MAGNO-sorb nucleic acid extraction kit

CE

IVD

For Professional Use Only

Instruction Manual

KEY TO SYMBOLS USED

REF	Catalogue number	Σ	Contains sufficient for <n> tests
LOT	Batch code		Use-by Date
IVD	*In vitro* diagnostic medical device		Consult instructions for use
VER	Version	C–	Negative Control of extraction
	Temperature limit	PCE	Positive Control of extraction
	Manufacturer	IC	Internal Control
	Date of manufacture		GHS02: Flame
EC REP	Authorized representative in the European Community		GHS05: Corrosion
	Caution		GHS07: Exclamation mark

1. INTENDED USE

MAGNO-sorb nucleic acid extraction kit is intended for extraction of DNA/RNA from the biological material and environmental objects for subsequent testing by the nucleic acid amplification techniques (NAT):

- blood plasma,
- whole blood,
- cerebrospinal fluid (liquor),
- discharge of the conjunctiva,
- saliva,
- nasopharyngeal and oropharyngeal swabs,
- sputum / pharyngeal aspirate,
- bronchoalveolar lavage fluid / bronchial washings,
- pleural / ascitic fluid,
- pus / necrotic content,
- tissue (biopsy, surgical, autopsy) native material,
- paraffin-embedded tissue (biopsy, surgical, autopsy) material,
- urogenital mucous discharge (swab, scrape),
- urine,
- feces,
- fecal / rectal swab (scrape),
- tick suspension,
- cultures of microorganisms,
- water sample concentrates,
- washes from environmental objects.

Indications and contra-indications for use of the reagent kit
DNA/RNA extraction is used in preanalytical stage of in vitro diagnostics by NAT.

2. PRINCIPLE OF NUCLEIC ACID EXTRACTION

A test sample is treated by the lysis solution in the presence of the magnetic silica particles (magnetic sorbent). As a result the cell membranes, viral envelopes and other biopolymer complexes are destructed and the nucleic acids are released. The dissolved nucleic acids bind to the sorbent particles while other components of the lysed biological material stay in the solution and are removed by sorbent precipitation at magnetic rack and subsequent washings. The nucleic acids are transferred from the sorbent surface to the solution after adding the buffer for elution to the magnetic sorbent. Then the solution is separated from the sorbent by magnetic force.
The obtained nucleic acid sample is highly purified and free from inhibitors of amplification, which provides high analytical sensitivity of NAT assay.

3. CONTENT

MAGNO-sorb nucleic acid extraction kit is produced in 4 forms:
variant 100-200, REF K2-16-200-CE, REF K3-1061-100-CE,
variant 100-1000, REF K2-16-1000-CE, REF K3-1062-100-CE,
variant 100-100M, REF K3-1063-100-CE,
variant 100-200M, REF K3-1064-100-CE.

Variant 100-200 or 100-1000 includes:

Reagent	Description	variant 100-200		variant 100-1000	
		Volume, ml	Quantity	Volume, ml	Quantity
Lysis Solution MAGNO-sorb	clear liquid from colorless to yellow or pink colour [1]	107	1 vial	90	3 vials
Component A	colorless clear liquid	1.0	1 tube	-	-
Component A-2	colorless clear liquid	-	-	1.0	2 tubes
Washing Solution 5	clear liquid from colorless to yellow or pink colour[1]	75	2 vials	75	2 vials
Washing Solution 6	colorless clear liquid	87	1 vial	87	1 vial
Washing Solution 7	colorless clear liquid[2]	35	1 vial	35	1 vial
Magnetized silica	suspension of magnetic particles	1.0	2 tubes	1.5	2 tubes
Buffer for elution	colorless clear liquid	1.25	8 tubes	1.25	8 tubes

Variant 100-200 is intended for DNA/RNA extraction from 100 samples (including controls). The volume of test material is 200 µl.
Variant 100-1000 is intended for DNA/RNA extraction from 100 samples (including controls). The volume of test material is 1,000 µl.

Variant 100-100M or 100-200M includes:

Reagent	Description	variant 100-100M		variant 100-200M	
		Volume, ml	Quantity	Volume, ml	Quantity
Lysis Solution MAGNO-sorb	clear liquid from colorless to yellow or pink colour[1]	40	1 vial	70	1 vial
Component A	colorless clear liquid	0.5	1 tube	1.0	1 tube
Washing Solution 5	clear liquid from colorless to yellow or pink colour[1]	60	1 vial	60	1 vial
Washing Solution 4	colorless clear liquid	60	1 vial	60	1 vial
Magnetized silica	suspension of magnetic particles	1.0	1 tube	1.0	2 tubes
Buffer for elution	colorless clear liquid	1.25	8 tubes	1.25	8 tubes

Variant 100-100M is intended for DNA/RNA extraction from 100 samples (including controls). The volume of test material is 100 µl.
Variant 100-200M is intended for DNA/RNA extraction from 100 samples (including controls). The volume of test material is 200 µl.

4. ADDITIONAL REQUIREMENTS

- 1.5-ml disposable polypropylene screwed or tightly closed tubes.
- 5-ml disposable polypropylene or polystyrene round-bottomed tubes, 12 mm diameter - when using **variant 100-1000**.
- 5-ml disposable polypropylene or polystyrene tubes, 12 mm diameter - when using **variant 100-1000.**
- Sterile DNase- and RNase-free pipette tips without filter (up to 200, 1,000, and 5,000 µl).
- Sterile DNase- and RNase-free pipette filter tips (from 200 to 1,000 µl).
- Tube racks.
- Magnetic racks for 1.5-ml tubes.
- Magnetic racks for 5-ml tubes (12 mm diameter) - when using **variant 100-1000.**
- Disposable powder-free gloves and a laboratory coat.
- Pipettes (adjustable).
- Vortex mixer.
- Desktop microcentrifuge.
- PCR box or biological cabinet.
- Thermostat for 1.5-ml tubes with capable of incubating at 25-100 °C.
- Thermostat for 5-ml tubes (12 mm diameter) with capable of incubating at 25-100 °C - when using **variant 100-1000.**
- Vacuum aspirator with flask for removing supernatant.
- Refrigerator at the temperature from 2 to 8 °C.
- Reservoir for used tips.

In case of using automated stations for nucleic acid extraction:

- Open automated DNA extraction systems with magnetic stirring (for example, Auto-Pure 96 (Hangzhou Allsheng Instruments Co., Ltd., China), KingFisher Flex (Thermo FS (Termo Fisher Scientific), Finland)).
- Open automated DNA extraction pipetting systems (for example, NEON 100 (Xiril AG, Switzerland), MicroLab STARlet (Hamilton Bonaduz AG, Switzerland)).
- Set of consumables for used automated system according to the manufacturer's recommendations including consumables for stations with magnetic stirring:
  - 96-tip comb – when using **variant 100-200, variant 100-100M, variant 100-200M** or 24-tip comb – when using **variant 100-1000**;
  - 96-deepwell plate – when using **variant 100-200, variant 100-100M, variant 100-200M** or 24-deepwell plate – when using **variant 100-1000**;
  - 96-elution plate – when using **variant 100-200, variant 100-100M, variant 100-200M**;
  - sterile self-adhesive film for plates.
- 1.5-5 ml disposable polypropylene or polysterol tubes with caps – to prepare the required volume of a mixture of Magnetized silica.
- Sterile pipette filter tips (up to 100 µl).
- Sterile pipette filter tips (up to 1,000 and 5,000 µl).
- Single-channel pipettes (adjustable).
- 8-channel pipettes.
- Reservoirs (baths) for filling 8-channel dispensers.

[1] If **Lysis Solution MAGNO-sorb** and **Washing Solution 5** are stored below 20 °C, crystalline precipitate may form.

[2] An empty vial is provided. Before the work with nucleic acid extraction kit, add 35 ml of acetone (mass fraction of acetone should be no less than 99.7 %) into the vial. Work in a fume hood.
WARNING! In order to prevent acetone evaporation the vial cap should be tightly closed.

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile DNase- and RNase-free pipette filter tips and use new tip for every procedure.
- Use disposable protective gloves and laboratory cloths, and protect eyes while samples and reagents handling. Thoroughly wash hands afterwards.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
- Do not use the kit if the internal packaging was damaged or its appearance was changed.
- Do not use the kit if the transportation and storage conditions according to the Instruction Manual were not observed.
- Do not use a kit after its expiration date.
- Dispose of all specimens and unused reagents in accordance with local regulations.
- Samples should be considered potentially infectious and handled in a biological cabinet in compliance with appropriate biosafety practices.
- Clean and disinfect all sample or reagent spills using a disinfectant, such as 0.5% sodium hypochlorite, or another suitable disinfectant.
- Avoid samples and reagents contact with the skin, eyes, and mucous membranes. If these solutions come into contact, rinse the injured area immediately with water and seek medical advice immediately.
- Safety Data Sheets (SDS) are available on request.
- Use of this product should be limited to personnel trained in the techniques of DNA/RNA extraction.
- Workflow in the laboratory must be one-directional, beginning in the Extraction Area and moving to the Amplification and Detection Area. Do not return samples, equipment and reagents to the area where the previous step was performed.

Lysis Solution MAGNO-sorb  Danger	Contains substance: isopropanol, guanidine thiocyanate, Triton X-100, 1-Thioglycerol H226: Flammable liquid and vapour H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H332: Harmful if inhaled. H336: May cause drowsiness or dizziness. H412: Harmful to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260: Do not breathe vapours. P273: Avoid release to the environment. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P501: Dispose of contents in accordance with national regulation.
Washing Solution 5  Danger	Contains substance: isopropanol, guanidine thiocyanate. H226: Flammable liquid and vapour H302: Harmful if swallowed. H312: Harmful in contact with skin. H314: Causes severe skin burns and eye damage. H319: Causes serious eye irritation. H332: Harmful if inhaled. H336: May cause drowsiness or dizziness H412: Harmful to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260: Do not breathe vapours. P273: Avoid release to the environment. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P501: Dispose of contents in accordance with national regulation.
Washing Solution 4  Danger	Isopropanol EC No 200-661-7 CAS No 67-63-0 H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261: Avoid breathing vapours. P264: Wash your hand thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P403+P233: Store in a well ventilated place. Keep container tightly closed. P501: Dispose of contents in accordance with national regulation.
Washing Solution 6  Warning	Contains substance: Isopropanol H226: Flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261: Avoid breathing vapours. P264: Wash your hand thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P403+P233: Store in a well ventilated place. Keep container tightly closed. P501: Dispose of contents in accordance with national regulation.
Washing Solution 7	Due to providing the empty glass vial, the labeling of Washing Solution 7 as a hazard reagent is absent. Then working with acetone, see hazard and precautionary statements provided by a supplier.

6. SAMPLING AND HANDLING

NOTE: See the information about the sampling, conditions of transportation and storage of the test material, the necessity and procedure of its pretreatment before DNA/RNA extraction in the Instruction manual for the PCR kit.

MAGNO-sorb nucleic acid extraction kit is recommended for DNA and RNA extraction from:

- blood plasma,
- whole blood,
- cerebrospinal fluid (liquor),
- discharge of the conjunctiva,
- saliva,
- nasopharyngeal and oropharyngeal swabs,
- sputum / pharyngeal aspirate,
- bronchoalveolar lavage fluid / bronchial washings,
- pleural / ascitic fluid,
- pus / necrotic content,
- tissue (biopsy, surgical, autopsy) native material,
- paraffin-embedded tissue (biopsy, surgical, autopsy) material,
- urogenital mucous discharge (swab, scrape),
- urine,
- feces,
- fecal / rectal swab (scrape),
- tick suspension,
- cultures of microorganisms,
- water sample concentrates,
- washes from environmental objects.

Interfering substances and limitations of using test material samples

The information about limitations of using test material samples is specified in the Instruction Manual of the PCR kit.

Potential interfering substances

Endogenous and/or exogenous substances that may be present in the biological material used for the study were selected to assess potential interference (see Table 1).
Model samples of various biological material without adding and with the addition of potentially interfering substances were tested. The maximum concentration of potentially interfering substances in model samples and interference presence are listed in Table 1.

Table 1

Test material	Type of potential interferent	Potential interferent	Tested concentration in a sample	Interference presence
Saliva, nasopharyngeal and oropharyngeal swabs, urogenital mucous discharge (swab, scrape)	Exogenous substances	Chlorhexidine bigluconate aqueous solution	2.5%	Not detected
Saliva, nasopharyngeal and oropharyngeal swabs, sputum/ pharyngeal aspirate, bronchoalveolar lavage fluid/bronchial washings, fecal/rectal swabs (scrapes), urogenital mucous discharge (swab, scrape)	Endogenous substances	Mucin	9 mg/ml	Not detected
Blood plasma, saliva, nasopharyngeal and oropharyngeal swabs, bronchoalveolar lavage fluid/bronchial washings, tissue (autopsy) native material, fecal/rectal swabs (scrapes), urogenital mucous discharge (swab, scrape)	Endogenous substances	Hemoglobin	0.21 g/l	Not detected
Sputum/pharyngeal aspirate, bronchoalveolar lavage fluid / bronchial washings, urine, pleural / ascitic fluid, pus / necrotic contents, feces, cerebrospinal fluid (liquor)	Exogenous substances	“Rifampicin”	9-17.5 µg/ml	Not detected
		“Isoniazid”	3-7 µg/ml	Not detected
		“Ethambutol”	2-5 µg/ml	Not detected
		“Pyrazinamide”	39 µg/ml	Not detected
		“Ofloxacin”	5.2 µg/ml	Not detected
		“Kanamycin”	22 µg/ml	Not detected
		“PASK”	75 µg/ml	Not detected
		“Cycloserine”	25-30 µg/ml	Not detected
	Endogenous substances	Blood	sample : blood 1:1	Not detected
Paraffin-embedded tissue (biopsy, surgical, autopsy) material	Exogenous substances	Formalin sour	—	Detected
		Buffered formalin	—	Not detected
Whole blood	Endogenous substances	Hemoglobin	250 g/l	Not detected
		Total bilirubin	210 µmol/l	Not detected
		Total cholesterol	78 mmol/l	Not detected
		Triglycerides	37.0 mmol/l	Not detected
	Exogenous substances	Lithium heparin	12-30 IU/ml	Detected
		Potassium EDTA	2.0 µg/ml	Not detected
Discharge of the conjunctiva	Exogenous substances	“Dicain®”	0.003%	Not detected
Urogenital mucous discharge (swab, scrape)	Endogenous substances	Lactoferrin	5 µg/ml	Not detected
		Glycogen	120 mg/ml	Not detected
	Exogenous substances	“Clotrimazole”	16 % (the drug volume to the volume of the test sample)	Not detected
		“Metronidazole”		Not detected
		“Miramistin®”		Not detected
		“Polygynax”		Not detected
		“Macmiror® Complex”		Not detected
		“Contex Silk”, silicone gel lubricant for intimate use		Not detected

7. WORKING CONDITIONS

MAGNO-sorb nucleic acid extraction kit should be used at the temperature from 20 to 28 °C and relative humidity from 15 to 75 %.

8. PROTOCOL

8.1 Variant 100-200

The volume of test sample for the extraction is 200 µl.
Test material:

- blood plasma,
- whole blood,
- cerebrospinal fluid (liquor),
- nasopharyngeal and oropharyngeal swabs,
- sputum / pharyngeal aspirate,
- bronchoalveolar lavage fluid / bronchial washings,
- urogenital mucous discharge (swab, scrape),
- urine,
- tick suspension,
- water sample concentrates.

NOTE: See the information about pretreatment of biological material for DNA/RNA extraction in the Instruction manual for the used PCR kit.

NOTE: To work with RNA, it is necessary to use only disposable sterile plastic consumables that have a special marking RNase-free, DNase-free.

NOTE: **Lysis Solution MAGNO-sorb** has unpleasant odor. Work in the PCR box.

Manual procedure when using magnetic racks

1 If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2 Prepare the required number of disposable 1.5-ml tubes (including a tube for the Negative Control of extraction (C) and a tube for the Positive Control of Extraction (PCE) if they are provided for analysis). Mark the tubes.
3. Mix in a separate tube **Internal Control (IC)** (if it is provided for analysis), **Component A**, and **Magnetized silica** in the following proportion calculated per one sample: **10 µl** of **Internal Control (IC)**, **10 µl** of **Component A**, and **20 µl** of **Magnetized Silica**. Do not forget to add extra volumes for one more reaction. For example:

Number of samples for DNA/RNA extraction	Internal Control (IC), µl	Component A, µl	Magnetized silica, µl
6	70	70	140
12	130	130	260
18	190	190	380
24	250	250	500

NOTE: It is allowed to change the volume of **Internal Control (IC)** according to the Instruction manual for the used PCR kit

4. Add **40 µl** of the resuspended mixture of **Internal Control (IC)**, **Component A**, and **Magnetized silica** into each tube (recalculate the volume of the mixture if the volume of Internal Control (IC) has been changed);
5. Add **900 µl** of **Lysis Solution MAGNO-sorb** into the tubes.
6. Add **200 µl** of **test sample** into each tube**.** Mix by vortexing.
7. Add **200 µl** of the **Negative Control (C–)** reagent into the tube for the Negative Control of extraction (C–) and **200 µl** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR). Tightly close the tubes and thoroughly mix by vortexing.

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–)** and **Positive Control** according to the Instruction manual for the used PCR kit.

8. Incubate the tubes at **60 °C** for **10 min**.
9. Centrifuge the tubes shortly, transfer the tubes to a magnetic rack, and incubate for **2 min**.

NOTE: If it is inconvenient/impossible to open the tubes in a magnetic rack without sorbent resuspension, it is necessary to open the tubes before placing them in a magnetic rack.

10. Leaving the tubes in the magnetic rack, carefully remove the supernatant inserting a tip near the internal tube wall and using vacuum aspirator. Take a new tip for each sample.
11. Add **700 µl** of **Washing Solution 5** to the tubes. Tightly close the tubes.

NOTE: If it is inconvenient/impossible to close tightly the tubes in a magnetic rack, it is necessary to place the tubes in a regular tube rack.

12. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation.
13. Place the tubes in a magnetic rack for **2 min**.
14. Open the tubes, then carefully remove the supernatant as described above.
15. Repeat washing procedure with **700 µl** of **Washing Solution 5** (steps 11-14).
16. Carry out washing procedure with **700 µl** of **Washing Solution 6** as described above.
17. Add **200 µl of Washing Solution 7** to each tube, mix, and vortex shortly to sediment drops.
18. Transfer the tubes into the magnetic rack for **1 min**, open the tubes and remove the supernatant.
19. Dry the magnetized silica. To do this, leave the tubes with open caps in the magnetic rack for **10-20 min**.
20. Add **100 µl** of **Buffer for elution** to each tube, close the tubes and mix on vortex.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

21. Incubate the tubes at **60 °C** for **5 min**. Vortex the tubes in 2 min.
22. Sediment the drops by short centrifugation and transfer the tubes to the magnetic rack. Incubate for **2 min**. Supernatant contains purified DNA and RNA.

NOTE: Do not take the tubes away from a magnetic rack when removing DNA/RNA.

Procedure for automated stations for nucleic acid extraction

The detailed information work with automated stations see in the *Instruction Manual* given by the manufacturer of the instrument.

Extraction using stations with magnetic stirring (for example, Auto-Pure 96 (Hangzhou Allsheng Instruments Co., Ltd., China), KingFisher Flex (Thermo FS, Finland)).
Only the protocols located on the amplisens.ru website should be used for extraction.

NOTE: The extraction protocol for the automated station contains specific parameters that are not available for manual extraction.

1. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2. Prepare the required number of 96-well plates (see point 3) compatible with the instrument; mark them according to the protocol.
3. Add in the plates according to the marking and quantity of samples for extraction:
   - **760 µl** of **Lysis Solution MAGNO-sorb** in a deepwell plate,
   - **700 µl** of **Washing Solution 5** per two deepwell plates,
   - **700 µl** of **Washing Solution 6** in a deepwell plate,
   - **200 µl** of **Washing Solution 7** in a deepwell plate,
   - **100 µl** of **Buffer for elution** in the plate for elution.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit

4. Mix in a separate tube in the following proportion calculated per one sample:
   - **10 µl** of **Internal Control (IC)** (if it is provided for analysis),
   - **10 µl** of **Component A**,
   - **20 µl** of **Magnetized silica**.

Prepare mixture for total number of test and control samples plus extra samples (for example, in case of extraction from 96 samples it is recommended to prepare mixture for 100 extractions, i.e. plus 4 extra samples).

NOTE: It is allowed to change the volume of **Internal Control (IC)** according to the Instruction manual for the used PCR kit.

5. Add **40 µl** of thoroughly resuspended mixture to each well with **Lysis Solution MAGNO-sorb** (recalculate the volume of the mixture if the volume of Internal Control (IC) has been changed).
6. Add **200 µl of test and control** (if they are provided for analysis) **samples** in each well with **Lysis Solution MAGNO-sorb** and mixture according to the marking.
7. Choose the protocol of extraction, place the prepared plates and tip-plate according to the protocol and placement indicators.
8. Run the nucleic acid extraction protocol.
9. If necessary, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction.

Extraction using pipetting stations (for example, NEON 100 (Xiril AG, Switzerland), MicroLab STARlet (Hamilton Bonaduz AG, Switzerland)).

1. Arrange the required number of the consumables on the desktop of the station: tips, test tubes/plates for elution.
2. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
3. Place the tubes with **Internal Control (IC)** (if it is provided for analysis), **Component A, Buffer for elution** and **Magnetized silica** on the desktop of the station.
4. Pour **Lysis Solution MAGNO-sorb**, **Washing Solution 5**, **Washing Solution 6** and **Washing Solution 7** into the appropriate containers placed on the desktop of the station.
5. Place the tubes with test samples on the desktop of the station. Choose the rack according to the type of used tubes.
6. Add no less than **150 µl** of **Negative Control (C–)** into the tube for the Negative Control of extraction (C–) and no less than **150 µl** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR).

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–) and Positive Control sample** according to the Instruction manual for the used PCR kit. The volume of control samples should be increased taking into account some extra volume.

7. Choose and run the protocol of extraction.
8. If the elution was carried out into a plate, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction if necessary.

Storage of purified nucleic acids

Purified DNA samples can be stored:
- at the temperature from 2 to 8 °C for 1 week;
- at the temperature from minus 24 to minus 16 °C for 1 year.

Purified RNA samples can be stored:
- at the temperature from 2 to 8 °C for 1 hours;
- at the temperature from minus 24 to minus 16 °C for 1 month;
- at the temperature not more than minus 68 °C for 1 year.

In case of manual extraction transfer the supernatant for purified nucleic acids storage into a new tube without disturbing the sediment.
In case of automatic extraction transfer eluate into the tubes for purified nucleic acids storage at subzero temperature.

8.2 Variant 100-1000

The volume of test sample for the extraction is 1,000 µl.
Test material:

- blood plasma,
- cerebrospinal fluid (liquor),
- urine,
- water sample concentrates.

NOTE: See the information about pretreatment of biological material for DNA/RNA extraction in the Instruction manual for the used PCR kit.

NOTE: To work with RNA, it is necessary to use only disposable sterile plastic consumables that have a special marking RNase-free, DNase-free.

NOTE: **Lysis Solution MAGNO-sorb** has unpleasant odor. Work in the PCR box.

Manual procedure when using magnetic racks

1 If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2 Prepare the required number of disposable 5-ml tubes (including a tube for the Negative Control of extraction (C) and a tube for the Positive Control of Extraction (PCE) if provided with the amplification kit) and tube caps. Mark the tubes.
3 Mix in a separate tube **Internal Control (IC)** (if it is provided for analysis of given infectious agent), **Component A-2,** and **Magnetized silica** in the following proportion calculated per one sample: **10 µl** of **Internal Control IC, 20 µl** of **Component A,** and **30 µl** of **Magnetized Silica**. Do not forget to add extra volumes for one more reaction. For example:

Number of samples for DNA/RNA extraction	Internal Control (IC), µl	Component A-2, µl	Magnetized silica, µl
6	70	140	210
12	130	260	390
18	190	380	570
24	250	500	750

NOTE: It is allowed to change the volume and dilution of **Internal Control (IC)** according to the Instruction manual for the used PCR kit.

4. Add **60 µl** of the thoroughly resuspended mixture of **Internal Control (IC)**, **Component A-2**, and **Magnetized silica** into each 5-ml tube (recalculate the volume of the mixture if the volume of Internal Control (IC) has been changed);
5. Add **2.6 ml** of **Lysis Solution MAGNO-sorb** into the tubes.
6. Add **1 ml** of **test sample** to each tube. Mix by pipetting. Cap the tubes.
7. Add **1 ml** of the **Negative Control (C–)** into the tube for the Negative Control of extraction (C–) and **1 ml** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR). Mix by pipetting. Cap the tube.

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–)** and **Positive Control** according to the Instruction manual for the used PCR kit.

8. Incubate the tubes at **60 °C** for **10 min**.

9. Open the tubes; transfer them to a magnetic rack and incubate for **6 min**.
10. Leaving the tubes in the magnetic rack, carefully remove the supernatant inserting the tip near the internal tube wall and using vacuum aspirator. Take a new 1,000-µl tip for each sample. Transfer the tubes to a regular tube rack.
11. Add **700 µl** of **Washing Solution 5** to the tubes. Cap the tubes.
12. Take the required number of disposable 1.5-ml tubes (including the tubes for the Positive and Negative Controls of extraction). Mark the tubes.
13. Vortex the tubes and then pipette to remove magnetic beads from tube walls. Transfer the entire content of the tubes to the prepared 1.5-ml tubes.
14. Place the 1.5-ml tubes in the magnetic rack and incubate for 2 min.

NOTE: If it is inconvenient/impossible to open the tubes in a magnetic rack without sorbent resuspension, it is necessary to open the tubes before placing them in a magnetic rack.

15. Carefully remove the supernatant as described above.
16. Add **700 µl** of **Washing Solution 5**, close the tubes.

NOTE: If it is inconvenient/impossible to close tightly the tubes in a magnetic rack, it is necessary to place the tubes in a regular tube rack.

17. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation and then repeat steps 14-15.
18. Carry out washing procedure with **700 µl** of **Washing Solution 6** as described above.
19. Add **200 µl** of **Washing Solution 7**, mix, and vortex shortly to remove drops.
20. Place the tubes to the magnetic rack for 1 min and then carefully remove the supernatant.
21. Dry the magnetized silica. To do this, open the tubes and incubate them in the magnetic rack for 10-20 min.
22. Add **100 µl of Buffer for elution** to each tube, close the tubes and mix on vortex.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

23. Incubate the tubes at **60 °C** for **5 min**. Vortex in 2 min.
24. Sediment the drops by short centrifugation and transfer the tubes to the magnetic rack. Incubate for 2 min.

Supernatant contains purified DNA and RNA.

NOTE: Do not take the tubes away from a magnetic rack when removing DNA/RNA.

Procedure for automated stations for nucleic acid extraction

The detailed information work with automated stations see in the Instruction Manual given by the manufacturer of the instrument.

Extraction using stations with magnetic stirring (for example, KingFisher Flex (Thermo FS, Finland)).

Only the protocols located on the amplisens.ru website should be used for extraction.

NOTE: The extraction protocol for the automated station contains specific parameters that are not available for manual extraction.

1. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2. Prepare the required number of 24-well plates (see point 3) compatible with the instrument; mark them according to the protocol.
3. Add in the plates according to the marking and quantity of samples for extraction:
   - **2.6 ml** of **Lysis Solution MAGNO-sorb** in a deepwell plate,
   - **700 µl** of **Washing Solution 5** per two deepwell plate,
   - **700 µl** of **Washing Solution 6** in a deepwell plate,
   - **200 µl** of **Washing Solution 7** in a deepwell plate,
   - **100 µl** of **Buffer for elution** in the plate for elution.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

4. Mix in a separate tube in the following proportion calculated per one sample:
   - **10 µl** of **Internal Control (IC)** (if it is provided for analysis),
   - **20 µl** of **Component A-2**,
   - **30 µl** of **Magnetized silica**.

Prepare mixture for total number of test and control samples plus extra samples (for example, in case of extraction from 24 samples it is recommended to prepare mixture for 26 extractions, i.e. plus 2 extra samples).

NOTE: It is allowed to change the volume and dilution of **Internal Control (IC)** according to the Instruction manual for the used PCR kit.

5. Add **60 µl** of thoroughly resuspended mixture to each well with **Lysis Solution MAGNO-sorb** (recalculate the volume of mixture if the volume of Internal Control (IC) has been changed).
6. Add **1 ml of test and control** (if they are provided for analysis) **samples** in each well with **Lysis Solution MAGNO-sorb** and mixture according to the marking.
7. Choose the protocol of extraction, place the prepared plates and tip-plate according to the protocol and placement indicators.
8. Run the nucleic acid extraction protocol.
9. If necessary, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction.

Extraction using pipetting stations (for example, NEON 100 (Xiril AG, Switzerland), MicroLab STARlet (Hamilton Bonaduz AG, Switzerland)).

1. Arrange the required number of the consumables on the desktop of the station: tips, test tubes/elution plates.
2. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
3. Place the tubes with **Internal Control (IC)** (if it is provided for analysis), **Component A-2, Buffer for elution** and **Magnetized silica** on the desktop of the station.
4. Pour **Lysis Solution MAGNO-sorb**, **Washing Solution 5**, **Washing Solution 6** and **Washing Solution 7** into the appropriate containers placed on the desktop of the station.
5. Place the tubes with test samples on the desktop of the station. Choose the rack according to the type of used tubes.
6. Add no less than **150 µl** of **Negative Control (C–)** into the tube for the Negative Control of extraction (C–) and no less than **150 µl** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR).

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–) and Positive Control sample** according to the Instruction manual for the used PCR kit. The volume of control samples should be increased taking into account extra volume.

7. Choose and run the protocol of extraction nucleic acid.
8. If the elution was carried out into a plate, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction if necessary.

Storage of purified nucleic acids

Purified DNA samples can be stored:
- at the temperature from 2 to 8 °C for 1 week;
- at the temperature not more than minus 16 °C for 1 year.

Purified RNA samples can be stored:
- at the temperature from 2 to 8 °C for 4 hours;
- at the temperature from minus 24 to minus 16 °C for 1 month;
- at the temperature not more than minus 68 °C for 1 year.

In case of manual extraction transfer the supernatant for purified nucleic acids storage into a new tube without disturbing the sediment.

In case of automatic extraction transfer eluate into the tubes for purified nucleic acids storage at subzero temperature.

8.3 Variant 100-100M

The volume of test sample for the extraction is 100 µl.

Test material:
- blood plasma,
- nasopharyngeal and oropharyngeal swabs,
- sputum / pharyngeal aspirate,
- bronchoalveolar lavage fluid / bronchial washings,
- tissue (biopsy, surgical, autopsy) native material,
- fecal / rectal swab (scrape).

NOTE: See the information about pretreatment of biological material for DNA/RNA extraction in the Instruction manual for the used PCR kit.

NOTE: To work with RNA, it is necessary to use only disposable sterile plastic consumables that have a special marking RNase-free, DNase-free.

NOTE: **Lysis Solution MAGNO-sorb** has unpleasant odor. Work in the PCR box.

Manual procedure when using magnetic racks

1 If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2 Prepare the required number of disposable 1.5-ml tubes (including a tube for the Negative Control of extraction (C) and a tube for the Positive Control of Extraction (PCE) if provided with the amplification kit). Mark the tubes.
3. Mix in a disposable tube **Internal Control (IC)** (if it is provided for analysis of given infectious agent), **Component A**, and **Magnetized silica** in the following proportion calculated per one sample: **10 µl** of **Internal Control (IC)**, **5 µl** of **Component A**, and **10 µl** of **Magnetized Silica**. Do not forget to add extra volumes for one more reaction. For example:

Number of samples for DNA/RNA extraction	Internal Control (IC), µl	Component A, µl	Magnetized silica, µl
6	70	35	70
12	130	65	130
18	190	95	190
24	250	125	250

NOTE: It is allowed to change the volume and dilution of **Internal Control (IC)** according to the Instruction manual for the used PCR kit

4. Add **25 µl** of the resuspended mixture of **Internal Control (IC)**, **Component A**, and **Magnetized silica** into each tube (recalculate the volume of the mixture if the volume of Internal Control (IC) has been changed);
5. Add **300 µl** of **Lysis Solution MAGNO-sorb** into the tubes.
6. Add **100 µl** of **test sample** into each tube**.** Mix by vortexing.
7. Add **100 µl** of the **Negative Control (C–)** reagent into the tube for the Negative Control of extraction (C–) and **100 µl** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR). Tightly close the tubes and thoroughly mix by vortexing.

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–)** and **Positive Control** according to the Instruction manual for the used PCR kit

8. Incubate the tubes at **60 °C** for **10 min**.
9. Centrifuge the tubes shortly, transfer the tubes to a magnetic rack, and incubate for **5 min**.

NOTE: If it is inconvenient/impossible to open the tubes in a magnetic rack without sorbent resuspension, it is necessary to open the tubes before placing them in a magnetic rack.

10. Leaving the tubes in the magnetic rack, carefully remove the supernatant inserting a tip near the internal tube wall and using vacuum aspirator. Take a new 200-µl tip for each sample.
11. Add **500 µl** of **Washing Solution 5** to the tubes. Tightly cap the tubes.

NOTE: If it is inconvenient/impossible to close tightly the tubes in a magnetic rack, it is necessary to place the tubes in a regular tube rack.

12. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation.
13. Transfer the tubes to a magnetic rack for **5 min**.
14. Remove the supernatant as described above.
15. Add **500 µl** of **Washing Solution 4** to the tubes. Tightly cap the tubes.
16. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation.
17. Transfer the tubes to a magnetic rack for **2 min**.
18. Remove supernatant as described above.
19. Dry the magnetized silica by placing the test tubes with open caps in a thermostat at 60°C for 5 minutes. In case of incomplete drying of the sorbent, the time may be increased up to 10 minutes.
20. Add **100 µl** of **Buffer for elution** to each tube, close the tubes and mix on vortex.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

21. Incubate the tubes at **60 °C** for **5 min**. Vortex the tubes in 2 min.
22. Sediment the drops by short centrifugation and transfer the tubes to the magnetic rack for 2 min.

Supernatant contains purified DNA and RNA.

NOTE: Do not take the tubes away from a magnetic rack when removing DNA/RNA.

Procedure for automated stations for nucleic acid extraction

The detailed information work with automated stations see in the *Instruction Manual* given by the manufacturer of the instrument.

Extraction using stations with magnetic stirring (for example, Auto-Pure 96 (Hangzhou Allsheng Instruments Co., Ltd., China), KingFisher Flex (Thermo FS, Finland)).

Only the protocols located on the amplisens.ru website should be used for extraction.

NOTE: The extraction protocol for the automated station contains specific parameters that are not available for manual extraction.

1. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2. Prepare the required number of 96-well plates (see point 3) compatible with the instrument; mark them according to the protocol.
3. Add in the plates according to the marking and quantity of samples for extraction:
   - **300 µl** of **Lysis Solution MAGNO-sorb** in a deepwell plate,
   - **500 µl** of **Washing Solution 5** in a deepwell plate,
   - **500 µl** of **Washing Solution 4** in a deepwell plate,
   - **100 µl** of **Buffer for elution** in the plate for elution.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

4. Mix in a separate tube in the following proportion calculated per one sample:
   - **10 µl** of **Internal Control (IC)** (if it is provided for analysis),
   - **5 µl** of **Component A**,
   - **10 µl** of **Magnetized silica**.

Prepare mixture for total number of test and control samples plus extra samples (for example, in case of extraction from 96 samples it is recommended to prepare mixture for 100 extractions, i.e. plus 4 extra samples).

5. Add **25 µl** of thoroughly resuspended mixture to each well with **Lysis Solution MAGNO-sorb** (recalculate the volume of mixture if the volume of Internal Control (IC) has been changed).
6. Add **100 µl** of **test and control** (if they are provided for analysis) **samples** in each well with **Lysis Solution MAGNO-sorb** and mixture according to the marking.
7. Choose the protocol of extraction, place the prepared plates and tip-plate according to the protocol and placement indicators.
8. Run the nucleic acid extraction protocol.
9. If necessary, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction.

Storage of purified nucleic acids

Purified DNA samples can be stored:
- at the temperature from 2 to 8 °C for 1 week;
- at the temperature from minus 24 to minus 16 °C for 1 year.

Purified RNA samples can be stored:
- at the temperature from 2 to 8 °C for 4 hours;
- at the temperature from minus 24 to minus 16 °C for 1 month;
- at the temperature not more than minus 68 °C for 1 year.

In case of manual extraction transfer the supernatant for purified nucleic acids storage into a new tube without disturbing the sediment.
In case of automatic extraction transfer eluate into the tubes for purified nucleic acids storage at subzero temperature.

8.4 Variant 100-200M

The volume of test sample for the extraction is 200 µl.
Test material:
- blood plasma,
- whole blood,
- cerebrospinal fluid (liquor),
- discharge of the conjunctiva,
- saliva,
- nasopharyngeal and oropharyngeal swabs,
- sputum / pharyngeal aspirate,
- bronchoalveolar lavage fluid / bronchial washings,
- pleural/ascitic fluid,
- pus/necrotic content,
- tissue (biopsy, surgical, autopsy) native material,
- paraffin-embedded tissue (biopsy, surgical, autopsy) material,
- urine,
- feces,
- fecal / rectal swab (scrape),
- tick suspension,
- cultures of microorganisms,
- water sample concentrates,
- washes from environmental objects.

NOTE: See the information about pretreatment of biological material for DNA/RNA extraction in the Instruction manual for the used PCR kit.

NOTE: To work with RNA, it is necessary to use only disposable sterile plastic consumables that have a special marking RNase-free, DNase-free.

NOTE: **Lysis Solution MAGNO-sorb** has unpleasant odor. Work in the PCR box.

Manual procedure when using magnetic racks

1 If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2 Prepare the required number of disposable 1.5-ml tubes (including a tube for the Negative Control of extraction (C) and a tube for the Positive Control of Extraction (PCE) if provided with the amplification kit). Mark the tubes.
3. Mix in a disposable tube **Internal Control (IC)** (if it is provided for analysis of given infectious agent), **Component A**, and **Magnetized silica** in the following proportion calculated per one sample: **10 µl** of **Internal Control (IC)**, **10 µl** of **Component A**, and **20 µl** of **Magnetized Silica**. Do not forget to add extra volumes for one more reaction. For example:

Number of samples for DNA/RNA extraction	Internal Control (IC), µl	Component A, µl	Magnetized silica, µl
6	70	70	140
12	130	130	260
18	190	190	380
24	250	250	500

NOTE: It is allowed to change the volume and dilution of **Internal Control (IC)** according to the Instruction manual for the used PCR kit.

4. Add **40 µl** of the resuspended mixture of **Internal Control (IC)**, **Component A**, and **Magnetized silica** into each tube (recalculate the volume of mixture if the volume of Internal Control (IC) has been changed);
5. Add **600 µl** of **Lysis Solution MAGNO-sorb** into the tubes.
6. Add **200 µl** of the **test sample** into each tube**.** Mix by vortexing.
7. Add **200 µl** of the **Negative Control (C–)** reagent into the tube for the Negative Control of extraction (C–) and **200 µl** of **required Positive Control sample** into the tube for the Positive Control of extraction (PCE) (if they are provided for PCR). Tightly close the tubes and thoroughly mix by vortexing.

NOTE: It is allowed to change the volume and dilution of **Negative Control (C–)** and **Positive Control** according to the Instruction manual for the used PCR kit.

8. Incubate the tubes at **60 °C** for **10 min**.
9. Centrifuge the tubes shortly, transfer the tubes to a magnetic rack, and incubate for **5 min**.

NOTE: If it is inconvenient/impossible to open the tubes in a magnetic rack without sorbent resuspension, it is necessary to open the tubes before placing them in a magnetic rack.

10. Leaving the tubes in the magnetic rack, carefully remove the supernatant inserting a tip near the internal tube wall and using vacuum aspirator. Take a new 200-µl tip for each sample.
11. Add **500 µl** of **Washing Solution 5** to the tubes. Tightly cap the tubes.

NOTE: If it is inconvenient/impossible to close tightly the tubes in a magnetic rack it is necessary to place the tubes in a regular tube rack.

12. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation.
13. Transfer the tubes to a magnetic rack for **5 min**.
14. Remove the supernatant as described above.
15. Add **500 µl** of **Washing Solution 4** to the tubes. Tightly cap the tubes.
16. Resuspend **Magnetized silica** by mixing on vortex. Then sediment the drops by short centrifugation.
17. Transfer the tubes to a magnetic rack for **2 min**.
18. Remove supernatant as described above
19. Dry the **Magnetized silica** by placing the test tubes with open caps in a thermostat at **60 °C** for **5 minutes**. In case of incomplete drying of the sorbent, the time may be increased up to 10 minutes.
20. Add **100 µl** of **Buffer for elution** to each tube, close the tubes and mix on vortex.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

21. Incubate the tubes at **60 °C** for **5 min**. Vortex the tubes in 2 min.
22. Sediment the drops by short centrifugation and transfer the tubes to the magnetic rack for 2 min.

Supernatant contains purified DNA and RNA.

NOTE: Do not take the tubes away from a magnetic rack when removing DNA/RNA.

Procedure for automated stations for nucleic acid extraction

The detailed information work with automated stations see in the *Instruction Manual* given by the manufacturer of the instrument.
Extraction using stations with magnetic stirring (for example, Auto-Pure 96 (Hangzhou Allsheng Instruments Co., Ltd., China), KingFisher Flex (Thermo FS, Finland)).
Only the protocols located on the amplisens.ru website should be used for extraction.

NOTE: The extraction protocol for the automated station contains specific parameters that are not available for manual extraction

1. If there is a precipitate in **Lysis Solution MAGNO-sorb** and **Washing Solution 5** warm them up at 60 ºC until crystals disappear. Resuspend **Magnetized silica** on vortex.
2. Prepare the required number of 96-well plates (see point 3) compatible with the instrument; mark them according to the protocol.
3. Add in the plates according to the marking and quantity of samples for extraction:
   - **600 µl** of **Lysis Solution MAGNO-sorb** in a deepwell plate,
   - **500 µl** of **Washing Solution 5** in a deepwell plate,
   - **500 µl** of **Washing Solution 4** in a deepwell plate,
   - **100 µl** of **Buffer for elution** in the plate for elution.

NOTE: It is allowed to change the elution volume according to the Instruction manual for the used PCR kit.

4. Mix in a separate tube in the following proportion calculated per one sample:
   - **10 µl** of **Internal Control (IC)** (if it is provided for analysis),
   - **10 µl** of **Component A**,
   - **20 µl** of **Magnetized silica**.

Prepare mixture for total number of test and control samples plus extra samples (for example, in case of extraction from 96 samples it is recommended to prepare mixture for 100 extractions, i.e. plus 4 extra samples).

NOTE: It is allowed to change the volume and dilution of **Internal Control (IC)** according to the Instruction manual for the used PCR kit.

5. Add **40 µl** of thoroughly resuspended mixture to each well with **Lysis Solution MAGNO-sorb** (recalculate the volume of mixture if the volume of Internal Control (IC) has been changed).
6. Add **200 µl** of **test and control** (if they are provided for analysis) **samples** in each well with **Lysis Solution MAGNO-sorb** and mixture according to the marking.
7. Choose the protocol of extraction, place the prepared plates and tip-plate according to the protocol and placement indicators.
8. Run the nucleic acid extraction protocol.
9. If necessary, seal the elution plate with the purified nucleic acid using a self-adhesive film at the end of the extraction.

Storage of purified nucleic acids

Purified DNA samples can be stored:
- at the temperature from 2 to 8 °C for 1 week;
- at the temperature from minus 24 to minus 16 °C for 1 year.

Purified RNA samples can be stored:
- at the temperature from 2 to 8 °C for 4 hours;
- at the temperature from minus 24 to minus 16 °C for 1 month;
- at the temperature not more than minus 68 °C for 1 year.

In case of manual extraction transfer the supernatant for purified nucleic acids storage into a new tube without disturbing the sediment.
In case of automatic extraction transfer eluate into the tubes for purified nucleic acids storage at subzero temperature.

9. TROUBLESHOOTING

These troubleshooting rules may be helpful in explaining any questions that may arise.
False negatives with extraction product:
- Degradation of the nucleic acid contained in the sample. It's necessary to use a new sample, store samples appropriately.
- Loss of nucleic acid pellet. Carefully draw off the washing solution and try not to remove the sorbent.
- Degradation of the extracted nucleic acid. It's necessary to use plastic free from DNases and RNases.

False positives with extraction product:
- Contamination during sample extraction. It's necessary to open one test tube at a time. Avoid spilling the contents of the test tube, always change tips.
- Contamination of the reagents prepared for the step. It's necessary to repeat the test.
- Contamination of the Extraction Area by amplicons. It's necessary to clean surfaces and instruments using aqueous detergents, wash lab coats, replace test tubes and tips in use. Use different laboratory coats in Extraction, Amplification and Detection areas.

If you have any further questions or if encounter problems, please contact our Authorized representative in the European Community.

10. TRANSPORTATION

MAGNO-sorb nucleic acid extraction kit should be transported at 2–25 °C for no longer than 5 days.

11. STABILITY AND STORAGE

All components of **MAGNO-sorb** nucleic acid extraction kit **variant 100-200**, **variant 100-100M, variant 100-200M** are to be stored at 2–25 °C, when not in use. All components of **MAGNO-sorb** nucleic acid extraction kit **variant 100-1000** are to be stored at 2–8 °C, when not in use. All components of **MAGNO-sorb** nucleic acid extraction kit are stable until the expiry date stated on the label. The shelf life of reagents before and after the first use is the same, unless otherwise stated.

12. REFERENCES

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3. Chiang C.-L., Sung C.-S., Wu T.-F., et al. Application of Superparamagnetic Nanoparticles in Purification of Plasmid DNA from Bacterial Cells // J. Chromatogr. B. 2005. V. 822. P. 54-60.

13. QUALITY CONTROL

In compliance with Federal Budget Institute of Science "Central Research Institute for Epidemiology" ISO 13485-Certified Quality Management System, each lot of the **MAGNO-sorb** nucleic acid extraction kit has been tested against predetermined specifications to ensure consistent product quality.

Please contact our Authorized representative in the European Community if side effects, undesirable reactions, facts and circumstances that pose a threat to the life and health of citizens and medical workers are identified during the use of the reagent kit.

List of Changes Made in the Instruction Manual

VER	Location of changes	Essence of changes
29.09.17 ME	5. General precautions, 14. Key to symbols used	Information about hazards was rewritten according to the Regulation 1272/2008/EC
26.02.19 PM	3.Content	The colour of the reagents was specified
08.04.20 KK	Through the text	The text formatting was changed
	Footer	The phrase "Not for use in the Russian Federation" was added
11.03.21 VA	—	The name, address and contact information for Authorized representative in the European Community was changed
08.06.22 MM	1. Intended use	The intended use was specified. The list of biological material was expanded. The "Indications and contra-indications for use of the reagent kit" subsection was added
	Through the text	Component A was changed to Component A-2 for variant 100-1000. Buffer for elution B was changed to Buffer for elution for variant 100-1000 and for variant 100-200. The variant 100-100M and variant 100-200M were added
	3. Content	Volumes and quantity of reagents were changed for variant 100-200 and for variant 100-1000. REF K3-1061-100-CE and REF K3-1062-100-CE were added for **variant 100-200** and **variant 100-200** respectively
	4. Additional requirements	The automatic stations for nucleic acid extraction and additional materials for their use were added
	5. General precautions	Hazard identification information for Lysis Solution MS-URO, Washing solution 4 and Mucolysin reagents were added in accordance with Regulation 1272/2008/EC
	6. Sampling and handling	"Interfering substances and limitations of using test material samples" and "Potential interfering substances" subsections were added
	8. Protocol	The procedure of manual extraction using magnetic racks was clarified for variant 100-200 and for variant 100-1000. The procedure of nucleic acid extraction using automated stations was added for variant 100-200 and for variant 100-1000. The procedure of nucleic acid extraction were added for variant 100-100M and variant 100-200M
	10. Transportation	The storage temperature of transportation was changed from 2-8 ºC to 2-25 ºC
	13. Quality control	The Authorized representative in the European Community was specified for the contact in case of undesirable effects when using the reagent kit

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