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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.

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