For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

℞ ONLY

QUIDEL | Sofia® SARS Antigen FIA

INTENDED USE

The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia and Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high 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.

The Sofia SARS Antigen FIA does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia and Sofia 2 instruments. The Sofia SARS Antigen FIA is only for use under the Food and Drug Administration's Emergency Use Authorization.

The Sofia SARS Antigen FIA should be used with Sofia or Sofia 2.

SUMMARY AND EXPLANATION

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.[1] The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths.[2]

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.[3] The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.[4]

PRINCIPLE OF THE TEST

The Sofia SARS Antigen FIA employs immunofluorescence technology in a sandwich design that is used with Sofia and Sofia 2 to detect nucleocapsid protein from SARS-CoV and SARS-CoV-2. This test allows for the detection of SARS-CoV and SARS-CoV-2. The test detects, but does not differentiate, between the two viruses.

The patient sample is placed in the Reagent Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If SARS-CoV or SARS-CoV-2 viral antigen is present, they will be trapped in a specific location.

NOTE: Depending upon the user's choice, the Test Cassette is placed inside Sofia or Sofia 2 for automatically timed development (WALK AWAY Mode) or placed on the counter or bench top for a manually timed development and then placed into Sofia or Sofia 2 to be scanned (READ NOW Mode).

Sofia and Sofia 2 will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia and Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen.

REAGENTS AND MATERIALS SUPPLIED

25-Test Kit:

- Individually Packaged Test Cassettes (25): Monoclonal anti-SARS antibodies
- Reagent Tubes (25): Lyophilized buffer with detergents and reducing agents
- Reagent Solution (25): Ampoules with salt solution
- Sterile Nasal Swabs (25)
- Small, Clear 120 µL Fixed Volume Pipettes (25)
- SARS Positive Control Swab (1): Swab is coated with non-infectious recombinant SARS antigens
- Negative Control Swab (1): Swab is coated with heat-inactivated, non-infectious Streptococcus C antigen
- Package Insert (1)
- Quick Reference Instructions (1)
- QC Card (located on kit box)

MATERIALS NOT SUPPLIED IN KIT

- Timer or watch
- Sofia or Sofia 2
- Nylon flocked nasopharyngeal swab
- Calibration Cassette (for use with either Sofia or Sofia 2)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only
- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate, high 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 test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 authorization is terminated or revoked sooner.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
- Do not reuse the used Test Cassette, Fixed Volume Pipettes, Reagent Tubes, solutions, or Control Swabs.
- The user should never open the foil pouch of the Test Cassette exposing it to the ambient environment until the Test Cassette is ready for immediate use.
- Discard and do not use any damaged or dropped Test Cassette or material.
- The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, the Package Insert instructions must be followed.
- The Calibration Cassette must be kept in the provided storage pouch between uses.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Sample collection and handling procedures require specific training and guidance.
- To obtain the most sensitive results, directly test patient specimens without transport media.
- When collecting a nasal swab sample, use the Nasal Swab supplied in the kit.
- When collecting a nasopharyngeal swab sample, use a nylon flocked nasopharyngeal swab.
- Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- **Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided Small, Clear 120 µL Fixed Volume Pipette when adding the sample to the Test Cassette.**
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Do not write on the barcode of the Test Cassette. This is used by Sofia and Sofia 2 to identify the type of test being run and to identify the individual Test Cassette so as to prevent a second read of the Test Cassette by the same Sofia or Sofia 2.
- As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia or Sofia 2 must be used for result interpretation.
- To obtain accurate results, an opened and exposed Test Cassette should not be used inside a laminar flow hood or in a heavily ventilated area.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

QUALITY CONTROL

There are three types of Quality Control for Sofia and Sofia 2 and the Test Cassette: Sofia Calibration Check procedure, built-in procedural control features, and External Controls.

Sofia Calibration Check Procedure

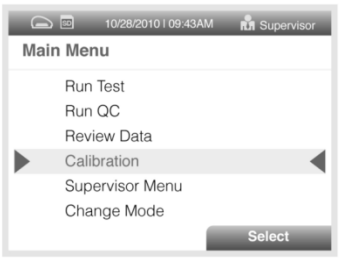
NOTE: This is a "Calibration Check" procedure.

The Calibration Check Procedure should be performed every 30 days. Sofia can be set to remind the user to complete the Calibration Check Procedure.

The Calibration Check is a required function that checks Sofia optics and calculation systems using a specific Calibration Cassette. This Calibration Cassette is supplied with the Sofia Installation Pack. Refer to the Sofia User Manual for details regarding the Calibration Check Procedure.

Important: Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect from exposure to light.

To check the calibration of Sofia, select "Calibration" from the Main Menu.



1. Following the prompts, insert the Calibration Cassette into Sofia and close the drawer. Sofia performs the Calibration Check automatically within two minutes with no user input required.



Sofia indicates when the Calibration Check is completed. Select **OK** to return to the Main Menu.

NOTE: If the Calibration Check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance Monday through Friday from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517 (in the U.S.); 858.552.1100 (outside the U.S.); Fax: 858.455.4960; customerservice@quidel.com (Customer Service); technicalsupport@quidel.com (Technical Support); or contact your local distributor.

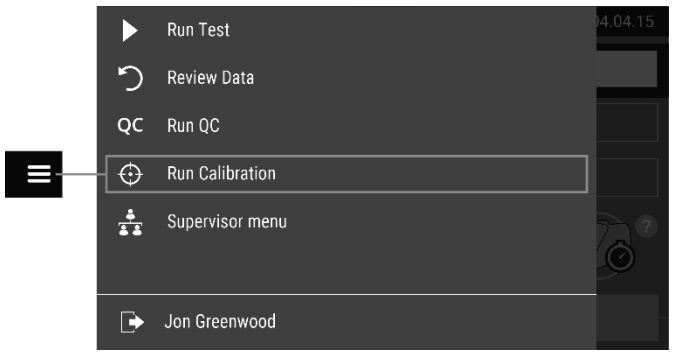
Sofia 2 Calibration Check Procedure

The Calibration Check Procedure should be performed every 30 days. Sofia 2 can be set to remind the user to complete the Calibration Check Procedure.

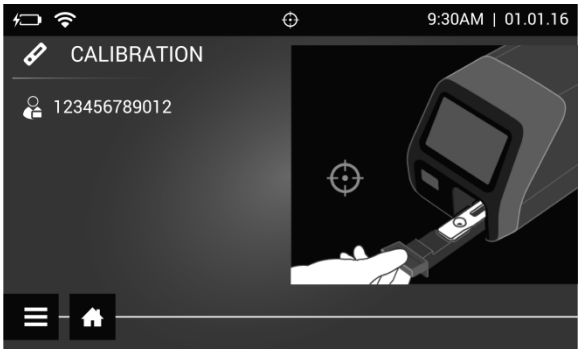
The Calibration Check is a required function that checks Sofia 2 optics and calculation systems using a specific Calibration Cassette. This Calibration Cassette is supplied with Sofia 2. Refer to the Sofia 2 User Manual for details regarding the Calibration Check Procedure.

Important: Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect from exposure to light.

1. To check the calibration of Sofia 2, select “Run Calibration” from the Main Menu.



2. Following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the Calibration Check automatically within one minute with no user input required.



Sofia 2 indicates when the Calibration Check is completed. Select ⌂ to return to the Run Test screen.

NOTE: If the Calibration Check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance Monday through Friday from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517 (in the U.S.); 858.552.1100 (outside the U.S.); Fax: 858.455.4960; customerservice@quidel.com (Customer Service); technicalsupport@quidel.com (Technical Support); or contact your local distributor.

Built-in Procedural Controls

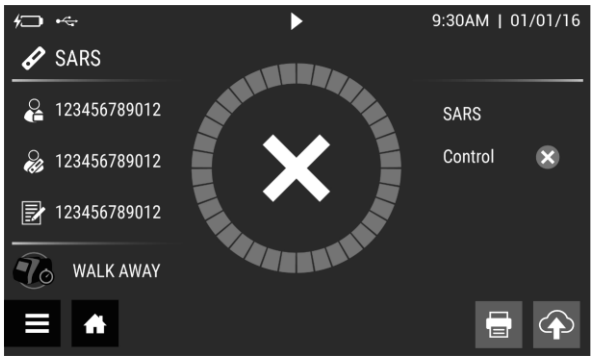
The Sofia SARS Antigen FIA contains a built-in procedural control feature. Each time a test is run in Sofia or Sofia 2, the procedural control zone is scanned by Sofia or Sofia 2 and the result is displayed on the Sofia or Sofia 2 screen.

The manufacturer's recommendation for daily control is to document the results of these built-in procedural controls for the first sample tested each day. This documentation is automatically logged into Sofia or Sofia 2 with each test result.

A valid result obtained from the procedural control demonstrates that the test flowed correctly and the functional integrity of the Test Cassette was maintained. **The procedural control is interpreted by Sofia or Sofia 2 after the Test Cassette has developed for 15 minutes. If the test does not flow correctly, Sofia or Sofia 2 will indicate that the result is invalid.** Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Cassette.



For example: This display shows an invalid result on Sofia.



For example: This display shows an invalid result on Sofia 2.

External Quality Control

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that Positive and Negative External Controls be run:

- once for each untrained operator
- once for each new shipment of kits – provided that each different lot received in the shipment is tested
- as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

The user must first select Run QC on the Main Menu of Sofia or Sofia 2 and then, when prompted, scan the QC Card (located on kit box). This card provides information specific to the kit lot, including lot number and expiration date.

The user will select the desired mode (WALK AWAY or READ NOW) then run the External Control swabs.

External Positive and Negative Control swabs are supplied in the kit and should be tested using the Swab Test Procedure provided in this Package Insert or in the Quick Reference Instructions. The SARS Positive Control Swab contains SARS antigen. **The Positive Control Swab must be run first, followed by the Negative Control Swab.**

When the QC run is complete, each result will be displayed as “Passed” or “Failed” on Sofia or ✓ or ✗ on Sofia 2, for the Positive Control and the Negative Control.

Do not perform patient tests or report patient test results if either of the QC test results fail. Repeat the test or contact Quidel Technical Support before testing patient samples.

If both the Positive and Negative Controls fail, repeat testing with new Positive and Negative Controls a second time. If only a single Control fails, the user has the option of repeating both the Positive and Negative Controls OR to repeat only the Control that failed. The user may select "Skip" on the Sofia display or » on the Sofia 2 display to skip the Control test that previously passed. The QC Results will show a skipped Control test as "unknown" or » on Sofia 2.

Additional External Control swabs may be obtained separately by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100.

SAMPLE COLLECTION AND HANDLING

SAMPLE COLLECTION

Nasal Swab Sample

Use the nasal swab supplied in the kit.

Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a nasal swab sample, carefully insert the swab (provided in the kit) into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

Nasopharyngeal Swab Sample

Use a nylon flocked nasopharyngeal swab, not supplied.

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

SAMPLE TRANSPORT AND STORAGE

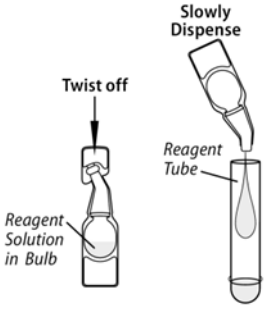
Samples should be tested as soon as possible after collection. Based on data generated with the SARS-CoV-2 Antigen FIA, nasal or nasopharyngeal swabs are stable for up to 48-hours at room temperature or 2° to 8°C.

TEST PROCEDURE

All clinical samples must be at room temperature before beginning the assay.

Expiration date: Check expiration date on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Swab Test Procedure (Nasal/Nasopharyngeal)



1. Verify that Sofia or Sofia 2 is set to the desired mode: **WALK AWAY** or **READ NOW**.
   See the "Using Sofia and Sofia 2" section for more information.
2. Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**
3. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.

Leave the swab in the Reagent Tube for 1 minute.



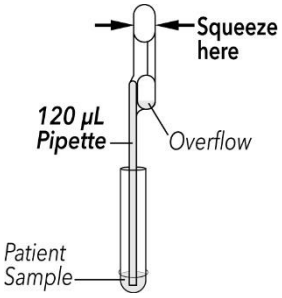


4. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.



5. Fill the provided **Small, Clear 120 µL Fixed Volume Pipette** with the patient sample from the Reagent Tube.

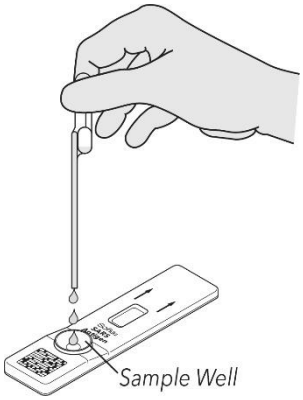
   To fill the Fixed Volume Pipette with the patient sample:
   - **a)** FIRMLY squeeze the top bulb.
   - **b)** Still squeezing, place the Pipette tip into the patient sample.
   - **c)** With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.



6. Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 µL Fixed Volume Pipette** into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.

   NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.

   NOTE: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.



7. Promptly proceed to the next section, "Using Sofia and Sofia 2," to complete the test.

USING SOFIA AND SOFIA 2

WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual for operating instructions.

Sofia and Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY Mode

In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia or Sofia 2. Sofia and Sofia 2 scans the Test Cassette periodically during the test development time. Positive and negative test results will be displayed in 15 minutes.

READ NOW Mode

Critically important: Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia or Sofia 2.

The user must first place the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia or Sofia 2. In READ NOW Mode, Sofia and Sofia 2 will scan and display the test result within 1 minute

Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia or Sofia 2 past this time may result in false results.

Tips for Batch Testing

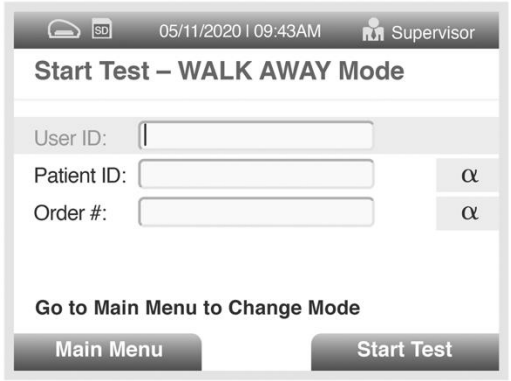
Depending on the workload, several options exist to make batch testing easier. The user can add the Reagent Solution to one or more Reagent Tubes, recap them, and store them on the bench at room temperature (RT) for up to 12 hours without loss of activity before adding the sample(s).

Critically important: The user should never open the foil pouch exposing the Test Cassette to ambient environment until ready for immediate use.

RUN TEST WITH SOFIA

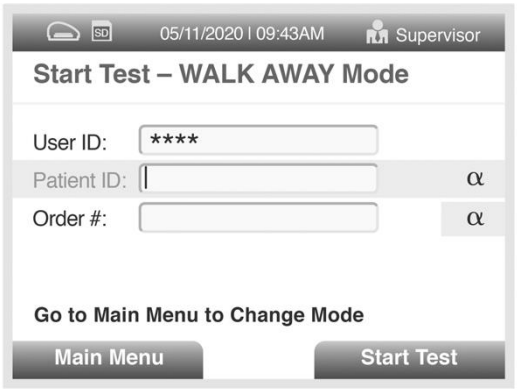
1. Input the User ID using the barcode scanner or manually enter the data using the key pad.

   NOTE: *If you mistakenly scan the incorrect barcode, use the Arrow Buttons on the Sofia key pad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*



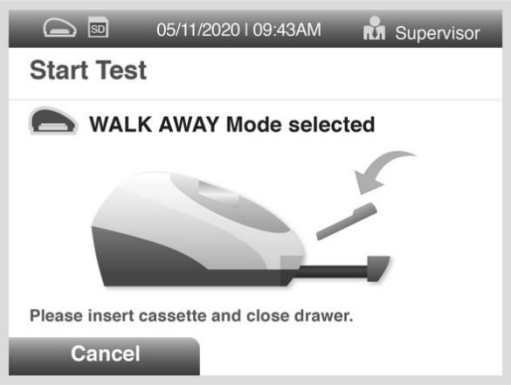


2. Input the Patient ID or Order # using the barcode scanner or manually enter the data using the key pad.





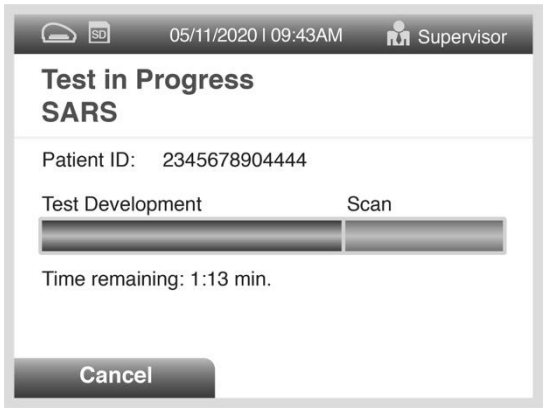
3. Press Start Test and the Sofia drawer will automatically open.



4. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Insert the prepared patient Test Cassette into the drawer of Sofia and close the drawer.

5. Sofia will start automatically and display the progress, as shown in the example below. In WALK AWAY Mode, the test results will be displayed on the screen in approximately 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.





For example: This display shows that the test in WALK AWAY mode has 12 minutes, 13 seconds remaining. Sofia will read and display the results after 15 minutes.

INTERPRETATION OF RESULTS USING SOFIA

When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, cannot be seen with the naked eye.

The Sofia screen will display results for the procedural control as being “valid or invalid,” and will individually provide a positive or negative result for SARS. If the procedural control is “invalid,” retest with a new patient sample and a new Test Cassette.

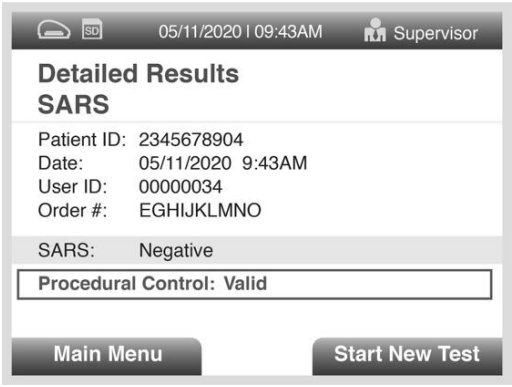
Positive Results:



For example: This display shows a valid <u>positive result for SARS</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.

Negative Results:



For example: This display shows a valid <u>negative</u> result for SARS.

Note: Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Invalid Results:



For example: This display shows an invalid result.

Invalid Result: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.

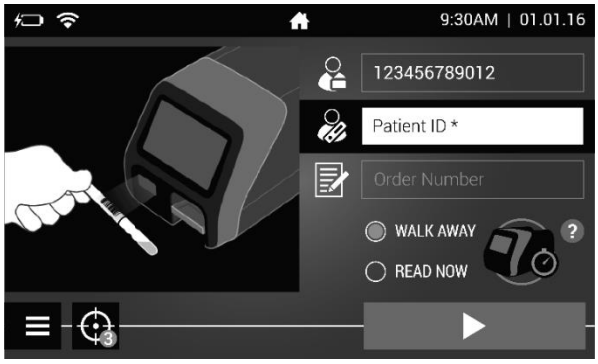
RUN TEST WITH SOFIA 2

1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen key pad.

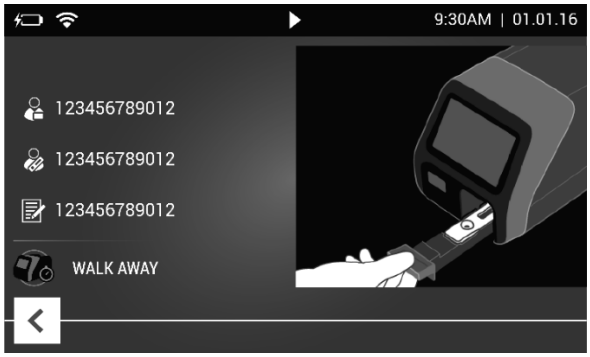
NOTE: *If you mistakenly scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*



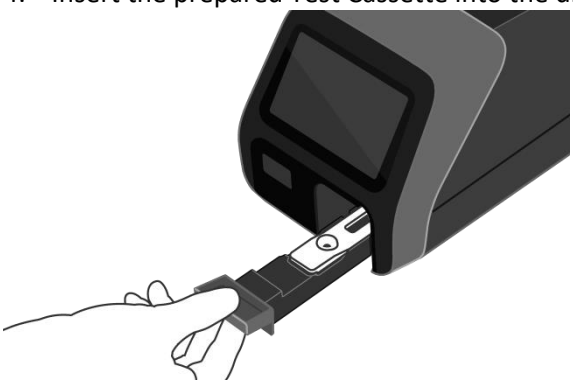
2. Input the Patient ID and Order #, if applicable, using the barcode scanner or manually enter the data using the on-screen key pad.



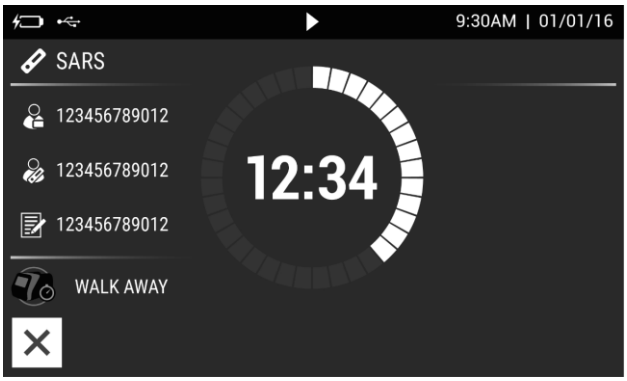
3. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Press ▶ and open the Sofia 2 drawer.



4. Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer.



5. Sofia 2 will start automatically and display the progress, as shown in the example below. In WALK AWAY Mode, the test results will be displayed on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Sofia 2 Interpretation of Results section.



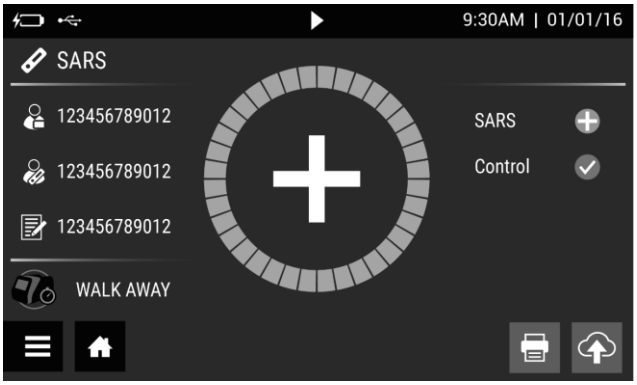
For example: This display shows that the test in WALK AWAY Mode has 12 minutes, 34 seconds remaining. Sofia 2 will read and display the results in 15 minutes.

INTERPRETATION OF RESULTS USING SOFIA 2

When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines, which are fluorescent, cannot be seen with the naked eye.

The Sofia 2 screen will display results for the procedural control as being ✓ or ✗, and will individually provide a ⊕ or ⊖ result for SARS. If the procedural control is ✗ retest with a new patient sample and a new Test Cassette. If a printer is connected, the results can be printed manually by selecting the print icon while the test results are displayed on the screen.

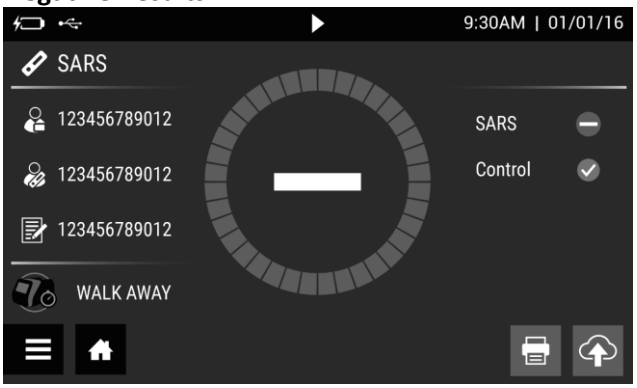
Positive Results:



For example: This display shows a valid <u>positive result for SARS</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.

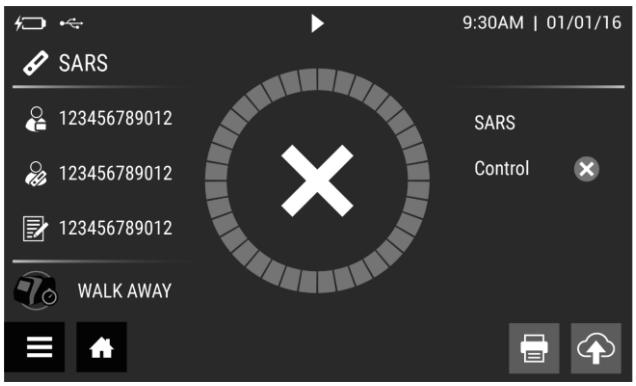
Negative Results:



For example: This display shows a valid <u>negative</u> result for SARS.

NOTE: Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Invalid Results:



For example: This display shows an invalid result.

Invalid Result: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.

LIMITATIONS

- Use of viral transport media may result in deceased test sensitivity, and directly testing specimens is recommended.
- Remel M4 and M4RT should not be used in with the Sofia SARS Antigen FIA Assay in either the Sofia or Sofia 2. Some lots of M4 and M4RT have been shown to cause false positive results when used with the Sofia SARS Antigen FIA Assay.
- The contents of this kit are to be used for the qualitative detection of SARS antigens from nasal swab and nasopharyngeal swab.
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Sofia SARS Antigen FIA Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

However, to assist clinical laboratories using the Sofia SARS Antigen FIA ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the "Sofia SARS Antigen FIA" Instructions for Use. Deviations from the authorized procedures, including the authorized

instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quidel (via email: QDL.COV2.test.event.report@quidel.com, or via phone by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Quidel Corporation, authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "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." as "authorized laboratories."

CLINICAL PERFORMANCE

Patient Demographics

Patient demographics (gender, age, elapsed time from date of on-set) are available for the two hundred nine (209) samples used in the study.

The specimen positivity breakdown based on age of the patient:

	Sofia SARS Antigen FIA (N=29)		
Age	Total #	Total Positive	Prevalence
≤ 5 years	0	0	N/A
6 to 21 years	28	5	17.9%
22 to 59 years	156	22	16.0%
≥ 60 years	25	2	8.0%

The specimen positivity based on days post onset:

Days Post Symptom Onset	# Specimens Tested	# Positive Specimens	% Positive
0	9	0	0
1	32	5	15.6%
2*	61	11	18.0%
3	39	3	7.7%
4	24	5	20.8%
5	16	2	12.5%
6	11	2	18.2%
7	17	1	5.9%

*** One specimen was Sofia SARS Antigen FIA Negative and Positive by Reference Extracted RT-PCR**

A study of two hundred nine (209) direct nasal swabs was performed. The samples were sequentially enrolled from symptomatic patients suspected of COVID-19 at five (5) locations and tested fresh at a single central laboratory. All patients had either a NP swab (for RT-PCR testing) and nasal swab (for Sofia testing) or matched nasal swabs collected for RT-PCR and Sofia testing. The order of swab collection was randomized between assays. The Sofia SARS Antigen FIA was compared to a Reference Extracted RT-PCR assay.

		Reference Extracted RT-PCR assay					95% CI	
		POS	NEG	Total	PPA	96.7%	83.3%	99.4%
Sofia SARS Antigen FIA Assay	POS	29	0	29	NPA	100.0%	97.9%	100.0%
	NEG	1	179	180	PPV	100.0%	88.3%	100.0%
	Total	30	179	209	NPV	99.4%	96.9%	99.9%
					Prevalence	14.4%	10.2%	19.8%
					% agreement	99.5%		

ANALYTICAL PERFORMANCE

Limit of Detection

a) Limit of Detection (LoD)*:*

The Limit of Detection (LoD) of the Sofia SARS Antigen FIA was determined using limiting dilutions of heat-inactivated SARS-CoV-2 (bei Resources NR-52286). The NR-52286 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020, that has been inactivated by heating at 65°C for 30-minutes. The material was supplied frozen at a concentration of $TCID_{50}$ of 3.40 $x10^5$ per mL.

The study to determine the Sofia SARS Antigen FIA LoD was designed to reflect the assay when using direct swabs. In this study a NP swab was spiked with approximately 50-µL of the virus dilution in saline. The spiked swab was added to the Sofia SARS Antigen FIA extractant concurrently to a NP swab containing NP matrix. The swabs were processed concurrently according to the package insert.

The LoD was determined in three steps:

1. **LoD Screening**
   10-fold dilutions of the heat inactivated virus were made in saline and processed for each study as described above. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD range finding.
   Based on this testing, the concentration chosen was $TCID_{50}$ of 3.40 $x10^2$ per mL.

2. **LoD Range Finding**
   Five (5) doubling dilutions were made of the $TCID_{50}$ of 3.40 $x10^2$ per mL concentration in saline processed for the study as described above. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD confirmation.

   Based on this testing the concentration chosen was $TCID_{50}$ of 1.13 $x10^2$ per mL.

3. **LoD Confirmation**
   The concentration $TCID_{50}$ of 1.13 $x10^2$ per mL dilution was tested an additional seventeen (17) times, for a total of twenty (20) results. Twenty (20) of twenty (20) results were positive.

   Based on this testing the concentration was confirmed as:
   Swab LoD: $TCID_{50}$ 1.13 $x10^2$ per mL

4. LoD Comparison between Instruments

To compare the LoD between the Sofia and Sofia 2 a study was performed using concurrent testing of 1x and 2x LoD concentrations (1.13 $x10^2$ and 2.26 $x10^2$, respectively) of heat-inactivated SARS-CoV-2.

The two instruments generated matching LoDs of $TCID_{50}$ 2.26 $x10^2$ in this study.

b) Cross-Reactivity*:*

Cross-reactivity and potential interference of the Sofia SARS Antigen FIA was evaluated by testing various microorganisms (8), viruses (16) and negative matrixes (3) with the Sofia SARS Antigen FIA. Each organism and virus were tested in triplicate in the absence or presence of $TCID_{50}$ 2.26 $x10^2$ per mL of heat inactivated SARS-CoV-2. The final concentration of the organisms and viruses are documented in the Table below.

Cross-Reactivity: Sofia SARS Antigen FIA – Wet testing					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactive Results****	**Interference Results****
Adenovirus	Type 1	Isolate	1 x $10^{5.53}$ U/mL	Negative	Positive
Coronavirus	229e	Isolate	1 x $10^{5.10}$ U/mL	Negative	Positive
Coronavirus	OC43	Isolate	9.55 x 10^5 $TCID_{50}$/mL	Negative	Positive
Coronavirus	NL63	Isolate	5 x $10^{3.67}$ U/mL	Negative	Positive
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudia Arabia_2014	Isolate	1.17 x 10^5 $TCID_{50}$/mL	Negative	Positive
Mycoplasma pneumoniae	M129	Isolate	3 x 10^6 CCU/mL	Negative	Positive
Streptococcus pyogenes	Z018	Isolate	3.8 x 10^6 cfu/mL	Negative	Positive
Influenza A H3N2	Brisbane/10/07	Isolate	1 x $10^{5.07}$ U/mL	Negative	Positive
Influenza A H1N1	New Caledonia/20/99	Isolate	1 x $10^{5.66}$ U/mL	Negative	Positive
Influenza B	Brisbane/33/08	Isolate	1 x $10^{5.15}$ U/mL	Negative	Positive
Parainfluenza	Type 1	Isolate	1 x $10^{5.01}$ U/mL	Negative	Positive
Parainfluenza	Type 2	Isolate	1 x $10^{5.34}$ U/mL	Negative	Positive
Parainfluenza	Type 3	Isolate	8.5 x 10^5 $TCID_{50}$/mL	Negative	Positive
Parainfluenza	Type 4b	Isolate	1 x $10^{5.53}$ U/mL	Negative	Positive
Enterovirus	Type 68	Isolate	1 x $10^{5.5}$ U/mL	Negative	Positive
Human Metapneumovirus	A1 (IA10-s003)	Isolate	1 x $10^{5.55}$ U/mL	Negative	Positive
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	1 x $10^{5.62}$ U/mL	Negative	Positive
Human Rhinovirus	N/A	Inactivated virus	Not available	Negative	Positive
Chlamydophila pneumoniae	AR-39	Isolate	2.9 x 10^6 IFU/mL	Negative	Positive

Cross-Reactivity: Sofia SARS Antigen FIA – Wet testing					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactive Results****	**Interference Results****
Haemophilus influenzae	Type b; Eagan	Isolate	7.87 x 10^6 cfu/mL	Negative	Positive
Legionella pneumophila	Philadelphia	Isolate	6.82 x 10^6 cfu/mL	Negative	Positive
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26 x 10^6 cfu/mL	Negative	Positive
Bordetella pertussis	A639	Isolate	6.37 x 10^6 cfu/mL	Negative	Positive
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56 x 10^6 cfu/mL	Negative	Positive

*****Coronavirus HKU1 was not tested for cross-reactivity due to lack of availability. Given that the 19 specimens in the clinical evaluation that were positive for this strain all resulted as negative, cross-reactivity wet testing was not required.

** Testing was performed in triplicate.

Based on the data generated by this study, the organisms or viruses tested Sofia SARS Antigen FIA do not cross-react or interfere.

c) Hook Effect*:*

As part of the LoD study the highest concentration of heat-inactivated SARS-CoV-2 stock available ($TCID_{50}$ of 3.40 x10^5 per mL) was tested. There was no Hook effect detected.

d) Endogenous Interference Substances Studies:

A study was performed demonstrate that fourteen (14) potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the Sofia SARS Antigen FIA Assay.

Interfering Substance	Active Ingredient	Concentration	Cross-Reactive Results*	Interference Results*
Afrin – nasal spray	Oxymetazoline	5%	Negative	Positive
Blood (human)	Blood	5%	Negative	Positive
Chloraseptic, Cepacol	Benzocaine, Menthol	0.7 g/mL	Negative	Positive
Flonase	Fluticasone	5%	Negative	Positive
Halls Relief Cherry Flavor	Menthol	0.8 g/mL	Negative	Positive
Nasocort Allergy 24 hour	Triamcinolone	5.00%	Negative	Positive
Neo-Synephrine	Phenylephrine hydrochloride	5%	Negative	Positive
Oseltamivir	Oseltamivir	2.2 µg/mL	Negative	Positive
Purified mucin protein	Mucin protein	2.5 mg/mL	Negative	Positive
Rhinocort	Budesonide (Glucocorticoid)	5%	Negative	Positive
Saline nasal spray	Saline	15%	Negative	Positive
Tobramycin	Tobramycin	1.25 mg/mL	Negative	Positive

Interfering Substance	Active Ingredient	Concentration	Cross-Reactive Results*	Interference Results*
Zanamivir	Zanamivir	282.0 ng/mL	Negative	Positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%	Negative	Positive

* Testing was performed in triplicate.

Based on the data generated by this study, the substances tested Sofia SARS Antigen FIA do not cross-react or interfere.

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please call Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S. contact your local distributor or technicalsupport@quidel.com. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

REF 20374 – Sofia SARS Antigen FIA – 25 Test

IVD

CE

EC REP

MDSS GmbH
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30175 Hannover,
Germany

Quidel Corporation
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quidel.com

Swab

CE 0086

MDD 93/42/EEC

EC REP

Emergo Europe
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The Netherlands

Puritan Medical Products Company LLC
31 School Street
Guilford, Maine 04443-0149

1438902EN00 (07/20)

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 25 determinations
CONT Contents/Contains	CONTROL + Positive control
CONTROL − Negative control	

REFERENCES

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3. Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006.
4. Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application, Ann Intern Med. 2020