CE

IVD For *in Vitro* Diagnostic Use

Mucolysin

Reagent for sputum preliminary treatment

Instruction Manual

AmpliSens®

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1. INTENDED USE.

Mucolysin reagent is intended for sputum preliminary treatment.

2. PRINCIPLE OF MUCOLYSIN USE.

Mucolysin is reagent for liquefaction of sputum. Liquefied sputum after centrifugation is used for nucleic acids extraction.

3. CONTENT.

Mucolysin reagent includes:

Reagent	*Description*	*Volume (ml)*	*Quantity*
Mucolysin	liquid	200	1 vial

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 flask for removing supernatant.
- Disposable 1.5 ml polypropylene tubes with screw or tightly closed caps.
- Tube racks.
- Waste bin with disinfecting solution.

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 expiry 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 other suitable disinfectant.
- Avoid contact with the skin, eyes and mucose membranes. If skin, eyes and mucose membranes contact immediately flush with water, seek medical attention.
- Material Safety Data Sheets (MSDS) are available on request.
- Use of this product should be limited to personnel trained in the techniques of DNA amplification.
- The laboratory process must be one directional; it should begin in the Extraction Area move to the Amplification and Detection Area. Do not return samples, equipment and reagents to the area in which the previous step was performed.

6. SAMPLING AND HANDLING.

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

Sputum samples are collected in 30-100 ml disposable graduated polypropylene containers with screw caps and wide neck. Samples can be stored 1 day at the temperature between 2 and 8°C, and for a long time at the temperature not more than 16°C.

7. PROTOCOL.

1. Add **Mucolysin** to container with sputum in ratio 5:1 (5 parts of **Mucolysin** and 1 part of sputum), using container graduation. Screw the cap, stir the content and incubate for 20-30 min at room temperature, periodically stirring the container (each 2-3 min).
2. After liquefaction of sputum (that is defined visually) transfer 0.1 ml of liquefied sputum, using tips with aerosol barrier, to the tube with screw or tightly closed cap.
3. Sample is ready to the nucleic acids isolation by extraction kits (for example, "DNA-sorb-B" REF K1-2-100-CE or K1-2-50-CE, "RIBO-sorb" REF K2-1-Et-50-CE or K2-1-Et-100-CE).
4. Residual part of liquefied sputum are to be stored in the container 1 day at the temperature between 2 and 8 °C and for a long time at the temperature not more than minus 16°C (if it is necessary to repeat nucleic acids extraction).

9. STABILITY AND STORAGE.

Mucolysin reagent is to be stored between 2 and 8°C, when not in use. It also must be stable until the expiry date stated on the label.

10. REFERENCES.

1. Manual “Sampling, transportation and storage of clinical material for PCR diagnostics”, developed by Federal State Institution of Science Central Research Institute of Epidemiology of Federal Service for Surveillance on Consumers’ Rights Protection and Human Well-Being, Moscow, 2008.

11. QUALITY CONTROL.

In accordance with Federal State Institution of Science “Central Research Institute of Epidemiology” ISO 13485 – certified Total Quality Management System, each lot of **Mucolysin** reagent is tested against predetermined specifications to ensure consistent product quality.

12. EXPLANATION OF SYMBOLS.

	Manufacturer		Temperature limitation
	Use by	LOT	Batch code
IVD	For *in Vitro* Diagnostic Use	VER	Version
REF	Catalogue number	ICc	Internal Control complex
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community.
	Consult instructions for use		Caution, consult accompanying documents
RG	For working with Rotor-Gene™ 3000/6000	iQ	For working with iQ5, iQ iCycler
CONTROL +	Positive control	CONTROL -	Negative control