

# Mucolysin

## Reagent for mucous material pretreatment



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 | <i>In vitro</i> diagnostic medical device |        | 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.

### 2. PRINCIPLE OF PCR DETECTION

**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 |
|------------------|------------------------|------------|----------|
| <b>Mucolysin</b> | 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.

|   |  |
|---|--|
| <br><b>Mucolysin</b><br>Warning                                       | Contains substance: 2-Mercaptoethanol  |
|   | H317: May cause an allergic skin reaction  |
|   | P261: Avoid breathing dust/fume/gas/mist/vapours/spray.                          |
|   | 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. |  |
| P363: Wash contaminated clothing 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).

**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.

### 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 **Mucolysin** 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** REF K1-2-100-CE or REF K1-2-50-CE, **RIBO-prep** REF K2-9-Et-100-CE or REF K2-9-Et-50-CE, **DNA-sorb-AM** REF K1-11-50-CE, REF K1-11-100-CE, REF K1-12-50-CE or REF K1-12-100-CE).
  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.

## 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.

List of Changes Made in the Instruction Manual

| VER            | Location of changes                             | Essence of changes   |
|----------------|---|--|
| 04.07.11<br>VV | Cover page, text                                | The name of Institute was changed to Federal Budget Institute of Science "Central Research Institute for Epidemiology"   |
| 20.10.17<br>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.  |
| 26.12.18<br>PM | 6. Sampling and handling, 8. Protocol           | Types of test material were added, the work order was specified  |
|                | 9. Transportation                               | The information about transportation was changed   |
| 08.11.19<br>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<br>PM | Through the text                                | The full name of Mucolysin reagent was specified   |
| 26.05.20<br>VA | Footer  | The phrase "Not for use in the Russian Federation" was added   |
| 11.03.21<br>VA | —   | The name, address and contact information for Authorized representative in the European Community was changed            |

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