AUDACIA BIOSCIENCE

BRIDGING THE GAP, CURATING RESULTS

Pending FDA 510(k) eua authorization, not yet available for sale

CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test

Value Proposition:

Antibody tests may provide evidence that someone has been exposed to the virus by detecting antibodies that are produced in response to the virus.[1, 2]

- Antibody tests can play a critical role in the fight against COVID-19
- Testing can help identify whether you have been exposed to COVID-19, even if you haven't had any symptoms
- Testing may determine whether you have developed an immune response to infection
- Repeat testing can determine whether your antibodies remain present, and for how long they remain present
- Right now, it is unclear whether those with antibodies may be less susceptible to infection, but in the future, use of antibody tests and clinical follow-up will provide us with more information about these antibodies and how much protection they offer

In addition, antibody tests may be very helpful in determining:[3]

- The incidence of COVID-19 in your community
- How widespread COVID-19 is in your community
- The true case fatality rate for your community
- Whether there are hot spots of COVID-19 in your community
- Whether public health measures are effective in your community
- How risky your work place is for exposure to COVID-19

Validation Studies:

Validation studies of the Audacia Bioscience CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test have been done comparing results of tests with PCR tests. These studies showed:

Sensitivity:
93.5% (95% confidence interval: 89.6% – 97.4%)

Specificity:
97% (95% confidence interval: 94.5% - 99.5%)

Accuracy:
95.5% Overall Test Accuracy

References:

1. FDA.gov (2020, July 7). FAQs on Testing for SARS-CoV-2. Retrieved from: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#serology

2. CDC.gov. (2020, May 23). Interim Guidelines for COVID-19 Antibody testing. Retrieved from: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

3. Gronvall, G. (2020, June 24). COVID-19 Antibody Testing Update: Why Does the Accuracy of SARS-CoV-2 Antibody Tests Vary So Much? How Much Does the Serosurvey Strategy Impact the Interpretation of Results? Retrieved from: https://www.vumedi.com/term/covid-19-testing

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PRODUCT SPECS

- Detects IgM and IgG antibodies to the SARS-CoV-2 (COVID-19) virus
- Can be performed on fingerprick blood samples, serum, or plasma (EDTA)
- Results in 10-15 minutes
- Dimensions:
  7cm (L) x 2cm (W) x .5cm (H)

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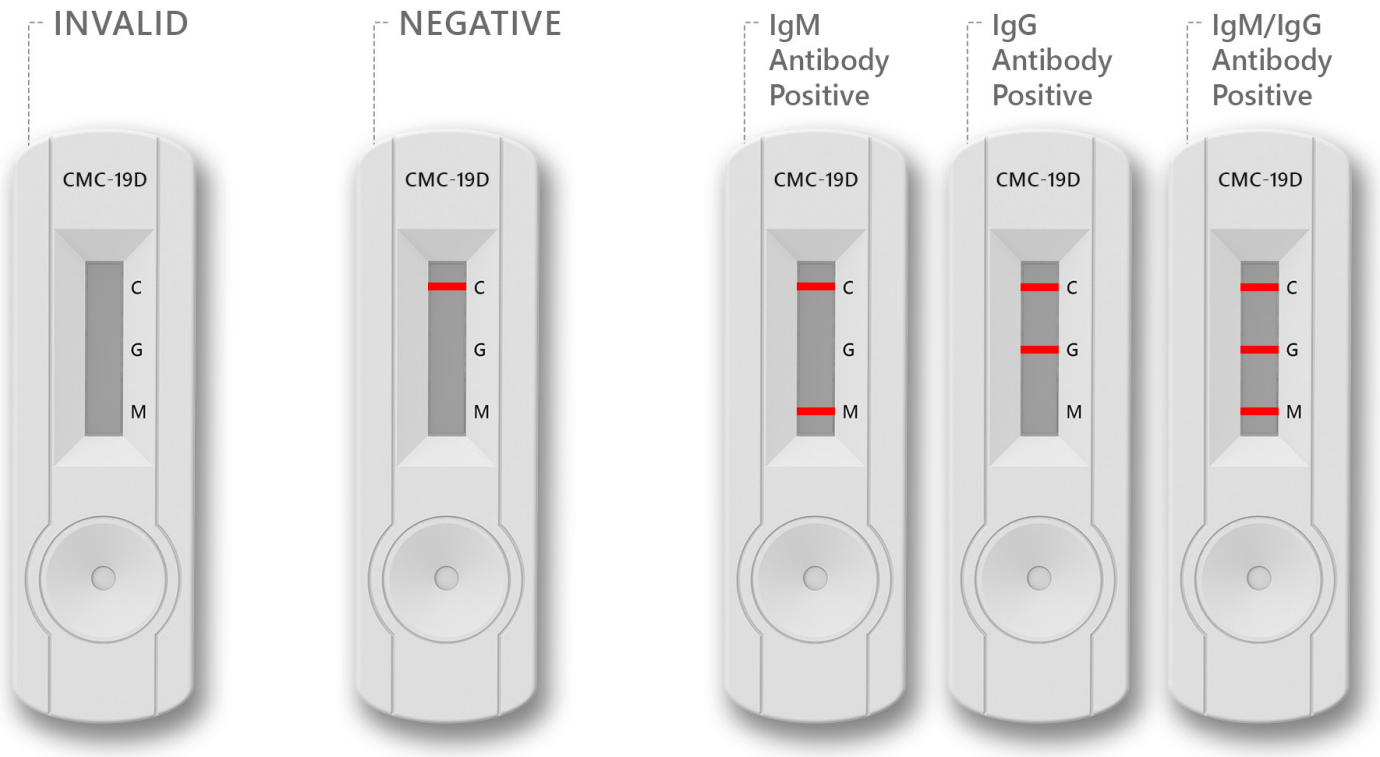

Intended Use

The Audacia Bioscience CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies of SARS-CoV-2 in serum, plasma (EDTA) or whole blood specimens from patients suspected of COVID-19 infection. The Audacia Bioscience CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test is an aid identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Results from the CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test should not be used as the sole basis for diagnosis. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used at the sole basis for patient engagement decisions. Antibodies may not be detected in the first few days of infection; the sensitivity of the CMC-19D SARS-CoV-2 (COVID-19) Rapid Antibody Test early detection after infection is unknown. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG/IgM assay.

For more information please contact:

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