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	**Anterior nasal swab**: Using a flocked or spun polyester swab, insert the entire absorbent tip inside the nostril and firmly rotate the swab against the nasal wall at least 4 times. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with same swab. Specimen can be held up to 4 days ambient or 30 days frozen. **Nasopharyngeal Swab**: Use a swab with a synthetic tip (such as polyester or Dacron®) and a plastic or aluminum shaft. 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. **Sputum**: 10.0 (min 5.0) mL, ambient (24 hrs) or refrigerated (7 days) in sterile plastic leak-proof container. For best results, collect 3 consecutive early morning samples. Ship with cold pack. **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

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing. This test uses a high-throughput process of reverse transcription followed by real-time polymerase chain reaction for the in vitro qualitative detection of SARS-CoV-2 (aka 2019-Novel Coronavirus) in respiratory samples. Two primer and probe sets are used for detection: N1 and N2, both specific for SARS CoV-2. 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.