Methodology: Qualitative Nucleic Acid Amplification


Specimen Preparation: Nasopharyngeal swab: Place in viral transport media, Liquid Amies, or saline (minimum volume 1 mL). Place each specimen in an individually sealed bag.
Oropharyngeal or nasal swab: Place in viral transport media, Liquid Amies, or saline (minimum volume 1 mL). Or collect using the Aptima Multitest Swab Collection Kit. Place each specimen in an individually sealed bag. Also acceptable: Media that is equivalent to viral transport media or universal transport media.
Storage/Transport Temperature: Frozen
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 1 month

Interpretive Data: This test should be ordered for the detection of the 2019 novel coronavirus SARS-CoV-2 in individuals who meet SARS-CoV-2 clinical and/or epidemiological criteria.

The Coronavirus SARS-CoV-2 (COVID-19) by nucleic acid amplification test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA) for US laboratories certified under CLIA to perform high complexity tests. This test has not been FDA cleared or approved. In compliance with this authorization, please visit https://www.aruplab.com/infectious-disease/coronavirus for more information and to access the applicable information sheets.

If the result is Not Detected, this does not rule out the presence of PCR inhibitors in the patient specimen or assay specific nucleic acid in concentrations below the level of detection by the assay.

HOTLINE NOTE: There is a clinically significant charting name change associated with this test. Change the charting name for component 3002640, from SARS-CoV-2 by PCR to SARS-CoV-2 by NAA.