



IVD

EUA Only

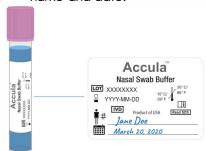


COV4100

FOR ANTERIOR NASAL SWAB SPECIMENS

Nasal sample self-collection guide:

Label Accula Nasal Swab
Buffer or Accula
SARS-CoV-2 Buffer with your
name and date.



Peel open the swab package and remove swab from package.



Hold the base of the swab. Do not touch the tip of the swab.

Watch yourself in a mirror and insert the tip of the swab into one nostril until you feel slight resistance (less than one inch).



Rotate the tip of the swab against all surfaces of nasal wall ten times.

Remove the swab from your nostril. Using the same swab, repeat step 3 in your other nostril.



Rotate the tip of the swab against all surfaces of nasal wall ten times.

Remove the swab from your nostril. While still holding the base of the swab, **remove** cap of the Buffer vial.



Do not touch the tip of the swab. Be careful **not to spill** liquid contents.

Insert tip of the swab into Buffer vial liquid.



Rotate the tip of the swab five times against inside wall of buffer vial.



Dispose of the swab as instructed by testing site personnel.



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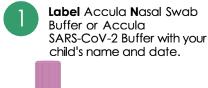
Replace Buffer cap. **Return** vial as instructed by testing site personnel.



Store the sample at room temperature until tested.

NOTE: If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.

Adult sampling guide for children ages 5 to 17:





Peel open the swab package and remove swab from package.



Hold the base of the swab. Do not touch the tip of the swab.

Tilt child's head back 45 – 70 degrees to gain access to child's nostril. Insert the tip of the swab slowly into one nostril until you feel slight resistance (less than 1/2 Inch).



Gently rub the tip of the swab against the child's nasal wall for 10 rotations.

Remove the swab from your child's nostril. Using the same swab, repeat step 3 in your child's other nostril.



10x

Gently rub the tip of the swab against the child's nasal wall for 10 rotations.

Remove the swab from the child's nostril. While still holding the base of the swab, **remove cap** of the Buffer vial.



Do not touch the tip of the swab. Be careful **not to spill** liquid contents.

6 Insert tip of the swab into Buffer vial liquid.



Rotate the tip of the swab five times against inside wall of Buffer vial.



Dispose of the swab as instructed by testing site personnel.



Replace Buffer cap. Return vial as instructed by testing site personnel.



Store the sample at room temperature until tested.

NOTE: If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.

NOTE: This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The product 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.



For questions or assistance, contact us at techsupport@thermofisher.com



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