Mucolysin

Reagent for mucous material pretreatment

CE IVD

For Professional Use Only

Instruction Manual

KEY TO SYMBOLS USED

REF	Catalogue number	EC REP	Authorized representative in the European Community
LOT	Batch code		Caution
IVD	*In vitro* diagnostic medical device	Σ	Contains sufficient for <n> tests
VER	Version		Use-by Date
	Temperature limit		Consult instructions for use
	Manufacturer		GHS07: Exclamation mark
	Date of manufacture		

1. INTENDED USE

Mucolysin reagent is intended for pretreatment of mucous clinical material for conducting microscopic studies or nucleic acid extraction for carrying out molecular genetic studies.

Indications and contra-indications for use of the reagent

The reagent is used for liquefaction of mucous clinical material before RNA/DNA extraction for subsequent in vitro diagnostics by nucleic acid amplification techniques (NAT).

2. PRINCIPLE OF MUCOLYSIN USE

Mucolysin is a reagent for mucous material liquefaction. Liquefied mucous material is used for nucleic acids extraction.

3. CONTENT

Mucolysin reagent is produced in 1 form:

Mucolysin, 2 vials of 100 ml, REF 180-CE.

Mucolysin reagent includes:

Reagent	Description	Volume, ml	Quantity
Mucolysin	colorless clear liquid	100	2 vials

4. ADDITIONAL REQUIREMENTS

- Vacuum aspirator with a flask for removing supernatant.
- Disposable powder-free gloves and a laboratory coat.
- Pipettes (adjustable).
- Sterile pipette tips with aerosol filters (up to 200 µl and up to 1000 µl).
- Mixer for mixing of sputum samples with Mucolysin.
- Desktop microcentrifuge with rotor for reaction tubes (RPM max. 12,000)
- PCR box or Biological cabinet.
- Disposable graduated polypropylene containers with screwed caps of at least 50 ml or 5 ml volume for taking different types of clinical material.
- Tubes with potassium-EDTA reagent with screw caps and graduations for pleural fluid acquisition.
- Disposable 1.5-ml polypropylene tubes with screwed or tightly closing caps.
- Tube racks.
- Object-plates.
- Sterile porcelain or glass beads (D=3–5 mm).
- Refrigerator for 2–8 °C.
- Deep-freezer at the temperature from minus 24 to minus 16 °C.
- Reservoir for used tips.

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile pipette tips with aerosol filters and use a new tip for every procedure.
- Store all extracted positive material (specimens, controls and amplicons) away from all other reagents and add it to the reaction mix in a distantly separated facility.
- Thaw all components thoroughly at room temperature before starting an assay.
- When thawed, mix the components and centrifuge briefly.
- 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 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 biological cabinet in compliance with appropriate biosafety practices.
- Clean and disinfect all samples or reagents 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 DNA amplification techniques.
- 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 in the area where the previous step was performed.

Mucolysin  Warning	Contains substance: 2-Mercaptoethanol H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of water. P333 + P313: If skin irritation or a rash occurs: Get medical advice. P362 + P364: Take off contaminated clothing and wash before reuse. P501: Dispose of contents in accordance with national regulations.

6. SAMPLING AND HANDLING

NOTE: Obtaining samples of biological materials for PCR-analysis, transportation, and storage are described in manufacturer's handbook [1]. It is recommended that this handbook is read before starting work.

Mucolysin reagent is intended for pretreatment of mucous clinical material (sputum, ejaculate, bronchoalveolar lavage, washing water of bronchial tubes, tracheal flushing, synovial fluid, pus, and pleural fluid).

Sampling

Samples of sputum and ejaculate are collected to 50-ml disposable graduated polypropylene containers with a screwed cap. **Bronchoalveolar lavage fluid** or **bronchial washing fluid** or **tracheal flushing, synovial fluid, pus, pleural fluid** are collected to 5-ml disposable polypropylene containers with screw caps. Then transfer **pleural fluid** (2 ml) into the container with 3% EDTA solution in a 1:20 ratio (1 part of 3% EDTA solution to 20 parts of the pleural fluid) or to a tube with a sputtered potassium-EDTA reagent with screwed caps and graduation. After this, the closed tube should be carefully inverted several times to mix the content.

Samples can be stored at 2–8 °C for 1 day and at the temperature not more than minus 16 °C for a long time.

Interfering substances and limitations of using test material samples

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

7. WORKING CONDITIONS

Mucolysin reagent should be used at 18–25 °C.

8. PROTOCOL

1. Add **Mucolysin** to a container with mucous material according to the container graduation. Depending on the type of mucous material, the volume of added **Mycolysin** is different: in case of sputum, the ratio is 5:1 (5 parts of **Mucolysin** and 1 part of sputum); in case of synovial fluid or ejaculate the ratio is 1:1. Other material types should be pretreated using **Mucolysin** with the ratio 1:1 only if they are mucous (it can be visually determined). Screw the cap, stir the contents, and incubate the container at room temperature for 20–30 min under occasional stirring (every 2–3 min) by hand or using a mixer for sample mixing. Add 3-5 sterile porcelain or glass beads to obtain appropriate consistence while treating the sputum. Reuse of these porcelain or glass beads is not allowed and they should be disposed.
2. After liquefaction of mucous material, which is detected visually;
   - apply thin layer of the material to the object-plate for microscopic study, or;
   - for nucleic acid extraction transfer **0.1 ml** of the **liquefied sputum/synovial fluid/ejaculate/pus** or **1 ml** of **bronchoalveolar lavage fluid/bronchial washing fluid/tracheal flushing/synovial fluid** to a tube with a screw or a tightly closing cap using tips with aerosol filter. Centrifuge the tubes at 10,000 g for 10 min, then remove the supernatant up to 0.1 ml volume using vacuum aspirator and a separate tip for each sample.
3. The sample is ready for DNA extraction with nucleic acid extraction kits (for example, **DNA-sorb-B**, **RIBO-prep**, **DNA-sorb-AM**).
4. The remained liquefied mucous material is to be stored in the container at 2–8 °C for 1 day or at the temperature not more than minus 16 °C for a long time.

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

Not for use in the Russian Federation

9. TRANSPORTATION

Mucolysin reagent should be transported at 2–8 °C for no longer than 5 days.

10. STABILITY AND STORAGE

Mucolysin reagent is to be stored at 2–8 °C when not in use. It is stable until the expiration date on the label. The shelf life of reagents before and after the first use is the same, unless otherwise stated.

11. REFERENCES

1. Handbook "Sampling, Transportation, and Storage of Clinical Material for PCR Diagnostics", developed by Federal Budget Institute of Science "Central Research Institute for Epidemiology" of Federal Service for Surveillance on Consumers' Rights Protection and Human Well-Being.

12. QUALITY CONTROL

In accordance with Federal Budget Institute of Science "Central Research Institute for Epidemiology" ISO 13485-Certified Total Quality Management System, each lot of **Mucolysin** reagent is 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.

List of Changes Made in the Instruction Manual

VER	Location of changes	Essence of changes
04.07.11 VV	Cover page, text	The name of Institute was changed to Federal Budget Institute of Science "Central Research Institute for Epidemiology"
20.10.17 PM	Through the text	Correction according to the template
	5. General precautions, 14. Key to symbols used	Information about hazards was added according to the Regulation 1272/2008/EC.
	6. Sampling and handling, 8. Protocol	Types of test material were added, the work order was specified
26.12.18 PM	9. Transportation	The information about transportation was changed
08.11.19 PM	Through the text	The full name of Mucolysin reagent was specified. The text formatting was changed. Corrections according to the template
03.12.19 PM	Through the text	The full name of Mucolysin reagent was specified
26.05.20 VA	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
01.02.22 KK	Through the text	The reference numbers of nucleic acid extraction kits were deleted
31.05.22 EM	1. Intended use	"Indications and contra-indications for use of the reagent" subsection was added
	6. Sampling and handling	"Interfering substances and limitations of using test material samples" subsection was added
	12. Quality control	The Authorized representative in the European Community was specified for the contact in case of undesirable effects when using the reagent
14.12.23 EM	5. General precautions	Information about hazards was rewritten according to the Regulation (EU) 2020/878

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EC REP

Ecoli Dx, s.r.o., Purkyňova 74/2
110 00 Praha 1, Czech Republic
Tel.: +420 325 209 912
Cell: +420 739 802 523

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
3A Novogireevskaya Street
Moscow 111123 Russia