

Rapid IgM/IgG SARS-CoV-2 Tests

FOR CLINICS AND HEALTH CARE PROVIDERS

APRIL 7, 2020

Current laboratory testing for COVID-19 and its causative pathogen, SARS-CoV-2, involves using real-time reverse transcription polymerase chain reaction (rRT-PCR) on upper or lower respiratory tract samples. This testing is currently available through the Minnesota Department of Health (MDH) Public Health Laboratory and various commercial labs for patients in certain priority testing categories¹.

The U.S. Food and Drug Administration (FDA) recently granted an Emergency Use Authorization (EUA) for a rapid serological test for SARS-CoV-2 from Cellex, specifically for the detection of anti-SARS-CoV-2 IgG and IgM antibodies in blood². An EUA does not mean that a test is FDA cleared or approved. This IgG/IgM assay is only authorized for use in laboratories certified under CLIA (Clinical Laboratory Improvement Amendments) to perform moderate- and high-complexity tests. Many other commercial manufacturers have notified the FDA that they have validated and are distributing various types of serological tests for use in the management of COVID-19, without pursuing or receiving authorization from the FDA³. FDA has also warned of companies marketing unauthorized and fraudulent home COVID-19 testing kits⁴.

Testing Concerns

MDH has specific concerns regarding the use of serological tests in the diagnosis and management of COVID-19:

- Negative results **do not** rule out SARS-CoV-2 infection, particularly in those who may be pre-symptomatic or immunocompromised.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains; for example, representing **cross-reactivity** with other common non-COVID-19 human coronaviruses.
- Results from antibody testing should **not** be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or immunity for occupational or other purposes.
- MDH is aware of reports of online scammers purporting to be test manufacturers offering rapid serology test kits that may be counterfeit or may be associated with malware.

Recommendations

- To date, evidence is lacking on the utility of serological testing in the management of individual patients with suspected or confirmed COVID-19.
- To avoid fraud, health care systems should exercise caution when evaluating kits from manufacturers or vendors of rapid serological tests for COVID-19 and should check [FDA: FAQs on Diagnostic Testing for SARS-CoV-2 \(https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2\)](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2), under section 6, “What serology tests are being offered..” for a list of bona fide commercial manufacturers and laboratories known to have developed these tests.

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- Health care providers should be cautious if asked to interpret the results of serological testing and should carefully consider the total clinical picture as well as the known test limitations as listed above.
- MDH or others may use these serological tests for seroprevalence studies.

References

1. [MDH: Health Advisory: Updated SARS-CoV-2 Testing \(PDF\)](https://www.health.state.mn.us/communities/ep/han/2020/apr1testing.pdf)
(<https://www.health.state.mn.us/communities/ep/han/2020/apr1testing.pdf>)
2. [FDA: SARS-CoV-2 IgG/IgM Rapid Test - Letter of Authorization for Emergency Use](https://www.fda.gov/media/136622/download)
(<https://www.fda.gov/media/136622/download>)
3. [FDA: FAQs on Diagnostic Testing for SARS-CoV-2](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2) (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>)
4. [FDA: Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments](https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments)
(<https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments>)

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