

Transport Medium for Storage and Transportation of Respiratory Swabs

Reagent for sampling, transportation, and storage of upper respiratory tract swabs



For Professional Use Only

Instruction Manual

KEY TO SYMBOLS USED

	Catalogue number		Caution
	Batch code		Sufficient for
	<i>In vitro</i> diagnostic medical device		Use-by Date
	Version		Consult instructions for use
	Temperature limit		Date of manufacture
	Manufacturer		Authorized representative in the European Community

1. INTENDED USE

Transport Medium for Storage and Transportation of Respiratory Swabs is a reagent intended for sampling, transportation and storage of upper respiratory tract swabs.

Indications and contra-indications for use of the reagent

Sampling, 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 for Storage and Transportation of Respiratory Swabs is a phosphate buffer solution supplemented with preservative and cryopreservative agents. The salt composition and pH of the medium prevent premature lysis of cell in swabs, the preservative agent prevents the growth of foreign microflora, and the cryopreservative agent stabilizes microorganisms during freeze-thaw transitions.

3. CONTENT

Transport Medium for Storage and Transportation of Respiratory Swabs is produced in 1 form:

1 vial of 100 ml, 958-CE.

Transport Medium for Storage and Transportation of Respiratory Swabs includes:

Reagent	Description	Volume, ml	Quantity
Transport Medium for Storage and Transportation of Respiratory Swabs	colorless clear liquid	100	1 vial

Transport Medium for Storage and Transportation of Respiratory Swabs is intended for 200 samples.

4. ADDITIONAL REQUIREMENTS

- Disposable powder-free gloves and a laboratory coat.
- Autoclave.
- Disposable polypropylene 2.0-ml tubes.
- Pipettes (adjustable).
- Sterile pipette tips with aerosol filters (up to 200 and 1000 µl).
- Flocked swabs with plastic shafts for nasopharyngeal swabs.
- Rayon swabs with plastic shafts for oropharyngeal swabs
- Tube racks.
- Refrigerator for 2–8 °C.
- 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 for Storage and Transportation of Respiratory Swabs is intended for sampling, transportation, and storage of the following clinical material:

- **Nasal swabs** are obtained using sterile dry flocked swabs with plastic shafts for nasopharyngeal swabs. If the nasal cavity is full of mucus it is recommended to blow the nose before the procedure. Gently insert the swab along the external nasal wall to a depth of 2–3 cm towards the inferior nasal concha. Then move the swab slightly lower, insert in the inferior nasal meatus under the inferior nasal concha, rotate, and remove it along the external nasal wall.
- **Oropharyngeal swabs** are obtained using sterile dry rayon swabs with plastic shafts for oropharyngeal swabs. Rotate the swab over the surface of tonsils, palatine arches, and posterior wall of pharynx after gargling the oral cavity with water.

The samples (clinical material placed in the **Transport Medium for Storage and Transportation of Respiratory Swabs**) can be stored:

- at room temperature for 1 hour;
 - at 2–8 °C for 1 day;
 - at the temperature not more than minus 16 °C for 1 week.
 - at the temperature not more than minus 68 °C for a long time
- Transport the samples in an insulated container with cooling elements:
- at 2–8 °C for 1 day;
 - under refrigeration for up to 1 week.

NOTE: Only one freeze-thawing cycle is allowed.

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 for Storage and Transportation of Respiratory Swabs should be used at 18–25 °C.

8. PROTOCOL

1. Take the required number of sterile disposable tubes and tips and autoclave them at 0.2 MPa at 131 °C for 20 min.
2. Dispense 0.5 ml of **Transport Medium for Storage and Transportation of Respiratory Swabs** to sterile 2.0-ml tubes. Tightly close the tubes and store at 2–8 °C.
3. Take the required number of tubes with **Transport Medium for Storage and Transportation of Respiratory Swabs**.
4. Place the swab with clinical material in the tube with 0.5 ml of **Transport Medium for Storage and Transportation of Respiratory Swabs**.

It is recommended to combine nasal and oropharyngeal swabs in a single tube.

NOTE: For this purpose, place the ends of both shafts into one tube containing **Transport Medium for Storage and Transportation of Respiratory Swabs** and analyze them as a single sample.

5. Break off the end of shaft or cut it off to allow tight closing of the tube cup.
6. Close tube with solution and the swab. 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 for Storage and Transportation of Respiratory Swabs should be transported at 18–25 °C for no longer than 5 days.

10. STABILITY AND STORAGE

Transport Medium for Storage and Transportation of Respiratory Swabs is to be stored at 2–8 °C when not in use. **Transport Medium for Storage and Transportation of Respiratory Swabs** 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.

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 for Storage and Transportation of Respiratory Swabs** 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
05.07.11 VV	Cover page, text	The name of Institute was changed to Federal Budget Institute of Science "Central Research Institute for Epidemiology"
23.07.12 IV	Content	New complement forms were added and described
	Footer	New catalogue numbers 959-CE; 958-CE were added
27.02.17 PM	Through the text	Corrections according to the template
27.06.17 ME	4. Additional requirements	The swabs that are used for sampling were specified
	6. Sampling and handling	The section was rewritten
13.04.20 VA	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 959-CE; REF 957-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

AmpliSens®



Ecoli Dx, s.r.o., Purkyňova 74/2
110 00 Praha 1, Czech Republic
Tel.: +420 325 209 912
Cell: +420 739 802 523



Federal Budget Institute of
Science "Central Research
Institute for Epidemiology"
3A Novogireevskaya Street
Moscow 111123 Russia