

## **Stratus Diagnostics**

12300 Ford Rd, Suite 403B Farmers Branch, TX 75234 Phone: (888) 318 - 9984

## **Final Report**

Organization: StratusDX Software Location: Farmers Branch

Patient: Jeremey Bond DOB: 01/01/1988 Accession: 1027

 Patient ID: 1155226
 Age: 32
 Provider: Do Not Bill Testing

 Home Phone: (214) 222 - 7711
 Gender: Male
 Collected: 09/16/2020 08:53 AM

Test Name Result Reference Interval Flag

## COVID-19 (SARS-CoV-2 RNA) PCR

SAR-COV-2 is a real time RT-PCR assay. It is a Laboratory Developed Test (LDT) validated by Lexar Labs(CLIA#45D2190535). Validationdemonstrated the assay has acceptable characteristics to detect COVID-19 from human clinical respiratory specimens. Independent review ofthis assay by the FDA is not final at this time but the LDT test has been submitted to the FDA under Emergency Use Authorization (EUA)guidelines. Positive (Detected) results are indicative of active infection with SARS-CoV-2. A positive result does not rule out bacterial infectionor co-infection with otherviruses. Detection of SARS-CoV-2 viral RNA may not indicate that SARS-CoV-2 is the causative agent for clinicalsymptoms. Negative (Not Detected) results do not exclude infection caused by SARS-CoV-2 and should not be used as the sole basis fortreatment or other patient management decisions. Positive and negative predictive values of testing are highly dependent on the amount of original material in the sample. Improper specimen collection and handling, sequence variability underlying assay primers and/or probes, or the presence of organisms in quantities less than the limit of detection of the assay may lead to false negative results. The SARS-CoV-2 test isintended for the presumptive qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens. The results must becorrelated with clinical presentation and evaluated in the context of other laboratory and epidemiological data

COVID-19 (SARS-CoV-2 RNA) PCR POSITIVE POSITIVE

Reviewed By: ts, Results Finalized on 09/16/2020 08:54 AM

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Medical Director: Eldon R. Jupe, PhD, HCLD/CC(ABB)

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