



Testing Laboratory

5635 W. 96th Street Suite 300 Indianapolis, IN 46278 Phone: (317) 733 - 9454 Final Report

Organization: Key Apex Location: Aria Test

Patient: Test Patient
Patient ID: TP0420

Home Phone: (317) 733 - 9454

DOB: 04/28/2020

Age: 0 Gender: Male Accession: 221862 Provider: TEST DOCTOR

Collected: 04/28/2020 05:51 PM

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 Mako Medical (CLIA#34D2141858). Validation demonstrated the assay has acceptable characteristics to detect COVID-19 from human clinical respiratory specimens. Independent review of this 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 infection or co-infection with otherviruses. Detection of SARS-CoV-2 viral RNA may not indicate that SARS-CoV-2 is the causative agent for clinical symptoms. Negative (Not Detected) results do not exclude infection caused by SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions. Positive and negative predictive values of testing are highly dependent on the amount of viral 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 is intended for the presumptive qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens. The results must be correlated with clinical presentation and evaluated in the context of other laboratory and epidemiological data.

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

Negative

Negative

Reviewed By: RB on 04/28/2020 05:51 PM

CLIA: 15D2096834

Printed: 04/28/2020 05:57 PM

Medical Director: : Dr. P.L. Reddy, Ph.D, DABCC,

ASCP

Accession: 221862

Page 1 of 1



Patient: Test Patient

Patient ID: TP0420



Testing Laboratory

5635 W. 96th Street Suite 300 Indianapolis, IN 46278

Phone: (317) 733 - 9454

DOB: 04/28/2020

Age: 0 Gender: Male Accession: 221861 Provider: TEST DOCTOR

Collected: 04/28/2020 05:50 PM

Final Report

Organization: Key Apex

Location: Aria Test

Result **Reference Interval Test Name** Flag

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

Home Phone: (317) 733 - 9454

SAR-COV-2 is a real time RT-PCR assay. It is a Laboratory Developed Test (LDT) validated by Mako Medical (CLIA#34D2141858). Validation demonstrated the assay has acceptable characteristics to detect COVID-19 from human clinical respiratory specimens. Independent review of this 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 infection or co-infection with otherviruses. Detection of SARS-CoV-2 viral RNA may not indicate that SARS-CoV-2 is the causative agent for clinical symptoms. Negative (Not Detected) results do not exclude infection caused by SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions. Positive and negative predictive values of testing are highly dependent on the amount of viral 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 is intended for the presumptive qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens. The results must be correlated 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: RB on 04/28/2020 05:51 PM

CLIA: 15D2096834

Printed: 04/28/2020 05:57 PM

Medical Director: : Dr. P.L. Reddy, Ph.D, DABCC,

ASCP

Accession: 221861 Page 1 of 1