CLINICAL BIOTECH LABORATORIES, INC.

Urgent
COVID-19 Testing Update

Biotech Clinical Laboratory has started performing a molecular diagnostic test for the determination of COVID-19 virus infection. This test, TaqPath COVID-19 Combo, became available from Thermo Fisher Scientific. We also have started performing a qualitative test for the detection of IgG antibodies to SARS-CoV-2 in serum on the Abbott Labs platform. Both were released by the FDA under the Emergency Use Authorization (EUA).

Test Name: COVID-19, PCR Test Code: 13995 CPT: 87635

The test is based on real-time reverse transcription polymerase chain reaction (RT-PCR) and intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

Results will be reported as ***Positive*** or ***Not detected***.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Not detected results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Non detected results must be combined with clinical observations, patient history, and epidemiological information.

Inconclusive results will be reported along with the comment to submit another specimen for testing.

Test Name: SARS-COV-2 IgG Test Code: 6032 CPT: 86769

The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CIMA) used for the qualitative detection of IgG antibodies to SARS-CoV-2 in serum on the ARCHITECT i System.

Results will be reported as ***Negative*** or ***Positive***

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status

This test was authorized by FDA under an Emergency Use Authorization (EUA) to be performed by laboratories that are CLIA certified to do high complexity testing.

For additional information or any questions contact Laboratory Supervisor Joe Khalifeh or Elena Dvorin, M.D. Technical Director at 248-912-1700