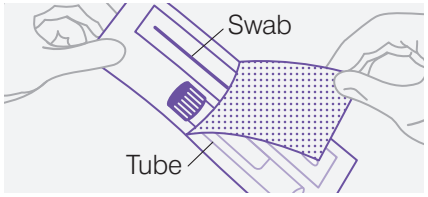
COVID-19
Point of Care

visby medical™

Recommended Health Care Provider Collection Instructions

NASOPHARYNGEAL SPECIMEN



Step 1 Open the Kit

Wash your hands. Put on a new pair of gloves.

Open the specimen collection kit. Set aside the tube.

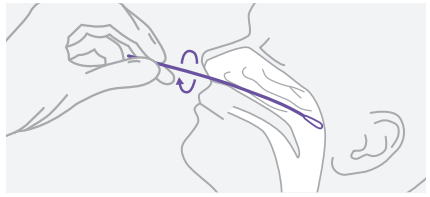
Step 2 Unwrap the Swab

Hold the swab handle in your hand, by placing it between your thumb and your index finger.

⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.

Step 3 Insert the Swab

Tilt patient's head back 70 degrees. Gently and slowly insert a minitip swab with a flexible shaft through the nostril parallel to the palate until resistance is encountered. The distance is equivalent to that from the nostril to the ear of the patient, indicating contact with the nasopharynx.

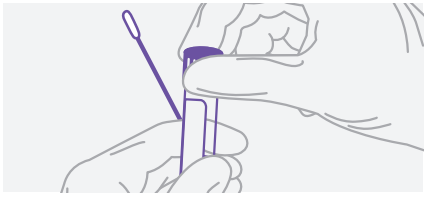


Step 4 Collect a Sample

Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions.

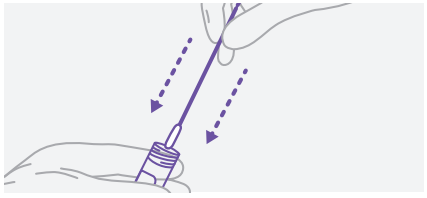
If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Slowly remove swab while rotating it.

Specimens can be collected from both nostrils, but it is not necessary if the swab is saturated with fluid from the first nostril.



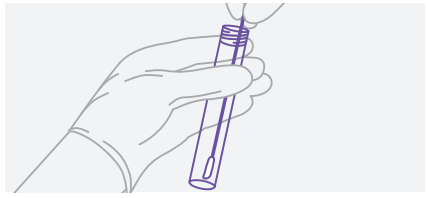
Step 5 Open the Tube

Carefully unscrew the cap ensuring the soft tip of the swab doesn't touch anything. Set the cap down.



Step 6 Insert the Swab

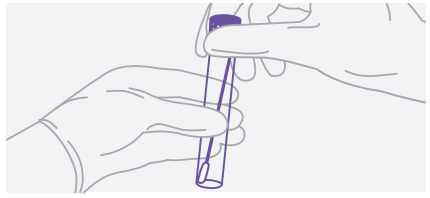
Carefully place swab, tip first, into the tube provided.



Step 7 Store the Swab

Once the tip is near the bottom, break the swab handle at the swab breakpoint by bending back and forth or cut it with sterile scissors. The swab should sit in the tube comfortably so that the cap can be screwed on.

Discard the swab handle immediately.



Step 8 Secure the Tube

Screw the cap back on tightly to prevent contamination.

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IMPORTANT INFORMATION

⚠ Users should read the complete collection procedure before performing specimen collection.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.