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شماره پذیرش: ۰۶-۲۹۵۳

ص ۱ از ۱

\* ارسالی از: رویان دارو

سن: ۳۹ سال

نام مراجعه کننده: خانم سپیده نامجو

**PCR**

Test	Result
Sample	NP/OP swab
SARS-CoV-2 (COVID-19) gene targets	
Gene target-1	Negative
Gene target-2	Negative

Method: Real-Time RT-PCR

Limit of Detection: The limit of detection of the SARS-CoV-2 Real-Time RT-PCR test is 200 Copies/mL.

Clinical Specificity: The clinical specificity of the SARS-CoV-2 Real-Time RT-PCR test is 92-100%.

## Comments:

- Positive results reflect only the detection of viral RNA and do not necessarily indicate presence of viable virus. A combination of Real-Time RT-PCR and clinical features could facilitate disease management. The positive result is considered if the gene targets cycle threshold (Ct) growth curves cross the threshold line within 40.00 cycles (<40.00 Ct). No criterion is recommended for report the Ct values of the gene targets or viral load according to the CDC guidelines. In addition, Ct values are not standardized by Real-Time RT-PCR platform nor have they been approved by FDA for use in clinical management.
- Negative results do not exclude possibility of COVID-19 and should not be used as the only criteria for a clinical decision and means that SARS-CoV-2 RNA was not present above the limit of detection. The negative results could be due to low viral load or point mutation in the sequence of the probe target region of the virus. Thus, negative results must be combined with clinical observation, patient history and epidemiological information for a final decision. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered.

## Test Interpretation:

- If two gene targets are positive: SARS-CoV-2 is detected.
- If two gene targets are negative: SARS-CoV-2 is not detected.
- If only one of the two gene targets is positive: the result is inconclusive, repeat sampling is recommended.

Checked by : Dr.Pouryasin

Sampling process was not done in Armin Lab. Therefore, the lab cannot take responsibility for the sampling procedure, storage, delivery and patient identification.

Lab Manager Dr. Sh. Sane