MatMaCorp COVID-19 2SF

Qualitative assay for use on the MatMaCorp Solas 8 Instrument

For Use Under an Emergency Use Authorization (EUA) Only
For *in vitro* diagnostic use
Rx Only

MatMaCorp COVID-19 2SF Test kit	Part Number: ST-CV19-2SF
Solas 8 device	Part Number: SOL8

Contents

1 Intended Use

The MatMaCorp COVID-19 2SF Test, is a molecular *in vitro* diagnostic test utilizing a combined RT-PCR and isothermal nucleic acid amplification reaction, intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (nasopharyngeal swabs, mid-turbinate swabs, anterior nasal swabs) from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient 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 results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patientâĂŹs recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The MatMaCorp COVID-19 2SF Test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The MatMaCorp COVID-19 2SF Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2 Summary and Explanation of the Test

2.1 Test Principle

The MatMaCorp COVID-19 2SF Test is used for the qualitative detection of SARS-CoV-2 from upper respiratory specimens (nasopharyngeal (NP) swabs, mid-turbinate (MT) swabs and anterior nasal (AN) swabs). The MatMaCorp COVID-19 2SF kit contains all components required to carry out an assay for SARS-CoV-2 on the Solas 8 device. The MatMaCorp COVID-19 2SF Test utilizes a combined RT- PCR and isothermal nucleic acid amplification technology for the qualitative detection of nucleic acid from SARS-CoV-2. The assay comprises two procedures: 1) sample preparation and 2) amplification and detection. Samples can be upper respiratory swab samples collected in universal/viral transport media (UTM/VTM).

2.1.1 Sample Preparation

Fifty (50) μl of each sample is treated with an equal volume of lysis buffer and incubated for 2 minutes at 95°C in the big block of the Solas 8 device, following the on-screen instructions. After this, 5 μl of the lysed sample is used directly in the detection step.

2.1.2 Amplification and Detection Step

As prompted by the user interface on the device, the RNA template from the Sample Preparation step above is added to the designated well of an 8-well PCR strip tube. From here on, there are 2 steps involved in getting the final data and they are all done in the same tube:

STEP 1

The initial cDNA synthesis and PCR amplification (RT-PCR) occurs at this step. The Step 1 Master Mix contains all the reagents required for amplification of SARS-CoV-2, as well as the internal control. The master mix has primers designed to target SARS-CoV-2 RNA that amplifies a unique region of the RdRp segment. The Step 1 Master Mix is added to all the wells of the 8-well PCR strip tube that have samples as directed by the instructions on the device. After the initial PCR reaction, a method that uses padlock probes is used to confirm that the amplification is specific to the SARS-CoV-2 target sequence. For this, a circularizing oligonucleotide probe (also called padlock probe) specific to the amplified region of the RdRp segment, along with a thermostable ligase, is also contained in the master mix. The thermostable ligase allows a cycling ligase reaction. This padlock probe is sequence-specific and designed to ligate if the correct amplified segment from the SARS-CoV-2 virus is present.

STEP 2

The ligated probe is amplified using an isothermal amplification method called rolling circle amplification (RCA). Step 2 reagents include Bst DNA polymerase and fluorescent labeled primers with quenchers that are used to identify each of the amplified RNA targets. There are two primers used in this step for each target. One is a forward primer (labeled) and the second is a reverse primer that is unlabeled. Real-time fluorescence is detected by the Solas 8 device.

2.2 Internal Control

MatMaCorp COVID-19 2SF Test has built-in procedural controls. This is referred to on the system as Human Internal Positive Control (HIPC). The result of the HIPC is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting the Reports function on the instrument. If needed, all the raw data generated by the instrument can be reviewed later.

2.3 External Positive and Negative Controls

MatMaCorp COVID-19 2SF kits contain a separate Positive Control reagent that is provided. The kits are formulated in 8 well PCR strips. The first well is hard-coded as a negative control and the 8th well is hard-coded as a positive control. The positive control is a synthetic RNA target that is identical to the RdRp segment of the SARS-CoV-2 genome. The negative control is used to monitor contamination introduced by the laboratory environment and the users in their routine use of the kit. The positive control is used to monitor the proper functioning of the reagents, particularly the reagents used in the detection of the SARS-CoV-2 RNA.

3 Reagents and Materials

3.1 Components Included with the Test Kit

All components of the test are manufactured by MatMaCorp and they include enough reagents to do

- 100 sample preparations,
- 100 COVID-19 2SF Test reactions - Amplification and Detection including negative and positive controls.

All these components are packed in a kit box labeled MatMaCorp COVID-19 2SF Test. The contents of the kit box are:

Kit Component	Description	Quantity
Aluminum Pouch 1	Step 1 Master Mix	17 screw cap tubes
Aluminum Pouch 2	Step 2 Master Mix	17 screw cap tubes
Aluminum Pouch 3	Negative Control	17 screw cap tubes
Aluminum Pouch 4	Positive Control pellet	17 capsules
Aluminum Pouch 5	Lysis Buffer	17 screw cap tubes
Plastic Bag 1	8 well PCR strip tubes	17 strips with attached lids
Plastic Bag 2	1.5 ml locking tubes for sample prep	100 tubes

3.2 Reagent Ingredients

Kit Component	Label on Tube	Reagent Ingredients
Step 1 Master Mix	S1 Mix	Tris buffer, Taq enzyme, reverse transcriptase enzyme, Primer probe, dNTPs, forward and reverse primers, ligase enzyme, NAD+, Triton X100
Step 2 Master Mix	S2 Mix	Tris buffer, Mg-sulfate, K-Chloride, dNTPs, forward and reverse primers, Bst DNA polymerase enzyme
Lysis Buffer	Buffer CNL	Tris buffer, EDTA and Guanidine isothiocyanate
Positive Control	Positive Control	Tris buffer, artificial RNA Ultramer, sugars
Negative Control	Negative Control	Universal Transport media, Tris buffer, EDTA, Guanidine isothiocyanate

NOTE: All reagents are provided with overages.

3.3 Reagent storage and handling requirements

All reagents are stored at room temperature. Their expiration dates are provided on the kit box and the storage container that each reagent is packed in. Once hydrated, use reagents immediately and discard – do not re-use or freeze-thaw.

Components required but not included with the kit

- Sterile Water or DEPC treated Sterile Water
- Pipettes
- Tips for pipettes (filter/barrier tip)
- Upper respiratory specimens (nasopharyngeal (NP) swabs, mid-turbinate (MT) swabs and anterior nasal (AN) swabs) collected in Copan UTM-RT or equivalent, stored according to CDC guidelines

3.4 Instrumentation Required

The Solas 8 instrument (part number: SOL8) is required. It comes with built-in software (version r3.2). For additional information, please refer to the Solas 8 User Guide that comes with the instrument.

4 Precautions and handling requirements

4.1 Warnings and Precautions

Good laboratory practices are essential to ensure that the test is performing as expected. As with any molecular test, care should be taken to keep reagents and amplification mixtures free of contamination.

- For *in vitro* diagnostic use only.
- This test has not been FDA cleared or approved but has been authorized for emergency use by authorized laboratories.
- This test has been authorized for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.
- To be used in conjunction with the Solas 8 device.
- All patient samples for testing should be handled as if infectious, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories and in the CLSI Document M29-A4.1,2.
- Personnel proficient in handling infectious materials and the use of the Solas 8 device should perform this procedure.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- If spillage of sample occurs, follow appropriate site procedures or immediately disinfect with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10).
- When using pipettes, the use of sterile disposable pipette tips with filters are recommended.
- Safety Data Sheets (SDS) are available on request from MatMaCorp customer support (+1) 402-387-7900. It is also available online at `http://matmacorp.com/product_matmacorp_covid_19_test_system.html`.
- Follow protocol steps and all provided recommendations to ensure that the test is performed correctly. Any deviation may affect test performance.
- To prevent false positive results that may occur, ensure that carryover of samples are adequately controlled during sample handling and processing.

4.2 Reagent handling

- Handle all reagents, controls, and samples according to good laboratory practices. This will prevent carryover of samples or controls into patient samples.
- Before use, visually inspect each reagent packaging, to ensure that all packing is intact. If there is any evidence of breakage or damage, do not use that material for testing.
- The MatMaCorp Lysis buffer (CNL Buffer) contains guanidine thiocyanate, a potentially hazardous chemical. Avoid contact of reagents with the skin, eyes, or mucous membranes. If contact does occur, immediately wash with generous amounts of water; otherwise, burns can occur.
- Do not allow CNL buffer which contains guanidine thiocyanate, to contact sodium hypochlorite (bleach) solution. This mixture can produce a highly toxic gas.
- Dispose of all materials that have come in contact with samples and reagents in accordance with country, state, and local regulations.

4.3 Good Laboratory Practice

- Wear laboratory gloves, laboratory coats, and eye protection when handling samples and reagents.
- Avoid contaminating gloves when handling samples and positive controls. If there is any question of having contaminated the gloves, immediately change gloves between handling samples and any test kit components.
- Wash hands thoroughly after after removing the gloves, particularly if samples were handled.
- Thoroughly clean and disinfect all laboratory work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite (bleach) in distilled or deionized water (dilute household bleach 1:10). Follow by wiping the surface with 70% ethanol. As stated above, do not allow CNL buffer which contains guanidine thiocyanate, to come in contact with sodium hypochlorite (bleach) solution. This mixture can produce a highly toxic gas.
- If spills occur on the Solas 8 instrument, follow the instructions in the User Guide to properly clean and decontaminate the surface of the instrument and the work surface.

- Do not eat, drink, or smoke in a laboratory.
- Use standard laboratory pipettes - mechanical or electronic but do not use any other pipetting method including mouth pipetting.

5 Sample Collection, Transport and Storage

5.1 Sample Collection

Collect upper respiratory specimens (nasopharyngeal (NP) swabs, mid-turbinate (MT) swabs and anterior nasal (AN) swabs) specimens according to standard collection technique using flocked or polyester-tipped swabs and immediately place in 1 ml or 3 ml of Copan Universal Transport Medium (UTM-RT) or equivalent.

5.2 Transport and Storage

Sample stability when using MatMaCorp COVID-19 2SF Test has not been established for suggested temperatures and time, but is based on viability data from testing similar viruses in the UTM-RT or UVT Systems as stated in, for example, on the Copan UTM-RT System Instructions For Use and shown below:

- After collection, the specimen should be stored at 2 to 8°C and processed within 72 hours.
- If delivery and processing exceed 72 hours, specimens should be transported in dry ice and once in laboratory frozen at -70°C or colder.

6 Instruction For Use

6.1 Procedural notes

- Do not use reagents after their expiry dates.
- All consumables provided in the kit are for one-time use only.
- Refer to the COVID-19 2SF Test Solas 8 User Guide for proper maintenance and use of the instrument.

6.2 Running the MatMaCorp COVID-19 2SF Test

Upper respiratory swab specimens collected in Copan UTM-RT or equivalent can be used. Minimum required sample volume for the test is 50 μl:

- Use caution when transferring specimens from a primary collection tube to a sample prep tube (tubes with locking lid).
- Use pipettes with aerosol-barrier (filter tip) when handling samples.
- Use a new pipette tip for each sample.
- If samples are frozen, ensure that samples are completely thawed before transfer to a sample prep tube.

To transfer patient sample from a primary collection tube into a sample prep tube (with locking lid):

- Label sample prep tube with the same sample ID as the sample tube.
- Unscrew the primary sample tube cap.
- Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube.
- Transfer 0.050 ml (50 μl) into the appropriately labeled sample prep tube. Immediately close the lid.
- Place sample prep tube into a tube rack.
- Close the primary sample tube cap and return to original location.

6.3 MatMaCorp COVID-19 2SF Test Procedure

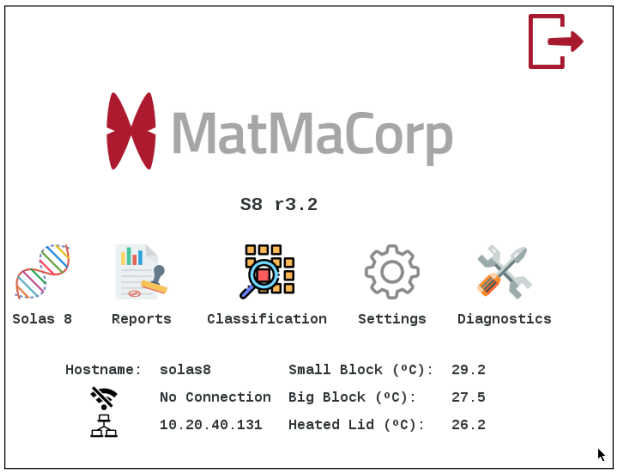
Before testing with the **COVID-19 2SF** Test Kit, make sure to have all patient samples and other materials supplied by the user ready, i.e. water, pipettes, tips, etc.

6.3.1 STEP 1 - Preparing the device for Testing Samples

Turn on the device - flip the **power switch** on the side of the instrument. The information that appears on the touch screen is shown to the right of the description.

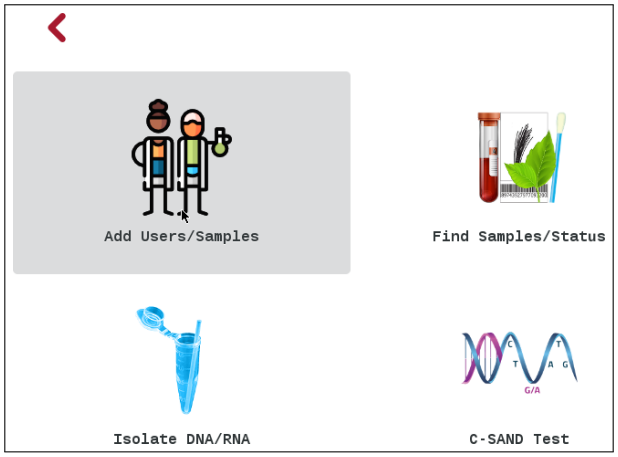
Navigate to "Solas 8 Menu"

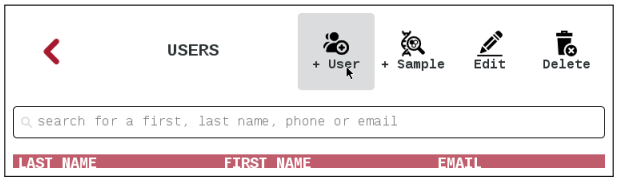
- Click the **Solas 8**  icon to navigate to the **Solas 8 Menu** screen.



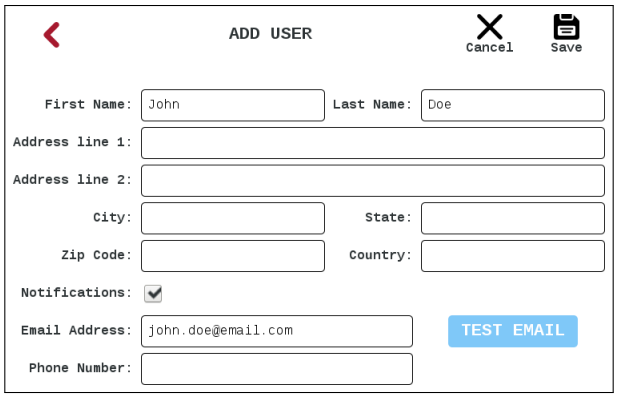
Navigate to "Add Users/Samples"

- Select **Add Users/Samples**.
- Click **+ User**  icon in the upper right of the screen to access the **User Information** screen and create a user.



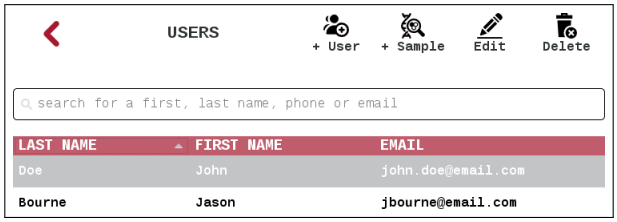


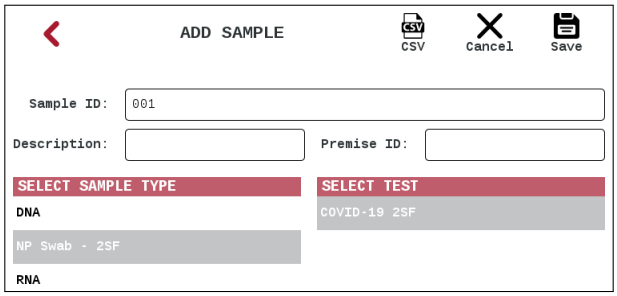
Enter All Necessary User Information



- Fill in the **First and Last Name** entries with the information of the person running the **COVID-19 2SF** Test Kit.
- Other entry fields are optional.
- If the device has an internet access, you can check the notification box to receive **notifications** during the **COVID-19 2SF** Test (end of steps 1 and 2 as well as results summary).
- Click **Save**  icon.

To Enter Patient Sample Information





- From the **Solas 8 Menu** screen, click **Add Users/Samples** and select a **User** from the users list.
- Click **+ Sample**  icon.
- Select **NP Swab - 2SF** from the **Sample Type** list. MT and AN swabs can be used as well.
- Select **COVID-19 2SF** from the **Test** list.
- Enter **Sample ID**.
- Click **Save**  icon.

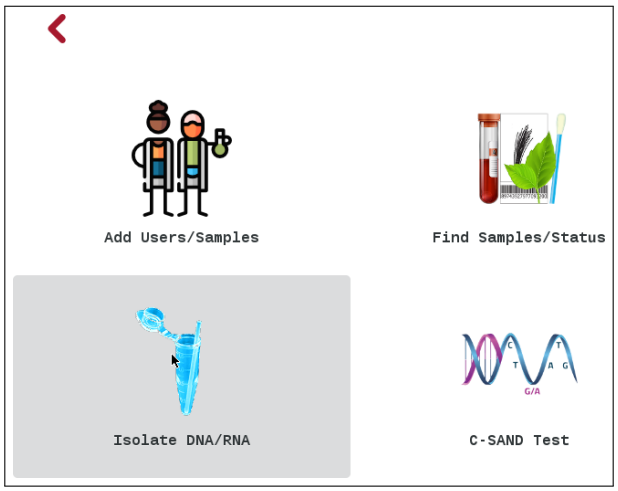
Note:

- Sample ID can be scanned using a USB bar code reader.
- Samples ID can be imported in batch using the CSV import option. Click **CSV**  icon and follow on screen instructions.

6.3.2 STEP 2 - Preparing Patient Sample

The sample preparation contents of the **COVID-19 2SF** Test Kit are required for this step. All needed items will be in the kit box.

- Select **Isolate DNA/RNA**.

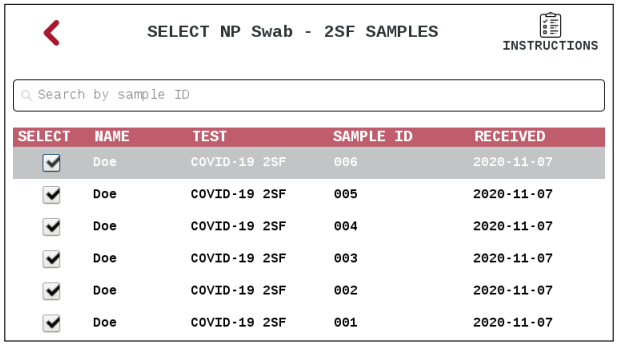


Select Kit Extraction Method

- Select **NP Swab - 2SF**. Only one method is available for the COVID-19 2SF Test and it is used with NP, MT and AN swabs.
- Click **Next**  icon to proceed to samples selection.

Select Samples

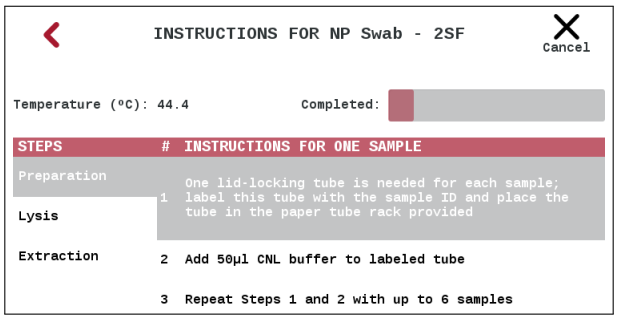
- **Select** up to **6 patient samples**.
- Click **Instructions**  icon to proceed to the **sample preparation protocol**.

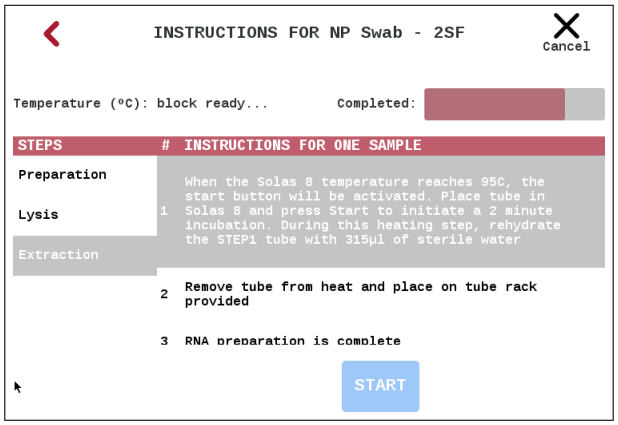


Follow On-Screen Instructions

The Instructions screen displays the protocol for the selected kit. What is seen on the screen is shown at the end of this section also. **Ensure that a fresh pipette tip is used for each step**.

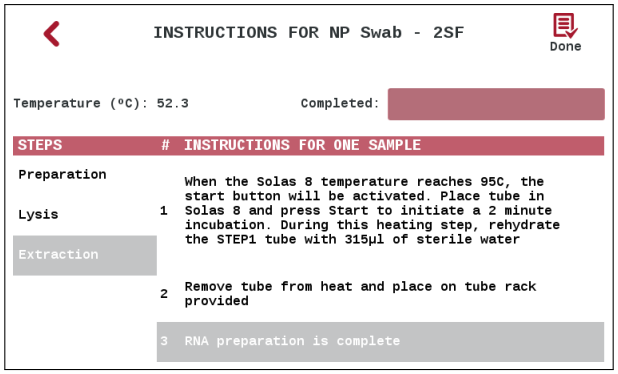
- **Highlight** the instructions to track progress.
- Progress can be monitored on the "Completed" bar.
- There are three steps in NP Swab - 2SF sample preparation: **Preparation**, **Lysis**, and **Extraction**. The right column contains the substeps for each step highlighted.
- When a step indicates on screen that an incubation **step is required**, **select the instruction (as shown on right)** and click **START**. If the **START** button is grey, the Solas 8® Device is still heating up and the button will turn blue when the device is ready. After the incubation time is over, the screen will return to the instructions.

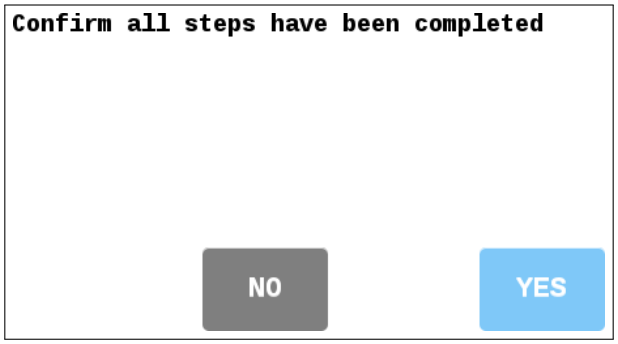




Finishing Sample Preparation

- Select the **last instruction** of the **last step** to reveal the **Done** icon.
- Click **Done** icon.
- **Confirm** all steps have been completed. This action tells the system **RNA is now available** for the selected samples to perform the **COVID-19 2SF** Test.





NP Swab - 2SF Extraction Protocol

Preparation

- One lid-locking tube is needed for each sample; label this tube with the sample ID and place the tube in the paper tube rack provided
- Add 50 μl CNL buffer to labeled tube
- Repeat Steps 1 and 2 with up to 6 samples

Lysis

- Vortex sample containing the swab for 30 seconds
- Add 50 μl of mixed sample to the tube already containing CNL buffer
- Briefly vortex to mix the sample and lysis buffer

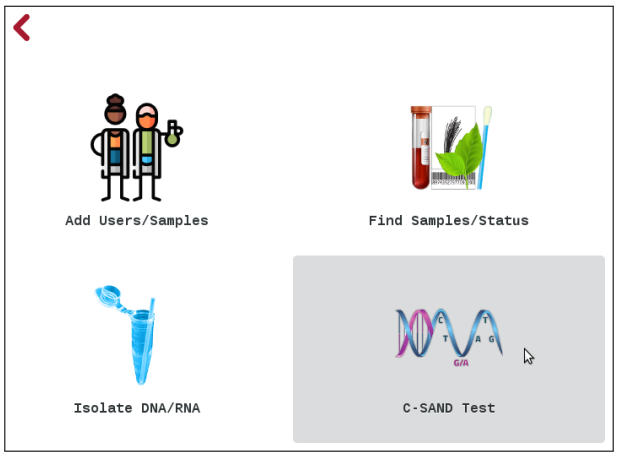
Extraction

- When the Solas 8 temperature reaches 95°C, the start button will be activated. Place tube in Solas 8 and press Start to initiate a 2 minutes incubation. During this heating step, rehydrate the STEP1 tube with 315 μl of sterile water
- Remove tube from heat and place on tube rack provided
- RNA preparation is complete

6.3.3 STEP 3 - Performing the COVID-19 2SF Test

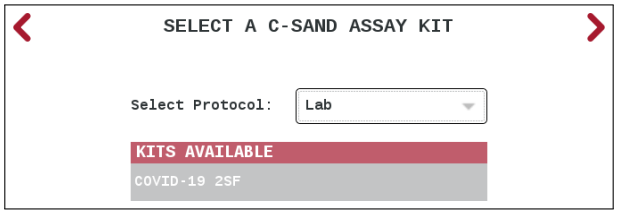
The contents of the **COVID-19 2SF** Test Kit are required for this step. All needed items will be in the kit box.

- Select **C-SAND Test**.



Select Assay

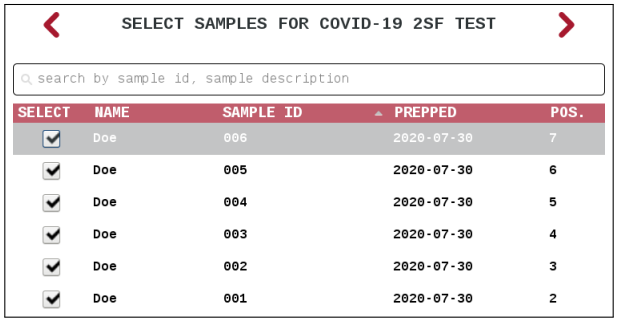
- From the dropdown menu, select **Lab**. This is the only option available for COVID-19 2SF Test.
- Select **COVID-19 2SF**.
- Click **Next**  icon to proceed to samples selection.



Select Samples

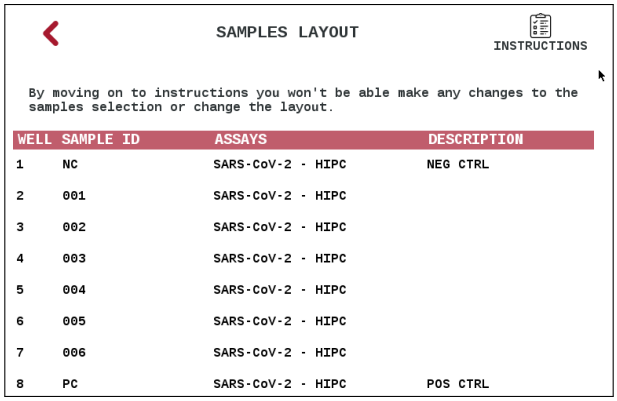
- **Select** up to **6 patient samples** in the order you want to position them.

NOTE: positions 1 and 8 are reserved for external **negative** and **positive** controls - **NC** and **PC** respectively. Therefore, the selected wells will be assigned starting with position 2. Samples are assigned to wells in the order that they are selected.



Confirm Sample Layout

- **Review** the Samples Layout screen.
- **NC** is assigned to well 1.
- **PC** is assigned to well 8.
- Click **Instructions**  icon to **proceed to protocol**.

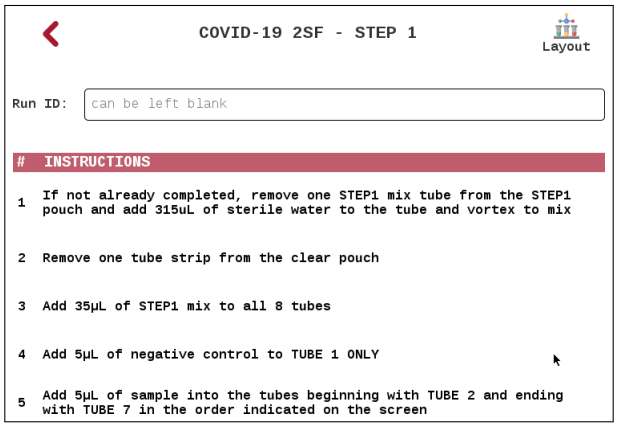


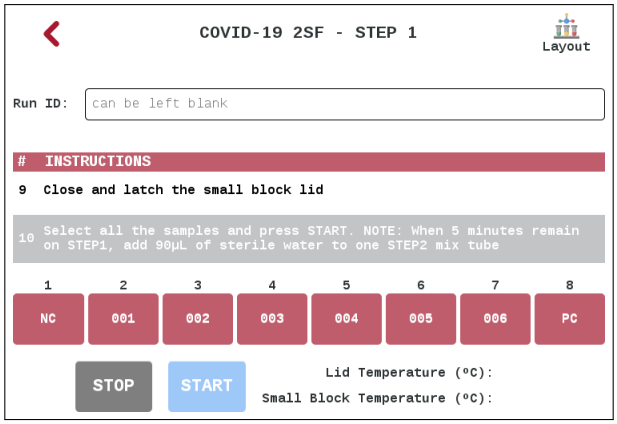
COVID-19 2SF - STEP 1

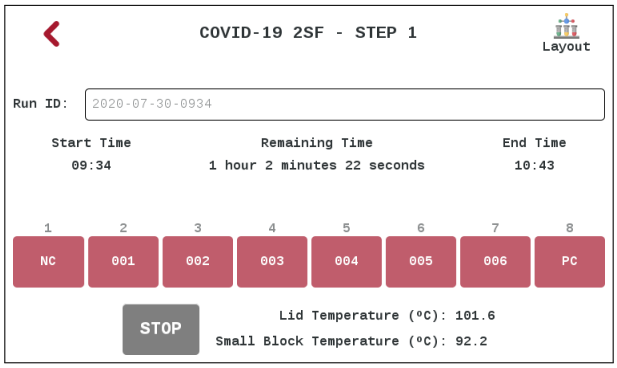
- Enter a **run ID**. If left blank, the system will use a Year-Month-Day-Time format ID.
- **Follow** instructions as shown on screen.
- **Highlight** the instructions to track progress through the protocol.
- **Scroll down** to complete protocol.
- Highlight the **last instruction** to reveal the STEP 1 controls.
- Select **all samples**.
- Ensure the samples inserted into the small block match the layout displayed on the screen.
- Close and Latch the lid.
- Click **START**.

NOTE:

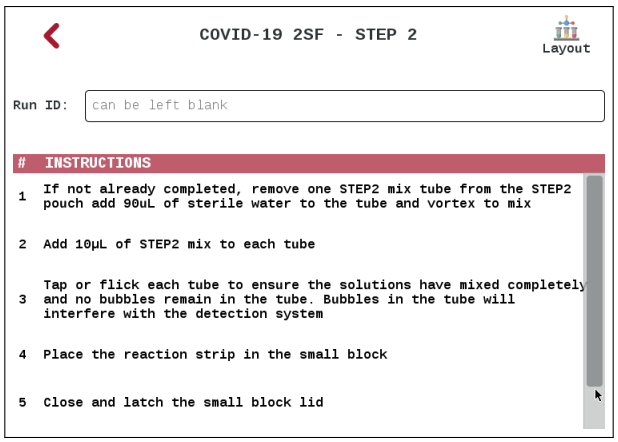
- DO NOT OPEN THE LID until STEP 2 appears on the screen.



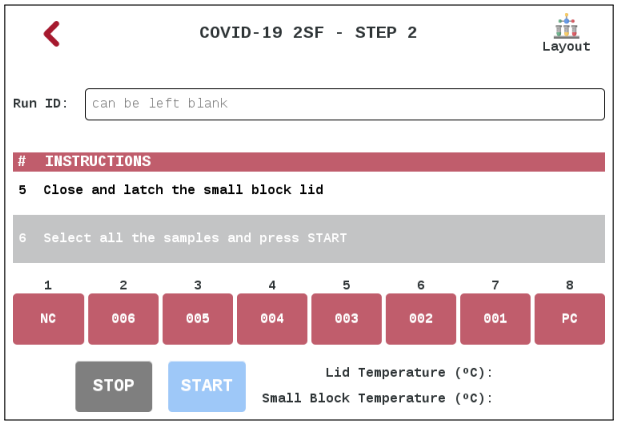




COVID-19 2SF - STEP 2

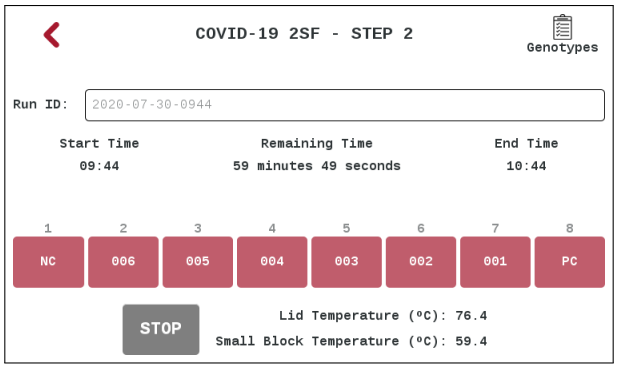


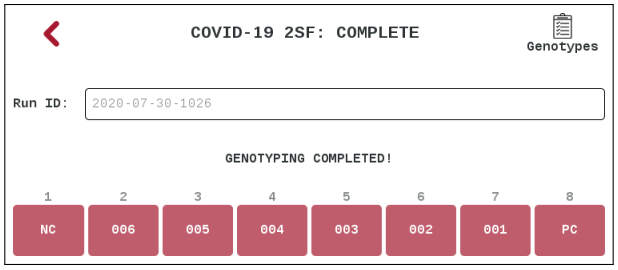
- **Follow** instructions as shown on screen.
- **Highlight** the instructions to track progres through the protocol.
- Highlight the **last instruction** to reveal the STEP 2 controls.
- Select **all samples**.
- Ensure the samples inserted into the small block match the layout displayed on the screen.
- Close and Latch the lid.
- Click **START**.



NOTE:

- **Strong signals** are usually identified within **10 minutes**.
- A preliminary report is generated when the first **SARS-CoV-2** positive samples are detected.
- Click **Genotypes**  icon to view the results real-time.
- When the assay is complete, the device will advance to **GENOTYPING COMPLETED!** screen.





MatMaCorp COVID-19 2SF STEP 1 and 2 Instructions

STEP 1

- If not already completed, remove one STEP1 mix tube from the STEP1 pouch and add 315 μl of sterile water to the tube and vortex to mix
- Remove one tube strip from the clear pouch
- Add 35 μl of STEP1 mix to all 8 tubes
- Add 5 μl of negative control to TUBE 1 ONLY
- Add 5 μl of sample into the tubes beginning with TUBE 2 and ending with TUBE 7 in the order indicated on the screen
- Add 1 Positive Control pellet to tube 8
- Mix well by flicking the tube strip, then tap the tube onto the counter to ensure all the solution is in the bottom of the tube
- Place the tube strip in the small block
- Close and latch the small block lid
- Select all the samples and press START. NOTE: When 5 minutes remain on STEP1, add 90 μl of sterile water to one STEP2 mix tube

STEP 2

- If not already completed, remove one STEP2 mix tube from the STEP2 pouch add 90 μl of sterile water to the tube and vortex to mix
- Add 10 μl of STEP2 mix to each tube
- Tap or flick each tube to ensure the solutions have mixed completely and no bubbles remain in the tube. Bubbles in the tube will interfere with the detection system
- Place the reaction strip in the small block
- Close and latch the small block lid
- Select all the samples and press START

7 Results

The MatMaCorp Solas 8 instrument automatically detects SARS-CoV-2 and the internal control for each individually processed sample as well as the controls. The results for the patient samples and the controls are displayed as well as the validity of the results and controls.

7.1 Quality Control and Validity of Results

Each batch of 6 samples that are run together has one negative control and one positive control, making it a total of 8 reactions. In the Solas 8 report for each set of samples, check for the results, POSITIVE or ND for Not Detected.

The results from each batch of samples are valid if the negative and positive controls are valid. Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

7.2 Interpretation of Results

Note that results provided by this test should only be interpreted along with clinical evaluation of the patient as well as available patient history. For each patient sample, the viral target will have a call of "POSITIVE" if the SARS-CoV-2 RNA was detected or "ND" (Not Detected) if the SARS-CoV-2 RNA was not present above the limit of detection. Each sample (wells 2 to 7) should have a result of "POSITIVE" for the human internal control (HIPC). In some cases, where the viral load is high, it is possible that the HIPC call may be "ND". In other cases, if the swab was not used properly during specimen collection, there may not be enough sample, and a "ND" call can be made for the internal control (HIPC). In such situations, if the positive and negative controls (wells 8 and 1) performed as expected, and the call made for the SARS-CoV-2 is POSITIVE, the result should be considered as a valid test.

7.3 External Controls Result Interpretation and Troubleshooting

Instrument Calls for Well 1: Negative Control (NC)

SARS-CoV-2	HIPC	Interpretation	Troubleshooting
ND	ND	Expected result	
ND	POSITIVE	All patients results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.
POSITIVE	ND	All patient results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.
POSITIVE	POSITIVE	All patient results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.

Instrument Calls for Well 8: Positive Control (PC)

SARS-CoV-2	HIPC	Interpretation	Troubleshooting
POSITIVE	ND	Expected result	
POSITIVE	POSITIVE	All patients results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF kit.
ND	POSITIVE	All patients results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF kit.
ND	ND	All patients results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF kit.

7.4 Patients Sample Results

For a valid assay, interpret the Patient Sample Results using the table below:

SARS-CoV-2	HIPC	Interpretation	Follow-Up Actions
POSITIVE	POSITIVE	Positive COVID-19 Detected	Positive results do not rule out bacterial infection or co-infection with other viruses. All positive and negative SARS-CoV-2 results should be reported to the appropriate public health officials.
ND	POSITIVE	Presumptive Negative COVID-19 not detected above Limit of Detection	Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests.
POSITIVE	ND	Positive COVID-19 Detected	Positive results do not rule out bacterial infection or coinfection with other viruses. All positive and negative SARS-CoV-2 results should be reported to appropriate public health officials.
ND	ND	Invalid	Repeat test from the beginning using the same sample. If repeated invalid results are obtained, repeat testing using a new sample.

In valid test, samples are analyzed based on the detection of the viral target. If viral target is "ND" and the human internal control is "Positive", the sample is considered "Below LoD" and resampling may be required later, at the discretion of the physician. If all targets (viral and human internal control) are "ND", the sample is considered an "Invalid" and should be repeated or re-sampled.

8 Procedural Limitations

- The MatMaCorp COVID-19 2SF Test has been evaluated only for use on the MatMaCorp Solas 8 instrument. None of the components in the kit will work with other instruments.
- Negative results should be treated as presumptive and tested with an alternative FDA authorized molecular assay, if necessary for clinical management, including infection control.
- How the sample was collected, stored and handled will influence the results that are generated from running this test.
- This test is intended to be used for the detection of SARS-CoV-2 RNA in nasopharyngeal (NP), mid-turbinate (MT) and anterior nasal (AN) swab samples collected in Universal viral transport media (Copan UTM-RT or equivalent) or Universal Viral Transport System (UVT) or equivalent media.
- Testing of other sample types using the MatMaCorp COVID-19 2SF Test may result in inaccurate or no results.
- Based on *in silico* analysis, the primers/probe in the MatMaCorp COVID-19 2SF Test may cross-react with SARS-CoV and cause a false positive result. This coronavirus is not known to currently circulate in the human population.
- Different factors may influence the detection of SARS-CoV-2 RNA including sample collection methods, patient factors (e.g., presence or absence of symptoms), and/or stage of infection etc.
- As with any molecular test, mutations within the target region of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- A Human Internal Positive Control (HIPC) is included in each reaction of the MatMaCorp COVID-19 2SF test to help identify the specimens containing substances that may interfere with nucleic acid isolation, amplification and detection. If interfering substances are present, false negative or invalid results may occur.
- Carefully following the recommendations provided in this Instructions For Use document along with good laboratory practices may help prevent contamination of samples.

Conditions of Authorization for the Laboratory

The MatMaCorp COVID-19 2SF Test 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/vitro-diagnostics-euas.

However, to assist clinical laboratories using the MatMaCorp COVID-19 2SF Test, the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using MatMaCorp COVID-19 2SF Test 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.

B. Authorized laboratories using MatMaCorp COVID-19 2SF Test will use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive MatMaCorp COVID-19 2SF Test will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using MatMaCorp COVID-19 2SF Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories will collect information on the performance of MatMaCorp COVID-19 2SF Test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and MatMaCorp (+1 402-387-7900) 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.

F. All laboratory personnel using MatMaCorp COVID-19 2SF Test must be appropriately trained in real-time PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. MatMaCorp, authorized distributors, and authorized laboratories using MatMaCorp COVID-19 2SF Test 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 requirements to perform high complexity tests" as "authorized laboratories."

9 Non-Clinical Performance evaluation - Key Performance Characteristics

9.1 Analytical Sensitivity

The goal of this study was to determine the lowest detectable concentration of SARS-CoV-2 at which 19 out of 20 replicates (95%) were positive. All the testing was performed on the MatMaCorp Solas 8 device.

Thirty clinical samples collected in Universal Transport Media determined to be negative using an Emergency Use Authorization (EUA) test authorized by the U.S. FDA were pooled and spiked with a gamma-irradiated SARS-Related Coronavirus 2, isolate (USA-WA1/2020 (NRC-52281 lot 70033641, provided by BEI Resources). As shown in the Table below, the LoD was determined by performing twenty independent reactions for each of the viral concentrations:

Concentration (genome equivalents/ml)	Results (Positive/Total)	Pos. Hit Rate (%)
5000	20/20	100
4000	20/20	100
3000	20/20	100
2000	20/20	100
1000	6/20	30
0	0/20	0

Based on the above results, the limit of detection, or LOD, is determined to be 2000 genome equivalents per ml (100 genome equivalents per 50 μl reaction).

9.2 Inclusivity/Reactivity

probes to an alignment of all SARS-CoV-2 sequences available in Genbank and GISAID databases as of August 28, 2020. Primers and probe sequences were entered into the respective databases and compared for homology.

To evaluate the inclusivity of the assay, the 39 nucleotide target sequence of the padlock probe (comprised of the 25 nucleotide 5' and 14 nucleotide 3' flanking sequences) was entered into the BLAST database (blast.ncbi.nlm.nih.gov). Highly similar sequences (megablast) were searched using the default search parameters.

Over 16,000 sequences were available in the database. The probe sequence matched 100% coverage and identity to all but 39 sequence accessions (99.8% inclusivity). The majority of the mismatches (18 of 29) were due to ambiguous or undetermined bases, which is likely an artifact of sequencing.

The BLAST search was also performed for the MatMaCorp SARS-CoV-2 Forward and Reverse primers. As with the probe analysis above, over 16,000 sequences were available in the database. The primer sequence matched 100% coverage and identity to all but 37 sequence accessions for the Forward primer (99.8% inclusivity) and 74 for the Reverse primer (99.5% inclusivity). Once again, many of the mismatches were due to ambiguous or undetermined bases in the sequence. The number of mismatches for each primer and probe sequence are listed in the table below.

# of mismatches	1	2	3	>3
Probe	28	2	2	7[a]
Forward Primer[b]	22	3	9	3
Reverse Primer[b]	53	13	0	8

[a] $<$ 90% sequence coverage due to incomplete sequences in database accession

[b] No mismatches on 3' end of primer

Based on the *in silico* inclusivity analysis, MatMaCorp expects that the MatMaCorp COVID-19 2SF Test will detect nearly 100% of all SARS-CoV-2 isolates. The target gene was selected due to its expected sequence stability. This is supported by the lack of any significant mutation events within the target sequences. While some variation is observed, it occurs in 1 or 2 isolates per 1000. Like any primer/probe-based molecular assay, minor variation that does not occur at the terminal base of the primer or the critical clamp position of the padlock probe may still be detected by the assay. Overall, our assessed risk for false negatives due to the sequences of the primers and probes is very low.

9.3 Cross-reactivity (Analytical Specificity)

Possible cross reactivity of the MatMaCorp COVID-19 2SF Test was evaluated by in silico analysis. Forward and reverse primers and padlock probes, for both the HIPC and the SARS-CoV-2 targets, in the test were individually compared to sequences available in the NCBI (GenBank) database.

Organisms that were checked for possible cross-reactivity are listed in the tables below. Based on the in silico analysis, SARS-CoV may cross-react with the MatMaCorp COVID-19 2SF Test primers/probes. However, SARS-CoV is not currently a circulating pathogen clinically relevant for the current SARS-CoV-2 pandemic. Additionally, sequences in Enterovirus A71 strain EV71 (KJ686167.1), rhinovirus strain 20693_1_HRV-A (MK989737.1), and Legionella spiritensis strain NCTC12082 (LR134374.1) had >80% homology to a single primer. However, an amplicon is not expected to be generated nor detection by the assay based on lack of homology to the other primer or padlock probe.

NUMBER	ORGANISM	NUMBER	ORGANISM
1	Human coronavirus 229E	2	Human coronavirus OC43
3	Human coronavirus HKU1	4	Human coronavirus NL63
5	SARS-coronavirus	6	MERS-coronavirus
7	Adenovirus	8	Human Metapneumovirus
9	Parainfluenza virus 1-4	10	Influenza A and B
11	Enterovirus	12	Respiratory syncytial virus
13	Rhinovirus	14	Chlamydia pneumonia
15	Haemophilus influenzae	16	Legionella pneumophila
17	Mycobacterium tuberculosis	18	Streptococus pneumonia
19	Streptococcus pyrogenes	20	Bordetella pertussis
21	Mycoplasma pneumoniae	22	Pneumocystis jirovecii (PJP)
23	Influenza C	24	Parechovirus
25	Candida albicans	26	Corynebacterium diphtheriae
27	Legionella non-pneumophila	28	Bacillus anthracosis
29	Moraxella cararrhalis	30	Neisseria elongate
31	Neisseria miningitidis	32	Pseudomonas aeruginosa
33	Staphylococcus epidermis	34	Streptococcus salivarius
35	Leptospirosis	36	Chlamydia psittaci
37	Coxiella burneti	38	Staphylococcus aureus

9.4 Endogenous Interference Substance Studies

An endogenous interference study was performed using contrived positive and negative samples, prepared from pooled matrix from natural clinical negative NP swab samples. Positive samples were prepared at 3x LoD using gamma-irradiated SARS-CoV-2 (BEI Resources, catalog 52281). Samples were processed using the MatMaCorp COVID-19 2SF Test on the MatMaCorp Solas 8 device, including sample lysis and assay, with negative and positive controls on each run. Each positive and negative sample was tested in triplicate, using the following interfering substance and concentration: nasal decongestant spray (15% v/v), lozenge (3 mg/ml), sore throat spray (5% v/v), mouth wash (5% v/v), human genomic DNA (10 ng/ul), mucin (2.5 mg/ml), saline-based nasal gel spray (1.25%), nicotine (0.03 mg/ml), toothpaste (0.5% v/v), and whole human blood (1%).

The average SARS-CoV-2 call score from each set of positive replicates was calculated, as well as the difference between the average score of the specific interfering substance and the "no interfering substance" control. No false positives or false negatives were observed and no endogenous interference is expected from the common interfering substances tested.

SUBSTANCES	CONCENTRATION	NEG.	POS.	MEAN SCORE
Nasal decongestant spray	15% v/v	0/3	3/3	96.6
Lozenges (benzocaine/menthol)	3 mg/ml	0/3	3/3	97.3
Sore Throat spray	5% v/v	0/3	3/3	93.7
Mouth Wash	5% v/v	0/3	3/3	95.5
Human Genomic DNA	10 ng/μl	0/3	3/3	98.5
Mucin: bovine submaxillary gland, type I-S	2.5 mg/ml	0/3	3/3	97.1
Saline-based nasal gel spray	1.25%	0/3	3/3	97.4
Nicotine	0.03 mg/ml	0/3	3/3	97.4
Toothpaste	0.5% v/v	0/3	3/3	92.4
Whole human blood	> 1%	0/3	3/3	98.7
No interfering substances	N/A	0/3	3/3	92.3

9.5 Clinical Evaluation

A study was performed to evaluate the performance of the MatMaCorp COVID-19 2SF Test using natural clinical positive and clinical negative nasopharyngeal swab specimens. Swabs were collected into 3 ml of viral transport media and initially tested with one of three EUA authorized comparator assays at different sites. Frozen remainders were shipped to MatMaCorp and testing was repeated on the Solas 8 device, according to the onscreen protocol and the Instructions for Use.

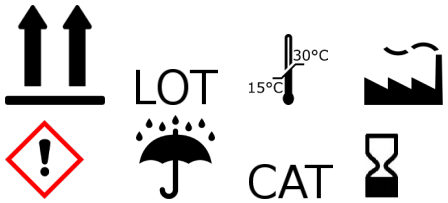
A total of 78 clinical positive samples, with Ct values ranging from 15-38, and 30 clinical negative samples were evaluated. Of the 60 clinical positive samples with Ct values available, 8 had a Ct $>$ 35 by the comparator method. Results from the study are summarized in the table below.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the MatMaCorp COVID-19 2SF Test relative to the expected results. Results of the clinical NP swab specimens are shown in the table below. The PPA was 88.5% (95% CI: 79.5% - 93.8%) and NPA was 100% (95% CI: 88.7% - 100%). No false positives were observed. All clinical positive samples with a Ct $<$ 30 were detected.

MatMaCorp COVID-19 2SF Test Clinical Performance	Expected Results		
	Positive	**Negative**	**Total**
Positive	69	0	69
Negative	9	30	39
Total	78	30	108
Positive Percent Agreement (PPA)	88.5% (95% CI: 79.5% - 93.8%)		
Negative Percent Agreement (NPA)	100% (95% CI: 88.7% - 100.0%)		

10 Symbols

The following symbols are used in labeling of MatMaCorp COVID-19 2SF test kits:



The Solas 8 instrument fulfills the following requirements:

Contact Us

(+1) 402-742-0357 (Main)
(+1) 402-387-7900 (Customer Support)
www.matmacorp.com
info@matmacorp.com

MatMaCorp®

COVID-19 2SF Test
Solas 8® User Guide

Effective 12/2020

Contents

WARNINGS:

- This product has not been FDA cleared or approved but has been authorized for emergency use with the MatMaCorp COVID-19 2SF Test by FDA under an EUA for use by authorized laboratories ;
- This product has been authorized only for use with the MatMaCorp COVID-19 2SF Test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- 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.

1 Getting Started

The Solas 8® instrument is used for the qualitative detection of SARS-CoV-2 from upper respiratory specimens (nasopharyngeal (NP), mid-turbinate (MT), and anterior nasal (AN) swabs) using the **COVID-19 2SF** test. The Solas 8® features a resistive touchscreen interface to enable robust, uninterrupted use even while wearing gloves.

1.1 Unpack

NOTE: If the main package was damaged in shipping, please notify the carrier immediately and do not accept the shipment.

- There are two boxes in a big brown box. Open the smaller white box (containing the power supply) using the flap on one end.
- Carefully unseal the top of the brown inner box with a blade less than 0.5"/1.25 cm in length. Your Solas 8® is suspended inside.
- Remove the suspension assembly from the inner box and place it on a stable surface.
- There are two flaps that are underneath the Solas 8®. Carefully unfold these flaps to release the tension on the plastic.
- Remove your Solas 8® from under the plastic sheet.

1.2 Connect to Power Supply

The Universal power supply that comes with the Solas 8® can run on voltages ranging from 100-240 Volts AC, with powerline frequencies from 50-60Hz. A country-specific power cable should be present with each power supply.

1.3 Detector Alignment

It is strongly recommended that you verify the Solas 8® detector alignment using the blue LED provided before using the device for the first time. The blue LED can be found taped inside a well in the heating block that is below the touch screen. Remove it and keep it in a safe place. From the Start Screen, go to **Diagnostics > Stepper Motor**. You will see two options:

STEP VARIATION

It checks for mechanical displacements. Press the  icon button and wait for test to complete.

ALIGNMENT

It checks the detector starting reference point. To run this function: turn on the blue LED. Insert the blue LED into well #1 of the small block (block above the touch screen). Press the  icon button. The device will automatically adjust the detector reference point which will be indicated as the New Reference point.

1.4 Connecting the Device to the Network

Your Solas 8® can connect to either wired (LAN) or wireless networks (WiFi). A network connection can be used to view results (graphic representation of raw data) on a modern browser (like Google Chrome or FireFox). To view results from your Solas 8®, ensure that it is powered on and connected to your local network or in Access-Point Mode. Type the device's hostname, or the device IP (this can be found on the Start screen of the Solas 8®) into your browser's address bar, depending on your network configuration. If the hostname does not work, your local network probably requires advanced configuration to make the device hostname visible.

WIRED NETWORK

To connect your Solas 8® device to your local network using the Ethernet port, simply plug in a Cat 5e or better Ethernet cable into the device. After a few seconds, depending on your network, the Start screen will show an IP address. If not, advanced configuration is required to allow the device to be part of the local network. Advanced parameters can be set from the **Start Screen** > **Settings > Ethernet**. If your local network configuration requires further advanced options that are not available through the User Interface, please contact the MatMaCorp Support team at (+1) 402-387-7900.

WiFi NETWORK

To connect to a wireless network, from the Start screen go to **Settings > WiFi - AP**. Check the Enable WiFi checkbox. If the device is in AP mode, it will automatically be disconnected. A list of detected networks will be displayed. If your network is not in the list, you can refresh the list of detected WiFi networks by clicking the Scan button. To connect to a network:

- Select your network from the list,
- Type in the network password.

NOTE: Presently, the Solas 8® doesn't handle WiFi networks that require a username and password authentication or a web login.

1.5 Access Point Mode (AP Mode)

The Access Point (AP) Mode option allows a Solas 8® to be turned into a router. Any WiFi enabled device with a web browser can access the web server running on the Solas 8®. This is very practical if the Solas 8® doesn't have access to any WiFi or LAN network, particularly in a remote location. This allows the user to access fluorescence data in real-time and see various reports generated by the machine.

To enable the Access Point (AP) Mode, go to **Settings > WiFi - AP** and select the Enable Access Point (AP) checkbox:

- Set an Access Point name ("Solas8" is the default),
- Click the Start AP button,
- From your WiFi enabled device, connect to the AP name set above,
- Once connected, the webserver is accessible by typing in the AP IP address in any web browser URL (default is 192.168.10.1).

2 Instruction for Running the COVID-19 2SF Test on the Solas 8® Device

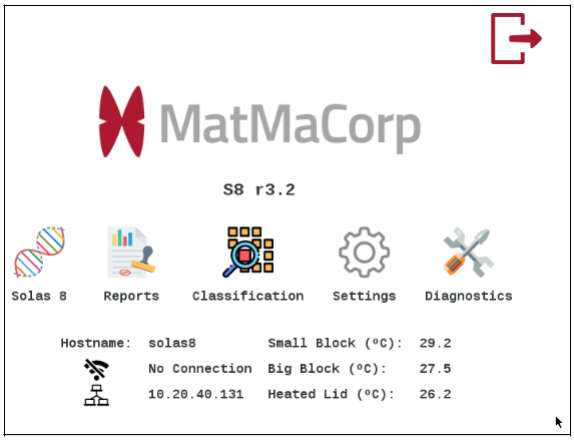
Before testing with the **COVID-19 2SF** test kit, make sure to have all patient samples and other materials supplied by the user ready, i.e. water, pipettes, tips, etc.

2.1 STEP 1 - Preparing the device for Testing Samples

Turn on the device - flip the **power switch** on the side of the instrument. The information that appears on the touch screen is shown to the right of the description.

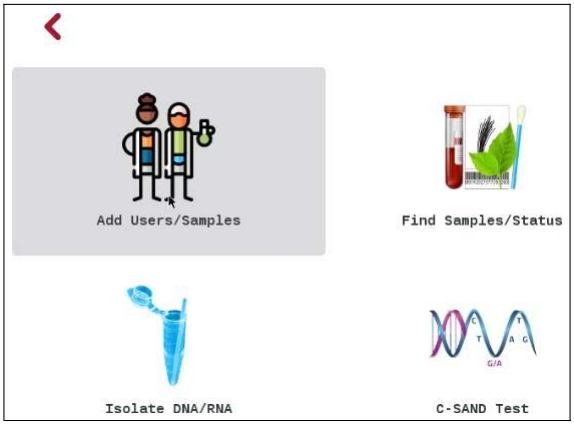
Navigate to "Solas 8 Menu"

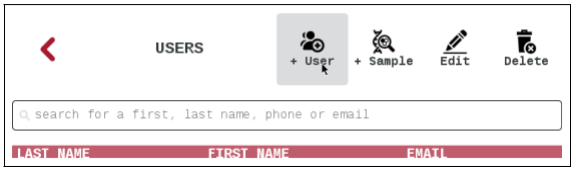
- Click the **Solas 8**  icon to navigate to the **Solas 8 Menu** screen.



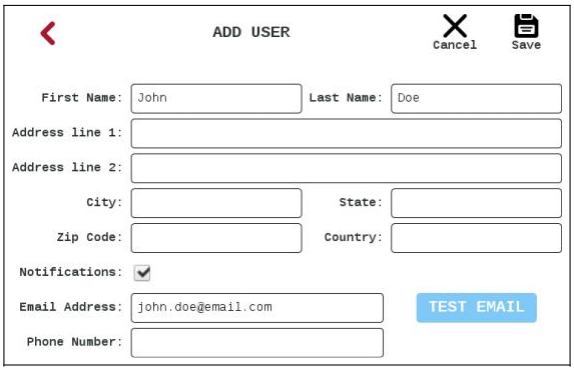
Navigate to "Add Users/Samples"

- Select **Add Users/Samples**.
- Click **+ User**  icon in the upper right of the screen to access the **User Information** screen and create a user.



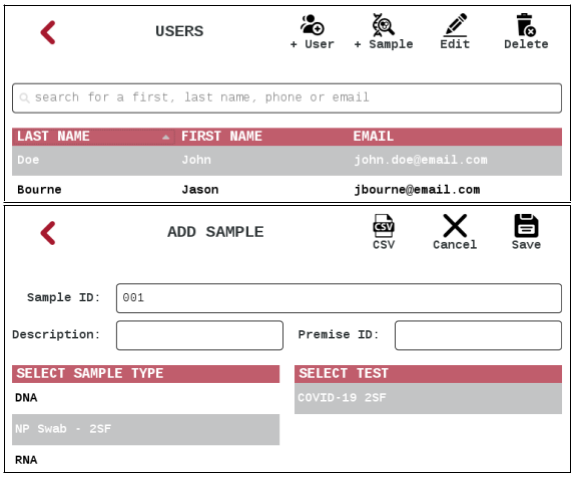


Enter All Necessary User Information



- Fill in the **First and Last Name** entries with the information of the person running the **COVID-19 2SF** test Kit.
- Other entry fields are optional.
- If the device has an internet access, you can check the notification box to receive **notifications** during the **COVID-19 2SF** test (end of steps 1 and 2 as well as results summary).
- Click **Save** icon.

To Enter Patient Sample Information



- From the **Solas 8 Menu** screen, click **Add Users/Samples** and select a **User** from the users list.
- Click **+ Sample** icon.
- Select **NP Swab - 2SF** from the **Sample Type** list. MT and AN swabs can be used as well.
- Select COVID-19 2SF from the **Test** list.
- Enter **Sample ID**.
- Click **Save** icon.

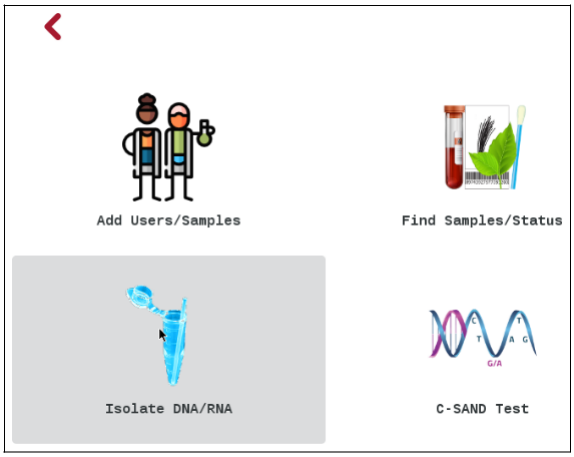
Note:

- Sample ID can be scanned using a USB bar code reader.
- Samples ID can be imported in batch using the CSV import option. Click **CSV** icon and follow on screen instructions.

2.2 STEP 2 - Preparing Patient Sample

The sample preparation contents of the **COVID-19 2SF** test Kit are required for this step. All needed items will be in the kit box. The lysis protocol in full text is available at the end of that section.

- Select **Isolate DNA/RNA**.

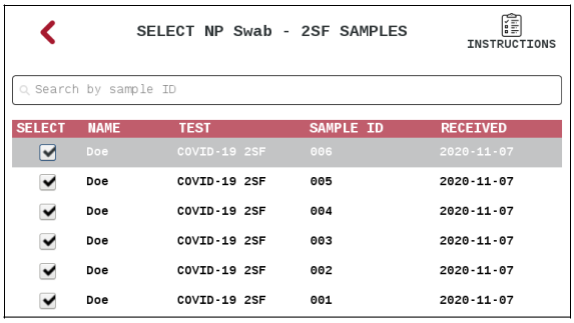


Select Kit Extraction Method

- Select **NP Swab - 2SF**. Only one method is available for COVID-19 and it works with NP, MT and AN swabs.
- Click **Next** icon to proceed to samples selection.

Select Samples

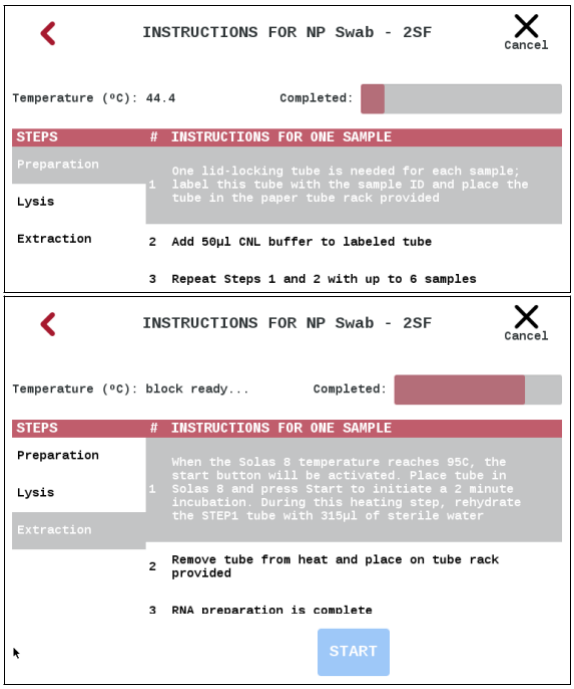
- **Select** up to **6 patient samples**.
- Click **Instructions** icon to proceed to the **sample preparation protocol**.



Follow On-Screen Instructions

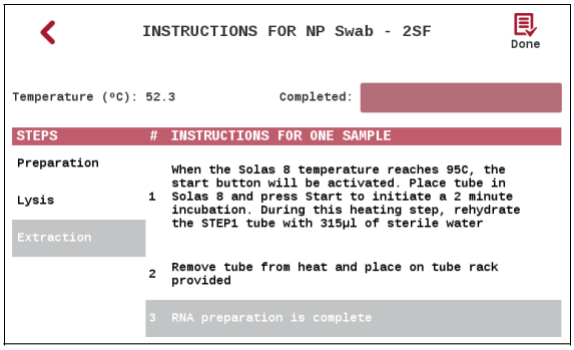
The Instructions screen displays the protocol for the selected kit. Ensure that a fresh pipette tip is used for each step. The protocol instructions are available at the end of that section.

- **Highlight** current instruction to track progress.
- Progress can be monitored on the "Completed" bar.
- There are three steps in NP Swab - 2SF sample preparation: **Preparation, Lysis, and Extraction**. The right column contains the instructions for each step highlighted.
- When a step indicates on screen that an incubation step is required (as shown on the right), **highlight instruction** to reveal the controls, and click **START**. If the **START** button is grey, the Solas 8® device is still heating up and the button will turn blue when the device is ready. After the incubation time is over, the screen will return to the instructions.



Finishing Sample Preparation

- Select the **last instruction** of the **last step** to reveal the **Done**  icon.
- Click **Done**  icon and **Confirm** all steps have been completed. This action tells the system **RNA is now available** for the selected samples to perform the **COVID-19 2SF** test.



NP Swab - 2SF Extraction Protocol

Preparation

- One lid-locking tube is needed for each sample; label this tube with the sample ID and place the tube in the paper tube rack provided
- Add 50 µL CNL buffer to labeled tube
- Repeat Steps 1 and 2 with up to 6 samples

Lysis

- Vortex sample containing the swab for 30 seconds
- Add 50 µL of mixed sample to the tube already containing CNL buffer
- Briefly vortex to mix the sample and lysis buffer

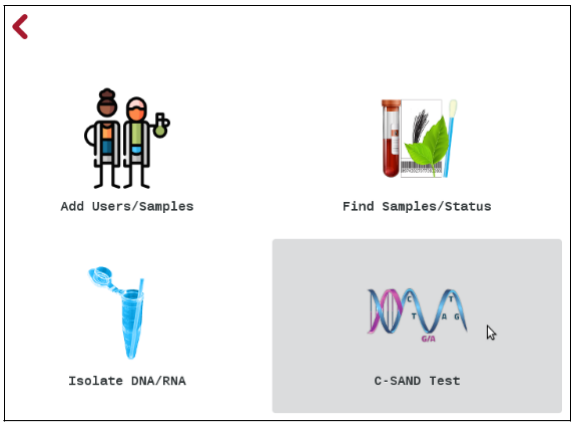
Extraction

- When the Solas 8 temperature reaches 95 °C, the start button will be activated. Place tube in Solas 8 and press Start to initiate a 2 minutes incubation. During this heating step, rehydrate the STEP1 tube with 315 µL of sterile water
- Remove tube from heat and place on tube rack provided
- RNA preparation is complete

2.3 STEP 3 - Performing the COVID-19 2SF Test

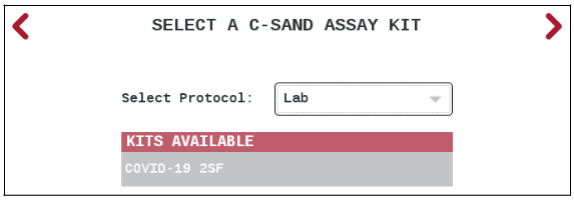
The contents of the **COVID-19 2SF** test kit are required for this step. All needed items will be in the kit box. The **COVID-19 2SF** test instructions for STEP 1 and 2 are available at the end of that section.

- Select **C-SAND Test**.



Select Assay

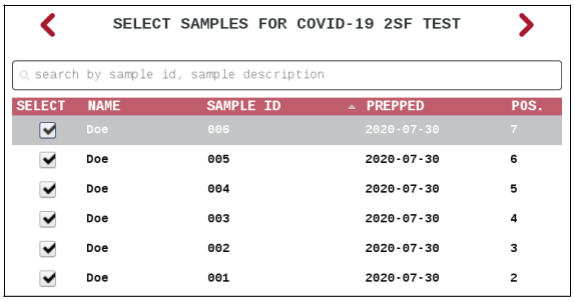
- Select COVID-19 2SF. Lab protocol is the only available protocol for COVID-19 2SF.
- Click **Next** icon to proceed to samples selection.



Select Samples

- **Select** up to **6 patient samples** in the order you want to position them.

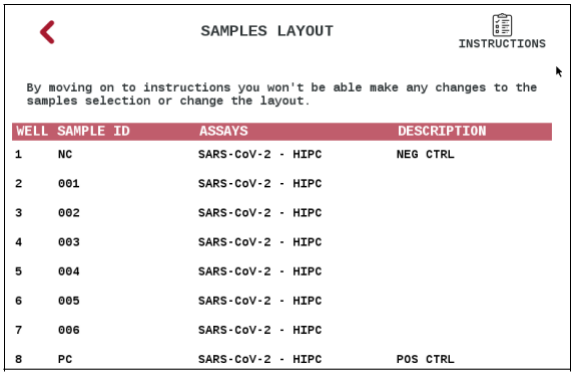
NOTE: positions 1 and 8 are reserved for external **negative** and **positive** controls - **NC** and **PC** respectively. Therefore, the selected wells will be assigned starting with position 2. Samples are assigned to wells in the order that they are selected.



Confirm Sample Layout

- **Review** the Samples Layout screen.
- **NC** is assigned to well 1.
- **PC** is assigned to well 8.
- Click **Instructions** icon to **proceed to protocol**.

NOTE: after this stage, no changes can be made to sample selection or layout

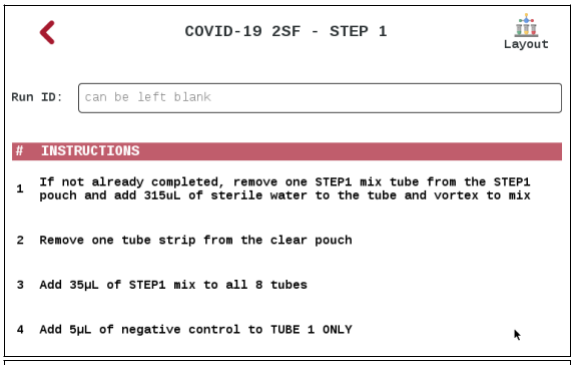


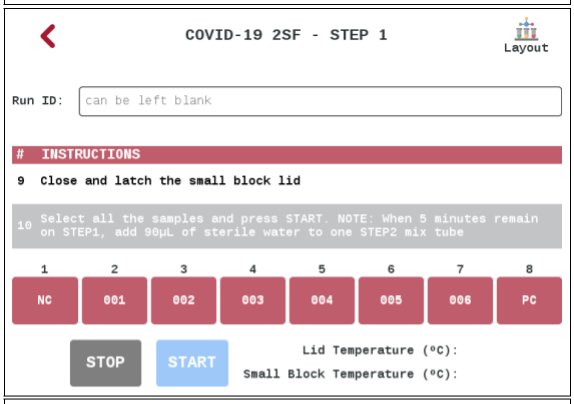
COVID-19 2SF - STEP 1

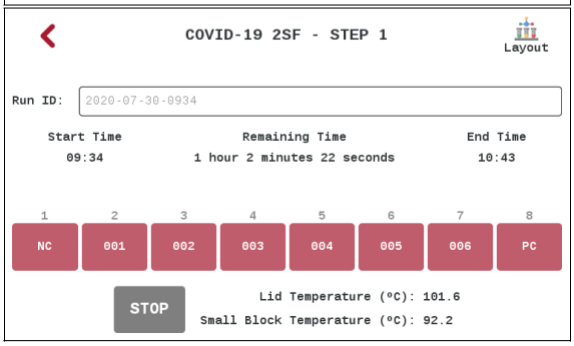
- Enter a **run ID**. If left blank, the system will use a Year-Month-Day-Time format ID.
- **Follow** instructions as shown on screen.
- **Highlight** current instruction to track progress through the protocol.
- **Scroll down** to complete protocol.
- Highlight the **last instruction** to reveal the STEP 1 controls.
- Select **all samples**.
- Ensure the samples inserted into the small block match the layout displayed on the screen.
- Close and Latch the lid.
- Click **START**.

NOTE:

- DO NOT OPEN THE LID until STEP 2 appears on the screen.





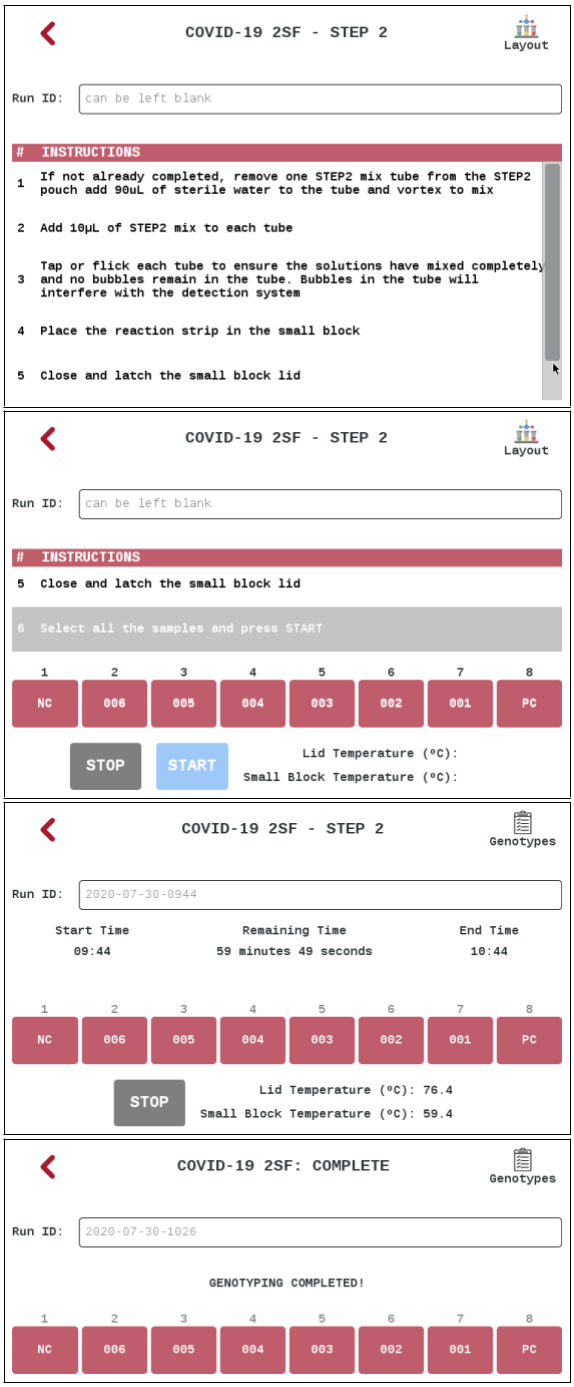


COVID-19 2SF - STEP 2

- **Follow** instructions as shown on screen.
- **Highlight** current instruction to track progress through the protocol.
- **Scroll down** to complete protocol.
- Highlight the **last instruction** to reveal the STEP 2 controls.
- Select **all samples**.
- Ensure the samples inserted into the small block match the layout displayed on the screen.
- Close and Latch the lid.
- Click **START**.

NOTE:

- **Strong signals** are usually identified within **10 minutes**.
- A preliminary report is generated when the first **SARS-CoV-2** positive samples are detected.
- Click **Genotypes**  icon to view the results real-time.
- When the assay is complete, the device will advance to **GENOTYPING COMPLETED!** screen.



COVID-19 2SF Instructions

STEP 1:

- If not already completed, remove one STEP1 mix tube from the STEP1 pouch and add 315 µL of sterile water to the tube and vortex to mix
- Remove one tube strip from the clear pouch
- Add 35 µL of STEP1 mix to all 8 tubes
- Add 5 µL of negative control to TUBE 1 ONLY
- Add 5 µL of sample into the tubes beginning with TUBE 2 and ending with TUBE 7 in the order indicated on the screen
- Add 1 Positive Control pellet to tube 8
- Mix well by flicking the tube strip, then tap the tube onto the counter to ensure all the solution is in the bottom of the tube
- Place the tube strip in the small block
- Close and latch the small block lid
- Select all the samples and press START. NOTE: When 5 minutes remain on STEP1, add 90 µL of sterile water to one STEP2 mix tube

STEP 2:

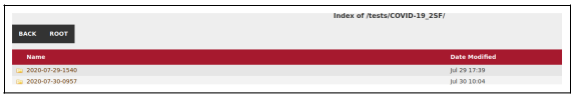
- If not already completed, remove one STEP2 mix tube from the STEP2 pouch add 90 µL of sterile water to the tube and vortex to mix
- Add 10 µL of STEP2 mix to each tube
- Tap or flick each tube to ensure the solutions have mixed completely and no bubbles remain in the tube. Bubbles in the tube will interfere with the detection system
- Place the reaction strip in the small block
- Close and latch the small block lid
- Select all the samples and press START

3 Access Real-Time Data

3.1 Viewing Real-Time Data and Results from a Wired or WiFi network

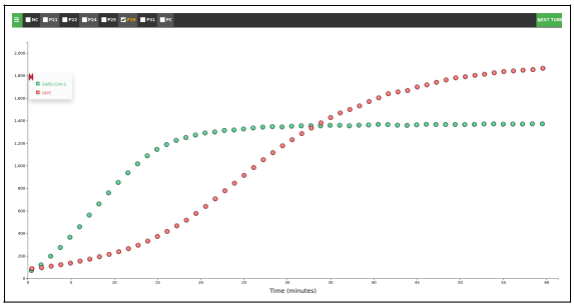
Once **COVID-19 2SF - STEP 2** is in progress, real time fluorescence data is available for viewing on a browser-enabled device or computer.

Navigating to the Real-Time Data



- **Access** the device from the local network or in Access Point mode.
- Navigate to **tests > COVID-19_2SF**.
- Select run.

Viewing the Real-Time Data

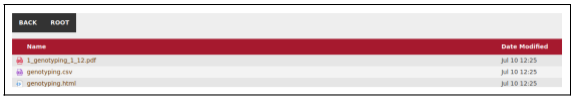


- Select a run.
- The **red signal** detects **HIPC** - Human Internal Positive Control.
- The **green signal** detects the presence of **SARS-CoV-2** in the prepared sample.

The top left green button gives access to different visualization options, as well as the data folder. The data folder contains the raw fluorescence signal in a CSV format and a pdf report that can be printed out directly from the web browser.

View the Genotyping Results

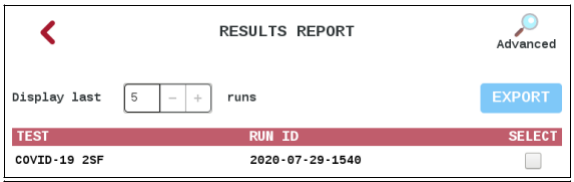
Once data collection and analysis are completed, a report in **PDF** format is automatically generated.

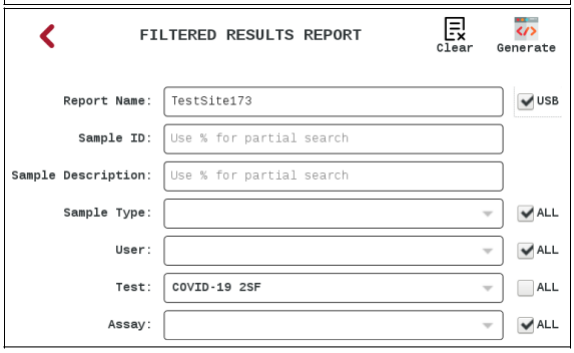


- **Access** the device from the local network or in Access Point mode.
- Navigate to **reports > solas8 > COVID-19_2SF**.
- Select run.

Export the Genotyping Results

From the **Start screen**, select the **Reports**  icon to navigate to the **Reports** screen.





- Select the run IDs you want to export.
- Insert a **USB drive**.
- Click **EXPORT**.

More detailed reports can be constructed and exported:

- Click **Advanced**  icon.
- **Name** the report.
- **Filter** your search.
- Insert a USB drive and check the USB box if you want to export the search.
- Click **Generate**  icon.
- **Advanced reports** can be accessed from reports section of the device webserver: **reports > advanced**

4 Results

Note that results provided by this test should only be interpreted along with clinical evaluation of the patient as well as available patient history. For each patient sample, the viral target will have a call of "POSITIVE" if the SARS-CoV-2 RNA was detected or "ND" (Not Detected) if the SARS-CoV-2 RNA was not present above the limit of detection. Each sample (wells 2 to 7) should have a result of "POSITIVE" for the human internal control (HIPC). In some cases, where the viral load is high, it is possible that the HIPC call may be "ND". In other cases, if the swab was not used properly during specimen collection, there may not be enough sample, and a "ND" call can be made for the internal control (HIPC). In such situations, if the positive and negative controls (wells 8 and 1) performed as expected, and the call made for the SARS-CoV-2 is POSITIVE, the result should be considered as a valid test.

4.1 Quality Control and Validity of Results

Each batch of 6 samples that are run together has one negative control and one positive control, making it a total of 8 reactions. In the Solas 8 report for each set of samples, check for the results, POSITIVE or ND for Not Detected. The results from each batch of samples are valid if the negative and positive controls are valid. Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

4.2 Results Interpretation and Troubleshooting

4.2.1 Instrument Calls for Controls

SARS-CoV-2	HIPC	Interpretation	Troubleshooting
Negative Control (Well 1)			
ND	ND	Expected result	
ND	POSITIVE	All patient results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.
POSITIVE	ND	All patient results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.
POSITIVE	POSITIVE	All patient results are invalid	Contamination: clean and disinfect lab and equipment used. Repeat testing of the samples.
Positive Control (Well 8)			
POSITIVE	ND	Expected result	
POSITIVE	POSITIVE	All patient results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF kit.
ND	POSITIVE	All patient results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF Kit.
ND	ND	All patient results are invalid	External control has failed. Repeat test. If same result a second time, replace the MatMaCorp COVID-19 2SF kit.

4.2.2 Instrument Calls for Wells 2 through 7: Patients Sample Results

For a valid assay, interpret the Patient Sample Results using the table below:

SARS-CoV-2	HIPC	INTERPRETATION	FOLLOW-UP
POSITIVE	POSITIVE	Positive COVID-19 Detected	Positive results do not rule out bacterial infection or coinfection with other viruses. All positive and negative SARS-CoV-2 results should be reported to appropriate public health officials.
ND	POSITIVE	Presumptive Negative COVID-19 not detected above Limit of Detection	Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests.
POSITIVE	ND	Positive COVID-19 Detected	Positive results do not rule out bacterial infection or coinfection with other viruses. All positive and negative SARS-CoV-2 results should be reported to appropriate public health officials.
ND	ND	Invalid	Repeat test from the beginning using the same sample. If repeated invalid results are obtained, repeat testing using a new sample.

In a valid test, samples are analyzed based on the detection of the viral target. If viral target is "ND" and the human internal control is "Positive", the sample is considered "Below LoD" and resampling may be required later, at the discretion of the physician. If all targets (viral and human internal control) are "ND", the sample is considered a "No Test" and should be repeated or re-sampled.

5 Limitations

- The **COVID-19 2SF** test has been evaluated only for use on the MatMaCorp Solas 8 instrument. None of the components in the kit will work with other instruments.
- Negative results should be treated as presumptive and tested with an alternative FDA authorized molecular assay, if necessary for clinical management, including infection control.
- How the sample was collected, stored and handled will influence the results that are generated from running this test.
- This test is intended to be used for the detection of SARS-CoV-2 RNA in nasopharyngeal (NP), mid-turbinate (MT), and anterior nasal (AN) swabs collected in Universal viral Transport Media (Copan UTM-RT or equivalent) or Universal Viral Transport System (UVT) or equivalent media. Testing of other sample types using the **COVID-19 2SF** test may result in inaccurate or no results.
- Based on *in silico* analysis, the primers/probe in the MatMaCorp **COVID-19 2SF** test may cross-react with SARS-CoV and cause a false positive result. This coronavirus is not known to currently circulate in the human population.

- Different factors may influence the detection of SARS-CoV-2 RNA including sample collection methods, patient factors (e.g., presence or absence of symptoms), and/or stage of infection etc.
- As with any molecular test, mutations within the target region of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- A Human Internal Positive Control (HIPC) is included in each reaction of the **COVID-19 2SF** test to help identify the specimens containing substances that may interfere with nucleic acid isolation, amplification and detection. If interfering substances are present, false negative or invalid results may occur.
- Carefully following the recommendations provided in this Instructions For Use document along with good laboratory practices may help prevent contamination of samples.

6 Preventing Contamination

Read and follow procedures and protocols as given in **COVID-19 2SF** test kit to ensure that the tests are performed correctly. If needed, the following guidelines will prevent contamination and related issues.

- Use **70% isopropanol** and **wipe** the touch screen, the small block and the heated lid. It is recommended that you use a lint free Kim Wipe or equivalent tissue. Bleach is not recommended for cleaning the device.
- Clean the work area around the device with 70% alcohol. A ten percent bleach solution can be used if necessary.
- Clean pipettes and other laboratory tools with 70% alcohol or bleach solution.
- Use filter tips for pipetting samples and reagents.

Contact Us

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Solas 8 instrument conforms to the following standards