IVD

For *in Vitro* Diagnostic Use

Transport Medium with Mucolytic Agent

Reagent for transportation and storage

of clinical material

Instruction Manual

AmpliSens®

EC REP

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1. INTENDED USE

Transport Medium with Mucolytic Agent is a reagent intended for transportation and storage of swabs and discharges collected from the urogenital tract, throat, rectum, eye conjunctiva, and erosive-ulcerative lesions of human skin and mucous membranes for subsequent analysis of the material for STIs and other reproductive tract infections by polymerase chain reaction (PCR) and nucleic acid sequence-based amplification (NASBA) with the use of reagent kits manufactured by CRIE.

2. PRINCIPLE

Transport Medium with Mucolytic Agent is a ready-to-use sterile pink buffer–salt solution supplemented with mucolytic, preservative, and stabilizing agents. The mucolytic agent ensures liquefaction of mucus, provides effective and homogenous mixing of clinical material with the transport medium. The preservative and stabilizing agents prevent the growth of nonspecific microflora and premature lysis of cell, providing long-term stability of RNA/DNA of microorganisms and viruses in a wide temperature range.

3. CONTENT

Transport Medium with Mucolytic Agent is produced in 1 form:

Transport Medium with Mucolytic Agent **REF** 952-CE.

Transport Medium with Mucolytic Agent includes:

Reagent	*Description*	*Volume (ml)*	*Quantity*
Transport Medium with Mucolytic Agent	Pink clear liquid	50	1 vial

Transport Medium with Mucolytic Agent is intended for 100 samples.

4. ADDITIONAL REQUIREMENTS

- Disposable powder-free gloves and laboratory coat.
- Disposable polypropylene Eppendorf 2.0-ml tubes (for example Axygen, USA).
- Automated pipette, 200-1000 µl.
- Sterile pipette tips with aerosol barriers, 1000 µl.
- Tube racks.
- Disposable sterile probes (tampons or cytobrushes) designed for collecting swabs and discharge from the urogenital tract (cervix, vagina, and urethra), throat, rectum, and erosive-ulcerative lesions of human skin and mucous membranes.
- Waste bin for used tips.

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile pipette tips with aerosol barriers and use new tip for every procedure.

- Use disposable gloves, laboratory coats, protect eyes while samples and reagents handling. Thoroughly wash hands afterward.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
- Do not use a reagent 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 accordance 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 mucosa. If skin, eyes and mucosa contact, immediately flush with water, 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.

Transport Medium with Mucolytic Agent is intended for transportation and storage of following clinical material: swabs and discharges collected from the urogenital tract, throat, rectum, eye conjunctiva, and erosive-ulcerative lesions of human skin and mucous membranes.

Storage and transportation of clinical material placed in the Transport Medium with Mucolytic Agent (make sure the tube is tightly closed):

- at room temperature (18-25 °C) for up to 28 days;
- at 2-8 °C for up to 3 month;
- at ≤–20 °C for a long time.

7. PROTOCOL

1. Dispense 0.5 ml of Transport Medium with Mucolytic Agent to 2.0-ml tubes using an aseptic technique. Tightly close the tubes and store them at 2 -25 °C.
2. Prior to opening a tube, make sure that the drops are removed from the tube cap.
3. Place the probe end with clinical material to a tube with Transport Medium with Mucolytic Agent, break off the shaft at the scratch mark (if applicable), and recap the tube. If there is no a scratch mark, sink the probe end in the medium, rotate the probe for 5-10 s pressing it to the tube wall, then remove the probe and recap the tube.

8. STABILITY AND STORAGE

Transport Medium with Mucolytic Agent is to be stored at 2–25 °C when not in use. Transport Medium with Mucolytic Agent is stable until the expiration date on the label.

9. REFERENCES

1. Handbook “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.

10. QUALITY CONTROL

In compliance with Federal State Institution of Science “Central Research Institute of Epidemiology” ISO 13485-Certified Quality Management System each lot of **Transport Medium with Mucolytic Agent** has been tested against predetermined specifications to ensure consistent product quality.

11. EXPLANATION OF SYMBOLS

	Manufacturer		Temperature limitation
	Use by	LOT	Batch code
IVD	For *in Vitro* Diagnostic Use	VER	Version
REF	Catalogue number		Caution, consult accompanying documents
	Contains sufficient for <n> tests	**CRIE**	Central Research Institute of Epidemiology (Moscow, Russia)
	Consult instructions for use		