Recommended Health Care Provider Collection Instructions

NASOPHARYNGEAL SPECIMEN

IVD For in vitro diagnostic use

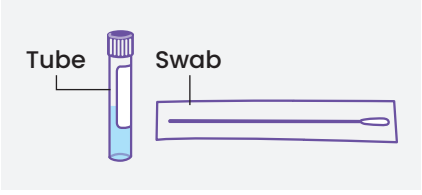
℞ Only For prescription use only

For use under Emergency Use Authorization (EUA) only

visby medical™

NOTE: 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.

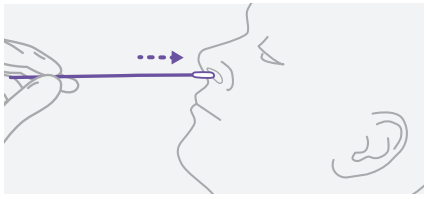
⚠ Do not use rayon or cotton swabs with this test.

STEP 2 Unwrap the Swab

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

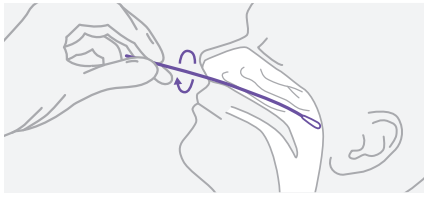
⚠ Do not touch the soft tip of the swab with your finger or on any surfaces. If you do, start again with a new kit.

STEP 3 Insert the Swab



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.

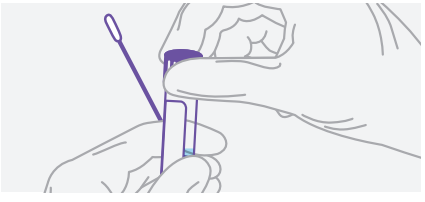
STEP 4 Collect a Sample



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

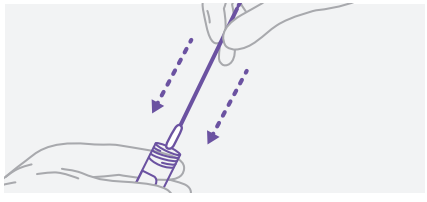
Do not over-insert the swab.

STEP 5 Open the Buffer Tube



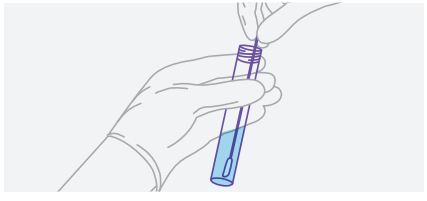
Carefully unscrew the cap of the buffer tube, ensuring the soft tip of the swab doesn't touch anything. Set the cap down.

STEP 6 Insert the Swab



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

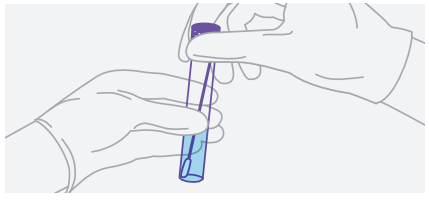
STEP 7 Store the Swab



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 8 Secure the Buffer Tube



Screw the cap back on tightly to prevent contamination.

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.