THE UNIVERSITY OF CHICAGO MEDICINE & BIOLOGICAL SCIENCES

DATE: February 17th, 2021
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, FAACC, Assistant Medical Director, Clinical Chemistry Laboratories
RE: Roche Anti-SARS-CoV-2 Spike (S) Antibodies Test

Effective **Feb 17th, 2021**, the Clinical Chemistry Laboratories will implement a **new, qualitative and semi-quantitative assay** for the detection of antibodies to the SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human serum and plasma. This assay uses a double-antigen sandwich principle and captures total antibodies (IgG, IgA and IgM) to the S-RBD protein. Results will be reported as U/ml with a positive of negative denotation. This 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. With this implementation, the previous anti-SARS-CoV-2 nucleocapsid (N) Ab test will be **discontinued**.

Specimen requirements and Ordering Information:

Test Name	Epic Order Code	Specimen
Anti-SARS-CoV-2 Spike Antibodies	**COVSPK**	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 samples.
Storage Conditions		Refrigerated: 1 week; Frozen: 1 month
Availability		This is a fully automated test and is available 24/7.

Interpretation:

- Less than 0.8 U/ml; Negative
- Equal or greater than 0.8 U/ml; Positive
- **No information is available on Immunoglobulins subtypes for positive samples**

Notes:

- The presence of anti-SARS-CoV-2 spike antibodies detects humoral responses arising from natural Covid-19 infection as well as recent vaccination (Pfizer or Moderna vaccine).
- The anti-SARS-CoV-2 antibody test does not differentiate between these humoral responses.
- Routine testing for antibody response after vaccination is not recommended.

If you have any questions, please contact either of us by email at jyeo@bsd.uchicago.edu or xvanwijk@bsd.uchicago.edu.

Limitations and 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 December 2, 2020 for the qualitative detection of spike antibodies to SARS-CoV-2 in human serum and plasma.
- This assay should not be used solely to diagnose or exclude acute SARS-CoV-2 infection.
- Results are for the detection of SARS-CoV-2 antibodies which are generally detectable in blood several days after initial infection.
- The Roche package insert indicates a sensitivity of 96.6 % (95% confidence interval of 93.35-98.51%) in individuals after 15 days of positive PCR results.
- The duration of time the antibodies are present post-infection is not well characterized.
- Negative results do not rule out SARS-CoV-2 infection. If acute infection is suspected, follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals.
- False positive results for this assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Reference

Roche Elecsys Anti-SARS-CoV-2 package insert.
https://diagnostics.roche.com/us/en/products/params/elecsys-anti-sars-cov-2-s.html