ID NOW™ COVID-19
Laboratory Procedure

For Use Under an Emergency Use Authorization (EUA) Only

1. Intended Use

ID NOW™ COVID-19 assay performed on the ID NOW™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider. Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW™ COVID-19 assay is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory samples during the acute phase of infection. 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. Testing facilities within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures history and the presence of clinical signs and symptoms consistent with COVID-19.

The ID NOW™ COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW™ Instrument. The ID NOW™ COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.