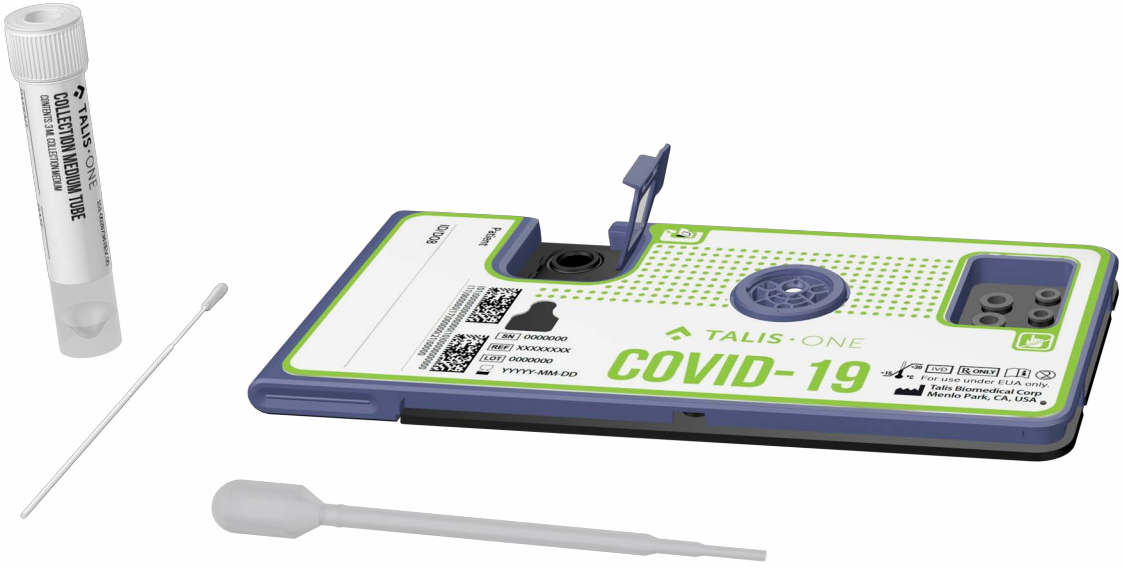
Talis One COVID-19 Test System

Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only

For *in vitro* diagnostic use

For prescription use only



TALIS·ONE

152-0028851 REV. 01

IVD Rx ONLY

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Contents

INTENDED USE

The Talis One COVID-19 Test System is a qualitative *in vitro* real-time Nucleic Acid Amplification Test (NAAT) System for the automated detection of nucleic acid from SARS-CoV-2 in nasal mid-turbinate swab specimens 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 the requirements to perform high, moderate, or waived complexity tests. The Talis One COVID-19 Test System 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasal mid-turbinate swab specimens 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 do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the Talis One COVID-19 Test System should be performed by trained operators who are proficient in performing tests with the Talis One COVID-19 Test System. The Talis One COVID-19 Test System is only for use under the Food and Drug Administration's Emergency Use Authorization.

EXPLANATION OF THE TEST

The Talis One COVID-19 Test System is a Point-of-Care (POC) *In Vitro* Diagnostic (IVD) test that is designed to detect nucleic acids of target pathogens. The Talis One COVID-19 Test System uses qualitative real-time reverse transcription isothermal amplification for the automated detection of nucleic acids.

The Talis One COVID-19 Test System includes:

- Talis One instrument (software version 4.0.0.244)
- Talis One COVID-19 Cartridge and pipette
- Talis One Nasal Mid-Turbinate Collection Kit

PRINCIPLES OF THE PROCEDURE

The Talis One COVID-19 Test System is an *in vitro* diagnostic device that is designed to detect nucleic acids of target pathogens in nasal mid-turbinate swab samples. The Talis One COVID-19 Test System uses a proprietary qualitative real-time isothermal amplification technology for the automated detection of SARS-CoV-2 RNA in nasal mid-turbinate specimens to aid in the diagnosis of COVID-19. The Talis One COVID-19 Test System utilizes primers that target sequences of the ORF-1ab gene and N gene.

The Talis One COVID-19 Test System is intended to be operated in a near-patient environment. The Talis One Nasal Mid-Turbinate Collection Kit stabilizes viral RNA in a lytic solution containing Guanidinium Thiocyanate among other components that have been shown to inactivate viruses[1]. The Talis One instrument automates and integrates sample metering, nucleic acid purification, nucleic acid amplification and detection of the target sequences on nasal mid-turbinate samples using the company's proprietary reverse transcriptase isothermal amplification technology on the Talis One COVID-19 Cartridge.

The Talis One instrument is an integrated platform that contains everything needed to run, read, and analyze Talis One COVID-19 Cartridges, as well as report results to system users using an embedded touch screen display.

The Talis One instrument contains thermal, mechanical, pneumatic, and optical sub-systems that actuate the Cartridge. The sample, all liquids and reagents remain isolated in the Cartridge and do not interact with the instrument.

Each Cartridge, when inserted into an instrument, will perform the following sequential functions automatically:

- It will meter the sample to determine if the sample volume is sufficient.
- It will extract and then amplify nucleic acid targets of both ORF1ab and N genes, as well as the Sample Processing Control (SPC).

The amplification happens in three wells on the Talis One COVID-19 Cartridge. Two of the wells contain identical primers and detection probes for amplification and detection of SARS-CoV-2 (if present), while the third well contains primers and detection probes for amplification and detection of the SPC.

1. (a) https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens (b) https:// files.zymoresearch.com/protocols/_r1100-50_r1100-250_r1200-25_r1100-125_dna_rna_shield.pdf

COVID-19 TEST SYSTEM REAGENTS AND MATERIALS

Materials Included - Available from Talis

Material	Quantity/Capacity	REF or Catalog#
Talis One instrument	1	REF: O10100AA
Talis One COVID-19 Cartridge Pack	• 25 Talis One COVID-19 Cartridges* • 30 Talis One Cartridge Pipettes • 1 Talis One COVID-19 Test System Quick Reference Instructions	REF: O11200-25
Talis One Nasal Mid-Turbinate Collection Kits	25	REF: O11300-25
COVID-19 Control Medium and Label Pack	6 positive 6 negative	REF: O11204-06

* Inside each Talis One COVID-19 Cartridge pouch is another small pouch containing desiccant that is placed under the Cartridge to protect it from damage due to humidity. Throw away the desiccant after opening the pouch.

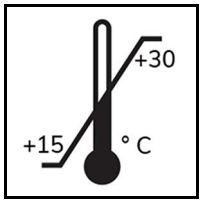
Materials Required but not Provided

Material	Quantity/Capacity	REF or Catalog#
Metrex CaviWipes (or equivalent alcohol-based cleaning agent)	50 (9 X 12 inch wipes)	Metrex #13-1155
	160 (6 X 6.75 inch wipes)	Metrex #13-1100

Materials Recommended but not Provided

Material	Quantity/Capacity	REF or Catalog#
Negative control: Helix/Elite™ Negative Cellularity Control (Inactivated Swab)	6	Catalog # HE0067NS Microbiologics (https://www.microbiologics.com)
Positive control: Helix/Elite™ Inactivated SARS-CoV-2 Whole Virus (Swab)	6	Catalog # HE0066NS Microbiologics (https://www.microbiologics.com)

Cartridge Storage and Handling Requirements



- **Packaged COVID-19 Cartridges must be stored at 15°C to 30°C.**
- **Cartridges must be kept in their sealed foil pouches until opened for immediate testing**, and may be open for a maximum of 30 minutes prior to initiating testing on the Talis One instrument. Opening Cartridge pouches more than 30 minutes prior to testing may impact test performance.

PRECAUTIONS

- For *in vitro* diagnostic use.
- For Use Under an Emergency Use Authorization (EUA) Only.
- For Prescription Use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- The emergency use of this 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.
- 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.
- Modifications to reagents, test protocol, or instrumentation are not permitted, and are in violation of the product Emergency Use Authorization.
- Handle Cartridge, kit supplies, and tray with gloves at all times to avoid contamination and change gloves between removal of used and new disposables.
- Handle samples carefully. Open one tube or one sample at a time to prevent sample contamination.
- Do not use expired Cartridges or other expired test materials.
- Always use fresh gloves when handling new samples.
- Follow Standard Precautions when handling clinical specimens, all of which may contain potentially-infectious materials. Standard precautions include hand hygiene and the use of personal protective equipment (PPE). Laboratory coats or gowns, gloves, and eye protection are strongly recommended because the collection medium contains harmful substances (see below).
- For spills during specimen collection or performing Talis One COVID-19 tests, blot dry and use CaviWipes or an alcohol-based cleaning agent for disinfection. **Do not use bleach, as it may react with the collection medium to create toxic fumes.** Following disinfection, restart the collection procedure with a new kit. Failure to use a new kit may invalidate the test results.
- **WARNING**: Collection medium contained in Collection Medium Tubes and control prep tubes is harmful if swallowed or inhaled, may cause skin irritation, and may cause serious eye irritation. Avoid direct skin/mucous membrane contact with or ingestion of medium provided with the Talis One Nasal Mid-Turbinate Collection Kits and control prep tubes. If ingested contact Poison Control at 1(800) 222-1222.

	**Classifications:** Acute toxicity, Category 4. Skin corrosion/irritation, Category 2. Serious eye damage/irritation, Category 2A.	**Hazard Statements:** Harmful if swallowed. Causes skin irritation. Causes serious eye irritation.

Important information regarding the safe handling, transporting and disposing of this product is contained in the Safety Data Sheets. Safety Data Sheets are available from Talis Biomedical Corporation. Inquire directly.

- If collection medium is spilled and makes contact with skin, immediately wash affected area with water and soap and rinse thoroughly.
- Do not allow bleach to come into contact with the contents of the Collection Medium Tubes or control prep tubes as hazardous gas can develop when the content of the tubes mixes with bleach. In the event that bleach comes into contact with contents, contact Poison Control at 1(800) 222-1222.
- Do not smoke, drink, chew, or eat in areas where specimens or kit reagents are being handled.
- Dispose of used Cartridges, pipettes. and sample tubes in a biohazardous bin and waste in accordance with local, state, provincial and/or federal regulations. Unused reagents should be disposed into regular hazmat waste streams.
- Dispose of all packaging materials in a safe manner in accordance with your institution's guidelines.

SPECIMEN COLLECTION / SAMPLE HANDLING

Note: *For the purposes of these instructions, the terms "specimen" and "sample" are defined as follows:*

- **Specimen:** Unaltered material collected from a patient (e.g., nasal mid-turbinate swab)
- **Sample:** Patient specimen or control that has been prepared in a Collection Medium Tube or control prep tube for testing on the Talis One Instrument.

Talis One COVID-19 Test System is validated with nasal mid-turbinate swab specimens collected with the Talis One Nasal Mid-Turbinate Collection Kit. Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting and Handling Specimens Safely, as applicable to Nasal mid-turbinate specimens (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard precautions include hand hygiene and the use of personal protective equipment (PPE). Laboratory coats or gowns, gloves and eye protection are strongly recommended because the collection medium contains harmful substances.

Nasal mid-turbinate swab specimens to be tested with Talis One COVID-19 Test System are to be clinician-collected in healthcare settings. Instructions are provided below, and also in the Talis One Nasal Mid-Turbinate Collection Kit Package Insert.

Specimen Collection Procedure (Clinician)

The following procedure is intended for collection of patient nasal (mid-turbinate) swab specimens by a clinician.

Note: *Personal protective equipment (PPE), including a lab coat, masks (surgical, dental, medical procedure, isolation, or laser masks), eye protection, and gloves must be worn at all times when collecting specimens.*

***Before* collection of each new specimen:**

- Disinfect work surfaces with CaviWipes or an alcohol-based cleaner. **Do not use bleach.**
- Put on a new pair of gloves.
- Check patient for nasal obstructions and clear as needed.

To collect a patient specimen (clinician):

1. Open the Nasal Mid-Turbinate Collection Kit pouch, remove the contents and inspect components for signs of damage. (Each kit pouch contains one capped Collection Medium Tube and one swab wrapped in its own paper pouch.)

2. Print patient Name, ID/Date of Birth, and collection date in the fields provided on the tube, or apply printed label.

3. Open the paper swab pouch carefully at the shaft end without touching soft swab tip. Leave the swab in the partially-opened pouch until ready to use. (The swab tip should not touch any surface, including gloves.)

4. Remove cap from the Collection Medium Tube and put aside (open side up), then place the open tube on a tube holder.

   IMPORTANT: *If liquid from the tube spills or swab tip touches any surface other than the nostril, restart the collection procedure with a new kit. The spillage should be immediately blotted dry and the surface should be decontaminated with CaviWipes or an alcohol-based cleaner.* ***Do not use bleach.***

5. Carefully remove the swab from the partially-opened pouch—ensure that the tip does not touch any surfaces—and hold at the breakpoint. Failure to hold at the breakpoint may cause the swab to break during specimen collection.

6. Tilt patient head back slightly (~70^{o}) and carefully insert the swab into either of patient's nostrils while rotating the swab until resistance is met at turbinates (less than 1 inch into the nasal cavity).

   Note*: Swab should be inserted in a horizontal direction, approximately parallel to the palate.*

7. Rotate swab against nasal wall for 3-5 seconds.

8. Remove the swab from the nostril, then repeat steps 6 and 7 in the other nostril using the same swab.

9. Insert the swab into the collection tube until the entire swab tip is visible below the liquid level.

10. Break the swab at the breakpoint against the lip of the collection tube, then discard the swab shaft and tightly screw the cap onto the tube.

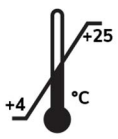
11. Hold the collection tube by the cap and swirl tube 6 times.

12. Disinfect the collection tube and store upright, then discard used gloves into appropriate waste receptacle.

Prior to collecting any additional specimens from additional patients, ensure that the work area has been decontaminated and that fresh gloves are used.

Sample Handling and Storage

Samples should be tested immediately or no later than 30 days from collection and kept at 4–25° Celsius. Prior to testing, bring samples to room temperature (15–30° C).

	**Keep samples at 4–25° Celsius.**

TEST PROCEDURE

Following are instructions for running a test on the Talis One System. This procedure applies to patient samples as well as controls. Keep all clinical samples and controls at room temperature before running the test. Do not use an expired Cartridge—the instrument will reject it and the sample will be lost.

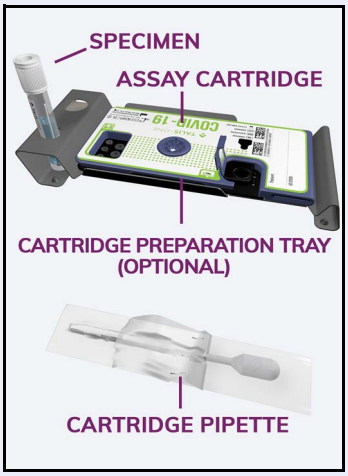
*Read the **Talis One Instrument User Guide** before running a Talis One COVID-19 test. The Instrument User Guide provides all the information needed to use the Talis One Instrument correctly and safely.*

***Caution:** Cartridges must be kept in their sealed foil pouches until opened for immediate testing, and may be open for a maximum of 30 minutes prior to initiating testing on the Talis One instrument.*

***Caution:** Use Standard Precautions and treat all patient samples and used test materials as potentially infectious. ▪ Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves must be worn at all times when performing patient tests. ▪ Disinfect work surfaces and change gloves before each new sample run. ▪ Handle and dispose of all used kit materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.*

Prior to running each test:

- Disinfect work surfaces with CaviWipes or an alcohol-based cleaning agent and put on a new pair of gloves. **Do not use bleach**, as it may react with collection medium to create toxic fumes.
- Gather materials:
  - Patient sample or control (room temperature)
  - **If running control:** Control Label (included with the COVID-19 Control Medium and Label Pack)
  - Talis One COVID-19 Cartridge (confirm Cartridge is undamaged and not expired)
  - Pipette tip (new and unwrapped)
  - Permanent marker or pen
  - Cartridge Preparation Tray (Optional)

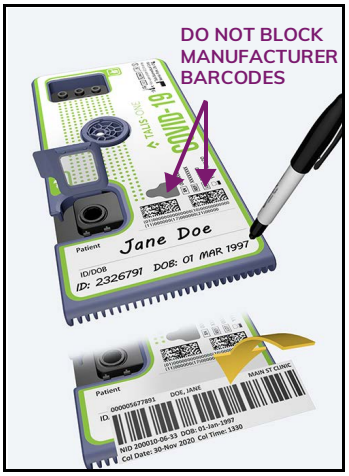


To run a test:

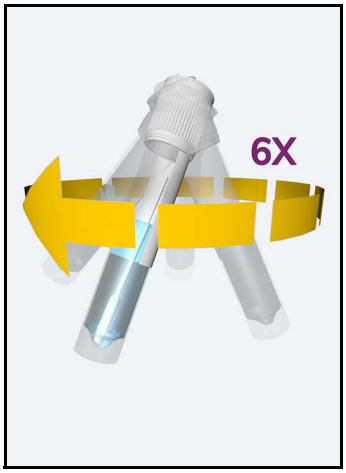
1. Print patient **Name** and **ID/DOB** in the spaces provided on the Cartridge label (print clearly in indelible ink), or apply pre-printed label (patient label or control label).

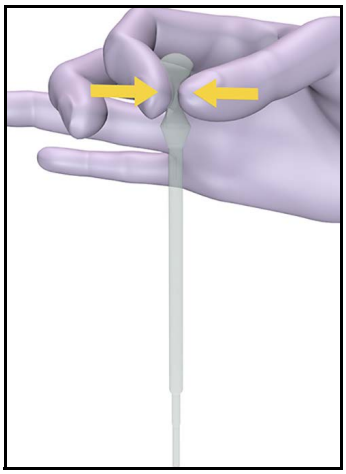
   IMPORTANT:

   - DO NOT cover the UDI/Manufacturing barcodes (pictured at right). If these barcodes cannot be read by the instrument, the Cartridge will be rejected.
   - Patient information provided on the Cartridge is permanently associated with the results of the test—ensure that it is legible and correct.

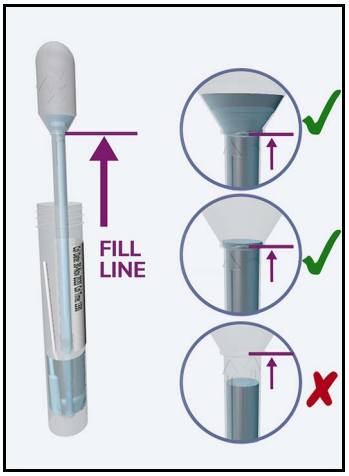


2. Swirl patient or control sample tube 6 times, then uncap and place on a tube holder or sample preparation tray (if used).



3. Carefully remove the cartridge pipette from pouch—**ensure that the tip does not touch any surface, including gloves**. 4. Squeeze and hold bulb of pipette, then gently insert pipette into tube until the tip is fully submerged.	
5. *Completely* release bulb and wait for the pipette to fill (minimum of 3 seconds). **Note**: ***Minimize bubbles***. *Bubbles can be introduced when removing the pipette before the liquid has completely filled the pipette. Wait a few seconds after the liquid has reached the fill line.*	

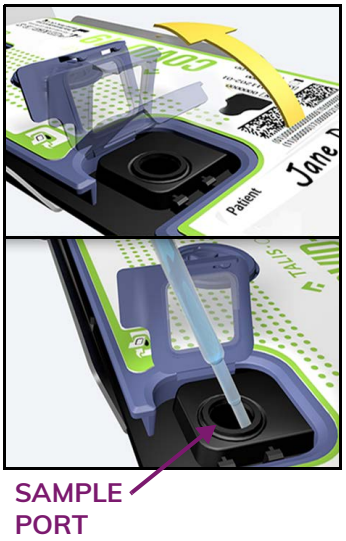
6. Ensure that liquid is at or above the **FILL LINE**. If not, or if large bubbles are present below the **FILL LINE**, dispense specimen back into the collection tube and repeat steps 4 and 5, compressing the bulb more firmly/fully.



7. Open the sample port lid and insert pipette tip into the sample port (pictured). Squeeze firmly ONCE, then keep bulb compressed and remove from sample port.

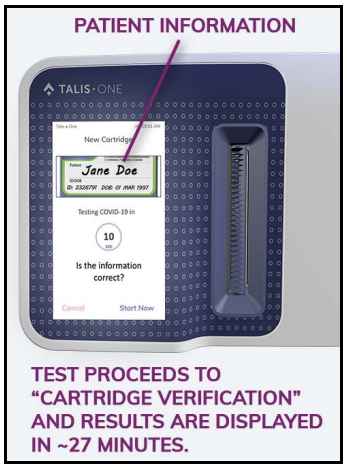
   Note: *Residual sample may remain in the pipette after dispensing.*

> **Caution:** *If there is a small spill on the label side of the Cartridge, wipe with a dry lint-free tissue and continue processing. If the non-labeled side of the Cartridge is contaminated with sample, the Cartridge should be discarded, and a new Cartridge prepared to avoid contamination of the instrument.*



8. Dispose of the pipette, then close the sample port lid until it clicks. 9. Cap sample tube.	
10. Insert Cartridge until it clicks, with the label facing right and sample port on top as pictured at right. "Reading Cartridge" is displayed on the interface as the instrument detects the Cartridge barcode and the test type, and records the image capture of the patient information.	

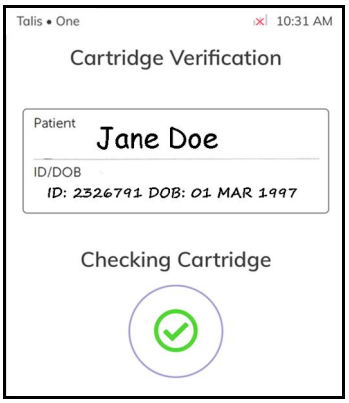
11. Wait while “Reading Cartridge” is displayed, then immediately verify the patient information when it appears and proceed as follows:
    - If the patient information is illegible or inaccurate, tap **Cancel**. In this case, fix the label and re-insert the Cartridge.
    - If the patient information displayed is accurate/ legible, tap **Start Now** or simply wait—the instrument will automatically proceed to Cartridge verification in ten seconds.



Test Proceeds to “Cartridge Verification.”

When the verification step is complete, the screen updates as follows:

- Green checkmark indicates that verification passed, and the test starts automatically.
- If verification does not pass, a specific error message will appear with instructions for resolution.

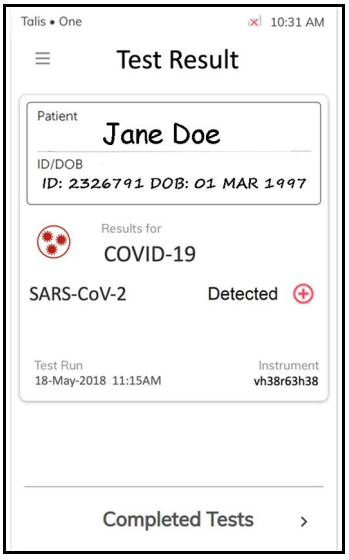


Results will display automatically after ~27 minutes.

After completion of the test, remove and dispose of ejected Cartridge in accordance with local, regional, and federal regulations.

For results definitions, see "INTERPRETATION OF RESULTS" on page 20.

Note: *Results of the latest test only remain on the screen for 1 minute. After that, tap* **Completed Tests** *or access the Menu ( ) to view.*



RETRIEVING AND VIEWING RESULTS

Following login, results of patient sample and control tests are accessible from the menu of the instrument user interface. Ensure that patient information matches that of the patient that is being diagnosed and then proceed to interpret the results (see “INTERPRETATION OF RESULTS” on page 20). Refer to the Talis One Instrument User Guide for more details on how to retrieve patient test results.

BUILT IN QUALITY CONTROLS

Process Timeouts—The instrument measures transfer times and the completion of lysis solution and wash buffer transfer. If transfer times are too short or too long, then the COVID-19 test is invalid and an Error is reported.

Sample Processing Control (SPC)—Ensures the sample was correctly processed. The SPC detects the presence of human β-actin RNA in the specimen and verifies the sample processing and target amplification.

USING EXTERNAL CONTROLS

External controls should be run as required by local, state and federal rules and regulation to show that the Talis One COVID-19 Test System is functioning adequately – a minimum test frequency is recommended below. Talis has validated Microbiologics (St. Cloud, MN) Helix Elite™ Inactivated Standard single-use swabs as controls. The positive control swab contains cultured and inactivated SARS-CoV-2 isolate USA/WA1/2020 and human A549 cells. The negative control swab contains human A549 cells.

***Important**: Detection of human RNA is required as a negative control to report out a negative result. Using a control prep tube that has not been prepared with a negative control will result in an invalid test.*

Control Run Workflow

In order to avoid wasting control material, the negative control should always be prepared and tested—with the result confirmed as "Not Detected"—prior to preparing and testing the positive control.

Following is the correct workflow for performing an external control run:

1. **Prepare negative control**
2. **Test negative control and confirm passing result ("Not Detected")**

   ***Note:** If the negative control test fails, contact Talis Technical Support—do not proceed to preparing/ testing positive control.*
3. **Prepare positive control**
4. **Test positive control and confirm passing result ("Detected")**

Recommended Control Run Frequency

Talis recommends that a SARS-CoV-2 negative and SARS-CoV-2 positive controls be run:

- Once after each instrument setup
- Once for each new lot or shipment of COVID-19 Cartridges received
- Once for each new operator
- As deemed additionally necessary in order to conform with internal quality control procedures, and with local, state and/or federal regulations, or accrediting groups.

If external control testing does not provide the expected result, repeat the test using a new control prep tube, control label, and COVID-19 Cartridge, or contact Talis Technical Support for assistance before testing patient samples.

Preparing External Controls

Following is the procedure for preparing external controls prior to running on the Talis One instrument. Once prepared, the procedure for running controls is the same as it is for testing patient samples.

Review the Microbiologics package inserts for controls, the Talis One COVID-19 Test System Instructions for Use, and the Talis One Instrument User Guide carefully before running controls.

Caution: *If liquid from the control prep tube spills, or if control swab tip touches any surface outside the tube, restart the procedure with a new kit.*

Caution: *Cartridges must be kept in sealed foil pouches until opened for immediate testing (open for a maximum of 30 minutes prior to initiating testing on the Talis One instrument).*

Caution: *Use Standard Precautions and treat inactivated control material as potentially infectious. ▪ Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves should be worn at all times when performing control tests. ▪ Disinfect work surfaces and change gloves before each new sample run. ▪ Handle and dispose of all used kit materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.*

***Prior to preparing controls*:**

- Disinfect work surfaces with CaviWipes or an alcohol-based cleaning agent and put on a new pair of gloves. **Do not use bleach**, as it may react with collection medium to create toxic fumes.
- Gather materials:
  - **1 Negative control swab**
    (Microbiologics; St. Cloud, MN, Helix/Elite™ Negative Cellularity Control [Inactivated Swab], Catalog # HE0067NS)
  - **1 Positive control swab**
    (Microbiologics, St. Cloud, MN, Helix/Elite™ Inactivated SARS-CoV-2 Whole Virus [Swab], Catalog # HE0066NS)
  - **2 Talis One COVID-19 Cartridges**
  - **2 Talis One Cartridge Pipettes**
  - **1 Talis One Positive Control Prep Tube and Positive Control Label**
  - **1 Talis One Negative Control Prep Tube and Negative Control Label**
  - **Cartridge Preparation Tray** (optional)

To prepare controls:
(Remember: Prepare and test negative control first!)

1. From the Talis One Control Medium and Label Pack box, retrieve one negative or positive pouch (negative first).

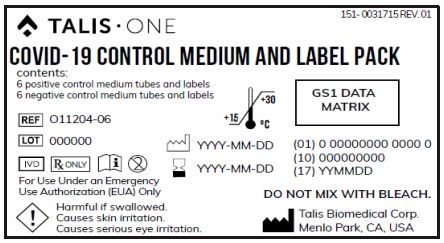
   Pouch contains:

   - 1 pre-labeled C19 control prep tube
   - 1 corresponding C19 control label

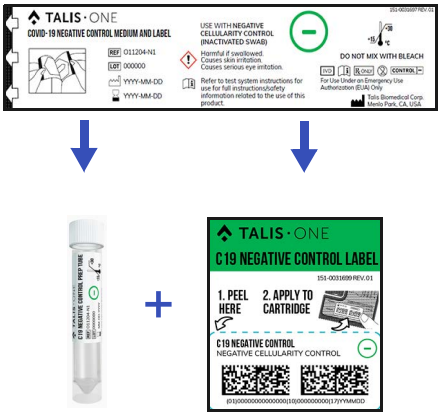
   Note: *Set aside cartridge label for use in Test Procedure after control sample is prepared.*

2. Uncap the control prep tube and place on a tube holder or on the cartridge preparation tray (if used).

PACK BOX



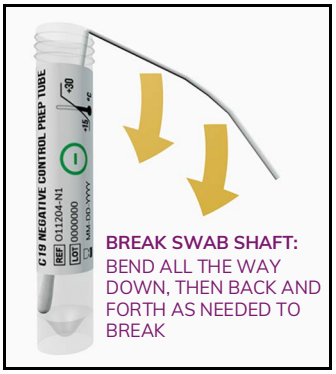
POUCH



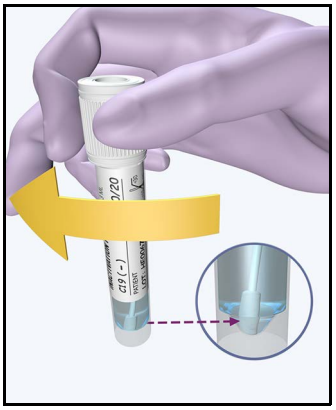
3. Tear open the control pouch at notch, and remove the swab from pouch,

   IMPORTANT: *Ensure that the swab tip does not make contact with any surfaces, including gloves.*

4. Insert swab fully into the control prep tube, then bend shaft against rim and down to break swab.



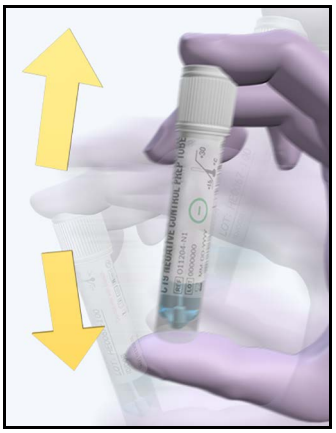
5. Leave control swab in tube and screw cap tightly.



6. Shake tube vigorously for 10 seconds, then wipe down tube with disinfectant.

7. Proceed to testing. See “TEST PROCEDURE” on page 8.

   Note: *Use the cartridge label set aside in step 1 to label the Cartridge in the test procedure:*



Testing Controls

Once prepared (“Preparing External Controls” on page 16), controls are individually tested by the same procedures as are used for patient samples—see the Test Procedure in this IFU (page 8) or the Talis One COVID-19 Test System Quick Reference Instructions.

Evaluating Control Results

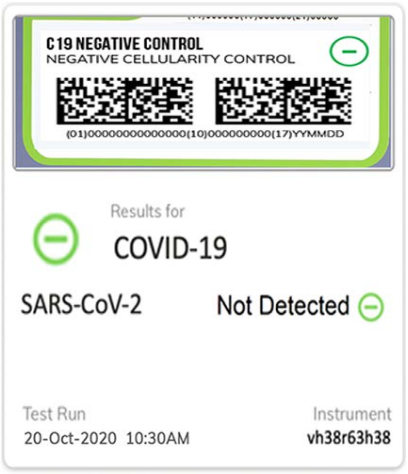
A successful external control run consists of achieving the expected result for both the negative (first), and then the positive control as detailed below.

***Important**: If either the positive or negative external control test fails to return the expected result, patient sample testing must not be performed. Contact Talis Technical Support.*

Negative Control “C19 (-)”

Expected result = “Not Detected” (negative):

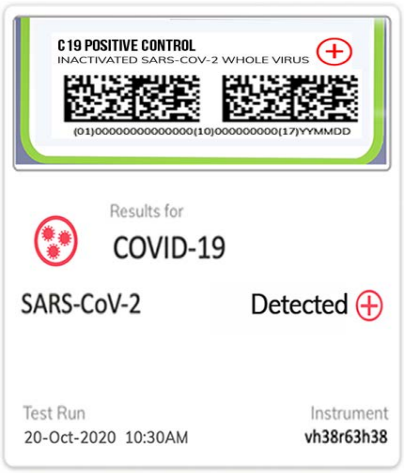
PASS NEGATIVE CONTROL



Positive Control “C19 (+)”

Expected result = “Detected” (positive):

PASS POSITIVE CONTROL



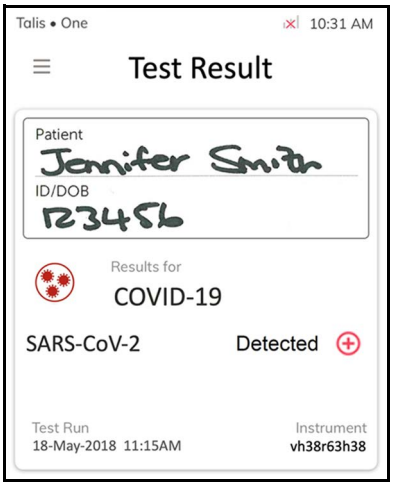
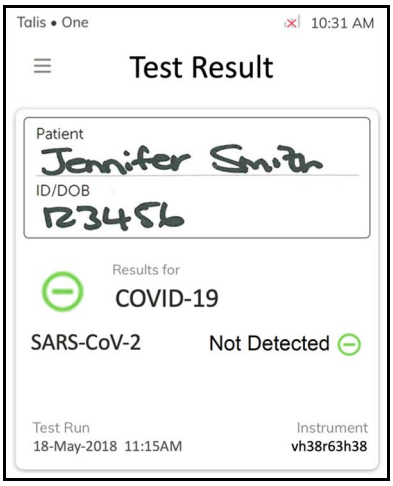
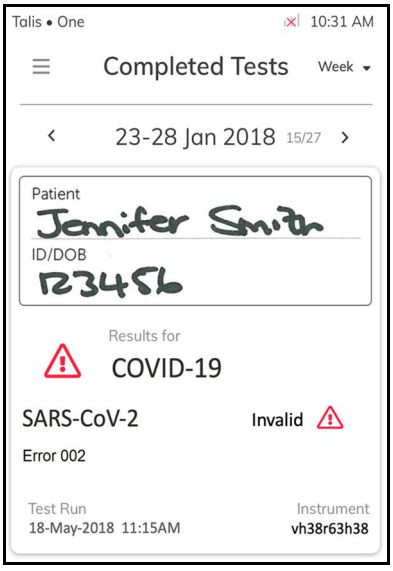
INTERPRETATION OF RESULTS

Test results are displayed on the instrument screen for one minute following test completion, and thereafter by tapping **Completed Tests** or selecting from the Menu (☰). Table 1 provides definitions of the symbols which may be associated with in-process or completed tests. Table 2 provides specific examples of positive, negative, and invalid results displayed in the user interface following a completed test.

Table 1. Symbol Definitions

Test Symbols	
Symbol	**Definition**
	One or more targets detected **Note:** *This icon refers to the overall result for the test. Results for SARS-CoV-2 are indicated by the "-" and "+" symbols below.*
	SARS-CoV-2 was not detected
	SARS-CoV-2 was detected
	Invalid result **Note:** *An invalid result is always associated with an error Message. Refer to the error message details.*
Instrument Alert Symbols	
Symbol	**Definition**
	Operator alert. Instrument encountered an error during test. User is prompted to take recommended actions.
	Instrument fault. The instrument is not ready to run a new test.

Table 2. Interpretation of Results

Results	Interpretation
	Targets detected with Talis One COVID-19 Test System. SARS-CoV-2 target nucleic acids are detected.
	Targets not detected with Talis One COVID-19 Test System. SARS-CoV-2 target nucleic acids are **NOT** detected.
	Test result invalid. Invalid results for Talis One COVID-19 Test System. Re-run the sample with a new Cartridge. If repeat test is Invalid, a new specimen must be collected and run using a new collection kit and Cartridge. **Note:** *For specific error code details and resolution steps, see the Troubleshooting section of the Talis One Instrument User Guide.*

LIMITATIONS OF THE PROCEDURE

- Reliable results depend on proper sample collection, storage, and handling procedures.
- This test has been designed for the detection of SARS-CoV-2 RNA.
- Performance of Talis One COVID-19 Test System has only been established with a nasal mid-turbinate swab specimen using the Talis One Nasal Mid-Turbinate Collection Kit.
- Detection of SARS CoV-2 may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
- As with any molecular test, mutations within the target regions of SARS CoV-2 could affect primer and/or probe binding, resulting in failure to detect the presence of virus.
- False negative or invalid results may occur due to interference. The β-actin sample processing control is included to help identify the specimens containing substances that may interfere with nucleic acid isolation and isothermal amplification.
- Recent exposure to Ayr Nasal Gel may cause false negative results.
- Good laboratory practices and careful adherence to the procedures specified in this Instructions For Use document are necessary to avoid contamination of reagents.
- The effect of interfering substances has been evaluated only for those listed within the labeling. Interference by substances other than those described may lead to erroneous results.
- The effect of homeopathic products for respiratory symptoms on Test System performance was not tested.
- Talis One COVID-19 Test System has not been evaluated for patients receiving intranasally administered influenza vaccine.
- Dispose of used products according to local, state, and national regulations. For information about the correct method of disposal, contact your local authorities.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Talis One COVID-19 Test System 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: fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist users using the Talis One COVID-19 Test System (referred to in the Letter of Authorization as "Your Product"), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories* 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.

B. 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 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 your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. 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.

E. 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 you (via email: support@talisbio.com; by phone: +1 855-956-3594) 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. Authorized laboratories must have a process in place to track invalid rates and report to the manufacturer the total number of tests performed, all initially invalid results and all repeat invalid results. Authorized laboratories must report this information 30 days, 90 days and 6 months following initial use of the product by the authorized laboratory.

G. All operators using your product should be appropriately trained in the use of your product and must use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

H. Talis Biomedical Corporation, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

* The letter of authorization refers to “authorized laboratories” as the following: 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

Clinical performance of the Talis One COVID-19 Test System was assessed by comparison to an FDA authorized molecular SARS-CoV-2 assay (EUA). Nasal mid-turbinate swab specimens were prospectively collected from 1,652 subjects at seven urgent care sites under an IRB approved Collection Protocol. Three swabs were collected from each patient: one swab was collected for the Standard of Care test at each site. Thereafter, two mid-turbinate study swabs were collected in a randomized/alternate fashion.

One swab was collected in the Talis One Nasal Mid-Turbinate Collection Kit for testing with the investigational device. The other nasal mid-turbinate swab specimen was collected in saline and shipped per the manufacturer's instructions to the reference laboratory for comparator testing with a highly sensitive EUA authorized RT- PCR test.

Samples were shipped and tested with the Talis One COVID-19 Test System at two external point-of-care clinical sites using a total of 4 intended-use operators in a blinded and randomized fashion.

A total of 243 subject samples were excluded due to the following reasons: sample stability out-of-window due to shipping delays, issues during sample transit, invalid comparator test results, and subject consent withdrawal. Of the 1,409 subjects included in the study, 52 subjects were confirmed positive by the reference comparator assay.

A total of 98 specimens (the first 49 consecutive positives and a subset of 49 consecutive negatives) were blinded and randomized and then shipped refrigerated to the two POC sites for Talis One Test System testing.

Of the 49 negative and 49 positive samples, the first 41 consecutive positives and 41 consecutive negatives were tested neat using the Talis One COVID-19 Test System. Due to the lack of low positive samples, the next 8 consecutive positives were diluted in individual negative clinical matrix and tested randomized with the next 8 consecutive negative specimens using the Talis One COVID-19 Test System (see the "Diluted Specimen Section" below for details.

Of the 41 consecutive positives and 41 consecutive negatives tested with the Talis One COVID-19 Test System, 3 positive and 2 negative samples had invalid results in both initial testing and upon retest with the Talis One COVID-19 Test System and were therefore excluded from the final data set for performance analysis when testing neat natural clinical nasal mid-turbinate swab specimens.

As shown in Table 3, the Talis One COVID-19 Test System demonstrated a positive percent agreement (PPA) of 100.0% (95% CI: 90.8%-100%) and a negative percent agreement (NPA) of 100.0% (95% CI: 91.0%- 100%) relative to the comparator test.

Table 3. Clinical Performance of Talis One COVID-19 Test System vs. EUA Comparator Assay

		FDA authorized molecular SARS-CoV-2 assay (EUA)		
		Positive	**Negative**	**Total**
Talis One COVID-19 Test System	**Positive**	38	0	38
	Negative	0	39	39
	Total	38	39	77
PPA	100.0% (95% CI: 90.8%-100%)			
NPA	100.0% (95% CI: 91.0%-100%)			

Diluted Specimen Testing

To obtain an adequate number of representative low titer specimens, testing was supplemented with eight additional consecutive positive samples, from the same clinical study described above, that were diluted in individual negative nasal mid-turbinate samples and randomized with an equivalent number (8) of negative samples.

Two-fold serial dilutions were carried out at the reference laboratory for samples that previously tested positive by the comparator test. Dilutions ranged from 4-fold to 131,072-fold to achieve a concentration within three cycle thresholds of the comparator test's LoD (i.e., Ct ≥ 31 for N1 and Ct ≥ 32 for N2). The dilutions were reproduced in-house at Talis Biomedical, and the final diluted samples were tested at the clinical sites. Samples were presented to the operators in a blinded fashion.

Six of the eight presumed positive specimens tested positive in concordance with the comparator test results and two tested negative. All negative specimens tested negative in concordance with the comparator test. The two false negative (FN) results corresponded to the specimens of highest dilution: one was diluted 32,768-fold, the other 131,072-fold. The corresponding neat specimens of the two FN specimens were tested in-house with the Talis One COVID-19 Test System to confirm the starting material was positive. Both samples tested positive.

The combined data set of diluted specimens with neat clinical specimens (from Table 3) demonstrated a PPA of 95.7% (95% CI: 85.5%-98.8%) and NPA of 100% (95% CI: 92.4%-100%). Refer to Table 4 below.

Table 4. Clinical Performance of Talis One COVID-19 Test System (Neat and Diluted Samples Combined)

		FDA authorized molecular SARS-CoV-2 assay (EUA)		
		Positive*	**Negative**	**Total**
Talis One COVID-19 Test System	**Positive**	44	0	44
	Negative	2	47	49
	Total	46	47	93
PPA	95.7% (95% CI: 85.5%-98.8%)			
NPA	100.0% (95% CI: 92.4%-100%)			

* *This combined dataset included a total of 8 low positive samples derived from individual consecutively collected positive specimens that were diluted in individual negative nasal mid-turbinate samples. Dilutions of comparator samples were performed by the reference laboratory based on the Ct values of the comparator. The dilution factor determined for the comparator swab sample based on the comparator test was then used to make the same dilution for the swab sample that was to be tested with the investigational device. All samples were tested at the PoC sites. The two false negative samples were diluted samples with the highest dilution factor.*

Near Cutoff Study

To assess performance near (1.9X) the LoD, contrived samples prepared in clinical nasal matrix with SARS-CoV-2 viral load near the LoD of the Talis One COVID-19 Test System were tested at the point-of-care sites. A total of 48 contrived low positive (24) and negative samples (24) were tested by the Talis One COVID-19 Test System at the point-of-care sites. Samples were integrated into the testing workflow and presented to the operators in a blinded fashion. Results are shown in Table 5 below. Each operator tested a minimum of three low positive samples and three negative samples.

Table 5. Summary of Contrived Sample Testing

Target Concentration	Number Concordant / Number Tested	% Agreement (95% CI)
Low Positive	24 / 24	100.0% (95% CI: 86.2%-100%)
Negative	24 / 24	100.0% (95% CI: 86.2%-100%)

Summary of Invalid Tests

A total of 146 specimens and 50 external controls were tested with the Talis One COVID-19 Test System, of which 17 were invalid upon initial run. All invalid runs were retested one time; 12 of the 17 had valid results and five were invalid upon repeat testing. The five specimens with no results were excluded from data analysis but are reported as part of the invalid rate. The invalid rate of the study was 8.7% (17/196).

ANALYTICAL PERFORMANCE

Analytical Sensitivity (Limit of Detection)

Analytical sensitivity studies were performed to determine the limit of detection (LoD), defined as the lowest concentration at which at least 95% of replicates test positive. Samples used in the studies were prepared by serial dilution of inactivated SARS-CoV-2 viral particles (Isolate USA-WA1/2020; BEI Resources) to desired concentrations, and spiked into pooled negative nasal mid-turbinate swab matrix.

To estimate the LoD range, initial testing of 3 replicates was performed at each prepared concentration level (0, 125, 250, 500, and 1,000 copies/mL) using Lot 1. Results are shown in Table 6.

Table 6. LoD Range Finding Results, SARS-CoV-2

Sample Concentration (copies/mL)	Cartridge Lot	Positive Call Frequency	Percent Frequency
0	Lot 1	0/3	0%
125	Lot 1	3/3	100%
250	Lot 1	3/3	100%
500	Lot 1	3/3	100%
1,000	Lot 1	3/3	100%

To confirm the LoD, testing was performed using 3 Talis One Instruments each study day, and 2 reagent Cartridge lots (designated Lot 1 and Lot 2). An additional 20 replicates were run at concentrations of 125 copies/mL and 250 copies/mL using Cartridge Lot 1. Testing of an additional 20 replicates at both 250 copies/mL and 500 copies/mL using a second Cartridge lot (Lot 2) yielded a positive call frequency of 18/20 (90%) and 20/20 (100%) respectively. The LoD of the Talis One COVID-19 Test System is therefore determined to be 500 copies/mL, the highest LoD across both of the Cartridge lots (as per CLSI EP17-A2).

Table 7. LoD Confirmation Results, SARS-CoV-2.

Sample Concentration (copies/mL)	Cartridge Lot	Positive Call Frequency	Percent Frequency
125	Lot 1	19/20	95%
250	Lot 1	20/20	100%
250	Lot 2	18/20	90%
500	Lot 2	20/20	100%

Analytical Reactivity (Inclusivity)

Analytical reactivity of the Talis One COVID-19 Test System was evaluated by *in silico* analysis of the test system primers and probes in relation to nucleotide sequences available from the NCBI database as of July 21, 2021. The initial alignment was done using BLAST on each of the individual primer sequences. This can result in some ambiguity between a terminal mismatch and an insertion. To ensure that all mismatches and gaps are counted as they would be in the amplicon, a more computationally intensive multiple sequence alignment was performed using MAFFT to align the full amplicon to all target sequences (replacing the BLAST step). Less than 0.15% of sequences were reassigned after the reprocessing.

Overall, the Talis One COVID-19 Test System is expected to amplify 171,565/172,577 or 99.41% of published sequences. 99.41% of the sequence combinations are a perfect match for at least one of the primer sets and therefore there is very low risk of false negative results due to the dual target design of the test.

Table 8. Mismatch Table

	N gene	ORF1 gene
Total Primer Length (nt)	179	158
Amplicon Length (base pairs measured from the 5' end of the F3 primer to the 5' end of the B3 primer)	218	197
Total strains	172,577	172,577
100% match	144,569	167,749
1 mismatch	24,818	4,176
2 mismatches	2,834	41
3 mismatches	324	1
>3 mismatches	32	610

For those sequences with one mismatch the risk is mitigated through the dual target design of the test. Of the analyzed sequences 0.58% of the combinations have at least one mismatch in both target genes but the location of the mismatch and/or the resulting change in annealing temperature is not expected to impact the performance of the Talis One COVID-19 Test System. Only 3 sequences have a mismatch at the 3' end of a primer in both primer sets. For sequences with 2 or 3 mismatches in primers and/or probe the population frequency is very low, i.e., 0.0064% and 0.0012%, respectively, and is therefore not expected to impact the performance of the Talis One COVID-19 Test System.

Variant Analysis: 589,887 US sequences from the GISAID database (accessed July 22, 2021) were analyzed to evaluate the impact of emerging viral mutations on test system performance. The prevalence of variants within the primer/probe regions was below the 5% total population threshold established by the FDA guidance with the exception of one single nucleotide polymorphism (SNP)— G29402T—which had 39,705 counts for a prevalence of 6.8%. The next most prevalent SNP within the primer/probe regions had 2,144 counts for a total prevalence of less than 1%. All other SNPs within the primer/probe regions were present in less than 1% of sequences added in the past 60 days (from the date of testing, July 22, 2021).

Further *in silico* analysis revealed two strains with a 3 bp deletion in the ORF1ab targets (Del 515-517 and Del 517-519) as well as two strains with point mutations in the N gene target (G29402T and C29509T).

Variant specific testing with *in vitro* transcripts for these variants has been performed. No loss in sensitivity was detected for these variants; based on that testing no impact is expected on the performance of the Talis One COVID-19 Test System's performance.

- ***Ongoing Variant Monitoring***

In February 2021, the FDA issued guidance for evaluating the potential impact of emerging and future viral mutations of SARS-CoV-2 on COVID-19 diagnostics tests (Policy for Evaluating Impact of Viral Mutation on COVID-19 Tests: Guidance for Test Developers and Food and Drug Administration Staff). This guidance recommends that nucleic acid amplification test developers routinely monitor for viral mutations that may impact test performance. Continued variant inclusivity for this test will be monitored based on routine in silico analysis using Rosalind or in-house analysis tools. Variants with a population prevalence of 5% or greater and having a mutation in the primer and/or probe binding site (i.e., it has the possibility to affect test system performance) will be selected for wet lab testing. Wet lab testing, if required, will be performed within six weeks (+/- one week).

Analytical Specificity (Cross-reactivity)

Analytical specificity of the Talis One COVID-19 Test System was established by determining any potential cross-reactivity to medically relevant concentrations of organisms representing background species in upper respiratory matrix. All organisms identified as relevant (Table 9) were assessed *in silico* and also tested *in vitro*.

In silico analysis of potential cross-reactivity was conducted by mapping primers and probes in the Talis One COVID-19 Test System to sequences downloaded from the NCBI database. For any alignment hits of individual primers, a second check was performed to determine if any 2 primers hit the same sequence. All sequences with more than 1 primer hit were examined for location and confirmed to have at least a 1,000 kb distance between them. Therefore, no cross-reactivity would be expected for any of the organisms listed in Table 9.

For *in vitro* testing, potentially cross-reacting organisms were spiked into pooled negative nasal mid-turbinate swab specimen matrix to achieve the initial testing concentrations shown in Table 9. Three (3) replicates were tested for each organism. Samples with 3/3 negative test results were considered "not cross-reactive".

As shown in Table 9, no cross-reactivity was observed for any organism at the concentration tested.

Table 9. Cross-Reactivity Testing, *In Vitro*

Organism Name	Testing Concentration	Frequency Detected (%) at Testing Concentration
Microorganisms from the same Genetic Family		
Coronavirus 229E	4.17×10^4 $TCID_{50}$/mL	0.0%
Coronavirus OC43	1.26×10^5 $TCID_{50}$/mL	0.0%
Coronavirus HKU1	1×10^5 genome copies/mL	0.0%
Coronavirus NL63	1.41×10^4 $TCID_{50}$/mL	0.0%
SARS-coronavirus	Ct 25-28*	0.0%
MERS-coronavirus	3.55×10^4 $TCID_{50}$/mL	0.0%
High Priority Organisms		
Adenovirus	1×10^6 $TCID_{50}$/mL	0.0%
Human Metapneumovirus	1.55×10^3 $TCID_{50}$/mL	0.0%
Parainfluenza virus 1	5.01×10^4 $TCID_{50}$/mL	0.0%
Parainfluenza virus 2	1.51×10^5 $TCID_{50}$/mL	0.0%
Parainfluenza virus 3	1×10^6 $TCID_{50}$/mL	0.0%
Parainfluenza virus 4	1.38×10^6 $TCID_{50}$/mL	0.0%

Table 9. Cross-Reactivity Testing, *In Vitro (Continued)*

Organism Name	Testing Concentration	Frequency Detected (%) at Testing Concentration
Influenza A	$1.41x10^4$ $TCID_{50}$/mL	0.0%
Influenza B	$1.17x10^4$ $TCID_{50}$/mL	0.0%
Enterovirus	$1.26x10^5$ $TCID_{50}$/mL	0.0%
Respiratory syncytial virus	$1.26x10^5$ $TCID_{50}$/mL	0.0%
Rhinovirus	$1.26x10^5$ $TCID_{50}$/mL	0.0%
Chlamydia pneumoniae	$1x10^6$ IFU/mL	0.0%
Haemophilus influenzae	$1x10^6$ CFU/mL	0.0%
Legionella pneumophila	$1x10^6$ CFU/mL	0.0%
Mycobacterium tuberculosis	$1x10^5$ genome copies/mL	0.0%
Streptococcus pneumoniae	$1x10^6$ CFU/mL	0.0%
Streptococcus pyogenes	$1x10^6$ CFU/mL	0.0%
Bordetella pertussis	$1x10^6$ CFU/mL	0.0%
Mycoplasma pneumoniae	$1x10^6$ CCU/mL	0.0%
Candida albicans	$1x10^6$ CFU/mL	0.0%
Pseudomonas aeruginosa	$1x10^6$ CFU/mL	0.0%
Staphylococcus epidermidis	$1x10^6$ CFU/mL	0.0%
Streptococcus salivarius	$1x10^6$ CFU/mL	0.0%
Pooled human nasal wash	10%	0.0%
*Pneumocystis jirovecii (PJP)***	$1x10^6$ nuclei/mL	0.0%

* Cycle threshold (Ct) range based on the Package Insert for the Zeptometrix in-house real time PCR assay targeting the envelope/membrane protein gene region.

** In other literature, may be referred to as *Pneumocystis carinii*, which was a term formerly used to classify this organism.

Endogenous and Exogenous Substance Interference

The effect of potentially-interfering substances commonly found in patient samples on test system performance was determined. Testing was performed on 3 instruments by at least 2 operators, using pooled, negative nasal mid-turbinate swab samples, and pooled, negative swab samples spiked with ~1.5xLoD inactivated SARS-CoV-2 viral particles.

Both the negative and ~1.5xLoD spiked samples were tested both with and without potential interferents in replicates of 3. Contrived positive samples with interferents returning 100% (3/3) positive results and negative samples with interferents returning 0% (0/3) positive results indicate that the associated substance was “non-interfering” at the testing concentration.

No interference was observed for any of the substances in Table 10 at the concentrations indicated.

Table 10. Non-Interfering Substances

Substance	Testing Concentration
Blood (human)	1% v/v
Afrin Original nasal spray	1.5% v/v
Cepacol Sore Throat (benzocaine/menthol lozenges)	5 mg/mL
Zanamivir	3.3 mg/mL
Oseltamivir Phosphate (Tamiflu)	2.2 µg/mL
Mupirocin[1]	5 mg/mL
Tobramycin	4 µg/mL
Flonase	1.5% v/v
Zyrtec (GoodSense All Day Allergy, Cetirizine HCl Tablets 10 mg)	1 mg/mL

1. Mupirocin ointment is a prescription drug, so the active ingredient in a powder form was purchased from Sigma and tested in this study.

Two (2) of the substances tested, Mucin and Ayr Gel, displayed interference at the initial testing concentration. Testing of additional dilutions determined the concentration at which no interference was observed, and at which they would therefore be acceptable for use (Table 11).

Table 11. Interfering Substances, Acceptable Use Concentrations

Substance	Interfering Concentration	Not Interfering Concentration
Mucin: bovine submaxillary gland, type I-S	1 mg/mL	0.75 mg/mL
Ayr Nasal gel	0.6% w/v	0.15% w/v

Precision

Studies were performed to confirm both within-lab and lot-to-lot precision of Talis One COVID-19 Cartridges run on the Talis One instrument.

For Within-Lab Precision: The 4 test panel members used consisted of titered, inactivated SARS-CoV-2 viral particles spiked into negative nasal mid-turbinate swab matrix at concentrations of (1) ~1xLoD, (2) ~2.5xLoD, and (3) ~10xLoD, and (4) unspiked negative matrix pool.

Three (3) Talis One instruments were used by each of 3 operators according to the schedule shown in Table 12. Three (3) replicates per panel member per instrument per day were tested on 3 nonconsecutive days using 1 lot of the Talis One COVID-19 Cartridges. A positive external control and a negative external control were run on each instrument prior to the start of sample testing on Day 1.

As shown in Table 12, the Talis One COVID-19 Test System demonstrated 100% concordance of results for SARS-CoV-2 samples across all runs (days), instruments, and operators.

Table 12: Functional Test Results – Summary of Within-Lab Precision

	Negative		1 x LoD		2.5 x LoD		10 x LoD	
	n/N	**Precision (%CI)**	**n/N**	**Precision (%CI)**	**n/N**	**Precision (%CI)**	**n/N**	**Precision (%CI)**
Day 1	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)
Day 2	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)
Day 3	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)	9/9	100% (70.1, 100)
Overall Concordance	27/27	100% (87.5, 100)	27/27	100% (87.5, 100)	27/27	100% (87.5, 100)	27/27	100% (87.5, 100)

For Lot-to-Lot Precision: Lot-to-Lot precision was determined by testing the following for each of 3 Talis One COVID-19 Cartridge Pack lots: 2 replicates per panel member on each of three instrument/operator pairs were tested on each of 2 non-consecutive days. A total of 6 positive (~1.5xLoD) and 6 negative samples were tested on each cartridge lot per day for a total replicate number of 12 per day. The test panel consisted of a sample at ~1.5x LoD and a negative sample.

As shown in Table 13, results from Lot 1 and Lot 2 displayed 100% concordance for all variables. For Lot 3, a negative result for 1 sample (1.5xLoD / Day 2 / Operator 3) resulted in a concordance of 91.7% (11/12).

Table 13. Functional Test Results - Summary of Lot-to-Lot Precision

Sample	**Lot 1**		**Lot 2**		**Lot 3**		**Overall**	
	n/N	**Precision (%CI)**	**n/N**	**Precision (%CI)**	**n/N**	**Precision (%CI)**	**n/N**	**Precision (%CI)**
Positive	12/12	100% (75.8, 100)	12/12	100% (75.8, 100)	11/12	91.7% (64.6, 98.5)	35/36	97.2% (85.8, 99.5)
Negative	12/12	100% (75.8, 100)	12/12	100% (75.8, 100)	12/12	100% (75.8, 100)	36/36	100% (90.4, 100)

Note: Lots are not confounded with Instrument/Operator 1, 2, and 3.

SYMBOL DEFINITIONS

Following are symbols and associated definitions used in Talis One labeling.

Symbol	Meaning	Symbol	Meaning
IVD	*in vitro* diagnostic medical device		Use by date
℞ ONLY	Prescription use only		Do not reuse
LOT	Batch code		Temperature limitation
REF	Catalog number		Humidity limitation
SN	Serial number		Consult instructions for use
	Health hazards		Manufacturer
	Caution		Date of manufacture
	Warning		Contains sufficient for <n> tests
	Biological risks		Maximum altitude
	Pinch point	CONTROL −	Negative control
		CONTROL +	Positive control

ORDERING AND CONTACT INFORMATION

Corporate Headquarters
Talis Biomedical Corporation 230 Constitution Drive Menlo Park, CA 94025 USA
Telephone: +1 (855) 956-3594
Customer Service: care@talisbio.com

Note: *Include Software Version and Serial Number for items needed.*

TECHNICAL ASSISTANCE

Refer to the About Menu or Technical Support and have available the following information including:

- Firmware version
- Organization
- Account number
- Instrument model
- Serial Number

Region	Telephone	Email
USA	+ 1 855-956-3594	support@talisbio.com

For Use Under an Emergency Use Authorization (EUA) Only

For prescription use only

For *In Vitro* Diagnostic Use

Talis Biomedical Corporation
230 Constitution Drive
Menlo Park, CA USA 94025

TEST PATIENT SAMPLES

TALIS ONE COVID-19 TEST SYSTEM · QUICK REFERENCE INSTRUCTIONS

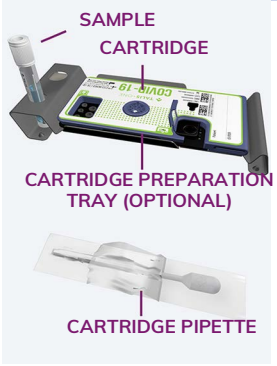
IVD | ℞ ONLY **For Use Under an Emergency Use Authorization (EUA) Only.** Read instructions carefully before performing test. *Store COVID-19 Cartridges at 15–30°C.*

This document does not provide the full instructions for use (IFU). For the complete IFU, please visit: https://talisbio.com/ifu/talis-one-covid-19-test
Please email care@talisbio.com if you require a printed copy free of charge. Refer to the Talis One COVID-19 Control Run Instructions for QC testing procedures.

Caution: *Cartridges must be kept in their sealed foil pouches until opened for immediate testing, and may be open for a maximum of 30 minutes prior to initiating testing on the Talis One instrument.*

Caution: *Use Standard Precautions and treat all patient samples and used test materials as potentially infectious. • Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves should be worn at all times when performing patient tests. • Disinfect work surfaces and change gloves before each new sample run. • Handle and dispose of all used test materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.*

1. Gather materials, confirm they are not expired, and log into instrument.



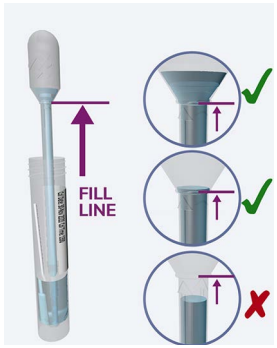
2. Write in patient information (print clearly), or apply label.

3. Get sample tube, bring to room temperature (if needed), and swirl 6 times.

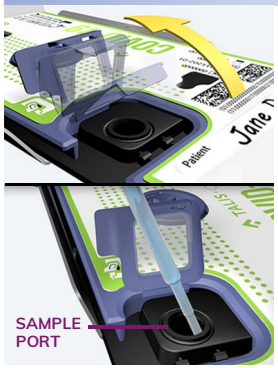
4. Remove pipette from pouch and squeeze firmly to fully compress.

5. Insert pipette into tube and completely release bulb; allow to fill.

6. Ensure liquid is at or above the **FILL LINE**, or repeat steps 4-5.



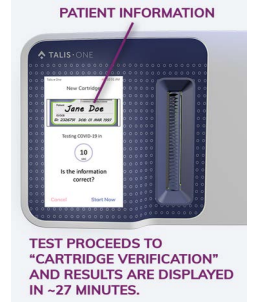
7. Open sample port and insert pipette tip. **Squeeze firmly ONCE**; while holding, remove from Cartridge.



8. Dispose of pipette and close lid until it clicks, then cap sample tube.

9. Insert Cartridge until it clicks, with label facing right. Instrument begins reading the Cartridge.

10. Wait while "Reading Cartridge" is displayed; then verify information.

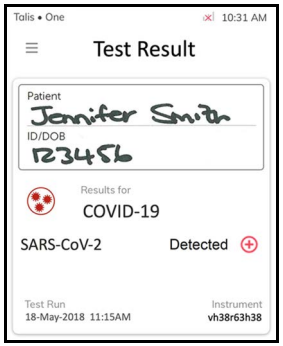
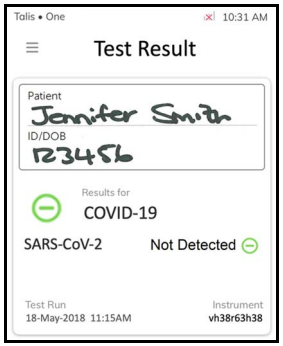
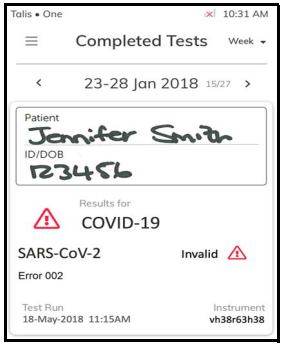


See back side for interpretation of results >>>

- *This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.*
- *This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.*
- *The emergency use of this 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.*
- *Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.*

Interpretation of Results

The table below provides examples and descriptions of the three results possible for a completed run in the Talis One COVID-19 Test System: Detected, Not Detected, and Invalid. For complete information on results interpretation and in-process errors, refer to the Talis One COVID-19 Test System Instructions For Use. For Troubleshooting, refer to the Talis One Instrument User Guide.

Results	Interpretation
	Targets detected with Talis One COVID-19 Test System. SARS-CoV-2 target nucleic acids **are** detected.
	Targets not detected with Talis One COVID-19 Test System. SARS-CoV-2 target nucleic acids **are NOT** detected.
	Test result invalid. Invalid results for Talis One COVID-19 Test System. Re-run the sample with a new Cartridge. If repeat test is Invalid, a new specimen must be collected and run using a new collection kit and Cartridge. **Note:** *For specific error code details and resolution steps, see the Troubleshooting section of the Talis One Instrument User Guide.*

Talis One Nasal Mid-Turbinate Collection Kit Package Insert

For Use Under an Emergency Use Authorization (EUA) Only

For *in vitro* diagnostic use

For prescription use only

This document does not provide the full instructions for use (IFU). For the complete IFU, please visit: https://talisbio.com/ifu/talis-one-covid-19-test To request a printed copy (free of charge), please email: care@talisbio.com.

Description

The Talis One Nasal Mid-Turbinate Collection Kit is a component of the Talis One COVID-19 Test System, for use by clinicians to collect nasal mid-turbinate swab specimens.

The Talis One COVID-19 Test System has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by 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.

The Talis One Nasal Mid-Turbinate Collection Kit, as a component of the Talis One COVID-19 Test System, 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 Talis One COVID-19 Test System has been authorized only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, using the Talis One COVID-19 Test System with nasal mid-turbinate swab specimens.

Materials Provided

25 Nasal Mid-Turbinate Collection Kits

Each kit contains:

Component	Quantity	Description
Swab	**1**	**Individually wrapped, sterile flocked swab for nasal mid-turbinate swab specimen collection.**
Collection Medium Tube	**1**	**A specimen tube containing 3 mL collection medium.**

Each package contains:

Component	Quantity	Description
Talis One Nasal Mid-Turbinate Collection Kit Package Insert	**1**	**Package Insert**
Talis One Nasal Mid-Turbinate Collection Kit	**25**	**One flocked Swab and one tube containing collection medium.**

Warnings and Precautions

- Wear protective gloves and eye protection at all times when handling collection medium contained in the Collection Medium Tubes—direct contact with skin, eyes, or mucous membranes will cause irritation.
- If collection medium is spilled and makes contact with skin, immediately wash affected area with water and soap and rinse thoroughly.
- Specimens may possess communicable organisms which may be infectious. Use standard precautions when handling specimens and used test materials.
- Do not allow bleach to come into contact with the contents of the Talis One Collection Medium Tubes or control preparation tubes as toxic fumes can develop when the content of the tubes mixes with bleach.
- **WARNING:** Collection medium contained in Collection Medium Tubes is harmful if swallowed or inhaled, may cause skin irritation, and may cause serious eye irritation. Avoid direct skin/mucous membrane contact with or ingestion of collection medium provided with the Talis One Nasal Mid-Turbinate Collection Kits and Talis One COVID-19 Control Medium and Label Pack. If ingested contact Poison Control at 1(800) 222-1222.

  Classifications:

  Acute toxicity, Category 4.
  Skin corrosion/irritation, Category 2.
  Serious eye damage/irritation, Category 2A.

Hazard Statements:

Harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.

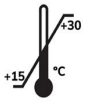
Important information regarding the safe handling, transporting, and disposing of this product is contained in the Safety Data Sheets. Safety Data Sheets are available from Talis Biomedical Corporation. Inquire directly.

- Avoid spilling contents of the Collection Medium Tube (collection tube). If a spill occurs, immediately blot dry and decontaminate impacted surfaces with CaviWipes or an alcohol-based cleaner (**do not use bleach**), then restart the collection procedure with a

new kit. Failure to use a new kit may invalidate the test results.

- Do not allow swab tip to touch anything except the nose.
- If precipitate is observed in the collection tube, do not use.
- If kit pouch is damaged, do not use.
- Dispose of all packaging materials in a safe manner in accordance with your institution's guidelines.
- Handle and dispose of all used kit materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.
- Personal protective equipment (PPE), including a lab coat, mask (surgical, dental, medical procedure, isolation, or laser mask), eye protection, and gloves must be worn at all times when collecting specimens.

Kit Storage Requirements



Nasal Mid-Turbinate Collection Kits should be stored at room temperature within the range of 15°-30°C.

Nasal Mid-Turbinate Swab Specimen Performance

The Test System performance characteristics, including Clinical and Analytical Performance of the nasal mid-turbinate swab specimen, are provided in the Talis One COVID-19 Test System Instructions For Use.

Nasal Mid-Turbinate Swab Specimen Collection by Clinician

The following procedure is intended only for collection of patient nasal mid-turbinate swab specimens by a clinician.

IMPORTANT: Personal protective equipment (PPE), including a lab coat, mask (surgical, dental, medical procedure, isolation, or laser mask), eye protection, and gloves must be worn at all times when collecting specimens.

***Before* collection of each new specimen:**

- Disinfect work surfaces with CaviWipes or an alcohol-based cleaner. **Do not use bleach**.
- Put on a new pair of gloves and protective eyewear.
- Check patient for nasal obstructions and clear as needed.

Specimen Collection Procedure (Clinician):

1. Open the Talis One Nasal Mid-Turbinate Collection Kit pouch, remove the contents and inspect components for signs of damage. (Each kit pouch contains one capped Collection Medium Tube and one swab wrapped in its own paper pouch.)
2. Print patient name, ID/Date of Birth, and collection date in the fields provided on the collection tube, or apply printed label.
3. Open the paper swab pouch carefully at the shaft end without touching the soft swab tip. Leave the swab in the partially-opened pouch until ready to use. (The swab tip should not touch any surface, including gloves.)
4. Remove cap from the collection tube and put aside (open side up), then place the open tube on a tube holder.

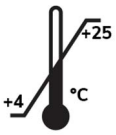
IMPORTANT: If liquid from the collection tube spills or swab tip touches any surface other than the nostril, restart the collection procedure with a new kit. The spillage should be immediately blotted dry and the surface should be decontaminated with CaviWipes or an alcohol-based cleaner. **Do not use bleach.**

5. Carefully remove the swab from the partially-opened pouch—ensure that the tip does not touch any surfaces—and hold at the breakpoint. Failure to hold at the breakpoint may cause the swab to break during specimen collection.
6. Tilt patient head back slightly (~70^{o}) and carefully insert the swab into either of the patient's nostrils while rotating the swab until resistance is met at turbinates (less than 1 inch into the nasal cavity).

   ***Note**: Swab should be inserted in a horizontal direction, approximately parallel to the palate.*
7. Rotate swab against nasal wall for 3-5 seconds.
8. Remove the swab from the nostril, then repeat steps 6 and 7 in the other nostril using the same swab.
9. Insert the swab into the collection tube until the entire swab tip is visible below the liquid level.
10. Break the swab at the breakpoint against the lip of the collection tube, then discard the swab shaft and tightly screw the cap onto the tube.
11. Hold the collection tube by the cap and swirl tube 6 times.
12. Disinfect the collection tube and store upright, then discard used gloves into appropriate waste receptacle.

Prior to collecting any additional specimens from additional patients, ensure that the work area has been decontaminated and that fresh gloves are used.

Specimen Handling and Storage



Specimens should be tested immediately or no later than 30 days from collection. Keep specimens at 4–25° Celsius.

IMPORTANT: Clinician should label the collection tube with the sample identification information, including date and time of the collection, as required.

Limitations

- *For in vitro* diagnostic use.
- For prescription use only.
- For Use Under an Emergency Use Authorization (EUA) Only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product is for use with a test 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 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.
- 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 high, moderate, or waived complexity tests.
- The Talis One COVID-19 Test System 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.
- Use this collection kit only with the Talis One COVID-19 Test System. Performance has not been established with other products.

Ordering, Contact Information, and Technical Assistance

Corporate Headquarters
Talis Biomedical Corporation **230 Constitution Drive** **Menlo Park, CA 94025** **USA**
Telephone: +1 (855) 956-3594
Technical Support: support@talisbio.com
Customer Service: care@talisbio.com

For Use Under an Emergency Use Authorization (EUA) Only

℞ ONLY **For prescription use only**

IVD **For *In Vitro* Diagnostic Use**

Symbol Definitions

Following are symbols and associated definitions used in Talis One labeling.

Symbol	Meaning	Symbol	Meaning
IVD	*in vitro* diagnostic medical device		Use by date
Rx ONLY	Prescription use only		Do not reuse
LOT	Batch code		Temperature limitation
REF	Catalog number		Humidity limitation
SN	Serial number		Consult instructions for use
	Health hazards		Manufacturer
	Caution		Date of manufacture
	Warning		Contains sufficient for <n> tests
	Biological risks		Maximum altitude
	Pinch point	CONTROL −	Negative control
		CONTROL +	Positive control

RUN CONTROLS

TALIS ONE COVID-19 CONTROL RUN INSTRUCTIONS

IVD Rx ONLY **For Use Under an Emergency Use Authorization (EUA) Only**

TALIS · ONE

Note: Talis recommends running controls to confirm test system performance, but it is not a requirement for testing patient samples with the Talis One COVID-19 Test System.

Review the following notices prior to running controls:

Review the Microbiologics package inserts for controls, the Talis One COVID-19 Test System Instructions for Use, and the Talis One Instrument User Guide carefully before running. This document does not provide the full instructions for use (IFU). For the complete IFU, please visit: https://talisbio.com/ifu/talis-one-covid-19-test Please email care@talisbio.com if you require a printed copy free of charge.

***Caution:** If liquid from a Control Prep Tube spills, or if control swab tip touches any surface outside the tube, restart the procedure with a new kit.*

***Caution:** Cartridges must be kept in sealed foil pouches until opened for immediate testing (open for a maximum of 30 minutes prior to initiating testing on the Talis One instrument).*

***Caution:** Use Standard Precautions and treat inactivated external control material as potentially infectious. ▪ Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves must be worn at all times when performing external control tests. ▪ Disinfect work surfaces and change gloves before each new sample run. ▪ Handle and dispose of all used kit materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.*

***WARNING:** Medium contained in the Control Prep Tubes is harmful if swallowed, may cause skin irritation, and may cause serious eye irritation. Avoid direct skin/mucous membrane contact with or ingestion of medium provided with the Talis One Nasal Collection Kit and Talis One Control Medium and Label Pack.*

Classifications:	**Hazard Statements:**
Acute toxicity, Category 4.	Harmful if swallowed.
Skin corrosion/irritation, Category 2.	Causes skin irritation.
Serious eye damage/irritation, Category 2A.	Causes serious eye irritation.

Important information regarding the safe handling, transporting and disposing of this product is provided in the Safety Data Sheets. Safety Data Sheets are available from Talis Biomedical Corporation. Inquire directly.

- *This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.*
- *This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.*
- *The emergency use of this 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.*
- *Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.*

SEE BACK FOR INSTRUCTIONS >>>

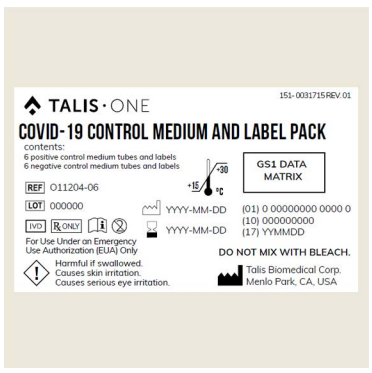
RUN CONTROLS

TALIS ONE COVID-19 CONTROL RUN INSTRUCTIONS

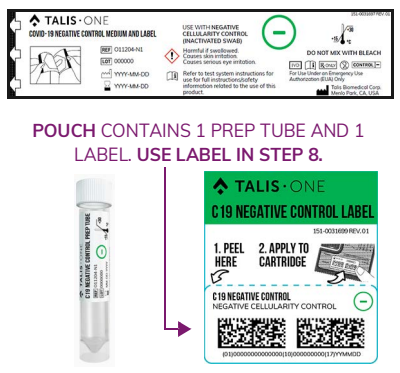
IVD Rx ONLY **For Use Under an Emergency Use Authorization (EUA) Only**

TALIS·ONE

To run controls: [Review notices on reverse side prior to running controls.]

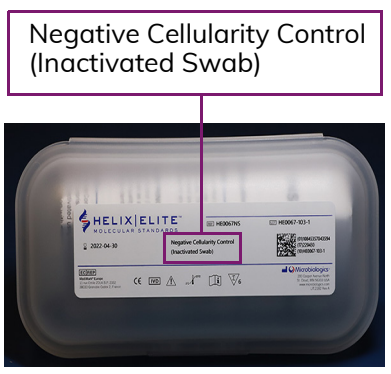


1a. Open the **Talis One Control Medium and Label Pack** box. Confirm pack is not expired.



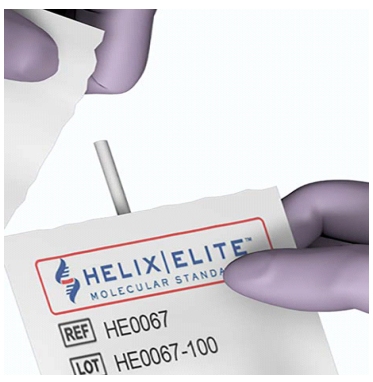
1b. Retrieve and open 1 **C19 Negative Control Medium and Label** pouch.

2. Uncap control prep tube and place in cartridge preparation tray.



3a. Open the **HELIX|ELITE™ Negative Cellularity Control Swab Kit**.

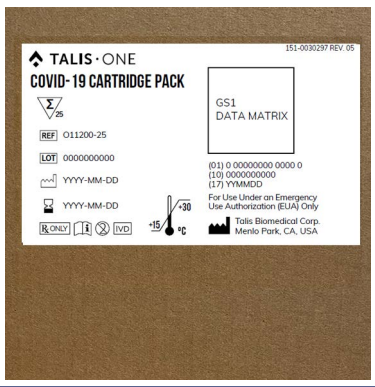
3b. Retrieve 1 **Negative Cellularity Control Swab**.



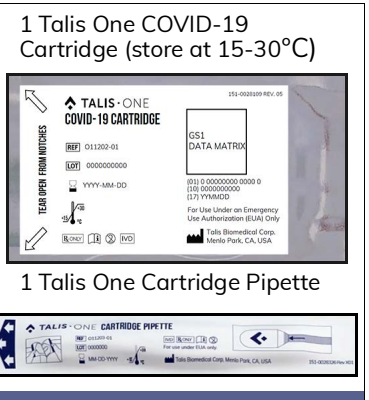
4. Remove control swab from pouch—**do not allow tip to touch any surfaces**.

5. Insert swab fully into tube, then bend shaft against rim and down to break swab.

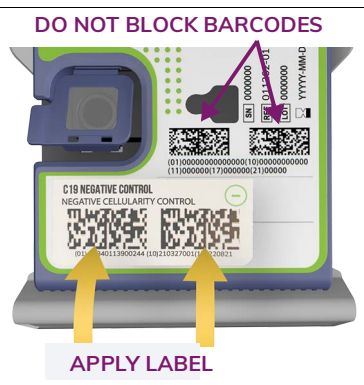
6. Re-cap tube with swab tip inside. Shake for 10 seconds, then **wipe with disinfectant**.



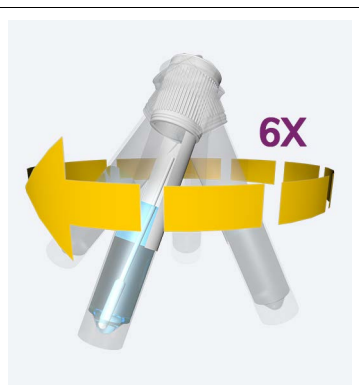
7a. Open the **Talis One COVID-19 Cartridge Pack** box. Confirm pack is not expired.



7b. Retrieve 1 **COVID-19 Cartridge** and 1 **Cartridge Pipette**.

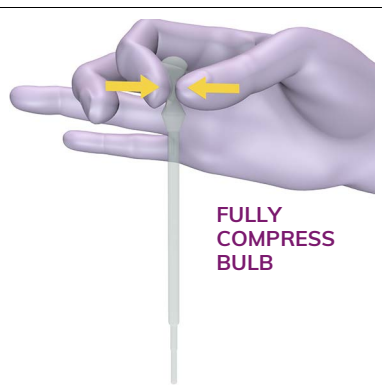


8. Remove Cartridge from pouch, place in tray and apply C19 Control Label (from Step 1b).

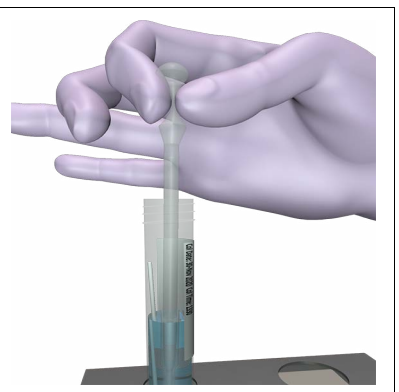


9. Swirl control prep tube 6 times.

10. Uncap tube and place back in cartridge preparation tray.



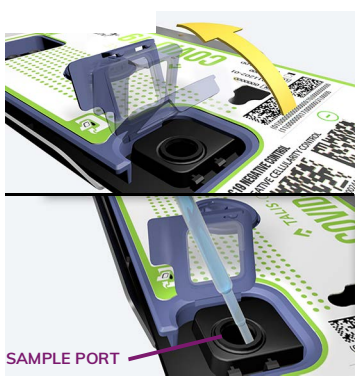
11. Remove cartridge pipette from pouch—**do not allow tip to touch any surfaces**—and squeeze bulb to fully compress.



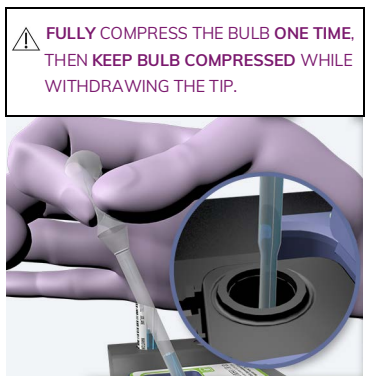
12a. Still squeezing the bulb, submerge tip in tube liquid, **then…**

12b. **…let go of pipette completely** and allow to fill.

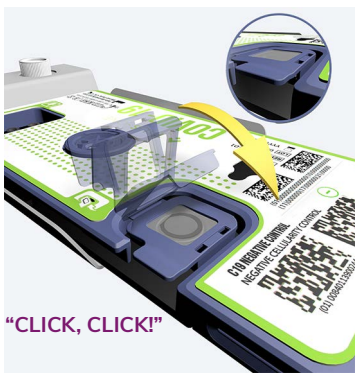
13. Ensure liquid is **at or above** the fill line and has no large bubbles. [If not, dispense back into tube and repeat aspiration.]



14. Open sample port lid and insert pipette tip into the port.



15. To dispense sample:
- **Squeeze bulb only ONCE**, and compress fully.
- **Keep compressed** while withdrawing tip from port.

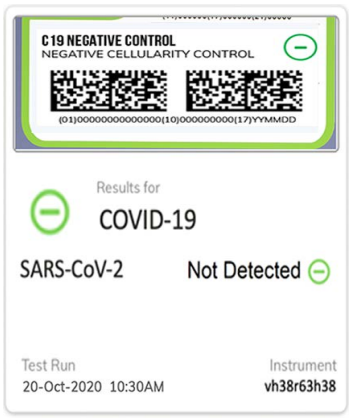


16. Dispose of pipette, then close sample port lid—lid will click when closed.

17. Insert Cartridge until it clicks, with label facing right. Instrument begins reading Cartridge.

Test proceeds to cartridge verification and results are displayed in ~27 minutes.

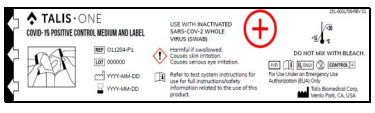
18. Wait while "Reading Cartridge" is displayed, then verify label.



19. Confirm passing result:
SARS-CoV-2 Not Detected

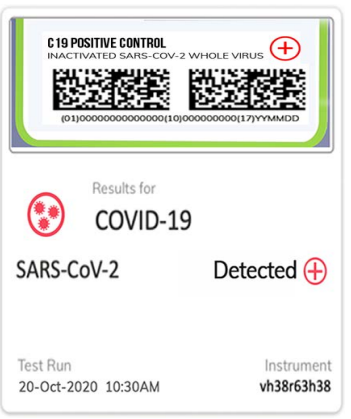
Note: If a passing result is not achieved, repeat test or contact Talis Technical Support at +1 (855) 956-3594.

- 1 C19 Positive Control and Label pouch:



- 1 Inactivated SARS-CoV-2 Whole Virus (Swab):

20. Repeat steps 2-18 for Positive Control using materials above.



21. Confirm passing result:
SARS-CoV-2 Detected

PROCEED TO: Test Patient Samples

[Refer to Quick Reference Instructions provided with the Cartridge Pack]

START HERE

TALIS ONE INSTRUMENT · SETUP GUIDE

IVD ℞ ONLY **For Use Under an Emergency Use Authorization (EUA) Only**

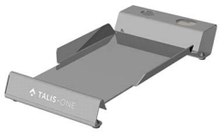
TALIS · ONE

Provided with the Talis One instrument:

Setup Instructions
Quick reference instruction sheets required for setup:
- **Instrument Setup** *(this sheet)*
- **Run Controls**

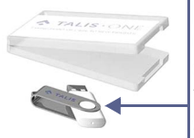

Power Supply
Use only power supply provided with instrument

Talis One Cartridge Preparation Tray
Optional accessory

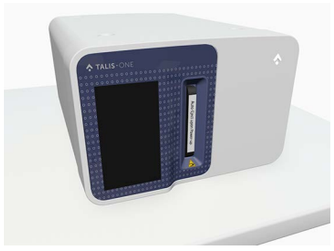


Talis One Quick Reference Booklet
(Not required for setup)

User Documentation USB
Electronic copies of instructions



PDFs of Talis One COVID-19 Test System instructions



1. Place instrument on a level surface.

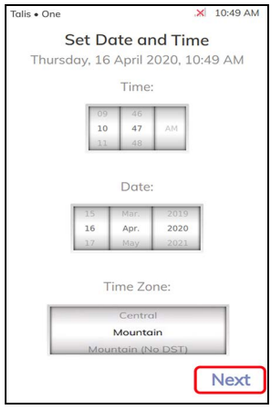
2. Connect adapter to rear power port with flat side facing left as shown.

3. Connect power cord to adapter and plug in.

4. Press rear power button to power up instrument.

5. After Welcome screen appears, remove ejected shipping block and set aside.

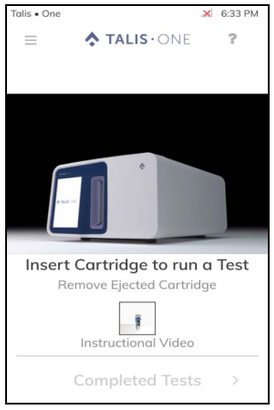
6. Start configuration.



7. Scroll to set Time, Date, and Time Zone, then tap **Next** to confirm entries.

8. Set Passcode.
(No repeated or sequential numbers.)

9. Review tutorial and instructional video. Tap **Finish** to complete each.



10. Instrument ready.

Note: To turn off the instrument, press and hold the power button for a few seconds until the screen shuts off.

PROCEED TO: Run Controls

- *This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.*
- *This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.*
- *The emergency use of this 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.*
- *Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.*
- *This document does not provide the full instructions for use (IFU). For the complete IFU, please visit: https://talisbio.com/ifu/talis-one-covid-19-test. Please email care@talisbio.com if you require a printed copy free of charge.*