



For *in Vitro* Diagnostic Use

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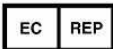
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**Transport Medium for Storage and
Transportation of Respiratory Swabs**

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

Instruction Manual

AmpliSens®



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1. INTENDED USE

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

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:

Transport Medium for Storage and Transportation of Respiratory Swabs, **REF** 957-CE.

Transport Medium for Storage and Transportation of Respiratory Swabs includes:

<i>Reagent</i>	<i>Description</i>	<i>Volume (ml)</i>	<i>Quantity</i>
Transport Medium for Storage and Transportation of Respiratory Swabs	colorless 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.
- Autoclave.
- Disposable polypropylene 2.0-ml Eppendorf tubes (for example, Axygen, USA).
- Pipette, 200-1000 µl.
- Sterile pipette tips with aerosol barriers (up to 1000 µl).
- Sterile probes (tampons).
- Tube racks.
- Refrigerator for 2–8 °C.
- 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 other suitable disinfectants.
- Avoid contact with the skin, eyes and mucosa. If skin, eyes and mucosa 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 is 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 taking, transportation, and storage of the following clinical material:

- Nasal swabs. If the nasal cavity of a patient is full of mucosa, make him to blow his nose prior to taking a swab. Insert the cotton bud end of a dry sterile swab into a nostril and rub firmly against the turbinate (to ensure that the swab contains cells as well as mucus).
- Throat swabs. Make a patient to rinse his mouth with water prior to sampling. Use a sterile cotton swab to swab both of the tonsils, palatine arches, and the posterior nasopharynx, without touching the sides of the mouth.

Storage and transportation of test material placed in the Transport Medium for Storage and Transportation of Respiratory Swabs:

Storage:

- at room temperature for 1 hour;
- at 2–8 °C for 1 day;
- at ≤–16 °C for 1 week.
- at ≤–68 °C for a long time.

Transportation (in a box with cooling packs):

- at 2–8 °C for 1 day;
- frozen up to 1 week.



Only one freeze–thaw cycle is allowed.

7. 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 Eppendorf 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 probe end 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. To do this, place probe ends with collected material in the same tube with the transport medium and analyze as a single sample.

5. Cut or break off the shaft and recap the tube firmly.
6. Make sure that the tube is secure. Label the tube.

8. STABILITY AND STORAGE

Transport Medium for Storage and Transportation of Respiratory Swabs is to be stored at the temperature 2–8 °C when not in use. Transport Medium for Storage and Transportation of Respiratory Swabs is stable until the labeled expiration date.

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 for Storage and Transportation of Respiratory Swabs** has been tested against predetermined specifications to ensure consistent product quality.

11. EXPLANATION OF SYMBOLS



Manufacturer



Temperature limitation



Use by



Batch code



For *in Vitro* Diagnostic Use



Version



Catalogue number



Caution, consult accompanying documents



Contains sufficient for <n> tests

CRIE

Central Research Institute of Epidemiology (Moscow, Russia)



Consult instructions for use