

DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

Date: 5/21/2020

From: Robert D. Nerenz, PhD, Jacqueline A. Hubbard, PhD, Mark A. Cervinski, PhD
Medical Directors of Clinical Chemistry

RE: SARS-CoV-2 Serology Testing

SARS-CoV-2 (COVID-19) antibody testing will be performed in the DHMC clinical laboratory beginning on Thursday, May 21st using eDH test code LAB4238.

This should not be considered a diagnostic test. In typical SARS-CoV-2 infection, antibodies are not detectable until at least 2-4 weeks after the onset of symptoms.

The selected assay is manufactured by Roche Diagnostics using a total antibody format with selectivity for IgG antibodies to SARS-CoV-2. Results will be reported as “Detected” or “Not Detected”. In studies performed by Roche Diagnostics, the assay did not cross-react with other related pathogens and demonstrated a specificity of 99.8%. In individuals with PCR-confirmed infection, sensitivity at 14 days post-PCR was 100%. Internal studies performed by the DHMC clinical laboratory confirmed these findings.

Interpretive Statements:

- Results cannot be used to diagnose acute SARS-CoV-2.
- A ‘Not Detected’ result does not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic test to SARS-CoV-2 should be considered for individuals with symptoms of active SARS-CoV-2 infection.
- A ‘Detected’ result in the context of appropriate clinical findings as defined by CDC suggests exposure to SARS-CoV-2. However, a ‘Detected’ result cannot be interpreted as conclusive evidence of protective immunity to the SARS-CoV-2 virus. Detection may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

The preferred specimen type is lithium heparin plasma (green top tube). Testing will be available seven days a week with an expected turnaround time of one hour from specimen receipt in the DHMC clinical laboratory. As “Detected” results are not considered critical values, ordering physicians will not be notified via phone.

For questions concerning this memo, please contact Dr. Nerenz at (603) 650-7171 or robert.d.nerenz@hitchcock.org