McKESSON

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

April 6, 2020

Dear Valued Customer,

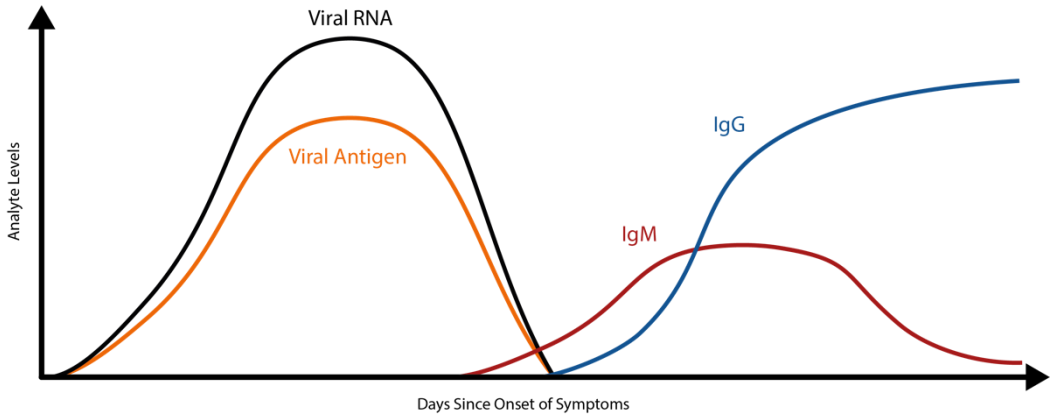
Thank you for taking care of patients during this crisis. Supporting you is a role we take very seriously.

Two names are commonly used in describing this Coronavirus. COVID-19 is this Coronavirus **disease**; SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) is the **virus** that causes this disease. We often use their names interchangeably when talking about the pandemic or lab testing methods.

Three types of clinical laboratory COVID-19 or SARS-CoV-2 tests are being developed:

- Molecular
- Viral antigen
- Host antibody tests (serology)

They detect the virus in different ways.



Note: Estimate of general biomarker levels during the typical time course of COVID-19/SARS-CoV-2 infection. Data from Liu et al. and Li et al. Please note that this is purely illustrative and should not be used as a primary reference. Image Source

During the rise of Viral RNA and Viral Antigen levels, a **molecular** (PCR or Isothermal nucleic acid amplification based) or **viral antigen test** detects the presence of the virus.

Host antibody (serology) tests detect the IgM and IgG antibodies that indicate your patient has developed an immune response to the virus.

Currently, all diagnostic tests are submitted to the U.S. Food and Drug Administration (FDA) for review through the Emergency Use Authorization (EUA) process. The FDA is beginning to authorize host antibody (serology) tests under EUA. While the they indicate these tests may be appropriate for use in clinical settings, the policies in the Policy for Diagnostic Tests for Coronavirus Disease-2019 do not provide a CLIA categorization and do not override any CLIA requirements. These tests are considered high complexity by default until or unless they are authorized and deemed appropriate to be performed as moderate or waived complexity tests, through an EUA authorization or general FDA review processes. . FDA has begun to authorize serology tests which could change the CLIA categorization for tests that go through this EUA process.

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Molecular Test Availability

As of April 2, 2020, 24 manufacturers have received EUA for their molecular tests; four are of particular importance to McKesson customers:

- Abbott Diagnostics (formerly Alere) ID NOW™
- Cepheid GeneXpert® Xpress
- QIAGEN QIAstat-Dx®
- Mesa Biotech Accula™ (May be marketed as Sekisui Diagnostics)

Cepheid and Abbott are starting production and getting tests to caregivers as fast as possible. Early distribution is focused on "hot zones" with the highest levels of infection. Both manufacturers are speeding up production but are not currently installing new instruments.

QIAGEN has received EUA on the QIAstat-DX. This is produced in Europe. Global demand is many times higher than maximum product capacity. QIAGEN will have limited allocation of COVID-19 tests for existing customers. You may order new analyzers, but it may take several months before they can be installed.

Mesa Biotech (Sekisui) has received EUA for their Accula SARS-CoV-2 test. U.S. distribution is under discussion.

We will update you once access to these tests become available.

Viral Antigen Testing

Several manufacturers are developing these tests. They will be like the typical visually read or reader-read flu tests you currently use or are familiar with. We are not aware of availability for any viral antigen tests, since reagent development requires time.

Host Antibody Serology Testing

On March 16, the FDA provided guidance for this type of testing. **The FDA has said these antibody serology tests should not be used as the sole basis for diagnosis of SARS-CoV-2.** Antibody serology testing identifies IgM and IgG antibodies in the bloodstream but does not provide definitive evidence of a current infection. For more information on host antibody serology testing, please read our earlier statement here.

McKesson is working with several suppliers. We will update you once access to these tests become available.

FDA Policies of Interest

- Updated policy for antibody serology testing
- List of manufacturers that have indicated intent to make and distribute serology tests

Your McKesson account manager is your primary contact as this situation develops. Thank you for your partnership, your trust and patience, and for continuing to serve on the frontline of our healthcare.

McKesson Medical-Surgical