


TEST PATIENT SAMPLES


TALIS ONE COVID-19 TEST SYSTEM · QUICK REFERENCE INSTRUCTIONS


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

Read instructions carefully before performing test.

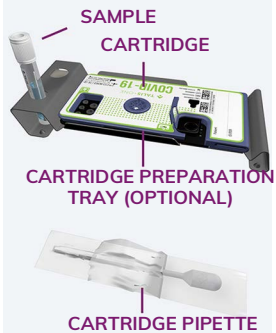
Store COVID-19 Cartridges at 15–30°C.

 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.



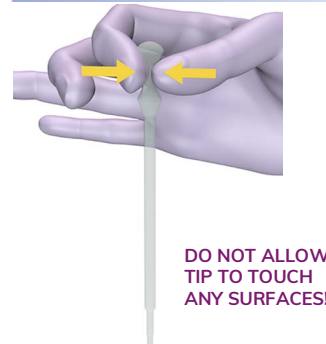
2. Write in patient information (print clearly), or apply label.



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



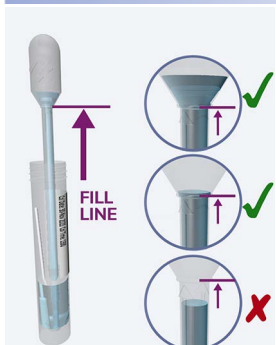
4. Remove pipette from pouch and squeeze firmly to fully compress.



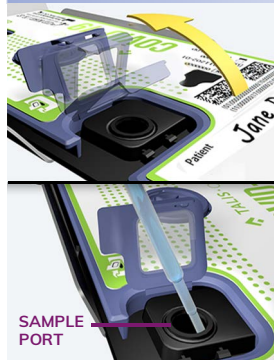
5. Insert pipette into tube and completely release bulb; allow to fill.



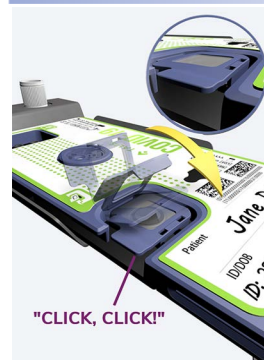
6. Ensure liquid is at or above the **FILL LINE**, or repeat steps 4-5.



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.



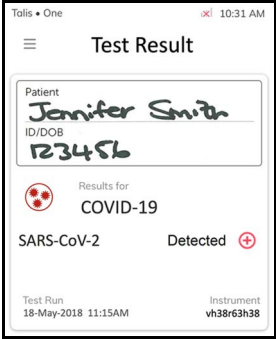
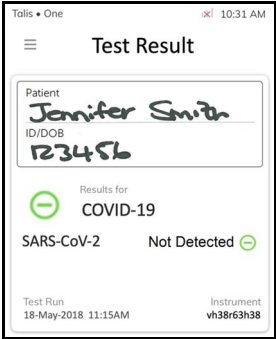
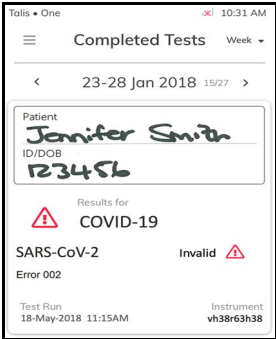
10. Wait while "Reading Cartridge" is displayed; then verify information.



- 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
 <p>Talis • One 10:31 AM</p> <p>Test Result</p> <p>Patient Jennifer Smith ID/DOB 123456</p> <p>Results for COVID-19</p> <p>SARS-CoV-2 Detected +</p> <p>Test Run 18-May-2018 11:15AM Instrument vh38r63h38</p>	<p>Targets detected with Talis One COVID-19 Test System.</p> <p>SARS-CoV-2 target nucleic acids are detected.</p>
 <p>Talis • One 10:31 AM</p> <p>Test Result</p> <p>Patient Jennifer Smith ID/DOB 123456</p> <p>Results for COVID-19</p> <p>SARS-CoV-2 Not Detected -</p> <p>Test Run 18-May-2018 11:15AM Instrument vh38r63h38</p>	<p>Targets not detected with Talis One COVID-19 Test System.</p> <p>SARS-CoV-2 target nucleic acids are NOT detected.</p>
 <p>Talis • One 10:31 AM</p> <p>Completed Tests Week</p> <p>< 23-28 Jan 2018 15/27 ></p> <p>Patient Jennifer Smith ID/DOB 123456</p> <p>Results for COVID-19</p> <p>SARS-CoV-2 Invalid Δ</p> <p>Error 002</p> <p>Test Run 18-May-2018 11:15AM Instrument vh38r63h38</p>	<p>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.</p> <p>Note: For specific error code details and resolution steps, see the Troubleshooting section of the Talis One Instrument User Guide.</p>