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, Sofia 2, and Sofia Q instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (NS) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. 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, which 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual'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 medical professionals or operators who are proficient in performing tests in a point of care setting

The Sofia SARS Antigen FIA should be used with Sofia, Sofia 2 or Sofia Q instruments. The Sofia SARS Antigen FIA test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

SUMMARY AND EXPLANATION

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China in December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.[1] The WHO declared the COVID-19 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 those of 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, Sofia 2, and Sofia Q to detect nucleocapsid protein from SARS-CoV and SARS-CoV-2 in respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19, or taken from asymptomatic individuals, as described in the authorized intended use. 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, Sofia 2, or Sofia Q 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, Sofia 2, or Sofia Q to be scanned (READ NOW Mode).

Sofia, Sofia 2, and Sofia Q will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia, Sofia 2, and Sofia Q 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 (Kits #20374) (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 Calibration Cassette (for use with Sofia, Sofia 2, or Sofia Q)
- Sofia SARS Antigen Control Swab Set for additional QC (20384)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This 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 proteins 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Test components are single-use. Do not re-use.
- 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.
- The test is intended to be used with direct anterior nasal swabs and is not validated for use with swabs in viral transport media.
- When collecting an anterior nasal swab sample, use the Nasal Swab supplied in the kit.
- 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, Sofia 2, and Sofia Q 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, Sofia 2, or Sofia Q.
- As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia, Sofia 2, or Sofia Q must be used for result interpretation.

- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- 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.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, and mouth. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Hazardous Ingredients for Liquid Reagent

Chemical Name / CAS	Harms (GHS Code) for each ingredient	Concentration
Tris Base/ 77-86-1	Causes skin irritation (H315) Causes serious eye irritation (H319) May cause respiratory irritation (H335)	0.135%
EDTA/ 10378-23-1	Harmful if swallowed (H302) Causes serious eye damage (H318)	1.103%
TCEP/ 51805-45-9	Causes severe skin burns and eye damage (H314) Causes serious eye damage (H318)	0.038%
Mouse IgG	-	0.002%
Empigen BB/66455-29-6	-	0.006%

- 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.
- For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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.

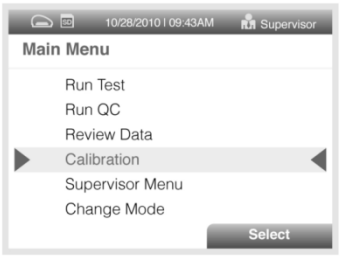
The Calibration Check Procedure should be performed every 30 days. Sofia can be set to remind the user to complete the Calibration Check Procedure.

The Calibration Check is a required function that checks Sofia optics and calculation systems using a specific

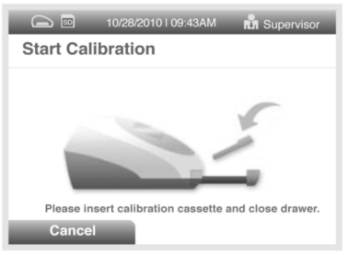
Calibration Cassette. This Calibration Cassette is supplied with the Sofia Installation Pack. Refer to the Sofia User Manual for details regarding the Calibration Check Procedure.

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

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



2. 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.

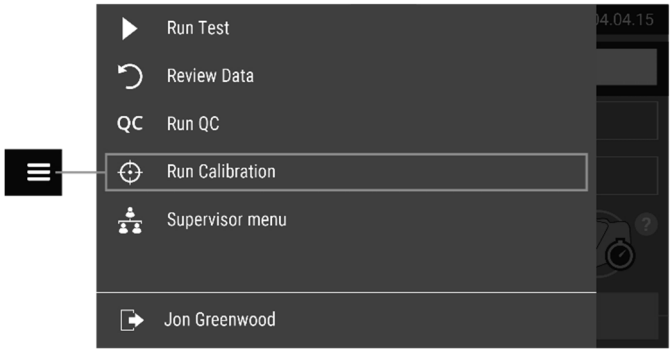
Sofia 2 Calibration Check Procedure

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.

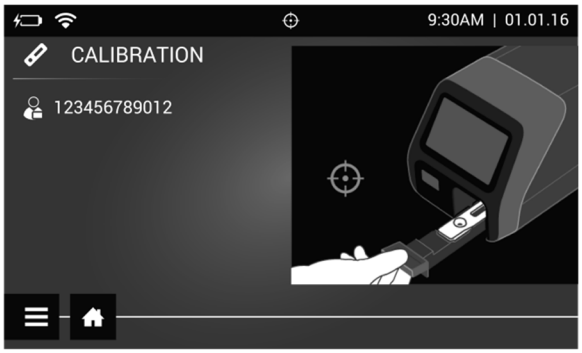
The Calibration Check is a required function that checks Sofia 2 optics and calculation systems using a specific Calibration Cassette. This Calibration Cassette is supplied with Sofia 2. Refer to the Sofia 2 User Manual for details regarding the Calibration Check Procedure.

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.

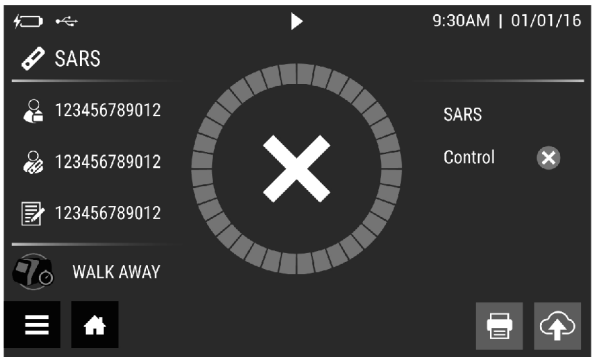
Built-in Procedural Controls

The Sofia SARS Antigen FIA contains a built-in procedural control feature. Each time a test is run in Sofia, Sofia 2, or Sofia Q, the procedural control zone is scanned by Sofia, Sofia 2, or Sofia Q and the result is displayed on the Sofia or Sofia 2 screen. The Sofia Q App will not display the outcome on the screen unless the test is invalid but interprets the built-in controls and evaluates them to determine whether the test is valid or not.

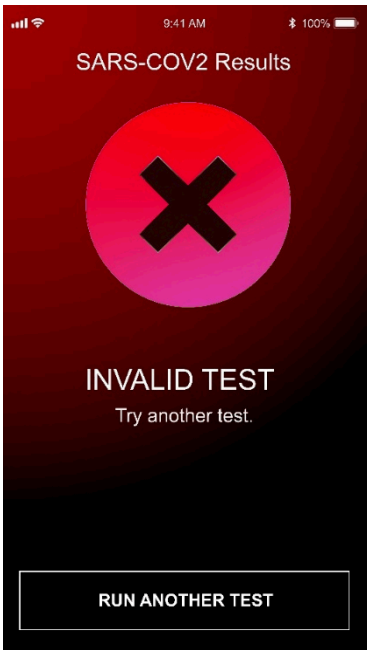
The manufacturer's recommendation for daily control is to document the results of these built-in procedural controls for the first sample tested each day. This documentation is automatically logged into Sofia or Sofia 2 with each test result.

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, Sofia 2, or Sofia Q after the Test Cassette has developed for 15 minutes. If the test does not flow correctly, Sofia, Sofia 2, or Sofia Q 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.



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

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.

QC procedure for Sofia and Sofia 2:

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.

QC procedure for Sofia Q:

The user can perform QC in the same manner as a patient test using the External Control swabs provided in the kit. The user does not need to scan the QC card located on the kit box. Once the test is complete, each result will be displayed as "Positive" or "Negative" on the Sofia Q App, for the Positive Control and the Negative Control. The user must check the result on the screen to ensure the expected result was received for each External Control swab. The user should make note of the QC results, as needed, as the result will not be stored within the Sofia Q App.

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

Direct Anterior Nares 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 direct anterior 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. Specimens collected from asymptomatic individuals cannot be synchronized to onset of symptoms and should be evaluated as part of a serial testing program.

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, direct anterior nasal swabs are stable for up to 48-hours at room temperature or 2° to 8°C.

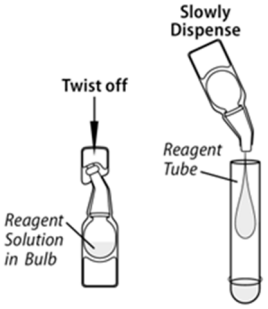
TEST PROCEDURE

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

Specimens processed in Reagent Tubes (rehydrated) have an in-use stability of up to 1 hour at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight.

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



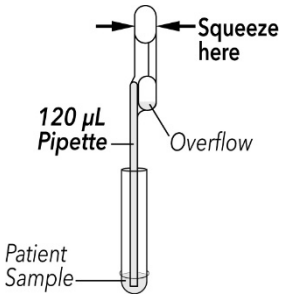
1. Verify that is set to the desired mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia, Sofia 2, and Sofia Q" section for more information.

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.

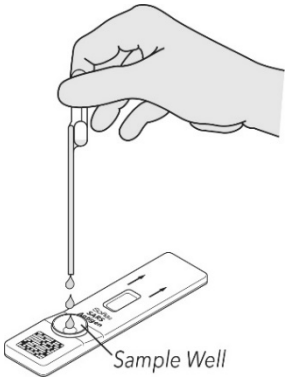
   Leave the swab in the Reagent Tube for 1 minute.

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, Sofia 2, and Sofia Q," to complete the test.

USING SOFIA, SOFIA 2, AND SOFIA Q

WALK AWAY/READ NOW Modes

Refer to the Sofia 2 or Sofia Q User Manual for operating instructions.

Sofia, Sofia 2, and Sofia Q 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, Sofia 2, or Sofia Q. 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, Sofia 2 or Sofia Q.

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

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

Tips for Batch Testing

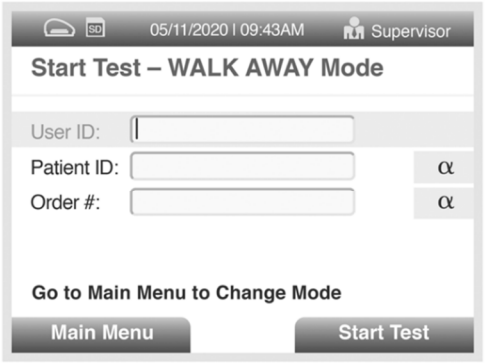
Depending on the workload, several options exist to make batch testing easier. The user can add the Reagent Solution to one or more Reagent Tubes, recap them, and store them on the bench at room temperature (RT) for up to 6 hours without loss of activity before adding the sample(s).

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

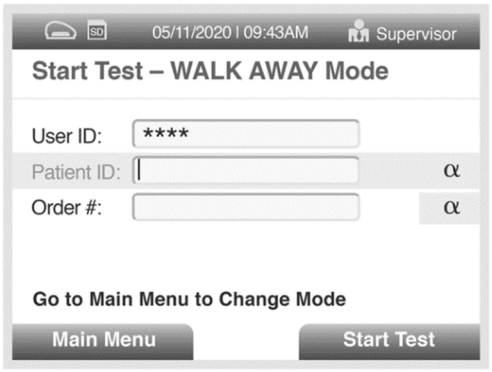
RUN TEST WITH SOFIA

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

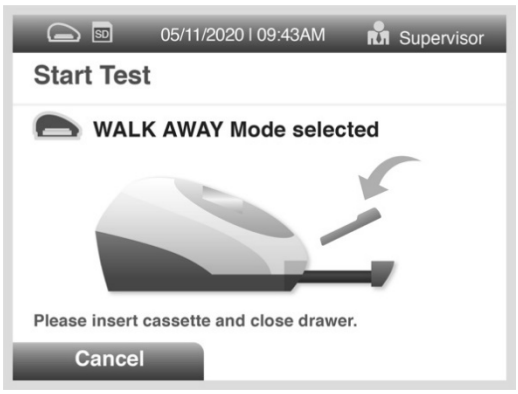
   NOTE: *If you mistakenly scan the incorrect barcode, use the Arrow Buttons on the Sofia keypad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*



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

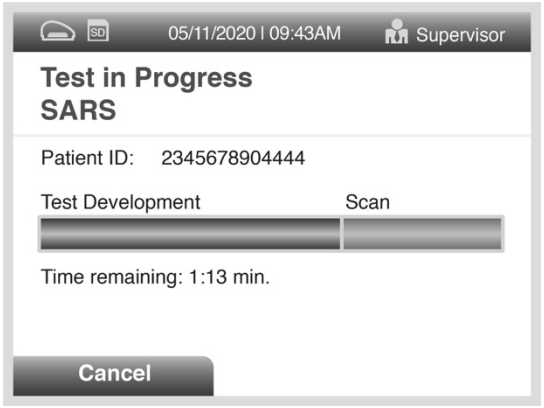


3. Press Start Test and the Sofia drawer will automatically open.



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.

Repeat testing does not need to be performed if patients have a positive result at any time.

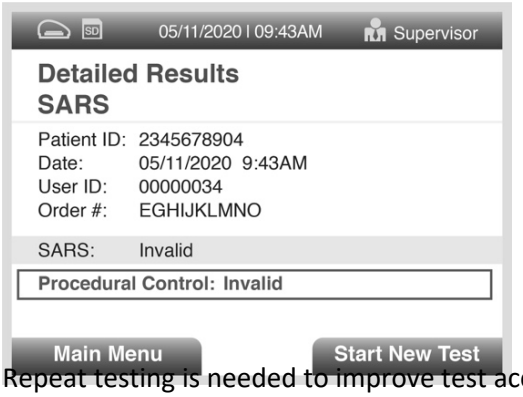
Negative Results:

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

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

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.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures,

history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

COVID-19 Positive (+)

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the [Test Name] should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

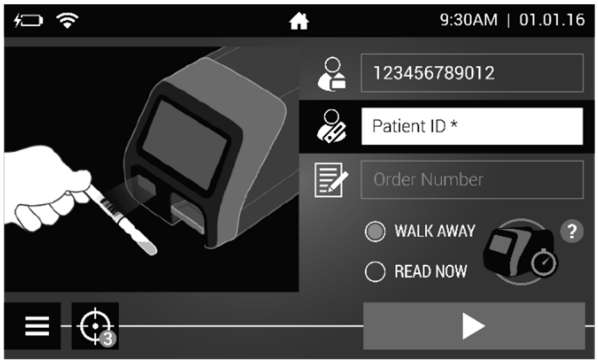
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

RUN TEST WITH SOFIA 2

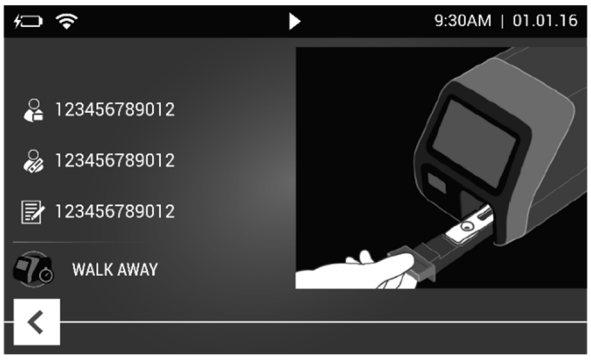
1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen keypad.

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.*

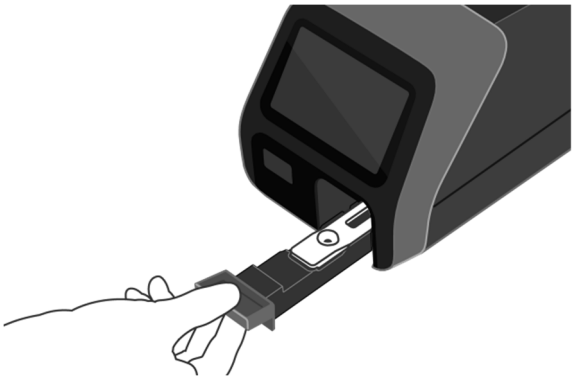
2. Input the Patient ID and Order #, if applicable, using the barcode scanner or manually enter the data using the on-screen keypad.



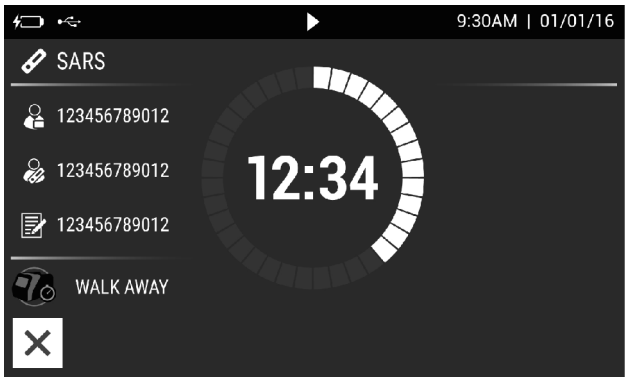
3. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Press ▶ and open the Sofia 2 drawer.



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.



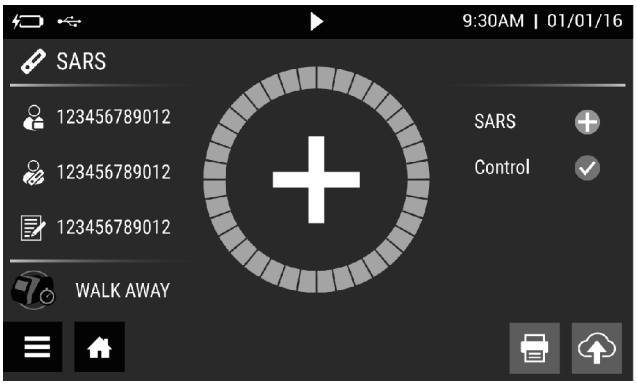
For example: This display shows that the test in WALK AWAY Mode has 12 minutes, 34 seconds remaining. Sofia 2 will read and display the results in 15 minutes.

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:

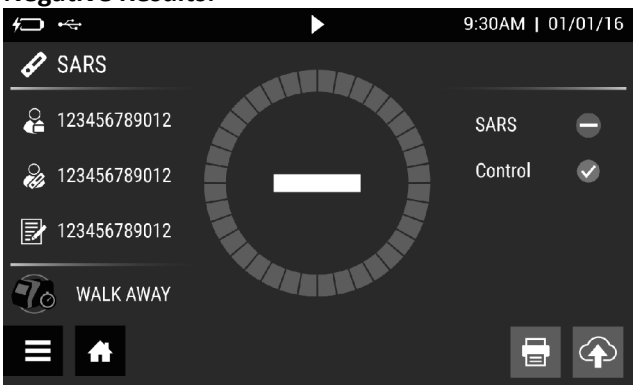


For example: This display shows a valid <u>positive result for SARS</u>.

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

Repeat testing does not need to be performed if patients have a positive result at any time.

Negative Results:

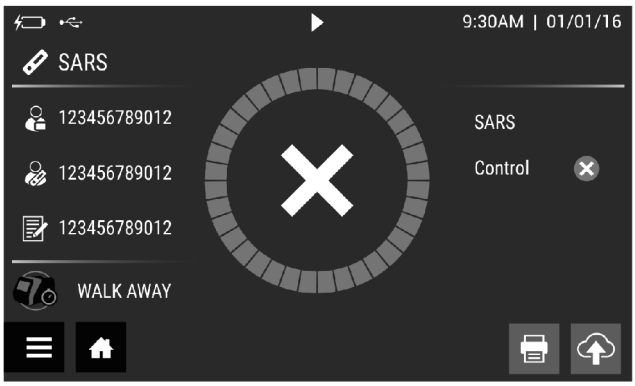


For example: This display shows a valid <u>negative</u> result for SARS.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

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.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

COVID-19 Positive (+)

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the [Test Name] should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

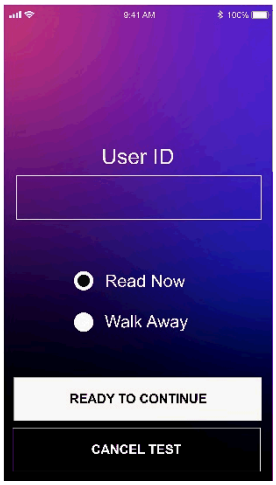
RUN TEST WITH SOFIA Q

Installing the Sofia Q App

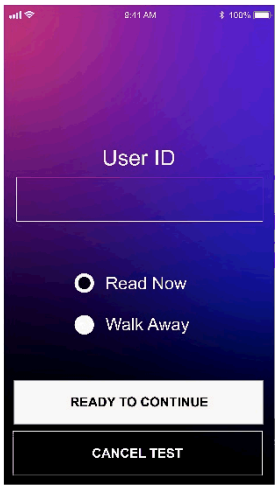
In order to begin using the Sofia Q system the Sofia Q App will need to be downloaded and installed from the Apple App Store. The application is compatible with iPhone 8 and above running iOS 13 and above. The App can be found by searching the Apple App Store for Sofia Q.

1. Once the App is installed, Tap the Sofia Q App icon to start the App. Press Run Test when ready.

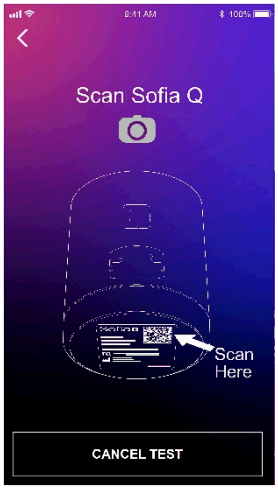
2. Input the user ID by tapping the field and using the onscreen keyboard. The USER ID field will only accept letters or numbers and no spaces.



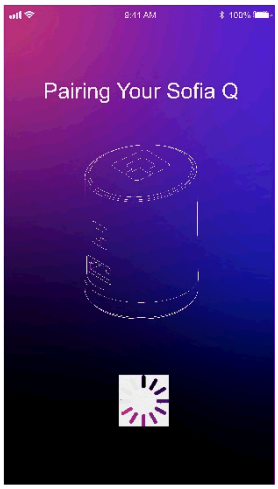
3. Select the preferred mode, Read Now or Walk Away. The selection will be retained for subsequent runs.



Input the Serial Code by tapping the camera icon on the screen, then using the smart phone's camera to scan the barcode on the bottom of the Sofia Q.



4. The Sofia Q App will then pair with the Sofia Q and alert the user when it is completed. Tap continue when ready.



5. The on-screen instructions will then prompt the user to remove the test cassette from its packaging, press continue when ready.

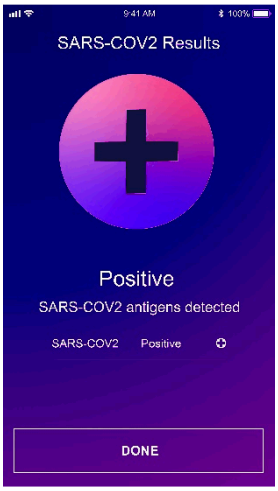
6. Scan the barcode located on the test cassette using the smart phone's camera.

7. Follow App instructions to prepare the test cassette. Insert the prepared test cassette into the slot on the Sofia Q and the system will start automatically. In Walk Away mode, the test results will be displayed on the Sofia Q App screen in 15 minutes. In Read Now mode, the test results will be displayed on the Sofia Q App screen in about 1 minute. See the Sofia Q Interpretation of Results section.

INTERPRETATION OF RESULTS USING SOFIA Q

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

Positive Results:

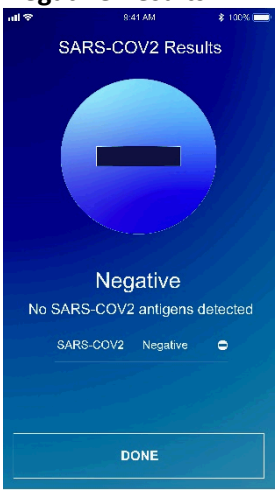


For example: This display shows a valid positive result for SARS.

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

Repeat testing does not need to be performed if patients have a positive result at any time.

Negative Results:

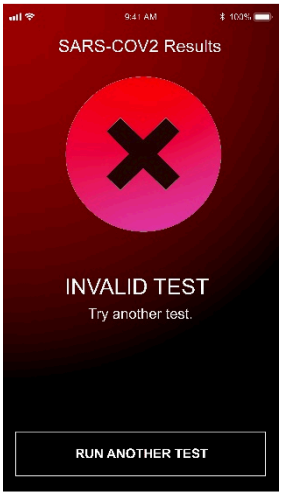


For example: This display shows a valid negative result for SARS.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

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.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

COVID-19 Positive (+)

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the [Test Name] should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

LIMITATIONS

- Use of viral transport media may result in decreased 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 direct anterior nasal swabs only.
- 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 should be treated as presumptive and confirmation with an FDA authorized 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.
- The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens collected between April 2020 and June 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.

- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

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 must 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 must use your product as outlined in the authorized labeling. 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 must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must 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 using your product must 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 "authorized laboratories" as: "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."

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:

Age	Sofia SARS Antigen FIA (N=29)		
	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 anterior 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 direct anterior 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. As with all antigen tests, performance may decrease as days since symptom onset increases due to lower viral loads later in the patient's disease course. Similarly, the inability to synchronize asymptomatic individuals with onset of infection may impact performance as specimens may be tested when viral loads are below the assay's limit of detection. Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.

	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%

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

COVID-19 Serial Screening

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARSCoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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 Sofia and Sofia 2 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.
   The LoD of 2.26 $x10^2$ $TCID_{50}$/mL equates to 1.13$x10^1$ $TCID_{50}$/swab.

5. **LoD Comparison between Sofia 2 and Sofia Q Instruments**

   To compare the LoD between the Sofia 2 and Sofia Q the LoD study was repeated using PCT-inactivated SARS-CoV-2 virus (isolate USA-WA1/2020; 2.65$x10^5$ pfu/mL) obtained from Cerus.

   For Sofia-Q the concentration 5.0 $x10^2$ pfu/mL dilution was tested a total of twenty (20) results. Twenty (20) of twenty (20) results were positive.

   For Sofia 2 the concentration 3.31 $x10^2$ pfu/mL dilution was tested a total of twenty (20) results. Twenty (20) of twenty (20) results were positive.

   Based on this testing the Sofia 2 and Sofia Q generated the similar LoD values (within 1 doubling dilution) when using the same limiting dilutions of SARS-CoV-2.

NIH/RADx Variant Testing

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the Sofia 2 SARS Antigen FIA detected 100% of live virus Omicron samples at a Ct-value of 24 (n=25, 5 lots tested at 5 replicates each). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 24) were not detected by the Sofia 2 SARS Antigen FIA in this study.

Omicron Pool 1 - Live	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	Quidel Sofia 2 SARS Antigen FIA Percent Positive (n=25)
Dilution 1	20.6	100	100	100
Dilution 2	21.5	100	100	100

Dilution 3	22.7	100	100	100
Dilution 4	24.0	100	100	100
Dilution 5	25.3	100	100	64
Dilution 6	26.0	100	100	0
Dilution 7	27.3	0	60	0
Dilution 8	28.8	0	0	0
Dilution 9	29.2	0	0	0
Dilution 10	30.6	0	0	0
Dilution 11	31.7	0	0	0
Dilution 11	32.6	0	0	0

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	$1 \times 10^{5.53}$ U/mL	Negative	Positive
Coronavirus	229e	Isolate	$1 \times 10^{5.10}$ U/mL	Negative	Positive
Coronavirus	OC43	Isolate	9.55×10^5 $TCID_{50}$/mL	Negative	Positive
Coronavirus	NL63	Isolate	$5 \times 10^{3.67}$ U/mL	Negative	Positive
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudia Arabia_2014	Isolate	1.17×10^5 $TCID_{50}$/mL	Negative	Positive
Mycoplasma pneumoniae	M129	Isolate	3×10^6 CCU/mL	Negative	Positive
Streptococcus pyogenes	Z018	Isolate	3.8×10^6 cfu/mL	Negative	Positive
Influenza A H3N2	Brisbane/10/07	Isolate	$1 \times 10^{5.07}$ U/mL	Negative	Positive
Influenza A H1N1	New Caledonia/20/99	Isolate	$1 \times 10^{5.66}$ U/mL	Negative	Positive
Influenza B	Brisbane/33/08	Isolate	$1 \times 10^{5.15}$ U/mL	Negative	Positive
Parainfluenza	Type 1	Isolate	$1 \times 10^{5.01}$ U/mL	Negative	Positive
Parainfluenza	Type 2	Isolate	$1 \times 10^{5.34}$ U/mL	Negative	Positive
Parainfluenza	Type 3	Isolate	8.5×10^5 $TCID_{50}$/mL	Negative	Positive
Parainfluenza	Type 4b	Isolate	$1 \times 10^{5.53}$ U/mL	Negative	Positive
Enterovirus	Type 68	Isolate	$1 \times 10^{5.5}$ U/mL	Negative	Positive
Human Metapneumovirus	A1 (IA10-s003)	Isolate	$1 \times 10^{5.55}$ U/mL	Negative	Positive
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	$1 \times 10^{5.62}$ U/mL	Negative	Positive

Cross-Reactivity: Sofia SARS Antigen FIA – Wet testing					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactive Results****	**Interference Results****
Human Rhinovirus	N/A	Inactivated virus	Not available	Negative	Positive
Chlamydophila pneumoniae	AR-39	Isolate	2.9×10^6 IFU/mL	Negative	Positive
Haemophilus influenzae	Type b; Eagan	Isolate	7.87×10^6 cfu/mL	Negative	Positive
Legionella pneumophila	Philadelphia	Isolate	6.82×10^6 cfu/mL	Negative	Positive
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26×10^6 cfu/mL	Negative	Positive
Bordetella pertussis	A639	Isolate	6.37×10^6 cfu/mL	Negative	Positive
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56×10^6 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 3.40×10^5 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
Zanamivir	Zanamivir	282.0 ng/mL	Negative	Positive

Interfering Substance	Active Ingredient	Concentration	Cross-Reactive Results*	Interference Results*
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 (nasal swabs)

IVD

EF1438907EN00 (02/23)

GLOSSARY

REF	CE
Catalogue number	CE mark of conformity
EC REP	LOT
Authorized Representative in the European Community	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 <n> determinations
CONTROL +	CONTROL −
Positive control	Negative control

REFERENCES

1. Baker, S., Frias, L., and Bendix, A. Coronavirus live updates: More than 92,000 people have been infected and at least 3,100 have died. The US has reported 6 deaths. Here's everything we know. Business Insider. March 03, 2020.
2. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen
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