COVID-19 TESTING

MARCH 19, 2020 | 11:00AM PST

WEBINAR

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# COVID-19: Key Clinical Information

## Disease
- Coronavirus Disease 2019 or COVID-19 (formally known as 2019-nCoV)
- Respiratory syndrome caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

## Symptoms
- Cough
- Fever
- Shortness of breath
- Asymptomatic carriers have been reported

## Transmission
- Close person-to-person contact through respiratory droplets from coughing and sneezing
- May also spread through airborne transmission, when tiny droplets remain in the air even after the person with the virus leaves the area

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**CDC Testing Recommendation & Guidelines:**

Clinicians should use their own judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested.

- Decisions on which patients receive testing should be based on the local epidemiology of COVID-19, as well as the clinical course of illness.
- Clinicians are encouraged to consider testing for other causes of respiratory illness, including infections such as influenza.
- Epidemiologic factors that may help guide decisions on whether to test include:
  - any persons, including healthcare workers, who have had close contact with a laboratory-confirmed COVID-19 patient within 14 days of symptom onset, or
  - a history of travel from affected geographic areas within 14 days of symptom onset.

World Health Organization declares COVID-19 a public health emergency of international concern.

JANUARY 30

FEBRUARY 29
FDA announces independent labs can begin COVID-19 testing while pending Emergency Use Authorization approval.

COVID-19: key milestones

Quest Diagnostics launches COVID-19 test, begins receiving specimens in SJC, CA. Scales up test services nationally on March 10th to serve growing demand

MARCH 9

MARCH 11
World Health Organization (WHO) publicly characterized COVID-19 as a pandemic.

MARCH 16-20

Quest to continue to raise testing capacity by expanding locations to perform our lab-developed test (LDT), and with the release of a high-throughput test (from Roche)

APRIL
Quest expects capacity of approximately 20,000 tests per day

20K
**COVID-19: Test offerings & collection guidance**

### Quest Diagnostics

**Lab Developed Test (LDT)**

- Quest can receive specimens and provide testing as of March 9, 2020
- The test should be ordered on its own dedicated requisition and not combined with any other test
- It is not a STAT test and a STAT pick-up cannot be ordered

Currently performing the test at high-complexity Quest laboratories including Quest Diagnostics Infectious Disease (QDID) on the San Juan Capistrano (SJC) campus, Marlborough, and Chantilly

- Nasopharyngeal (NP) Swab AND/OR Oropharyngeal (OP) swab
- Lower Respiratory (e.g. bronchial lavage/wash, sputum/tracheal aspirate and nasopharyngeal aspirate/wash)
- Specimens should be shipped frozen packaged with dry ice (preferred). However, specimens can be transported refrigerated (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 transported to your local Quest Diagnostics accessioning laboratory according to standard operating procedures

Designated by the FDA for Emergency Use Authorization (EUA)

**NOTE:** These tests have not been FDA cleared or approved. These tests have been authorized by 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 sooner.

### High-throughput test (By Roche)

- Quest can receive specimens and provide testing as of the week of March 16th - 20th (live date differs by location)
- The test should be ordered on its own dedicated requisition and not combined with any other test
- It is not a STAT test and a STAT pick-up cannot be ordered

Expands testing capacity to other regional Quest laboratories including NY/NJ metro, Dallas, Miami, Los Angeles, Chicago, Kansas City, Pittsburgh and Phoenix (In addition to SJC, Marlborough and Chantilly)

- Nasopharyngeal (NP) Swab AND/OR Oropharyngeal (OP) swab
- Specimens can be transported at room temperature or refrigerated (2°C - 25°C) and are stable for up to 48 hours.
- Cold packs/pouches should be used if placing specimens in a lockbox for courier pick-up
- 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

Designated by the FDA for Emergency Use Authorization (EUA)
Collection device guidance: SARS COVID-2 Collection Devices

In order of preference (left to right)

**Nasopharyngeal (NP) swab**
- PeopleSoft item #: 142059
- PeopleSoft product ID: S05
- Quanum™ product ID: S05
- Ordered by the EA (each)

**Oropharyngeal (OP) swab**
- PeopleSoft item #: 142060
- PeopleSoft product ID: S03
- Quanum™ product ID: S03
- Ordered by the EA (each)

Note: Both swabs are the same – only one is necessary for specimen collection

FULL GUIDE AVAILABLE

[Image of COVID-19 specimen collection guidelines]

Quest specimen requirements and acceptable supplies for Quest's LDT test code 39432:

Nasopharyngeal (NP) and/or oropharyngeal (OP) swabs

Specimen collection:
- Use only nasal/throat swab moistened with physiologic saline.
- Specimens should be collected in a specimen transport vial suitable for viral transport.
- Do not introduce antiseptics, medications, or disinfectants into oropharyngeal swabs prior to patient insertion or transport.

Note: Both swabs are the same – only one is necessary for specimen collection.
Where can patients be tested for COVID-19?

- Hospitals
- Physician offices
- Clinics

- Samples can ONLY be collected for this testing at hospitals and appropriate healthcare settings
- Ordering provider (not patient) may drop off specimens to a Quest Patient Service Center (PSC) following standard procedures

- Quest PSCs
- IOPs
- QuestDirect™

- Samples can NOT be collected at Quest PSCs or in-office phlebotomists (IOP) as these sites do not collect respiratory samples for any condition
- Patients may NOT drop off a specimen at a PSC that was collected by their ordering provider given the special refrigeration and handling requirements of the test
- Patients can NOT order this testing through QuestDirect or any other consumer-initiated testing
COVID-19: protocol for reporting results

**Priority 1 (P1) reporting**
- Positive (both) and inconclusive (TC 39433 only) results will be a P1 category and will follow our current P1 process for contacting our customers.
- Other results will be delivered through the customer’s normal delivery method.

**CDC confirmatory testing**
- Routine confirmatory testing of positive samples by the CDC or state health labs is no longer required. Our test has met FDA requirements for positive and negative sample comparison.

**Public health reporting**
- Results will be sent to appropriate public health agencies.

**MyQuest™**
- In MyQuest, patients will receive results in the same way they typically receive results for all other Quest testing.
COVID-19: Additional insights

We are monitoring the situation closely, and evolving & adapting to serve testing needs across the US

**Turnaround times**
Test results are typically available 3-4 days from the time of specimen pick-up and may be impacted by high demand.

**Supplies**

**PSCs & IOPs**

**Social distancing**

Want to provide feedback or need assistance? [http://health.questdiagnostics.com/Covid19](http://health.questdiagnostics.com/Covid19)
COVID-19: Client support resources

Quest – CNECT alliance & account support
Trouble-shooting, problem-solving, guidance, solutions.

Specimen Collection Guides
Detailed guide for supplies, collection & transport of specimens

Quest Diagnostics COVID-19 Webpage
Email alerts, FAQs, turnaround time tracker, dedicated inbox
QuestDiagnostics.com/COVID19/HCP
IN CONCLUSION

Quest is expanding test capacity to help meet demands in the US

Lab-developed test & high-throughput testing available to hospitals, physician offices & clinics

Quest PSC locations and IOPs CANNOT collect specimens

Resources are available: Quest webpage, provider FAQs, collection guides, client support mailbox, email update opt-in

We’re here to help: take advantage of the Quest – CNECT alliance and reach out to reps for assistance

QuestDiagnostics.com/COVID19/HCP

FOR THE LATEST INFORMATION