



For Professional Use Only

Mucolysin

Reagent for mucous material pretreatment

Instruction Manual

AmpliSens[®]



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1. INTENDED USE

Mucolysin reagent is intended for mucous material pretreatment.

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 includes:

<i>Reagent</i>	<i>Description</i>	<i>Volume (ml)</i>	<i>Quantity</i>
Mucolysin	colorless clear liquid	100	2 vials

4. ADDITIONAL REQUIREMENTS

- Disposable powder-free gloves and laboratory coat.
- Pipettes (adjustable).
- Sterile pipette tips with aerosol barriers (up to 200 µl and up to 1000 µl).
- Sterile laminar flow hood.
- Vacuum aspirator with a flask for removing supernatant.
- Disposable 1.5-ml polypropylene tubes with screwed or tightly closing caps.
- Tube racks.
- Waste bin with a disinfecting solution.
- Sterile porcelain or glass beads (D=3–5 mm).

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile RNase-free pipette tips with aerosol barriers and use new tip for every procedure.
- Store extracted positive material (samples, controls, and amplicons) away from all other reagents.
- Thaw all components thoroughly at room temperature before starting an assay.
- When thawed, mix the components and centrifuge briefly.
- Use disposable gloves, laboratory coats, 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 samples and unused reagents in compliance with local authorities

requirements.

- 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 contact with the skin, eyes, and mucous membranes. If skin, eyes, or mucous membranes contact, immediately flush with water and seek medical attention.
- Material Safety Data Sheets (MSDS) are available on request.

6. SAMPLING AND HANDLING



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.

Sputum samples are collected to 50-ml disposable graduated polypropylene containers with a screwed cap and a wide neck. **Bronchoalveolar lavage fluid** or **bronchial washing fluid** is collected to 5-ml disposable polypropylene containers with screw caps (to prevent cell adhesion to the inner surface of containers). **Synovial fluid** is collected to the dry disposable tube. Samples can be stored at 2–8 °C for 1 day and at ≤ –16 °C for a long time.

7. WORKING CONDITIONS

Mucolysin 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 bronchoalveolar lavage fluid or bronchial washing fluid (if the mucous nature of these material types can be detected visually) and synovial fluid, the ratio is 1:1. When homogenizing sputum, put sterile porcelain or glass beads to the container (3-5 beads). Screw the cap, stir the contents, and incubate the container at room temperature for 20–30 min under occasional stirring (every 2–3 min).
2. After liquefaction of mucous material, which is detected visually, transfer 0.1 ml of the liquefied sputum or synovial fluid or 1 ml of bronchoalveolar lavage fluid / bronchial washing fluid to a tube with a screw or a tightly closing cap using tips with aerosol barrier.
3. The sample is ready for DNA extraction with nucleic acid extraction kits (for example, DNA-sorb-B **REF** K1-2-100-CE or K1-2-50-CE, RIBO-prep **REF** K2-9-Et-100-CE or K2-9-Et-50-CE).
4. The remained liquefied mucous material is to be stored in the container at 2–8 °C for 1 day or at ≤ –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 should be transported at 18–25 °C.

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

Manual “Sampling, Transportation, and Storage of Clinical Material for PCR Diagnostics”, developed by Federal Budget Institute of Science “Central Research Institute for Epidemiology”.

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.

13. KEY TO SYMBOLS USED

	Catalogue number		Caution
	Batch code		Sufficient for
	<i>In vitro</i> diagnostic medical device		Expiration Date
	Version		Consult instructions for use
	Temperature limitation		Manufacturer
	Authorised representative in the European Community		Date of manufacture

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"