BioAgilytix Diagnostics

Detection of SARS-CoV-2 Viral RNA using the TaqPath COVID-19 Combo Kit Technical Brief

Specimen Type	One (1) Nasopharyngeal (NP) and/or Oropharyngeal (OP) swab collected in viral transport media (VTM), or universal (UTM) - must be collected to be compatible with PCR amplification.
Specimen Volume	2 mL
Collection	Should be performed by an individual trained in the collection of SARS-CoV-2 (COVID-19) respiratory swab samples following all current and applicable local and national guidelines for COVID-19 sample collection.
Minimum Volume	1 mL
Handling	Ship refrigerated on gel packs
Rejection Criteria	Specimens received at ambient temperature. Specimens clearly not VTM or UTM and not containing an NP or OP swab. Specimens outside of documented stability.
Stability	Refrigerated for 3 days.
Methodology	Real-time RT-PCR
Reference Range	Not Detected
Turnaround Time	3 Days
CPT Code	**87635** Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19], amplified probe technique
Clinical Significance	Use of this assay as an in vitro diagnostic (IVD) assay, performed under the FDA Emergency Use Authorization (EUA) is limited to laboratories certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) authorized to perform high complexity testing. This qualitative multiplex molecular assay is used for the identification of SARS-CoV-2 RNA in respiratory samples. SARS-CoV-2 is a highly infectious coronavirus and is the causative agent of the COVID-19 global pandemic of 2020. SARS-CoV-2 infections can range from asymptomatic through mild to severe symptoms and in some, patients' death. Positive results indicate the presence of SARS-CoV-2 viral RNA in the respiratory sample, generally present in acute phase of infection. Other diagnostic information and the patient's clinical history should be taken into consideration when determining the patient's infection status. A positive SARS-CoV-2 result does not rule out other infections, which may be the definitive cause of disease. A negative result does not preclude SARS-CoV-2 infection and this test should not be used as sole determinant

BioAgilytix Diagnostics

Detection of SARS-CoV-2 Viral RNA using the TaqPath COVID-19 Combo Kit Technical Brief

	for decisions on patient management. Currently all SARS-CoV-2 testing results must be reported to relevant local health authorities by the performing laboratory.
Principle	Multiplex real-time reverse transcription polymerase chain detection (RT-PCR) is used to assess qualitative detection of RNA from the SARS-CoV-2 virus within respiratory samples. Specifically, RNA is extracted from respiratory samples using MagMAX viral/pathogen nucleic acid isolation kit. Extracted RNA is reverse transcribed to cDNA and amplified/detected using the ThermoFisher TaqPath™ COVID-19 Combo Kit on an Applied Biosystems 7500 Fast Dx Real-Time PCR instrument. This assay contains probes to detect and amplify three SARS-CoV-2 specific target genes: ORF1ab, N gene, and S gene. The real-time data of fluorescent intensity increase are analyzed and interpreted by the Applied Biosystems™ COVID-19 Interpretative Software. This assay is being run under FDA Emergency Use Authorization (EUA) initially granted for this assay on 13 March 2020 and is inclusive of subsequent amendments. This testing is limited to laboratories certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity testing.