GENETIC ASSAYS
A Molecular Diagnostics Laboratory

CV-19 SARS-CoV-2 by RT-rPCR

GA Test Code	**2682**
Method	Reverse Transcriptase - Real-Time Polymerase Chain Reaction (RT-rPCR)
Specimens	**Nasopharyngeal Swab**: Use a swab with a synthetic tip (such as polyester or Dacron®) and a plastic or aluminum shaft. Do not use a calcium alginate or wood-shafted swab. Insert the swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Place swab in 1-2 mL universal transport medium or eswab viral transport media (liquid Amies). Specimen can be held up to 4 days at room temperature or 30 days frozen. **Other Samples**: Please contact GA for questions about other specimens.
Causes for Rejection	Calcium alginate or wood-shafted swab; time and/or temperature instructions not followed as specified; quantity not sufficient (QNS) for analysis.
Reference Range	Not Detected
Turnaround Time	Same or Next Day (may vary due to high demand)
CPT Code	87635 (rate of $100 applied for insurance payers - effective 5-18-2020)
HCPCS Code	U0003

Description

This test uses the CDC's Emergency Use Authorization (EUA) protocol, issued by the FDA, for the detection of SARS-CoV-2 (aka 2019-Novel Coronavirus). A high-throughput process of reverse transcription followed by real-time polymerase chain reaction is used for the in vitro qualitative detection of the virus in respiratory samples. Three primer and probe sets are used for detection: N1 and N2 are specific for SARS CoV-2 and N3 is for the universal detection of SARS-like coronaviruses. The human RNAse P gene is also tested to assess specimen quality.

Clinical Utility

A Detected result indicates that RNA from SARS-CoV-2 was detected and that the patient is considered infected with the virus and presumed to be contagious. A Not Detected (negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, it does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.