Laboratory Bulletin – April 6, 2020

SARS-CoV-2 virus IgG and IgM Antibody Test

Dear Customer:

This bulletin describes the regulatory status of CoreMedica regarding our SARS-CoV-2 virus IgG and IgM antibody test. CoreMedica is under the regulatory jurisdiction of the U.S. Department of Health and Human Services who enforces the Clinical Laboratory Improvement Amendments (CLIA) program. Any organization must have a CLIA certificate in order to provide clinical laboratory services in the United States. The CLIA program is administrated by the Centers of Medicare and Medicaid (CMS), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

Our complete test system (self-collection to analysis) has been scientifically validated and approved in order to analyze and report findings on human specimens under the CLIA program. Our CLIA certificate means CoreMedica has met all federal and state requirements for operating a clinical laboratory in our chosen specialty. CoreMedica is also accredited by the College of American Pathologist (CAP). The Centers for Medicare and Medicaid Services granted the CAP Laboratory Accreditation Program deeming authority to inspect and validate all activities performed by accredited laboratories. CAP is also recognized by the federal government as being equal to or more stringent than the government's own inspection program.

Recently, CoreMedica has implemented a simple, easy-to-use, capillary blood self-collection and transport kit for professional analysis of SARS-CoV-2 virus IgG and IgM antibodies. The capillary specimen can be collected any time and practically anywhere and with no additional requirements. As it does NOT require professional collection or self-collection under the supervision of a healthcare professional, it does not require any additional FDA approval prior to release.

Our regulatory status, in the context of SARS-CoV-2 antibody testing, is summarized as follows:

1. Under the FDA Convenience Kits Guidance (May 20, 1997), our DROP™ capillary blood self-collection and transport kit does NOT require an FDA 510k Premarket Approval. Under Clinical Chemistry and Toxicology, our offering is a Blood Collection Kit (Non-sterile and not for HIV testing).

2. The HemaSpot-SE Blood Collection and Transport Device is listed with the FDA as a Class I device (general controls), Product Code: NNK, and under 21 CFR 864.3250. This device is exempt from the premarket notification and does not require FDA approval.

3. The reagent(s) for our SARS-CoV-2 virus IgG and IgM antibody test are already approved by the FDA as an EUA.
    a. Serology IgG Analysis using KT-1032 EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit; Product Code: QKO, and Class: EUA-Emergency Use Authorization.
    b. IgM Analysis by COVID-19 IgM-IgG Rapid Test; Product Code: QKO, and Class: EUA-Emergency Use Authorization.

4. CoreMedica is certified as a “High Complexity” laboratory (CLIA # 26D2013888).

5. CoreMedica’s SARS-CoV-2 virus IgG and IgM antibody has been approved by the College of American Pathologist and listed in our activity menu as nCoV 2019 antibodies - Special Chemistry. (CAP # 7537862)

6. CoreMedica has met all requirements to begin processing capillary blood samples and reporting our analysis under our item number (COVID-19) to health awareness participants.

Additionally, CoreMedica has elected (though not required) to formally submit our application as a kit manufacturer for in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) as recommended. Our submission is led by our regulatory consultant group, Bring Life Sciences Consulting, and is expected to be filed no later than April 30, 2020.

In summary, CoreMedica, with locations in Missouri and Switzerland, can help fight the war against the novel coronavirus disease. Our innovative specimen collection method is currently the only clinical laboratory product that helps to prevent and control personal exposure to the virus through remote specimen self-collection. This strategy benefits hospital personnel and first responders by allowing them to focus on public health solutions rather than allocating time and PPE resources on specimen collection and handling.

Please be safe and be aware!

Healthfully Yours,

Cory Zuehlsdorf
COO & Director Americas