DATE: April 30th, 2020
TO: UCM Medical Staff, Housestaff, Patient Care Centers, and Outpatient Clinics
FROM: Kathleen G. Beavis, MD, Medical Director, Microbiology and Immunology Laboratory
Vera Tesic, MD, MS, Associate Medical Director, Microbiology and Immunology Lab.
Scott Matushek, Manager, Microbiology and Immunology Laboratory
RE: Testing for SARS-CoV-2 Antibodies (COVID-19 IgA and IgG serology panel)

Effective immediately, the Clinical Microbiology and Immunology laboratory will test for SARS-CoV-2 antibodies using the EUROIMMUN enzyme-linked immunosorbent assay (ELISA) that provides semi-quantitative in vitro determination of IgA and IgG antibodies.

The clinical value of the SARS-CoV-2 antibody test has not been fully demonstrated. It is not yet known how to interpret a positive result, or if a positive result serves as an indicator of protective or sustained immunity. At this time, available serological testing can not be used to inform infection control practices, including recommendations for physical distancing, personal protective equipment, or clearance to return to work.

Specimen requirements and ordering information:

Test name	Epic Order Code	Specimen
SARS-CoV-2 Antibodies	COVDAB	Test is performed on serum. Collect 5 mL blood in a red-top tube. The specimen must be refrigerated within 8 hours of collection.

Test information:

Blood specimens were collected from patients who were positive for SARS-CoV-2 by PCR:

Time from positive SARS-CoV-2 PCR	Within 2 days	More than 2 days
IgA positive	28/38 (74%)	29/31 (94%)

Time from positive SARS-CoV-2 PCR	Within 4 days	More than 4 days
IgG positive	14/41 (34%)	28/28 (100%)

Specimens from twenty-nine patients previously positive for a Coronavirus endemic to humans (HKU1, NL63, CV229E, and OC43) were tested and minimal cross-reactivity was seen.

Turnaround Time

Testing will be performed twice a week.

Interpretation

Results for both IgG and IgA are reported and interpreted as follows:

- < 0.8 Negative
- ≥ 0.8 to ≤1.0 Borderline Positive
- ≥ 1.1 Positive

Additional Information

This test has received the CE mark and has not been reviewed by the FDA. FDA clearance or approval is not currently required for clinical use; however, the FDA requires that the following be appended to results:

"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. 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 assay should be considered to rule out infection in these individuals. Positive results may be due to past or present infection with common non-SARS-CoV-2 human coronavirus strains, including types HKU1, NL63, OC43, or 229E."

If you have any questions regarding antibody testing, please call Microbiology at (773) 702-6133, or Ana Abeleda, Chief Medical Technologist, at (773) 795-3807 or AnaPrecy.Abeleda@uchospitals.edu.