MCKESSON

Coronavirus (COVID-19): Understanding Lab Testing Methods – For Customers

April 24, 2020

Dear Valued Customer,

Thank you for taking care of patients during this ever-changing time. Supporting you is a role that we take very seriously.

We are committed to providing updates on McKesson's approach to lab testing for COVID-19 or SARS-CoV-2. For the latest updates, visit https://mms.mckesson.com/content/coronavirus-update. Locate the Lab section, where you can find our previous customer letters covering the different methods of testing for COVID-19 or SARS-CoV-2.

Host antibody (serology) tests continue to be a focus in healthcare with many changes in the past few weeks and very specific updates released by the U.S. Food and Drug Administration (FDA) on April 17. As a reminder, antibody serology tests detect the IgM and IgG antibodies that may indicate your patient has developed an immune response to the virus. The FDA has issued Emergency Use Authorization (EUA) for some of these tests. However, some antibody serology tests are being marketed without EUA. COVID-19 antibody serology tests without EUA currently default to a high complexity status. In addition, the accuracy and quality of those tests may vary greatly.

As it relates to rapid antibody serology testing, our approach at this time will be to offer **only antibody serology tests receiving an EUA**. This is important because serology tests on the market that have not received an EUA (as in the Policy for Diagnostic Tests for Coronavirus Disease-2019), have not been reviewed or authorized by the FDA. We believe that reliance on the FDA's EUA process is the best approach to supporting better patient care at this time.

McKesson is working with several manufacturers of rapid antibody tests, and we will update you once access to these tests become available.

Regarding high-throughput antibody testing, McKesson is currently offering tests from Ortho Clinical Diagnostics and Abbott Diagnostics. Ortho is EUA authorized for their Vitros 3600, 5600 and 7600XT analyzers for two assays: an IgG/IgM total assay and an IgG only assay. Abbott is EUA authorized for their IgG test on Architect platforms; McKesson is selling the Abbott and Ortho reagents, calibrators and controls to customers that are CLIA certified to perform moderate and high complexity testing. Additional high-throughput manufacturers Beckman Coulter, Siemens and others have or will be announcing serology tests. They will be seeking EUA approval. Your McKesson account manager will update you once these tests become EUA approved and product is available.

Recent Resources to Review:

- FDA's April 17 Letter to Health Care Providers: The use of serological (antibody) tests for COVID-19
- FDA's FAQs Guide on Diagnostic Testing for SARS-CoV-2
- FDA Fact Sheet: Serological Testing for Antibodies to SARS-CoV-2 infection

Continue to reach out to your McKesson account manager as your primary contact during this time. Thank you for your partnership, your trust and patience, and for continuing to serve on the front line of our healthcare.

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