

# **Product Specifications**

**Disposable sampler  
Inactivated Transport Media**

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# Disposable sampler

## 1. Product Introduction

### 1.1 Intended Use

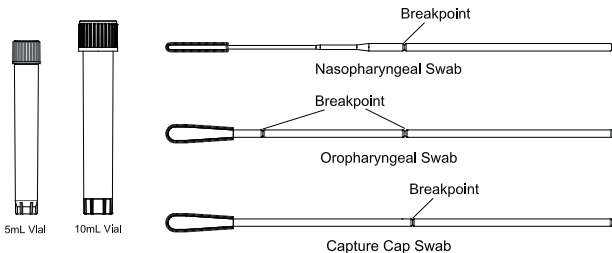
NEST ITM is an enclosed system intended for the collection, stabilization and transportation of pharyngeal and nasal swabs from the collection site to the testing laboratory. The specimen transported in NEST ITM can be used for molecular detection in the laboratory.

 Note: the product is disposable and intended for sample collection, transportation and storage, etc. Usage for purposes beyond the intended use is forbidden.

### 1.2. Product Structure

The product is composed of preservation tubes filled with ITM (Inactivated Transport Media), with or without swabs, depending on the product type.

- NEST ITM is composed of Guanidine isothiocyanate, TCEP, sodium acetate, Tris, Hcl, purified water, etc.
- The preservation tube is made of medical-grade PP materials.
- The swab head is made of flocked nylon fiber, and the rod is made of ABS (acrylonitrile butadiene styrene).



### 1.3. Principles of The Procedure

The NEST ITM device consists of a preservation tube with the preservation solution. These components are intended to destruction of cellular structure, lyse cells, disrupt/lyse lipid membranes, denatures proteins, inactivates enzymes, and stabilize DNA/RNA .

### 1.4. Application Environment

The sample solution can be stored for 20 days at ambient temperature after sampling.

### 1.5. Storage Temperature

Ambient temperature transportation and storage.

## 2. Guidelines for Use

- Take out the proper disposable sampler.
- Check if the product package is intact.
- Open the carton from the opening at one end of the pack.
- Take out the sample swab and the preservation tube.
- Unscrew the cap of the preservation tube and set aside for later use.
- Open the packing bag of the swab and take a sample from the specified sampling site with the swab head.

**Oropharyngeal Specimen Collection Swab:** With the patient seated, if possible, tilt the head back 70 degrees. Gently insert swab into back of the throat and tonsillar area. Rub the swab over both tonsillar pillars and the posterior oropharynx, avoid touching the tongue, teeth and gums.

**Nasopharyngeal Specimen Collection Swab:** With the patient seated, if possible, tilt the head back 70 degrees. Gently insert swab into the nostril along the septum floor of the nose extending straight back until the posterior nasopharynx is reached (distance from nostrils to external opening of ear). Rotate the swab several times while the swab is in contact with the nasopharyngeal wall.

- After sampling, put the swab vertically into the opened preservation tube and break the tube at the breaking mark. Keep the swab head in the preservation tube and dispose of the rod in the medical waste box.

- Put the cap of the preservation tube on and screw it tightly, shake the tube up and down until the swab head is completely immersed in the preservation solution.
- Record the information of the person who performed sampling in the writing area of the preservation tube.
- Sample collection is completed and should be stored at ambient temperature for maximum 20 days before testing.



### 3. Maintenance and Storage

Vehicles like automobiles are used for transportation; the shipping boxes should be strong enough to ensure that products won't be damaged under normal transportation conditions.

When transported in open vehicles, the shipping boxes should be well covered with tarpaulin and the overlap part of the tarpaulin should be placed in a way that the rainwater flows to its sides to avoid invasion of rainwater into the boxes.

The products should be stored in a dry, clean and well-ventilated environment at ambient temperature, without corrosive gases, avoiding direct sunlight. The lifetime of the product is 24 months.

### 4. Performance Characteristics

#### 4.1. Appearance

Transparent clarifying solution

#### 4.2. Sample Preservation Effect


Parainfluenza Virus 2, adenovirus and Influenza A were used to verify the preservation ability of NEST ITM. 2\*LoD and 20\*LoD concentration of the samples were stored in NEST ITM at 2°C-8°C and 25°C, and the PCR nucleic acid tests were performed at 20 days after storage.


All the PCR tests were positive, and there was no significant difference for the different storage temperature.

## 5. Precautions

### 5.1. Explanations for Symbols Used In The Label


 Automatically invalid after one-time use.

 Important warning information for users, which they need consult the Operating Manual for reference

 The medical device should not be used if the package has been damaged or opened

### 5.2. Safety Requirements

- Please do not use if the individual package has been damaged before use.
- Please do not use if the preservation solution is turbid or leaking or the preservation tube is broken.
- Do not use expired products or products with damaged package.
- Infiltrating the swab with preservation solution before sampling is forbidden.
- Do not pour out or spill the preservation solution.
- The preservation solution is forbidden to be directly touched by the sampled Person.
- The sampling should be performed by a professional strictly per the sampling procedure; sample tests should be conducted in a laboratory that meets the required safety grade.
- Personal protective measures like gloves and masks are required when using this product.
- Used sample collection solution should be discarded as medical waste.
- Keep the product away from the reach of children (or persons with low-grade intelligence).
- The product is disposable and intended for sample collection, transportation and storage, etc. Usage for purposes beyond the intended use is forbidden.

 1. If you accidentally come into contact with the preservation solution, please wash the affected site with plenty of water immediately.

2. If the preservation solution gets into the mouth or eye or is swallowed accidentally, please get medical attention immediately.

### 5.3 Use Requirements

- Please read the Operating Manual of this product carefully before use.
- Please use the product in strict accordance with the operating steps.
- Please do not forcibly pull out the tube cap or it would cause poor air tightness and the tube will not work properly.
- Please use the device immediately once opened.
- Please do not break the swab if not yet using it.
- Before use, please wash hands with disinfectant and wear gloves and masks.
- Please do not directly touch the swab with the hands to prevent contamination.
- After sampling, the samples should not be stored at ambient temperature for more than 20 days.
- After use, please properly dispose of it as medical waste.
- Please use the product before its expired date.



1. Used sample collection solution should be discarded as medical waste.

### 6. Failures and Solutions

Failure	Cause	Solution
The tube cap cannot be opened	Slightly more force is needed to open the cap at first time	Unscrew the cap with the help of slip-proof gloves

## 7. Quality Assurance

- If the user encounters quality problems caused by manufacturing reasons during the lifetime when following the storage and use conditions specified in this Manual, please contact us or the designated agent of our company.
- For any product failures, please contact us or the franchised agent of our company; never open the product components for repair without authorization. Our company do not take any responsibility for product repair performed without our authorization or for product repair by someone other than the agent designated by us.
- During the product lifetime, the costs of materials, logistics, business trips and other costs arising from product damage due to non-compliance with this manual, shall be paid by the user.
- The indicators and functions in this Manual are subject to changes after registration without notice.

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