Technical Bulletin

Serology Tests for SARS-CoV-2 (COVID-19) Expands

TO: Medical Staff and Clients

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SUBJECT: FDA EUA-approved tests for SARS-CoV-2 (COVID-19) available at DLS includes total antibody

Effective May 26, 2020, DLS will begin performing the Roche Elecsys Anti-SARS-CoV-2, which is an FDA Emergency Use Authorization (EUA) approved test for SARS-CoV-2 (COVID-19) total immunoglobulin (antibody) - **DLS order code 7203**. This will be the default antibody test because it is expected to be a more sensitive indicator of mature antibody response without sacrificing specificity. Venipuncture is available at all DLS sites for **ASYMPTOMATIC** patients. The Abbott IgG test is still available (see Technical Bulletin dated May13, 2020); however, it will only be performed if specifically requested.

In an April 18, 2020 FDA Letter to Health Care Providers, serology should be used for evidence of **past infection** and NOT for diagnosis – especially IgM because "IgM antibodies may not develop early, or at all, in infected patients." A possible exception to this is seroconversion from negative to positive in acute and convalescent serum, respectively.

FDA also now requires the performance of non-EUA tests in a laboratory certified by CMS to perform high complexity testing in accordance with the federal Clinical Laboratory Improvement Amendments. It is no longer allowed for providers to perform these tests.

Some reminders:

- Testing for active infection should be with a molecular diagnostic assay. A single serum negative result does not rule out the possibility of SARS-CoV-2 infection.
- Antibody tests should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to assess infection or immune status.
- Positive results indicate past infection with SARS-COV-2; Negative results indicate no previous infection.
- Antibody usually forms around 8-14 days after onset of symptoms; it's unclear how long antibody lasts.
- Patients with conditions such as autoimmunity, immunocompromised, HIV, etc. have not been evaluated.
- It is not yet known if detected antibody signifies immunity - partial or complete.
- Results should NOT be used to make decisions such as return to work/school, to discontinue personal protective equipment, or to discontinue social distancing measures.

Performance of all EUA serology tests is posted on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.

To diagnose active SARS-CoV-2 infection, order the molecular diagnostic test: **DLS order code 7179**.

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