Transport Medium with Mucolytic Agent

Reagent for transportation and storage of clinical material

Instruction Manual

CE IVD

For Professional Use Only

KEY TO SYMBOLS USED

REF	Catalogue number		Caution
LOT	Batch code		Sufficient for
IVD	*In vitro* diagnostic medical device		Use-by Date
VER	Version		Consult instructions for use
	Temperature limit		Date of manufacture
	Manufacturer	**FBIS CRIE**	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
EC REP	Authorized representative in the European Community		

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 FBIS CRIE.

Indications and contra-indications for use of the reagent

Transportation and storage of clinical material is used in preanalytical stage of in vitro diagnostics by nucleic acid amplification techniques (NAT).

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:

1 vial of 50 ml, 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 a laboratory coat.
- Pipettes (adjustable).
- Sterile pipette tips with aerosol filters (up to 1000 µl).
- Disposable polypropylene 2.0-ml tubes.
- 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.
- Reservoir for used tips.

5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile RNase/DNase-free 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 reagent 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 a 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 other 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.
- The reagent is intended for analysis of specified number of samples (see the section "Content").
- The reagent is ready for use in accordance with the Instruction Manual. Use the reagent strictly for intended purpose.
- 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.

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.

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 the temperature not more than minus 20 °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

Transport Medium with Mucolytic Agent should be used at 18–25 °C.

8. 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. Mark the tube.

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

9. TRANSPORTATION

Transport Medium with Mucolytic Agent should be transported at 2–25 °C.

10. 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 expiry date stated on the label. The shelf life of the reagent 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.

Not for use in the Russian Federation

12. QUALITY CONTROL

In compliance with Federal Budget Institute of Science "Central Research Institute for 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.

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
24.06.11 LA	Cover page, text	The name of Institute was changed to Federal Budget Institute of Science "Central Research Institute for Epidemiology"
23.07.12 Ivl	Content	New complement form was added and described
	Footer	New catalogue number 953-CE was added
27.02.17 PM	Through the text	Corrections according to the template
08.04.20 MA	Through the text	The text formatting was changed
	Footer	The phrase "Not for use in the Russian Federation" was added
21.10.20 MM	Footer, 3. Content	The information about REF 953-CE was deleted
11.03.21 VA	—	The name, address and contact information for Authorized representative in the European Community was changed
31.05.22 EM	1. Intended use	"Indications and contra-indications for use of the reagent" subsection was added
	5. General precautions	The phrase "for single use" was deleted
	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

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