Technical Bulletin

Serology Tests for SARS-CoV-2 (COVID-19) Now Includes Antibody against Spike Protein

TO: Medical Staff and Clients

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SUBJECT: New serology test for SARS-CoV-2 (COVID-19) antibody against spike protein available at DLS

On May 26, 2020 DLS began performing the FDA Emergency Use Authorization (EUA) approved Roche Elecsys Anti-SARS-CoV-2 which detects total immunoglobulin (antibody) to **viral nucleocapsid (NC) protein** (DLS order code 7203). Beginning February 22, 2021, DLS is pleased to add the semi-quantitative Roche Elecsys Anti-SARS-CoV-2 S that detects total antibody to **viral spike (S) protein** (DLS order code 7681). Recently approved mRNA vaccines utilize expression of spike protein as the immunogen. Antibody to spike protein has virus neutralization characteristics *in vitro*.

This is a semi-quantitative assay, so a number will be included as part of the result. A specimen is considered positive if the value exceeds 0.8 U/ml and the linear range extends to >250 U/ml. There is no accepted international unit thus far and it is not yet known what level confers protection, so the numerical value will not come with an interpretation.

Although **not** included in the Instructions for Use (IFU) for either antibody tests or vaccines, it is reasonable to expect that most people that had an infection would develop antibody to both NC and S proteins whereas those that were vaccinated would develop antibody to only the S protein. To date there is not enough data to claim that a positive result signifies protection, so other preventative measures such as distancing, hand washing, and face coverings are still necessary.

Venipuncture is available at all DLS site for **ASYMPTOMATIC** patients. Serology should be used for evidence of **past exposure** and NOT for diagnosis. IgM is not helpful because IgM antibodies may not develop early, or at all, in infected patients. Some reminders:

- Testing for active infection should be with a molecular diagnostic assay (**DLS order code 7179**).
- 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 exposure to virus and/or vaccine, depending on the antibody pattern; Negative results indicate no previous exposure or a lack of an antibody response.
- Antibody usually forms around 8-14 days after onset of symptoms or exposure; it's unclear how long antibody lasts.
- Patients with conditions such as autoimmunity, immunocompromised, HIV, etc. may have different responses.
- It is not yet known if detected antibody signifies immunity - partial or complete.
- Serology results should NOT be used to make decisions such as discontinuing personal protective equipment, hand hygiene, or physical distancing.

Performance of all EUA tests is posted on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

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