



Molecular Pathology Report

Facility Information	Patient Information	Specimen Information
Facility Name: Inhealth Diagnostics, LLC	Name: Doe,John	Lab Accession Number:
Provider Name: Not Provided	DOB:	Date Collected:
NPI: N/A	Gender:	Date Received by Lab:
Address: 17742 Preston Road Ste.210 Dallas, TX 75252		Date Reported:
		Sample Type: Nasopharynx Swab

Detected Results Summary

Special Target	Results	Probe Detected
COVID-19 Coronavirus (SARS-CoV-2)	Detected	Positive

Inhealth COVID-19 Coronavirus (SARS-CoV-2) PCR (polymerase chain reaction) assay was designed, validated, and is intended for, medically indicated diagnostic testing, in symptomatic patients. The assay's PCR probes (Agena SCV-2-RUO Kit) target the SARSCoV-2 replicase complex (ORF 1 ab), spike (S), and nucleocapsid (N) genes. Healthcare providers of any person with a "Positive Result" for this assay, should IMMEDIATELY contact their Local and/or State Health Department(s), for consultation and guidance. Additional information on Coronavirus Disease 2019 (COVID-19) can be obtained from the CDC: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Inhealth Diagnostics Labs COVID-19 Coronavirus (SARS-CoV-2) Assay is authorized for use by the US FDA, under the following Emergency Use Authorization (EUA) approvals: EUA200354 (Inhealth Diagnostic Laboratories SARS-CoV-2 Assay), EUA200010 (Agena SCV-2-RUO Kit).

Tested Assay Results

All tested microbe-related results (see below) are **NOT DETECTED (NEGATIVE)**, unless indicated as **DETECTED (POSITIVE)**, in above **Detected Results Summary** section.

COVID-19 Coronavirus (SARS-CoV-2)

Analyzed By: Jaime De Leon

Date: 08/07/2020

Processing and Detection Methodology: DNA/RNA extraction from the sample was performed. Reverse transcriptase polymerase chain reaction (Agena qPCR) was utilized for detection. *Estimated copies of target nucleic acid per mL, are validated via known-concentration standard bacterial culture material and/ or synthetic plasmid material.

Testing performed at Inhealth Diagnostic, LLC. (CLIA#45D2117218) Medical Director: Chester Gwinn III, M.D. This test was developed and its performance characteristics determined by Inhealth Diagnostics, LLC It has not been cleared or approved by the FDA. However, such approval/ clearance is not required, as the laboratory is regulated and qualified under CLIA to perform high-complexity testing. This test is used for clinical purposes, and should not be regarded as investigational or for research.