Memorandum – Immunology #11

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

From: John Schmitz, Ph.D.
Director, Immunology/Histocompatibility and Immunogenetics Laboratories

Eric Weimer, Ph.D.
Associate Director, Immunology/Histocompatibility and Immunogenetics Laboratories

Herbert C. Whinna, M.D., Ph.D.
Medical Director, McLendon Clinical Laboratories

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Subject: Semi-Quantitative SARS-CoV-2 Trimeric S IgG Antibody Testing

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Effective 1/31/2022 the Immunology Laboratory will offer SARS-CoV-2 (COVID-19) Semi-Quantitative Trimeric S IgG antibody testing on the DiaSorin Liaison microparticle chemiluminescent platform in replacement of the SARS-Cov-2 Ig S1/S2 microparticle chemiluminescent assay. This assay detects IgG antibodies to a recombinant trimeric spike protein of the SARS-CoV-2 virus.

The DiaSorin SARS-CoV-2 IgG test has Emergency Use Authorization by the FDA as of May 20, 2021. The manufacturer's performance specifications indicate a negative percent agreement of 99.5% (95% CI of 99.0% - 99.7%) based on analysis of 1,899 samples from patients who tested negative by SARS-CoV-2 PCR. The positive percent agreement (PPA) was based on testing of 70 samples from patients who tested positive by a SARS-CoV-2 PCR assay, varying by the time after disease onset. PPA for samples collected zero to seven days after onset was 21.4% (95% CI of 7.6% - 47.6%). The PPA on samples collected eight to fourteen days after onset was 70.8% (95% CI of 50.8% - 85.1%) and 96.9% (95% CI of 84.3% - 99.4%) for samples collected greater

than or equal to 15 days after onset. The limit of detection (LOD) for the assay was found to be 0.717 AU/mL and the limit of quantitation (LOQ) was found to be 1.63 AU/mL.

Values <13 AU/ml are reported as negative
Values ≥13 AU/ml are reported as positive

This test is not recommended for samples collected less than seven days after disease onset due to low sensitivity in the first week after onset. This test detects antibodies induced by currently approved vaccines as well as by infection with SARS-CoV-2.

The test can be ordered as LAB21125. The test will be run daily.

Please note that an alternative test that detects antibodies to the SARS-CoV-2 nucleocapsid antigen is available (LAB19414). The nucleocapsid antibody test does not detect vaccine induced antibody.

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