Introduction to the Accula Platform

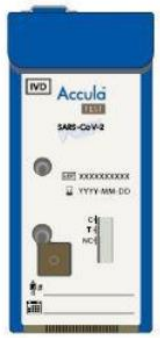
The world leader in serving science

Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test*

- Rapid (~30 minutes)
- Easy to use
- Simple workflow
  (no need to send testing out)
- Immediately actionable results

* 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.

Inside the Accula SARS-CoV-2 Test Kit



SARS-CoV-2 Test Cassette

SARS-CoV-2 Buffer

Transfer Pipette

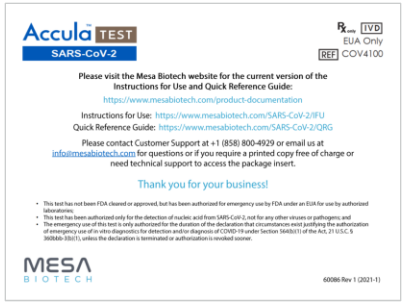
Sterile Swabs

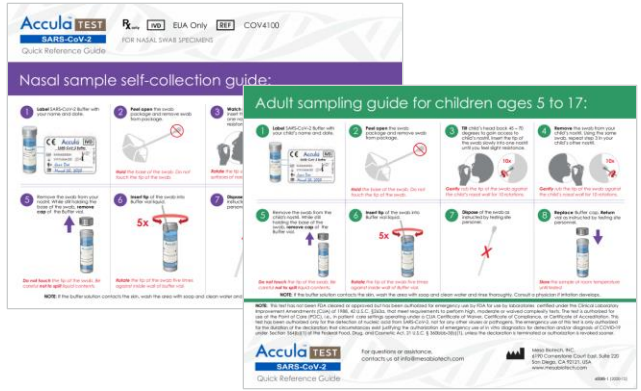
SARS-CoV-2 High Positive Control Swab
SARS-CoV-2 Low Positive Control Swab
SARS-CoV-2 Negative Control Swab

Accula SARS-CoV-2 Test Kit:

- 25 cassettes
- 25 transfer pipettes
- 25 buffers
- 25 swabs
- 3 controls (high positive, low positive, negative)
- Extra transfer pipettes
- Self-collection quick reference guide
- Electronic “Instructions For Use” (IFU) card

Electronic dock operator’s guide card with dock

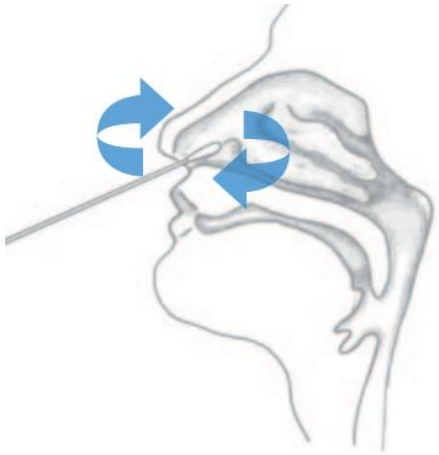


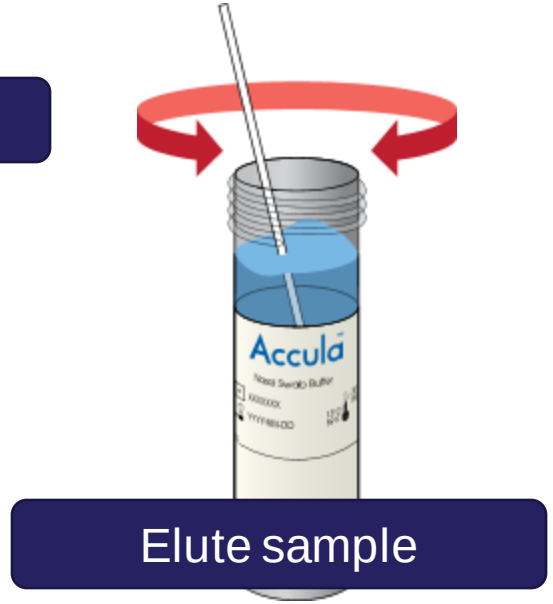


Simple workflow like conventional lateral flow tests

Combining molecular PCR accuracy with a traditional visual result

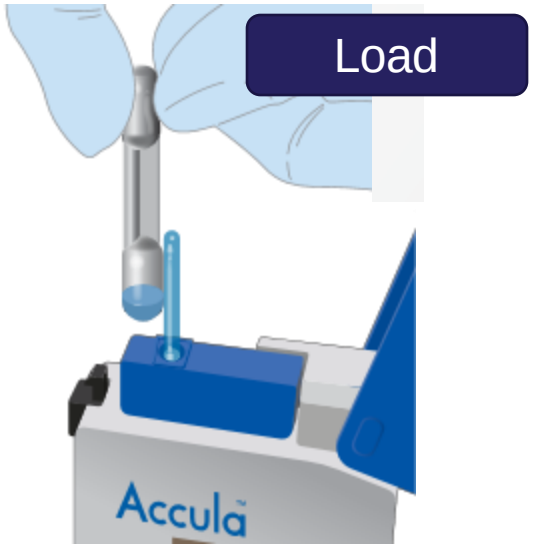
Collect sample





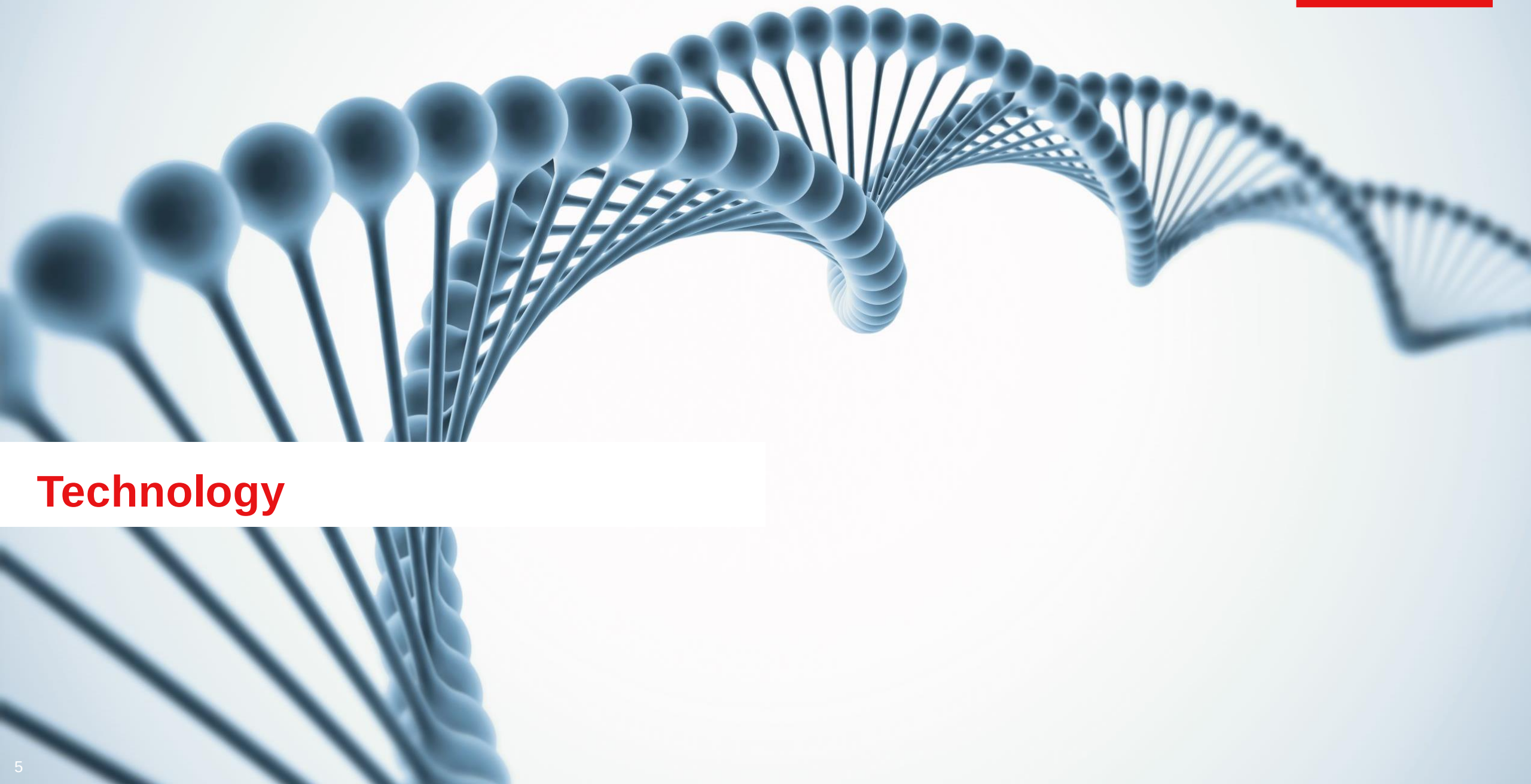
Elute sample

Load



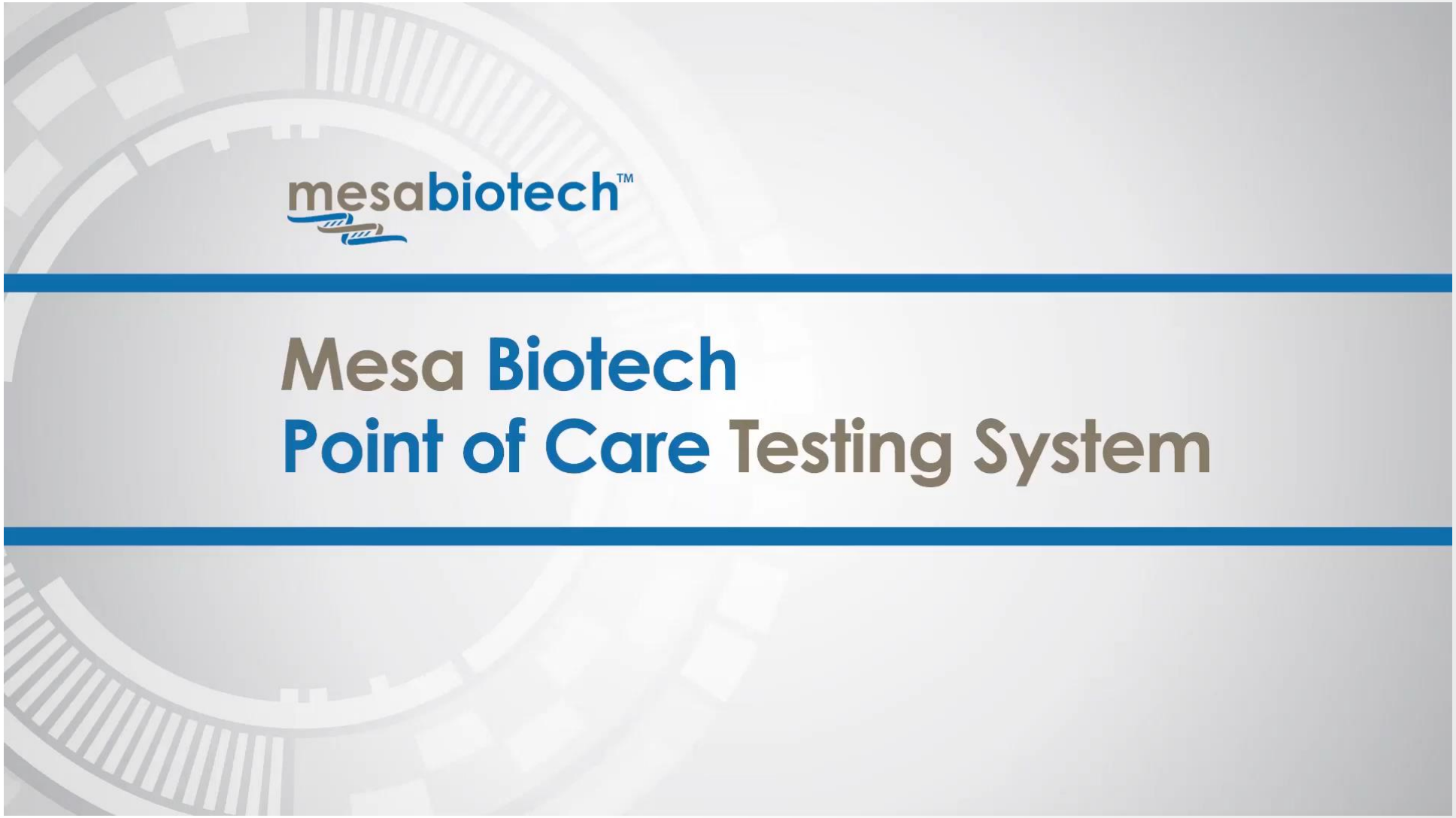
Read

PCR accuracy | Easy to use | Room temperature storage | Small footprint



Technology

Technology—inside the cassette



Accula SARS-CoV-2 Test

Set up the Accula Dock

- **Place the dock on a clean, flat surface.**
- **Connect** the AC adapter to the power cord.
- **Insert** the AC adapter into the dock. Plug the power cord into the electrical outlet.

Start-up messages:

MESA BIOTECH, INC.
MOLECULAR POC

FIRMWARE
P/N 210405 v. B

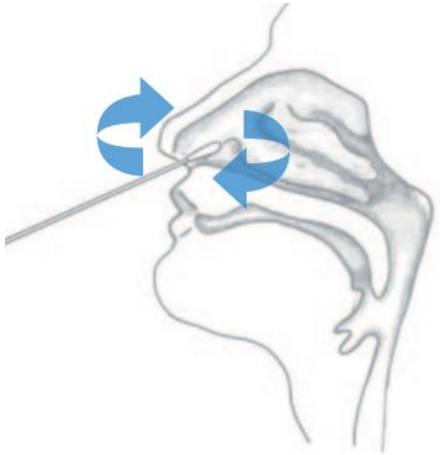
AMBIENT
TEMPERATURE: 25C

DOCK READY
INSERT CASSETTE

DOCK READY
INSERT CASSETTE

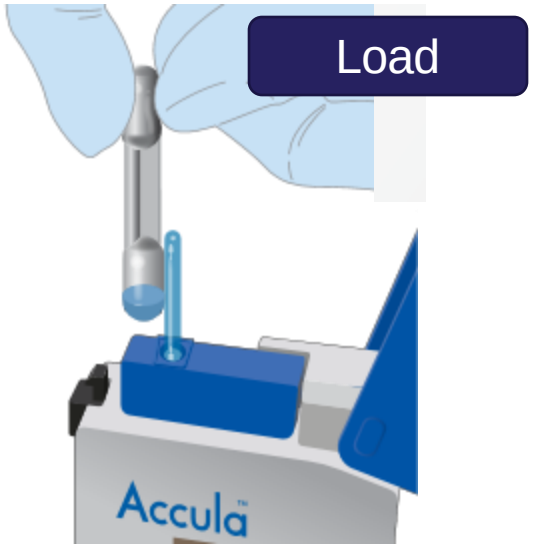
Accula SARS-CoV-2 Test workflow

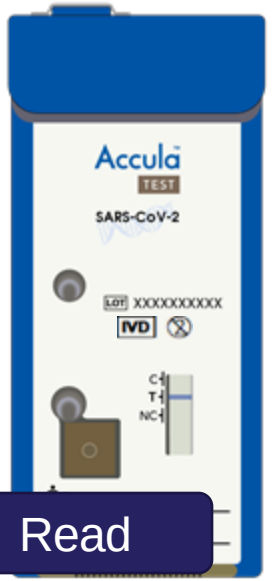
Collect sample



Elute sample

Load

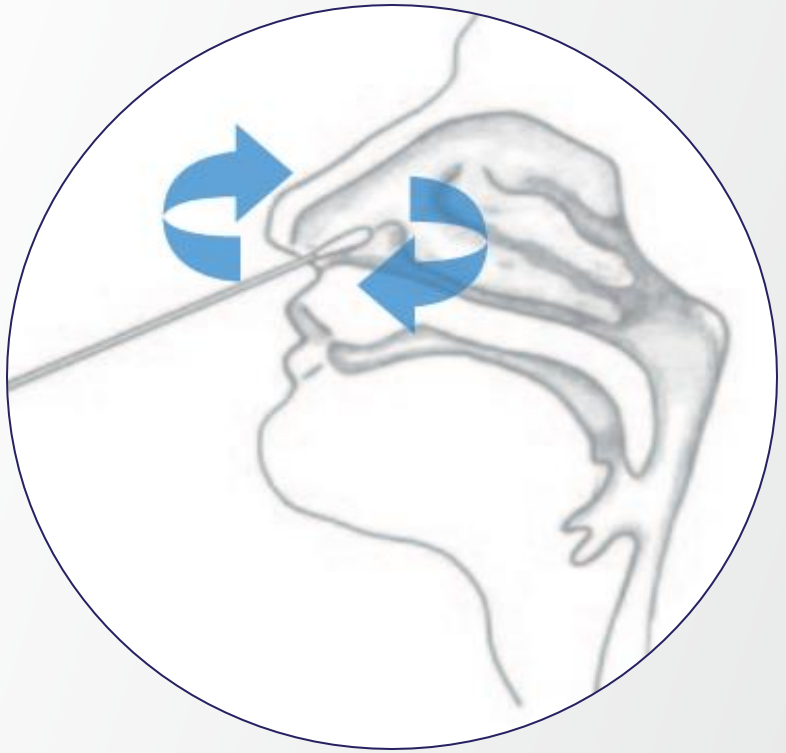




Read

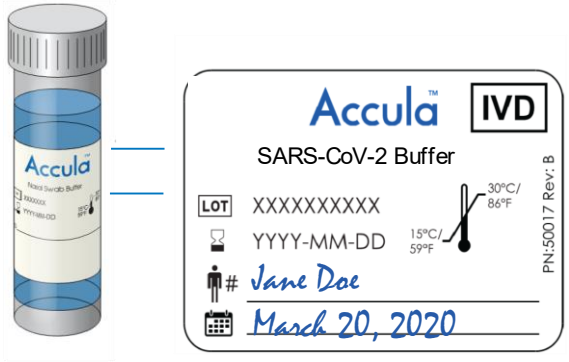
Collect the nasal swab

- **Insert** the swab into the nostril until resistance is met where the nasal passage begins to narrow.
- **Rotate** the swab firmly against the side of the nasal wall **10 times. Sample collection should not be painful.**
- Using the same swab, **repeat** this sampling in the other nostril.

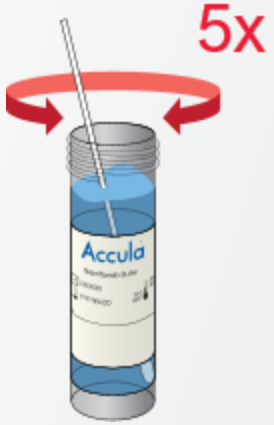


Collect sample with a firm but gentle swab. Do not aggressively swab.

Elute the sample immediately after collection



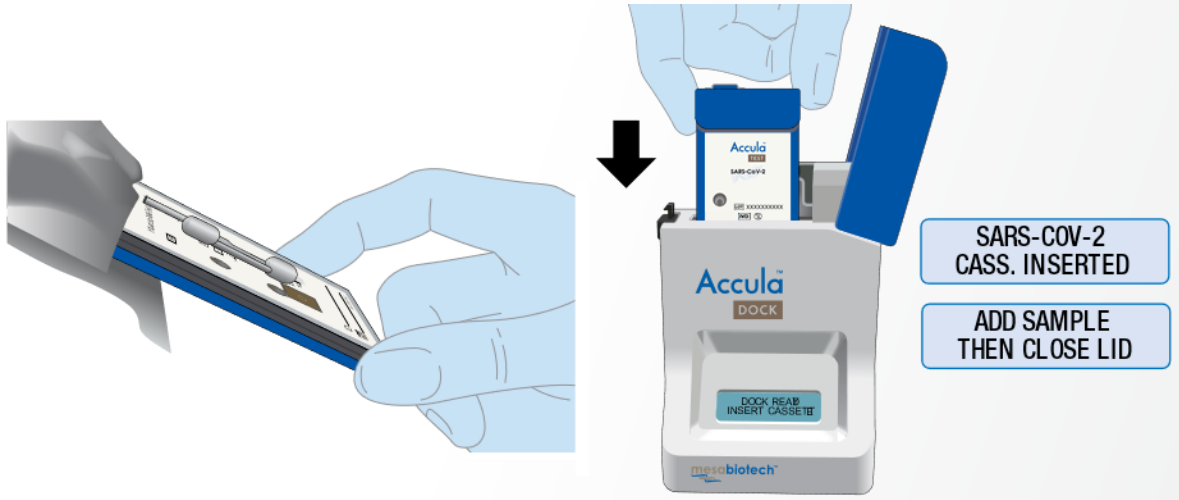
Label Accula SARS-CoV-2 Buffer vial.



- **Insert** nasal swab specimen into buffer (fully submerge).
- **Rotate** swab exactly **5 times against wall of vial.** Be sure to maintain contact with the wall of the vial for better elution.
- **Replace** the cap on the SARS-CoV-2 Buffer vial.

Rotating the swab more than indicated can result in an invalid test result.

Insert the test cassette



Remove test cassette from foil pouch and **label** test cassette. This step must be **completed no more than 30 minutes prior** to running the test.

Insert test cassette into Accula Dock. Once the test cassette is placed into the dock, add sample into the test cassette **within 5 minutes**.

Do not close dock lid or remove foil tab.

Pipetting technique is key to ensuring a valid test result

Top bulb
Squeeze here.

The top bulb is used to aspirate the sample from the buffer vial and dispense the sample into the cassette.

Overflow chamber

Any additional volume will flow into the overflow chamber. Do NOT squeeze the overflow chamber.

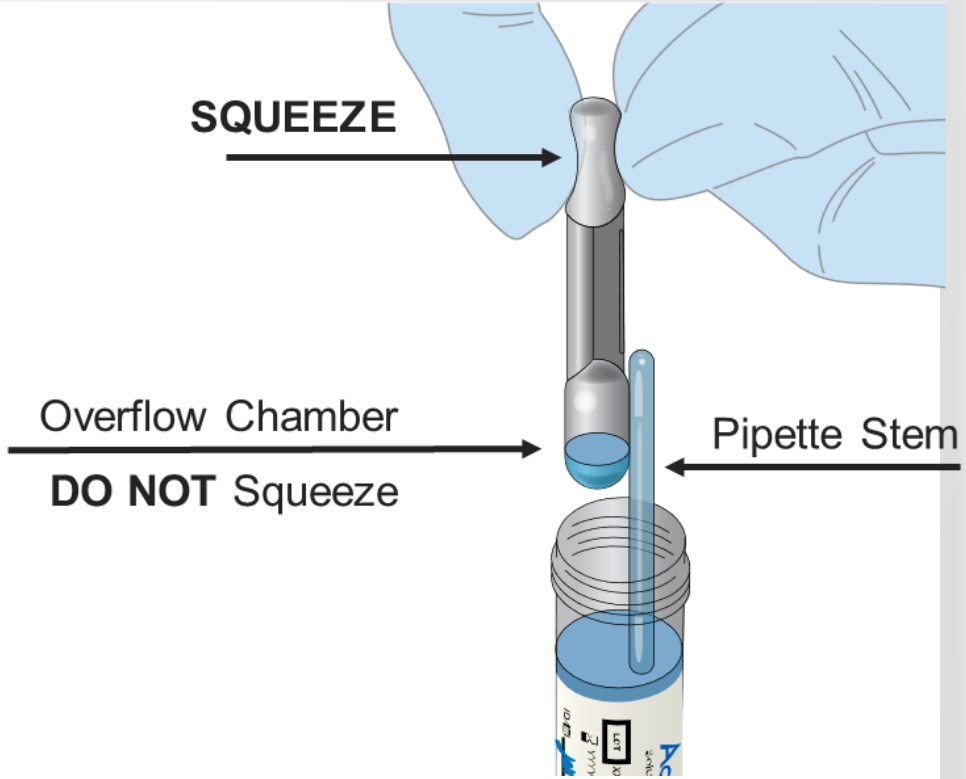
Pipette stem

The pipette stem must be submerged into the buffer vial.

Pipette is calibrated to aspirate a specific volume. Use only the pipette in the kit.

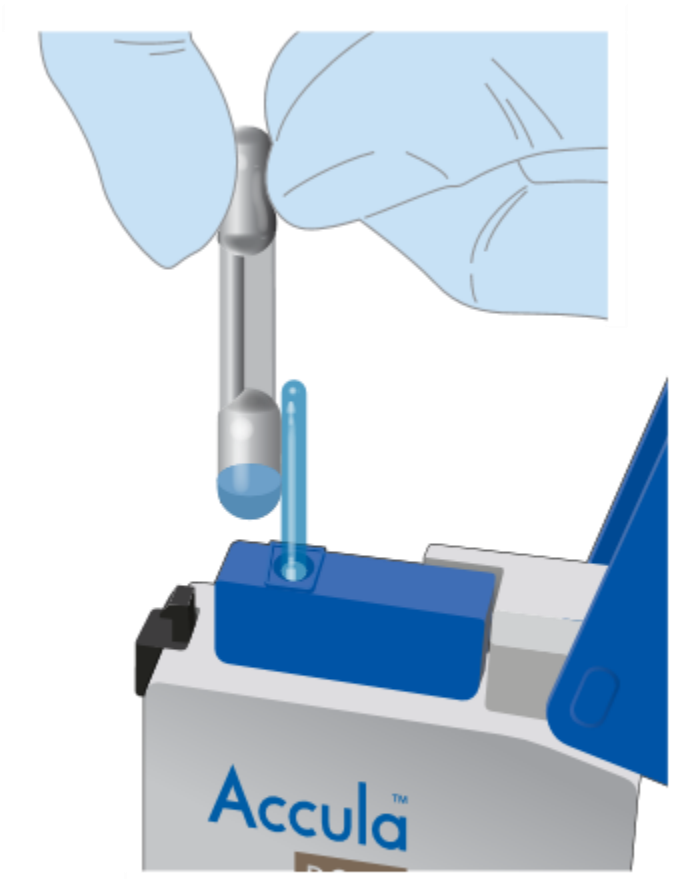
Aspirate the sample

- **Invert** SARS-CoV-2 Buffer vial to mix
- **Fill** the pipette by **firmly** squeezing the **top bulb** and placing the pipette tip into the sample
- **Slowly release the** bulb while the tip is still in sample
- Make sure there is liquid in the overflow chamber and no air bubbles in the lower part of the pipette/pipette stem



Improper pipetting technique can result in either too much or too little sample and can cause invalid results.

Load the sample



- Remove the foil tab. Sample must be added within 5 minutes of foil tab removal.
- Insert the pipette tip into the bottom of the sample port until resistance is met
- Squeeze the **top bulb** of the pipette firmly to dispense the sample into the test cassette
- While still squeezing the top bulb, **remove** the pipette from the sample port—do not wait for the dock to confirm the sample has been loaded before removing the pipette. **The dock can take up to two minutes to register that the sample has been loaded.**

Start the test

When the prompt below appears, **close** the lid of Accula Dock to automatically begin the test.

SAMPLE LOADED
CLOSE LID

Do not move, unplug dock, or open lid while test is running, or results will be invalidated.

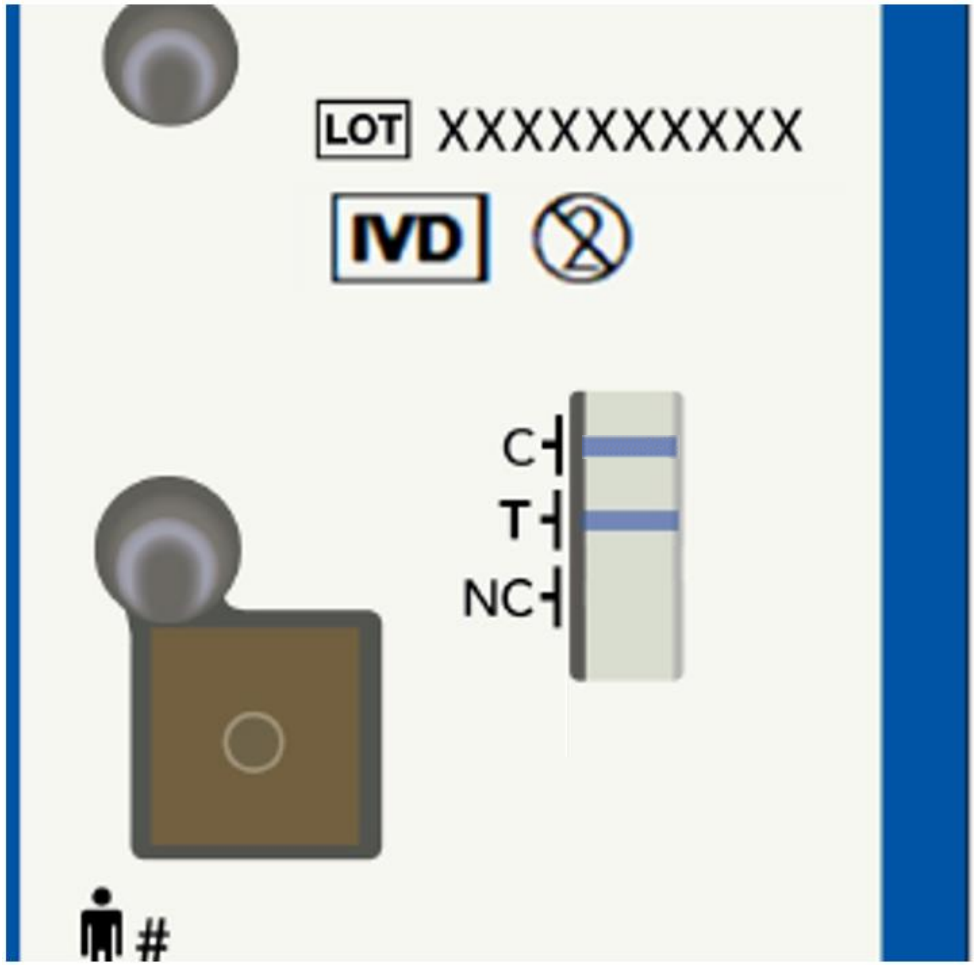
Read the result

- When the prompt below appears, open the dock lid and remove the test cassette.
- Interpret and record the results

TEST COMPLETE
READ RESULTS

Remove cassette within 1 hour of completion and read result immediately upon removal.

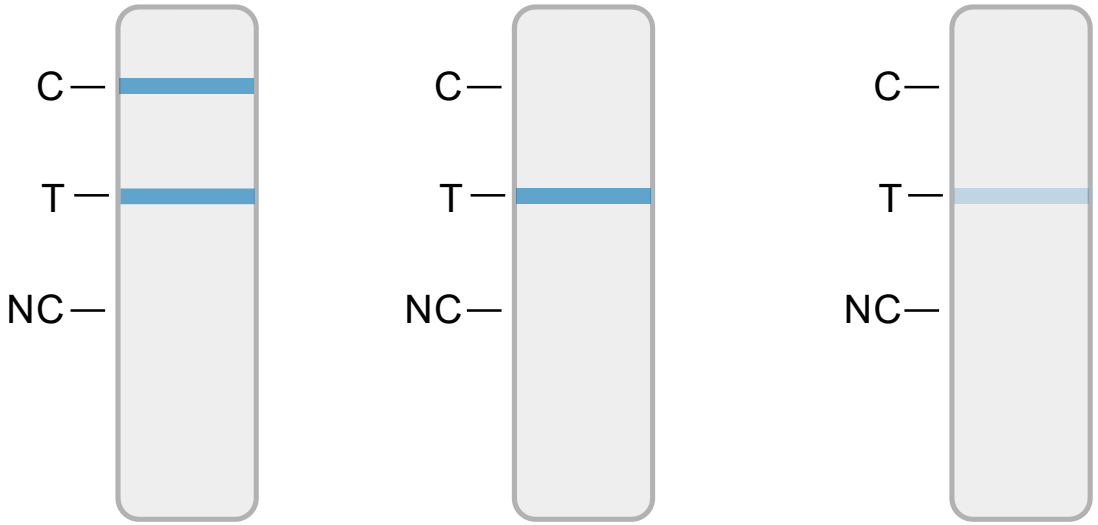
Interpreting the result



- C = Internal positive control
- T = SARS-CoV-2
- NC = Internal negative control

Positive test result

The appearance of **any** shade of a blue test line at the T test position is a valid result that is interpreted as a positive result for SARS-CoV-2 viral RNA



Positive test for SARS-CoV-2

C = Internal positive process control

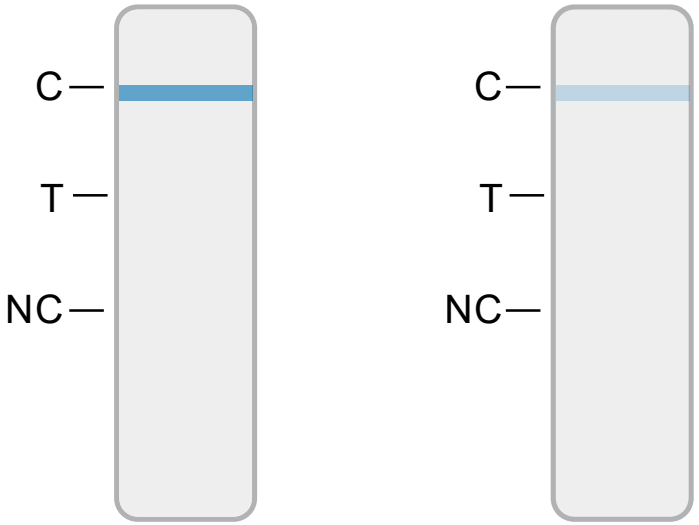
T = SARS-CoV-2

NC = Internal negative process control

NOTE: The absence of a Blue Test Line at the "C" position in conjunction with a Blue Test Line at the "T" position means that the SARS-CoV-2 target was amplified and detected as a valid result. This can occur due to the overabundance of SARS-CoV-2 target that competes with the Control target.

Negative test result

The absence of a blue line at the T test position AND the appearance of a blue line at the C control line indicates a negative result for SARS-CoV-2



Negative test for SARS-CoV-2

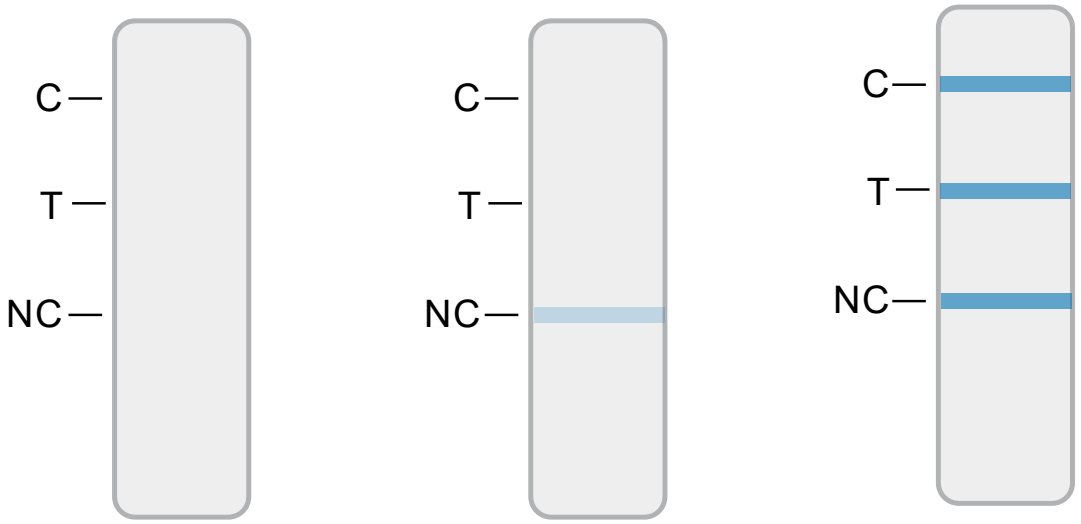
C = Internal positive process control

T = SARS-CoV-2

NC = Internal negative process control

Invalid test results*

1. The appearance of any shade of a negative process control line at the NC position indicates an invalid test
2. The appearance of ALL or NO lines at the C, T, and NC position indicates an invalid test



Invalid tests for SARS-CoV-2

C = Internal positive process control

T = SARS-CoV-2

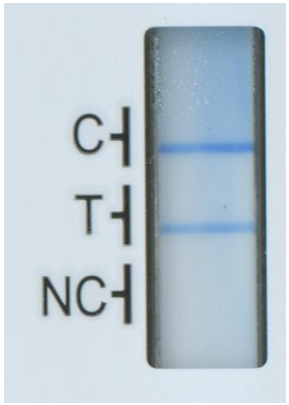
NC = Internal negative process control

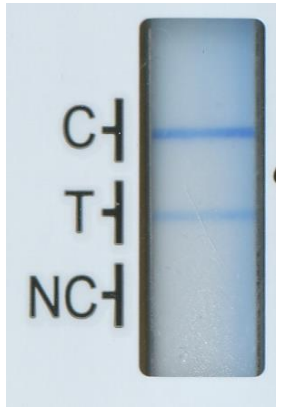
In the case of an invalid result: the eluted sample can be re-run with a fresh test cassette, provided the sample has been at room temperature (15–30°C, or 59–86°F) for **under two hours**. Alternatively, a fresh sample can be collected and retested.

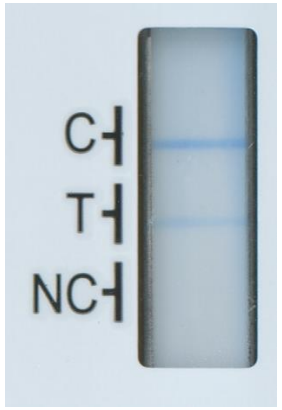
Actual test results

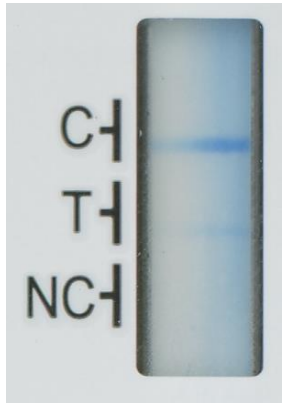
ThermoFisher SCIENTIFIC

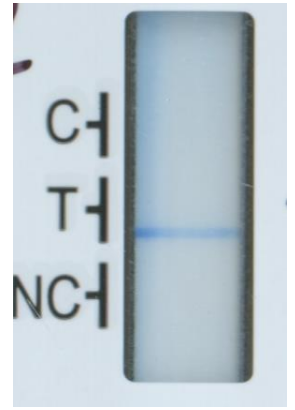
Positive



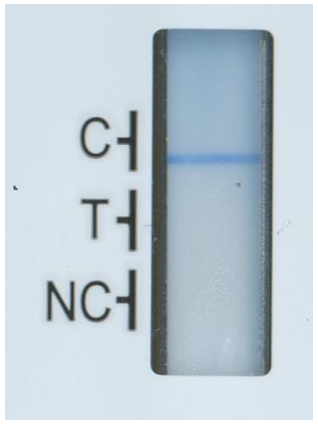


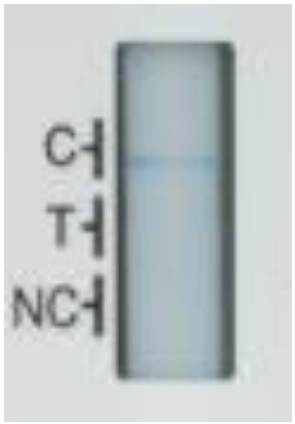




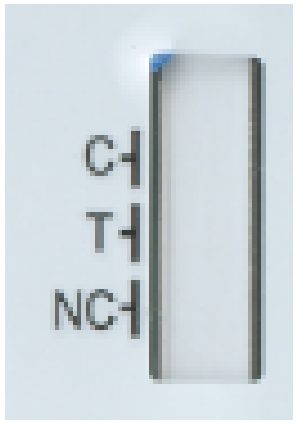


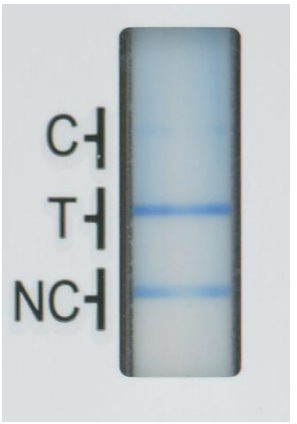
Negative





Invalid





Blue streaking on the test strip is normal, as the blue conjugate travels up the strip.

External quality control

The kit contains three control swabs:

1 high positive SARS-CoV-2 swab

1 low positive SARS-CoV-2 swab

1 negative SARS-CoV-2 swab

Thermo Fisher Scientific recommends that a SARS-CoV-2 positive and a negative control be run:

Once for each new lot or shipment of kits received

Once for each new operator

As required to conform with your internal quality control procedures; with local, state, and/or federal regulations; or accrediting groups

Accula Dock cleaning and maintenance

- When not in use, store the dock with the lid closed
- Wipe external surfaces of the dock and surrounding area daily using either:
  - CaviWipes™ germicidal disposable wipes
  - 70% ethanol or 10% bleach solution on a damp, lint-free cloth
  - If you choose to use a 10% bleach solution, follow up with water or 70% alcohol to remove any residual salts.

Reminders

1. While the workflow is simple, the Accula requires precise adherence to stated workflow for sample collection, handling, processing and storage to minimize the potential for errors and invalid and inaccurate results.
2. Use only the contents provided in the kit; additional approved swabs are listed in the IFU.
3. Swab the nostril firmly but gently to collect only the nasal secretions.
4. Elute the patient sample immediately after collection.
5. For best results, test the patient sample immediately after sample collection & elution.
   - The prepared sample may be used for repeat testing if needed.
6. Do not open the foil pouch until the sample is ready for testing (within 30 minutes).
   - Once the foil tab covering the sample port is removed, the sample must be added immediately (within 5 minutes).
7. Do not move or tilt the dock while in operation.
   - Store the dock on a flat surface away from anything that may generate movement or heat (i.e. a centrifuge).
8. When testing is not being performed, keep dock lid closed.

Reminders: Pipetting

1. Invert the buffer vial before filling the sample pipette.
2. To fill the sample pipette, firmly squeeze the top bulb on the pipette.
3. Slowly release the top bulb to completely fill the pipette stem with sample.
   - Make sure there are no bubbles in the pipette stem.
   - Confirm there is liquid in the overflow chamber.
4. Insert the pipette into the sample port of the cassette until resistance is met.
5. Squeeze the top bulb of the pipette firmly to dispense all of the sample from the pipette stem into the test cassette.
   - It is normal for some liquid to remain in the overflow chamber.
   - Forcing the contents from the overflow reservoir may cause invalid results.
6. Transfer Pipette is for one use – when in doubt, use an extra.

Accula Dock error codes

Error Code	Displayed Error Description	Cause/Remedy
01	ALTITUDE OUT OF VALID RANGE	The maximum operational altitude is 8000 feet (2438 meters) above sea level. The Dock will check the altitude on its initial power up and not continue if the altitude range has been exceeded. To continue, the Dock must be re-located to an altitude below 8000 feet.
02	TEMPERATURE OUT OF VALID RANGE	**DOCK:** The valid ambient operating temperature range of the Dock is 59-86°F (15 – 30°C). This is checked during power up and whenever the Dock is reset. Move the Dock to an acceptable ambient temperature environment and let it sit for at least 5 minutes to acclimate.
03	TEMPERATURE OUT OF VALID RANGE	**CASSETTE:** The valid operating temperature range of the Test Cassette is 59-86°F (15 – 30°C). This is checked as soon as a Test Cassette is inserted into the Dock. Insure that the Test Cassette temperature is valid, and re-insert it into the Dock.
04	UNKNOWN TYPE OF CASSETTE	This error is caused when the Test Cassette is not recognized by the Dock. The most likely reason for this would be that the latest program revision has not been installed into the Dock. See section C: Operation, ***Re-programming the Dock*** above. It is also possible that the Test Cassette is not firmly seated into the Dock. In this case, remove the Test Cassette, wait a couple of seconds, and re-insert it, pressing it firmly into position.
05	CASSETTE ALREADY USED! REPLACE!	Each Test Cassette may only be used one time. Even if a test does not complete, that Test Cassette may not be used again if the previous test was started or if the lid was closed.
06	CASS. NOT SEATED PROPERLY. RESEAT	When inserting the Test Cassette into the Dock, it must be pressed firmly into place. If this error occurs, remove the Test Cassette, wait a couple of seconds, and re-insert it, ensuring that the Test Cassette has come to a firm stop. If this error continues after trying multiple Test Cassettes, contact your distributor to replace the Dock.
07	TEST ABORTED! CASSETTE REMOVED	This error occurs when a Test Cassette has been removed before the assay test has been completed. To avoid this error and guarantee accurate testing, the Test Cassette must not be removed until the test is complete. See section C. Running the Assay above.

Error Code	Displayed Error Description	Cause/Remedy
08	INADEQUATE SAMPLE	This error will occur if the lid is closed before the sample is loaded into the Test Cassette. To avoid this error, never close the lid before sample addition. If a sample was added but not detected, discard that Test Cassette and insert a new Test Cassette. Ensure the sample is at room temperature. Ensure sufficient sample volume is added to the Test Cassette.
09	REMOVE UNATTENDED CASS.	Each Test Cassette must be used in a timely manner when removed from its protective pouch. If the Test Cassette has been sitting in the Dock for more than 5 minutes, the test will abort and the Test Cassette must be discarded.
10	CASSETTE SEAL FAILED. REPLACE	If this error occurs, replace the Test Cassette and run the test again. If this failure repeats, contact your distributor and replace the Dock.
11	DOCK EXPIRED REPLACE DOCK	When the Dock has completed 3,000 runs, this error will appear. Contact your distributor to purchase a replacement Dock.
12	TEST ABORTED! TILT ERROR!!	The Dock must be kept level at all times when operating. Do not bump, lift, or tilt the Dock during operation. If this error occurs the test is aborted and must be re-run with a new Test Cassette.
13	TEST ABORTED! POWER IS LOW	The Dock's power supply voltage has fallen below acceptable limits. The run is aborted and another run is not allowed to start until the power supply voltage is within acceptable limits.
14	TEST ABORTED! FAN/COOLING FAIL	The Dock is not temperature cycling as expected. This may be caused by a fan malfunction, or a problem with the liquid flow inside the Test Cassette. The run is aborted and must be re-run with a new Test Cassette. If this error happens repeatedly, the Dock must be replaced.
15	TEST ABORTED! FLOW ERROR	The Dock is not heating properly during temperature cycling. This is indicative of a problem inside the Test Cassette with fluid flow. The test is aborted and must be re-run with a new Test Cassette.

Customer support

Technical support
techsupport@thermofisher.com
(800) 955-6288 (option 2, then 1, then 2)

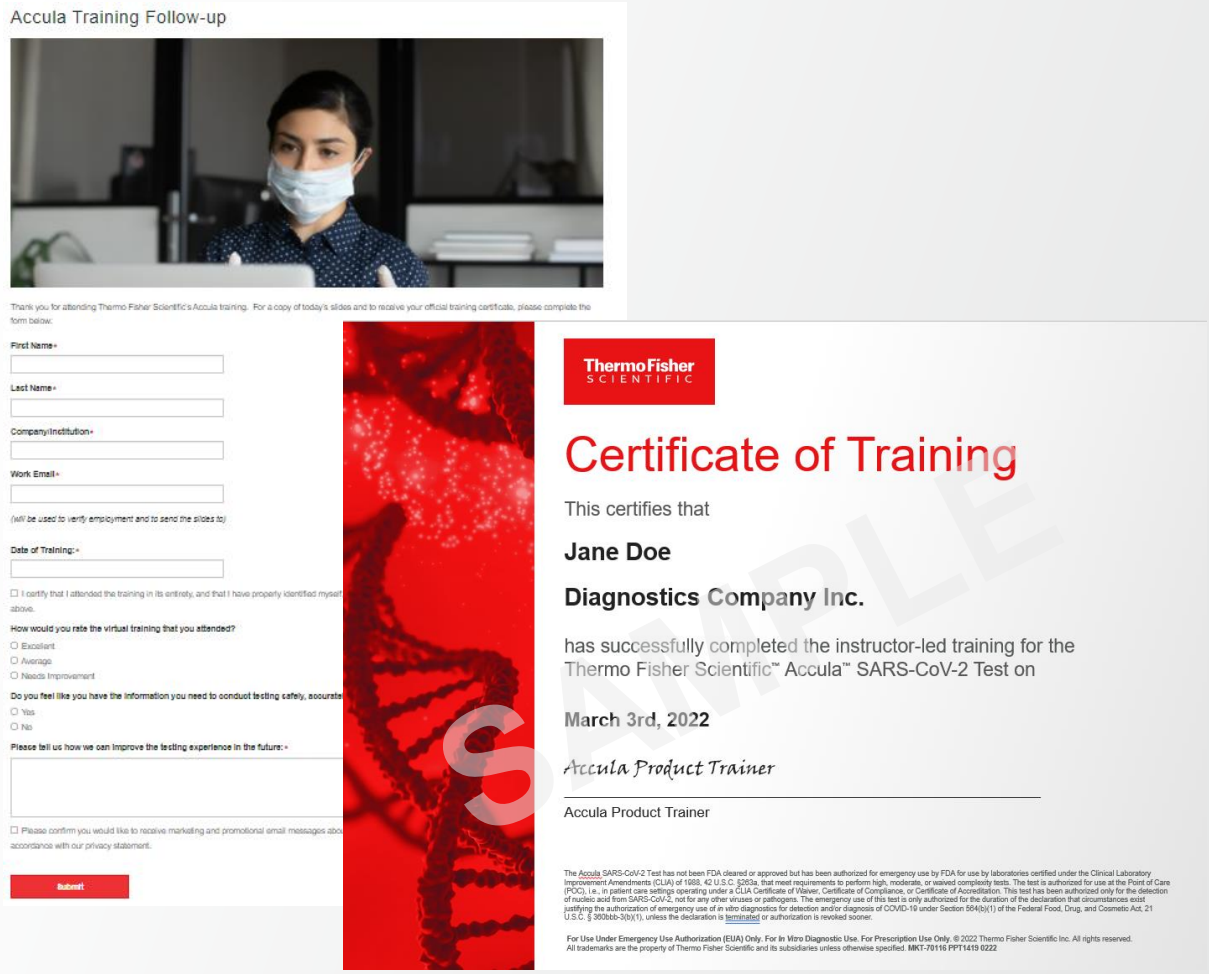
Training support

Accula Product Training
acculaproduct.training@thermofisher.com
+1 (978) 705-5033

Request Training Slides & Certificate

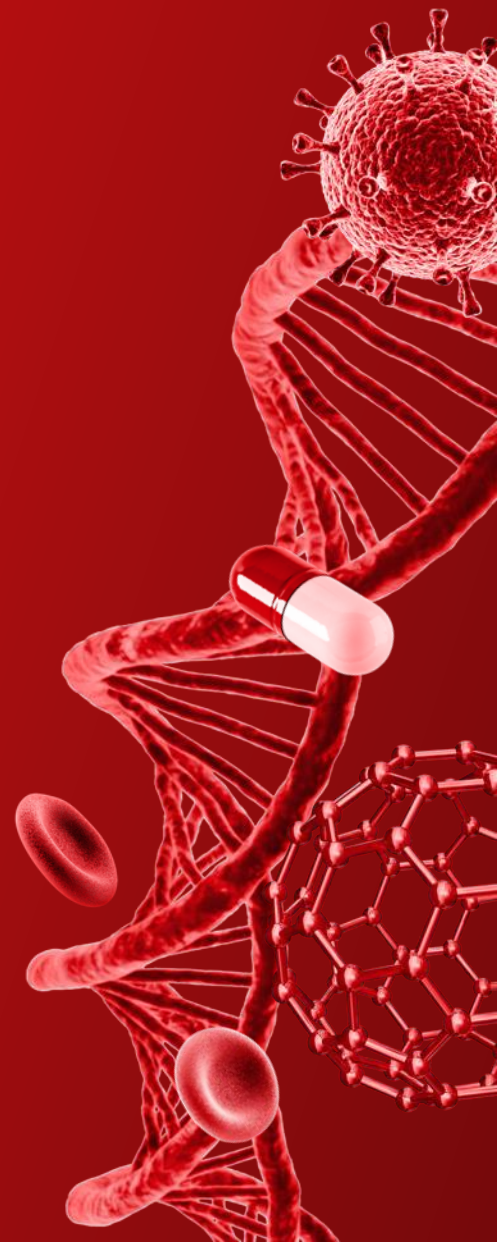
To request your training slides and certificate, please see below:

- Go to www.thermofisher.com/acculatrained and fill out your contact information. Each individual should complete the form to receive their certificates.
- After completing the form, you'll be able to download the slides immediately.
- The Accula Product Training team will send your training certificate by email.




Questions?

Thank you



The Accula™ SARS-CoV-2 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.