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 or 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:**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Epic Order Code</th>
<th>Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-SARS-CoV-2 Spike Antibodies</td>
<td>COVSPK</td>
<td>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.</td>
</tr>
<tr>
<td>Unacceptable Conditions</td>
<td></td>
<td>Grossly hemolyzed, icteric or severely lipemic samples.</td>
</tr>
<tr>
<td>Storage Conditions</td>
<td></td>
<td>Refrigerated: 1 week; Frozen: 1 month</td>
</tr>
<tr>
<td>Availability</td>
<td></td>
<td>This is a fully automated test and is available 24/7.</td>
</tr>
</tbody>
</table>

**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.
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.