

For Professional Use Only

Transport Medium Plus

Reagent for transportation and storage

of clinical material

Instruction Manual



¥ 100

KEY TO SYMBOLS USED



NAME Transport Medium Plus

INTENDED USE

Transport Medium Plus is a reagent intended for transportation and storage of swabs and discharges collected from the urogenital tract, throat, rectum, eye conjunctiva, and erosiveulcerative 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).

PRODUCT USE LIMITATIONS

The **Transport Medium Plus** kit is not for use with human whole blood, tissue, stool samples, or cultured cells.

The kit performance has not been evaluated with other than swabs samples.

QUALITY CONTROL

In accordance with Sacace's ISO 13485-Certified Quality Management System, each lot is tested against predetermined specifications to ensure consistent product quality.

PRINCIPLE OF ASSAY

Transport Medium Plus 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.

MATERIALS PROVIDED

Transport Medium Plus includes:

Reagent	Description	Volume (ml)	Quantity
Transport Medium Plus	Pink clear liquid	50	1 vial

Transport Medium Plus is intended for 100 samples.

MATERIALS REQUIRED BUT NOT PROVIDED

- 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 erosiveulcerative lesions of human skin and mucous membranes.
- Waste bin for used tips.

WARNINGS AND 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.
- Identify each tube with sample to avoid the risk of jumbling of specimens.

SPECIMEN COLLECTION AND CONSERVATION



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

Transport Medium Plus 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 Plus** 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.

WORKING CONDITIONS

Transport Medium Plus should be used at 18-25 °C.

PROTOCOL

- 1. Dispense 0.5 ml of **Transport Medium Plus** 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 Plus**, 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.

TRANSPORTATION

Transport Medium Plus should be transported at 2–25 °C.

STABILITY AND STORAGE

Transport Medium Plus is to be stored at 2–25 °C when not in use. **Transport Medium Plus** is stable until the expiration date on the label. The shelf life of an opened reagent is the same as that of unopened reagent, unless otherwise stated.



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