UOL COVID-19 Test

Instructions for Use (IFU)

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR *IN VITRO* DIAGNOSTIC USE

FOR PRESCRIPTION USE ONLY

FOR PROFESSIONAL USE ONLY

CONTENTS

INTENDED USE

The UOL COVID-19 Test is a real-time RT-LAMP test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens from individuals suspected of COVID-19 by a healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The UOL COVID-19 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.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in anterior nasal 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, **should** be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The UOL COVID-19 Test is intended for use by trained operators who are proficient in performing tests with the UOL COVID-19 Test. The UOL COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY & EXPLANATION OF THE TEST

The UOL COVID-19 Test is a rapid molecular diagnostic test that can be run at point of care settings from healthcare provider-collected anterior nasal swab samples from individuals suspected of COVID-19. The UOL COVID-19 Test consists of the UOL COVID-19 Test Kit, the UOL COVID-19 Instrument, and the Uh-Oh Labs Dx Pro Mobile App.

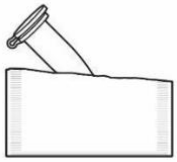
PRINCIPLE OF THE PROCEDURE

The UOL COVID-19 Test is a real-time reverse transcription loop-mediated isothermal amplification (rRT-LAMP) test. The SARS-CoV-2 primer set is designed to detect RNA from SARS-CoV-2 in anterior nasal swabs from patients suspected of COVID-19 by their healthcare provider. As an internal control, a second primer set is designed to detect human mRNA in anterior nasal swabs.

Amplification of each specific nucleic acid measurand is detected by spectrally duplexed fluorescence using the UOL COVID-19 Instrument ("Instrument"). The fluorescent signal measured by the Instrument is sent to the Uh-Oh Labs Dx Pro mobile app by Bluetooth. The data is analyzed in real time by an algorithm which automatically detects amplification events, and classifies test results as positive, negative, invalid (patient samples only), or pass or fail (controls only).

REAGENTS AND MATERIALS

Materials Provided

				
Instrument and Power Adapter	**Foil Pouch with Assay Tube** (containing dried reagent and desiccant)	**Squeeze Vial** (with non-toxic rehydration buffer solution)	**Sterile Rigid Nasal Swab**	**Winged "USED" Sticker**

Instrument

- UOL COVID-19 Instrument (Part No. UOL002): a reusable unit to be used with the UOL COVID-19 Test Kit and External Controls only.
- Power Adapter (Part No. UOL003): a reusable 100-240V AC 50/60Hz to 5V DC 2A USB-C wall power adapter (GlobTek Inc., model WR9HA2000USBCFMEDR6W or WR9HA2000USBCFMEDR6B) that is part of the Instrument equipment and is used to power the UOL COVID-19 Instrument.

Test Kits

- Test Kit (Part No. UOL001):
  - Squeeze Vial with non-toxic rehydration buffer solution (Part No. UOL004)
  - Sterile Nasal Swab (Part No. YM201)
  - Winged "Used" Sticker (Part No. UOL006)
  - Foil Pouch containing Assay Tube with dried reagent (Part No. UOL007)
- Quick Reference Guide (QRG, Part No. UOL024)
- Product Information Card (PIC, Part No. UOL027)
- Instructions for Use (IFU) available online at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Contact Uh-Oh Labs at support@uhohlabs.com or call toll-free at 1-877-UHOHLAB (877-846-4522) 8am–5pm (US Pacific Time) Monday through Friday if any component is missing or damaged or not properly sealed.

Materials Required but Not Provided

- Internet-enabled Apple mobile device (iPhone, iPad, iPod Touch) running iOS 14 or later.
- Uh-Oh Labs Dx Pro mobile app.

Mobile App Set-Up

Wi-Fi or cellular data connectivity is required for Uh-Oh Labs Dx Pro mobile app setup.

1. Enable Bluetooth on your iOS device via your Settings.
2. From the Apple Store, download the Uh-Oh Labs Dx Pro mobile app onto an iOS device running iOS 14 or later.
3. Open the app.
4. Select 'Create account'. Follow the prompts to create an account and log in. Creating an account only occurs once for first time app users.
5. User must be logged into an account on the mobile app in order to run tests.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For emergency use authorization only.
3. For prescription use only.
4. 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.
5. 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.
6. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
7. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
8. Do not position the Instrument so that it is difficult to disconnect from the Power Adapter.
9. The UOL COVID-19 Instrument has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Locating the device away from any sources of radiation may help to eliminate any potential interference.
10. Warning, no modification of the Test is allowed.
11. In the case of a spill in the work area or on/into the Instrument, wipe up the spilled contents with a disposable towel and dispose of the towel according to local regulations.
12. Proper sample collection and sample handling are essential for accurate results.
13. Do not touch the swab tip when handling the swab.
14. The swab is supplied sterile by ethylene oxide or gamma irradiation. Do not use the swab if the packaging is opened or compromised before use. In the event of damage to the sterile packaging, use a new Test Kit.

15. Warnings on Squeeze Vial containing the rehydration buffer:
    a. Do not ingest
    b. Avoid contact with skin and eyes
    c. If contact with the body occurs, rinse with water. If irritation persists, seek medical advice
16. Do not use any kit components with visible damage or broken seals.
17. Do not use kit components after their expiration date.
18. If any kit components are missing or damaged, discard the entire kit and use a new one.
19. If any opened kit component spills, discard the entire kit and use a new one.
20. Choose a leveled location to do this test where you can let the test run undisturbed for 40 minutes.
21. Keep the instrument out of direct sunlight. Sunlight can increase the temperature of the instrument beyond the recommended operating range.
22. All Test Kit components are single use items. Do not reuse Test Kits with multiple specimens.
23. Dispose of used Test Kit components and patient samples according to all local regulations.
24. **NEVER** open a used assay tube as this can cause contamination of the testing area and lead to false results.
25. Test Kits are to be used with the UOL COVID-19 Instrument and the Uh-Oh Labs Dx Pro mobile app.
26. Performance characteristics of this test have been established only with the Test Kit components provided, including the specific rigid anterior nares swab in the kit (YM201). The performance with alternate components, swabs, or sample types has not been validated.
27. Positive Control samples contain non-infectious synthetic DNA. However, all swabs should be handled as though they could transmit disease. Observe established procedures against microbial hazards during use and disposal.
28. The UOL COVID-19 Instrument indicates test status by its light color and flashing pattern; as a result, interpreting Instrument status may be difficult for people with color blindness.
29. In point of care settings, it is important to clean the workspace to remove any environmental contamination. Prior to testing, wipe the testing area, with a CDC approved wipe (such as Sani-Cloth® cleaning wipes) or 10% bleach solution.
30. Follow universal precautions when handling patient samples. All patient samples should be treated as potentially infectious.
31. Wear PPE when handling patient samples. Change gloves between patients.
32. The Instrument must remain plugged in while the test is running as power interruption will cancel the test.
33. Operation of the Instrument can be stopped immediately by unplugging the Instrument from the Power Adapter.
34. For best results, keep all software components (including mobile device operating system and Uh-Oh Labs Dx Pro mobile app) up to date.

35. For any misplaced or stolen iOS devices, breach of user account security, or operator account termination, please contact technical support (support@uhohlabs.com).
36. Log out of the Uh-Oh Labs Dx Pro mobile app when usage is complete.

STORAGE AND STABILITY

- The UOL COVID-19 Test should be stored and run in a dry environment (<95% humidity) at 2–30°C away from direct sunlight in accordance with the storage conditions on the different components.
- Once removed from the foil pouch, Assay Tubes should be used within 60 minutes; they are not designed for storage outside of the sealed foil pouch.
- Store the UOL COVID-19 Test on a flat and secure surface.
- Do not freeze the Instrument or Test Kits. In case of exposure to cold temperatures, do not use the UOL COVID-19 Test until each component has reached its minimum operating temperature.
- Do not use the Test Kit components beyond the expiration date listed on the label.
- Do not store Test Kits in direct sunlight.
- Do not reuse Test Kit components.
- Request additional Test Kit materials from Uh-Oh Labs at support@uhohlabs.com.

QUALITY CONTROL

Procedural Controls

The UOL COVID-19 Test contains an internal process control that ensures a sample has been collected, the reagents are functioning, there were no other interfering factors in the sample, and the procedure was performed correctly. In samples giving a positive signal for SARS-CoV-2, the internal control is redundant and is ignored. If the internal process control fails when no SARS-CoV-2 is detected, the result will be invalid.

External Positive and Negative Controls

External Positive and Negative Controls should be used in accordance with internal quality control procedures, local, state, and federal accrediting organizations policies as applicable.

External Positive and Negative controls are not provided with this test but are available for purchase separately and only through Uh-Oh Labs. DO NOT use controls provided by any other manufacturer. Contact Uh-Oh Labs at support@uhohlabs.com, 1-877-UHOHLAB (846-4522), or visit www.uhohlabs.com/support for more information.

⚠ Always test the positive control prior to the negative control to ensure no contamination. If controls are required, they should be run prior to collecting a patient swab.

Uh-Oh Labs recommends that external controls for the UOL COVID-19 Test should be run daily when COVID-19 testing is performed using this test. Additionally, running of the external controls is recommended:

- Once for each new lot or shipment of tests received.
- Once for each new operator.
- When problems with testing are suspected or identified.

RUNNING EXTERNAL CONTROLS

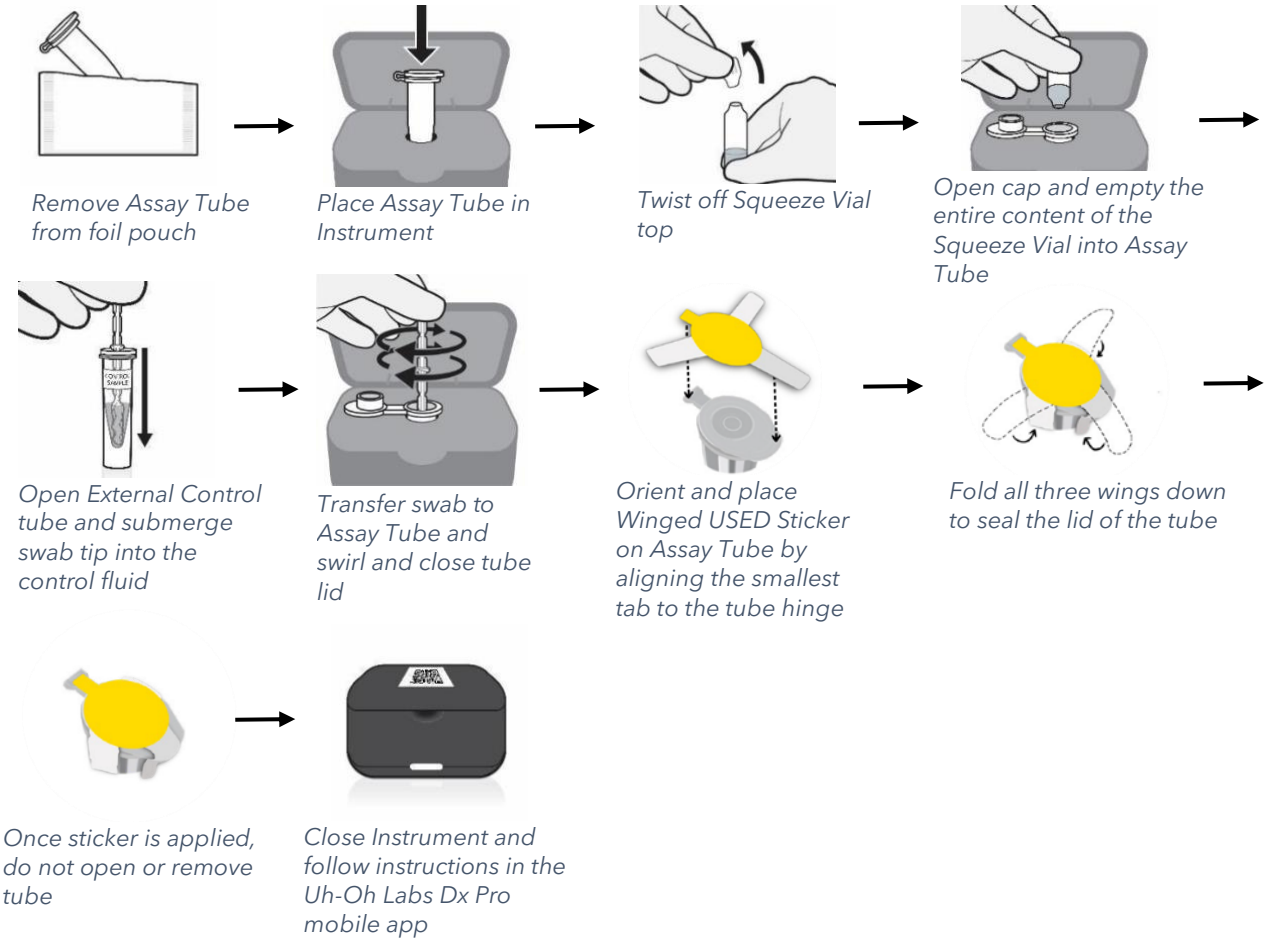
Additional Materials Needed (but not provided) for Running External Controls

- Positive Control (with one Test Kit per control, UOL008)
- Negative Control (with one Test Kit per control, UOL009)

UOL COVID-19 Test Set-Up

- Ensure the Instrument is on a flat, stable surface and plugged into a power source.
- Ensure the device has a solid green light to signify it is ready to run (for more information on instrument light patterns, see Troubleshooting > Instrument).

Control Procedure



1. To begin a control test, select "Start Test" in the Uh-Oh Labs Dx Pro mobile app.
2. On the screen asking: "What kind of COVID-19 test are you running today?" select "Control", then select either "Positive" or "Negative". Uh-Oh Labs recommends always running the Positive External Control before the Negative External Control.
3. Follow the prompts in the app to scan the Test Kit QR code.
4. Follow the prompts in the app to scan the Instrument QR code to connect to the Instrument.
5. At the sample collection screen, stop and put down the mobile device to begin control assay preparation.
6. Remove the Assay Tube from the pouch. Check that the white bead in the Assay Tube is at the bottom of the cone. If not, see Troubleshooting > Test Components.

   ⚠ Always use a new test kit with each positive and negative control. Always check Assay Tubes before proceeding with a test. A new Assay Tube should not have any liquid inside, only a white bead. If an Assay Tube is found with liquid inside prior to starting a new test, DO NOT OPEN. Discard immediately and use a new Test Kit.

7. Insert the Assay Tube into the instrument. Open the Assay Tube lid.
8. Twist off the Squeeze Vial top and dispense the entire contents of the Squeeze Vial into the Assay Tube by firmly squeezing the Squeeze Vial.
9. Discard the empty Squeeze Vial.

10. Dip the tip of the swab into the External Control liquid. Rotate the swab in the External Control liquid for 10 seconds. Transfer the swab to the Assay Tube.

    ⚠ Always test the Positive control before testing the Negative control to confirm no contamination.

11. Insert the swab into the Assay Tube until the swab touches the bottom.
12. Rotate the swab for 10 seconds to mix. Remove swab.
13. Discard the swab and close the Assay Tube lid. Do not re-open the Assay Tube after this step.
14. Remove the Winged "USED" Sticker from its backing and apply the sticker to the Assay Tube lid by aligning the smallest tab to the tube hinge.
15. Fold all three wings down to seal the lid of the tube. Do not open or remove the tube.
16. Close the instrument.

    ⚠ DO NOT remove the Assay Tube from the instrument during use. DO NOT open the instrument lid during use. The instrument must remain on a stable surface during testing.

17. Return to the Uh-Oh Labs Dx Pro mobile app. Follow the prompts in the app to confirm that the sample is collected and the instrument is closed before proceeding to the next step.
18. After reviewing the test information, select “Submit Test”. Once the test is running the instrument status LED will flash green.

    ⚠ DO NOT unplug or move the instrument once the test is running.

19. When the test is complete the status LED will flash blue while the instrument cools down. For more information on instrument light patterns, see Troubleshooting section below. For more information on result interpretation please see Control Result Interpretation section below.
20. Carefully remove and dispose of the used Assay Tube. See Disposal & Cleaning.

    ⚠ ***NEVER OPEN A USED ASSAY TUBE!***

Control Result Interpretation

- To view results in the Uh-Oh Labs Dx Pro mobile app, navigate to the Test Results tab. Select the desired test. The test result will display the result (Pass or Fail) alongside the interpretation.
- Both controls resulting in a PASS result indicates that the assay works in the hands of the user without introduction of contamination.
- If either control results in a FAIL, do not run patient samples or report patient results until both positive and negative controls pass.
- See Troubleshooting or Contact Technical Support at (877) 846-4522.

RUNNING A PATIENT TEST

Preparing to test

- Use freshly collected specimens for optimal test performance.
- 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), such as laboratory coats or gowns, gloves, masks, and eye protection.
- The provided Nasal Swab must be used with the UOL COVID-19 Test components.
- Before running a test, check that all materials are present, undamaged, and have not expired.
- Ensure that you have downloaded the Uh-Oh Labs Dx Pro mobile app and have also created a new user account (see section "Mobile App Set-up" for instructions).

Step 1: Test setup and preparing the assay tube

1. To begin a patient test, select "Start Test" in the Uh-Oh Labs Dx Pro mobile app.
2. On the screen asking: "What kind of COVID-19 test are you running today?" select "Patient".
3. Follow the prompts in the app to scan the Test Kit QR code.
4. Follow the prompts in the app to scan the Instrument QR code to connect to the Instrument.
5. Fill out patient information.
6. At the Collect Sample screen, stop and put down the mobile device to prepare the Assay Tube.

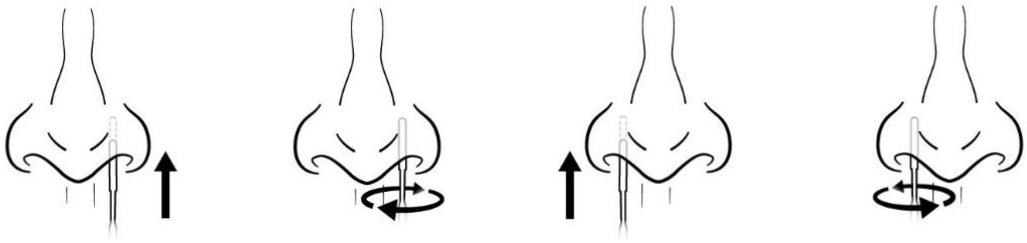
Step 2: Preparing the assay tube

1. Remove the Assay Tube from the foil pouch. Check that the white bead in the Assay Tube is at the bottom of the cone. If not, see Troubleshooting > Test Components.

   ⚠ Always check Assay Tubes before proceeding with a test. A new Assay Tube should not have any liquid inside, only a white bead. If an Assay Tube is found with liquid inside prior to starting a new test, DO NOT OPEN. Discard immediately and use a new Test Kit.

2. Insert the Assay Tube into the instrument. Open the Assay Tube lid.
3. Twist off the Squeeze Vial top and dispense the entire contents of the Squeeze Vial into the Assay Tube by firmly squeezing the Squeeze Vial.
4. Discard the empty Squeeze Vial.
5. Proceed to Specimen collection and handling.

Step 3: Specimen collection and handling



1. Remove the swab from the sterile packaging. Make sure not to open from the swab tip end.

> ⚠ If the swab is dropped or damaged, use a whole new Test Kit to rerun. NEVER touch the tip of the swab to anything other than the inside of a patient's nose.

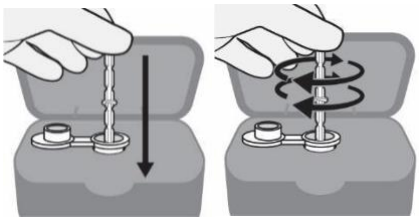
2. Use the same swab to collect a sample from both nostrils.
3. Insert the swab approximately ½ inch into one nostril. Make large circles around the inside of the nose 5 times. Remove. DO NOT just twist the swab; circle the interior of the nose.
4. Insert the same swab into the other nostril approximately ½ inch and repeat making large circles 5 times.

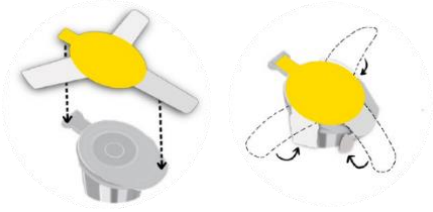
> ⚠ Do not use excessive force when collecting a nasal sample. Avoid collecting extra mucus as this could lead to an invalid result. You may not see any material on the swab after swabbing a nose; this is normal, and the test will function correctly.

5. Proceed to the Running a Test section.

The swab sample should be inserted into the Assay Tube within 5 minutes after collection; this test is not validated to work with samples that have been stored in liquid/transport media.

Step 4: Running a test





1. Insert the swab into the Assay Tube until the swab touches the bottom.
2. Rotate the swab for 10 seconds to mix. Remove the swab.
3. Discard the swab and close the Assay Tube. To avoid contamination, <u>do not</u> re-open the assay tube after this step.
4. Remove the Winged "USED" Sticker from its backing and apply the sticker to the Assay Tube lid by aligning the smallest tab to the tube hinge.
5. Fold all three wings down to seal the lid of the tube. Do not open or remove the tube.
6. Close the instrument.

> ⚠ DO NOT remove the Assay Tube from the instrument during preparation or while running a test. DO NOT open the instrument lid during use. The instrument must remain plugged in and on a stable surface during testing.

Step 5: Continue test in mobile app

1. Return to the Uh-Oh Labs Dx Pro mobile app. Follow the prompts in the app to confirm that the sample has been collected and the instrument is closed before proceeding to the next step.

For best results, keep the iOS device within 15 feet of the instrument during the test for proper Bluetooth connectivity.

2. Confirm the patient information is correct and select "Submit Test". Once the test is running the instrument status LED will flash green.

   ⚠ DO NOT open the instrument lid, unplug, or move the instrument once the test is running; this may result in an invalid or canceled test.

3. When the test is complete, the status LED will change to flashing blue (for more information on instrument light patterns, see Troubleshooting section below). To view results, select the "Test Results" tab (there may be a brief delay after the instrument finishes while data is transferred to the app). To understand the test results, see Results Interpretation section below.

4. Carefully remove and dispose of the used assay tube. See Disposal & Cleaning.

   ⚠ ***NEVER OPEN A USED ASSAY TUBE!***

DISPOSAL & CLEANING

- When testing with the UOL COVID-19 Test is complete, carefully remove and dispose of the used Assay Tube. NEVER open a used Assay Tube.
- Wipe the inside and surface of the reusable instrument with a disinfectant wipe to prepare for the next use. The instrument needs to be cleaned between each sample testing.
- All components of the used test kit may be safely disposed of following your institution's protocol.
- Follow institutional cleaning guidelines, and change gloves in between patient samples and External Controls.
- Consult local guidelines and requirements for proper disposal of the single use test components after use.
- Consult local guidelines and requirements for proper disposal of the Instrument and power adapter at the end of its service life.

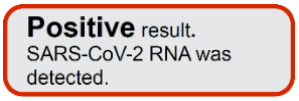
RESULTS INTERPRETATION

To view UOL COVID-19 Test results:

1. Ensure the test is complete (status LED has changed to flashing blue or solid green).

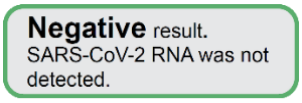
   ⚠ DO NOT open the instrument lid, unplug, or move the instrument until the test is done running; this may result in an invalid or canceled test.

2. Navigate to the Test Results tab.
3. Select the desired test.
4. The patient's test result will be displayed (Positive, Negative, Invalid, or Canceled).



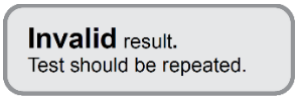
POSITIVE: SARS-CoV-2 RNA was detected.

A Positive result indicates that the virus that causes COVID-19 was detected.
Test results should not be the sole basis for treatment. Results of the COVID-19 test should be interpreted in conjunction with medical history, symptoms, and/or possible exposures.



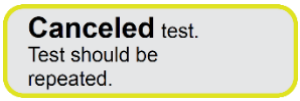
NEGATIVE: SARS-CoV-2 RNA was not detected.

A Negative result indicates that the virus that causes COVID-19 was not found in the patient's sample. Negative results should be considered presumptive and should not be the sole basis for treatment. Results of the COVID-19 test should be interpreted in conjunction with medical history, symptoms, and/or possible exposures.



INVALID: Test should be repeated.

An Invalid result indicates that a sample result could not be generated e.g., because the sample was degraded, or the test did not run properly. See Troubleshooting in the QRG and the IFU before repeating the test.



CANCELED: Test should be repeated.

A Canceled result indicates that the test was not completed and needs to be repeated.

An Invalid or Canceled test may be repeated using a new test kit and a new swab sample. If the repeat test is invalid, please contact technical support at 1-877-846-4522 for further assistance.

LIMITATIONS

- This test has been evaluated for use with human anterior nasal specimens only.
- This test has not been clinically evaluated for all SARS-CoV-2 variant strains.
- This test does not detect other viral, fungal, or bacterial pathogens.
- This test is designed for use with freshly collected swab samples.
- Excessive levels of mucin may inhibit the test and lead to false or invalid results.
- If collecting additional swabs, operators should instruct the patient to blow their nose to remove excess mucus and wait 15 minutes prior to collecting the anterior nasal swab for the UOL COVID-19 Test. Excess mucus production following a swab collection from the upper respiratory tract can lead to invalid results.
- False negative or false positive results may occur if a specimen is improperly collected or handled.
- False negative results may occur if:
    - Inadequate levels of viruses are present in the specimen.
    - The virus mutates in the regions targeted by the test.
    - Inhibitors are present in the sample.
- Operators should wait at least 30 minutes after patient use of Afrin or glucocorticoid nasal spray before collecting a sample, as these substances can result in false negative results.
- Nasal regurgitation of dissolved throat lozenges could interfere with the test. Avoid throat lozenge use just prior to or during sample collection.
- Invalid results may occur if there is blood on the swab. Do not use the swab if blood is visible on the tip.
- The Instrument lid must remain closed for the duration of the test. Opening the Instrument lid during the test may lead to false positive results.
- Performance of the UOL COVID-19 Test has only been established with the provided anterior nasal swab and Test Kit components.
- Performance has not been established in patients without known exposure to SARS-CoV-2 infected individuals or without signs or symptoms of SARS-CoV-2 infection.
- 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 UOL COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers (HCP), the authorized Fact Sheet for Patients, and the authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas. However, to assist clinical laboratories and patient care settings (authorized laboratories[1] using the UOL COVID-19 Test, "your product" in the conditions below), 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@uhohlabs.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

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

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

[1] The letter of authorization refers to, "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests" and "the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

The ability of untrained operators to successfully run the UOL COVID-19 Test was evaluated using prospectively collected samples from three separate and geographically diverse point of care sites in the U.S. that reflected a spectrum of point of care uses. The study was IRB approved and patients were consented according to the protocol. Patients presenting to the 3 point of care settings with signs and/or symptoms of COVID-19 or possible exposure to COVID-19 individuals were tested using the UOL COVID-19 Test. A total of 207 individuals were tested with the UOL COVID-19 Test and the results compared to those generated on a paired NP swab tested with an EUA authorized high-sensitivity RT-PCR assay as the comparator assay. The positive percent agreement (PPA) was 87.7% and the negative percent agreement (NPA) was 100% (Table 1). The significant majority (7/8) of the false negative results were from samples with high Ct values of the comparator (Ct ≥33.4 or not detected) when tested by the comparator assay.

Table 1. UOL COVID-19 Test Clinical Performance

UOL COVID-19 Test	**High-sensitivity FDA authorized RT-PCR assay**		
	Positive	**Negative**	**Total**
Uh-Oh Labs Positive	57	0	57
Uh-Oh Labs Negative	8*	142	150
Total	65	142	207
Positive Percent Agreement (PPA)	87.7% (95% CI = 77.2–94.5%)		
Negative Percent Agreement (NPA)	100% (95% CI = 97.4 to 100%)		
Overall Agreement (OA)	96.1% (95% CI = 92.5 to 98.3%)		

** Six (6) of the 8 discordant results had Cts above the reported mean Ct at the LoD of the comparator test. Three (3) of the 8 discordant results were detected for a single target only on the comparator. Of those, two samples were 'presumptive positive' because the comparator only detected target 2 with Cts of 39.4 and 35.6 (both below the mean Ct at the comparator LoD) respectively.*

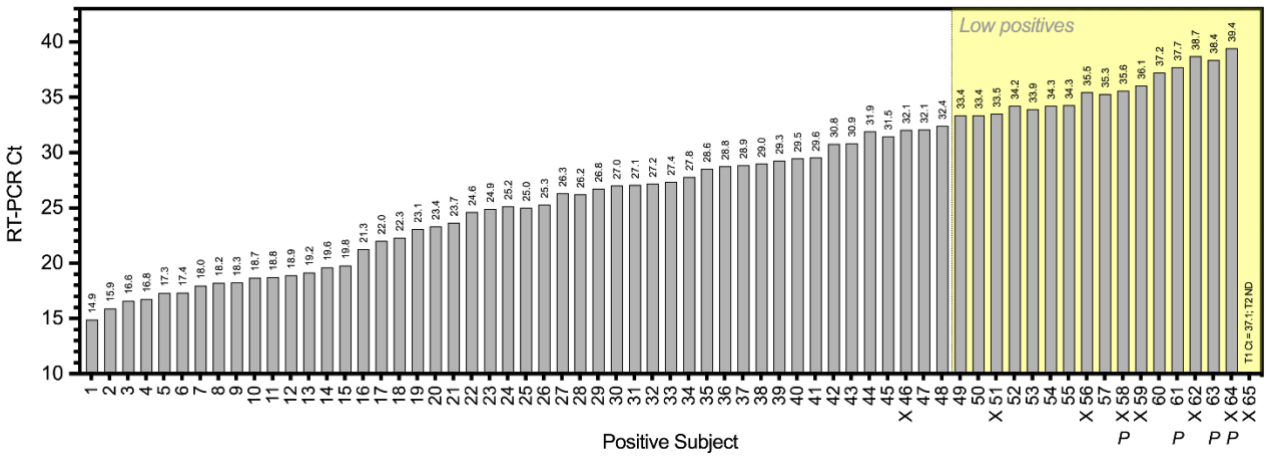


Figure 1. The UOL COVID-19 Test detected 97.9% of SARS-CoV-2 positive samples, excluding those with very low levels of virus. This graph shows the measured Ct values for Target 2 by the EUA authorized high-sensitivity RT-PCR comparator for each evaluable subject in the clinical study. The Ct values are written above each bar. UOL COVID-19 Test false negatives are marked with an X below the subject number, and comparator presumptive positives are marked with a P. The yellow shaded area denotes the range at which samples are considered low positives (Ct ≥ 33.4).

Analytical Sensitivity (Limit of Detection, LoD) - Heat Inactivated SARS-CoV-2 Virus

The LoD studies establish the lowest SARS-CoV-2 viral concentration (copies per swab) in a specimen that can be detected by the UOL COVID-19 Test at least 95% of the time. The preliminary LoD was determined by testing six input concentrations (1600, 800, 400, 200, 100 and 50 copies per swab) of heat-inactivated SARS-CoV-2 virus spiked into negative anterior nares swab samples in rehydration buffer. The preliminary LoD estimate of 400 copies per swab was confirmed by testing 20 additional samples (Table 2). The initial LoD of 400 copies per swab was used in the clinical study.

Table 2. Initial LoD Study results used in clinical study.

Genome copies/swab	SARS-CoV-2 detected/tested	% Detected
1600	3/3	100%
800	3/3	100%
400 (preliminary)	3/3	100%
400 (confirmation)	**20/20**	**100%**
200	5/6	83%
100	5/6	83%
50	1/3	33%

The LoD was reestablished after the Squeeze Vial rehydration buffer was updated. The preliminary LoD was determined by testing six input concentrations (3200,1600, 800, 400, 200, and 100 copies per swab) of heat-inactivated SARS-CoV-2 virus spiked into negative anterior nares swab samples in rehydration buffer. The preliminary LoD estimate of 800 copies per swab was confirmed by testing 20 additional samples (Table 3).

Table 3. Updated LoD Study results, established using reformulated Squeeze Vial rehydration buffer.

Genome copies/swab	SARS-CoV-2 detected/tested	% Detected
3200	3/3	100%
1600	3/3	100%
800 (preliminary)	3/3	100%
800 (confirmation)	**20/20**	**100%**
400	2/3	66.6%
200	3/3	100%
100	1/3	33%

Analytical Reactivity (Inclusivity)

All published SARS-CoV-2 sequences from GISAID databases were queried on December 13, 2021, using the ROSALIND® DxM platform to look for any sequence mismatches between primers and available SARS-CoV-2 sequence data (5,266,757 sequences). Of 34 noted mismatches, none are expected to cause a loss in the ability to detect SARS-CoV-2. All the sequence mismatches have either a low severity score, which correlates to the risk that the mutation could affect the diagnostic assay, or a very low percent prevalence. The mutation with the highest expected severity had a 0.09% prevalence among current sequences. The mutation with the highest prevalence (0.85% for all time) was not expected to impact diagnostic sensitivity.

Analytical Specificity (Cross Reactivity)

Uh-Oh Labs performed a nucleotide BLAST (NCBI) search for homology between the SARS-CoV-2 primers and the genetic sequences of the organisms listed in Table 4, as recommended by the FDA for upper respiratory samples. The Taxonomy ID (taxid) numbers used for organisms are provided in Table 4. SARS-CoV-2 (taxid:2697049) was explicitly excluded from the BLAST search to identify off-target homology.

Table 4. In silico cross reactivity.

Organism	**Taxonomy ID(s)**	**SARS-CoV-2 primer set contiguous homology ≥80%**
Human coronavirus 229E	11137	None
Human coronavirus OC43	31631	None
Human coronavirus HKU1	290028	None
Human coronavirus NL63	277944	None
SARS-coronavirus	694009	None
MERS-coronavirus	1335626	None
Adenovirus (C1 Ad. 71)	1643649	None
Human Metapneumovirus (hMPV)	162145	None
Parainfluenza virus 1	188538, 11210, 31605	None
Parainfluenza virus 2	11214, 11213	None
Parainfluenza virus 4a	11224, 11225	None
Parainfluenza virus 4b	11226, 11227	None
Influenza A	11320	None
Influenza B	11520	None
Enterovirus (general and D68)	12059, 42789	None
Respiratory syncytial virus	12814, 208893, 208895	None
Rhinovirus	12059	None
Chlamydia pneumoniae	83558	None
Haemophilus influenzae	727	*F3 = 88.9% noncontiguous*
Legionella pneumophila	446	None
Mycobacterium tuberculosis	1773	None
Streptococcus pneumoniae	1313	None
Streptococcus pyogenes	1314	None

Organism	Taxonomy ID(s)	SARS-CoV-2 primer set contiguous homology ≥80%
Bordetella pertussis	520	None
Mycoplasma pneumoniae	2104	None
Pneumocystis jirovecii (PJP)	42068	None
Candida albicans	5476	None
Pseudomonas aeruginosa	287	F3 = 83%
Staphylococcus epidermidis	1282	None
Streptococcus salivarius	1304	F3 = 83%

Wet testing was performed on three (3) high priority organisms likely to be present in a respiratory sample and which had 80% or greater homology to one (1) of the SARS-CoV-2 primers (Table 5). *H. influenzae* was also included in wet testing due to high noncontiguous homology (88.9%) and a T_m within 10°C of the reaction temperature.

Table 5. Results of cross-reactivity wet testing for high priority organisms with > 80% contiguous homology to any primer, and for pooled human nasal wash.

Organism Tested	Concentration (CFU/ml)	# pos / # valid tests	Cross-reactive
S. salivarius	$3x10^6$	0/3	No
P. aeruginosa	$3x10^6$	0/3	No
H. influenzae	$3x10^6$	0/3	No
Pooled human nasal wash (representing diverse microbial flora in the upper respiratory tract)	10% v/v	0/5	No

A pooled 1:1:1 mix of the three organisms with >80% homology was added to the assay at a final concentration of $3x10^6$ cfu/mL each in negative nasal matrix with a dilution of heat-inactivated SARS-CoV-2 spiked in at 3x LoD to determine any interference with the detection of SARS-CoV-2. No interference was observed (Table 6).

Table 6. Results of microbial interference wet testing for high priority organisms with > 80% contiguous homology to any primer.

Condition tested (CFU/mL)	**# pos / # valid tests**	**Interference**
Pooled 1:1:1 H. influenzae($3x10^6$), *S. salivarius* ($3x10^6$), *P. aeruginosa* ($3x10^6$) and 3x LoD SARS-CoV-2	5/5	No
Pooled 1:1:1 H. influenzae($3x10^6$), *S. salivarius* ($3x10^6$), *P. aeruginosa* ($3x10^6$), no virus control	0/5	No

Interfering Substances

Potentially interfering substances that might be present in upper respiratory samples were tested to evaluate potential cross-reactivity or interference with the detection of SARS-CoV-2 in the UOL COVID-19 Test.

Eleven (11) common interfering substances were tested in pooled negative nasal matrix. Either saline or 2x LoD heat-inactivated SARS-CoV-2 was spiked onto the swab prior to testing in the UOL COVID-19 Test (Table 7). One false negative result (out of three replicates) occurred with throat lozenges. Throat lozenge material is unlikely to be found in the anterior nares. Whole blood at a concentration of 5% v/v resulted in invalid tests. During the clinical evaluation there were no reports of Yukon swabs causing nosebleeds. The concentrations tested for Afrin and glucocorticoid nasal spray (at 15% v/v and 5% v/v respectively) were above clinically achievable concentrations. If used at concentrations stated on the medication instructions, there was no interference observed.

Table 7. Potential Endogenous Interference Substances for Nasal Swabs.

Substance	Concentration tested	No SARS-C0V-2, (Negative/Total)= % Agreement)	2x LoD, (Positive/Total)= % Agreement	Interfering substance? (Y/N)
Mucin	2.5 mg/mL	0/3	3/3	No
Blood (whole)	5% v/v	0/0*	0/0*	Yes*
Blood (whole)	0.6125% v/v	0/3	3/3	No
Afrin	15% v/v	0/3	0/3	Yes
Afrin	Used according to instructions	0/3	3/3	No
NeilMed Nasal Gel	1.25% v/v	0/3	3/3	No
Zinc (Zicam nasal spray)	1.25% v/v	0/3	3/3	No
Glucocorticoid nasal spray	5% v/v	0/3	0/3	Yes
Glucocorticoid nasal spray	Used according to instructions	0/3	3/3	No
Sore throat lozenge	5 mg/mL	0/3	2/3**	Yes
Zanamivir	3.3 mg/mL	0/3	3/3	No
Tamiflu (Oseltamivir Phosphate)	2.2 µg/mL	0/3	3/3	No
Mupirocin	5 mg/mL	0/3	3/3	No
Tobramycin	4 µg/mL	0/3	3/3	No
No Substance	N/A	0/3	3/3	N/A

* Resulted in invalid tests

**One test resulted in a negative result

Carryover Contamination

A carryover contamination study was conducted to determine the risk of amplicon contamination during use of the UOL COVID-19 Test. The experiment was designed to mimic a worst-case scenario, outlined in Table 8, where 5 instruments are set up in close proximity and running alternating high SARS-CoV-2 positive samples (containing 10^6 cp/mL) and SARS-CoV-2 negative samples for a total of 20 tests. No carryover contamination was observed.

Table 8. Results of carry-over contamination testing

	Instrument 1	**Instrument 2**	**Instrument 3**	**Instrument 4**	**Instrument 5**
Run 1	NEG	POS	NEG	POS	NEG
Run 2	POS	NEG	POS	NEG	POS
Run 3	NEG	POS	NEG	POS	NEG
Run 4	POS	NEG	POS	NEG	POS
Results	Pass (4/4)	Pass (4/4)	Pass (4/4)	Pass (4/4)	Pass (4/4)

TROUBLESHOOTING

Bluetooth Connection Lost

- If the Mobile Device is farther than 15 feet away from the instrument, Bluetooth connectivity could fail. The test will still run in the instrument, but you may not receive real-time test status in the app. Return the Mobile Device to within 15 feet of the instrument to receive updated results (there may be a slight delay). If the LED is flashing yellow, make sure the instrument lid is fully closed.
- Bluetooth settings can be changed in the Settings menu of your Mobile Device.
- If Bluetooth updates are delayed, try closing the app by double clicking on the home button and swiping the app up. Afterwards, reselect the app icon on the home screen to open it again.

Test Kit Components

- If the white bead is at the lid of the Assay Tube, return the bead to the bottom cone by holding the tube upright (lid at the top) and gently tapping the Assay Tube onto a tabletop.
- If the Squeeze Vial is not fully emptied, the test may not run properly. Do Not add liquid from more than one Squeeze Vial.
- If the Nasal Swab touches anything other than the inside of a patient's nose (or Control Sample, if running external controls), discard the swab immediately and use a new swab and a new kit.
- Do not place an opened swab onto any surface before testing a patient or controls. If an opened swab is set down, discard the swab immediately and use a new one.

Understanding Instrument Status LED

- If the Instrument LED light is not on, make sure the Instrument is plugged into power.
- If the LED is flashing yellow, make sure the instrument lid is fully closed.
- If the LED is flashing blue, the instrument is cooling down. Unplugging it will not make it cool faster, please wait for it to be solid green before further use or storage. If the instrument is taking a long time to cool down, check the ambient temperature. Operating conditions are 2°C–30°C.
- If the LED light flashes red at any point, contact Technical Support at support@uhohlabs.com or 1-877-846-4522.

Mobile App

- If you have trouble logging into your account, reset your password from the app login screen
- If you receive an error message at any point, follow prompts on the screen or contact Technical Support at support@uhohlabs.com or 1-877-846-4522.

TECHNICAL SPECIFICATIONS

UOL COVID-19 Instrument

Part number	UOL002
Product description	UOL COVID-19 Instrument
Sample capacity (wells)	1 well per instrument
Reaction volume	150 microliters
Excitation source	Blue and green LEDs
Detection channels	FAM, HEX
Multiplexing	2 channels
Thermal element	Resistive cartridge heater
Temperature accuracy	+/- 1°C, maximum +/- 2.5°C
Custom dye/chemistry	Loop-de-Loop™ RT-LAMP
Connectivity	Bluetooth
Power Supply Input	100–240V AC 50/60Hz
Power Supply Output	5VDC, 2A, USB-C
Operating and storage conditions	Temperature: +2°C to +30°C Relative humidity: < 95% RH non-condensing Atmospheric pressure: 70 kPa to 106 kPa
Other environmental requirements	Keep out of direct sunlight, keep dry (regular cleaning per IFU is OK), use upright
Transit conditions	Temperature: -18°C to +60°C Relative humidity: < 90% RH Atmospheric pressure: 59 kPa to 106 kPa
Protection against electric shock	Class II
Dimensions	60 mm x 100 mm x 65 mm
Weight	106 grams

UOL COVID-19 Test Kit

Operating and storage conditions	Temperature: +2°C to +30°C Relative humidity: < 95% RH non-condensing Atmospheric pressure: 70 kPa to 106 kPa
Transit conditions	Temperature: -18°C to +60°C Relative humidity: < 90% RH Atmospheric pressure: 59 kPa to 106 kPa

SYMBOLS

	Consult instructions for use		Storage temperature		Keep dry
	Manufacturer	LOT	Lot number	Rx Only	Prescription Only
IVD	In Vitro Diagnostic	REF	Catalog number		Keep away from sunlight
	Use by	STERILE	Sterile		Do not use if package is damaged
	Do not re-use		Caution		

TECHNICAL ASSISTANCE/CUSTOMER SUPPORT

If you have questions or concerns about this test, contact Uh-Oh Labs Technical Support at support@uhohlabs.com or call 1-877-UHOHLAB (877-846-4522) Monday–Friday 8am–5pm US Pacific Time.

To purchase UOL COVID-19 External Controls, contact Uh-Oh Labs Technical Support at support@uhohlabs.com or call 1-877-UHOHLAB (877-846-4522).

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