



Sample Preservation Solution

Instruction for Use

English VER 5.0

REF Refer to Box Label.

PRODUCT NAME

Sample Preservation Solution

PACKAGING SPECIFICATION

20 Sets/Kit, 36 Sets/Kit, 50 Sets/Kit, 100 Sets/Kit etc.

INTENDED USE

This kit is intended for collection, transport and preservation of clinical specimens to be processed with molecular diagnostic platforms. For Professional Use.

PRINCIPLE

The main components of the preservation solution are guanidine salt, surfactant, buffer, etc. This kit could inactivate the pathogens such as virus and bacteria in the samples, inhibit the nuclease activity and stabilize the DNA/RNA in pathogens and human cells. Keeping the nasopharyngeal and oropharyngeal swabs in the preservation solution benefits the subsequent nucleic acid analysis.

MAIN COMPONENTS

1. Tubes with Medium
2. Swab(s)
3. Biosafety Bags (Optional)





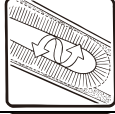






STORAGE CONDITION AND EXPIRATION

Expiration: 2 years

Storage condition: 2-30 °C

USAGE METHOD

1. Fill the necessary information on the label before sampling.
2. According to the sample collection requirements of different positions, collecting the sample in the corresponding position with disposable swabs.
3. Please refers to the table below for swab sample collection steps:

Nasopharyngeal sampling		Oropharyngeal sampling	
	Take out the swab.		Take out the swab
	Gently and slowly insert the swab through the nostril parallel to the palate until resistance is encountered.		Insert swab into the posterior pharynx and tonsillar areas, rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
	Gently rub and roll the swab at least 3 times, leaving it in place for 15-30 seconds to absorb secretions. Slowly remove the swab while rotating it.		After the sample collected, insert the swab into the tube containing preservation solution.
	After the sample is collected, place the swab into the tube containing the preservation solution.		Break the swab at breakpoint, leave the swab head in the solution.
	Break the swab at breakpoint, leave the swab head in the solution.		Close the tube tightly.
	Close the tube tightly.		

4. Samples are recommended to test as soon as possible, when the samples cannot be tested in 24 hours, keep them at $-(20\pm 5)^{\circ}\text{C}$. Keep the samples at -70°C for a long-time storage.
5. If the transportation cannot be guaranteed at $-(20\pm 5)^{\circ}\text{C}$, the sample should be transported at least at $0-8^{\circ}\text{C}$.















PRECAUTIONS

1. The person who uses the kit should be trained and wear a mask, gloves, and other relevant protective equipment.
2. Never touch the swab head with hands or other items when using the swab.
3. The product is disposable. Never reuse it.
4. Never use the product when its package is broken.
5. Never use the product when the preservation solution isn't clear, or the tube is broken.

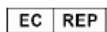
6. Never use the product when it expires.
7. The risk of choking! Be careful when the sampling swab is inserted into the mouth, throat, or nasal cavity.
8. The risk of breakage! Do not use violent force during the swab sampling process to prevent the swab from breaking.
9. The samples used and their culture wastes should be regarded as potentially infectious substances, and should be handled in accordance with the operating specifications of the infectious disease laboratory before they can be discarded.
10. When collecting samples, professionals should strictly follow the national sampling procedures; when samples are tested, they should be operated in laboratories that meet the safety level.
11. If there is any serious incident occurs in relation to the device, please report to the manufacturer and the competent authority in your country immediately.

Manufacturing date and expiration date: view on label

INDEX OF SYMBOLS

	Consult Instructions for Use		Contain \leftrightarrow tests		Do not use if package is damaged and consult instruction for use
	In vitro diagnostic medical device		Use-by date		Authorized Representative in the European Community
	Catalogue #		Lot Number		Temperature limit 2 to 30°C
	Manufacture Date		Manufacturer		CE conformity marking
	Caution		Do not reuse		

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Revision History

Version	Date	Description
English VER 0.0	2020-11-09	First Release
English VER 1.0	2021-02-19	Change the manufacturer address from 6th to 6-7 th.
English VER 2.0	2021-04-15	2-8 grade to 2-30 grade
English VER 3.0	2021-12-17	Change the kit components
English VER 4.0	2022-01-20	Add Biosafety Bags in Main Components
English VER 5.0	2022-05-08	Modified according to IVDR