

To: Penn Medicine Physicians and Staff
Date: March 1, 2021

From: Eline T. Luning Prak, MD, PhD
Joyce Gonzalez, BS, M (ASCP)
Andrew Gaano, BS

Re: **SARS-CoV-2 Serology, antibodies, immunoassay (RBD assessment)**

The HUP Immunology Laboratory is now offering the SARS-CoV-2 immunoassay RBD (Receptor Binding Domain) assessment. This is a laboratory-developed enzyme-linked immunosorbent assay that separately detects IgG and IgA antibodies that bind RBD, which is a region in the viral spike protein that is important for viral entry into cells. The assay will be performed on the DYNEX DSX instrument on human serum. The assay separately measures IgG antibodies, which, based on in-house testing, are correlated with virus neutralization titer, and IgA antibodies, which are associated with a mucosal immune response.

*The primary use of the HUP SARS-CoV-2 RBD assay is to determine if an immunocompromised person has mounted a potentially protective immune response to either the SARS-CoV-2 virus or to a spike/RBD vaccine. If this assay is being used to evaluate the immune response to either the Moderna or the Pfizer RBD mRNA vaccine, we recommend testing 1-2 weeks after the administration of the second dose. This assay is **not** recommended for routine monitoring of antibody responses in immunocompetent individuals. For the evaluation of prior viral exposure, we recommend using the COVID-19 (SARS-CoV-2) Antibodies assay (Abbott Diagnostics Nucleocapsid IgG), as this assay measures antibodies that bind to a different protein from the spike/RBD. Serologic testing is not suitable for evaluating active infection with SARS-CoV-2.*

Ordering Information:

In EPIC: **SARS-CoV-2 serology, antibodies, immunoassay (RBD assessment)**

Collection: serum separator tube

Two assays will be performed and reported SARS-CoV-2 RBD, IgA and SARS-CoV-2 RBD, IgG:

SARS-CoV-2 RBD IgG:

NEGATIVE: (≤ 0.300 AU)

EQUIVOCAL: (0.301 AU- 0.699 AU)

POSITIVE: (≥ 0.700 AU)

SARS-CoV-2 RBD IgA:

NEGATIVE: (≤ 0.250 AU)

EQUIVOCAL: (0.251-0.499 AU)

POSITIVE: (≥ 0.500 AU)

We thank our colleagues, Drs. David Allman, Dan Herman, Ping Wang, Charlene Bierl, Paul Bates, Malek Kamoun, Mike Feldman and Scott Hensley, for their assistance in standing up these assays.

For clinical questions related to this change, please contact the Immunology Resident at 215-980-9871.

For questions regarding research studies or test interpretation, please contact Dr. Luning Prak (luning@penmedicine.upenn.edu). For operational questions related to this change, please contact Joyce Gonzalez at Joyce.Gonzalez@penmedicine.upenn.edu or 215-662-6023.