COVID-19 RT-qPCR Test

For use to aid detection of active virus and diagnosis of COVID-19 in individuals with associated symptoms, or for those with exposures to individuals with symptoms.

Methodology:

The COVID-19 RT-qPCR Test is a real-time reverse transcription polymerase chain reaction (RT-qPCR) test. This test uses two primers and probe sets to detect two regions in the SARS-CoV-2 Nucleocapsid (N) gene (N1 and N2) and one primer and probe set to detect human RNase P (RP) in a clinical sample.

Specimen and Transport:

Saliva is collected using the Oragene Dx OGD-510 device (DNA Genotek, FDA 510(k) # K141410). The collection kit is self-administrable, eliminating need for specialized training and minimizing risk due to close contact. After collection, the tube is shipped to Phosphorus using included packaging and envelope at ambient temperature.

Turnaround Time:

Within 72 hours from date of receipt at the laboratory

Performance:

- Limit of Detection: 5 viral copies / μL
- Sensitivity: 97.1%
- Specificity: 98.2%
- Positive Predictive Value: 97.1%
- Negative Predictive Value: 98.2%

Clinical & Stability Study:

- Clinical Performance: 91 Samples (35 positives and 57 negatives - confirmed by clinical assessment and qPCR testing by 3rd party EUA approved laboratories).
- Stability: 40 saliva samples analyzed at room temperature through live FedEx transport and through simulated temperatures between 22°C and 40°C for up to 56 hours.

More Information:

https://www.phosphorus.com/covid-19-rt-qpcr-test

This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by the authorized laboratory. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergence use of in vitro diagnostics 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.