

To improve your experience, aafp.org will be unavailable August 13 at 6pm CT through August 17. [Learn More](https://www.aafp.org/sitelaunch) (https://www.aafp.org/sitelaunch)

AMERICAN FAMILY PHYSICIAN®

Letters to the Editor

Beware of False-Positive Results with SARS-CoV-2 Antibody Tests

Am Fam Physician. 2020 Jul 1;102(1):5-6.

To the Editor: Antibody testing will become increasingly important as the coronavirus disease 2019 (COVID-19) pandemic progresses. In the setting of highly selected antigen testing, antibody tests will help public health officials determine the extent of previous infection, even among asymptomatic individuals and those with mild symptoms who did not seek medical care. Antibody testing is also likely to be part of the foundation for determining the pace of relaxing current physical distancing measures. Finally, clinicians will use antibody testing to counsel individual patients about whether they have recently had COVID-19 or to determine their immunity.

New rapid antibody tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, are qualitative. Analogous to home pregnancy tests, these antibody tests are positive or negative. By varying the cutoff that defines a positive test result for immunoglobulin G (IgG) or IgM, test developers can choose to favor a high sensitivity, a high specificity, or take a balanced approach. Cellex, the first antibody test approved by the U.S. Food and Drug Administration for the virus, has a reported sensitivity of 94% and specificity of 96%.¹ However, as we begin widespread testing in a population in which the prevalence of previous SARS-CoV-2 infection is unknown, there is a risk of false-positive results. When initially diagnosing acute infection, it is important to avoid false-negatives because this can falsely reassure patients and hinder appropriate contact tracing and isolation. However, when assessing whether patients had a previous infection and may be immune, it is important to avoid false-positives so that patients do not think they are immune when they are not.

Table 1 summarizes the false-positive rates at various population prevalence for the Cellex test and for a hypothetical test that is 90% sensitive and 99% specific.¹ At relatively low population prevalences, which likely reflect current conditions in the United States and elsewhere, we would argue that false-positive rates are unacceptably high with the Cellex test. Many of the other tests with provisional approval by the U.S. Food and Drug Administration have not been appropriately evaluated for accuracy.²



 [Enlarge \(hi-res/afp20200701p5a-t1.gif\)](#)  [Print](#)

TABLE 1.

Antibody Testing for COVID-19: False-Positive Rates by Population Prevalence and Test Specificity

~~FALSE POSITIVE RATE~~ False Discovery Rate

PREVALENCE OF PREVIOUS SARS- COV-2 INFECTION		
	CELLEX TEST (SENSITIVITY = 94%; SPECIFICITY = 96%)	HYPOTHETICAL SARS-COV-2 ANTIBODY TEST (SENSITIVITY = 90%; SPECIFICITY = 99%)
1%	80.8%	52.4%
5%	44.7%	17.4%
10%	27.7%	9.1%
20%	14.5%	4.3%
30%	9.0%	2.5%

50%	4.1%	1.1%
70%	1.8%	0.5%
90%	0.5%	0.1%

COVID-19 = coronavirus disease 2019; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Information from reference [1](#).

Therefore, we encourage family physicians to look for appropriately validated antibody tests with adequate specificity (ideally 99% or higher), even if it means sacrificing some sensitivity. Also, they should encourage laboratories to report test results in a way that reflects the local population prevalence based on widespread testing and include the false-positive rate. This information is needed to help family physicians better inform shared decision-making regarding previous infection and return to work or school.

Editor's Note: Dr. Ebell is deputy editor for evidence-based medicine for *AFP*.

Mark H. Ebell, MD, MS

Athens, Ga.

Email: ebell@uga.edu (<mailto:ebell@uga.edu>)

Henry C. Barry, MD, MS

East Lansing, Mich.

Author disclosure: No relevant financial affiliations.

Published online April 27, 2020.

REFERENCES


1. Cellex qSARS-CoV-2 IgG/IgM Rapid Test. Accessed April 19, 2020. <https://cellexcovid.com/> (<https://cellexcovid.com/>)
2. Cheng MP, Papenburg J, Desjardins M, et al. Diagnostic testing for severe acute respiratory syndrome-related coronavirus 2: a narrative review. *Ann Intern Med*. 2020;172(11):726–734.

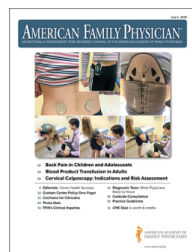
Send letters to afplet@aafp.org (<mailto:afplet@aafp.org>), or 11400 Tomahawk Creek Pkwy., Leawood, KS 66211-2680. Include your complete address, e-mail address, and telephone number. Letters should be fewer than 400 words and limited to six references, one table or figure, and three authors.

Letters submitted for publication in *AFP* must not be submitted to any other publication. Possible conflicts of interest must be disclosed at time of submission. Submission of a letter will be construed as granting the AAFP permission to publish the letter in any of its publications in any form. The editors may edit letters to meet style and space requirements.

This series is coordinated by Kenny Lin, MD, MPH, Associate Deputy Editor for *AFP* Online.

0 comments

 [Sign In](#) to comment



Continue reading from July 1, 2020 (<https://www.aafp.org/afp/2020/0701/>)

View the full table of contents >> (<https://www.aafp.org/afp/2020/0701/>)

Copyright © 2020 by the American Academy of Family Physicians.

This content is owned by the AAFP. A person viewing it online may make one printout of the material and may use that printout only for his or her personal, non-commercial reference. This material may not otherwise be downloaded, copied, printed, stored, transmitted or reproduced in any medium, whether now known or later invented, except as authorized in writing by the AAFP. Contact afpserv@aafp.org (<mailto:afpserv@aafp.org>) for copyright questions and/or permission requests.

Want to use this article elsewhere? [Get Permissions](https://www.aafp.org/journals/afp/permissions/requests.html) (<https://www.aafp.org/journals/afp/permissions/requests.html>)

Beware of False-Positive Results with SARS-CoV-2 Antibody Tests - Letters to the Editor - American Family Physician
<https://www.aafp.org/afp/2020/0701/p5a.html>

Copyright © 2020 American Academy of Family Physicians. All rights reserved.
11400 Tomahawk Creek Parkway • Leawood, KS 66211-2680
800.274.2237 • 913.906.6000 • Fax: 913.906.6075 • contactcenter@aafp.org
