CLINICAL LABS OF HAWAII

SARS-CoV-2 (COVID-19)
NUCLEIC ACID AMPLIFICATION TESTING
June 29, 2020

CLH Test Code: **COV19P (4142)**

Test Name:

SARS-CoV-2 Molecular Testing

CPT Code: 87635 or U0003

Specimen type:

1) Nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swab immediately placed in viral transport media (VTM)

2) Nasopharyngeal wash/aspirate or nasal aspirate

Storage:
Refrigerate immediately upon collection

Estimated Turn-around time:
24 - 48 Hours

Testing performed:
7 days a week

Client Services

808.677.7998.....Oahu

866.281.6816 ..... Oahu (Toll free)

Visit our website at:

www.clinicallabs.com

On May 19, 2020, Clinical Laboratories of Hawaii (CLH) will begin testing for SARS-CoV-2, the virus that causes COVID-19, using a new high-throughput system, called the Aptima® SARS-CoV-2 Assay conducted on the Hologic Panther instrument. This test has received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) and is being implemented to support increasing demand. The new assay will be conducted in addition to our original assay using the Luminex ARIES system. With the increased test capacity, all specimens are planned to be analyzed in Hawaii, with our sister laboratory (Sonic Reference Laboratory) on the mainland acting as a backup. With local testing, the estimated test result time will be within 24 - 48 hours. Please know that our goal is to support all local testing needs. However, should there be a significant increase in demand due to a community cluster or outbreak, CLH will work with all healthcare providers to prioritize patient specimens based on healthcare guidelines.

The Aptima® assay is a nucleic acid amplification test (NAAT) that utilizes real time transcription mediated amplification technology and detects RNA from SARS-CoV-2, where a positive result indicates active infection. A negative test result, by itself, does not necessarily preclude SARS-CoV-2 infection, as such information must be combined with clinical observations, patient history, and epidemiological information for a diagnosis. This assay has been authorized for a variety of upper respiratory tract specimen types.

Test clinical performance (from assay product insert):*
The Positive Percent Agreement (PPA) (analogous to "sensitivity") and Negative Percent Agreement (NPA) (analogous to "specificity") were calculated in relation to a separate real time PCR-based NAAT as the reference result. Using patient samples, the Aptima SARS-CoV-2 assay showed a PPA and NPA of 100% and 98.2%, respectively.

Please coordinate with your healthcare provider for specimen collection sites. For assistance, please contact the CLH Client Services Department at (808) 677-7998. You may also visit our website at www.clinicallabs.com for additional information.

We also recommend that providers follow the guidelines from the Centers for Disease Control (CDC) and the Hawai'i Department of Health (HDOH).

Insurance coverage is based on determination of medical necessity. Healthcare providers and patients are advised to contact their insurance company directly for coverage eligibility.

Thank you for choosing Clinical Labs of Hawaii.

*https://www.fda.gov/media/138096/download