CONFIRM BIOSCIENCES
COVID-19 TEST STATEMENT

On March 16, 2020, the U.S. Food and Drug Administration issued a policy update entitled "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."

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency

Subsection C of the Guidance provides that commercial manufacturers of diagnostic test kits may develop and distribute their products prior to Emergency Use Authorization submission. Significantly, the FDA Guidance provides "In light of the increasing numbers of COVID-19 cases throughout the country and the urgent need to expand the nation's capacity for COVID-19 testing during the public health emergency, FDA does not intend to object to a commercial manufacturer's development and distribution of SARS-CoV-2 test kits for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website."

https://www.federalregister.gov/documents/2020/03/06/2020-04630/policy-for-diagnostics-testing-in-laboratories-certified-toperform-high-complexity-testing-under

This statement is written to assure the customers of Confirm BioSciences Inc, a U.S. commercial provider of Rapid IgG/IgM Rapid test cassette (Rapid Test) and SARS-CoV-2 qPCR Detection Kit (PCR Test) diagnostic tests for the detection of novel coronavirus (COVID-19), that the FDA has received the necessary intent to launch notices before 3/18/2020.

On 3/23/2020, FDA provided EUA number #200056 for the EUA application of device: COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma).

In compliance with the FDA guidelines, all tests will have a notice that the test has not been reviewed by the FDA and 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.