Created: 6/6/2024
Updated: 9/16/2024

SalivaDirect Information Sheet

Overview

MDL Test Name

Saliva Direct (SARS-Cov-2 by RT-PCR (Saliva Only))

MDL Test Code

pCOVSAL

Ask at Order Questions

Several

Specimen Source

Saliva

Specimen Requirements

Container/Tube

5mL Screw Cap Eppendorf Tube

Specimen Volume (minimum)

0.5 mL

Sample Stability Time

72 hours at 20 – 22°C

7 days at 2 – 8°C

Transport/Storage Conditions

Refrigerated (4 – 8°C) or Ambient (20 – 22°C)

Patient Preparation / Collection Instructions

The patient must not eat, drink, or use tobacco products within 30 minutes of collection.

Refer to the Viral Saliva Specimen Collection Instructions.

Performance

Days Performed

Daily; Monday – Friday at 11:30 AM

Report Available (TAT) – (once received at MDL)

< 48 hours

Specimen Retention Time

7 days

Method Description

Real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for qualitative detection of nucleic acid from SARS-CoV-2.

Reference Values

Not Detected

Interpretation

A positive (detected) result indicates SARS-CoV-2 RNA is present, suggesting infection of COVID-19

A negative (undetected) result indicates that SARS-CoV-2 is not present in the patient's sample, this can be influenced by the stage of infection, and/or quality of specimen collected for testing. Results should be correlated with the patient's history and clinical presentation.

An inconclusive result indicates the presence or absence of SARS-CoV-2 RNA in the specimen could not be determined with certainty, possibly due to real-time, reverse transcription polymerase chain inhibition. Submission of a new specimen for testing is recommended if clinically indicated.

Cautions

Undetected results do not rule out COVID-19 in patients and should not be used as the sole basis for treatment. Results should be correlated with the patient's history and clinical presentation.

This test is specific for SARS-CoV-2. Positive results do not exclude the possibility of concurrent infection with other respiratory viruses.

The sensitivity of the assay is dependent on the timing of specimen collection in relation to symptom onset, and the quality of specimen submitted for testing.

FDA cleared for use under Emergency Use Authorization (EUA) only.