

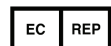
Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
	<i>In vitro</i> diagnostic medical device		Use-by date
	Manufacturer		Do not re-use
	Date of Manufacture		Consult instructions for use
	Batch code		CE Symbol
	Authorized representative in the European Community / European Union		Unique device identifier
	Caution		Catalogue number
	Keep Dry		Do not use if package is damaged and consult instructions for use

Basic Information



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Version: A/0

Sample Collection Kit Instructions for Use

Packaging Specifications

50 tests/box; 50 sets/pack

Intended Use

Sample Collection Kit is intended for collecting, stabilization and inactivation of human upper respiratory specimens. It consists of Disposal Swab and Viral Sample Preservation Solution (Inactivated).

Disposable Collection Swab is designed for collecting specimens. Disposable Collection Swab is sterile and individually packaged. There are one and/or two kinds of Disposable Collection Swab in the package. The Type N swab is used for collecting nasopharyngeal (NP) swab, nasal swab (NS), the break point of the nasopharyngeal/nasal swab is far away from swab head. The Type O swab is used for collecting oropharyngeal (OP) swab, and break point of the oropharyngeal swab is closer to the swab head.

Viral Sample Preservation Solution (Inactivated) is designed for stabilization and inactivation of specimens at room temperature for up to 1 week. It contains 3 mL solution which is comprised of the following reagents: urea x sodium dodecyl sulfate (SDS) x TRIS x EDTA x Ethanol (molecular grade) x Nuclease-free water.

Sample Collection Kit is intended for use by qualified clinical personnel and *in vitro* diagnostic procedures.

Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.

The product can be stored at 2-35°C for 12 months before use.

The product can be transported at 2-40°C within 30 days.

Specimen Collection, Handling, and Storage

The product is used to collect upper respiratory Specimens (e.g., nasopharyngeal (NP) swab, oropharyngeal (OP) swab, nasal swab (NS)).

The collected specimens could be stored at room temperature (37°C below) for up to 1 week, for longer storage, store samples at -80°C.

Use Methods

1. Clean hands before sampling, tear open the package, and take out the swab. Be careful not to touch the swab head.
2. According to different sampling requirements, carefully collect the sample from corresponding parts. Samples are collected in accordance with clinical standards.

2.1 Collecting an NP specimen (performed by a trained personnel):

- 2.1.1 Tilt patient's head back 70 degrees.
- 2.1.2 Gently and slowly insert a disposal swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- 2.1.3 Gently rub and roll the swab.
- 2.1.4 Leave swab in place for several seconds to absorb secretions.
- 2.1.5 Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the disposal swab is saturated with fluid from the first collection.
- 2.1.6 If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
- 2.1.7 After the collection is completed, unscrew cover of Viral Sample Preservation Solution (Inactivated), and put swab into tube.
- 2.1.8 Break off the redundant swab handle at the nozzle and leave the swab head in the Viral Sample Preservation Solution (Inactivated).
- 2.1.9 Rotate the tube cover and the Viral Sample Preservation Solution (Inactivated) tube shall be tightened.

2.2 Collecting an OP specimen (performed by a trained personnel):

- 2.2.1 Insert swab into the posterior pharynx and tonsillar areas.
- 2.2.2 Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
- 2.2.3 After the collection is completed, unscrew cover of Viral Sample Preservation Solution (Inactivated), and put swab into tube.
- 2.2.4 Break off the redundant swab handle at the nozzle and leave the swab head in the Viral Sample Preservation Solution (Inactivated).

2.2.5 Rotate the tube cover and the Viral Sample Preservation Solution (Inactivated) tube shall be tightened.

2.3 Collecting an NS specimen (performed by a trained personnel):

- 2.3.1 Blew the patient's noses with toilet paper, Tilt patient's head slightly.
- 2.3.2 The sampler gently holds the head of the person to be collected with one hand, sticks the swab to one side of the nostril and enters the area, slowly dives into the nose along the bottom of the lower nasal canal 1-1.5cm backward, then sticks the swab to the nasal cavity and rotates it for at least 4 times (the stay time is not less than 15 seconds), then repeats the same operation in the other nasal cavity with the same swab.
- 2.3.3 After slowly removing the swab, dip the swab head into the sample container containing preservation solution.

Warnings and Precautions

1. This product is intended for professional use only.
2. Check the package of disposal swab before use it. If damaged, it is strictly prohibited to use.
3. DO NOT insert swab into the reagent before collecting a sample.
4. For single use only. Avoid reuse.
5. Carefully collect the sample avoid injuring the patients when sampling.
6. DO NOT drink, touch or remove the reagent from the vial.
7. The reagent can be harmful if ingested and may cause irritation if exposed to the skin and eyes. IF swallowed: call a POISON CENTER or doctor/physician if you feel unwell. If on skin: wash with plenty of soap and water. If in eyes: rinse cautiously with water for several minutes, remove contact lenses, if present and easy to do, continue rinsing.
8. Used products maybe contain virus, that will cause infection. Used product and product that are past their shelf-life must be disposed of as special waste in accordance with local guidelines.
9. Do not bend swabs prior to specimen collection.
10. If any serious incident that has occurred in relation to the product shall be reported to the manufacturer and the competent authority.



GHS07

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.