

Disposable Swab

Instruction for use

EN Ver No: 20220508

PRODUCT NAME

Disposable Swab

PRODUCT MODEL

N-8, N-10, O-3, O-8, O-9

Model	Product description	Sampling site
N-8	150mm, minitip size nylon flocked swab with 80 mm breaking point	Nasopharynx
N-10	150mm, minitip size nylon flocked swab with 100 mm breaking point	
O-3	150mm, regular size nylon flocked swab with 30 mm breaking point	Oropharynx
O-8	150mm, regular size nylon flocked swab with 80 mm breaking point	
O-9	150mm, regular size nylon flocked swab with two breaking points (30 mm and 80 mm breaking point)	

PACKAGING SPECIFICATIONS

1Pcs/Bag, 100 Pcs /Box, 200 Pcs /Box, 300 Pcs /Box, 500 Pcs /Box

INTENDED USE

Used for sample collection.

PRODUCT DESCRIPTION

Individual swabs. (The swab is not sterile.)

TEST PRINCIPLE

Swabs are available with different size and shape of both shaft and tip for the different body collection sites. Different types of fiber tips including nylon are available. These materials can help to collect enough samples and make no impacts on subsequent experiments. The swab shaft is made of plastic, which is designed to be easily broken.

PRODUCT COMPONENTS

The swab contains the shaft and tip. The swab tip is made of synthetic fiber, and the swab shaft is made of plastic rod.

STORAGE




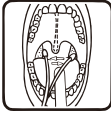
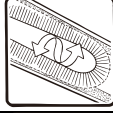





Shelf-life: 3 years.

Storage condition: 2-30 °C

DIRECTIONS FOR USE

1. Select an appropriate swab to collect samples according to sampling requirements;
2. Open the package and take out the swab.
3. According to the sampling requirements of different parts, collect the sample in the corresponding parts with disposal swabs.
4. Process the swab according to internal laboratory procedure. Alternatively put the swab into the sample collection tube immediately after collecting the sample.
5. Send the sample to the laboratory for immediate testing.

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.

WARNINGS AND PRECAUTIONS















- Operators who use this product should be trained and wear mask, gloves and other relevant protective equipment.
- During use, do not touch the swab head with hands or other objects.
- The product is only used for sample collection, for one-time use only and cannot be reused.
- Don't use the product when its package is damaged.
- Don't use the product when it expires.
- The collected samples must be sent for inspection as soon as possible to ensure the accuracy of the results;
- The risk of choking! Be careful when the sampling swab is inserted into the mouth, throat, or nasal cavity.
- The risk of breakage! Do not use violent force during the swab sampling process to prevent the swab from breaking.
- Ensure that the top of the sampling swab does not touch any surface before collection;
- 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;
- 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.
- The product should be stored in a dry, ventilated, non-radiation and no corrosive gas clean room.
- 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.

WASTE DISPOSAL

- Unused swabs may be considered as non-hazardous waste and disposed of accordingly.
- Dispose of used swabs as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

Manufacturing date and expiration date: view on label

INDEX OF SYMBOLS

	Consult Instructions for Use		Biological risks		EU-Authorized Representative
	Medical Device		Use-by-date		Do not reuse
	Do not use if package is damaged		Batch Code		Caution
	Catalogue number		Manufacturer		CE Symbol
	Non-Sterile		Manufacture Date		



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【Revision history】

Version	Description	Date
20210204	First Release	2021-02-04
20210219	Changes in the "Storage" section	2021-02-19
20210223	Changes in the "Warnings and precautions"	2021-02-23
20220508	Modified according to MDR	2022-05-08