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INSTRUCTION FOR USE

Kit for DNA/RNA Extraction from Clinical Material «NA-Extra»

according to TS 21.20.23-013-97638376-2019

Содержание

Introduction

Target analyte. The kit «NA-Extra» is used during the phase of preparation of a sample for the subsequent testing. The kit is not designed for isolation of NA as a target analyte.

Scientific validity.

NA extraction is an important step in sample preparation. Many methods, such as amplification, reverse transcription, detection of accumulation of amplification products by real-time PCR, etc., cannot be performed directly on clinical samples without preliminary purification of nucleic acids.

NA extraction is a preliminary stage in performing genetic tests used for medical purposes, particularly in diagnostics of a novel coronavirus *SARS-CoV-2* infection.

The use area of the reagent kit is clinical laboratory diagnostics.

Indications and Contraindications for Use.

Indications for use: The kit «NA-Extra» is recommended for use during preliminary analytical stage when performing tests in clinical laboratory diagnostics. Extracted human NA is suitable for tests performed by reverse transcription (NA), particularly in diagnostics of a novel coronavirus *SARS-CoV-2* infection.

Contraindications for Use: when used by specially trained personnel and taking into account the intended use, contraindications have not been identified.

1. Intended Use

Intended use: The kit «NA-Extra» is designed for DNA/RNA extraction from clinical material (venous blood, venous blood plasma, sputum, nasopharyngeal swabs, oropharyngeal swabs, vaginal mucosa swabs, cervical scraping, urethral scraping, urine cellular sediment, prostate secretion) using the technic based on the reversible binding of nucleic acids on the surface of magnetic microbeads for subsequent analysis in clinical laboratory diagnostics by the method of reverse transcription (RNA), polymerase chain reaction (DNA).

Functional purpose: The kit «NA-Extra» is designed for use during preliminary analytical stage of molecular genetic testing. DNA/RNA extracted from human biological sample is not the basis for a diagnosis, but it can be used for subsequent analysis in clinical laboratory diagnostics by the method of reverse transcription (RNA), polymerase chain reaction (DNA).

For example, the following medical devices can be used together for subsequent analysis of extracted DNA/RNA:

- Kit for qualitative detection of coronavirus DNA/RNA (*SARS-CoV-2*) by real-time RT-PCR "CoV-2-Test" according to TS 21.20.23-015-97638376-2020, manufactured by TestGene, LLC (Registration certificate No. RZN 2020/10364 of 15 May 2020) and other reagent kits for coronavirus DNA/RNA detection by real time RT-PCR, duly registered in the Russian Federation.

Potential users of the medical device

The kit is designed for professional use in medical institutions and clinical diagnostic laboratories. Professional level of potential consumers - doctor of clinical laboratory diagnostics, medical laboratory technician.

Sterility: the product is not sterile.

Specific pathology, condition or risk factor which a medical device is intended to determine, detect or differentiate: The kit «NA-Extra» is used for DNA/RNA extraction from human clinical material for subsequent testing in clinical laboratory diagnostics by reverse transcription**.** DNA/RNA extracted with the use of the reagent kit is not the basis for a diagnosis. To diagnose any pathology, condition, or risk factor in an DNA/RNA sample isolated from clinical

material using the kit «NA-Extra», medical devices for in vitro diagnostics designed for reverse transcription assays are used.

2. Method Principle

Type of sample to test

Material for nucleic acids extraction are venous blood, venous blood plasma, sputum, nasopharyngeal swabs, oropharyngeal swabs, vaginal mucosa swabs, cervical scraping, urethral scraping, urine cellular sediment, prostate secretion

Detection Principle

The kit is based on the principle of reversible binding between DNA/RNA and the surface of magnetic microbeads. After lysis of the sample, the nucleic acids contained in it bind to magnetic microbeads. Then magnetic microbeads should be washed with washing solutions No. 1 and No. 2, which are part of the kit. After several washing cycles, the magnetic particle sediment must be dried, and then nucleic acids can be eluted. Extraction can be modified to scale up if more final material is required. To scale up the process, it is required to change proportion of the number of reagents.

The functionality of the kit allows using it for the process of DNA/RNA extraction by automatic stations.

Method Limitation

Contamination of biological material may occur during sample preparation or during DNA/RNA extraction.

Breach of the package integrity during transportation.

Use of an expired kit.

Violation of storage conditions and transporting conditions of samples.

Total time for DNA/RNA isolation:

- 40 min. for extraction from 1 sample using reagent kit in configuration1 (“NA-Extra-M”) for manual extraction;

- 40 min. for extraction from 96 samples simultaneously in a single runusing reagent kit in configuration1 (“NA-Extra-M”) and Tecan robotic workstation Freedom EVO® for sample preparation;

- 40min. for automated extraction from 96 samples simultaneously in a single run using reagent kit in configuration2 (“NA-Extra-KF-r”) or in configuration3 (“NA-Extra-KF-u”) and KingFisher Flex Magnetic Particle Processor.

3. Reagent Kit Components

The reagent kit is produced in three configurations:

1) Configuration 1: “NA-Extra-M” reagent kit for manual extraction and extraction with the use of automated sample preparation stations,

2) Configuration 2: “NA-Extra-KF-u” reagent kit (not pipetted) for automated extraction with the use of KingFisher Flex Magnetic Particle Processor to purify nucleic acids, cells, and proteins.

3) Configuration 3: “NA-Extra-KF-r” reagent kit (pipetted) for automated extraction with the use of KingFisher Flex Magnetic Particle Processor to purify nucleic acids, cells, and proteins.

Number of Testing Samples

Kit in configuration 1 (“NA-EXTRA-M”) is designed for multiple application, and offers the number of reagents for DNA/RNA extraction from 96 testing samples.

Kit in configuration 2 (“NA-EXTRA-KF-u”) is designed for multiple application, and offers simultaneous DNA/RNA extraction from 1 to 96 testing samples during one cycle using KingFisher Flex Magnetic Particle Processor.

Kit in configuration 3 (“NA-EXTRA-KF-r”) is designed for one-time application and offers DNA/RNA extraction from 96 samples simultaneously for one cycle using KingFisher Flex Magnetic Particle Processor.

Kit Components

Table 1 – Components of NA-Extra reagent kit, configuration 1

No.	Reagent	Description	Quantity, Volume
1	Binding buffer	Transparent colorless liquid	1 bottle (48 ml)
2	Magnetic microbeads	Brown suspension	1 tube (960 µl)

No.	Reagent	Description	Quantity, Volume
3	Washing solution No. 1	Transparent colorless liquid	1 bottle (68 ml)
4	Washing solution No. 2	Transparent colorless liquid	2 bottles (68 ml each)
5	Eluent	Transparent colorless liquid	1 bottle (21 ml)

Table 2 – Components of NA-Extra reagent kit, configuration 2

No.	Reagent	Description	Quantity, Volume
1	Binding buffer	Transparent colorless liquid	1 bottle (48 ml)
2	Magnetic microbeads, MP	Brown suspension	1 tube (960 µl)
3	Washing solution No. 1	Transparent colorless liquid	1 bottle (68 ml)
4	Washing solution No. 2	Transparent colorless liquid	2 bottles (68 ml each)
5	Eluent	Transparent colorless liquid	1 bottle (21 ml)
6	KingFisher 96 deep-well plate	Empty colorless polypropylene 96 deep-well plate 2,200 µl	5 pcs
7	KingFisher 96 well plate (200 µl)	Empty colorless polypropylene 96-well plate 200 µl	1 pc
8	KingFisher 96 tip comb for deep-well magnets	Colorless polypropylene tip comb for DW magnets	1 pc

Table 3 – Components of NA-Extra reagent kit, , configuration 3

No.	Reagent	Description	Quantity, Volume
1	Plate 1 – Magnetic microbeads	Brown suspension	96-well plate, 100 µl of solution in each well
2	Plate 2 – Binding buffer	Transparent colorless liquid	96-well plate, 500 µl of solution in each well
3	Plate 3 – Washing solution No. 1	Transparent colorless liquid	96-well plate, 700 µl of solution in each well
4	Plates 4 and 5 – Washing solution No. 2	Transparent colorless liquid	two 96-well plates, 700 µl of solution in each well
5	Plate 6 – Eluent	Transparent colorless liquid	96- well plate, 200 µl of solution in each well
6	KingFisher 96 well plate (200 µl)	Empty colorless polypropylene 96-well plate 200 µl	1 pc
7	KingFisher 96 tip comb for deep-well magnets	Colorless polypropylene tip comb for DW magnets	1 pc

Reagent Composition

The binding buffer is ready for use and includes: guanidine thiocyanate; tris hydrochloride; triton X-100; urea; sodium dodecyl sulfate.

Magnetic microbeads are ready for use and include: solution of magnetic microbeads, deionized water.

Washing solution No. 1 is ready for use and includes: guanidine thiocyanate; tris hydrochloride; ethanol.

Washing solution No. 2 is ready for use and includes: tris hydrochloride; sodium chloride; ethanol.

Eluent is ready for use and includes: tris hydrochloride; EDTA.

KingFisher 96 well plate, 200 µl, included in the reagent kit design versions 2 and 3 (“NA-Extra-KF-u» and “NA-Extra-KF-r”) is ready for

use. It is a polypropylene 96-well 200 µl low plate (produced by A-Gen, China).

KingFisher 96 tip comb for deep-well magnets included in the reagent kit design versions 2 and 3 ("NA-Extra-KF-u» and "NA-Extra-KF-r") is ready for use. It is a colorless polypropylene comb of tips for DW magnets (produced by A-Gen, China).

KingFisher 96 deep-well plate included in the reagent kit in configuration2 ("NA-Extra-u») is ready for use. It is a colorless polypropylene 96-deep well plate, 2,200 µl (produced by A-Gen, China).

The extraction kit does not include calibrators or control materials.

The kit does not contain medicinal products for medical use, substances of human or animal origin.

Note: the product does not contain other ingredients that may affect the procedure.

4. Reagent Kit Characteristics

4.1 Technical and Functional Characteristics

Table 4 – Technical and Functional Characteristics of the kit «NA-Extra»

Parameter Name	Characteristics and Standards
1. Technical Characteristics	
1.1. Visual appearance	
1.1.1. Configuration 1: NA-Extra-M reagent kit for DNA/RNA manual extraction and extraction with the use of automated sample preparation stations	
Binding buffer	Transparent colorless liquid
Magnetic microbeads, MP	Brown suspension
Washing solution No. 1	Transparent colorless liquid
Washing solution No. 2	Transparent colorless liquid
Eluent	Transparent colorless liquid
1.1.2. Configuration 2: NA-Extra-KF-u reagent kit (not pipetted) for automated extraction with the use of KingFisher Flex Magnetic Particle Processor to purify nucleic acids, cells, and proteins.	
Binding buffer	Transparent colorless liquid
Magnetic microbeads, MP	Brown suspension
Washing solution No. 1	Transparent colorless liquid

Washing solution No. 2	Transparent colorless liquid
Eluent	Transparent colorless liquid
KingFisher 96 deep-well plate	Empty colorless polypropylene 96 deep-well plate 2,200 µl
KingFisher 96 well plate (200 µl)	Empty colorless polypropylene 96-well plate 200 µl
KingFisher 96 tip comb for deep-well magnets	Colorless polypropylene tip comb for DW magnets
1.1.3. Configuration 3: NA-Extra-KF-r (pipetted) for automated extraction with the use KingFisher Flex Magnetic Particle Processor to purify nucleic acids, cells, and proteins.	
Plate 1 – Magnetic microbeads	Brown suspension
Plate 2 – Binding buffer	Transparent colorless liquid
Plate 3 – Washing solution No. 1	Transparent colorless liquid
Plates 4 and 5 – Washing solution No. 2	Transparent colorless liquid
Plate 6 – Eluent	Transparent colorless liquid
KingFisher 96 well plate (200 µl)	Empty colorless polypropylene 96-well plate 200 µl
KingFisher 96 tip comb for deep-well magnets	Colorless polypropylene tip comb for DW magnets
1.2. Physical and chemical parameters	
Hydrogen ion concentration, pH	
Binding buffer	min 6,0 pH, max 8,0 pH
Washing solution No. 1	min 6,0 pH, max 8,0 pH
Washing solution No. 2	min 6,0 pH, max 8,0 pH
1.3. Completeness	Configuration 1: - NA-Extra reagent kit, configuration 1; - Quality certificate, - Instruction for use. Configuration 2: - NA-Extra reagent kit, configuration 2; - Quality certificate, - Instruction for use. Configuration 3: - NA-Extra reagent kit, configuration 3; Quality certificate,

	- Instruction for use.
1.4. Marking	Labelling in accordance with GOST R 51088-2013 (clause 6.2), GOST R ISO 18113-1-2015, GOST R ISO 18113-2-2015. Graphic design of the marking is made according to GOST R ISO 15223-1-2014. Labels made of adhesive paper according to GOST 7625-86.
1.5. Packaging	Configuration1: **Primary containers** – individual plastic bottles, 100 ml and 10 ml, plastic test tubes, 1.5 ml: Binding buffer – 100 ml bottle, Washing solution 1 – 100 ml bottle, Washing solution 2 – 100 ml bottle, Eluent – 10 ml bottle, Magnetic microbeads – 1.5 ml test tube. **Secondary packaging** – all kit components are packed in a plastic Zip-Lock bag (GOST R 50962), size of the bag – 17*22 cm. Test tube with magnetic microbeads additionally packed in a separate plastic Zip-Lock bag, size: 4*7 cm. Configuration2: **Primary containers –** individual plastic bottles, 100 ml and 10 ml, plastic test tube, 1.5 ml: Binding buffer – 100 ml bottle, Washing solution 1 – 100 ml bottle, Washing solution 2 – 100 ml bottle, Eluent – 100 ml bottle, Magnetic microbeads – 1.5 ml test tube. KingFisher deep well 96 plates (5 pcs) are placed in a Zip-Lock bag made of high pressure polyethylene (ac. to GOST 16337-77). KingFisher 96 plate (200 µl) and KingFisher 96 tip comb for deep-well magnets are placed in Zip-Lock plastic bags, 35 µm, size - 15*20,

	high pressure polyethylene (ac. to GOST 16337-77). **Secondary packaging** – all bottles and a test tube are placed in a plastic Zip-Lock bag (GOST R 50962), size: 17*22 cm. Test tube with magnetic microbeads additionally packed in a separate plastic Zip-Lock bag, size: 4*7 cm. KingFisher deep well 96 plates (5 pcs), KingFisher 96 plate (200 µl) (1 pc), KingFisher 96 tip comb for deep-well magnets (1 pc) are placed in a carton box, size: 350x135x95 mm (ac. to GOST 12301). Configuration3: **Primary containers** - KingFisher 96 deep-well plates, produced by A-Gen, China. Plates 1-6 with reagents are covered with 18 µm aluminum foil sheets, width - 12 cm (ac. to GOST 745-2014). Each three plates are placed in one sleeve made from synthetic film, 90µm, width 20 cm (ac.to GOST R 58061-2018) and hermetically sealed by air pumping. On the bottom and between the plates pads made of 2.5 mm thick corrugated cardboard are used (ac. to GOST R 52901-2007). KingFisher 96 well plate (200 µl) and KingFisher 96 tip comb for deep-well magnets are placed in Zip-Lock bags, 35 µm, size: 15*20 cm made from high pressure polyethylene (ac. to GOST 16337-77). **Secondary packaging** - a carton box, size: 350x135x95 mm (ac. to GOST 12301)
2. Performance Characteristics	
2.1 Purity of DNA/RNA isolation, A260/280, not less	1.7
2.2 No contamination	Negative result with a negative control sample in the control PCR
2.3 Efficiency of DNA / RNA extraction,%, not less	25

4.2 Clinical Effectiveness

According to the results of the conducted clinical trials, the effectiveness of the medical device when used in accordance with its intended purpose was confirmed by analyzing the new coronavirus SARS-CoV-2 infection by reverse transcription with samples of isolated DNA/RNA from 48 sputum samples, 48 samples of nasopharyngeal swabs and 48 samples of oropharyngeal swabs.

Using configuration1 of the reagent kit DNA/RNA was extracted in two ways provided by the manufacturer in the operational documentation: manually and using Tecan robotic sample preparation station Freedom EVO ®.

Using configuration 2 and configuration 3 of NA-Extra reagent kit DNA/RNA was extracted with the help of KingFisher Flex magnetic particle processor for the purification of nucleic acids, cells, and proteins.

Clinical and laboratory test data was statistically processed using Clopper-Pearson confidence interval. (Clopper-Pearson Confidence Interval; Clopper, C., & Pearson, E. (1934). The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomi-al. Biometrika, 26(4), 404-413. doi:10.2307/2331986).

The results of the study of diagnostic characteristics for all design versions of the medical device under study by samples of clinical material are shown in Table 5.

The lower fence of the confidence interval is determined by Clopper-Pearson method

Table 5 – Clinical Trial Results

Type of testing sample	Design version	DNA/RNA extraction method	Number of tests	Diagnostic characteristics	**CI** - 95% confidence interval
venous blood	Configuration 1	Manual	24	100%	100% (95% CI:96%-100%)
		Tecan robotic workstation Freedom EVO®	24	100%	100% (95% CI:96%-100%)

	Configuration 2	KingFisher Flex	28	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	28	100%	100% (95% CI:96%-100%)
venous blood plasma	Configuration 1	Manual	28	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	22	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	22	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	24	100%	100% (95% CI:96%-100%)
sputum	Configuration 1	Manual	24	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	24	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	36	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	36	100%	100% (95% CI:96%-100%)
nasopharyngeal swabs	Configuration 1	Manual	40	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	40	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	40	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	42	100%	100% (95% CI:96%-100%)
oropharyngeal swabs	Configuration 1	Manual	42	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	44	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	44	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	44	100%	100% (95% CI:96%-100%)
	Configuration 1	Manual	32	100%	100% (95% CI:96%-100%)

vaginal mucosa swabs		Tecan серии Freedom EVO®	32	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	32	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	32	100%	100% (95% CI:96%-100%)
cervical scraping	Configuration 1	Manual	32	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	22	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	22	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	24	100%	100% (95% CI:96%-100%)
urethral scraping	Configuration 1	Manual	24	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	24	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	18	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	18	100%	100% (95% CI:96%-100%)
urine cellular sediment	Configuration 1	Manual	20	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	20	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	20	100%	100% (95% CI:96%-100%)
	Configuration 3	KingFisher Flex	20	100%	100% (95% CI:96%-100%)
prostate secretion	Configuration 1	Manual	20	100%	100% (95% CI:96%-100%)
		Tecan серии Freedom EVO®	24	100%	100% (95% CI:96%-100%)
	Configuration 2	KingFisher Flex	24	100%	100% (95% CI:96%-100%)

	Configuration 3	KingFisher Flex	24	100%	100% (95% CI:96%-100%)

5. Risks Associated With the Use of NA-Extra Reagent Kit,

The border risk zone includes the following:

- loss of functional properties of reagents included in the kit due to transportation, storage or operation under inappropriate conditions,
- contaminants in DNA/RNA,
- DNA/RNA extraction from insufficient quantity of clinical material,
- failure to meet requirements for sample preparation, testing and disposal due to the fact that unqualified personnel work with the kit,
- use of an unsuitable kit (use after the expiration date or if the packaging is broken).

In the area of the unacceptable zone, no risks were identified.

Total residual risk of using a medical device NA-Extra reagent kit for DNA/RNA extraction from clinical material, , produced by TestGene, LLC is acceptable; the benefit of its use exceeds the risk.

6. Precautions When Working With the Kit

Potential risk Class – 3 in accordance with Nomenclature Classification of Medical Devices approved by the Order of the Ministry of Health of the Russian Federation dated June 6, 2012 No.4n.

The material should be considered as infected or suspected of being infected with *SARS-CoV-2* and handled in accordance with the requirements of sanitary and epidemiological rules for the safety when working with microorganisms in pathogenicity (hazard) groups 3 and 4[1] (Health Regulations 1.3.3118-13), Methodology Guidelines "Organization of Laboratory Work Using Methods of Nucleic Acid Amplification When Working With Material Containing Microorganisms of Pathogenicity Groups I-IV" (Methodology Guidelines 1.3.2569-09), temporary guidelines "Prevention, Diagnosis and Treatment of a Novel Coronavirus Infections *(2019-nCoV)*, Version 3 of 03.03.2020

[1] Temporary guidelines "Prevention, Diagnosis and Treatment of Novel Coronavirus Infection (COVID-19)", Version 4 (27.03.2020) (Ministry of Health of the Russian Federation).

(Approved by the Ministry of Health of the Russian Federation and Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor)), and Information letter from Rospotrebnadzor dated 21.01.2020 No. 02/706-2020-27 “Temporary Recommendations for Organization of Laboratory Diagnostics of a Novel Coronavirus Infection (*2019-nCoV*)”.

Personnel should ensure and comply with the rules of biological safety and requirements for organization of work and conduct it in order to prevent contamination of premises and equipment with nucleic acids and(or) amplicons of tested samples.

The work should be carried out in a laboratory that performs molecular biological (PCR) studies of clinical material in compliance with the Sanitary and Epidemiological Rules and Regulations SanPiN 2.1.7.2790-10 “Sanitary and Epidemiological Requirements for Medical Waste Handling”. Personnel should follow recommendations set out in Methodology Guidelines 287-113, Methodology Guidelines 1.3.2569-09.

When working it is required:

▪ testing samples should be considered as contagious and hazardous, the work and storage should be organized in accordance with Health Regulations 1.3.2322-08 “Safety of Work with Microorganisms of Pathogenicity (Hazard) Group III-IV and Parasites” or Health Regulations 1.3.3118-13 “Safety of Work with Microorganisms of Pathogenicity (Hazard) Groups I-II” depending on the type of the test;

▪ to remove and disinfect spilled samples or reagents, using disinfectants in accordance with Health Regulations 1.3.2322-08 “Safety of work with microorganisms of pathogenicity group III–IV (hazard) and parasites”;

▪ testing process in a laboratory should be unidirectional. The analysis is performed in separate rooms (zones). Work should start in the Extraction Zone and continue in the Amplification and Detection Zone. Do not return samples, equipment, or reagents to the area where the previous stage of the process is performed;

▪ unused reagents, expired reagents, and used reagents should be disposed in accordance with the requirements of SanPiN 2.1.7.2790-10 “Sanitary and Epidemiological Requirements for Medical Waste Handling”;

▪ use and change disposable tips for automatic dispensers with a filter after each operation. Disposable plastic dishes must be removed into a special container containing a disinfectant that can be used for decontamination of medical waste;

▪ table surfaces, as well as the rooms where PCR is performed, must be exposed to UV-radiation in accordance with accepted standards before and after the work is completed;

▪ ▪ use the kit strictly for its intended purpose, according to this instruction;

▪ only specially trained personnel is allowed to work with the kit;

▪ not to use the kit after the expiration date;

▪ not to use the reagent kit if the inteDNA/RNAl packaging is broken or the appearance of the reagent does not match the description;

▪ use disposable gloves, lab coats, and eye protection when handling samples and reagents. Wash hands thoroughly after work;

▪ all kit components are non-toxic to humans in the concentrations used. In case of contact with the skin or mucous membranes, the contact area must be washed with plenty of water.

It is not required to take precautions against influence of magnetic fields, exteDNA/RNAl electrical influence, electrostatic discharges, pressure or pressure drops, overload, or sources of thermal ignition.

The kit contains no substances of human or animal origin that have a potential infectious nature, so it is not required to take precautions against any special, unusual risks when using or selling the product.

7. Required Equipment and Materials

Equipment:

1. Sterile laminar box (e.g., BAVp-01-Laminar-S-1,2, Laminar Systems, Russia),
2. Thermostat for Eppendorf type test tubes from 25°C to 100 °C (e.g., “Thermo 24-15”, Biokom”, Russia),
3. Vortex (for example, «TETA-2», «Biokom», Russia),
4. Separate set of automatic variable volume dispensers (e.g., “Eppendorf”, Germany),
5. Refrigerator for +2°C to +8 °C,
6. Freezer for -2°C to -40 °C,

7. Magnetic Particle Processor KingFisher Flex, (Thermo Fisher Scientific, Finland) used with NA-Extra-KF-u and with NA-Extra-KF-r reagent kits for purification of nucleic acids, cells and proteins,
8. It is possible to use robotic sample preparation station Tecan Freedom EVO® when working with NA-Extra-M reagent kit (TECAN, Switzerland, Austria),
9. When NA-Extra-KF-u reagent kit is used it is possible to use multi-channel automated pipettes of variable volume (e.g., Eppendorf, Germany) or robotic sample preparation station Tecan Freedom EVO® (TECAN, Switzerland, Austria) for dispensing reagents to KingFisher Flex plates,
10. With NA-Extra-KF-u kit 100 ml solution basins (e.g. Biolongix, China) can be used for adding reagents in plates for KingFisher Flex

Additionally it can be used:

11. Aspirator with trap flask (e.g., "FTA-1", Biosan, Latvia).

Materials and Reagents not Included in the kit:

1. Ethyl alcohol (95%),
2. Disposable polypropylene screw-cap or leak-tight when closed micro-tubes, 1.5 mL, DNA/DNA/RNA and DNase/DNA/RNAse free (e.g., Axygen, USA),
3. Disposable polypropylene screw-cap or leak-tight when closed micro-tubes, 15 mL, DNA/DNA/RNA and DNase/DNA/RNAse free (e.g., Axygen, USA),
4. 15 mL and 1.5 mL test tube racks (e.g., InterLabService, Russia) and pipette tips (e.g., Axygen, USA),
5. Magnetic stand for 1.5.mL – 2 mL Eppendorf type test tubes,
6. Disposable pipette tips for variable 100 µL, 1,000 µL, and 5 µL volume dispensers with an aerosol barrier, DNA/DNA/RNA and DNase/DNA/RNAse free (e.g., Axygen, USA),
7. Disposable pipette tips for variable 100 µl, 1,000 µl volume dispensers, DNA/DNA/RNA and DNase/DNA/RNAase free (e.g., Axygen, USA),
8. Isolation or disposable gown coat and disposable gloves
9. Container with disinfectant.

Additionally it can be used:

10. STOR-EX reagent kit for DNA/RNA stabilization in bioassays according to TU 9398-099-46482062-2017 produced by DNA-Technology TS, LLC (Registration certificate No. RZN 2018/7775 of 08.11.2018) or similar designed for biomaterial preservation, transportation and DNA/RNA stabilization at the same time.
11. Sterile saline solution (0,9% NaCl) (e.g., NPP "PanEco", Russia),
12. Deionized sterile water, free from DNase/DNA/RNAse (e.g., LifeTechnologies, USA).

When DNA/RNA is extracted from sputum:

13. 10% solution of trisodium phosphate,
14. 1M of HCl solution,
15. 5% chloramine solution,
16. Mucolysin.

Use of other materials and reagents that are not part of the product is not provided.

Measuring equipment is not required when using the kit.

8. Test Samples

Before the work, it is required to study Guidelines "Sampling, Transportation and Storage of Clinical Material for PCR-Diagnostics", developed by the Federal State Budgetary Institution of Science Central Research Institute of Epidemiology of Federal service for surveillance on consumers' rights protection and human well-being (Rospotrebnadzor), Moscow, 2012.

Conditions for transportation and storage of source clinical material.

Table 6 – Biological material storage and transporting conditions

Sample type	**Material collection requirements**	**Transportation and storage conditions**
Sputum	Collect at least 1.0 ml sputum into a disposable graduated screw-cap wide neck sterile bottle with at least 50 ml volume	- 6 hours at room temperature; - 3 days at 2-8 °C; - 1 week at - 20 °C; - long time at - 70 °C. Only single freeze-thawing of the material is allowed.

		Preliminary processing of samples is required.
Nasopharyngeal specimens	Smear (mucus) is collected with dry sterile cotton swabs with plastic shafts. Gently insert a swab through the nostril along its outer wall to a depth of 2-3 cm to the inferior nasal concha. Then slightly lower it down, insert into the lower nasal passage under the lower nasal concha, rotate the swab and remove it along the outer wall of the nostril. After that a swab with collected specimen on a soft end is placed into a disposable sterile test tube with viral transport medium (or 500ml of sterile saline solution), then a plastic shaft is carefully snap off at a distance of 0.5 cm from the soft ens. The specimen is left in a transport medium. The cap is placed on the tube and screwed down tightly.	6 hours at room temperature; - 3 days at 2-8 °C; - 1 month at - 20 °C; - long time at - 70 °C. Only single freeze-thawing of the material is allowed
Oropharyngeal specimens	Smear is collected with dry sterile cotton swabs with plastic shafts. Rotate and rub the swab on tonsils, faucial pillars, and on the back of the throat. After that a swab with collected specimen on a soft end is placed into a disposable sterile test tube with viral transport medium (or 500ml of sterile saline solution), then a plastic shaft is carefully snap off at a distance of 0.5 cm from the soft ens. The specimen is left in a transport medium. The cap is placed on the tube and screwed down tightly.	6 hours at room temperature; - 3 days at 2-8 °C; - 1 month at - 20 °C; - long time at - 70 °C. Only single freeze-thawing of the material is allowed

To increase the shelf life of the test material for subsequent DNA/RNA isolation, it is recommended to use a reagent kit for DNA/RNA stabilization in bioassays STOR-EX according to TS 9398-

099-46482062-2017 produced by “DNA-Technology TS”, LLC (Registration Certificate No. RZN 2018/7775 of 08.11.2018) or similar, designed for storage and transportation of biomaterial with simultaneous DNA/RNA stabilization. Samples with a reagent for DNA/RNA stabilization can be stored for 48 hours at a temperature of +18...+25°C and for 7 days at a temperature of +2...+8°C. Repeated freezing or thawing of samples during storage should be avoided. Stabilization reagent is not recommended for DNA/RNA preserving in whole blood, plasma, or serum, since these fluids contain high concentration of proteins.

Preparation of Clinical Material for Nucleic Acids Extraction

1. Nasopharyngeal and oropharyngeal specimens

1.1. Centrifuge the test tube containing the test material during 10 minutes at 13,000 g.

2.2. Remove the supeDNA/RNAtant, leaving approximately 100 µl in the test tube (sediment + liquid fraction).

2. Sputum

Method 1

2.1. Transfer approximately 500 µl of the sample to a sterile container and close the lid tightly.

2.2. Add an equal volume of 10% solution of trisodium phosphate to the sample, shake intensely.

2.3. Incubate the solution during 18-24 hours at 37°C, then add 1M HCl to neutralize it to pH 6.8-7.4.

2.4. Centrifuge during 20 minutes at 1,000 g.

2.5. Remove supeDNA/RNAtant to 5% chloramine solution for disinfection.

2.6. Add 500 ml of distilled water to the sediment, mix by pipetting and transfer to a 1.5 ml plastic test tube.

2.7. Centrifuge the test tube during 10 minutes at 13,000 g.

2.8. Remove the supeDNA/RNAtant, leaving approximately 100 µl (sediment + liquid fraction) in the test tube. The obtained material is ready for the nucleic acids extraction.

Method 2

Add mucolysin to a container with sputum sample in ratio 5:1 (5 parts of mucolysin to 1 part of sputum), follow to container calibration. Tighten the container lid, shake the contents and incubate for 20-30 minutes at room temperature (18-25 ° C), shaking the container every 2-3 minutes. The resulting material is ready for isolation of nucleic acid. The processed sample can be stored in a container for a day at a temperature of +2 ... +8°C or for a long time at a temperature not higher than minus 16 °C (if DNA/RNA re-isolation is required).

Interfering substances

The effect of potentially interfering substances on the function of NA-Extra reagent kit was tested for potentially interfering substances that may occur during clinical material sampling and during DNA/RNA isolation from clinical material.

PCR inhibitors that may occur during DNA/RNA extraction from clinical material are the following: sodium dodecyl sulfate and urea (included in the binding buffer), ethanol (included in washing solution No. 1 and washing solution No. 2), which may be contained in eluate with DNA/RNA as a result of their incomplete removal during DNA/RNA extraction

Maximum concentrations of interfering substances that can occur during DNA/RNA extraction from clinical material and that do not affect amplification of the laboratory control sample are: sodium dodecyl sulfate - 0.007 mcg/ml, urea - 20 mM/ml, ethanol - 5 mcl/ml.

Potentially interfering substances (Table 7) that can occur during collecting clinical materials are:

Table 7 - Interfering substances and their concentrations that inhibit PCR

Interfering substances	Maximum concentration
Endogenous interfering substances and anticoagulants	
Haemoglobin	1 mg/ml
Mucin	5%
Biotin	100 mcg/ml
Bilirubin	> 342 mcM
Exogenous interference substances	

Anti-inflammatory drugs	
Acetaminophen	200 mcM
Acetylsalicylic acid	3,7 mM
Ibuprofen	2,5 mM
Antibiotics	
Erythromycin	81,6 mcM
Ciprofloxacin	31 mcM
Tobramycin	5 mcg/ml
Nasal spray and drops	
Neosynephrine (Phenylephrine)	10%
Afrin (Oxymetazoline)	10%
Saline nasal spray	10%
Drugs administrated orally	
Ambrobene (ambroxol hydrochloride)	0,003 mg/ml
Bromhexine (bromhexine)	0,016 mg/ml
Kaletra (lopinavir, ritonavir)	0,02 mg/ml
Interferon (interferon alfa)	0,2 U/ml
Theraflu (paracetamol, pheniramine, phenylephrine)	0,071 mg/ml

Based on the results of the study, potentially interfering substances encountered during DNA/RNA isolation from clinical material, evaluated at concentrations that are expected to occur with normal use of NA-Extra reagent kit are removed during DNA/RNA isolation using NA-Extra kit and do not have an interfering effect.

To reduce the number of PCR inhibitors, it is necessary to observe the rules for collecting biological material.

Restrictions on the use of the tested material:

- after completion of DNA/RNA extraction the subsequent analysis should be immediately started;
- testing material is not subject to use in case of violation of storage and transportation conditions (temperature, duration, repeated freezing and thawing);
- use of samples contaminated with foreign biological material is not allowed.

9. Preparation of the Components for Testing

It is not required to install, assemble, adjust, or calibrate a medical device before operation

When using Configuration 1 for manual extraction:

1) Separation of layers or sedimentation do not affect the quality of solutions. If in one of the bottles separation of the components or sedimentation is observed, it is required to warm it at 70°C and mix thoroughly until the sediment is completely dissolved and homogenous solution is obtained.

2) Before operation and before each manipulation with magnetic microbeads solution, it should be completely re-suspended via vortex or pipetting, since the suspension of magnetic microbeads is two-phase, it easily and quickly forms two clearly separated phases.

3) All components of the kit must be thoroughly mixed before the operation.

4) With a large number of tested samples, it is allowed to transfer all magnetic microbeads (960 µl) from the test tube to a bottle with binding buffer before operation starts. This mixture can be stored for 7 days. The prepared suspension of magnetic microbeads should be thoroughly mixed in the binding buffer before each use.

When using configuration 1 with robotic sample preparation station Tecan of Freedom EVO®:

1) Separation of layers or sedimentation do not affect the quality of solutions. If in the plate wells separation of the components or sedimentation is observed, it is necessary to warm it at 70°C and mix until the sediment is completely dissolved and homogenous solution is obtained.

2) All components of the kit must be thoroughly mixed before the work.

3) Transfer all magnetic microbeads (960 µl) from the test tube to a bottle with binding buffer. This mixture can be stored for 7 days. The prepared suspension of magnetic microbeads should be thoroughly mixed in the binding buffer before each use.

4) Prepare Tecan robotic sample preparation station of Freedom EVO® series in accordance with instruction for its use.

5) Transfer prepared solutions from the bottles into the cuvettes and load them into the station in the order described in the station operation protocol.

6) Load to the station special tips, test tubes for DNA/RNA extraction and test tubes for extracted DNA/RNA in the order described in the station operation protocol.

When using Configuration 1 of the reagent kit together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1) Separation of layers or sedimentation do not affect the quality of solutions. If in the plate wells separation of the components or sedimentation is observed, it is necessary to warm it at 70°C and mix until the sediment is completely dissolved and homogenous solution is obtained.

2) Transfer all magnetic microbeads (960 µl) from the test tube to a bottle with binding buffer. This mixture can be stored for 7 days. The prepared suspension of magnetic microbeads should be thoroughly mixed in the binding buffer before each use.

3) Label plates 2,200 µl for KingFisher 96 and add reagents according to the order given in Table 8:

Table 8 – Order for adding reagents in plates when NA-Extra-M configuration is used together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins

Plate No	Added component	Volume added to each plate well
Plate 1	Mixture of magnetic microbeads and binding buffer	510 µl
Plate 2	Washing solution No. 1	700 µl
Plate 3	Washing solution No. 2	700 µl
Plate 4	Washing solution No. 2	700 µl
Plate 5	Eluent	200 µl

A single-channel or multi-channel automatic dispenser of variable volume can be used for adding of reagents. Reagents can also be added

using an automatic sample preparation station (for example, Tecan of Freedom EVO® series). Attention: each reagent is added with a separate tip, it is not allowed to get the remains of one reagent into the other.

4) Prepare the equipment in accordance with the Instruction for Use.

5) Upload protocol from KingFisher Flex - NA-Extra-KF-u file (file is enclosed), in accordance with the procedure given below:

- lysis (Plate 1): duration - 5 minutes, heating - fast, temperature - 80°C, mixing, repeat in 2 and 4 minutes;

- extraction (Plate 1): duration – 10 minutes, temperature – 25 ºC, mixing, repeat during the 2-4-6-8 minutes, collecting magnetic microbeads – 15 seconds

- washing 1 (Plate 2): duration - 120 seconds, temperature – 25 ºC, mixing, collecting magnetic microbeads – 10 seconds

- washing 2 (Plate 3): duration - 120 seconds, temperature – 25 ºC, mixing, collecting magnetic microbeads – 10 seconds

- washing 3 (Plate 4): duration - 120 seconds, temperature – 25 ºC, mixing, collecting magnetic microbeads – 10 seconds

- elution (Plate 5): duration – 10 minutes, temperature – 80 ºC, mixing – slow, repeat in 2-4-6-8 minutes, collecting magnetic microbeads – 10 seconds.

When using Configuration 2 of the reagent kit together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1) Separation of layers or sedimentation do not affect the quality of solutions. If in the plate wells separation of the components or sedimentation is observed, it is necessary to warm it at 70°C and mix until the sediment is completely dissolved and homogenous solution is obtained.

2) Transfer all magnetic microbeads (960 µl) from the test tube to a bottle with binding buffer. This mixture can be stored for 7 days. The prepared suspension of magnetic microbeads should be thoroughly mixed in the binding buffer before each use.

3) Label plates 2,200 µl for KingFisher 96 and add reagents according to the order given in Table 9:

Table 9 – Order for adding reagents in plates when NA-Extra-KF-u (not pipetted) configuration is used together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins

Plate No	Added component	Volume added to each plate well
Plate 1	Mixture of magnetic microbeads and binding buffer	510 μl
Plate 2	Washing solution No. 1	700 μl
Plate 3	Washing solution No. 2	700 μl
Plate 4	Washing solution No. 2	700 μl
Plate 5	Eluent	200 μl

A single-channel or multi-channel automatic dispenser of variable volume can be used for adding of reagents. Reagents can also be added using an automatic sample preparation station (for example, Tecan of Freedom EVO® series). Attention: each reagent is added with a separate tip, it is not allowed to get the remains of one reagent into the other.

4) Prepare the equipment in accordance with the Instruction for Use.

5) Upload protocol from KingFisher Flex - NA-Extra-KF-u file (file is enclosed), in accordance with the procedure given below:

- lysis (Plate 1): duration - 5 minutes, heating - fast, temperature - 80°C, mixing, repeat in 2 and 4 minutes;

- extraction (Plate 1): duration – 10 minutes, temperature – 25 °C, mixing, repeat during the 2-4-6-8 minutes, collecting magnetic microbeads – 15 seconds

- washing 1 (Plate 2): duration - 120 seconds, temperature – 25 °C, mixing, collecting magnetic microbeads – 10 seconds

- washing 2 (Plate 3): duration - 120 seconds, temperature – 25 °C, mixing, collecting magnetic microbeads – 10 seconds

- washing 3 (Plate 4): duration - 120 seconds, temperature – 25 °C, mixing, collecting magnetic microbeads – 10 seconds

- elution (Plate 5): duration – 10 minutes, temperature – 80 °C, mixing – slow, repeat in 2-4-6-8 minutes, collecting magnetic microbeads – 10 seconds.

When using Configuration 3 of the reagent kit together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1) Separation of layers or sedimentation do not affect the quality of solutions. If in the plate wells separation of the components or sedimentation is observed, it is necessary to warm it at 70°C and mix until the sediment is completely dissolved and homogenous solution is obtained.

2) Prepare the equipment following the Instruction for Use.

3) Upload protocol from KingFisher Flex - NA-Extra-KF-r file (file is enclosed), in accordance with the procedure given below:

- lysis (Plate 2): duration - 5 minutes, heating - fast, temperature - 80°C, mixing, repeat after 2 and 4 minutes;

- collect MPs and transfer from plate 1 to plate 2: collecting magnetic microbeads 60 seconds, speed – slow, temperature - 25° C,

- extraction (Plate 2): duration – 10 minutes, temperature – 25° C, mixing, repeat during the 2-4-6-8 minutes, collecting magnetic microbeads – 15 seconds

- washing 1 (Plate 3): duration - 120 seconds, temperature – 25° C, mixing, collecting magnetic microbeads – 10 seconds

- washing 2 (Plate 4): duration - 120 seconds, temperature – 25° C, mixing, collecting magnetic microbeads – 10 seconds

- washing 3 (Plate 5): duration - 120 seconds, temperature – 25° C, mixing, collecting magnetic microbeads – 10 seconds

- elution (Plate 6): duration – 10 minutes, temperature – 80 °C, mixing – slow, repeat in 2-4-6-8 minutes, collecting magnetic microbeads – 10 seconds.

10. Testing Procedure

Only specially trained personnel with PCR analysis skills are allowed to work with the kit.

DNA/RNA extraction with the use of NA-Extra reagent kit configuration 1 for manual extraction.

Prepare and label one 1.5-2 ml test tube for each test sample.

1. Add 500 µl of binding buffer to each test tube and 10 µl of magnetic particle solution. In case of pre-mixing of magnetic microbeads with binding buffer, add 510 µl of mixture to each test tube.

2. Add 100 µl of sample to each tube, vortex for 3-5 seconds.

3. For lysis incubate the test tubes during 5 min at 70°C, mix solution 1-2 times during incubation using vortex.

4. After the lysis place the test tubes in a test tube rack and incubate the mixture for DNA/RNA binding during 10 min at room temperature stirring the solution during incubation 2-3 times upturning the test tubes.

5. Place the test tube in a magnetic stand, wait until the microbeads are completely collected on the tube wall (usually it takes 1-2 minutes) and remove the supeDNA/RNAtant using a dispenser or aspirator.

6. Add 700 µl of washing solution No. 1 to each test tube, close the lids tightly, re-suspend the magnetic microbeads using vortex, and remove the drops by short centrifugation.

7. Place the test tubes in a magnetic stand, wait until the microbeads are completely collected on the tube walls, and remove supeDNA/RNAtant.

8. Add 700 µl of washing solution No. 2 to each test tube, close the lids tightly, re-suspend the magnetic microbeads using vortex, and remove the drops by short centrifugation.

9. Place the test tubes in a magnetic stand, wait until the microbeads are completely collected on the tube walls, and remove the supeDNA/RNAtant.

10. Repeat 9 and 10.

11. Place the tubes with open lids in the thermostat and incubate at 70°C for 5 minutes to dry the magnetic microbeads and remove the residual ethyl alcohol.

12. Add 50 µl of eluent to each test tube using a separate tip with a filter. Carefully re-suspend the magnetic microbeads by pipetting, close the lids tightly.

13. Incubate the test tubes at 70°C for 10 minutes. During incubation mix the contents of the test tube 2-3 times carefully shaking the sediment.

14. Place the test tubes in a magnetic stand and wait until the microbeads are completely collected on the tube walls.

15. Transfer supeDNA/RNAtant containing extracted DNA/RNA to new test tubes. ATTENTION! Do not remove the test-tubes from the magnetic stand before the purified DNA/RNA is collected.

It is recommended to use DNA/RNA immediately for performing a reverse transcription reaction.

DNA/RNA extraction with the use of NA-Extra reagent kit configuration 1 together with robotic work station Tecan of Freedom EVO® for sample preparation:

1. In the software of TECAN station Freedom EVO®, download the appropriate protocol for extraction while working with NA-Extra reagent kit, configuration 1.
2. Start the station.
3. After DNA/RNA extraction is completed, collect the test tubes with the isolated DNA/RNA from the station.
4. It is recommended to use DNA/RNA immediately for performing a reverse transcription reaction.
5. Remove the used consumables from the station, clean up following the instruction.

DNA/RNA extraction with the use of NA-Extra reagent kit configuration 1 together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1. Add 100 μl of tested clinical material sample to each well of plate 1, mix by pipetting.
2. Place the plates according to the device's instruction and start DNA/RNA extraction using loaded operation protocol for magnetic particle processor KingFisher Flex for nucleic acids, cells and proteins purification.
3. When the operation of the device is completed, wells of panel 5 contain the supeDNA/RNAtant with extracted DNA/RNA.

DNA/RNA extraction with the use of NA-Extra reagent kit configuration 2 together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1. Add 100 μl of tested clinical material sample to each well of plate 1, mix by pipetting.

2. Place the plates according to the device's instruction and start DNA/RNA extraction using loaded operation protocol for magnetic particle processor KingFisher Flex for nucleic acids, cells and proteins purification.
3. When the operation of the device is completed, wells of panel 5 contain the supeDNA/RNAtant with extracted DNA/RNA.

DNA/RNA extraction with the use of NA-Extra reagent kit configuration 3 together with Magnetic Particle Processor KingFisher Flex for purification of nucleic acids, cells and proteins:

1. Add 100 μl of tested clinical material sample to each well of plate 2, mix by pipetting.
2. Place the plates according to the device's instruction and start DNA/RNA extraction using loaded operation protocol for magnetic particle processor KingFisher Flex for nucleic acids, cells and proteins purification.
3. When the operation of the device is completed wells of panel 6 contain the supeDNA/RNAtant with extracted DNA/RNA.

11. Possible Problems and Solutions

1. Low yield of DNA/RNA, cause and possible solution:

▪ state of the sample (the sample contains an insufficient quantity of DNA/RNA; the sample was long preserved, or improperly stored, or repeatedly frozen and thawed) – possible solutions: take more of the source material or perform elution in a smaller amount of the buffer; repeat collection of the material;

▪ insufficient drying of the microbeads before adding the eluent - increase the drying time after removing washing solution No.2;

▪ incomplete lysis - after adding lysing solution, suspend the sample as thoroughly as possible;

▪ large amount of buffer for elution - select the optimal buffer size to obtain the desired DNA/RNA concentration.

2. Protein contamination – it is necessary to achieve the most thorough suspension of magnetic microbeads.

3. Possible degradation of DNA/RNA, cause and possible solution: an old sample, or the sample was frozen and thawed – it

is necessary to collect the material again. Avoid freezing the sample during transport and storage. Extracted DNA/RNA sample should not be stored, because DNA/RNAses that cause DNA/RNA degradation are diverse, extremely active, present everywhere, and their inactivation is very time-consuming. To prevent DNA/RNA degradation it is required to use DNA/RNAse decontamination material to treat work surfaces of laboratory equipment and PCR consumables. Working surfaces and rooms where DNA/RNA extraction is performed, should be exposed to radiation of bactericidal lamps for 1 hour before and after the work.

12. Storage, Transportation and Usage Conditions

Storage. The reagent kit should be stored at temperatures from +2°C to +30°C and relative humidity up to 90%. Atmospheric pressure is not controlled, because it does not affect the quality of the product.

A reagent kit stored in violation of storage conditions cannot be used.

Expiration date of opened kit components for configuration 1 and 2 is 12 months from the date of acceptance by the manufacturer's Quality Control Department, provided that the kit is stored at temperatures from +2°C to +30°C.

The reagent kit in configuration 3 extraction is designed for one-time application and offers DNA/RNA extraction from 96 samples simultaneously during one run using KingFisher Flex Magnetic Particle Processor.

A reagent kit stored in violation of storage conditions cannot be used.

Transporting. NA-Extra reagent kit, can be transported by all types of covered vehicles in accordance with the transport rules applicable to this type of transport. It is allowed to transport the kit at temperatures from +2°C to +30°C, and relative humidity up to 90%. Atmospheric pressure is not controlled, because it does not affect the quality of the product.

A reagent kit transported in violation of temperature conditions cannot be used.

Shelf Life. Shelf-life for NA-Extra reagent kit, is 12 months from the date of acceptance by the manufacturer's Quality Control Department, provided that all conditions of transportation, storage and operation are observed. A reagent kit with expired shelf life cannot be used.

13. Disposal

Reagent kits that have become unusable, including shelf life expiration, are subject to disposal in accordance with SanPiN 2.1.7.2790-10 requirements “Sanitary and Epidemiological Requirements for Medical Waste Handling”.

According to medical waste classification, the kits belong to Class A (epidemiologically safe waste close in composition to solid household waste). Unused reagents in accordance with paragraph 4.28 of SanPiN 2.1.7.2790-10 “Sanitary and Epidemiological Requirements for Medical Waste Handling” are collected in a single-use labeled packaging of any color (except yellow and red).

Test tubes and materials after the use are disposed in accordance with Methodology Guidelines 287-113 (Methodology Guidelines for Disinfection, Pre-Sterilization Cleaning and Sterilization of Medical Devices).

Liquid components (reagents) are disposed by draining into a sewer with preliminary dilution of a reagent with tap water 1: 100 and removing the remains of packages as industrial or household garbage.

Consumer packaging of NA-Extra reagent kit, is subject to mechanical destruction with the removal of residues as industrial or household garbage.

Personnel disposing reagent kits must comply with the safety rules for conducting a particular method of disposal.

14. Warranty Obligations, Contacts

The manufacturer guarantees that NA-Extra reagent kit, meets quality and safety requirements during its shelf-life until its expiration date subject to compliance with established requirements for transportation, storage and use.

In case of complaints about the reagent kit quality, undesirable events or incidents, submit information to:

Limited Liability Company “TestGene”
(TestGene, LLC),
9 44th Inzhenerny Proezd, office 13, Ulyanovsk 432072
Tel.: +7 (499) 705-03-75
www.testgen.ru

Technical Support Service:
Tel.: +7 927 981 58 81
E-mail: help@testgen.ru

Instruction for Use complies with the requirements of Order of Ministry of Health of Russia dated 09.01.2014 No. 2n, Order of Ministry of Health of Russia dated 19.01.2017 No. 11n, State Standard GOST 51088-2013.