Accula™ TEST

SARS-CoV-2

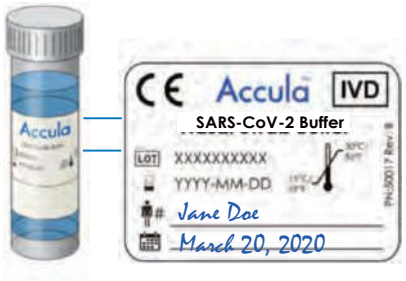
Quick Reference Guide

℞ only | IVD | EUA Only | REF | COV4100

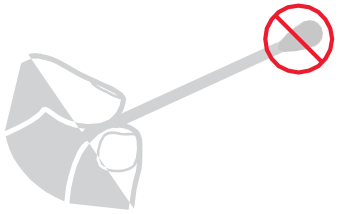
FOR NASAL SWAB SPECIMENS

Nasal sample self-collection guide:

1 **Label** SARS-CoV-2 Buffer with your name and date.

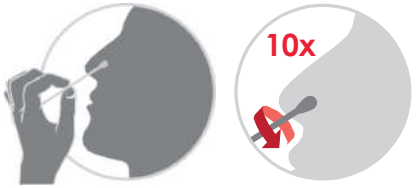


2 **Peel open** the swab package and remove swab from package.



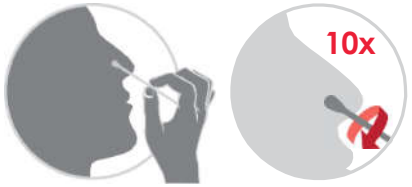
Hold *the base of the swab. Do not touch the tip of the swab.*

3 **Watch** yourself in a mirror and insert the tip of the swab into one nostril until you feel slight resistance.



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

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

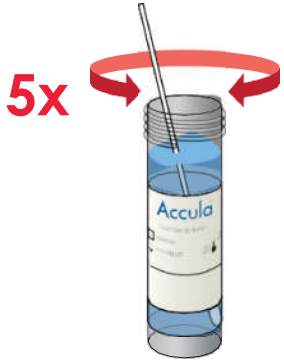


Rotate *the tip of the swab against all surfaces of nasal wall ten times.*

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

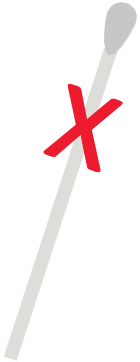
Do not touch *the tip of the swab. Be careful* ***not to spill*** *liquid contents.*

6 **Insert tip** of the swab into Buffer vial liquid.



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

7 **Dispose** of the swab as instructed by testing site personel.



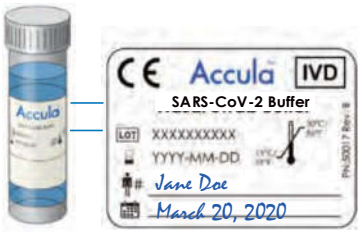
8 **Replace** Buffer cap. **Return** vial as instructed by testing site personnel.

Store *the sample at room temperature until tested.*

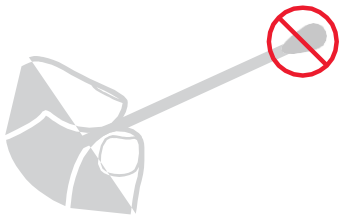
NOTE: If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.

Adult sampling guide for children ages 5 to 17:

1 **Label** SARS-CoV-2 Buffer with your child's name and date.

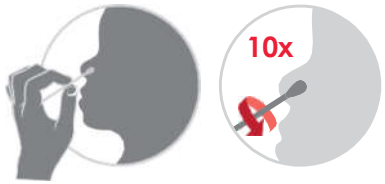


2 **Peel open** the swab package and remove swab from package.



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

3 **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.



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

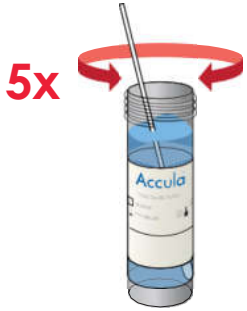
4 **Remove** the swab from your child's nostril. Using the same swab, repeat step 3 in your child's other nostril.

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

5 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.*

7 **Dispose** of the swab as instructed by testing site personel.

8 **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 test has not been FDA cleared or approved but has been authorized for emergency use by FDA for use by 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 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 test 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 test 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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Quick Reference Guide

For questions or assistance, contacts us at info@mesabiotech.com

Mesa Biotech, INC.
6190 Cornerstone Court East, Suite 220
San Diego, CA 92121, USA
www.mesabiotech.com

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