

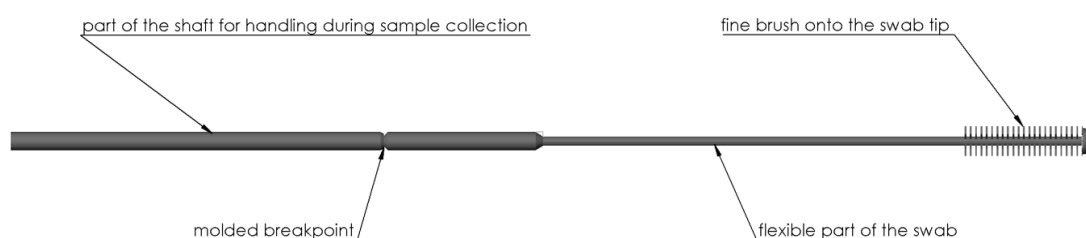
3D printed nasopharyngeal swab (fine brush)

Product insert & specific instructions regarding specimen collection

Description

3D swabs are steam or EO sterile. They are packed individually or by 3 in a medical grade peel pouch.

The unique design of the swab ensures good sample uptake and optimal elution of the specimen into the transport medium.



Each swab has a molded breakpoint facilitating easy breakage of the swab into the transport tube.

Intended use

3D Swab is a ready-for-use device intended for the collection of nasopharyngeal secretions.

The **3D Swab** is one unit to be part of a collection kit (not provided) including a tube with 1-3 ml of appropriate liquid transport media as Liquid Amies Medium or UTM.

For safe transportation of the collected specimen, following sampling, the swab must be placed immediately into sterile tubes containing the appropriate transporting media. The screw cap of the tube is replaced and secured tightly. Then, the tube should be transferred directly to the laboratory. If transportation or processing is delayed, the specimens should be stored refrigerated at 4-8°C

Warnings - precautions

- This product is for single use only.
- It cannot be re-sterilized or re-used.
- To be handled by trained healthcare provider only
- **Not intended for paediatrics patients**
- **Not recommended for patients under anticoagulant treatment**
- In all cases, when collecting specimens from patients, **never use excessive force or bending of the swab** to prevent accidental breakage of the swab shaft

Collection guidelines for diagnostic of Covid-19

Proper collection of specimens is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false negative test results. The following specimen collection guidelines follow standard recommended procedures

For initial diagnostic testing for Covid-19, a nasopharyngeal specimen is the preferred choice for upper respiratory swab-based sample collection. 3D swabs can be used for testing asymptomatic persons.

All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider.

Insert the 3D swab with a flexible shaft 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. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. 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 tip is saturated with fluid from the first collection. 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.

Swab should be placed immediately in a sterile transport tube containing Amies transport medium or UTM.

Disclaimer

The 3D Swab is placed on the market on the basis of a derogation granted by the Minister de Block and the The Federal Agency for Medicines and Health Products of Belgium (FAMHP) for the marketing and for the implementation of medical devices which are not CE marked. This is part of the exceptional measures taken during the COVID-19 pandemic in the interest of health protection. The usage of the 3D Swab is strictly limited to Belgium and cannot be exported. Any-Shape specifically disclaims any responsibility if the present instructions are not correctly followed and on the final result of the COVID-19 diagnostic testing. The collecting act remains entirely under the responsibility of the healthcare provider.