AvellinoCoV2

Patient Report

Patient Information and Requesting Institution

Patient Identification Number or Name:	MRN123456		
Physician Name:	Dr. ABCD	Sample ID Number:	COV12345
Clinic Name:	Clinic DCS	Date of Birth:	01/01/2000
Date Received:	3/8/2020	Sex:	M
Date Reported:	3/8/2020	Sample Collection Date:	3/7/2020

Test Description

Avellino SARS-CoV-2/COVID-19 Test uses Real-time Reverse Transcriptase (RT)-PCR assays for the presumptive in vitro qualitative detection of nucleic acid from SARS-CoV-2 virus in nasopharyngeal and oropharyngeal swabs collected from suspected individuals. The SARS-CoV-2/COVID-19 primer and probe sets are designed for the detection of SARS-like coronaviruses and for specific detection of the COVID-19 virus. This virus can cause life-threatening disease and condition, including severe respiratory diseases. Positive results are indicative of active infection but do not rule out bacterial infection or other viral infection. Negative results do not preclude the COVID-19 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. This test is for use under the Food and Drug Administration's Emergency Use Authorization.

Test Result

Test Name	Result	Interpretation
Avellino SARS-CoV-2/ COVID-19 Test	**Negative**	**If Positive**: indicative of active infection but do not rule out bacterial infection or other viral infections. **If Negative**: does not preclude the COVID-19 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Comment

These tests were developed, and their performance characteristics determined by Avellino Lab USA, Inc. They have been authorized by the FDA under the Emergency Use Authorization. This laboratory is regulated under CLIA as qualified to perform high-complexity testing. These tests are used for clinical purposes only. They should not be regarded as investigational or for research. A false negative result may occur if inadequate numbers of organisms are present in the specimen due to improper collection, transport or handling. RNA viruses in particular show substantial genetic variability. Although efforts were made to design real-time RT-PCR assays to conserved regions of the viral genomes, variability resulting in mismatches between the primers and probes and the target sequences can result in diminished assay performance and possible false negative results.

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