COVID-19 IgG and IgM Rapid Test

On March 16, the U.S. government took an unprecedented step towards access to Coronavirus Disease (COVID-19) testing by allowing developers of certain tests to commercialize the products in the U.S. without the requirement for an FDA approval or Emergency Use Authorization (EUA)[1].

As a result, many manufacturers have given notice to the FDA of their intent to launch the COVID-19 IgG and IgM Rapid Test for whole blood (including fingerstick), plasma and serum, in compliance with the regulation.

The manufacturer's intent to commercialize these products has been submitted to the FDA in compliance with all FDA requirements and is published under the FDA product code QKO.

The COVID-19 IgG and IgM Rapid Test is designed to detect the antibodies that develop in the body following exposure to Coronavirus. Symptoms of COVID-19 are expected to appear 1-14 days following viral exposure. Primary infection is characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection. Secondary infection is characterized by the elevation of SARS-COV-2-specific IgG.

In most cases, this is accompanied by elevated levels of IgM. To comply with the regulation, the following statements must be included in any test reports using the COVID-19 Rapid Test:

• This test has not been reviewed by the FDA.
• Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
• Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
• Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

In addition, these statements are included throughout the product package insert, aligning with the technical sections to which they pertain.

---

[1]U.S. Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff.

Issued March 16, 2020. Docket Number FDA-2020-D-0987.