QUEST DIAGNOSTICS
REFERENCE LABORATORY
SERVICE UPDATE
APRIL 1, 2020 | 11:00AM PDT

WEBINAR

KAREN P. HAMLIN
Executive Sales Director
Southern California & Nevada
Quest Diagnostics
Industry-leading GPO

Founded in 1979

Affiliated with Premier, inc.

Over 8,000 members

Our diversified members include:

- Business & Industry
- Education
- First Responders
- Home Care
- Ambulatory Care
- Hospitals
- Imaging Centers
- Long Term Care
- Physician Offices
- Surgery Centers
CNECT COVID-19 Newsletter

Sign up for our COVID-19 email list

Senate Passes $2 Trillion Emergency COVID-19 Stimulus Package

The Senate unanimously passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748), which provides more than $1.3 trillion for the healthcare system to respond to the COVID-19 outbreak. While the process remains fluid, the House is expected to approve the package under unanimous consent, with the President signing it in short order. Congressional leaders and the White House are already signalling that there will be a fourth, and perhaps fifth, emergency COVID-19 stimulus package.

For highlights of the provisions of the CARES Act that most directly impact our membership click here.

CNECT Contract Support

Quantum Medical

Contract: FP-M05-6640
Contact: Chris Siegura, chris@quantummedical.com
Ph: (615) 426-9545
Medical and healthcare supply storage with over 9,000 SKUs on contract including:

- High density secure mobile storage
- Rapid response medical carts
- Stainless workstations and aluminum isolation carts
- Wire shelving and solid shelving
Karen Hamlin
Executive Sales Director

Tab Toochinda, MD
Medical Director
West Hills Clinical Laboratory

Sam Landon
Senior Marketing Manager
COVID-19: key clinical information

Disease
- Coronavirus Disease 2019 or COVID-19 (formerly 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

CDC testing recommendation & guidelines for whom should be tested:

CRITERIA TO GUIDE EVALUATION OF PERSONS UNDER INVESTIGATION (PUI) FOR COVID-19:

- Clinicians should use their 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 priority guidelines (PRIORITY 1, 2 & 3) as outlined by the CDC. For detailed information visit: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html
- Per CDC guidelines, clinicians should consider testing for other causes of respiratory illness, including infections such as influenza.

COVID-19: key milestones

**JANUARY 30**
World Health Organization declares COVID-19 a public health emergency of international concern.

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

**MARCH 9**
Quest Diagnostics launches COVID-19 test, begins receiving specimens in SJC, CA. Scales up test services nationally on the next day to serve growing demand.

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

**MARCH 16-20**
Quest raises testing capacity by expanding locations to perform our lab-developed test (LDT), and with the release of a high-throughput test (from Roche)

**MARCH 31**
Quest receives EUA for LDT

Quest capacity is approximately 30K tests per day
COVID-19: test offerings

**Roche**

39444

High-throughput test

Upper Respiratory Specimens:
- One Nasopharyngeal (NP) swab (preferred)
- One Oropharyngeal (OP) swab, or
- NP/OP swabs
- Anterior nares specimen (foam swab)

Collected in the following:
- Multi microbe media (M4, M4RT, M5, M6)
- VCM medium (green-cap) tube
- Equivalent (UTM)

**Quest Diagnostics**

39433

Lab-developed Test (LDT)

Same Upper Respiratory specimen type and collection supplies as Roche

Or

Lower Respiratory Specimens collected in a plastic, sterile, leak-proof container:
- Bronchoalveolar lavage/wash (BAL)
- Nasopharyngeal aspirate/wash
- Tracheal aspirate
- Sputum sample

PREFERRED TRANSPORT FOR BOTH TESTS IS FROZEN

Specimens should be transported to local lab according to standard operating procedures.

STABILITY FOR ALL TESTS (ROCHE & LDT) & ALL SPECIMEN TYPES HAS BEEN UPDATED:
- Room temperature: 5 Days
- Refrigerated (2-8° C): 5 Days
- Frozen (-20° C): 7 Days
- Frozen (-70° C): Acceptable
## COVID-19: test offerings

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Code</th>
<th>Test Name</th>
<th>Key Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PREFERRED</strong></td>
<td>39444</td>
<td>Roche High-throughput test</td>
<td>• Upper respiratory specimens only (NP and/or OP, or anterior nares)</td>
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<tr>
<td></td>
<td></td>
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<td>• 0.6 mL minimum volume</td>
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<td></td>
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<td>• Results: Detected, Not Detected, Presumptive Positive, Invalid</td>
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<td></td>
<td>• Higher capacity, performed regionally across the nation</td>
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<tr>
<td><strong>Lab-developed Test (LDT)</strong></td>
<td>39433</td>
<td>Quest Diagnostics Lab-developed Test (LDT)</td>
<td>• Upper and lower respiratory specimens</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 0.35 mL minimum volume</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Results: Detected, Not Detected, Inconclusive</td>
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<tr>
<td></td>
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<td></td>
<td>• Lower capacity, performed at high complexity laboratories</td>
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</tbody>
</table>

**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.
Collection guidance: SARS COVID-2

IN ORDER OF PREFERENCE (LEFT TO RIGHT)

Nasopharyngeal (NP) swab

S05 – SWAB, VCM, NASAL, FLOCKED, 1/EA

Oropharyngeal (OP) swab

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

S03 – SWAB, VCM, LESION FLOQSWAB, 1/EA

FULL GUIDE AVAILABLE
Updated 3.30.20

COVID-19 specimen collection guidelines

SARS COVID-2

IN ORDER OF PREFERENCE (LEFT TO RIGHT)

Nasopharyngeal (NP) swab

S05 – SWAB, VCM, NASAL, FLOCKED, 1/EA

Oropharyngeal (OP) swab

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S03 – SWAB, VCM, LESION FLOQSWAB, 1/EA

Full guide available
Updated 3.30.20
Collection guidance: FDA has identified saline as an acceptable transport medium if better alternatives are not available.

Use where commercial viral transport media are unavailable:

- **Sterile plastic vial**: 10 mL falcon tube or equivalent; round or conical bottom
- **Volume**: Between 2 mL and 3 mL
- **Sterile Swab**
  - Flocked swab (preferred)
  - Foam or spun synthetic (may not be sufficient to rule out infection)
- **Phosphate buffered saline (PBS)**
  - 1 x pH 7.4 (range 7.2-7.4)
  - Saline (0.85% to 0.90%)

Ensure label includes all required information and lid/cap is tightly secured.

Refer to the Specimen Collection Guide.

Quest will accept appropriately collected upper respiratory swab specimens transported in commercially available prefilled saline or PBS vials.
COVID-19: key information for TC 39433 & TC 39444

**SEPARATION**
One specimen vial, one order, one requisition, one sealed bag.
*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*

**STAT PICKUP (NOT AVAILABLE)**
TC 39433 & TC 39444 are not STAT tests and a STAT pick-up cannot be ordered

**PRIORITY SPECIMEN HANDLING PROGRAM**
Quest has implemented a COVID-19 Priority Specimen Handling Program for specimens obtained from hospital inpatients who have been admitted for treatment and are suspected of COVID-19 infection, and symptomatic healthcare workers (HCWs).

**EMERGENCY USE AUTHORIZATION**
TC 39433 & TC 39444 are designated by the FDA for Emergency Use Authorization (EUA)
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 TIME**

- TAT: currently ~4-5 days across the network (as of 4/1/20)
- May vary pending demand
- Priority handling
- Contact Quest rep for individual location TAT

**SUPPLIES**

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 Quest to send us testing.

Please visit [QuestDiagnostics.com/COVID19/HCP](https://www.QUESTDiagnostics.com/COVID19/HCP) regularly for specimen collection resources.

**PSCs**

Patients 60 years of age or older, or who have other conditions that put them at greater risk for COVID-19 can go to a Quest location during the first hour of each day for VIP care through our new **Peace of Mind program**.

**PSC closures** due to COVID-related call outs will be communicated via our regular process

**SOCIAL DISTANCING**

Quest representatives are following recommended social distancing/stay-at-home protocol, but are still readily available for client inquiries and support
COVID-19: Client support resources

**Quest representative account support**

Trouble-shooting, problem-solving, guidance, solutions.

**Specimen Collection Guides**

Detailed guide for supplies, collection & transport of specimens

**Quest Diagnostics COVID-19 Webpage**

The most up to date info, including email alerts, FAQs, dedicated inbox

[QuestDiagnostics.com/COVID19/HCP](https://www.QuestDiagnostics.com/COVID19/HCP)
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 local Quest account support by reaching out to reps for assistance

Want to provide feedback or need assistance? http://health.questdiagnostics.com/Covid19
Q & A