UOL COVID-19 TEST | QUICK REFERENCE GUIDE

For Emergency Use Authorization (EUA) Only

Uh-Oh LABS

-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.

-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.

- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.

-This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

List of Required Materials

Storage and testing conditions 2°C–30°C.

| Instrument (Reusable) | Power Adapter (Reusable) | Test Kit Bag (contains consumables) | Sterile Nasal Swab | Foil Pouch | Assay Tube with dried reagent (inside Foil Pouch) | Squeeze Vial with Rehydration Buffer Solution* | Winged "USED" Sticker |

NOTE: Instrument and Test Kits are packaged separately.

Not pictured: Quick Reference Guide (QRG) provided.

Required Materials Not Provided: Uh-Oh Labs Dx Pro mobile app, Internet connected Apple mobile device (iPad, iPhone, or iPod Touch) running iOS 14 or higher, gloves, a disinfectant wipe, and Instructions For Use (IFU).

*Do not ingest; avoid contact with skin and eyes; if contact with body occurs, rinse with water; if irritation persists, seek medical advice.

Preparing to test

Before You Begin

1. Wash your hands.

2. Prior to testing and between each sample, wipe the testing area with a CDC approved wipe (such as Sani-Cloth® cleaning wipes) or 10% bleach solution.

3. Wear Personal Protective Equipment (PPE) in accordance with CDC guidelines, and change gloves between patients.

4. Before running a test, check that all materials are present, undamaged, and not expired.

> **! IMPORTANT**
> Read all instructions provided in this Quick Reference Guide and the Instructions for Use.
>
> Read the complete test procedure before you begin. Do not open the foil pouch or nasal swab packaging until instructed to do so.
>
> Running External Controls? See Quick Reference Guide for External Controls (page 5).

Mobile App Account Set-Up

1. Download the Uh-Oh Labs Dx Pro mobile app, from the Apple App Store, on an Apple mobile device running the operating system iOS 14 or higher. WiFi or cellular data connectivity is required to download the app.

2. Open the app and follow the prompts to create a new user account. Continue to page 2 for instructions on the System Set-up.

Download on the App Store

Create account

**TECHNICAL SUPPORT | ** Contact us for more information at support@uhohlabs.com | 1-877-UHOHLAB (846-4522) | www.uhohlabs.com

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STEP 1 System Set-Up

NOTE: If you are a new user, run the Positive and Negative Controls first. See page 5 for External Controls.

Start Test

1a Set the Instrument on a clean, flat surface away from direct sunlight. Connect to power. No further calibration is required.

! NOTE: Instrument must remain plugged in for the duration of the test. Keep out of direct sunlight.

1b Enable Bluetooth 📶 on your iOS device via your Settings ⚙ . In the Uh-Oh Labs Dx Pro mobile app, go to the home screen and select "Start Test." Follow the prompts to scan the test kit QR code, scan the instrument QR code, and enter patient info.

1c After entering patient info, on the "Collect Sample" screen, set aside the mobile device. Pick up your Test Kit to prepare a patient sample. Continue to Step 2.
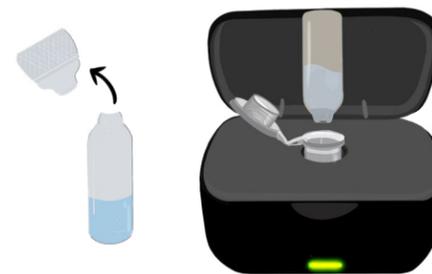
STEP 2 Prepare the Assay Tube

2a Remove the Assay Tube from the pouch. Make sure the white dried reagent bead is at the bottom of the tube.
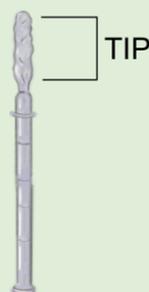
2b Place the Assay Tube in the Instrument. Open the Assay Tube lid.

2c Twist off the Squeeze Vial top. Dispense all of the liquid into the Assay Tube by firmly squeezing the Squeeze Vial. Discard the empty Squeeze Vial.
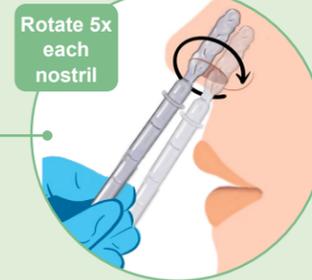
STEP 3 Swab Nose

TIP

Rotate 5x each nostril

3a Remove Nasal Swab from sterile packaging.

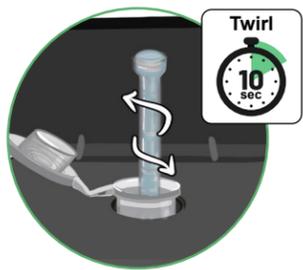**! NOTE: DO NOT** touch the tip with your hand or to any surface.

3b Insert swab about 1/2 inch into a nostril. Make BIG CIRCLES inside the nostril 5 times.

3c Repeat Step 3b in the opposite nostril with the same swab. Swab both nostrils.

! NOTE: Move directly to the next step within 5 minutes of sample collection.

Twirl 10 sec

4a Insert the tip of the swab into the Assay Tube until the swab tip touches the bottom. Twirl the swab for 10 seconds to mix. Remove the swab. Discard the swab, and close the Assay Tube firmly.
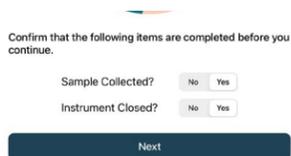
4b Remove the Winged "USED" Sticker from its backing. Apply the sticker to the Assay Tube lid by aligning the smallest tab to the tube hinge. Fold all three wings down to seal the lid of the tube. Do not open or remove the tube.

4c Shut the lid of the Instrument. Return to the mobile device and indicate that you have collected your sample and closed the instrument. Proceed with Step 5.

STEP 5 Continue Test in Mobile App

Confirm that the following items are completed before you continue.

Sample Collected? No Yes
Instrument Closed? No Yes

Next

Approximate Run Time 40 min

5a Tap the "Next" button that appears at the bottom of the screen. Confirm the patient information is correct and select "Submit Test." Once the test is running, the instrument's status LED will flash green. The mobile device must stay near the instrument during the test.

5b When the status LED flashes blue or returns to solid green, carefully remove the Used Assay Tube and discard. Test run time is 40 minutes or less.

❗ NOTE: NEVER OPEN A USED ASSAY TUBE. Do not open, unplug, or move the instrument once the test is running.

5c In the mobile app, view results by navigating to the "Test Results" page from the menu bar and select the desired test you wish to view.

Understanding the Test Result

Positive result. 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 result. 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 result. 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. Test should be repeated.

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

3

After the Test

Disposal & Cleaning

1 When the test is complete, carefully remove and dispose of the Used Assay Tube. NEVER OPEN a Used Assay Tube. All components of a used test kit (swab, assay tube, squeeze vial, foil pouch, test kit bag) can be safely disposed of per your institution's protocol.

2 Wipe the inside of the reusable Instrument with a disinfectant wipe prior to the next use.

3 Change gloves before processing a new sample.

Warnings and Precautions

Test Kit

• If the Squeeze Vial is not fully emptied into the Assay Tube, the test may not run properly. Do not add liquid from more than one Squeeze Vial.

• To prevent contamination, do not set an opened swab on any surface before testing a patient or controls. If an opened swab is set down, discard the swab immediately and use a new one.

• If any opened kit component spills, discard the entire kit and use a new one.

• Use a new test kit if components are missing, damaged, or expired. Do not pull individual items from another kit.

• Invalid results may occur if there is blood in the sample.

• Operators should wait at least 30 minutes after patient Afrin or glucocorticoid nasal spray use before collecting a sample, as these substances can result in false negative results.

• If collecting additional swabs, operators should instruct the patient to blow their nose and wait 15 minutes prior to collecting the anterior nasal swab for the UOL COVID-19 Test.

• Never re-use or open a used assay tube. 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.

Instrument

• If the Instrument's LED light is not on, make sure the Instrument is plugged into power. The instrument must be plugged into a power source at all times during use. Unplugging the instrument before results have been completed will cause a "Canceled" test result.

• The Instrument lid must stay closed while a test is running. A flashing yellow light on the instrument alerts the user that the lid is open during the test.

• Keep out of direct sunlight. Sunlight can increase the temperature of the instrument beyond the recommended operating range.

Mobile App

• Creating an account only occurs once for first time app users. If you experience login issues, reset your password or contact Technical Support.

System

• Test Kits are to be used with the UOL COVID-19 Instrument and the Uh-Oh Labs Dx Pro mobile app only.

• Ensure the Mobile App is up to date with the latest stable release.

• Ensure your iOS device operating system software is kept up to date.

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 results in the app. Return the mobile device within 15 feet of the Instrument to receive updated results. Bluetooth/WiFi settings can be changed in your mobile device's settings.

Mobile App

• If you have trouble logging into your account, reset your password from the mobile app login screen.

• If you receive an error message at any point, follow instructions on the screen or contact Technical Support at support@uhohlabs.com or call 1-877-846-4522.

Technical Support Hours of Operation
Uh-Oh's trained technical staff are available Monday through Friday, 8am-5pm US Pacific Time at 1-877-UHOHLAB (845-4522), or by e-mail 7 days a week at support@uhohlabs.com.

Instrument status LED key

SOLID GREEN	FLASHING GREEN	FLASHING BLUE	FLASHING YELLOW	FLASHING RED
Instrument is Ready For Use	Instrument is in Use/ Running a Test	Instrument is Cooling Down *Wait until Solid Green*	Instrument Lid Open During Use *Keep lid closed during the test*	Instrument Error *Contact Uh-Oh Labs for Technical Support*