VitalAxis COVID19 - Details

Component Results

Component	Your Value	Reference Range
SARS coronavirus 2-VITALAXIS	**Your Value** **Detected**	*Reference Range* *Not Detected*

Disclaimer :
Reference Range: NOT DETECTED
Test Information
The PRL SARS-CoV-2(COVID-19) test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The SARS-CoV-2 primer and probe set is designed to amplify and detect RNA from the SARS-CoV-2 in respiratory specimens from patients as
recommended for testing by public health authority guidelines. The assay employs the CDC-designed primer/probe sequences as included in the SARS-CoV-2 (2019-nCoV) CDC qPCR Probe Assay and listed below. SARS-CoV-2-specific sequences target two separate
regions of the viral nucleocapsid (N) gene. Also included is an internal control targeting the human RNase P (RP) gene. All three targets are detected in a single assay in multiplex, each with a unique fluorophore-quencher combination
Limitations:
1. The test was validated for use only with upper and lower respiratory specimens.
2. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole ba
sis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not
been determined.
3. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
4. A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the
specimen.
5. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely when prevalence of disease is high. False positive test results are more likely when prevalence is moderate to low.
6. If the virus mutates in the RT-PCR target region, SARS-CoV-2 may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false negative re
sult.
7. An interference study evaluating the effect of common cold medications was not performed.
8. Test performance can be affected because the epidemiology and pathology of disease caused by SARS-CoV-2 is not fully known. For example, clinicians and laboratories may not know the optimum types of specimens to collect, and

Component	Your Value	Reference Range

when during infection
these specimens are most likely to contain levels of virus that can be readily detected.
9. Detection of viral RNA may not indicate the presence of infectious virus or that SARS-CoV-2 is the causative agent for clinical symptoms.
10. The performance of this test has not been established for monitoring treatment of SARSCoV-2 infection.
11. The performance of this test has not been established for screening of blood or blood product for the presence of SARS-CoV-2.
12. This test cannot rule out diseases caused by other bacterial or viral pathogens.
This test was developed, and its performance characteristics determined by the Pandem
ic Response Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not
necessary. The test methodology has been validated in-house and the methodology as well as the validation data, reviewed by the Clinical Laboratory Evaluation Program of the New York State Department of Health. The validation data is available at the
Laboratory at the address below. The laboratory also participates in inter-laboratory testing under the auspices of the College of American Pathologists, in keeping with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). Therefore, this
test is used for clinical purposes. It should not be regarded as investigational or for research on this basis alone.

General Information

Ordered by Emelia Baah, NP

Collected on 01/23/2021 11:26 AM from Nares (Anterior Nares)

Resulted on 01/24/2021 8:50 AM

Result Status: Final result

This result was released by an automatic process. Your provider may not have reviewed this result yet. Please contact the ordering provider or your usual provider with any questions or concerns. When possible, we recommend using the Message My Doctor's Office function in MyChart to contact your provider's office.