FDA, CDC, Resources

Research

FDA, CDC, Resources

Research

Independent Evaluations of COVID-19 Serological Tests

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 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 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 who may have developed an 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 serology tests properly, it is important to understand their performance characteristics and limitations. Moreover, studies are underway to address questions that will better inform the appropriate use of these tests, such as whether the presence of antibodies conveys a level of immunity that would prevent or reduce the severity of re-infection as well as the duration for which immunity lasts.

Key Facts

Source of the data:	Independent testing by US Government Laboratories
Changes to the source data:	openFDA annotates the original records with special fields and converts the data into JSON, which is a widely used machine readable format.

EUA Authorized

Euroimmun SARS-COV-2 ELISA (IgG)

Manufacturer: Euroimmun

Device: SARS-COV-2 ELISA (IgG)

Date Performed: 2020-04-21

Lot Number: E200330DT

Panel: Panel 1

Marketing Status: EUA Authorized

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgG	Specificity	100% (80/80)	(95.4%; 100%)
IgG	PPV at prevalence = 5%	100%	(46.0%; 100%)
IgG	NPV at prevalence = 5%	99.5%	(98.6%; 99.8%)

NCI's Independent Evaluation Report

Data File

Phamatech COVID19 RAPID TEST

Manufacturer: Phamatech

Device: COVID19 RAPID TEST

Date Performed: 2020-04-21

Lot Number: NCP20030239

Panel: Panel 1

Marketing Status: Should not be distributed – Voluntarily withdrawn

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgM	Sensitivity	26.7% (8/30)	(14.2%; 44.4%)
IgM	Specificity	97.5% (78/80)	(91.3%; 99.3%)
IgG	Sensitivity	86.7% (26/30)	(70.3%; 94.7%)
IgG	Specificity	96.2% (77/80)	(89.5%; 98.7%)
Combined	Sensitivity	86.7% (26/30)	(70.3%; 94.7%)
Combined	Specificity	93.8% (75/80)	(86.2%; 97.3%)
Combined	PPV at prevalence = 5%	42.4%	(21.1%; 64.9%)
Combined	NPV at prevalence = 5%	99.3%	(98.2%; 99.7%)

June 4, 2020

Transport Media Safety Risk - Use Compatible Transport Media with SARS-CoV-2 Tests that Use Bleach - Letter to Clinical Laboratory Staff and Health Care Providers

Letters to Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds laboratory staff to use transport media (the liquid that maintains a specimen sample while it is transported to a laboratory) that are compatible with the SARS-CoV-2 testing platforms and the processes used in their laboratory to process samples collected from people who are being tested for SARS-CoV-2. There is a risk of exposure to harmful cyanide gas, a by-product of a reaction between guanidine thiocyanate or similar chemicals and bleach (sodium hypochlorite), when certain transport media are used with an incompatible testing platform or laboratory process. Guanidine thiocyanate may be referred to as guanidinium rhodanide, guanidinium thiocyanate, or guanidinium.

There are numerous transport media that contain guanidine thiocyanate or similar chemicals. PrimeStore molecular transport media (MTM) (LH-1-02 and LH-1-03), Zymo

Content current as of:
06/04/2020

Regulated Product(s)
Medical Devices

Health Topic(s)
Coronavirus

- PrimeStore MTM (LH-1-02* and LH-1-03*), Zymo DNA/RNA Shield, and Spectrum Solutions Saliva Collection Device contain a transport medium which maintains patient specimens while they are transported to a laboratory for RNA and DNA testing.
- These media contain guanidine thiocyanate or similar chemicals, which produces a potentially hazardous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite) and should not be used in a testing platform, or in laboratory processes, that use bleach.
- Many laboratories may use bleach in their cleaning or decontamination processes in response to laboratory spills.

- Other transport media may contain guanidine thiocyanate or other similar chemicals, and ingredients in transport media may not be listed on individual tubes.
- If laboratory staff do not know the ingredients in the transport media, they should handle it as though it has guanidine thiocyanate or similar chemicals to avoid a potential reaction.

EUA Authorized Serology Test Performance

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 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 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 who may have developed an 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 serology tests properly, it is important to understand their performance characteristics and limitations. Moreover, studies are underway to address questions that will better inform the appropriate use of these tests, such as whether the presence of antibodies conveys a level of immunity that would prevent or reduce the severity of re-infection as well as the duration for which immunity lasts.

Content current as of:
06/04/2020

Regulated Product(s)
Medical Devices

Health Topic(s)
Coronavirus

Abbott Alinity i SARS-CoV-2 IgG

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

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	100% (34/34)	(89.9%; 100%)
IgG	Specificity (NPA)	99.0% (99/100)	(94.6%; 99.8%)
IgG	PPV at prevalence = 5%	84.0%	(46.7%; 96.3%)
IgG	NPV at prevalence = 5%	100%	(99.4%; 100%)

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
IgG	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%)
IgG	NPV at prevalence = 5%	100%	(99.8%; 100%)

Public Health Guidance for Community-Related Exposure

Print Page

The following guidance is provided for definitions and management of contacts of people with COVID-19. Separate guidance is available for international travelers. Healthcare personnel (HCP) should follow CDC's Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19 regarding work restrictions if they have potential exposure to people with COVID-19. However, such HCP should also follow this Guidance for Community-Related Exposure for what to do in the community. See also CDC's guidance for Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19. Individuals should always follow guidance of the state and local authorities.

Public health recommendations have been updated to accommodate new scientific evidence, evolving epidemiology, and the need to simplify risk assessment. New recommendations are based on:

- Growing evidence of transmission risk from infected people without symptoms (asymptomatic) or before the onset of recognized symptoms (presymptomatic);

- Public health recommendations have been updated to accommodate new scientific evidence, evolving epidemiology, and the need to simplify risk assessment. New recommendations are based on:
  - Growing evidence of transmission risk from infected people without symptoms (asymptomatic) or before the onset of recognized symptoms (presymptomatic);
  - Increased community transmission in many parts of the country;
  - A need to communicate effectively to the general public;
  - Continued focus on reducing transmission through social distancing and other personal prevention strategies.

Person	Exposure to	Recommended Precautions for the Public

• Individual who has had close contact (< 6 feet)** for ≥15 minutes***	• Person with COVID-19 who has symptoms (in the period from 2 days before symptom onset until they meet criteria for discontinuing home isolation; can be laboratory-confirmed or a clinically compatible illness)
	• Person who has tested positive for COVID-19 (laboratory confirmed) but has not had any symptoms (in the 2 days before the date of specimen collection until they meet criteria for discontinuing home isolation)
		• Stay home until 14 days after last exposure and maintain social distance (at least 6 feet) from others at all times
		• Self-monitor for symptoms
		  ○ Check temperature twice a day
		  ○ Watch for fever*, cough, or shortness of breath, or other symptoms of COVID-19
		• Avoid contact with people at higher risk for severe illness from COVID-19
		• Follow CDC guidance if symptoms develop

Communication Toolkit

For Migrants, Refugees, and Other Limited-English-Proficient Populations

Other Languages | Print Page

CDC created this communication toolkit to help public health professionals, health departments, community organizations, and healthcare systems and providers reach populations who may need COVID-19 prevention messaging in their native languages.

This toolkit provides:

- Current messaging from a trusted source.
- Information in plain language available for downloading and sharing.
- Translated materials to help communities disseminate messages to a wider audience.

Get Email Updates

Print Resources

Find print resources in multiple languages. Navigate to the Print Resources webpage and search by the language you are looking for, or click on the language below.

COVID-19 materials are available in:

Amharic
Arabic
Burmese
Chinese
Chuukese
Dari
Farsi
French
Haitian-Creole
Karen
Kinyarwanda
Korean
Kunama
Marshallese
Nepali
Oromo
Pashto
Portuguese
Russian
Somali
Spanish
Swahili
Tagalog
Thai
Tongan
Tigrinya
Ukrainian
Vietnamese

Audiovisual Resources

- Social Media Toolkit
- Buttons & Badges
- Public Service Announcements (PSAs)
- Videos
- CDC YouTube channels
  - English
  - Spanish
- Ad Council Coronavirus Response Toolkit

Interim COVID-19 Contact Tracing Communications Toolkit for Health Departments

Print Page

Updated June 4, 2020

This page will be updated as new resources become available.

Main Message

We all need to work together with health departments to help slow the spread of COVID-19. Contact tracing and self-quarantining of people with COVID-19 and close contacts are critical to help slow transmission of COVID-19 in our communities.

The messages in this toolkit use COVID-19, but you may want to use "coronavirus" instead of COVID-19 if that's the term most often used in your community.

FAQ on Infection Control

- People can fight stigma by providing social support in situations where you notice this is occurring.
- Stigma affects the emotional or mental health of stigmatized groups and the communities they live in.
- Stopping stigma is important to making communities and community members resilient. See resources on mental health and coping during COVID-19.
- Everyone can help stop stigma related to COVID-19 by knowing the facts and sharing them with others in your community.

Sample Public Service Announcements

15 second

The [*insert health department name*] is working hard to slow the spread of COVID-19. If you have been exposed, we will call you and ask you to self-quarantine at home based on when you were exposed. Help us slow transmission and **answer the call to slow the spread.**

30 second

The [*insert health department name*] is working hard to slow the spread of COVID-19. If you have been exposed to COVID-19, we will call you to notify you. You should self-quarantine at home and follow our instructions. Making a choice to help us in the fight against COVID-19 keeps you, your family, and your community safe. Help us slow transmission and **answer the call to slow the spread.** For more information, visit [*insert URL*]. This is a message from the [*insert health department name*].

Additional COVID-19 Public Service Announcements

- COVID-19 Everyday Prevention Actions
  - English
  - Spanish

WEBCAST

Webinar Series - Respirators for Health Care Personnel Use during COVID-19 Pandemic

JUNE 9, 2020

More Meetings, Conferences, and Workshops

Workshops & Conferences (Medical Devices)

2020 Medical Device Meetings and Workshops

On This Page

Date: June 9, 2020

Time: 12:00 PM - 1:00 PM ET

Content current as of:
06/05/2020

- On Tuesday, June 9, 12:00 pm – 1:00 pm ET, the U.S. Food and Drug Administration (FDA), along with speakers from Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA)

- Starting a webinar series on the topic of Respirators for Health Care Personnel Use during COVID-19 Pandemic.

- FDA will share information and answer questions about emergency use authorizations (EUAs) for respirators, importing respirators, and overall FDA actions to help assure health care personnel on the front lines have the necessary supplies of respirators to meet the demand.

FDA, CDC, Resources

Research

Medical Workers Should Use Respirator Masks, Not Surgical Masks

The surgical masks used in risky settings like hospitals offer much less protection against the coronavirus, an analysis found.

N95 masks to be sterilized with ultraviolet light at the Cleveland Clinic Abu Dhabi, in the United Arab Emirates, in April. Christopher Pike/Reuters

Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis

*Derek K Chu, Elie A Akl, Stephanie Duda, Karla Solo, Sally Yaacoub, Holger J Schünemann, on behalf of the COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors**

Summary

Background Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes COVID-19 and is spread person-to-person through close contact. We aimed to investigate the effects of physical distance, face masks, and eye protection on virus transmission in health-care and non-health-care (eg, community) settings.

Methods We did a systematic review and meta-analysis to investigate the optimum distance for avoiding person-to-person virus transmission and to assess the use of face masks and eye protection to prevent transmission of viruses. We obtained data for SARS-CoV-2 and the betacoronaviruses that cause severe acute respiratory syndrome, and Middle East respiratory syndrome from 21 standard WHO-specific and COVID-19-specific sources. We searched these data sources from database inception to May 3, 2020, with no restriction by language, for comparative studies and for contextual factors of acceptability, feasibility, resource use, and equity. We screened records, extracted data, and assessed risk of bias in duplicate. We did frequentist and Bayesian meta-analyses and random-effects meta-regressions. We rated the certainty of evidence according to Cochrane methods and the GRADE approach. This study is registered with PROSPERO, CRD42020177047.

Findings Our search identified 172 observational studies across 16 countries and six continents, with no randomised controlled trials and 44 relevant comparative studies in health-care and non-health-care settings (n=25 697 patients). Transmission of viruses was lower with physical distancing of 1 m or more, compared with a distance of less than 1 m (n=10 736, pooled adjusted odds ratio [aOR] 0·18, 95% CI 0·09 to 0·38; risk difference [RD] −10·2%, 95% CI −11·5 to −7·5; moderate certainty); protection was increased as distance was lengthened (change in relative risk [RR] 2·02 per m; $p_{interaction}$=0·041; moderate certainty). Face mask use could result in a large reduction in risk of infection (n=2647; aOR 0·15, 95% CI 0·07 to 0·34, RD −14·3%, −15·9 to −10·7; low certainty), with stronger associations with N95 or similar respirators compared with disposable surgical masks or similar (eg, reusable

Published Online
June 1, 2020
https://doi.org/10.1016/S0140-6736(20)31142-9

See Online/Comment
https://doi.org/10.1016/S0140-6736(20)31183-1

*Study authors are listed in the appendix and at the end of the Article

Department of Health Research Methods, Evidence and Impact (D K Chu MD, S Duda MSc, K Solo MSc, Prof E A Akl MD, Prof H J Schünemann MD), **and Department of Medicine** (D K Chu, Prof H J Schünemann), **McMaster University, Hamilton, ON, Canada; The Research Institute of St Joe's Hamilton, Hamilton, ON, Canada** (D K Chu); **Department of Internal Medicine** (Prof E A Akl), **and Clinical Research Institute** (Prof E A Akl, S Yaacoub MPH), **American University of Beirut,**

For health-care workers and administrators, our findings suggest that N95 respirators might be more strongly associated with protection from viral transmission than surgical masks. Both N95 and surgical masks have a stronger association with protection compared with single-layer masks. Eye protection might also add substantial protection.

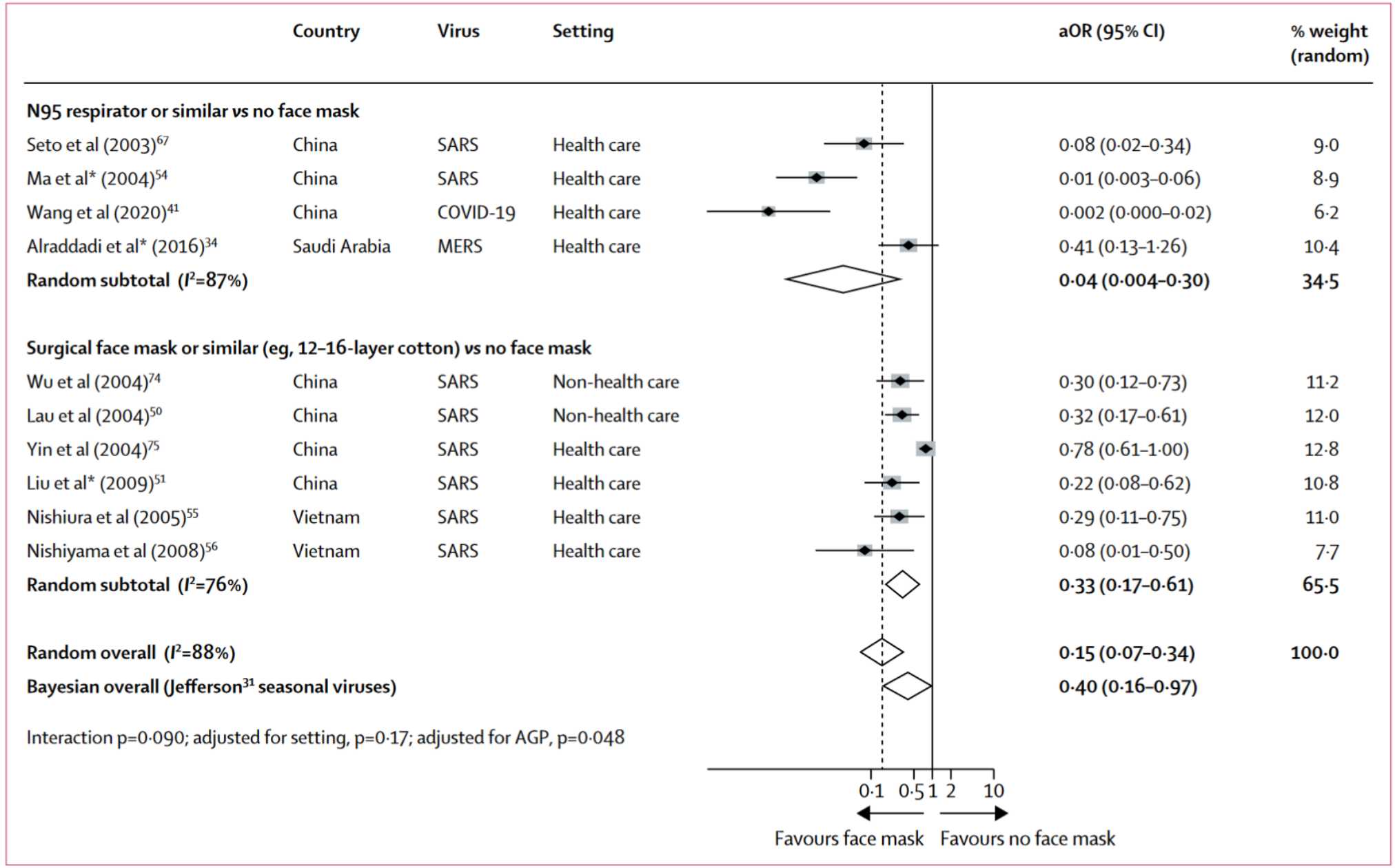


Figure 5: **Forest plot showing adjusted estimates for the association of face mask use with viral infection causing COVID-19, SARS, or MERS**

SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. RR=relative risk. aOR=adjusted odds ratio. AGP=aerosol-generating procedures. *Studies clearly reporting AGP.

Research Letter

ONLINE FIRST FREE

June 4, 2020

Correlation Between N95 Extended Use and Reuse and Fit Failure in an Emergency Department

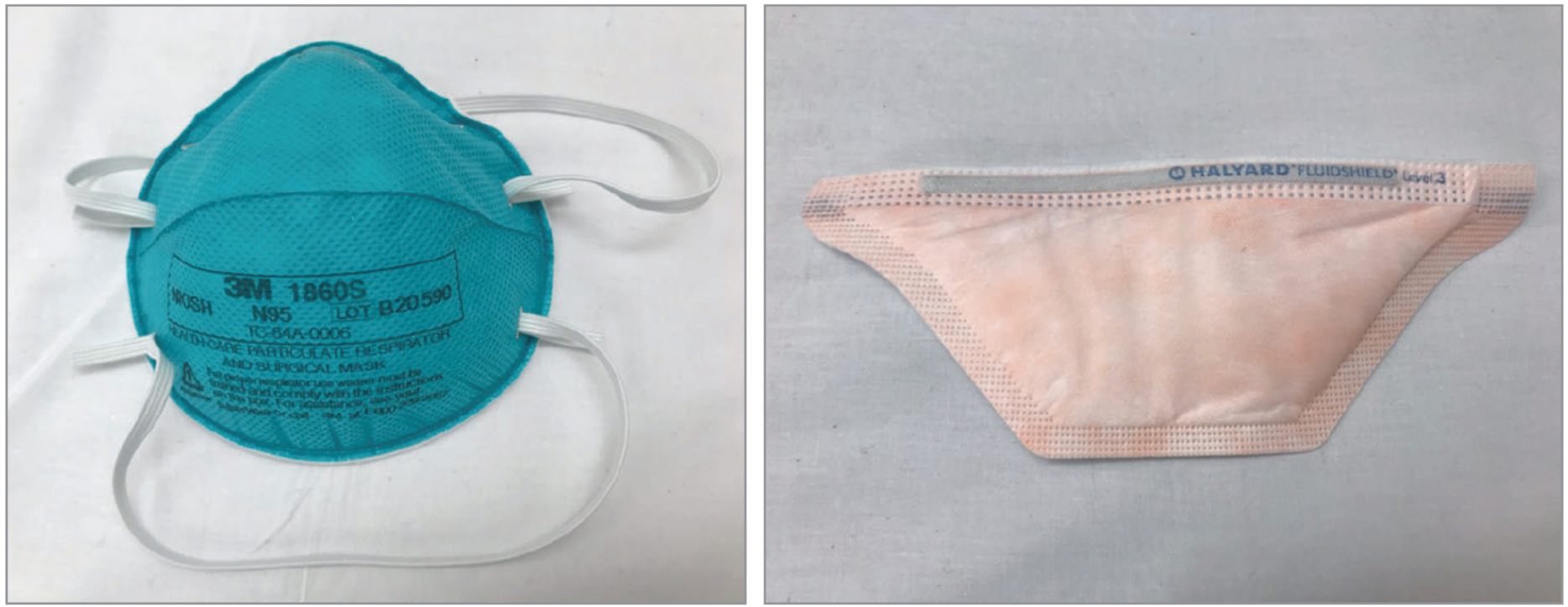
Nida F. Degesys, MD[1]; Ralph C. Wang, MD, MAS[1]; Elizabeth Kwan, MD[1]; et al

Author Affiliations | Article Information

JAMA. Published online June 4, 2020. doi:10.1001/jama.2020.9843

Frontline health care workers are at high risk of contracting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19).[1] Personal protective

Figure. N95 Mask Types



Left, Dome-shaped. Right, Duckbill.

- Among 68 participants, 66.2% were women and 48.5% were nurses.
- Participants used
  - Dome-shaped N95s: 51 of 68 (75.0%)
  - Duckbill N95s: 17 of 68 (25.0%)
- Overall, 38.2% of participants failed the fit test
  - 12 of 17 (70.6%) duckbill masks failed
  - 14 of 51 (27.5%) dome-shaped masks
- Among wearers of dome-shaped masks, fit test failure was associated with
  - Increased number of shifts worn (median, 4 shifts [interquartile range {IQR}, 3-5] vs 2 shifts [IQR, 1-3]; $P < .001$),
  - Increased donnings/doffings (median, 15 [IQR, 13-18] vs 8 [IQR, 4-12]; $P < .001$)
  - Increased hours worn (14 [IQR, 10-30] vs 12 [IQR, 6-16]; $P = .048$)

Perspective

False Negative Tests for SARS-CoV-2 Infection — Challenges and Implications

Steven Woloshin, M.D., Neeraj Patel, B.A., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

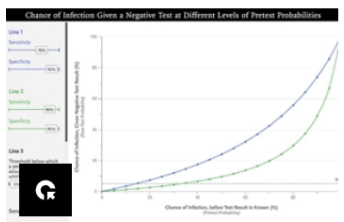
June 5, 2020
DOI: 10.1056/NEJMp2015897

5 References

THERE IS BROAD CONSENSUS that widespread SARS-CoV-2 testing is essential to safely reopening the United States. A big concern has been test availability, but test accuracy may prove a larger long-term problem.

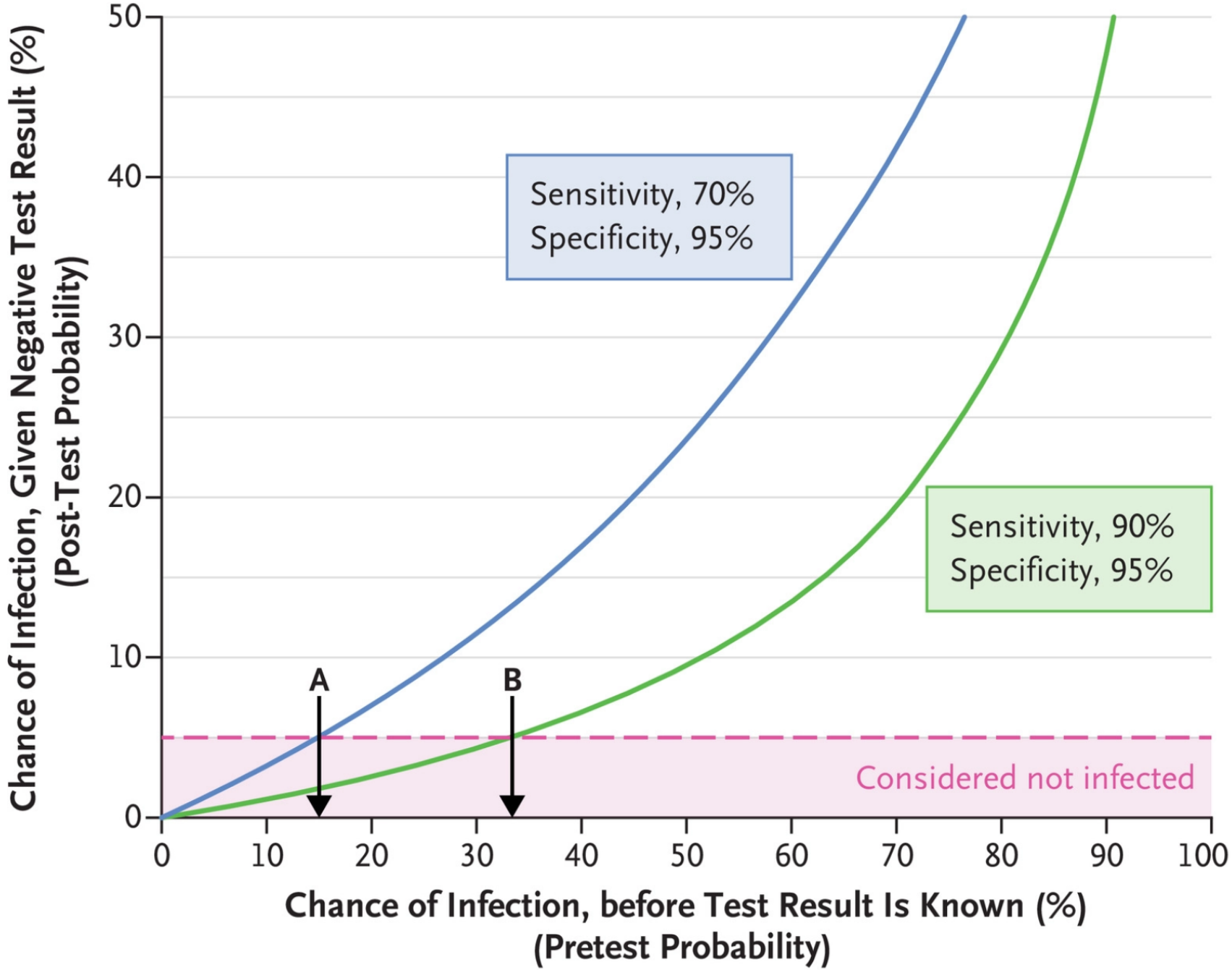
While debate has focused on the accuracy of antibody tests, which identify prior

Interactive Graphic



Chance of Infection Given a Negative Test at Different Levels of Pretest Probabilities

- To calculate how likely a negative test is truly negative, one can use Bayes' theorem, which incorporates information about both the person and the accuracy of the test.
- For a negative test, there are two key inputs:
  - Pretest probability, an estimate, before testing, of the person's chance of being infected
  - Test sensitivity
  - Pretest probability might depend on local Covid-19 prevalence, SARS-CoV-2 exposure history, and symptoms.


Chance of Infection, Given Negative Test Result (%)
(Post-Test Probability)
50
40
30
20
10
0
Sensitivity, 70%
Specificity, 95%
Sensitivity, 90%
Specificity, 95%
A
B
Considered not infected
0
10
20
30
40
50
60
70
80
90
100
Chance of Infection, before Test Result Is Known (%)
(Pretest Probability)

Chance of Infection Given a Negative Test at Different Levels of Pretest Probabilities

Line 1

Sensitivity: 70%

Specificity: 95%

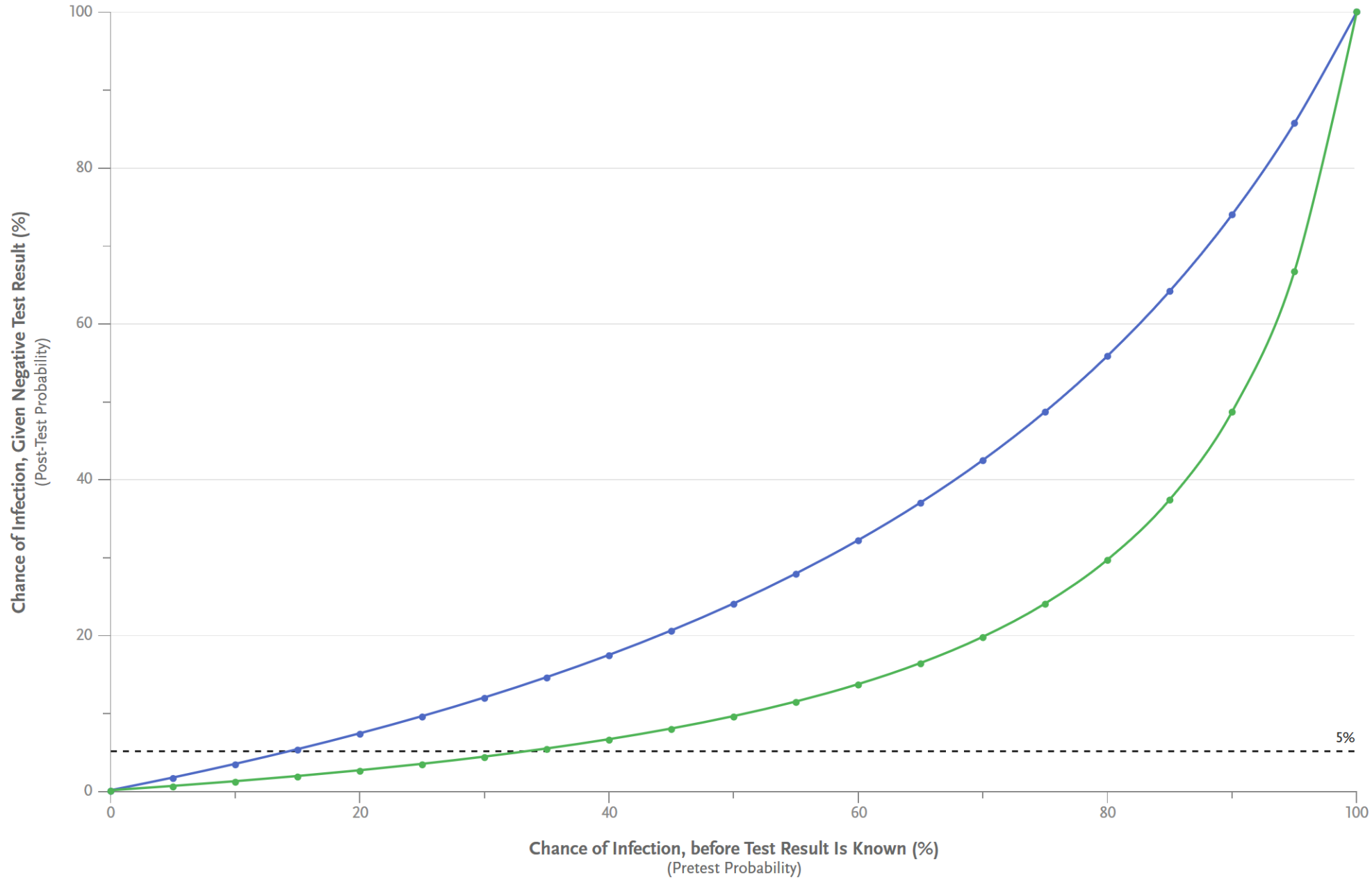
Line 2

Sensitivity: 90%

Specificity: 95%

Line 3

Threshold below which a person can be assumed to be uninfected: 5%



Sensitivity

Chance that the test will be positive in someone who is infected. Low sensitivity means lots of false negative results (ie, the test is negative but the person is actually infected).

References

- https://open.fda.gov/apis/device/covid19serology/
- https://www.fda.gov/medical-devices/letters-health-care-providers/transport-media-safety-risk-use-compatible-transport-media-sars-cov-2-tests-use-bleach-letter
- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance
- https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html
- https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/communication-toolkit.html#audiovisual-resources
- https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing-comms.html
- https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-respirators-health-care-personnel-use-during-covid-19-pandemic-06092020-06092020
- https://www.nytimes.com/2020/06/01/health/masks-surgical-N95-coronavirus.html?smid=em-share
- https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31142-9.pdf
- https://jamanetwork.com/journals/jama/fullarticle/2767023
- https://scholar.google.com/scholar_url?url=https://jamanetwork.com/journals/jama/articlepdf/2767023/jama_degesys_2020_ld_200059.pdf&hl=en&sa=T&oi=ucasa&ct=ufr&ei=dXDeXo-kFr2I6rQP2febkA8&scisig=AAGBfm1pd12LOYogAOsfuEfaQrOkoCfj_Q
- https://www.nejm.org/doi/full/10.1056/NEJMp2015897

Thank You