNA extraction is <u>not required.</u>
8. Simultaneously with the extraction of NA, a negative control sample should go through all stages of NA extraction.
9. For sample preparation and extraction use DNAse and RNAse free filter tips (without filter for electric aspirator).

10. 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, change the tip.
11. Proceed the tubes with samples and negative control equally.

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

WARNING! When used in conjunction with the kits for the analysis of nucleic acids by RT-PCR/PCR, for which the use of internal control sample is provided, at this stage it should be added into the tubes (in the amount according to the instructions for use for the corresponding kit).

WARNING! If used in conjunction with the RT-PCR kits for detection of nucleic acids of human acute respiratory viral infections' pathogens produced by "DNA-Technology", LLC that include internal control RNA-IC "A", add 10 µL of the corresponding pre-vortexed internal control (RNA-IC "A") into each tube.

8.2. Add 300 µL of lysis buffer into each tube without touching the tube's walls. Close the tubes.

8.3. Add 100 µL of prepared samples into the marked tubes. Do not add samples to the "C-" tube.

8.4. Add 100 µL of transport medium (for example, **STOR-F**, **STOR-M**) or sterile physiological saline solution in the "C-" tube. Close the tubes tightly, vortex on vortex mixer for 3-5 seconds.

8.5. Incubate the tubes for 5 minutes at 65 °C.

8.6. Spin down the drops by centrifuging on vortex mixer for 1-3 seconds.

8.7. Add 400 µL of the precipitation buffer into each tube.

8.8. Vortex the tubes on vortex mixer for 3–5 seconds.

8.9. Centrifuge the tubes at RCF(g) 12000[2] - 16000 for 5 minutes.

8.10. Remove the supernatant fully. Use a new tip for each tube. Avoid touching the precipitate.

8.11. Add 500 µL of the washout solution to the precipitate.

WARNING! The washout solution should be added into the tube slowly, avoiding splashing of liquid inside the tube.

8.12. Mix by inverting the tubes 3-5 times.

WARNING! It is allowed that the liquid remains in the cone of the tube (the lower part of the tube with NA, visually - the precipitate), since the tube is inverted to remove the remnants of the previous solutions from the walls and the cap of the tube. If the precipitate has moved away from the wall/bottom of the tube, make sure that it is in the liquid before the next step.

8.13. Centrifuge the tubes at RCF(g) 12000[2] - 16000 for 1 minute.

8.14. Remove the supernatant fully. Use a new tip for each tube. Avoid touching the precipitate.

WARNING! Try to remove the liquid as completely as possible avoiding contact with the precipitate. It is allowed to leave a small amount of liquid in the tube (5.0-10 µL), if there is a danger of contact with the precipitate. At this stage, the precipitate can be on the back wall of the test tube, as well as on the bottom.

8.15. Add 50 µL of the dilution buffer to the precipitate.

8.16. Spin down the drops by centrifuging on vortex mixer for 1-3 seconds.

8.17. Incubate the tubes at 65 °C for 5 minutes.

8.18. Vortex the tubes on vortex mixer for 5-7 seconds to distribute the nucleic acids evenly

[2] If used in conjunction with RT-PCR kits for detection of nucleic acids of human acute respiratory viral infections' pathogens produced by "DNA-Technology", LLC, a centrifuge with RCF(g) no less than 12000 is allowed

(visually–precipitate) in the liquid.

8.19. Centrifuge the tubes at RCF(g) 12000[2] - 16000 for 30 seconds.

The NA preparation is ready for RT-PCR/PCR.

The resulting NA preparation must be used immediately for RT-PCR/PCR. If it is needed, the resulting RNA preparation can be stored at temperatures from 2 °C to 8 °C for no longer than 2 hours, the resulting DNA preparation can be stored at temperatures from 2 °C to 8 °C for no longer than 3 days.

The resulting NA preparation must be stored at temperatures not above minus 20 °C for no longer than one month or at temperatures not above minus 68 °C for no longer than one year with a single defrost before RT-PCR/PCR.

9. SPECIFICATIONS

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

b. Interfering substances.

The maximum concentration of interfering substances that may be in biomaterial samples (nasopharyngeal and oropharyngeal smears), which do not affect the reverse transcription and polymerase chain reaction: whole blood – 5% v/v, chlorhexidine (0.05% water solution) – 10% v/v, xylometazoline hydrochloride 0.1% – 10% v/v.

c. Analytical sensitivity

Analytical sensitivity in conjunction with the kits for detection of SARS-CoV-2 and similar SARS-CoV RNA by reverse transcription and polymerase chain reaction in real-time: no more than 500 copies per 1 mL of biomaterial sample (nasopharyngeal and oropharyngeal smears taken into transport medium)

d. Medical devices the NA extraction kit is intended for.

The **PREP-NA-S DNA/RNA Extraction Kit** can be used together with medical devices intended for nucleic acid analysis by real-time PCR.

The **PREP-NA-S DNA/RNA Extraction Kit** is validated together with the RT-PCR kits for detection of nucleic acids of human acute respiratory viral infections' pathogens ("DNA-Technology", LLC, Russia).

e. Effectiveness of the kit

Number of assays (N) – 140.

Effectiveness of the medical device:

for DNA extraction – 100% (Ptrue = 96.94%);

for RNA extraction – 100% (Ptrue = 98.22%).

f. Within-batch and between-batch precision

Within-batch precision – 100 % (91.96% - 100%).

Between-batch precision - 100 % (91.96% - 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-NA-S DNA/RNA Extraction Kit**.

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11. KEY TO SYMBOLS

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

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