



Memorandum - Immunology #3

To: UNC Health System Attending and Faculty Practice Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads, and Supervisors

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Date: April 27, 2020

Subject: SARS-CoV-2 IgG Antibody Testing

Effective April 28, 2020 the Immunology Laboratory will offer SARS-CoV-2 (COVID-19) IgG antibody testing on the Abbott Architect microparticle chemiluminescent platform. This assay detects IgG antibodies to a recombinant nucleocapsid protein of the SARS-CoV-2 virus.

The Abbot SARS-CoV-2 IgG test has Emergency Use Authorization by the FDA as of April 26, 2020. The manufacturer's performance specifications indicate a negative percent agreement of 99.63% based on analysis of 997 pre-COVID-19 outbreak samples and 73 samples from patients with other respiratory illnesses who tested negative by SARS-CoV-2 PCR. Positive percent agreement (PPA), based on testing of 122 samples from 31 patients who tested positive by a SARS-CoV-2 PCR assay, varies by the time after disease onset. PPA for samples collected three to seven days after onset was 25%. The PPA on samples collected eight to fourteen days after onset was 86.36% and 100% for samples collected greater than or equal to 14 days after onset.

The following comments will be appended to all results:

- This assay is for in vitro diagnostic use under the FDA Emergency Use Authorization
- This test detects IgG antibodies to a recombinant SARS-CoV-2 nucleocapsid protein
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals.
- Positive results do not rule out the potential for re-infection or indicate immunity to SARS-CoV-2 infection.
- This test is not recommended for samples collected less than eight days after onset due to low sensitivity in the first week after onset.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

The test can be ordered by COVID IgG (LAB19414). The test will be run daily (M-F) with a 24 to 72 hour turn-around time for results.

Please address questions to the Immunology laboratory at 984-974-1815.