

Access Dr. Taylor's bio here:

<https://files.asprtracie.hhs.gov/documents/healthcare-operations-speaker-series-bio-jill-taylor.pdf>

Access the recording here: [https://](https://attendee.gotowebinar.com/recording/2571032430647217421)

attendee.gotowebinar.com/recording/2571032430647217421

Access the entire webinar series here: [https://](https://files.asprtracie.hhs.gov/documents/aspr-tracie-healthcare-operations-during-covid-19-pandemic-webinar-series.pdf)

files.asprtracie.hhs.gov/documents/aspr-tracie-healthcare-operations-during-covid-19-pandemic-webinar-series.pdf



T R A C I E
HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

Healthcare Operations during the COVID-19 Pandemic- Speaker Series

November 2020

Unclassified//For Public Use

ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE



Analysis. Answers. Action.

www.aphl.org

Essential Information for Use of Point-of-Care Tests for COVID-19 Diagnosis

Jill Taylor, Ph.D.
Senior Advisor for Scientific Affairs
Association of Public Health Laboratories

Disclaimer

I have no professional or personal relationship with any of the companies I will mention by name. They are included in this presentation for purposes of education and illustration only.

Diagnostic Tests for COVID-19

Laboratory-based

- Moderate or high complexity
 - Molecular: 189 FDA EUA-authorized
 - Antigen: seven are FDA EUA-authorized
 - Serology: not diagnostic (57/1)

Point-of-Care (P.O.C)

- Molecular: seven are FDA EUA-authorized and waived
- Antigen-based: six are FDA EUA-authorized and waived

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Characteristics of P.O.C Diagnostic Tests for COVID-19

- Performed Close-to-Patient to inform rapid decision making
- Fast turnaround time
- Relatively inexpensive
- Generally less sensitive than lab-based tests
- Often regulated for use in a CLIA-waived setting - **waived tests** are **simple tests** with a **low risk** for an incorrect result
- Requires training in use and carefully following manufacturer's instructions

Examples of P.O.C Molecular Tests



<https://www.abbott.com/IDNOW.html>



<https://www.cephheid.com/coronavirus>



<https://diagnostics.roche.com/us/en/products/params/cobas-sars-cov-2-influenza-a-b-nucleic-acid-test.html>

Examples of P.O.C. Antigen Tests



<https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html#/>

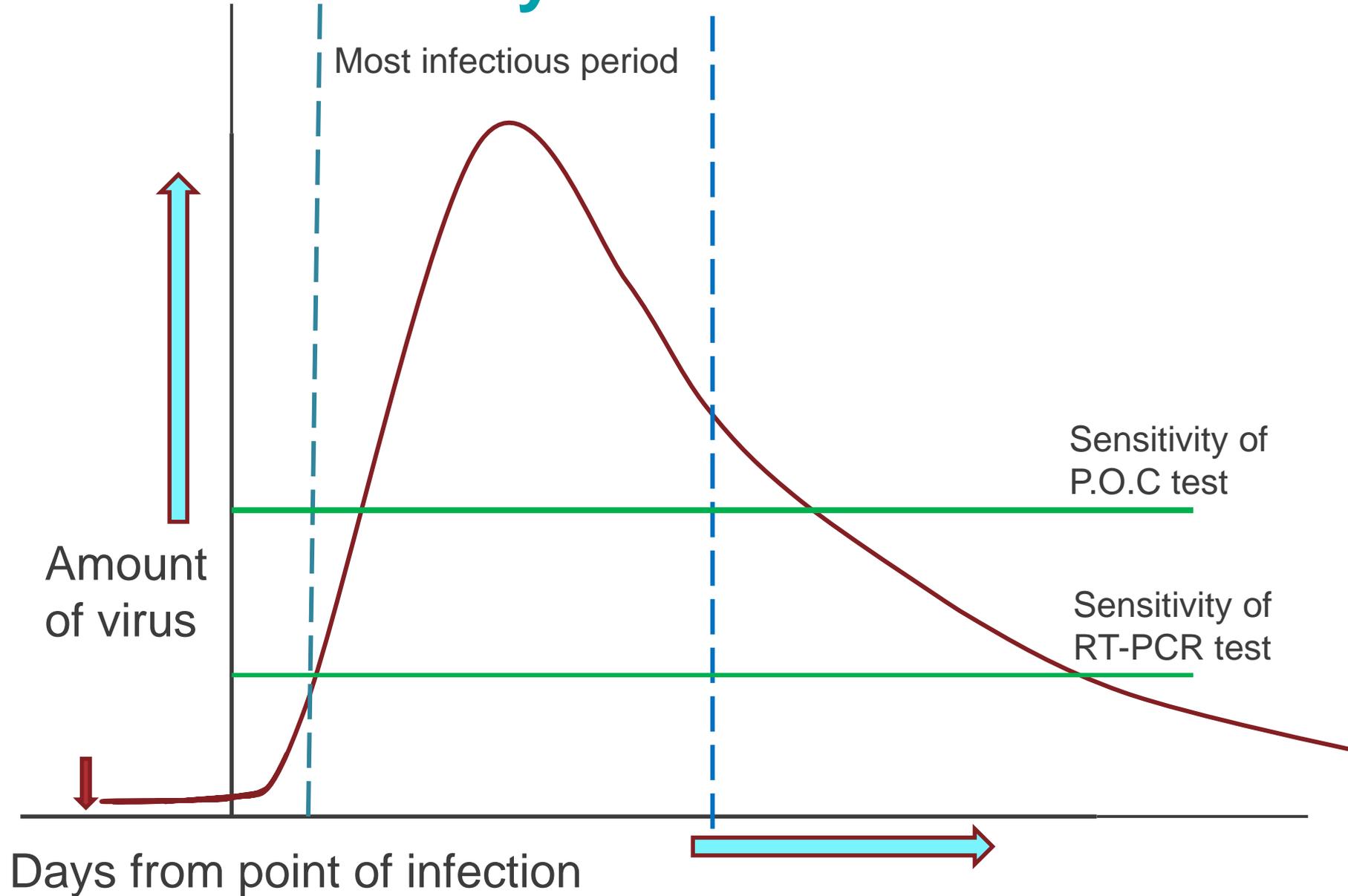


<https://www.bd.com/en-us/offerings/capabilities/microbiology-solutions/point-of-care-testing/bd-veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing>



<https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia>

COVID-19 “Detectability” Curve



A Few Definitions...

- **Sensitivity** refers to a test's ability to designate an individual with disease as positive. A highly **sensitive** test **means** that there are few false negative results, and thus fewer cases of disease are missed.
- The **specificity** of a test is its ability to designate an individual who **does not** have a disease as negative. A highly **specific** test means that there are few false positives and thus fewer people are falsely diagnosed.
- Antigen-based tests for COVID-19 as well as some molecular rapid tests have sensitivity limits.
- Antigen test manufacturers report sensitivity values of 67-100% and specificity of 92-100% **when used according to manufacturer's instructions**.

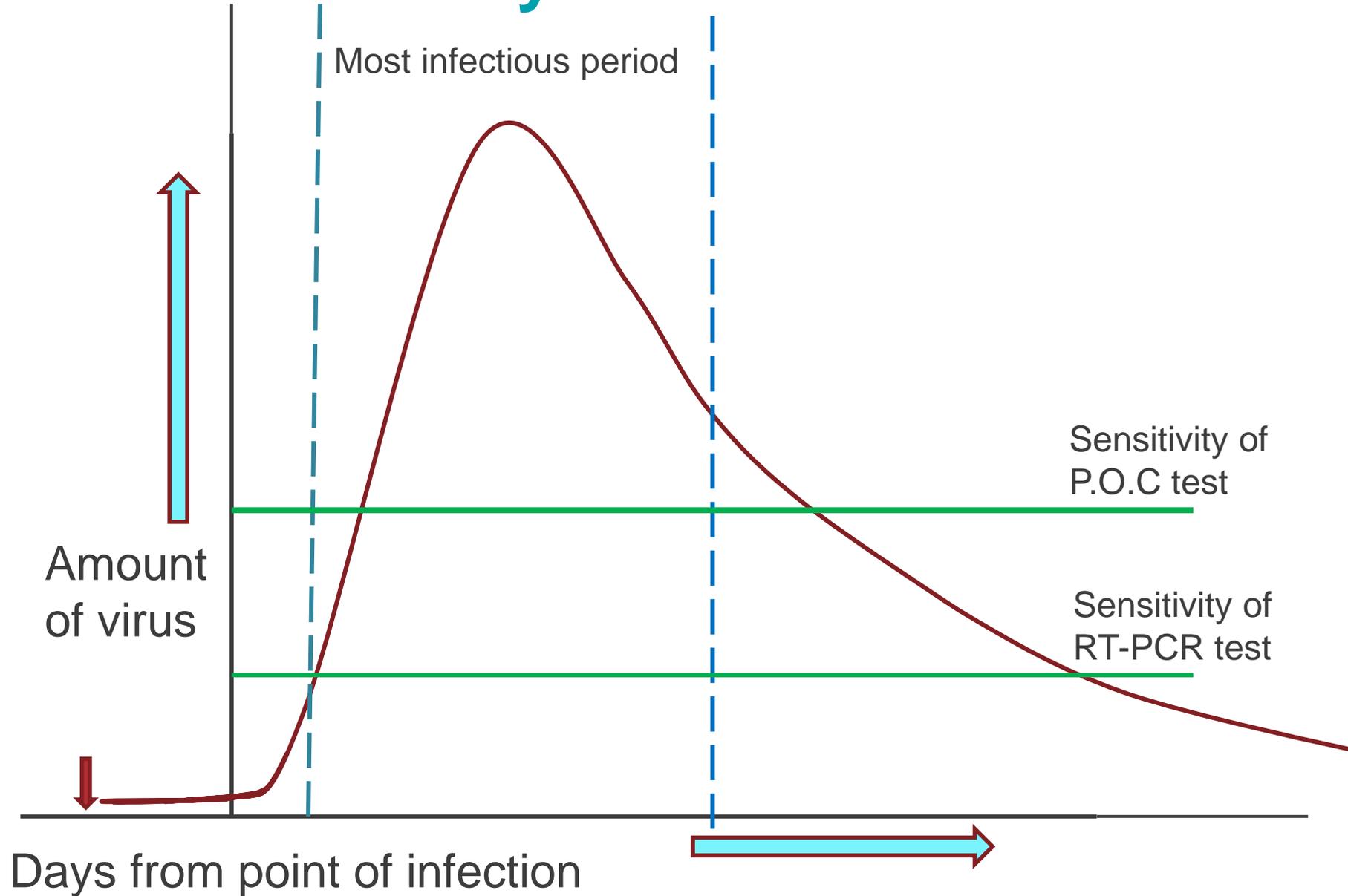
How do we Measure if a Test is of High Quality?

- **Positive predictive value (PPV)** is the probability that individuals with a **positive** result truly have the disease
- **Negative predictive value (NPV)** is the probability that individuals with a **negative** result truly don't have the disease
 - Positive predictive value varies with disease prevalence when interpreting results from diagnostic tests
 - As disease prevalence decreases, the percent of test results that are false positives increases

Prevalence of Disease is Important!

- A test with 98% specificity would have a PPV of just over 80% in a population with 10% prevalence
 - ➔ **20 out of 100 positive results would be false positives**
- The same test would only have a PPV of approximately 30% in a population with 1% prevalence
 - ➔ **70 out of 100 positive results would be false positives**

COVID-19 “Detectability” Curve



Based on Current Knowledge, Where are P.O.C Tests Most Useful?

P.O.C tests provide the most value when:

- The individual is tested in the early stages of infection with COVID-19, when viral load is generally highest - within 5-7 days of symptom onset
- An individual is symptomatic
- An individual has a known exposure to a confirmed case of COVID-19
- Used for screening in outbreak settings (e.g., high-risk congregate settings in which frequent repeat testing could quickly identify persons with a SARS-CoV-2 infection)

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

How to Maximize Correct Results with P.O.C Tests

- Follow manufacturer's instructions
- Use 5-7 days after symptom onset
- Perform correct nasal sample collection
- Store test appropriately
- Provide adequate training and quality systems
- Allow time to perform test correctly
- Read test result at the correct interval
- Monitor the environment (e.g., temperature and humidity)
- Avoid cross-contamination – change gloves
- Understand disease prevalence in the local area
- Interpret the results in context



← Home / Medical Devices / Medical Device Safety / Letters to Health Care Providers

/ Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers



https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory?utm_medium=email&utm_source=govdelivery



Conclusions

When interpreting results, especially from P.O.C. tests, consider positive and negative results in context

- Clinical observations
- Patient history (e.g., travel and contacts)
- Epidemiological information

Consider whether

- Confirmation by lab-based RT-PCR is required
- Frequent serial testing may add more information

Thank you!

Jill.taylor@aphl.org



Contact Us



asprtracie.hhs.gov



1-844-5-TRACIE



askasprtracie@hhs.gov