# Recommended Self-Collection Instructions in Health Care Settings

DUAL NOSTRIL ANTERIOR NASAL SPECIMEN

IVD
For in vitro diagnostic use

℞ Only
For prescription use only

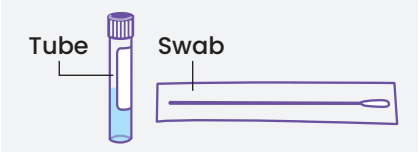
For individuals 14 years of age or older, under the supervision of a Healthcare Provider

For use under Emergency Use Authorization (EUA) only

visby medical™

**NOTE:** Please swab **both nostrils** with the same swab. Read the complete instructions before collecting specimen.

## STEP 1 Prepare Materials

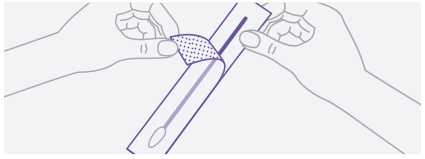



Wash your hands.

Identify the Visby Medical Respiratory Health Buffer tube.

⚠ Do not use rayon or cotton swabs with this test. Use only swabs provided by your healthcare provider.

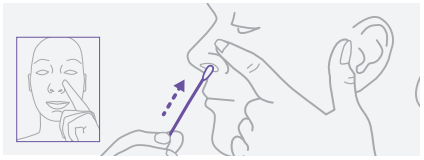
## STEP 2 Unwrap the Swab



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.

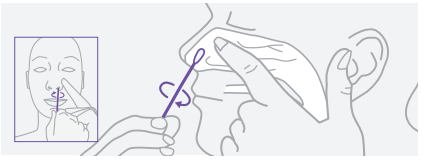
## STEP 3 Insert the Swab



Place your index finger above the rim of your nostril and gently insert the soft tip of the swab into one nostril just until the soft tip is no longer visible (½ to ¾ inch or 1 to 1.5 cm).

⚠ If you experience pain, stop immediately. Do not over-insert the swab.

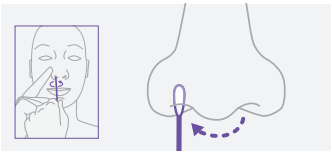
## STEP 4 Collect First Nostril



Rotate the swab slowly in your left nostril, making at least four sweeping circles around the inside wall of your nostril. This should take approximately 10-15 seconds per nostril. Withdraw the swab slowly.

⚠ Ensure the soft tip does not touch anything after removing it from the nostril.

## STEP 5 Collect Second Nostril



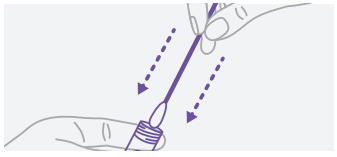
Use the same swab and repeat Steps 3 & 4 in your right nostril.

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

## STEP 6 Open the Buffer Tube

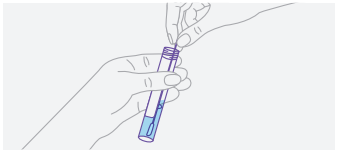
Carefully unscrew the cap of the buffer tube, ensuring the soft tip of the swab doesn't touch anything. Set the cap down.

## STEP 7 Insert the Swab



Hold the buffer tube opening away from you and carefully insert the soft tip of the swab into the buffer tube.

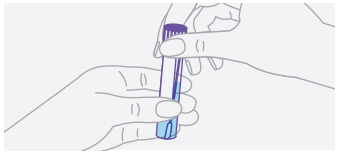
## STEP 8 Store the Swab



Once the tip is near the bottom of the buffer tube, 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 9 Secure the Buffer Tube



Screw the cap back on tightly to prevent contamination.

Wash your hands with soap and water.

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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 and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B, 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.

# Recommended Health Care Provider Collection Instructions

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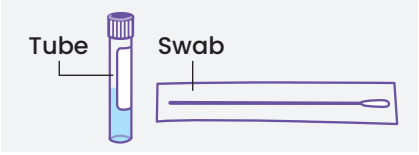
**NOTE:** Please swab **both nostrils** with the same swab. Read the complete instructions before collecting specimen.

## STEP 1 Prepare Materials

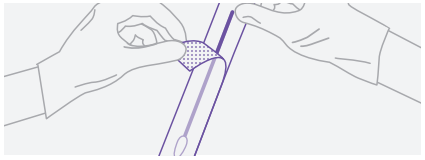



Wash your hands. Put on a new pair of gloves.

Identify the Visby Medical Respiratory Health Buffer tube.

⚠ Do not use rayon or cotton swabs with this test.

## STEP 2 Unwrap the Swab



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

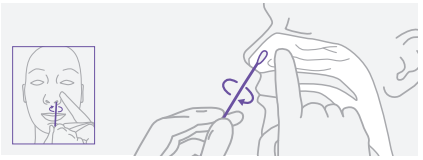
⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.

## STEP 3 Insert the Swab

Place your index finger directly above the rim of the patient's nostril. Gently insert the swab into the nose until the swab touches the inner walls of the nose.

Do not over-insert the swab.

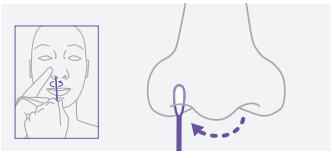
## STEP 4 Collect First Nostril



Rotate the swab slowly in the patient's left nostril, making at least four sweeping circles around the inside wall of the nostril. This should take approximately 10-15 seconds per nostril. Withdraw the swab slowly.

⚠ Ensure the soft tip does not touch anything after removing it from the nostril.

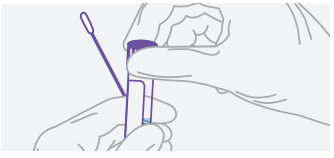
## STEP 5 Collect Second Nostril



Using the same end of the swab, repeat Steps 3 & 4 in the second nostril.

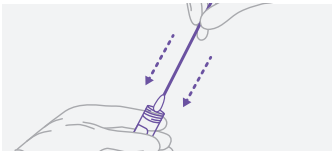
⚠ Keep the swab in your hand during Step 5 and make sure the soft tip does not touch anything after removing the swab from the nostril.

## STEP 6 Open the Buffer Tube



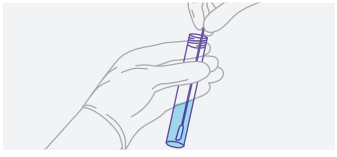
Carefully unscrew the cap of the buffer tube, ensuring the soft tip of the swab doesn't touch anything. Set the cap down.

## STEP 7 Insert the Swab



Hold the buffer tube opening away from you and carefully insert the soft tip of the swab into the buffer tube.

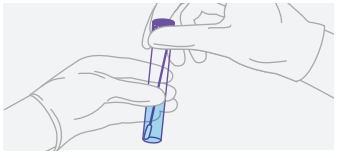
## STEP 8 Store the Swab



Once the tip is near the bottom of the buffer tube, 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 9 Secure the Buffer Tube



Screw the cap back on tightly to prevent contamination.

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