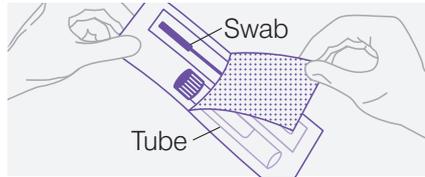


Recommended Health Care Provider Collection Instructions

MID-TURBINATE DUAL NOSTRIL SPECIMEN

Note: Please swab both nostrils with the same swab.



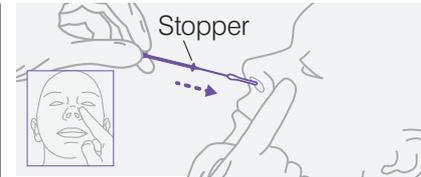
Step 1 Open the Kit

Wash your hands. Put on a new pair of gloves.
Open the specimen collection kit. Set aside the tube.



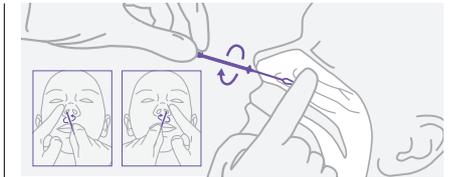
Step 2 Unwrap the Swab

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. Use a flocked tapered swab. Some swabs come with a stopper, which indicates proper nasal insertion depth. While gently rotating the swab, insert the soft tip of the swab less than one inch (about 2 cm) into the nostril parallel to the palate until resistance is met at turbinates.



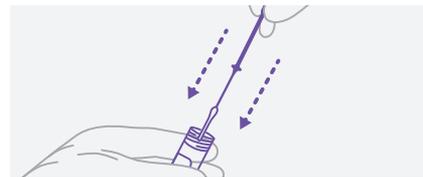
Step 4 Collect a Sample

Rotate the swab several times against the nasal wall. Withdraw the swab slowly.
Using the same end of the swab, repeat steps 3-4 with the other nostril.
⚠ Ensure the soft tip does not touch anything after removing it from the nostril.



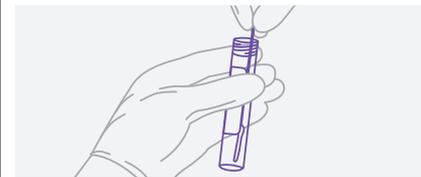
Step 5 Open the Tube

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.

IMPORTANT INFORMATION

⚠ Users should read the complete collection procedure before performing specimen collection. Do not over-insert the swab.

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.

COVID-19

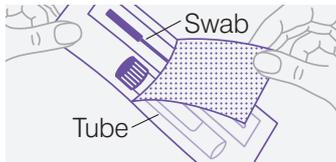
Point of Care

Recommended Self-Collection Instructions in Health Care Settings

visby medical™

MID-TURBINATE DUAL
NOSTRIL SPECIMEN

Note: Please swab both your nostrils with the same swab.



Step 1 Open the Kit

Wash your hands.
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.

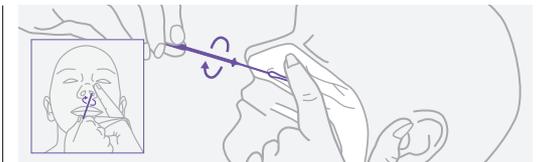
⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.



Step 3 Insert the Swab

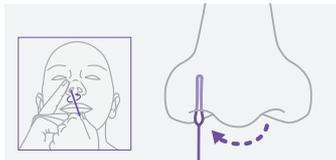
Your sample collection swab includes a stopper which indicates when to stop inserting the swab. Tilt your head back, look up towards the ceiling, and place your index finger directly above the rim of your nostril. While gently rotating the swab, insert the soft tip of the swab parallel to the roof of your mouth until the stopper touches the edge of your nostril and you feel resistance.

⚠ If you experience pain, stop immediately.



Step 4 Collect a Sample from First Nostril

Rotate the swab several times against the nasal wall. Withdraw the swab slowly.



Step 5 Collect a Sample from Other Nostril

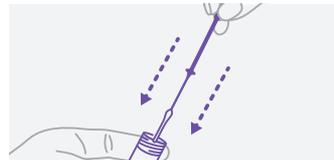
Use the same swab and repeat Steps 3 & 4.

⚠ Keep the swab in your hand during Step 5 and make sure the soft tip does not touch anything after removing it from your nostril.



Step 6 Open the Tube

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



Step 7 Insert the Swab

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



Step 8 Store the Swab

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

Discard the swab handle immediately.



Step 9 Return Tube

Screw the cap back on tightly to prevent contamination. Wash your hands with soap and water.

IMPORTANT INFORMATION

⚠ Users should read the complete collection procedure before performing specimen self-collection. Do not over-insert the swab.

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.

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