CLIAwaived™ Inc.

PHONE: 858.481.5031
FAX: 801.720.7568
WEB: www.cliawaived.com

Statement and Agreement for the CoronaChek™ COVID-19 Test

In compliance with the US FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency dated March 16, 2020[i] that describes the regulations for the development and US distribution of serology tests for the detection of antibodies to SARS-CoV-2, any test reports resulting from the use of the CORONACHEK™ COVID-19 IgG/IgM Rapid Test Cassette for whole blood, plasma and serum must bear the following information:

- This test has not been reviewed by the FDA and not FDA Cleared.
- 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.
- Not for the screening of donated blood.

These statements are also found in the package insert for the product either in the Limitations section or in the technical section pertaining to the statement.

CLIA Categorization: CoronaChek™ is not currently deemed a waived test and does not have a CLIA Categorization; therefore this test is CLIA Classified High Complexity. All licensed labs purchasing Covid-19 rapid tests should check with State CLIA office on any specific requirements for offering Covid-19 rapid testing.

To ensure clarity on the limitations of the use of this device, please see the following statement:

Pursuant to the labeling in the CORONACHEK™ COVID-19 IgG/IgM Rapid Test and the regulations set forth by the FDA as defined above, the signature below indicates your acknowledgement and acceptance that results from this test will bear the information. Furthermore, you acknowledge this test is for professional diagnostic use only including point of care and does not have a CLIA Categorization. It cannot be sold for Over-the-Counter (OTC) or home use by laypersons. The resale of this device to any other third party including medical professionals is strictly prohibited.

Lab Director / Physician_____ Lab License #_____

Signature _____ Lab License Expiration Date_____

Date Signed _____

Company Represented _____

Job Title _____

US 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.