THE UNIVERSITY OF CHICAGO MEDICINE & BIOLOGICAL SCIENCES

DATE: May 28th, 2020
TO: UCM Medical Staff, Housestaff, Nursing Staff, Patient Care Centers, and Outpatient Clinics
FROM: KT Jerry Yeo, PhD, DABCC, FAACC, Medical Director, Clinical Chemistry Laboratories
Xander van Wijk, PhD, DABCC, Assistant Medical Director, Clinical Chemistry Laboratories
RE: SARS-CoV-2 Total Antibodies Roche Automated Test

Effective **May 28th, 2020**, the Clinical Chemistry Laboratories will implement the SARS-CoV-2 total antibodies using the Roche Elecsys double-antigen, sandwich electrochemiluminescent assay. This assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of total antibodies (IgG, IgA, and IgM) against SARS-CoV-2. Results will be reported as positive or negative. With the implementation of this Roche assay, the EuroImmun Covid-19 IgA and IgG test will be **discontinued** by the Microbiology Laboratory. Currently there is no known advantage of assays whether they test for IgG, IgM or total antibody[1].

Specimen requirements and Ordering information:

Test Name	Epic Order Code	Specimen
SARS-CoV-2 Total Antibodies	COVABT	Serum preferred. Collect 5 ml. blood in a gold serum separator tube (SST). Mint-green PST, EDTA tube acceptable. Separate serum or plasma from blood ASAP or within 2 hrs of collection.
Unacceptable conditions		Grossly hemolyzed, icteric or severely lipemic specimens
Storage conditions		Refrigerated:1 week; Frozen: 1 month.

Test Information:
Roche's package insert indicates the following:

Time from positive SARS-CoV-2 PCR	0-6 days	7-13 days	≥14 days
Clinical Sensitivity % (95% CI)	65.5 (56.1-74.1) n=116	88.1 (77.1-95.1) n=59	100 (88.1-100) n=29

- Using 39 positive SARS-CoV-2 PCR samples (≥14 days post PCR+) and 40 pre-pandemic samples we have independently verified a clinical sensitivity and specificity of 100%.
- We observed **no** cross-reactivity in the Roche anti-SARS-CoV-2 assay with:
  - 26 samples with common coronavirus strains (HKU1, NL63, CV299E and OC43) and RSV
  - 20 samples with positive HIV serologies, 15 samples with positive HepB Ab, 17 samples with positive HCV Ab

Availability/TAT:
This is a fully automated test and will be available 24/7.

Interpretation:
- Cutoff Index of <1.0, Negative
- Cutoff Index of ≥1.0, Positive
- **No information will be available on Immunoglobulins subtypes for positive samples**

If you have any questions, please contact either of us by email at jyeo@bsd.uchicago.edu, xvanwijk@bsd.uchicago.edu, or Sarah Groboske, Laboratory Manager, in the Clinical Chemistry Laboratories at 773-702-1318.

Additional Information:

The Roche Elecsys Anti-SARS-CoV-2 antibody test has not received US FDA approval.
It has received US FDA Emergency Use Authorization (EUA) on May 3, 2020 for the qualitative detection of antibodies to SARS-CoV-2 in human serum and plasma. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Currently it is unknown how long antibodies persist following infection or if the presence of antibodies confers protective immunity. This assay should not be used solely to diagnose or exclude acute SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection, particularly in individuals 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 occasionally be due to prior or present infection with non-SARS-CoV-2 coronavirus strains, such as HKU1, NL63, OC43, or 229E.

Reference

1. Interim Guidelines for Covid-19 Antibody Testing, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html