



COVID-19: KEEPING UP WITH A MOVING TARGET

October 21, 2020 UPDATE



Paul Auwaerter, MD, MBA, FIDSA
Clinical Director, Division of Infectious Diseases
Sherrilyn and Ken Fisher Professor of Medicine
Fisher Center for Environmental Infectious Diseases
Johns Hopkins University School of Medicine



Postgraduate Institute
for Medicine



JOHNS HOPKINS
NURSING





CME Information

Jointly provided by Postgraduate Institute for Medicine, DKBmed, and the Institute for Johns Hopkins Nursing.

Disclosure of Conflicts of Interest

Postgraduate Institute for Medicine (PIM) requires instructors, planners, managers, and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest (COI) they may have as related to the content of this activity. All identified COI are thoroughly vetted and resolved according to PIM policy. PIM is committed to providing its learners with high quality activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

The faculty reported the following financial relationships or relationships they or their spouse/life partner have with commercial interests related to the content of this continuing education activity:

Name of Faculty or Presenter	Reported Financial Relationship
Paul G. Auwaerter, MD, MBA, FIDSA	Scientific Advisor: DiaSorin, Shionogi Inc. JNJ: Ownership equity

Dr. Auwaerter has indicated that he will be referencing the unlabeled or unapproved use of agents currently being investigated in on-going studies and trials, including a monoclonal antibody cocktail, dexamethasone, and several vaccine platforms.

All activity, content, and materials have been developed solely by the activity directors, planning committee members, and faculty presenters, and are free of influence from a commercial entity.





CME Information

To attest for CME/CE/AAPA credit, please visit
COVID19.dkbmed.com





Learning Objectives

- Discuss limitations of current testing
- Describe the difference between molecular tests and antigen tests





Thank You

This activity is supported by an educational grant from Pfizer, Inc. and in-kind support by DKBmed, LLC.

All activity content and materials have been developed solely by the activity directors, planning committee members, and faculty presenters.

Please see **COVID19.DKBmed.com** for additional resources and educational activities





Paul Auwaerter, MD, MBA, FIDSA
Clinical Director, Division of Infectious Diseases
Sherrilyn and Ken Fisher Professor of Medicine
Fisher Center for Environmental Infectious Diseases
Johns Hopkins University School of Medicine





SARS-CoV-2 Testing

9 months in, still many questions



Comprehensive Assessments of Approved Testing

ZERO,
ZILCH,
naDa





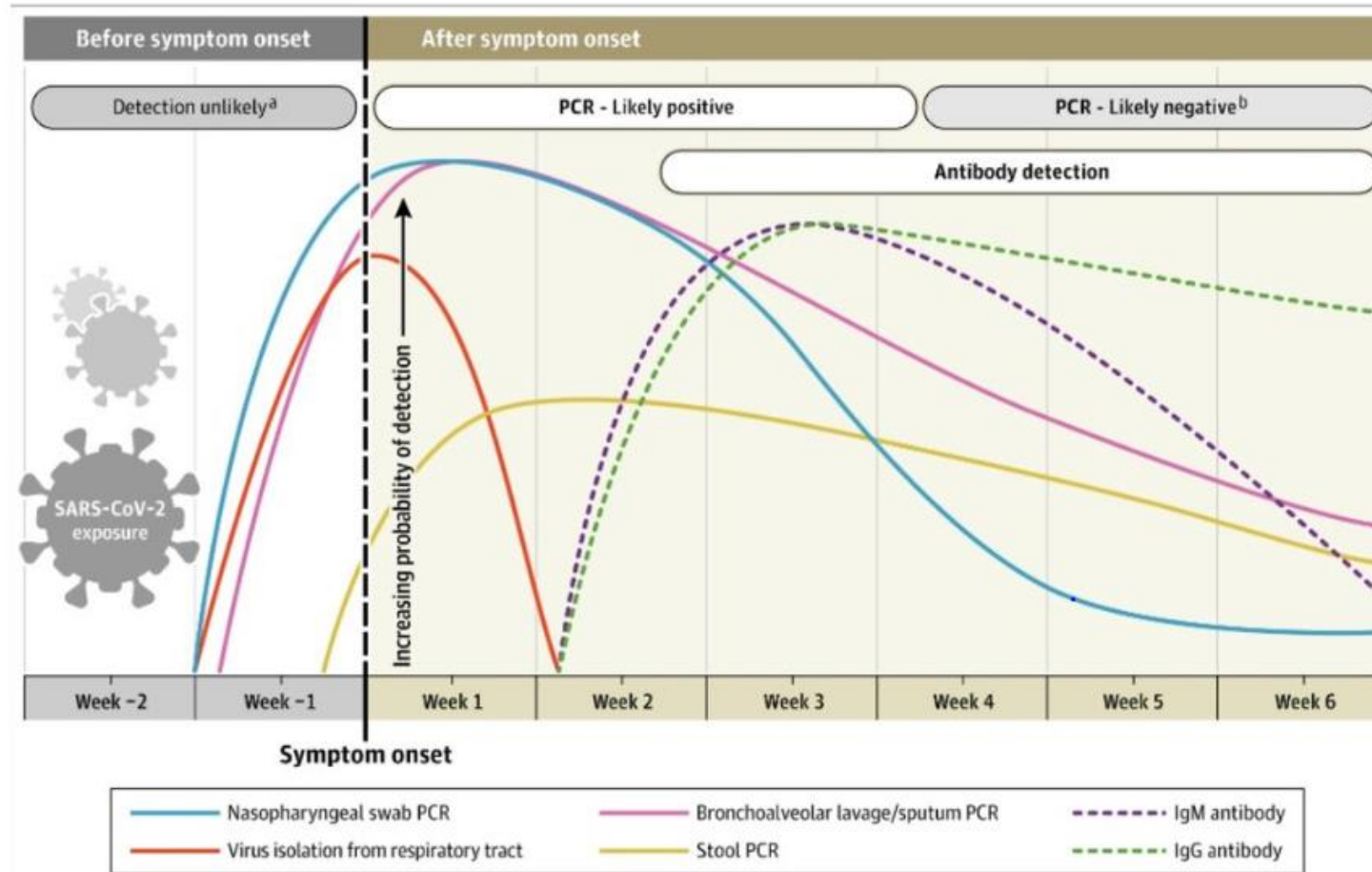
Limitations of Approved Testing

- Conditional approval (EUA):
 - Analytical validity
 - Small sample size
 - Samples from symptomatic COVID-19 hospitalized patients (higher titer)
 - No large clinical validation
 - No gold standard/benchmark
 - Molecular testing best, but unclear what is the standard
 - CT values vary among platforms



Sensitivity

Test Sensitivity Varies With Time Since Symptom Onset

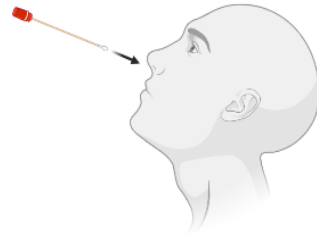


RT-PCR

COVID-19 Diagnostic Test through RT-PCR

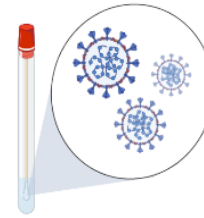
1 Nasopharyngeal swab <15 min

Cotton swab is inserted into nostril to absorb secretions.



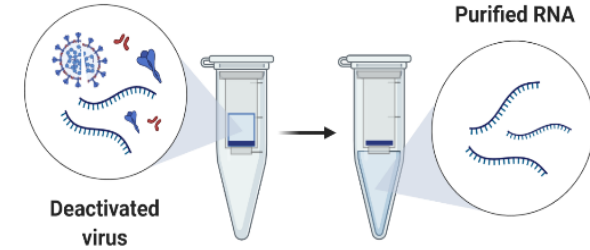
2 Collected specimen 0-72 h

Specimen is stored at 2-8°C for up to 72 hours or proceed to RNA extraction.



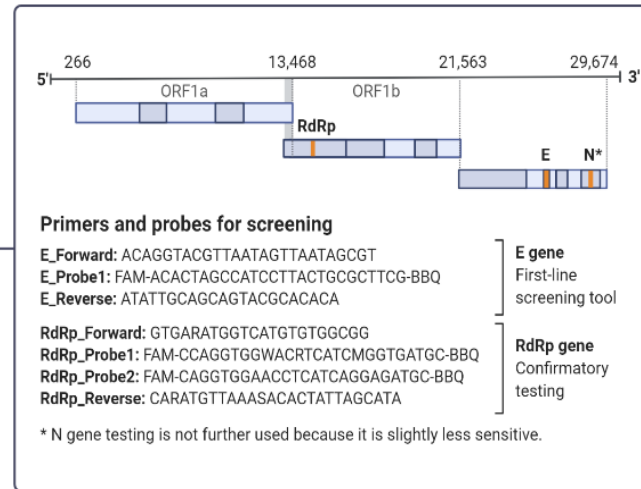
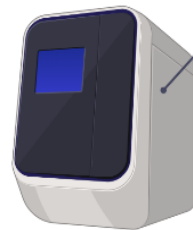
3 RNA extraction ~45 min

Purified RNA is extracted from deactivated virus.



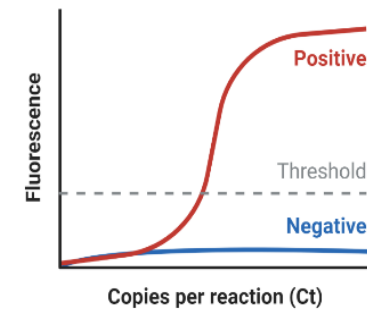
4 RT-qPCR ~1 h per primer set

Purified RNA is reverse transcribed to cDNA and amplified by qPCR.



5 Test results real-time

Positive SARS-CoV2 patients cross the threshold line within 40.00 cycles (< 40.00 Ct).





PCR Turkey Talk

- False negatives: range 2-37%
 - Depends on stage of illness, technique acquiring sample
 - May need to repeat test if clinically suspicious
- Pooled testing: may reduce costs by batching
 - Positive pool = all in that pool need individual testing—delay.
 - Not widely used
 - Most useful if community rates are declining and low



Saliva-Based Tests: Is Drool Good?

- Emerging
- Likely less sensitive than nasopharyngeal swab
 - Detects only ~ 90%
- No tests widely available
- Decreases barrier to testing
 - Who is most contagious?

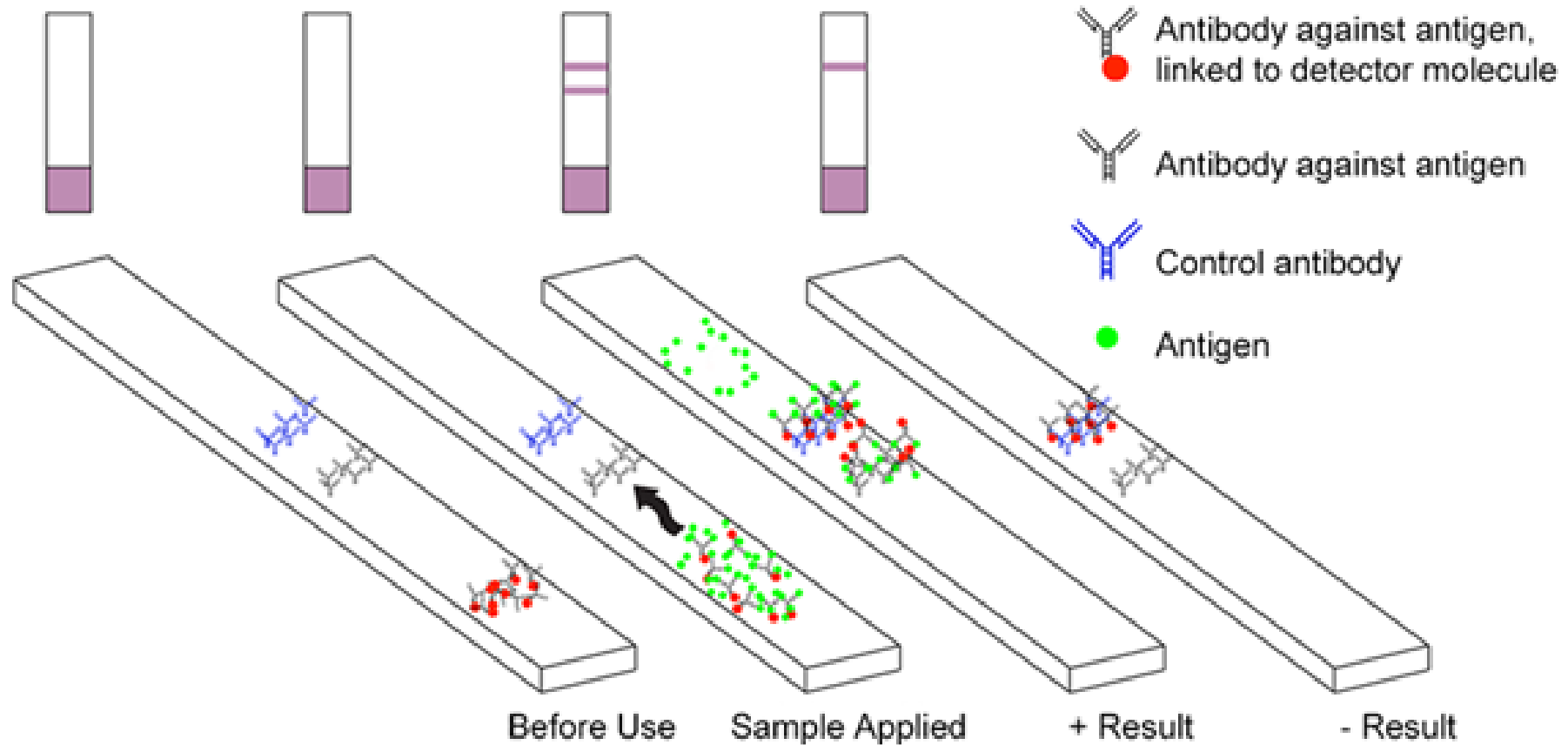


A woman spits into a tube so that her saliva can be tested for the presence of the novel coronavirus. UNIVERSITY OF ILLINOIS, URBANA-CHAMPAIGN

Service RF, Science, 2020



Antigen Testing



Adapted from: Ian M. Campell, https://commons.wikimedia.org/wiki/File:Diagnostic_Medical_Dipstick.png

ASM (8/19/20)



Rapid Testing





COVID-19 Molecular v. Antigen

Table 2. Summary of Some Differences between RT-PCR Tests and Antigen Tests

	RT-PCR Tests	Antigen Tests
Intended Use	Detect current infection	Detect current infection
Analyte Detected	Viral RNA	Viral Antigens
Specimen Type(s)	Nasal Swab, Sputum, Saliva	Nasal Swab
Sensitivity	High	Moderate
Specificity	High	High
Test Complexity	Varies	Relatively easy to use
Authorized for Use at the Point-of-Care	Most devices are not, some devices are	Yes
Turnaround Time	Ranges from 15 minutes to >2 days	Approximately 15 minutes
Cost/Test	Moderate	Low

CDC
(accessed 9/12/20)





Can the Role of Antigen Tests be Widened?

- Date: Mon 19 Oct 2020 17:01
From: Salerno, Reynolds
(CDC/DDPHSS/CSELS/DLS)
<[REDACTED]@cdc.gov>

We are working on a number of studies with different partners to evaluate the performance of all of the widely available antigen tests on asymptomatic persons. The FDA authorizations for these tests are limited to their use on symptomatic persons. We will share data as soon as we are able.

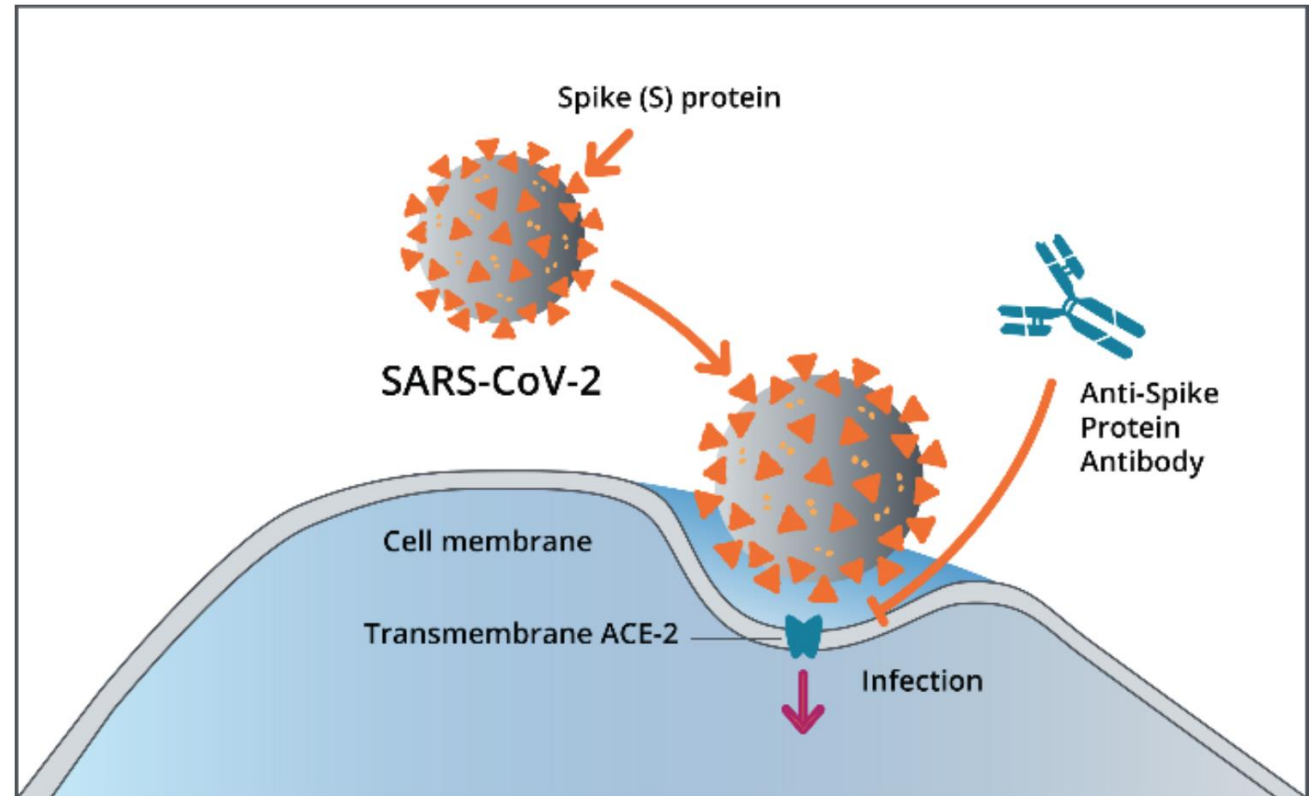
Ren Salerno
CDC
Atlanta, GA (POSTED TO EIN
NETWORK)

- Uncertain
- Tests hard to obtain (most purchased by the government)
- FDA EUA: only for symptomatic patients
- Low sensitivity
 - If repeated, increased false positive tests
 - Asymptomatic screening—likely with lower sensitivity as pretest probability lower.



SARS-CoV-Antibody Testing (Available Versions)

- A positive test may reflect exposure to other coronaviruses
- A positive test should not be taken as evidence of immunity
- A positive test does not mean a COVID-19 diagnosis





Testing FAQs

Q: I am a close contact, tested negative = Can I get out of jail?

A: No, incubation 2-14 d, average 5-6 to symptom onset.

Q: I have had COVID-19, I don't need to be tested?

A: Perhaps. However, many states requiring testing for entry without quarantine. There is yet no test for protective immunity.





To submit your own question, please email QA@dkbmed.com





To receive CME/CE/AAPA credit:

- Complete the evaluation on at COVID19.DKBmed.com
- Upon registering and successfully completing the activity evaluation, you will have immediate access to your certificate.

To access more resources related to COVID-19:

- Access our resource hub at COVID19.DKBmed.com

To ask your own question, email: QA@dkbmed.com

