Test Definition: SCOVT

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), RNA Detection, ddPCR, Tissue

Overview

Useful For

Detection of severe respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19) in formalin-fixed, paraffin-embedded tissue

Highlights

This test detects severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA in formalin-fixed, paraffin-embedded tissue.

This test method is a laboratory-developed modification of the Bio-Rad SARS-CoV-2 droplet digital polymerase chain reaction (ddPCR) test, which received FDA emergency use authorization (EUA) during the coronavirus disease 2019 (COVID-19) pandemic.

Method Name

Droplet Digital Polymerase Chain Reaction (ddPCR)

NY State Available

No

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Specimen Type: Formalin-fixed, paraffin-embedded tissue.
Sources: Lung tissue, sputum (cell block), tracheal aspirate (cell block), bronchoalveolar fluid (cell block), cardiac tissue, brain tissue, kidney tissue, other

Preferred:
Specimen Type: Tissue
Container/Tube: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tissue block.

Acceptable:

Specimen Type: Tissue
Container/Tube: Slides
Specimen Volume: 5 unstained
Collection Instructions: Submit 5 unstained, non-baked slides with 10-micron thick sections of tissue, preferably along with an Hematoxylin and Eosin slide (not required).

Acceptable:
Specimen Type: Tissue
Container/Tube: Scrolls
Specimen Volume: 5 scrolls
Collection Instructions: Submit 5 scrolls of FFPE tissue cut at 10 microns thick, preferably along with an H&E slide (not required).

Specimen Minimum Volume
See Specimen Required

Reject Due To

Specimens that have been decalcified (all methods) Specimens that have not been formalin-fixed, paraffin-embedded	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus is a positive-sense, single-stranded RNA virus that causes coronavirus disease 2019 (COVID-19). Like other coronaviruses that infect humans, SARS-CoV-2 can cause both upper and lower respiratory tract illness. Symptoms can range from mild (ie, the common cold) to severe (ie, pneumonia) in both healthy and immunocompromised patients. SARS-CoV-2 transmission occurs primarily via respiratory droplets. As the disease progresses, the viral load tends to decrease in the upper respiratory tract, at which

point, lower respiratory tract specimens (eg, sputum, tracheal aspirate, bronchoalveolar fluid, transbronchial biopsy, wedge biopsy of lung, autopsy lung specimen) would be more likely to have detectable SARS-CoV-2. Infection of other tissue has been reported.

The SARS-CoV-2 RNA detection in formalin-fixed and paraffin-embedded (FFPE) tissue by droplet digital polymerase chain reaction (ddPCR) assay will be used to detect the nucleocapsid N1 and N2 target sequences of SARS-CoV-2 virus in FFPE surgical and autopsy tissue. The identification of SARS-CoV-2 in surgical tissue may aid in the diagnosis of COVID-19 and may lead to a better understanding of unusual disease presentations. Detection of SARS-CoV-2 in deceased patients (autopsy tissue) may similarly confirm a suspected diagnosis among individuals with clinical or pathologic manifestations of COVID-19 (ie, pulmonary, cardiac) and may increase understanding of SARS-CoV-2 pathobiology.

Reference Values

Not applicable

Interpretation

This test will be reported as positive, negative, or indeterminate. An "indeterminate" result indicates that the presence or absence of severe respiratory syndrome coronavirus 2 (SARS-CoV-2 RNA) in the specimen could not be determined with certainty after repeated testing in the laboratory. This could be due to reverse transcriptase polymerase chain reaction (RT-PCR) inhibition or very low viral load. Submission of a new specimen for testing is recommended.

Test results should always be considered in the context of patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.

Cautions

The assay is adapted from an qualitative severe respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA detection assay that has received FDA emergency use authorization (EUA), and it is modified by the performing laboratory for qualitative detection of SARS-CoV-2 RNA present in formalin-fixed and paraffin-embedded (FFPE) tissue.

The sensitivity of the assay is dependent on the timing of the specimen collection (in relation to symptom onset) and the quality, quantity, and type of specimen submitted. This test is not normalized to the size of the submitted tissue per section.

The test is specific for detection of SARS-CoV-2. Therefore, negative results do not exclude the possibility of infection with other respiratory viruses.

Negative results do not rule out coronavirus disease 2019 (COVID-19) in patients and should not be used as the sole basis for treatment or other patient management decisions. Result should be correlated with patient's history and clinical presentation.

Clinical Reference

1. Zhu N, Zhang D, Wang W, et al: A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020 Feb;382(8):727-733. doi: 10.1056/NEJMoa2001017
2. Holshue ML, DeBolt C, Lindquist S, et al: First case of 2019 novel coronavirus in the United States. N Engl J Med. 2020 Mar 5;382(10):929-936. doi: 10.1056/NEJMoa2001191

3. Loeffelholz MJ, Tang YW: Laboratory diagnosis of emerging human coronavirus infections-the state of the art. Emerg Microbes Infect. 2020;9(1):747-756. doi.org/10.1080/22221751.2020.1745095
4. Liu X, Feng J, Zhang Q, et al: Analytical comparisons of SARS-COV-2 detection by qRT-PCR and ddPCR with multiple primer/probe sets. Emerg Microbes Infect. 2020 Dec;9(1):1175-1179
5. Suo T, Liu X, Feng J, et al: ddPCR: a more accurate tool for SARS-CoV-2 detection in low viral load specimens. Emerg Microbes Infect. 2020 Dec;9(1):1259-1268

Performance

Method Description

The assay is a laboratory-developed modification of the Bio-Rad severe respiratory syndrome coronavirus 2 (SARS-CoV-2) droplet digital polymerase chain reaction (ddPCR) assay to generate results in formalin-fixed paraffin-embedded (FFPE) tissue specimens. RNA is extracted from either scraped unstained slides or tissue scrolls. The eluate is incorporated into the reaction mixture, followed by generation of individual reaction droplets by the QX200 Automated Droplet Generator. After completion of PCR, the droplets are analyzed for presence or absence of amplified viral target sequences using the QX200 Droplet Reader.

The PCR reaction mixture contains primers and probes for 2 target sequences within the SARS-CoV-2 nucleocapsid gene (N1 and N2) and a reference human ribonuclease P protein subunit 30-encoding gene (*RPP30*) sequence. Results are generated and reported as positive, negative, or indeterminate. The sensitivity of the assay is dependent on the timing of the specimen collection (in relation to symptom onset) and the quality, quantity, and type of specimen submitted. This test is not normalized to the size of the submitted tissue per section. The limit of detection varies based on the number of droplets generated but is approximately 5 copies of the viral genome.(Package insert: Bio-Rad SARS-CoV-2 ddPCR Test for use on the QX200 and QXDx Droplet Digital PCR Systems. Bio-Rad Laboratories, Inc; 04/2020)

PDF Report

No

Day(s) Performed

Weekly

Report Available

7 to 10 days

Specimen Retention Time

Unused portions of blocks will be returned. Unused slides and/or scrolls are stored indefinitely.

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87635

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SCOVT	SARS CoV-2 RNA ddPCR, Qual, FFPE	94316-7

Result ID	Test Result Name	Result LOINC® Value
610691	Result	94316-7
610692	Additional Information	94736-6
MG141	SARS CoV-2 Specimen Source	31208-2
610693	Method	85069-3
610694	Disclaimer	62364-5