DIAGNOSTIC LABORATORY OF OKLAHOMA

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, DLO's joint venture partner, 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:

- **DLO and Quest Diagnostics is receiving COVID-19 specimens and tests are being performed nationally.**
- To meet the growing demand of our healthcare providers and patients, Quest Diagnostics has rapidly expanded testing capacity with the addition of both the Roche Diagnostics high-throughput test and the Quest Diagnostics lab-developed test (LDT) running simultaneously in many of our laboratories across the country.
- The Roche test (test code 39444) is now the preferred test for upper respiratory specimens due to its high throughput capacity.
- For other specimen types, including bronchial lavage/wash (BAL), nasopharyngeal aspirate/wash, tracheal aspirate, or sputum, customers must order the Quest Diagnostics LDT (test code 39433).
- Both tests can utilize the nasopharyngeal (preferred) and/or oropharyngeal specimen types.
- **DLO patient service centers are not accepting patients with suspected or confirmed COVID-19 and are not collecting specimens for COVID-19 testing.** The personnel at these centers are trained in collecting a range of specimens, including blood and urine, for various medical health conditions, but not respiratory specimens for COVID-19 or other respiratory illnesses such as influenza. DLO is accepting and performing testing on COVID-19 specimens submitted by healthcare providers in Oklahoma.

For more details on DLO's COVID-19 testing, please visit **QuestDiagnostics.com/COVID19/HCP**.

Additional information ▶

DIAGNOSTIC LABORATORY OF OKLAHOMA

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?
There are two options for testing. The first is SARS Coronavirus CoV-2 RNA, Qualitative Real-Time RT-PCR (Roche) and the test code is 39444 (preferred). The second is SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Quest LDT) and the test code is 39433. Both can be found in the Quest Test Directory.

How do I order the COVID-19 test?

- Physicians may order the test using the appropriate test code. The test must be ordered on a separate requisition from other tests.
- With the Roche test now available broadly, customers should be ordering the Roche test when submitting upper respiratory specimens. The Roche platform provides high-throughput automation, which will enable us to provide more testing capacity.
- For lower respiratory specimens, including bronchial lavage/wash (BAL), nasopharyngeal aspirate/wash, tracheal aspirate, or sputum, customers must order the LDT (test code 39433) for those specimen types.

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.

Is saline an acceptable transport media?
Saline has been indicated by the FDA as an acceptable transport media that can be used in situations where commercial viral transport media is unavailable for molecular RT-PCR SARS-CoV-2 assays (such as those in use for the Quest LDT and Roche tests). For saline, a sterile glass or plastic vial containing between 1 mL and 3 mL of phosphate buffered saline is appropriate. The FDA believes that sample collection with a flocked swab is preferred. When options are limited, collection by a foam swab or spun synthetic swab is also acceptable but may not be sufficient to rule out infection. Collection should be conducted with a sterile swab.[1]

Where can I find sample collection guidelines?
Please visit QuestDiagnostics.com/COVID19/HCP regularly for specimen collection resources.

How do I order appropriate supplies for COVID-19 testing?
We are still accepting orders for COVID-19 testing. As a reminder, DLO and Quest do not manufacture the collection supplies used in testing. Due to extraordinary demand, we are temporarily unable to accept orders for upper respiratory specimen collection and transport supplies online. Please call your local order entry team for more information. You do not have to use supplies from DLO or Quest to send us testing. Please refer to the Quest Diagnostics Test Directory at TestDirectory.QuestDiagnostics.com for a list of acceptable specimen collection and transport supplies for COVID-19 testing.

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***. Current turnaround time can be found at QuestDiagnostics.com/COVID19/HCP.

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.

The Quest Diagnostics and Roche tests have not been FDA cleared or approved; these tests have been authorized by the FDA under an EUA for use by authorized laboratories. These tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and these tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked.

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**.

1. US Food and Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. FDA website. Updated March 21, 2020. Accessed March 23, 2020. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#troubleobtainingviraltransport

SARS Coronavirus CoV-2 RNA, Qualitative Real-Time RT-PCR (Roche)

Test Code
39444 (preferred test)

CPT Code(s)
87635 (HCPCS: U0002)
Please be aware that depending on operational capacity, and in order to process and result your test request for SARS-CoV-2 RNA as quickly as possible, it may be necessary to change your original test order to another FDA/EUA assay. Be aware that this change will not affect pricing.

Clinical Significance
SARS Coronavirus with CoV-2 RNA, Qualitative Real-Time RT-PCR - The SARS Coronavirus with CoV-2 RNA, Qualitative Real-Time RT-PCR test is a qualitative multi-target molecular diagnostic test that aids in the detection of COVID-19. This test is intended to be performed on respiratory specimens collected from individuals who meet the Centers for Diseases Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing. For details visit https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html.

Result Interpretation:
- A Detected result is considered a positive test result for COVID-19. This indicates that RNA from SARS-CoV-2 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.
- 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. However, it does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

Test results are typically available 3-4 days from the time of specimen pickup, and may be impacted by high demand.

Methodology
Real-Time Reverse Transcriptase Polymerase Chain Reaction

Assay Category
This test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.

Reference Range(s)

Overall Result	Not detected
SARS-CoV-2 RNA	Negative
Pan-SARS RNA	Negative

Alternative Name(s)
SARS, Novel Coronavirus, nCOV, COVID-19, COVID, Wuhan, Coronavirus

DIAGNOSTIC LABORATORY OF OKLAHOMA

Preferred Specimen(s)
One (1) nasopharyngeal swab collected in a VCM medium (green-cap) tube or equivalent (UTM)

Alternative Specimen(s)
One (1) oropharyngeal swab, or NP/OP collected in a VCM medium (green-cap) tube or equivalent (UTM)

Minimum Volume
1 swab

Collection Instructions
Please read detailed instructions below related to collection and transport.

COVID-19 specimens can ONLY be collected in physician offices and hospitals. Quest Diagnostics Patient Service Centers and Quest in-office phlebotomist do not collect respiratory specimens, including those from patients suspected to have COVID-19.

Specimens can be transported at room temperature (2-25° C), or refrigerated and are stable for up to 48 hours. Specimens should be transported to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. Cold packs/pouches should be used if placing specimens in a lockbox for courier pick-up. STAT pick-up cannot be ordered for this test. Frozen specimens are acceptable when packaged with dry ice.

The CDC has expanded their guidance regarding specimen collection. Nasopharyngeal (NP) and/or oropharyngeal (OP) swabs can now be collected and transported in their own vial or combined in a single vial for testing. Each COVID-19 specimen transport vial that is submitted should be accompanied by its own separate requisition and transported in its own sealed bag.

Transport Container
Swab

Transport Temperature
Preferred: Frozen -70° C (dry ice)
Acceptable: Room temperature (2-25° C) or refrigerated

Specimen Stability
Room temperature: 48 hours
Refrigerated: 48 hours
Frozen (less than or equal to -70° C): See Collection Instructions

Reject Criteria
Calcium alginate swabs • Cotton swabs with wooden shaft • Received room temperature or refrigerated more than 48 hours after collection • M4 • Amies liquid or gel transport

Setup Schedule
Set up: Daily; Report available: 1-2 days (may be impacted by high demand)

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

SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Quest LDT)

Test Code
39433

CPT Code(s)
87635

Clinical Significance
SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR - The SARS-CoV-2 RNA, Real-time RT-PCR test is a qualitative multi-target molecular diagnostics test that aids in the detection of COVID-19. This test is intended to be performed on respiratory specimens collected from individuals who meet the Centers for Diseases Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing. For details visit https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html.

Result Interpretation:
- A Detected result is considered a positive test result for COVID-19. This indicates that RNA from SARS-CoV-2 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.
- 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. However, it does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions.
- An Inconclusive result means not all of the testing targets were detected, additional sample collection may be considered.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

Test results are typically available 3-4 days from the time of specimen pickup, and may be impacted by high demand.

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

DIAGNOSTIC LABORATORY OF OKLAHOMA

Preferred Specimen(s)
One (1) nasopharyngeal swab collected in a multi microbe media (M4), VCM medium (green-cap) tube, Amies liquid elution swab (ESwab), or equivalent (UTM)

Alternative Specimen(s)
Upper or lower respiratory specimens such as (1) oropharyngeal swab or NP/OP swabs collected in a multi microbe media (M4), VCM medium (green-cap) tube, Amies liquid elution swab (ESwab), or equivalent (UTM) or 0.85 mL bronchoalveolar lavage/wash, nasopharyngeal aspirate/wash, tracheal aspirate, or sputum sample collected in a plastic sterile leak-proof container

Minimum Volume
1 swab • 0.35 mL

Collection Instructions
COVID-19 specimens can ONLY be collected in physician offices and hospitals. Quest Diagnostics Patient Service Centers and Quest in-office phlebotomist do not collect respiratory specimens, including those from patients suspected to have COVID-19.

The preferred method of transport is frozen specimen (packaged with dry ice). However, specimens can be transported refrigerated (2-8° C) and are stable at this temperature for up to 72 hours. Specimens should be transported to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. Cold packs/pouches must be used if placing specimens in a lockbox for courier pick-up. STAT pick-up cannot be ordered for this test.

The CDC has expanded their guidance regarding specimen collection. Nasopharyngeal (NP) and/or oropharyngeal (OP) swabs can now be collected and transported in their own vial or combined in a single vial for testing. Each COVID-19 specimen transport vial that is submitted should be accompanied by its own separate requisition and transported in its own sealed bag.

Transport Container
Multi microbe media (M4), VCM medium (green-cap) tube, Amies liquid elution swab (ESwab), or equivalent (UTM)

Transport Temperature
Frozen -70° C (dry ice)

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

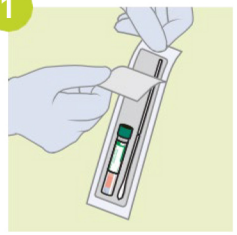
Quest Diagnostics Test Directory Link
https://testdirectory.questdiagnostics.com/test/home

Nasopharyngeal Specimen Collection

COVID-19 testing with SARS Coronavirus CoV-2 RNA, Qualitative Real-Time RT-PCR (test code 39444) or SARS-CoV-2-RNA, Qualitative Real-Time RT-PCR (test code 39433)

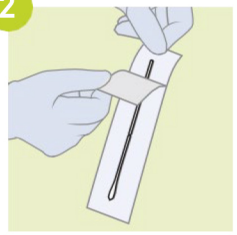
These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act 21, U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

1



Open the individual collection package that contains the swab and Viral Transport Medium tube. Set the tube aside before beginning to collect the specimen.

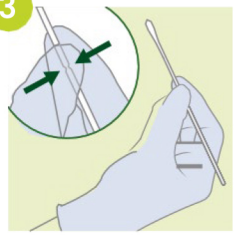
2



Open the collection swab wrapper by peeling open the top of the wrapper.

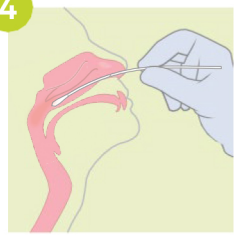
Remove the swab, taking care not to touch the tip of the swab or lay it down.

3



Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.

4



Gently insert the swab into the nostril. Keep the swab near the septum floor of the nose while gently pushing the swab into the post nasopharynx.

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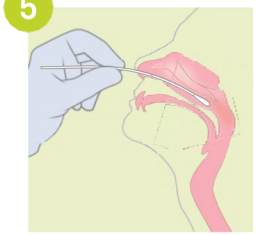
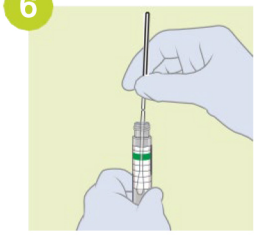


As a visual reference, the swab should be inserted about half the distance from the opening of the patient's nostril and the ear.

Rotate the swab several times.

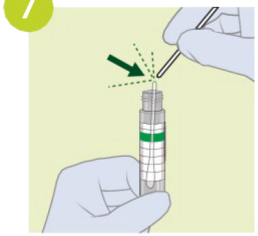
6



While holding the swab in the same hand, aseptically remove the cap from the tube.

Insert the swab into the tube with the transport medium.

7

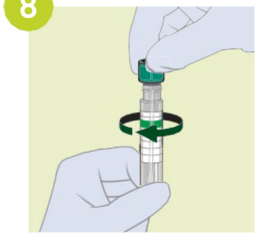


Identifying the scoreline, **break the swab shaft** against the side of the tube. If needed, gently rotate the swab shaft to complete the breakage.

Discard the top portion of the swab shaft.

Avoid splashing contents on the skin. Wash with soap and water if exposed.

8



Replace the cap onto the tube and close tightly.

For test code 39433:
The preferred method of transport is frozen specimen (packaged with dry ice). However, specimens can be transported refrigerated (2°-8° C) and are stable at this temperature for up to 72 hours.

For test code 39444:
Specimens can be transported at room temperature (2°-25° C), or refrigerated and are stable for up to 48 hours. Frozen specimens are acceptable when packaged with dry ice.

Specimens should be transported to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. Cold packs/pouches should be used if placing specimens in a lockbox for courier pick-up. STAT pick-up cannot be ordered for this test.

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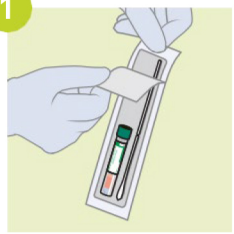
Oropharyngeal Specimen Collection

COVID-19 testing with SARS Coronavirus CoV-2 RNA, Qualitative Real-Time RT-PCR (test code 39444) or SARS-CoV-2-RNA, Qualitative Real-Time RT-PCR (test code 39433)

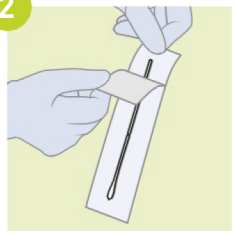
These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act 21, U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

1



Open the individual collection package that contains the swab and Viral Transport Medium tube. Set the tube aside before beginning to collect the specimen.

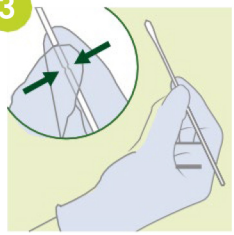
2



Open the collection swab wrapper by peeling open the top of the wrapper.

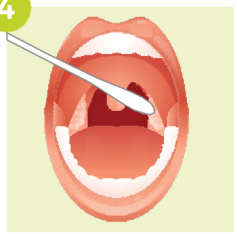
Remove the swab, taking care not to touch the tip of the swab or lay it down.

3



Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.

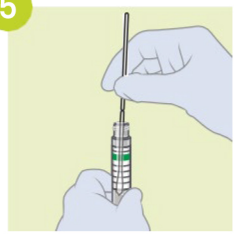
4



Vigorously swab tonsillar area and posterior oropharynx using the swab.

Rotate the swab several times.

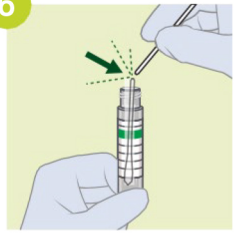
5



While holding the swab in the same hand, aseptically remove the cap from the tube.

Insert the swab into the tube with the transport medium.

6

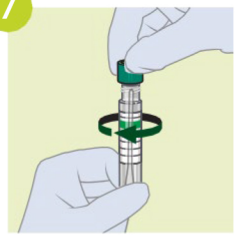


Identifying the scoreline, **break the swab shaft** against the side of the tube. If needed, gently rotate the swab shaft to complete the breakage.

Discard the top portion of the swab shaft.

Avoid splashing contents on the skin. Wash with soap and water if exposed.

7



Replace the cap onto the tube and **close tightly** to prevent leaks.

For Test Code 39433:

The preferred method of transport is frozen specimen (packaged with dry ice). However, specimens can be transported refrigerated (2 °C-8 °C) and are stable at this temperature for up to 72 hours.

For Test Code 39444:

Specimens can be transported at room temperature or refrigerated (2 °C-25 °C) and are stable for up to 48 hours. Frozen specimens are acceptable when packaged with dry ice.

Specimens should be transported to your local Quest Diagnostics accessioning laboratory according to standard operating procedures. Cold packs/pouches should be used if placing specimens in a lockbox for courier pick-up. STAT pick-up cannot be ordered for this test.

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