LABORATORY ALLIANCE of Central New York, LLC

Transcription Mediated Amplification Assay for SARS-CoV-2

Effective January 12, 2021, the Microbiology department at Laboratory Alliance of Central New York will be implementing the use of a new instrument platform and molecular assay for the detection of SARS-CoV-2 in nasopharyngeal specimens submitted to the laboratory in an appropriate viral transport medium. This new gene amplification test, called hybrid capture transcription mediated amplification (TMA), will complement the other SARS-CoV-2 PCR assays and increase the laboratory's capability for additional testing.

Clinical Significance

An outbreak of respiratory illness that was first documented in China in December of 2019 rapidly spread globally to produce a worldwide pandemic. As a result, a large number of molecular gene amplification assays were developed to accommodate the erroneous surge in laboratory testing. The increase in testing resulted in supply chain shortages throughout the country requiring laboratories to perform SAR-CoV-2 testing on several different instrument platforms, such as the one that is being implemented now at Laboratory Alliance.

Performance Characteristics

The clinical performance of the Aptima SARS-CoV-2 assay was evaluated in comparison to the Panther Fusion SARS-CoV-2 assay (Hologic, Inc.) using a panel of remnant clinical specimens. For the study, remnant clinical nasopharyngeal specimens were collected from US patients with signs and symptoms of respiratory infection. The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) was calculated in relation to the Panther Fusion assay as the reference result. The Aptima SARS-CoV-2 assay showed positive and negative agreements of 100% and 98.2%, respectively.

Test:	SAR-CoV-2
Test Code:	SRSCV
Method:	Hybrid Capture Transcription Mediated Amplification (TMA)
Specimen Requirement:	Nasopharyngeal Swab (NP) in Universal Transport Media (UTM) or Viral Transport Media (VTM) or Med Schenker (UTM). Also nasal wash or nasal aspirate acceptable.
Unacceptable Conditions:	Any swab other than Dacron or flocked swabs and any transport medium other than UTM or VTM.
Transport & Stability:	Transport nasopharyngeal specimens at room temperature. Specimens placed in transport medium following collection can be stored for 24 hours at 15-30°C or store specimens refrigerated at 2-8°C for up to 7 days.
Schedule of Testing:	Mon-Fri, 0800 - 1630
CPT Code:	U0003
Billing Code:	3010463

Please contact Dr. Paul Granato, Director of Microbiology at 315-263-9078, paulgranatophd@lacny.com or Mr. Russ Rawling, Manager of Microbiology, at 315-410-7060, russellrawling@lacny.com if you have any questions or concerns.

References:

1. Hologic Aptima® SARS-CoV-2 Assay (Panther® System), IFU
2. Centers for Disease Control