

COVID-19: Oversight, Tests, Results, Supply & Demand, Explained



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Objectives

- Understanding, HHS, CMS, FDA and CDC roles
- Steps/principles of viral testing
- Positive vs Infectious
- Steps/principles of antibody testing
- Supply Chain Challenges
- Attempts at Supply Chain Solutions

At HHS, who does what?

CDC – Centers for Disease Control and Prevention

- Detecting and responding to new and emerging health threats
- Developed the first FDA authorized for detecting SARS-COV-2

FDA – Food and Drug Administration

- Approves products and processes for diagnostics and treatment of COVID-19
- Runs the “EUA” Process – Emergency Use Authorizations
 - Expedited application to FDA that authorizes use of a process or technology. This is not an approval.

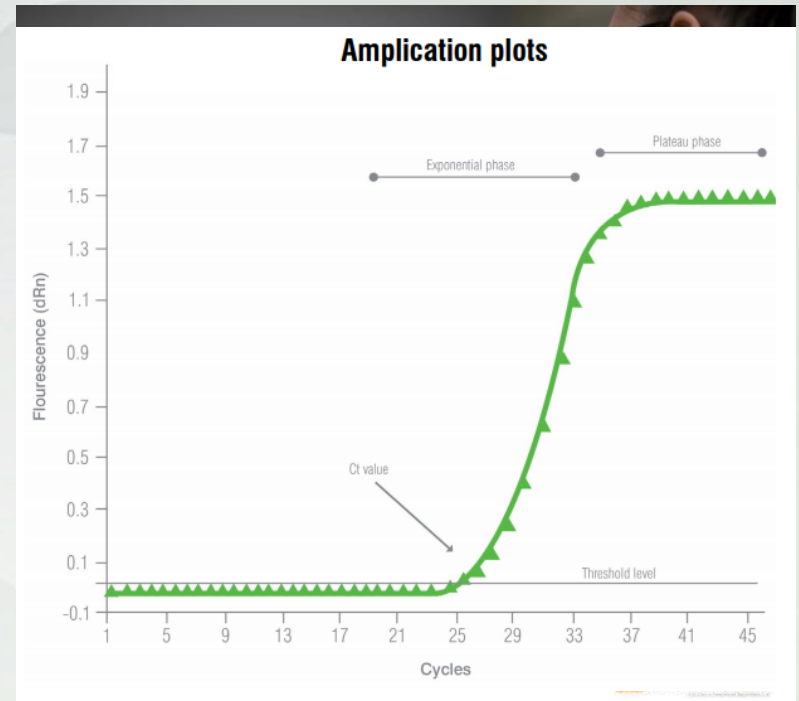
CMS – Centers for Medicare and Medicaid Services

- Sets reimbursement rates for COVID-19 testing for Medicare / Medicaid
- Interprets and manages the standards for accrediting laboratories under the Clinical Laboratory Improvement Amendments (CLIA)
- CLIA labs are the only ones allowed to develop and run new tests

How does viral testing work?

- **Direct Testing (for virus) – *Must have active virus in body to detect***
 - Collect a sample (nasopharyngeal swab, nasal swab, saliva kit)
 - Extract viral genetic material
 - Transcribe viral RNA into DNA
 - Amplify and detect

- Dangers: False negatives due to sensitivity

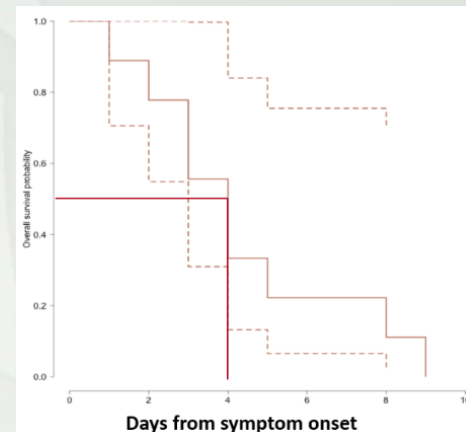
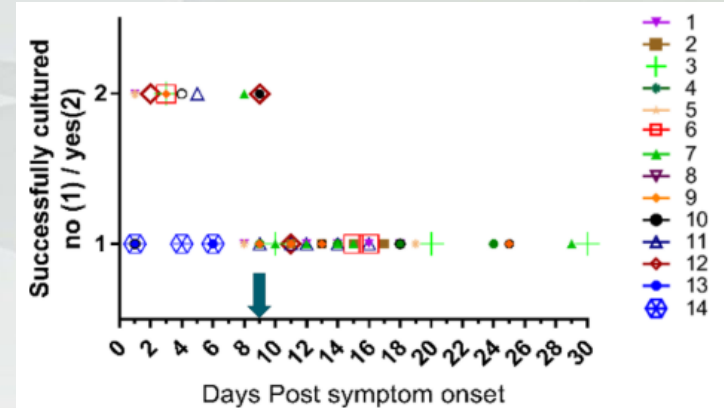


Viral Tests: “Positive” vs “Infectious”

CDC Advisory, May 3 –

“For persons recovered from COVID-19 illness, CDC recommends that isolation be maintained for at least 10 days after illness onset and at least 3 days (72 hours) after recovery. Illness onset is defined as the date symptoms begin.”

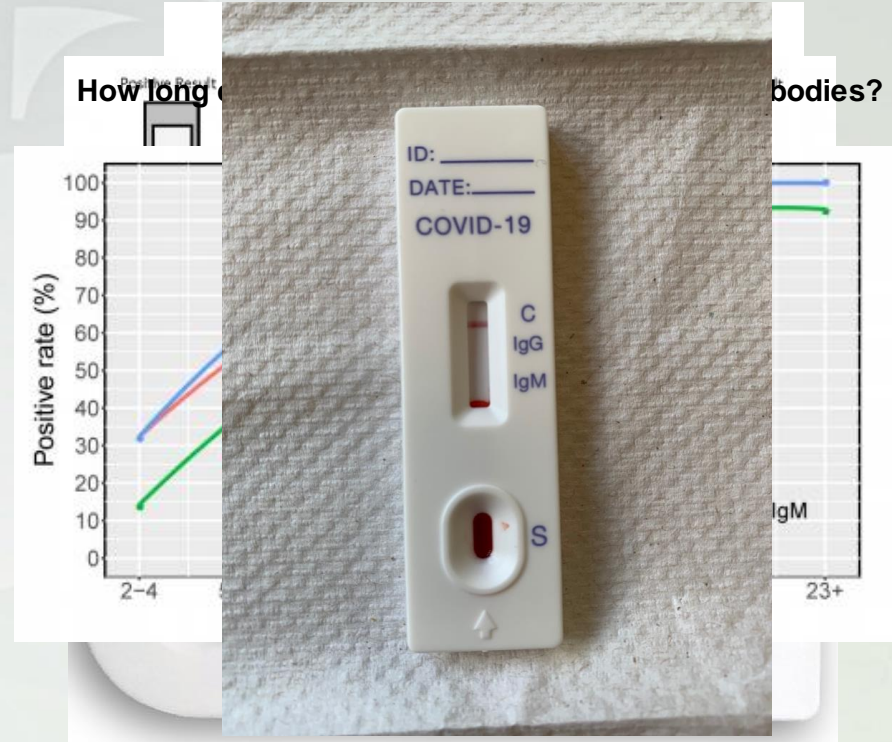
- NOTE: People may test positive for virus for up to 6 weeks
- HOWEVER, after 10 days people may test positive for virus, but the virus cannot be grown in the lab suggesting they are no longer infectious
- Recommended isolation time is now 10 days up from 7 days.



How does antibody testing work?

- Indirect Testing (for antibody) – immune response after viral exposure.
 - Collect a sample (blood via fingerstick)
 - Mix with a solution
 - Sample placed on a cartridge to determine reaction for IgM or IgG
 - IgM – “short-term immune memory”
 - IgG – “long-term immune memory”

- Dangers: False positives **AND** false negatives



Supply and Demand Challenges

✗ **Critical Shortages**
⚠ **In Danger of Shortages**
✓ **No shortage**

■ Viral Tests -

- 48 authorized commercial tests
- 25 Lab-developed tests (10 at universities).

■ Supplies for Tests

- Collection tools ✗
- Extraction Reagents ✗
- Transcription Reagents ✓
- Detection Reagents ✓
- Plates, tips, other supplies ⚠

■ Antibody Tests

- **March 15th** - FDA allowed multiple unapproved platforms without EUAs ✓
- **May 4th** - FDA backtracked and is now requiring EUAs as unproven and fraudulent tests have flooded the market
 - Results of this policy may continue to reverberate as these are still in circulation
- **May 7th** - 12 EUA authorized serology tests ⚠

Simultaneously Not Enough Tests and Too Many Tests

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OPINION | COMMENTARY

We Have a Coronavirus Test—Let Us Use It

Suspend regulations that prevent research labs from conducting diagnostic checks.

By *Jack W. Lipton* and *Caryl E. Sortwell*

April 15, 2020 12:44 pm ET

WSJ | **OPINION**



Tests for COVID-19: Has the FDA said yes too many times?

BY ROBERT M. KAPLAN AND DIANA ZUCKERMAN, OPINION CONTRIBUTORS — 05/06/20 09:00 PM EDT
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

126 COMMENTS

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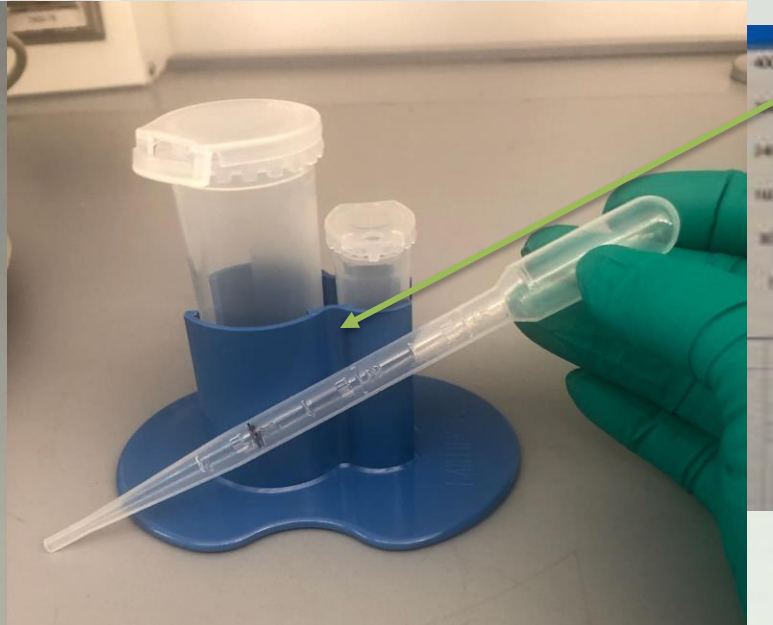
Innovative Solutions from MSU

Saliva kit / Droplet Digital Molecular Test

\$25



\$3



Questions?

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