DNA-TECHNOLOGY

671 2021-08-10

CE IVD

For professional use only

PREP-NA DNA/RNA Extraction Kit

PREP-NA PLUS DNA/RNA Extraction Kit

USER MANUAL

EC REP

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REF P-002/1EU
P-002/2EU

VER 671.2021.08.10

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1. INTENDED USE

The ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** are intended for DNA/RNA extraction from biological materials (see Table 1) for further analysis with reverse transcription (RNA) and/or polymerase chain reaction (DNA). In the PREP-NA PLUS DNA/RNA Extraction Kit the total volume of purified DNA/RNA is larger (300 µL) comparing to standard PREP-NA DNA/RNA Extraction Kit (50 µL) for more PCR tests.

Table 1. Biological material for DNA/RNA extraction by PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits

Extraction Kit	PREP-NA DNA/RNA Extraction Kit	PREP-NA PLUS DNA/RNA Extraction Kit
Biological material	Blood plasma, saliva, phlegm, milk, urine, ejaculate, prostate fluid, cerebrospinal fluid, epithelial scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, swabs and washouts from nasal and oropharyngeal cavities, faeces, material from dead and sick animals (swabs and washouts from trachea, nasal cavity, pharyngeal cavity, cloaca, faeces, internal organs) etc.	Blood plasma, saliva, phlegm, milk, urine, ejaculate, prostate fluid, cerebrospinal fluid, epithelial scrapes from posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, etc.

 When operating with reagent kits:

- HCV PCR detection Kit (Conventional, FLASH, Real-time);
- HCV Real-time PCR genotyping Kit;
- HBV PCR detection Kit;
- Influenza A virus subtype H5N1 PCR detection Kit (FLASH, Real-time);
- HIV PCR detection Kit (FLASH, Real-time);
- HAV, HDV, HGV PCR detection Kits;
- Acute viral respiratory infections Real-Time PCR Detection Kit;
- SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit;
- Influenza A virus REAL-TIME PCR Detection Kit;
- Influenza B virus REAL-TIME PCR Detection Kit;
- Influenza A virus (subtype H1N1) REAL-TIME PCR Detection Kit.

only PREP-NA kit must be used

The ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** 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 user manual.

2. METHOD

The ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** are based on DNA/RNA extraction with precipitation. In order to extract specific product nucleic acids (NA), the biological samples' cells are pretreated with NA extraction solution. The following steps for NA extraction are performed to prepare the lysed NA specimen for amplification.

3. CONTENT

The ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits**' content is represented in Tables 2 and 3.

Table 2. The PREP-NA DNA/RNA Extraction Kit content, for P-002/1EU

Reagent	Description	Total volume	Amount
Lysis buffer	Light blue slightly foaming liquid	30 mL	1 vial
Precipitation buffer	Colorless transparent liquid	40 mL	1 vial
Washout solution №1	Colorless transparent liquid	50 mL	1 vial
Washout solution №2	Colorless transparent liquid	30 mL	1 vial
Dilution buffer	Colorless transparent liquid	5.0 mL (1.25 mL per tube)	4 tubes
Negative control	Colorless transparent liquid	3.0 mL (1.5 mL per tube)	2 tubes
Internal control (RNA-IC)	Colorless transparent liquid	1.0 mL	1 tube
Internal control (DNA-IC)	Colorless transparent liquid	1.0 mL	1 tube

Table 3. The PREP-NA PLUS DNA/RNA Extraction Kit content, for P-002/2EU

Reagent	Description	Total volume	Amount
Lysis buffer	Light blue slightly foaming liquid	15 mL	1 vial
Precipitation buffer	Colorless transparent liquid	20 mL	1 vial
Washout solution №1	Colorless transparent liquid	25 mL	1 vial
Washout solution №2	Colorless transparent liquid	15 mL	1 vial
Dilution buffer	Colorless transparent liquid	15 mL	1 vial

Dilution buffer differs for PREP-NA and PREP-NA PLUS kits. Using of dilution buffer from another kit is not allowed.

The ***PREP-NA*** **DNA/RNA Extraction Kit** is designed for NA extraction from 100 analyzed samples (including negative controls). The ***PREP-NA PLUS*** **DNA/RNA Extraction Kit** is designed for NA extraction from 50 analyzed samples (including negative controls).

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

- Specimen collection swabs: use only dacron, rayon, or calcium alginate tipped collection swabs with plastic or non-aluminum wire shafts;
- Use specimen transport medium: "DNA-Technology" made "PREP-RAPID" (REF P-001/1EU) or STOR-M (REF P-910-1/1EU) or STOR-F (REF P-901-1/1EU, P-901-N/1EU, P-901-R/1EU are recommended for Influenza A virus subtype H5N1 PCR detection Kit (FLASH, Real-time); Acute viral respiratory infections Real-Time PCR Detection Kit; SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit; Influenza A virus REAL-TIME PCR Detection Kit; Influenza B virus REAL-TIME PCR Detection Kit; Influenza A virus (subtype H1N1) REAL-TIME PCR Detection Kit) or equivalent or physiological saline solution or sterile PBS for the transportation of the sample;
- Blood specimen collection: use Vacuette type tubes, containing ethylenediaminetetraacetic acid disodium salt (EDTA) or sodium citrate anticoagulant.

4.2. NA extraction

- Biological safety cabinet class II;
- Refrigerator;
- Vortex micro-centrifuge;
- High speed centrifuge (RCF 16000 x g);
- Solid-state thermostat that supports temperatures from 25 °C to 98°C;
- 1.5 mL tubes;
- PCR tube rack for 1.5 mL tubes;
- Single channel pipettes (volume range 20-200 µL, 200-1000 µL);
- RNase and DNase free filtered pipette tips (volume 200 µL, 1000 µL);
- Pump with a trapping flask for supernatant removal;
- RNase and DNase free pipette tips for pump with a trapping flask;
- Powder-free surgical gloves;
- Disinfectant solution;
- Container for used pipette tips, tubes and other consumables;
- Physiological saline solution 0.9% NaCl (Sterile).

When extracting NA from phlegm (method 1):

- 10% trisodium phosphate x $12H_2O$;
- 1M HCl solution;
- 5% chloramines solution;
- distilled water.

When extracting NA from phlegm (method 2): mucolysin.

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

All components of the ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** must be stored at temperatures from 2 °C to 8 °C during the storage period.

The kit can be transported by all types of roofed transport at temperatures from 2°C to 8°C over the transportation.

Shelf-life of the kit following the first opening of the primary container: the components of the kit should be stored at temperatures of 2°C to 8 °C during the storage period.

The kit stored in under undue regime should not be used.

An expired ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** 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-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** to the prescribed technical requirements is subject to compliance of storage, carriage and handling conditions recommended by manufacturer.

Contact our official representative in EU by quality issues of the ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits.**

If you face to any undescribed issues contact our representative in EU or customer service department regarding quality issues with the kit:

Technical support E-mail: hotline@dna-technology.ru.

6. WARNINGS AND PRECAUTIONS

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. 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. Use a powder-free surgical gloves. Use 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 coming in contact with the biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121ºC before disposal.

All the liquid solutions are designed for single use and can not be used more than once. 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 dispensers, 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 breach;
- 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*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits** is designed to extract DNA/RNA from a wide variety of biological sample types, such as blood plasma, saliva, phlegm, milk, urine, ejaculate, prostate fluid, cerebrospinal fluid, scrapes of epithelial cells from the posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault, etc.

Sample collection and preparation

Blood plasma

The whole blood samples should be taken into 2.0 or 4.0 mL Vacuette type tubes, containing ethylenediaminetetraacetic acid disodium salt (EDTA) in final concentration of 2.0 mg/mL. The use of sodium citrate anticoagulant is also applicable. Invert the tube 2-3 times to mix the blood with anticoagulant.

The use of heparin anticoagulant is not allowed.

- Centrifuge the tubes with blood at 900 x g for 20 min at the room temperature (from 18 °C to 25 °C).
- Take the upper fraction (plasma) with a semi-automatic pipettes and put it into the new 1.5 mL tube.

Time from peripheral blood sampling to obtaining plasma must not exceed 6 hours. Plasma storage at minus 20 °C for not longer than 3 months is accepted.

Mix plasma just before NA extraction.

Phlegm

Method 1:

- Put approximately 500 µL of biological sample into sterile container and close it tightly.
- Add to the sample an equal volume of 10% triple-substituted sodium phosphate x12H2O and mix intensively.
- Incubate the mixture at 37 °C for 18–24 hours, then neutralize with 1M HCl (down to pH 6.8–7.4).
- Centrifuge at 100 x g for 20 min.
- Take out the supernatant into the 5% solution of chloramine for disinfection.
- Add 500 µL of distilled water to precipitate, mix by pipetting and put to the new 1.5 mL tube.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Method 2:

- Add mucolysin to the sampling container in the 5:1 ratio (5 parts of mucolysin to 1 part of phlegm), referring to container calibrations.
- Close the container, mix the content and incubate for 20–30 min at room temperature, shake the container every 2-3 min.

Storage of processed phlegm in a container is accepted at temperatures from 2 to 8 °C for one day or at temperatures not above minus 16 °C for along time (in case of repeated RNA/DNA extraction necessity).

Epithelial scrapes

- Put an epithelial scrape (posterior pharyngeal wall, urethra, cervical canal, posterior vaginal vault) using sterile sample brush into 1.5 mL tube with transport medium (or alternatively with 500 µL of sterile buffered saline), mix thoroughly.
- Remove the sample brush, pressing it to the tube wall and squeezing the excess of liquid. Close the tube tightly.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

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

Urine

- Take the portion (approximately 50 mL) of the first-void urine to sterile container and close it tightly.
- Transfer 1.0 mL of the sample into 1.5 mL tube.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant completely.
- Add 1.0 mL of sterile buffered saline to the precipitate.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Saliva, cerebrospinal fluid, synovial fluid

- Collect the saliva, cerebrospinal fluid, synovial fluid (approximately 500 µL) to the sterile container and close it tightly.
- Transfer 500 µL of the sample into 1.5 mL tube.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 50 µL (precipitate+liquid fraction).
- Add 500 µL of sterile buffered saline to the precipitate.
- Centrifuge the tube at 16000 g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction).

Ejaculate, prostate fluid

- Put 100 µL of the liquid sample into the 1.5 mL tube with transport medium (or alternatively with 500 µL of sterile buffered saline), vortex the tubes for 5-10 sec.
- Centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Milk

- Collect the sample into the sterile container and close it tightly.
- Mix thoroughly and put 1.0 mL of the sample into the 1.5 mL tube.

Milk collection period must not exceed 24 hours. Keep at temperatures from 2 °C to 8 °C during the collection period.

Swabs and lavages

- Centrifuge the tube with analyzed material at 16000 x g for 10 min.
- Remove the supernatant leaving approximately 100 µL (pellet + liquid fraction).

Do not perform centrifugation and removal of the supernatant when testing samples for presence of infections caused by RNA-containing viruses. The sample is ready to RNA extraction.

Faeces

- Put approximately 250 mg (µL) of faeces into the 1.5 mL tube with 1.0 mL of sterile buffered saline.
- Vortex the tube for 5-10 sec.
- Centrifuge the tube at 100 x g for 2-3 min.
- Transfer 800–1000 µL liquid material into 1.5 mL tube, centrifuge the tube at 16000 x g for 10 min.
- Remove the supernatant, leaving approximately 100 µL (precipitate+liquid fraction) in the tube.

Animal internal organs

- Transfer ~250 mg analyzed material into 1.5 mL tubes.
- Add 1.0 mL sterile saline.
- Vortex the tube for 3–5 sec, centrifuge the tube at 1000 x g for 3-5 sec.
- Remove the supernatant.

The samples are ready for DNA/RNA extraction.

Transportation and storage of the samples

Samples may be transported and stored in physiological saline at temperatures from 2 °C to 8° C 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

Nucleic acid extraction

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

Assay procedure:

The lysis buffer can form the precipitate. Dissolve it at 65 °C for 10 min prior to use.

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

For pre-processed samples with obtaining pellet and supernatant (phegm method 1, saliva, cerebrospinal fluid, urine, ejaculate, prostatic fluid, swabs and lavages, faeces) tubes with 100 µL of material prepared for testing must be marked.

- Add 10 µL of premixed internal control to each marked tube:

RNA-IC	DNA-IC
Reagent kits: HCV PCR Detection Kit (Conventional, FLASH, Real-time); HCV Real-time PCR Genotyping Kit; HIV PCR Detection Kit (FLASH, Real-time); Influenza A virus subtype H5N1 PCR Detection Kit (FLASH, Real-time); HAV, HDV, HGV PCR Detection Kits; SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit[1]	HBV PCR Detection Kit (Conventional, FLASH, Real-time)

[1]In case of SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit, RNA-IC from the PREP-NA DNA/RNA Extraction Kit are not used. Use RNA-IC from SARS-CoV-2/SARS-CoV Multiplex REAL-TIME PCR Detection Kit.

Do not use RNA-IC or DNA-IC at the sample preparation stage for the PCR kits which are not mentioned in the Table above.

Addition of both (RNA-IC and DNA-IC) internal controls is required when you do simultaneous analyses for presence of infections caused by RNA-containing viruses (HAV, HCV, HDV, HGV and HIV) and DNA-containing viruses (HBV).

- Add 300 µL of the lysis buffer into the each tube avoiding contact of the pipette tip with an edge of the tube.
- Add 100 µL of the sample into the marked tubes (except for sample tubes passed preprocessing to obtain a precipitate (phegm method 1, saliva, cerebrospinal fluid, urine, ejaculate, prostatic fluid, swabs and lavages, faeces), and "C-" tube).
- Add 100 µL of negative control (PREP-NA kit), transport medium or sterile physiological saline (PREP-NA PLUS kit) into the tube marked "C-". Close the tube tightly, vortex for 3-5 sec.
- Incubate the tubes for 15 min at 65 °C, centrifuge at 16000 x g for 30 sec.

In case of Influenza A virus RNA extraction from animal organ incubate the tubes at 65 °C for 30 min, spin down condensate by centrifuging at 100 x g for 3–5 sec and remove the supernatant into new 1.5 mL tube.

- Add 400 µl of the precipitation buffer. Close the tubes tightly and vortex them for 3–5 sec.

At HAV, HCV, HDV, HGV, HBV and HIV NA extraction it is necessary to vortex the tubes twice.

- Centrifuge the tubes at 16000 x g for 15 min.
- Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- Add 500 µL of the wash-out solution №1 to the precipitate and mix by inverting the tube 3-5 times.
- Centrifuge the tubes at 16000 x g for 5 min.
- Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- Add 300 µL of the wash-out solution №2 to the precipitate and mix by inverting the tube 3-5 times.
- Centrifuge the tubes at 16000 x g for 5 min.
- Remove the supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- Open the tubes and dry the precipitate at 65 °C for 5 min.
- Add 50 µL (PREP-NA kit) or 300 µL (PREP-NA PLUS kit) dilution buffer to pellet (if it is necessary to increase the sensitivity of the study or if this is indicated in the detection kit user manual, the volume of the dilution buffer can be reduced).

Dilution buffer differs for PREP-NA and PREP-NA PLUS kits. Using of dilution buffer from another kit is not allowed.

Dissolve pellet in dilution buffer is recommended when testing clinical material for presence of infections caused by RNA-containing viruses alone (in 16.5 µL dilution buffer when working with HCV PCR detection Kit, HCV Real-time PCR genotyping Kit, HIV PCR detection Kit; HAV, HDV, HGV PCR detection kit, in 35 µL dilution buffer when working with Acute viral respiratory infections Real-Time PCR Detection Kit and in 50 µL dilution buffer when working with SARS-CoV-2/ SARS-CoV Multiplex REAL-TIME PCR Detection Kit; Influenza A virus REAL-TIME PCR Detection Kit; Influenza B virus REAL-TIME PCR Detection Kit; Influenza A virus (subtype H1N1) REAL-TIME PCR Detection Kit), because dilution buffer volume increase leads to proportional sample dilution and decrease of analysis sensitivity. Dissolve pellet in 25 µL dilution buffer when working with HBV PCR detection kit and when simultaneously testing samples for presence of infections caused by RNA-containing viruses (HAV, HCV, HDV, HGV and HIV) and DNA-containing viruses (HBV).

- Spin the drops down by centrifuging for 1-3 sec.
- Incubate the tubes at 65 °C for 10 min, vortex them for 3–5 sec
- Centrifuge the tubes at 16000 x g for 30 sec.

The DNA/RNA preparation is ready for reverse transcription and/or PCR.

The obtaining RNA preparation must be used immediately for reverse transcription reaction. It can not be stored. DNA preparation can be stored at temperatures from minus 18 °C to minus 20 °C for no longer than 1 month or at temperatures from 68 °C to minus 70 °C for not longer than 1 year.

9. QUALITY CONTROL

"DNA-Technology Research&Production", LLC declares that the above mentioned 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 by quality issues of ***PREP-NA*** and ***PREP-NA PLUS*** **DNA/RNA Extraction Kits**:
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10. KEY TO SYMBOLS

	In vitro diagnostic medical device		Date of manufacture
	Temperature limitation		Consult instructions for use
	Sufficient for		Catalogue number
	Use by		Manufacturer
	Batch code		Version
	Caution		Non-sterile
	Authorized representative in the European Community		Do not reuse