



Carolina Liquid Chemistries Now Offers COVID-19 Rapid Screen Antibody Test

Carolina Liquid Chemistries, Corp. now offers the AllTest™ 2019-nCoV IgG/IgM Rapid Screen Antibody Test Cassette

GREENSBORO, NC, USA, March 27, 2020 /EINPresswire.com/ -- Carolina Liquid Chemistries, Corp. (CLC), an innovative biotechnology company, now offers the AllTest™ [2019-nCoV IgG/IgM Rapid Screen Antibody Test Cassette](#) in accordance with Sections C and D of the FDA's March 16, 2020 "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency."

[COVID-19 \(Corona Virus Disease\)](#) is caused by 2019-nCoV (SARS-COV-2) which is mainly transmitted through respiratory droplets. Symptoms of COVID-19 may appear 2-14 days after exposure. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.¹

The 2019-nCoV IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimen. The test can be stored sealed at room temperature or refrigerated. The 2019-nCoV IgG/IgM Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick), serum or EDTA plasma (K2, Heparin sodium, Citrate sodium and Potassium Oxalate). Internal procedural controls are included in the cassette.

The test has been validated by the manufacturer. Cross-reactivity has been tested for anti-influenza A virus and anti-influenza B virus, anti-RSV, anti-adenovirus, HBsAg, anti-Syphillis, anti-H.Pylori, and anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity. Comparing the test with commercially available PCR, the performance results show that 2019-nCoV IgG/IgM Rapid Test Cassette has a high sensitivity and specificity. IgG Results have Relative Sensitivity of 100% (95% confidence interval 86.0-100%), a Relative Specificity of 98.0% (CI 89.4-99.9%), and Accuracy of 98.6% (CI 92.3%-99.96%). IgM Results have Relative Sensitivity of 85.0% (95% CI 62.1%-96.5%), Relative Specificity of 96.0% (95%CI 86.3-99.5%), and Accuracy of 92.9% (95% CI 84.1-97.6%).

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.

"These are unprecedented times," says Phillip Shugart, Chief Executive Officer of Carolina Liquid Chemistries. "The rapid screen is a fast and easy screen for antibodies that compliments other tests and symptoms to give a fuller picture."

This test should be used for detection of IgG and IgM antibody to 2019- nCoV. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCoV can be determined by this qualitative test. The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to 2019-nCoV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCoV infections. As with all diagnostic tests, all results must be considered with other clinical

information available to the physician. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

About Carolina Liquid Chemistries Corp.

Headquartered in Greensboro, NC, Carolina Liquid Chemistries is a ISO 13485:2016 certified manufacturer, repackager/relabeler, distributor, and technical service provider of chemistry systems and reagents for clinical and toxicology laboratories. The company offers chemistry analyzers that range in throughput from 300 to 6,400 tests per hour and markets a wide menu of general chemistry, special chemistry, and toxicology reagents, along with affordable service contracts. For more information, visit carolinachemistries.com or email contactsales@carolinachemistries.com. Citation:

1. World Health Organization (WHO). Coronavirus. <https://www.who.int/health-topics/coronavirus>

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