DLO is now testing Coronavirus (COVID-19)

Healthcare Provider Information

This document contains important information regarding COVID-19. Please read it in its entirety.

On January 30, 2020 the World Health Organization declared the COVID-19 outbreak a public health emergency of international concern.

Diagnostic Laboratory of Oklahoma (DLO) and Quest Diagnostics are monitoring the situation closely and are committed to helping you provide the best care for your patients. Our priority is the health and safety of our employees, patients, and the communities we serve. We encourage healthcare providers to periodically check QuestDiagnostics.com/COVID19/HCP for updates on our joint response to the outbreak.

Important information for our clients:

- The DLO/Quest Diagnostics SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test is now available nationally. Please be sure to check our website regularly for any COVID-19-related updates.

- The new test aids the confirmatory detection of nucleic acid in respiratory specimens of patients meeting the CDC's clinical criteria for COVID-19 testing.

- Patients should be prioritized for testing of COVID-19 if they meet the CDC criteria, including those who may have been exposed to the virus or had contact with someone confirmed to have COVID-19, who show signs and symptoms (e.g., fever, cough, difficulty breathing), or who live in or recently traveled to a place where transmission of COVID-19 is prevalent.

- DLO Patient Service Centers and DLO’s in-office phlebotomists do not collect respiratory specimens, including those from patients suspected of having COVID-19. COVID-19 specimens can ONLY be collected in physician offices and hospitals.

- The test has not been FDA cleared or approved or authorized. The test has been validated according to CLIA, but FDA’s independent review of this validation is pending.

For additional information on DLO’s COVID-19 testing, please visit QuestDiagnostics.com/COVID19/HCP
What to know about DLO’s COVID-19 testing

What is COVID-19?
COVID-19 is the name for the respiratory syndrome caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

What is the test name and test code?
The test name in the Quest Test Directory is SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR and the test code is 39433.

What is Quest’s test for COVID-19?
The SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test is a qualitative molecular assay, which amplifies the RNA of the SARS-CoV-2 virus in human specimens such as nasopharyngeal or throat swabs (upper respiratory). Alternative specimens, including bronchial lavage/wash, nasopharyngeal aspirate/wash, or sputum/tracheal aspirate are also acceptable. The technique is a real-time reverse transcription PCR assay.

How do I order the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test?
Physicians may order the test using test code 39433. The test must be ordered on a separate requisition from other tests.

What facilities can collect specimens?
Specimens are to be collected by hospitals, physician offices, and clinics. DLO Patient Service Centers and DLO’s in-office phlebotomists do not collect respiratory specimens, including those from patients suspected of having COVID-19.

What type of specimen is collected?
Currently, nasopharyngeal (NP) or oropharyngeal (OP) swab testing is being performed. Lower respiratory specimen tests, including bronchial lavage/wash, nasopharyngeal aspirate/wash, or sputum/tracheal aspirate samples can also be ordered but will be frozen upon receipt, with testing initiating on 3/16/2020. One SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test will be performed per swab.

Can I put multiple specimen vials in one bag?
No. Each specimen vial must be transported in its own sealed bag.

What type of swab should be utilized to collect the upper respiratory sample?
Upper respiratory samples should be collected using 1 nasopharyngeal swab and/or oropharyngeal swab in M4, VCM or UTM media. Nasopharyngeal and/or oropharyngeal swabs can now be collected and transported in their own vial or combined in a single vial for testing. Each vial collected should be ordered on a separate requisition and transported in its own sealed bag. Only sterile Dacron® or Rayon swabs should be used. Do not use calcium alginate as they may contain substances that inhibit PCR testing. Wooden shaft swabs, Eswabs, and swabs transported in Amies liquid or gel transport must not be used.

How do I order appropriate supplies for COVID-19 testing?
Please follow your standard process for ordering DLO supplies.

What is the specimen stability?
Specimens have a 72-hour stability refrigerated.

Are there any special storage or transport procedures for COVID-19 specimens?
Samples should be shipped frozen (preferred). However, samples can be shipped refrigerated at 2 °C–8 °C and are stable at this temperature for 72 hours. Cold packs/pouches must be used if placing specimens in a lockbox for courier pick-up. Specimens should be shipped overnight to your local DLO accessioning laboratory according to standard operating procedures. SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR test is not a STAT test and STAT pick-up cannot be ordered.

What is expected turnaround time?
Test results are typically available 3-4 days from the time of specimen pick-up and may be impacted by high demand.

How do I get my results?
Providers will receive a phone call if the test result is positive or inconclusive. Patients will be notified through MyQuest™ if they signed up for it.

For additional information on DLO’s COVID-19 testing, please visit QuestDiagnostics.com/COVID19/HCP
For questions, contact your DLO representative or call 1.800.891-2917.
SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR

Test Code
39433

CPT Code(s)
87635

Clinical Significance
The SARS-CoV-2 RNA, Real-time RT-PCR test is a qualitative multi-target molecular diagnostic test that aids in the diagnosis of COVID-19. This test is intended to be performed on respiratory specimens collected from individuals who meet Centers for Disease Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing. CDC COVID-19 criteria for testing on human specimens are available at the CDC's webpage Information for Healthcare Professionals: Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html).

A Detected result is considered a positive test result for COVID-19. This result indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and that the patient is considered infected with the virus and presumed to be contagious. If requested by public health authorities, specimens will be sent for additional testing.

An Inconclusive result means not all of the testing targets were detected; additional sample collection may be considered. A Not Detected (negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. A negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions.

Methodology
Real-Time Reverse Transcriptase Polymerase Chain Reaction

Assay Category
This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. This test is pending the Food and Drug Administration's Emergency Use Authorization.

Reference Range(s)
Not detected

Alternative Name(s)
SARS, Novel Coronavirus, nCOV, COVID-19, COVID, Wuhan, Coronavirus
Preferred Specimen(s)
One (1) Nasopharyngeal and/or Oropharyngeal swab collected in a multi microbe media (M4), VCM medium (green-cap) tube or equivalent (UTM)

Please note that testing of below Acceptable lower respiratory specimen types will begin 3/16/2020. Acceptable specimens received prior to 3/16/2020 will be stored frozen and tested as first in first out.

Acceptable: 0.85 mL (0.35 mL minimum) bronchial lavage/wash, tracheal aspirate, or sputum sample collected in a plastic, sterile, leakproof container

Minimum Volume
1 swab • 0.35 mL

Collection Instructions
Read the Healthcare Provider Fact Sheet:

Order SARS-CoV-2 RNA, RT PCR separately from other tests - on a separate requisition and place each transport tube with paperwork into its own sealed bag. The SARS-CoV-2 test will be prioritized if submitted on a shared requisition. One specimen transport tube will be tested per order.

It is acceptable to place both an NP and an OP swab at the time of collection into a shared media transport tube. Do not combine other specimen sources.

IMPORTANT: Samples from client sites without access to dry ice should be refrigerated (2-8 degrees C) for Logistics pick up.

Shipping and storage: -70° C is acceptable

Transport Container
Swab

Transport Temperature
Refrigerated (cold packs)

Specimen Stability
Room temperature: Unacceptable
Refrigerated: 72 hours
Frozen -70° C: See Collection Instructions

Reject Criteria
Calcium alginate swabs; cotton swabs with wooden shaft; received refrigerated more than 72 hours after collection; Eswab; swabs in Amies liquid or gel transport

Setup Schedule
Setup Days: Sunday-Saturday

Performing Laboratory
Quest Diagnostics Infectious Disease, Inc., San Juan Capistrano, CA

Quest Diagnostics Test Directory Link
https://testdirectory.questdiagnostics.com/test/home
Nasopharyngeal Specimen Collection

1. Open the individual collection package that contains the swab and transplant medium.

2. Collect the specimen.

3. Hold the swab in your hand, dispose of your thumb and forefinger in the middle of the swab shaft, and carefully remove the cap from the tube. Rotate the swab several times.

4. Gently insert the swab into the nostril. Insert the swab tip 1/2 downward into the posterior nasopharynx.

5. Keep the swab near the septum. Slight pressure on the nose while gently pushing the swab near the septum. Keep the swab near the septum. Slight pressure on the nose while gently pushing.

6. As visual reference, the swab should be inserted about 1.3cm (0.5 inches) from the tip of the swab. Take care not to touch.

7. Remove the swab, being careful not to touch the top of the wrapper open the top of the wrapper, open the collection swab wrapper by peeling.

8. The test has not been FDA cleared or approved, at authorized. The test has been validated according to CLIA.

COVID-19 Testing with SARS-COV-2 RT-PCR Qualitative Real-Time RT-PCR