

# Research

# CDC, FDA

# Research

## May 29, 2020



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- The best available evidence suggests that most persons recovered from illness with detectable viral RNA (either persistent or recurrent) are likely no longer infectious, but conclusive evidence is not currently available.
- Prolonged viral shedding has been demonstrated without direct correlation with replication competent virus. Although persons may produce PCR-positive specimens for up to 6 weeks, it remains unknown whether these PCR-positive samples represent the presence of infectious virus.
- Such persons should consult with their healthcare provider; strategies to address this might include additional PCR testing. When a test-based strategy is not feasible or desired, consider consultation with local infectious disease experts about discontinuing home isolation for patients who might have prolonged viral shedding, including those who are immunocompromised.

## May 22, 2020

- Home / Medical Devices / Medical Device Safety / Emergency Situations (Medical Devices) / EUA Authorized Serology Test Performance

## **EUA Authorized Serology Test Performance**

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Emergency Situations (Medical Devices)

Medical Devices and the COVID-19 Pandemic

Emergency Use Authorizations

Contacts for Medical Devices During the COVID-19 Pandemic

Medical Devices and Hurricane Emergencies

### About this page

Serology tests detect the presence of antibodies in the blood when the body is responding to a specific infection, like COVID-19. In other words, the tests detect the body's adaptive immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's adaptive immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19, and this is one reason serology tests should not be used as the sole basis to diagnose COVID-19. Serology tests could play a role in the fight against COVID-19 by helping healthcare professionals identify individuals have developed an adaptive immune response to SARS-CoV-2. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19. However, to use these tests properly, it is important to understand their performance characteristics and limitations. Content current as of: 05/22/2020

Regulated Product(s) Medical Devices

Health Topic(s) Coronavirus

## Abbott Architect SARS-CoV-2 IgG

Developer: Abbott Test: Architect SARS-CoV-2 IgG Technology: High Throughput CMIA Target: Nucleocapsid

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
lgG	Sensitivity (PPA)	100% (88/88)	(95.8%; 100%)
IgG	Specificity (NPA)	99.6% (1066/1070)	(99.0%; 99.9%)
IgG	PPV at prevalence = 5%	92.9%	(83.4%; 98.1%)
lgG	NPV at prevalence = 5%	100%	(99.8%; 100%)

### **Test Facts:**

- Information for Healthcare Providers
- Information for Recipients
- Instructions for Use

## Cellex qSARS-CoV-2 IgG/IgM Rapid Test

Developer: Cellex, Inc. Test: qSARS-CoV-2 IgG/IgM Rapid Test Technology: Lateral Flow Target: Spike and Nucleocapsid

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
Combined	Sensitivity (PPA)	93.8% (120/128)	(88.2%; 96.8%)
Combined	Specificity (NPA)	96.0% (240/250)	(92.8%; 97.8%)
Combined	PPV at prevalence = 5%	55.2%	(39.2%; 69.8%)
Combined	NPV at prevalence = 5%	99.7%	(99.3%; 99.8%)

### **Test Facts:**

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# Research

## May 27, 2020



Article Info

Figures

syndrome coronavirus 2 (SARS-CoV-2). Although data on factors related to this transmission are scarce, the spread of SARS-CoV-2 is thought to mostly be via the transmission of respiratory droplets coming from infected individuals.<sup>1</sup> Small droplets, from submicron to approximately 10 µm diameter, produced during speech and coughing, have been shown to contain viral particles,<sup>2</sup> which can remain viable and infectious in aerosols for 3 h.<sup>3</sup> The droplets can be transmitted either directly by entering the airway through the air (aerosols),<sup>4</sup> or indirectly by contact transfer via contaminated hands. The mode of transmission could affect whether an infection starts in the upper or lower respiratory tract, which is thought to affect the severity of the disease progression.<sup>5</sup> Notably, the dose– response relationship of SARS-CoV-2 infection is still unclear, especially with respect to aerosol transmission of the virus. However, aerosols containing a small concentration of virus in poorly ventilated spaces, combined with low humidity and high temperature,<sup>6</sup> might result in an infectious dose over time. • To better understand the spreading of respiratory droplets and possible preventive measures, we analysed droplet production due to coughs and speech by measuring the droplet size distribution, travel distance and velocity, and the airborne time in relation to the level of air ventilation.



- The authors analyzed droplet production from coughs and speech by measuring droplet size distribution, travel distance and velocity, and the airborne time in relation to the level of air ventilation.
- Small droplets of 5µm radius take 9 minutes to reach the ground when produced at a height of 160cm.
- The number of droplets halved in 30 seconds in the best ventilated room, but in about 5 minutes in the room with no ventilation.
- The authors believe that health-care authorities should consider the recommendation to avoid poorly ventilated public spaces as much as possible.

## May 27, 2020



An understanding of protective immunity to SARS-CoV-2 is critical for vaccine and public

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- A key unanswered question is whether infection with SARS-CoV-2 results in protective immunity against re-exposure.
- Researchers developed a rhesus macaque model of SARS-CoV-2 infection and observed that macaques had high viral loads in the upper and lower respiratory tract, humoral and cellular immune responses, and pathologic evidence of viral pneumonia.

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- Researchers developed a rhesus macaque model of SARS-CoV-2 infection and observed that macaques had high viral loads in the upper and lower respiratory tract, humoral and cellular immune responses, and pathologic evidence of viral pneumonia.
- Following initial viral clearance, animals were rechallenged with SARS-CoV-2 and showed 5  $\log_{10}$  reductions in median viral loads in bronchoalveolar lavage and nasal mucosa compared with primary infection.
- Anamnestic immune responses following rechallenge <u>suggested that</u> protection was mediated by immunologic control.

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- Anamnestic immune responses following rechallenge <u>suggested that</u> <u>protection was mediated by immunologic control</u>.
- These data show that <u>SARS-CoV-2 infection induced protective immunity</u> against re-exposure in nonhuman primates.



# Research

### Guide to COVID-19 Guidelines, Information, and Websites as of May 27, 2020

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Home / THE UW METACENTER

### THE UW METACENTER

The University of Washington MetaCenter for Pandemic Preparedness and Global Health Security aims to save lives by limiting the extent of infectious disease epidemics. We are fostering a bold, interdisciplinary, comprehensive, and integrated systems approach spearheaded by top scientists and practitioners that focuses on improving readiness before epidemics hit.

### WHO WE ARE

The UW MetaCenter connects diverse expertise across UW that includes public health, medicine, statistical modeling, computer science, pharmacy, environmental and behavioral sciences, engineering, urban planning and law, in collaboration with local and international partners.

Seven core groups focus on three strategic areas:

#### DATA AND ANALYTICS, GEOSPATIAL, RISK FACTOR AND DISEASE MODELING

The Institute for Health Metrics and Evaluation (IHME)

The Center for Health and the Global Environment (CHanGE)

The Center for One Health Research (COHR)

#### **UPCOMING WEBINARS**

New Webinar Series with Kenyatta National Hospital: Lessons from Washington's COVID-19 Epidemic » Clinician Outreach and Communication Activity (COCA): Key emergency preparedness and response topics (CDC webinar) »

#### **NEW RESOURCES**

COVID-19 Literature Situation Report

This daily (M-F) newsletter provides a succinct summary of the latest scientific literature related to the COVID-19 pandemic. Subscribe here, and scroll to the end of this page for previous editions.

#### **DAILY COVID-19 NEWSLETTER**

This new daily newsletter that provides a succinct summary of the latest scientific literature related to the COVID-19 pandemic. Each day, there is a firehose of new scientific information emerging about COVID-19 and SARS-CoV-2. This initiative is an attempt to focus that hose to highlight new findings that are most relevant to the public health response. To that end, we will be providing a report that includes brief summaries of 10-15 articles that we judge to have the highest public health relevance, along with additional links to pertinent commentaries and other resources. <u>Click here to subscribe</u>.



<u>May 28, 2020</u>	
<u>May 27, 2020</u>	
<u>May 26, 2020</u>	
<u>May 22, 2020</u>	
<u>May 21, 2020</u>	
<u>May 20, 2020</u>	
<u>May 19, 2020</u>	





## COVID-19 Literature Situation Report

#### MAY 28, 2020

The scientific literature on COVID-19 is rapidly evolving and these articles were selected for review based on their relevance to decision-making around COVID-19 response efforts. Included in these Lit Reps are some manuscripts that have been made available online as pre-prints but have not yet undergone peer review. Please be aware of this when reviewing articles included in the Lit Reps.

Today's summary is based on a review of 399 articles (335 published, 64 in preprint).

### **KEY TAKEAWAYS**

- A randomized trial found comparable outcomes for 5-day and 10-day courses of remdesivir for hospitalized COVID-19 patients.
- Black patients are disproportionately represented among COVID-19 hospitalizations and deaths (>70%) in Louisiana. Black race was

# References

- <u>https://www.cdc.gov/coronavirus/2019-nCoV/hcp/disposition-in-home-patients.html</u>
- <u>https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance</u>
- <u>https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30245-</u> <u>9/fulltext</u>
- <u>https://science.sciencemag.org/content/early/2020/05/19/science.abc4776.full</u>
- <u>https://globalhealth.washington.edu/uwmetacenter</u>
- <u>https://globalhealth.washington.edu/sites/default/files/COVID%20newsletter%20-%20May%2028%20%28pdf%29.pdf</u>

# **Thank You**