



Memorandum – Immunology #7

To: UNCHCS Attending Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads, and Supervisors

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Date: February 8, 2021

Subject: SARS-CoV-2 IgG Antibody Testing

The Clinical Immunology Laboratory is providing an additional testing option for SARS-CoV-2 IgG antibody. Effective February 10, 2021 the laboratory will offer SARS-CoV-2 (COVID-19) IgG antibody testing using the Diasorin Liaison® SARS-CoV-2 S1/S2 IgG assay. This assay detects IgG antibodies to the spike protein of SARS-CoV-2. This test is offered in addition to the Abbott SARS-CoV-2 IgG test that detects IgG antibodies to the nucleocapsid protein of SARS-CoV-2.

The Diasorin SARS-CoV-2 IgG test is performed under Emergency Use Authorization by the FDA. The manufacturer's performance specifications indicate a negative percent agreement of 99.3% based on analysis of 1090 samples expected to be negative for SARS-CoV-2 antibodies. Positive percent agreement (PPA), based on testing of 76 hospitalized patients who tested positive by a SARS-CoV-2 PCR assay, varies by the time after disease onset. PPA for samples collected less than five days after onset was 25%. The PPA on samples collected six to fourteen days after onset was 89.8% and 97.56% for samples collected greater than or equal to fifteen days after onset.

The following comments will be appended to Diasorin IgG results:

- This assay is for in vitro diagnostic use under the FDA Emergency Use Authorization

- This test detects IgG antibodies to SARS-CoV-2 S1/S2 “spike” protein
- Negative results do 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 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 six 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.
- The laboratory has verified that this test detects antibodies induced by COVID-19 spike vaccines.
- **A positive test for anti-spike protein antibodies in a vaccine recipient does NOT confirm immunity to SARS-CoV-2 infection.**

Ordering Instructions:

Clinicians ordering directly in EPIC should order COVID IgG - LAB19414 and answer the accompanying vaccination question accordingly.

Clinicians and clinics not ordering directly in EPIC, using paper requisitions, should order COVID IgG (**LAB19414**) for diagnostic purposes (**Pre-Vaccine** patients) and COVID IgG Spike Protein (**LAB21125**) for **POST-Vaccine** patients.

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