PDL TEST UPDATE:

COVID Saliva Test Sensitivity



May 19, 2021

COVID-19 (SARS-CoV-2)

Pacific Diagnostic Laboratories (PDL) now offers a **SALIVA COVID-19 (SARS-CoV-2), NAA** (LAB10941) in addition to our COVID-19 for nasopharyngeal and nasal source (LAB10789).

COVID-19 TEST SENSITIVITY: COLLECTION, SOURCE AND TEST PERFORMANCE

COVID-19 test sensitivity is dependent on a number of variables. The key areas of consideration include:

- The specimen collection process
- The source of the specimen
- The analyzer and reagent used to perform the testing.

<u>SPECIMEN COLLECTION PROCESS</u>: Studies have shown that close supervision of the collection in a Hospital or healthcare environment reduces variation with the collection of the specimen compared to other environments where supervision may vary such as airports and schools.

<u>SPECIMEN SOURCE</u>: The gold standard is a nasopharyngeal (NP) source for a COVID-19 specimen; however, this requires a trained healthcare provider to collect, some patients do not tolerate the NP collection process well, and the collection presents an aerosolization risk so PPE and facility considerations must be taken related to this type of collection. Anterior nasal source has a reduced risk of aerosolization during collection and can be done by a healthcare provider or be an observed self-collection. Similar to the NP collection, some patients may not tolerate this type of collection well. Saliva source is a good option when a nasopharyngeal or anterior nasal swab is problematic to collect such as pediatric patients, patients who do not tolerate nasal collections, and Individuals requiring frequent testing for surveillance. The saliva collection must be an observed collection to ensure specimen adequacy.

<u>TEST PERFORMANCE</u>: PDL tests saliva for COVID-19 using the Hologic Panther analyzer, which is one of the most sensitive Nucleic Acid Amplification Tests (NAATs) utilized nationally. The PDL evaluation demonstrated a 96.43% sensitivity for NP specimen collection versus a 96.00% sensitivity for saliva (collection done under close supervision). The evaluation was completed using specimens from hospital patients (not outpatient).

BACKGROUND INFORMATION

A recent meta-analysis (Journal of Molecular Diagnostics, Vol. 23, No., 3, March 2021) comparing the sensitivity of NP

COVID-19 Specimen Collection Method	Sensitivity
Hospital Collected Nasopharyngeal	96.43%
Hospital Collected Saliva (Close Supervision)	96.00%
Nasopharyngeal	94%
Varied Supervision Saliva	89%

specimens to saliva utilizing inpatient, outpatient clinic, airport, tent collection, etc. (varied supervision), demonstrated a 94% sensitivity for NP swabs and an 89% sensitivity for saliva, a 5% difference. This meta-analysis demonstrates the value of closely supervised saliva collections as opposed to varied supervision and was a key

factor in PDL's decision to accept only closely supervised saliva specimens.

Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html