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RUO

For research use only

PREP-NA-ULTRA viral DNA/RNA Extraction Kit

INSTRUCTION FOR USE

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1. INTENDED USE

The **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** is designed for viral nucleic acid extraction from blood plasma and blood serum with preconcentration for subsequent real-time PCR/RT-PCR analysis.

Indications for the analysis: the need to extract viral DNA/RNA from blood plasma, blood serum.

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

The **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** can be used in research practice.

Potential users: qualified personnel trained in molecular research methods and rules of work in the laboratory.

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

2. METHOD

The **method principle** is treating the sample with a multicomponent reagent that concentrates the nucleic acids from the primary sample volume, lysis of the resulting concentrate (precipitate), alcohol precipitation of the nucleic acids, washing and subsequent dissolution of the nucleic acids in buffer. The sample is then ready for PCR or RT-PCR.

Preconcentration of the sample increases the sensitivity of pathogen detection in biomaterial.

3. CONTENT

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

Table 1. The **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** content, package N for P-017-N/1ER

Reagent	Description	Total volume	Amount
Concentrating solution	Colorless transparent liquid*	80 mL	1 vial
Lysis solution	Light blue foamy liquid**	30 mL	1 vial
Precipitation buffer	Colorless transparent liquid	40 mL	1 vial
Wash solution No. 1	Colorless transparent liquid	50 mL	1 vial
Wash solution No. 2	Colorless transparent liquid	50 mL (25 mL in each vial)	2 vials
Dilution buffer	Colorless transparent liquid	10 mL	1 vial
Negative control	Yellow transparent or slightly opalescent liquid	42 mL	1 vial
* - Presence of precipitate that dissolves upon heating is allowed ** - Presence of crystals that dissolve upon heating is allowed			

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

The kit is designed for DNA extraction from 100 analyzed samples (including controls).

In case of quantitative test, the manufacturer guarantees that the reagents are sufficient for 5 independent extractions, 7 test samples each. In case of the qualitative test, the manufacturer guarantees that the reagents are sufficient for 5 independent extractions, 19 test samples each.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

The following equipment, reagents and consumables are required:

Equipment, reagents and consumables	Extraction from 1,000 µL	Extraction from 500 µL	Extraction from 250 µL
Biological safety cabinet class II-III	yes	yes	yes
Solid-state thermostat, maintaining up to 65 °C	yes	yes	yes
High speed centrifuge (RCF(g) at least 1,600) for Vacuette tubes	yes	yes	yes
High speed centrifuge (RCF(g) at least 14,000) for 1.5 - 2.0 mL tubes; centrifuge without cooling is allowed	yes	yes	yes
Vortex mixer	yes	yes	yes
Refrigerator with freezer	yes	yes	yes
Vacuette-type vacuum plastic tubes with EDTA salt or sodium citrate	yes	yes	yes
RNase and DNase free 1.5 mL tubes with caps	no	yes	yes
RNase and DNase free 2.0 mL tubes with caps	yes	no	no
Tube rack for 1.5 mL tubes;	no	yes	yes
Tube rack for 2.0 mL tubes	yes	no	no
Single channel pipettes (dispensers covering 2.0-1,000 µL volume range)	yes	yes	yes
Pipette rack	yes	yes	yes
RNase and DNase free filter pipette tips (volume 20 µL, 200 µL, 1,000 µL)	yes	yes	yes
Electric laboratory aspirator with trap flask for the removal of supernatant	yes	yes	yes
RNase and DNase free pipette tips for aspirator with trap flask	yes	yes	yes
Container for used pipette tips, tubes and other consumables	yes	yes	yes
Powder-free surgical gloves;	yes	yes	yes
Disinfectant solution	yes	yes	yes

5. STORAGE AND HANDLING REQUIREMENTS

Expiry date – 12 months from the date of production.

5.1. Storage conditions

All components of the **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** must be stored in a refrigerator or a cooling chamber at the temperature from 2 °C to 25 °C and out of light throughout the shelf life of the kit.

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

5.2. Transport conditions

Transportation of the reagent kit is carried out in thermoboxes with ice packs by all types of roofed transport at the temperature inside the container corresponding to the 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 the temperature inside the container from 2 °C to 25 °C for no longer than 5 days.

WARNING! Reagent kits transported with violation of temperature conditions must not be used.

5.3. Shelf-life of the kit following the first opening of the primary container

- Solution for concentration, lysis solution and wash solution No. 2 must be stored at room temperatures (from 18 °C to 25 °C) over the storage period; lysis solution must be stored out of light.
- Negative control and dilution buffer must be stored at temperatures from 2 °C to 25 °C over the storage period.
- Precipitation buffer and wash solution No. 1 must be stored at temperatures from 2 °C to 25 °C and used chilled over the storage period.

WARNING! The kits stored under undue regime must not be used.

An expired **PREP-NA-ULTRA viral 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-ULTRA viral 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 research and the rules of work in the laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the test 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 test. 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. 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

Blood plasma and blood serum obtained from human peripheral whole blood is used for the test.

7.1. General requirements

- The quality of sampling, sample storage, transport and pretreatment are of great importance for obtaining correct results. Incorrect sampling may lead to unreliable results and, therefore, to the necessity for repeated sampling.
- Use RNase and DNase free filtered tips during biomaterial preparation and NA extraction.
- To prevent contamination, only open the cap of the tube you are working with and close it before proceeding to the next tube.

7.2. Interfering substances

The presence of PCR inhibitors in a sample may cause controversial (uncertain) results. The sign of PCR inhibition is the simultaneous absence of internal control and specific product of amplification.

The maximum concentration of interfering substances, which do not affect the reverse transcription and amplification of the laboratory control and internal control: triglycerides – up to 40 mmol/L of plasma/serum sample, hemoglobin – up to 2.0 g/L, bilirubin – up to 340 µmol/L, total protein – 60 g/L.

7.3. Peripheral blood collection

WARNING! Preparation of peripheral blood samples before NA extraction is required!

Method limitations: intravenous heparin injections, infusion of parenteral nutrition less than 6 hours before the test.

Peripheral blood sampling is carried out in vacuum plastic tube. It may be 2.0 – 6.0 mL Vacuette blood collection tubes with anticoagulant, for example salt of ethylenediaminetetraacetate (EDTA) at a final concentration of 2.0 mg/mL. The use of sodium citrate anticoagulant is also applicable (if it does not contradict the requirements to the PCR/RT-PCR reagent kit used together with the **PREP-NA-ULTRA viral DNA/RNA Extraction Kit**). After taking the material, it is necessary to mix the blood with anticoagulant inverting the tube 2 – 3 times.

WARNING! It is not allowed to use heparin as an anticoagulant.

Using tubes with clot activator and barrier gel is allowed.

Fill the tube until the filling mark.

7.4. Transportation and storage of the samples

WARNING! The overall storage of the sample should not exceed 6 hours.

The transportation and storage temperature from collecting the sample until analysis should be from 2 °C to 8 °C for up to 12 hours.

WARNING! Whole blood cannot be frozen!

Note. It is not recommended to transport and store tubes with plasma at temperature below 0 °C to avoid gel damage and sample contamination with hemolysis products and gel fragments.

7.5. Obtaining blood plasma/serum

1. Centrifuge the tube with blood at RCF(g) 800-1,600 for 20 minutes at room temperature from 18 °C to 25 °C.
2. Take the upper fraction (plasma/serum) with a dispenser and put it into the new 1.5-2.0 mL tube. Do not touch the barrier gel (if using tubes with barrier gel).

Tubes with serum and barrier gel must be centrifuged once to separate the serum.

WARNING!

1. If using tubes with barrier gel, second centrifugation is prohibited to avoid gel damage and sample contamination with hemolysis products.
2. Avoid gel getting into the serum sample as it may result in PCR/RT-PCR inhibition.

Blood plasma/serum can be stored at temperature from 2 °C to 8 °C for no longer than 5 days, at minus 22 °C to minus 18 °C for no longer than 3 months, at minus 72 °C to minus 68 °C for no more than one year.

WARNING! Avoid repeated freezing and thawing of samples.

8. PROCEDURE

To prevent cross-contamination of the biological material in the laboratory, the following rules are recommended:

1. Visual assessment of the incoming biomaterial and cull test tubes with broken integrity are necessary.
2. it is necessary to use negative control samples, starting from the stage of NA extraction in each protocol.
3. Use tips with aerosol filters at all stages of the test.
4. Observe the procedure, open Eppendorf-type tubes using tweezers (avoid touching the inner part of the tube cap with gloved hand); do not touch the edge of the tube with the tip when adding reagents (if this happened, change the tip immediately).

8.1 Preparation of plasma/serum samples for NA extraction

Preparation of plasma/serum samples for NA extraction is carried out according to Table 1.

Table 1. Orders of plasma/serum samples preparation

Storage temperature for plasma/serum samples	Preparation of plasma/serum samples
Minus 18 °C and below	1. Thaw plasma/serum samples at room temperature (18 °C to 25 °C) or at 2 °C to 8 °C. 2. Shake plasma/serum samples on vortex and centrifuge at RCF(g) 14,000 for 5 minutes.
	W A R N I N G ! For NA extraction use supernatant. Do not touch the precipitate (if any).
From 2 °C to 8 °C	Shake plasma/serum samples on vortex and spin on vortex for 1-3 seconds.

8.2 Use of controls during nucleic acid extraction

Using controls at NA extraction stage is prescribed by instructions for use to the PCR/RT-PCR reagent kits.

To exclude false negative results and for quality control, using internal control is recommended.

8.2.1 Internal control

An **internal control** must be added to test samples during NA extraction stage. Internal control is added to the test sample in the amount specified in the instructions for use of the corresponding PCR/RT-PCR kit.

8.2.2 Negative control

To exclude false positive results and sample preparation assess use a **negative control** from the NA extraction stage, simultaneously with NA extraction from test samples.

8.2.3 Standards

Standards (according to the instructions for use of the corresponding PCR/RT-PCR kit) can be used for quantitative tests. Standards can be used starting from NA extraction stage, simultaneously with NA extraction from test samples. Standards are prepared according to the instructions for use of the corresponding PCR/RT-PCR kit.

WARNING!

1. Use only RNase and DNase free filter tips at NA extraction stage, except for the supernatant collection with aspirator. In this case, use RNase and DNase free tips without filter.
2. Change the tip after each solution removal from the tube.
3. To prevent contamination, only open the cap of the tube you are working with and close it before proceeding to the next tube.
4. Be careful when adding solution to the tube with biomaterial. Do not touch the walls of the tube. If touching occurred, change the tip.

8.3 Preparation of reagent kit

Before starting work:

- Heat thermostat to 65 °C.
- Warm the solution for concentration and lysis solution at 65 °C on the thermostat for 15 minutes. Then mix the solutions by turning the vial upside down 5-10 times, avoiding foaming. If the solution for concentration and lysis solution are stored at room temperature (18 °C to 25 °C), preheating is not necessary.

Use the precipitation buffer and wash solution No. 1 cooled down for better precipitate visualization. For this purpose, it is recommended to take them out of the refrigerator immediately before work. If the precipitation buffer and wash solution No. 1 were stored at room temperature (18 °C to 25 °C), cool them down before work.

8.4 Preparation and NA extraction

WARNING! Tube caps may open during heating! Use tubes with locking caps (e.g. Eppendorf Safe-Lock Tubes) or programmable thermostats with a clamp lid (e.g. solid-state programmable small-size thermostat TT-1-DNA-Technology, manufactured by “DNA-Technology R&P”, LLC.).

8.4.1. Mark the required number of 1.5-2.0 mL tubes:

- one tube for each plasma/serum sample;
- one tube for negative control “C-“.

For quantitative tests using **reagent kits manufactured by “DNA-Technology”**[1], mark additionally:

- three tubes for standard "ST1" (if specified in the instructions for use for the quantitative test kit);
- three tubes for standard "ST2" (if specified in the instructions for use for the quantitative test kit).

WARNING! The reagents are intended for up to 5 separate extraction procedures considering variable number of test samples and 1 negative control “C-“ per run. If the obtained NA is used for quantitative tests and the use of standards is prescribed by the quantitative reagent kit instruction, 3 additional tubes for ST1 and 3 tubes for ST2 are allowed in each run.

8.4.2. Add controls and standards according to the instructions for use for the corresponding reagent kits.

[1] - If using reagent kits from other manufacturers, please refer to the instructions for use to the corresponding kits.

When using **reagent kits manufactured by "DNA-Technology"**, add into all the marked tubes:

- for RNA extraction – 10 µL of RNA-IC "A";
- for DNA extraction – 10 µL of DNA-IC "A";
- in case of simultaneous RNA and DNA extraction – 10 µL of RNA-IC "A" and 10 µL of DNA-IC "A".

Notes:

1. When extracting NA from 1,000 µL of sample, it is allowed to add 500 µL of solution for concentration per sample. However, remember that decrease in the volume of solution for concentration will lead to more protein precipitate, which in turn may complicate NA extraction.
2. For small volumes of biomaterial, extraction from 500 and 250 µL is allowed. Use solution for concentration at a rate of 250 µL of solution per 500 µL of sample and 125 µL of solution per 250 µL of sample.

8.4.3. Add 800 µL/250 µL/125 µL of solution for concentration to each tube (depending on the volume of sample for NA extraction).

8.4.4. Shake the tubes with negative control and standards on vortex and spin on vortex for 1-3 seconds.

8.4.5. Enter 1,000 µL/500 µL/250 µL of prepared samples of blood plasma/serum into the corresponding marked tubes. Close the tubes. Do not enter plasma/serum samples into the "C-", "ST1", "ST2" tubes.

8.4.6. Add 1,000 µL/500 µL/250 µL of negative control into the "C-" tube. Close the tube.

8.4.7. For quantitative tests using **reagent kits manufactured by "DNA-Technology"**[2], enter 20 µL of the corresponding standard and 980 µL/480 µL/230 µL of negative control into the "ST1" and "ST2" tubes (3 tubes per each standard). Close the tubes.

Note. In case of quantitative test for several infections, preparation of mixed standards is allowed. To make it, add 20 µL of ST1 from each reagent kit into each tube for ST1; add 20 µL of ST2 from each reagent kit into each tube for ST2. Then, reach the final volume of 1,000 µL/500 µL/250 µL by adding negative control.

Example:

1. Extraction from 1,000 µL:

If quantitative HCV and HBV tests are planned in one run, add 20 µL of HCV-ST1 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL of HBV-ST1 from the HBV Quantitative REAL-TIME PCR Kit into ST1 tubes; add 20 µL of HCV-ST2 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL of HBV-ST2 from the HBV Quantitative REAL-TIME PCR Kit into ST2 tubes. Then, add 960 µL of negative control into each tube.

2. Extraction from 500 µL:

If quantitative HCV and HBV tests are planned in one run, add 20 µL of HCV-ST1 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL of HBV-ST1 from the HBV Quantitative REAL-TIME PCR Kit into ST1 tubes; add 20 µL of HCV-ST2 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL of HBV-ST2 from the HBV Quantitative REAL-TIME PCR Kit into ST2 tubes. Then, add 460 µL of negative control into each tube.

3. Extraction from 250 µL:

If quantitative HCV and HBV tests are planned in one run, add 20 µL of HCV-ST1 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL of HBV-ST1 from the HBV Quantitative REAL-TIME PCR Kit into ST1 tubes; add 20 µL of HCV-ST2 from the HCV Quantitative REAL-TIME PCR Kit and 20 µL

[2] - If using reagent kits from other manufacturers, please refer to the instructions for use to the corresponding kits.

of HBV-ST2 from the HBV Quantitative REAL-TIME PCR Kit into ST2 tubes. Then, add 210 µL of negative control into each tube.

8.4.8. Shake the tubes on a vortex mixer for 1-3 seconds.

8.4.9. Centrifuge at RCF(g) 560-800 for 3 minutes at room temperature (18 °C to 25 °C).

Note. Quantity and nature of the precipitate depend on the individual features of the sample and the volume for NA extraction. For extraction from 1,000 µL centrifuge at RCF(g) 560; for extraction from 250-500 µL – at RCF(g) 800.

8.4.10. Remove supernatant completely from each tube using a separate tip. Do not touch the precipitate.

Note. In tubes with standards "ST1" and "ST2", negative control, as well as in some tubes with the test samples, the precipitate may not be visualized.

8.4.11. Add 300 µL of lysis solution to each tube without touching the edge of the tube; close the tubes.

8.4.12. Shake all tubes on a vortex mixer for 10-15 seconds.

8.4.13. Incubate the tubes at room temperature (18 °C to 25 °C) for 15 minutes until the precipitate is completely dissolved. During the incubation shake the tubes twice at 5 minutes intervals on a vortex mixer for 1-3 seconds.

Note. In the case of highly heterogeneous lysates, specify centrifugation parameters, since exceeding optimal RCF/RPM values may result in precipitates that are difficult to dissolve with lysis buffer.

8.4.14. Shake all the tubes on vortex for 3-5 seconds.

8.4.15. Centrifuge the tubes at RCF(g) 14,000 or vortex for 30 seconds.

8.4.16. Add 400 µL of pre-cooled precipitation buffer to each tube. Close tube caps.

8.4.17. Shake all the tubes on a vortex mixer for 3-5 seconds.

8.4.18. Centrifuge the tubes at RCF(g) 14,000 for 10 minutes at room temperature (18 °C to 25 °C).

8.4.19. Remove the supernatant completely from each tube using a separate tip without touching the sediment.

8.4.20. Add 500 µL of wash solution No. 1 to the precipitate, close the tube caps and gently invert each tube 3-5 times.

8.4.21. Centrifuge the tubes at RCF(g) no less than 14,000 for 1 minute.

8.4.22. Remove supernatant completely from each tube using a separate tip. Do not touch the precipitate.

8.4.23. Add 500 µL of wash solution No. 2 to the precipitate, close tube caps and gently invert each tube 3-5 times. It is necessary to invert each tube individually.

8.4.24. Centrifuge the tubes at RCF(g) 14,000 for 1 minute at room temperature (18 °C to 25 °C).

8.4.25. Remove supernatant completely from each tube using a separate tip. Do not touch the precipitate.

8.4.26. Open tube caps and dry the precipitate at 65 °C for 5 minutes.

8.4.27. Add 100 µL of dilution buffer to each tube with the precipitate. Close tube caps.

8.4.28. Shake the tubes on a vortex mixer for 1-3 seconds.

8.4.29. Heat the tubes in thermostat at 65 °C for 10 minutes.

8.4.30. Shake the tubes on vortex for 1-3 seconds.

8.4.31. Centrifuge the tubes at RCF(g) 14,000 for 30 seconds.

NA preparation is ready for PCR/RT-PCR.

8.5 NA preparation storage and use

8.5.1. If NA preparation is intended for RT or RT-PCR (RNA test), NA preparation storage is allowed at 2 °C – 8 °C for up to 2 hours.

8.5.2. If NA preparation is intended for PCR (DNA test), NA preparation storage is allowed at minus 22 °C – minus 18 °C for up to 1 month or at minus 72 °C – minus 68 °C for up to 1 year without thawing prior to the test.

8.5.3. If NA preparations have been stored at minus 22 °C – minus 18 °C or at minus 72 °C – minus 68 °C, thaw NA preparations, negative control and standards at room temperature (18 °C – 25 °C) before use.

WARNING! Only one thawing is allowed for NA preparation!

8.5.4. Before using NA preparation for PCR/RT-PCR after storage, shake the tubes with NA preparation, negative control and standards on vortex for 3-5 seconds and spin on vortex for 1-3 seconds.

NA preparation is ready for PCR/RT-PCR.

9. SPECIFICATIONS

a. The **minimal amount of biomaterial** for nucleic acids extraction is 250 µL.

Recommended amount of biomaterial to increase the sensitivity of the test: 500 µL or 1,000 µL.

b. **Effectiveness of the reagent kit**

Efficiency of HCV RNA extraction is 100% (97.8-100%), confirmed for extraction from 60 blood plasma/serum samples, compared to reference method.

Efficiency of HBV DNA extraction is 100% (97.8-100%), confirmed for extraction from 60 blood plasma/serum samples, compared to reference method.

c. Medical devices compatible with the **PREP-NA-ULTRA viral DNA/RNA Extraction Kit**:

The **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** for viral nucleic acid extraction from blood plasma and blood serum with preconcentration can be used together with the PCR/RT-PCR reagent kits.

The **PREP-NA-ULTRA viral DNA/RNA Extraction Kit** for viral nucleic acid extraction from blood plasma and blood serum with preconcentration is validated with the following PCR/RT-PCR reagent kits:

- **HCV Quantitative REAL-TIME PCR Kit** (“DNA-Technology R&P”, LLC, Russia);
- **HCV REAL-TIME PCR Kit** (“DNA-Technology R&P”, LLC, Russia);
- **HBV Quantitative REAL-TIME PCR Kit** (“DNA-Technology R&P”, LLC, Russia);
- **HBV REAL-TIME PCR Kit** (“DNA-Technology R&P”, LLC, Russia).

10. QUALITY CONTROL

The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of 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-NA-ULTRA viral DNA/RNA Extraction Kit**:

Technical support:

E-mail: hotline@dna-technology.ru

https://www.dna-technology.com

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https://www.dna-technology.com

11. KEY TO SYMBOLS

RUO	For research use only		Date of manufacture
	Temperature limit		Consult instructions for use
	Contains sufficient for <n> tests	REF	Catalogue number
	Use-by date		Keep away from sunlight
LOT	Batch code	VER	Version
	Manufacturer		Caution
	Non-sterile		

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