Updated 4.9.20

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.

- **Healthcare professionals can now order COVID-19 testing using a single code—39448.** The new test code authorizes DLO/Quest to select which test type to perform and result—the FDA-Emergency Use Authorized Quest Diagnostics lab-developed test (LDT), the FDA-Emergency Use Authorized Roche Diagnostics test, or any subsequent similar PCR detection test platforms Quest introduces for COVID-19. Ordering COVID-19 testing with a single code allows DLO and Quest to more efficiently distribute testing to whichever platform offers the most access at a given time. 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 ▶

Updated 4.9.20

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?
DLO is using a single test code – 39448 – which authorizes DLO and Quest to select which test type to perform and result – the FDA-Emergency Use Authorized Quest Diagnostics lab-developed test (LDT), the FDA-Emergency Use Authorized Roche Diagnostics test, or any subsequent similar PCR detection test platforms Quest introduces for COVID-19. Ordering COVID-19 testing with a single code allows Quest to more efficiently distribute testing to whichever platform offers the most access at a given time.

How do I order the COVID-19 test?
Providers may order the test using the 39448 test code. The test must be ordered on a separate requisition from other tests.

What is happening to the previous COVID-19 test codes?
Individual order codes 39433 and 39444 are being replaced by the single order code and will no longer be orderable effective May 4, 2020.

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 2-4 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 CoV 2 RNA (COVID 19), QUALITATIVE NAAT

Test Code
39448

CPT Code(s)
87635

Clinical Significance
SARS CoV 2 RNA (COVID 19), QUALITATIVE NAAT - The SARS-CoV-2 RNA (COVID-19), 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 Disease 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 send 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. This could be due to a sample with viral concentrations near the limit of detection of the test or other factors. An 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
Nucleic Acid Amplification Test (NAAT) includes PCR or TMA. This test has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.

Reference Range(s)
Not detected

Preferred Specimen(s)
One (1) nasopharyngeal (NP) swab collected in a multi microbe media (M4, M4RT, M5, M6), VCM (UTM) medium (green-top) tube, Amies liquid elution swab (ESwab), or equivalent Viral Transport Media (VTM)

Alternative Specimen(s)
(1) Upper respiratory specimens such as: One (1) oropharyngeal (OP) swab; combination NP/OP swabs collected together; or an anterior nares specimen (collected using only a foam swab) in a multi microbe media (M4, M4RT, M5, M6), VCM (UTM) medium (green-top) tube, Amies liquid elution swab (ESwab), or equivalent Viral Transport Media (VTM), or

(2) Lower respiratory specimens such as: 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. DLO Patient Service Centers and in-office phlebotomists do not collect respiratory specimens, including those from patients suspected to have COVID-19.

Anterior nares specimens (use one swab for both nares) should be collected by a healthcare professional or by healthcare-directed onsite self-collection by using a round foam swab. 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.

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
Preferred sample: Multi microbe media (M4, M4RT, M5, M6); VCM medium (green-cap) tube or equivalent (UTM)

Acceptable specimen: Plastic, sterile, leak proof container

Transport Temperature
Frozen

Specimen Stability
Room temperature: 5 days
Refrigerated (2-8 degrees C): 5 days
Frozen (-70 degrees Celsius): Acceptable

Reject Criteria
Thaw/Other: Calcium alginate swabs; Cotton swabs with wooden shaft; Amies liquid or gel transport used for bacterial cultures

Setup Schedule
Setup Days: Sunday-Saturday

Interface Mapping
Result Code: 86028546
Result Name: SARS CoV 2 RNA

Performing Site
Quest Diagnostics Infectious Disease, Inc.

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

https://testdirectory.questdiagnostics.com/test/test-detail/39448/sars-cov-2-rnacovid-19qualitative-naat?p=r&q=39448&cc=DLO

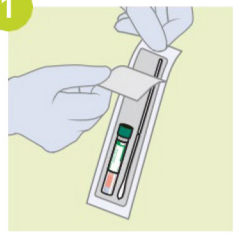
Nasopharyngeal Specimen Collection

COVID-19 testing with SARS CoV-2 RNA (COVID-19), Qualitative NAAT (test code 39448)

For specimen collection by a healthcare professional. Not for self-collection.

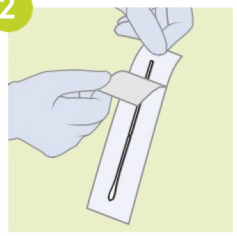
These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration 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.

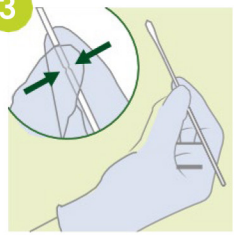
2



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

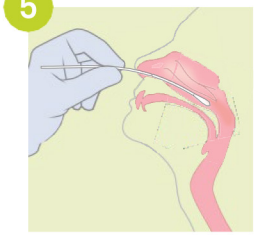


Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.

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.

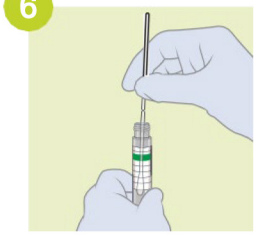
5



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.

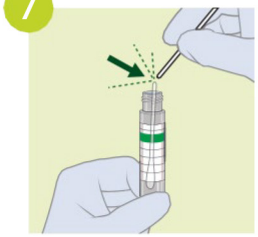
6



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

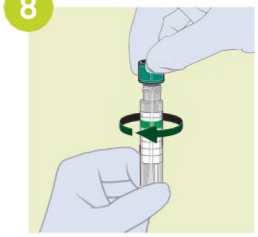


Identifying the scoreline, **break the swab shaft** against the side of the tube. If needed, gently rotate the swab shaft to complete the breakage.

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** to prevent leaks.

Specimen stability for all specimen types is as follows:

Room temperature: 5 days

Refrigerated (2 °C–8 °C): 5 days

Frozen (-20 °C): 7 days

Frozen (-70 °C):

Acceptable

Specimens should be transported to your local DLO 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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DLO DIAGNOSTIC LABORATORY OF OKLAHOMA

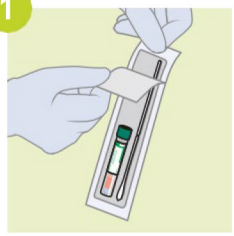
Oropharyngeal Specimen Collection

COVID-19 testing with SARS CoV-2 RNA, (COVID-19) Qualitative NAAT (test code 39448)

For specimen collection by a healthcare professional. Not for self-collection.

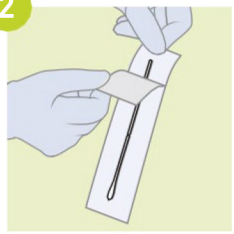
These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration 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.

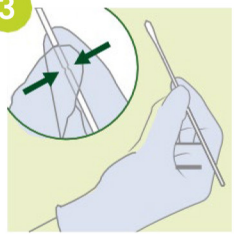
2



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

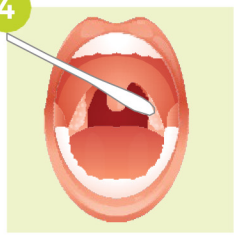
Remove the swab, taking care not to touch the tip of the swab or lay it down.

3



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

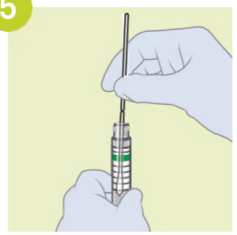
4



Vigorously swab tonsillar area and posterior oropharynx using the swab.

Rotate the swab several times.

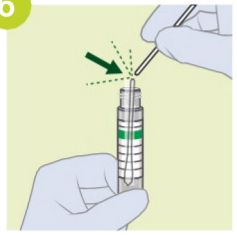
5



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

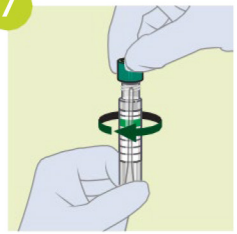


Identifying the scoreline, **break the swab shaft** against the side of the tube. If needed, gently rotate the swab shaft to complete the breakage.

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.

Specimen stability for all specimen types is as follows:

Room temperature: 5 days

Refrigerated (2 °C–8 °C): 5 days

Frozen (-20 °C): 7 days

Frozen (-70 °C): Acceptable

Specimens should be transported to your local DLO 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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DIAGNOSTIC LABORATORY OF OKLAHOMA

Sputum Specimen Collection

COVID-19 testing with SARS-CoV-2 RNA (COVID-19), Qualitative NAAT (test code 39448)

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories and has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is 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 container. Set the container aside before beginning to collect the specimen.

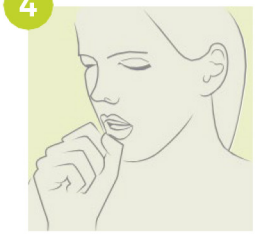
2

Instruct the patient to rinse their mouth with water.

3

Hold the container in your hand.

4



Instruct the patient to **obtain material from a deep cough**.

5

Press the rim of the container under the patient's lower lip to catch the entire specimen.

Instruct the patient to avoid dispensing saliva or nasopharyngeal discharges into the vial containing the medium.

6

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

Induction of sputum is **not** recommended by CDC for COVID-19 testing.

Specimens should be transported by DLO Logistics to your local DLO 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.

Specimen stability is as follows:

Room temperature: 5 days

Refrigerated (2 °C–8 °C): 5 days

Frozen (-20 °C): 7 days

Frozen (-70 °C): Acceptable

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