Quick tips

The Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test uses polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of nucleic acid from SARS-CoV-2 from individuals suspected to have COVID-19 by their health care provider.

To help ensure success when using the Accula SARS-CoV-2 Test with the Accula™ Dock, always follow the Accula Dock Operator’s Guide and the Accula SARS-CoV-2 Test Instructions for Use. Failing to adhere to the Instructions for Use can result in inaccurate or invalid results. See the Accula SARS-CoV-2 Test Instructions for Use and Accula Dock Operator’s Guide for more information.

Tips for sample collection, elution, and handling
• Do not use visually bloody or overly viscous samples

• Elute specimen swabs in Accula™ SARS-CoV-2 Buffer immediately after sample collection; do not elute samples in media other than the Accula SARS-CoV-2 Buffer

• Eluted samples may be stored at room temperature for up to two hours

• Bring refrigerated or frozen samples to room temperature before beginning the assay

Tips for pipetting
• Squeeze the top bulb prior to inserting the pipette stem into the patient sample; squeezing the bulb after the pipette tip is submerged can create air bubbles

• While continuing to squeeze the top bulb, place the pipette tip well below the surface of the liquid in the buffer vial; slowly release the top bulb to aspirate the sample

• Ensure the pipette stem is filled with the sample and there are no bubbles in the stem

• Pipettes are for single use only; if the pipetted sample has air bubbles, insufficient sample, or other issues, discard the pipette into a biohazardous waste container and use a new pipette from the bag of extra pipettes provided in the test kit to aspirate a new sample

Tips for loading the sample into the cassette
• Insert the pipette stem into the sample port of the cassette until resistance is met

• Squeeze the top bulb of the pipette firmly and quickly to load the sample into the cassette in a single, quick bolus

• Load only the volume of sample in the pipette stem; do not try to force the contents in the overflow reservoir into the cassette

Tips for the dock
• Do not operate the dock near an open window or heater that may cause temperatures to fluctuate—ensure the dock runs in constant ambient temperatures (15 to 30°C or 59 to 86°F) throughout the test

• Store the dock on a flat surface away from anything that may generate movement or heat (e.g., a centrifuge)
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.