Quest Diagnostics™

QUEST DIAGNOSTICS REFERENCE LABORATORY

SERVICE UPDATE

APRIL 1, 2020 | 11:00AM PDT

WEBINAR

KAREN P. HAMLIN
Executive Sales Director
Southern California & Nevada
Quest Diagnostics

cnect®

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- EDUCATION
- FIRST RESPONDERS
- HOME CARE
- AMBULATORY CARE
- HOSPITALS
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- LONG TERM CARE
- PHYSICIAN OFFICES
- SURGERY CENTERS

CNECT COVID-19 Newsletter

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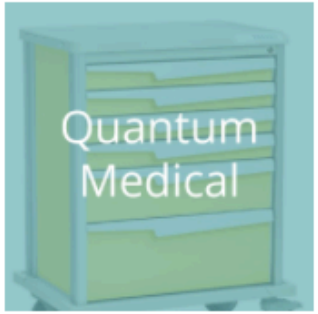
Supporting our **Community Health Center and Physician members** through the **COVID-19** Crisis

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 $130 billion 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 signaling 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: PP-MM-640
Contact: Chris Stegura, chriss@quantummedical.com
P: (615) 428-9545
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

provider update

COVID-19

WHAT YOU NEED TO KNOW

Quest Diagnostics™

Updated March 26, 2020

Quest Diagnostics: on today's call

Karen Hamlin
Executive Sales Director

Tab Toochinda, MD
Medical Director
West Hills Clinical Laboratory

Sam Landon
Senior Marketing Manager

Quest Diagnostics™

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

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.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fclinical-criteria.html, accessed March 30, 2020

COVID-19: key milestones

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.

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 9

MARCH 11

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

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)

Quest receives EUA for LDT

MARCH 16-20

MARCH 31

Quest capacity is approximately

30,000

tests per day

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COVID-19: test offerings

Roche

PREFERRED

39444

High-throughput test

Quest Diagnostics®

39433

Lab-developed Test (LDT)

SPECIMENS

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)

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

TRANSPORT

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

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COVID-19: test offerings

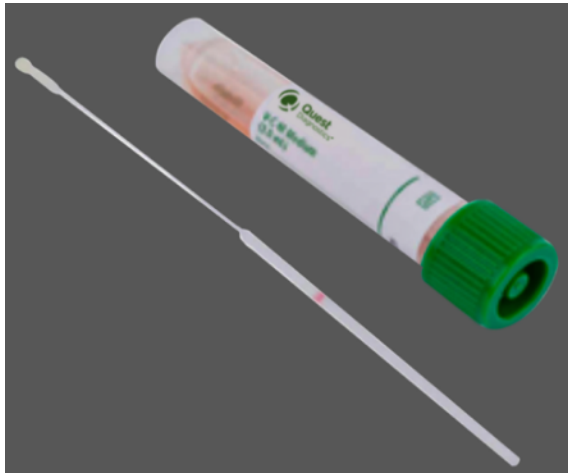
	Roche	Quest Diagnostics®
	PREFERRED 39444 **High-throughput test**	39433 **Lab-developed Test (LDT)**
KEY DIFFERENCES	• Upper respiratory specimens only (NP and/or OP, or anterior nares) • 0.6 mL minimum volume • Results: Detected, Not Detected, Presumptive Positive, Invalid • Higher capacity, performed regionally across the nation	• Upper and lower respiratory specimens • 0.35 mL minimum volume • Results: Detected, Not Detected, Inconclusive • Lower capacity, performed at high complexity laboratories

***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

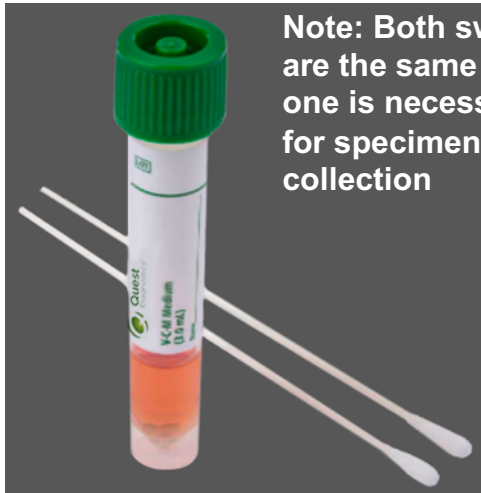
IN ORDER OF PREFERENCE (LEFT TO RIGHT)

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


Revision 3/30/20

Quest Diagnostics

COVID-19 specimen collection guidelines

Quest specimen requirements and acceptable supplies for SARS Coronavirus w/CoV 2 RNA, Qualitative Real-Time RT-PCR (test code 39444) and SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (test code 39433)

Acceptable COVID-19 specimen transport media and swabs for test codes 39444 and 39433

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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

FDA guidance on **saline** for COVID-19 upper respiratory swab samples

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

Revision 3/30/20

Quest Diagnostics

COVID-19 specimen collection guidelines

Quest specimen requirements and acceptable supplies for SARS Coronavirus w/CoV 2 RNA, Qualitative Real-Time RT- PCR (test code 39444) and SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (test code 39433)

Quest does 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 Quest to send us samples for testing. Please refer to the information below and to the QuestTest Directory at TestDirectory.QuestDiagnostics.com for a list of acceptable specimen collection and transport supplies for COVID-19 testing.

These tests are being offered under an Emergency Use Authorization (EUA) by the FDA. The EUA stipulates the tests may be used only by Quest laboratories and only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The authorization is valid only for the duration of the declaration that circumstances exist justifying the EUA for in vitro diagnostic tests for the 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.

This guide is intended to describe the collection devices to be used for upper respiratory specimens for COVID-19.

New information on samples from anterior nares

Anterior nares specimen: Collected by a healthcare professional or a patient self-collected sample is acceptable when the patient is in an appropriate clinical setting (such as a drive-thru testing site).

Collection instructions: Use a single foam swab for collecting specimens from both nares of asymptomatic patient. Insert foam swab into 1 nostril straight back (not upwards). Once the swab is in place, rotate it in a circular motion 2 times and keep it in place for 15 seconds. Repeat this step for the second nostril using the same swab. Remove foam swab and insert the swab into an acceptable viral transport medium listed in this guide.

Acceptable foam swab: Puritan 6" Sterile Standard Foam Swab w/ Polystyrene Handle (SKU # 25-1606 1PF)

Specimen stability for all specimen types for all tests (LDT and Roche) is now 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 Quest Diagnostics 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 these tests.

Refer to the Specimen Collection Guide

Quest will accept appropriately collected upper respiratory swab specimens transported in commercially available prefilled saline or PBS vials

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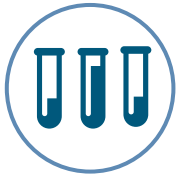
COVID-19: key information for TC 39433 & TC 39444



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)

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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

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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

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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** 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

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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

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COVID-19

PROVIDER UPDATE

SUMMARY

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

QuestDiagnostics.com/COVID19/HCP

FOR THE LATEST INFORMATION

Q & A

Every link stronger.