COVID-19: Testing Update

Jill Taylor, PhD
Director
Wadsworth Center
New York State Department of Health

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By the numbers:

FDA-EUA* authorized assays

Diagnostic

Lab-based RT-PCR:	165 high or moderate complexity tests
	5 waived/point-of-care tests
	388 labs approved by NYS
Antigen detection:	4 waived/point-of-care tests

Serology

Antibody:	47 tests, all high or moderate complexity
	1 waived/point-of-care tests
	146 labs approved by NYS

* US Food and Drug Administration Emergency Use Authorization (EUA)
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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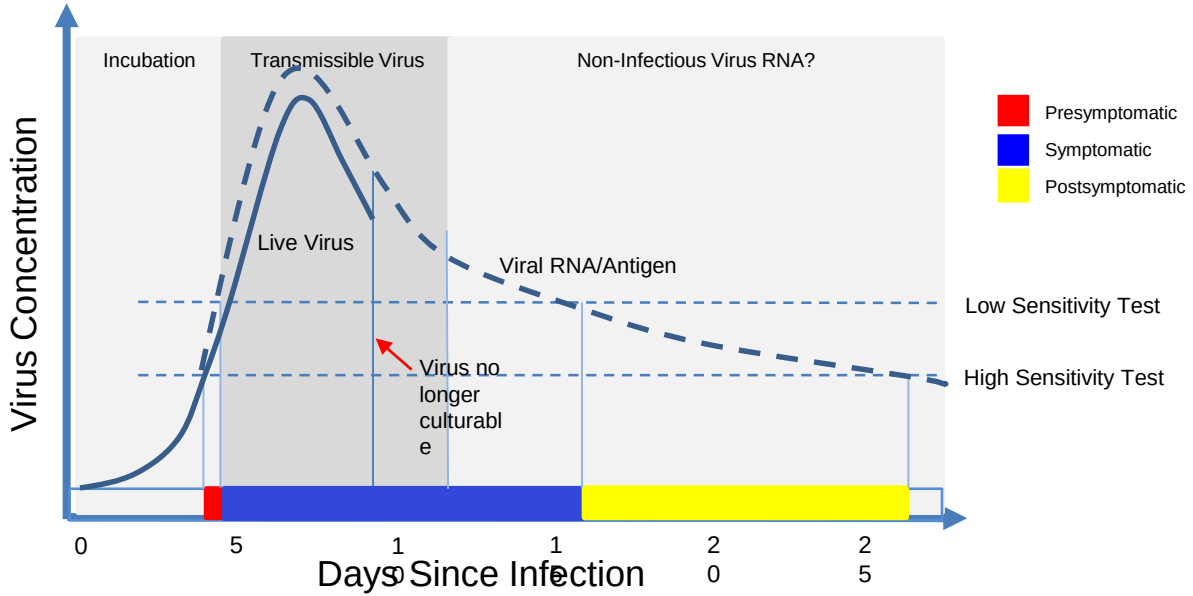
Diagnostic Tests: When to test?



Adapted from Dr. Michael Mina's graph, with the Harvard T. H. Chan School of Public Health, with permission

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Diagnostic lab-based RT-PCR: Which test to use?

- FDA SARS-CoV-2 Reference Panel
https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/
sars-cov-2-reference-panel-comparative-data
  - Of 154 test developers, 54 responded
  - **Limit of detection ranges from 180 to 180,000 NAAT* detectable units/ml**
- Potential Sample Types (if included in the validation)
  - Nasopharyngeal swab
  - Nasal swab (both nares)
  - Saliva
  - Oropharyngeal swabs

*NAAT = Nucleic Acid Amplification Test

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Rapid Point-of-Care Molecular Assay

Characteristics

- Qualitative detection: Resulted as “Positive” “Negative” or “Invalid”.
- **Direct** nasal, NP or throat swabs used within one hour of collection
- Collected with first **seven** days of symptom onset
- Isothermal RT-PCR
- Limit of Detection 300,000 NAAT detectable units/ml

“Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. **Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.** “

https://www.fda.gov/media/136525/download

Antigen-based Point-of-Care Diagnostic Assays

Four assays are FDA-EUA authorized and waived complexity

- Lateral flow, Fluorescence, Instrument read
- Chromatographic Digital Immunoassay, Instrument read
- Microfluidic Immunofluorescence Assay, Instrument read
- Lateral Flow, Visual read on Card, No Instrument

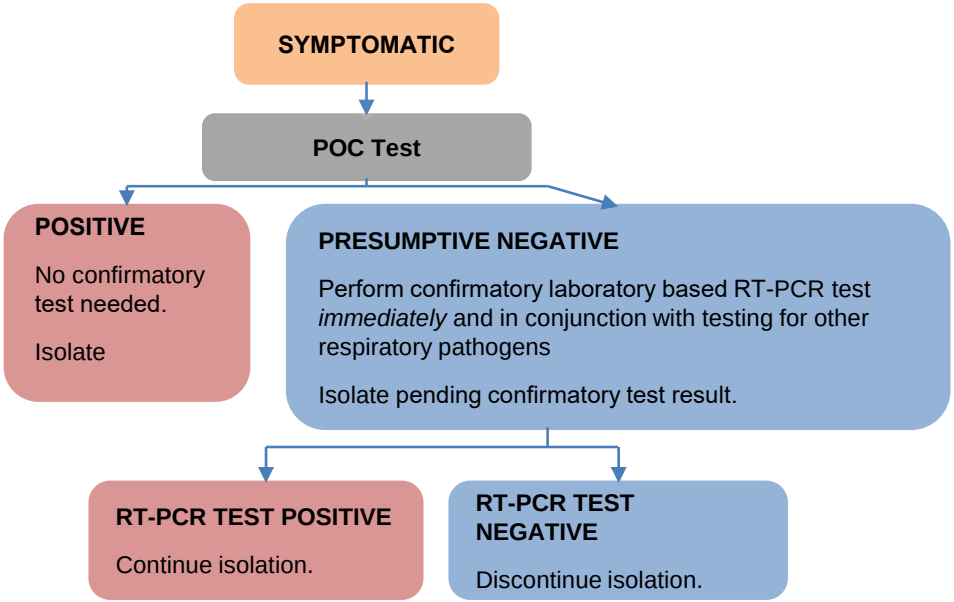
- All detect nucleocapsid protein
- Turnaround time 15 minutes
- Specificity 100%
- Sensitivity 84 to 97.6%
- Validated for symptomatic patients

Utility of an Antigen-based Point-of-Care

Consider……..

- Most helpful in testing symptomatic patients or asymptomatic patients during an outbreak/high prevalence settings, but may also be used to screen asymptomatic patients in low prevalence settings.
- Offer less expensive alternative compared to a laboratory-based test, quick results, and can be easy to administer.
- Due to decreased sensitivity of these tests, results must be considered in the broader context of symptoms, the patient's exposure history, and community prevalence.
- A system for further testing (i.e., additional antigen-based POC testing and laboratory based RT-PCR) must be in place.

Algorithm for Responding to POC Test Results: *Symptomatic* Patients



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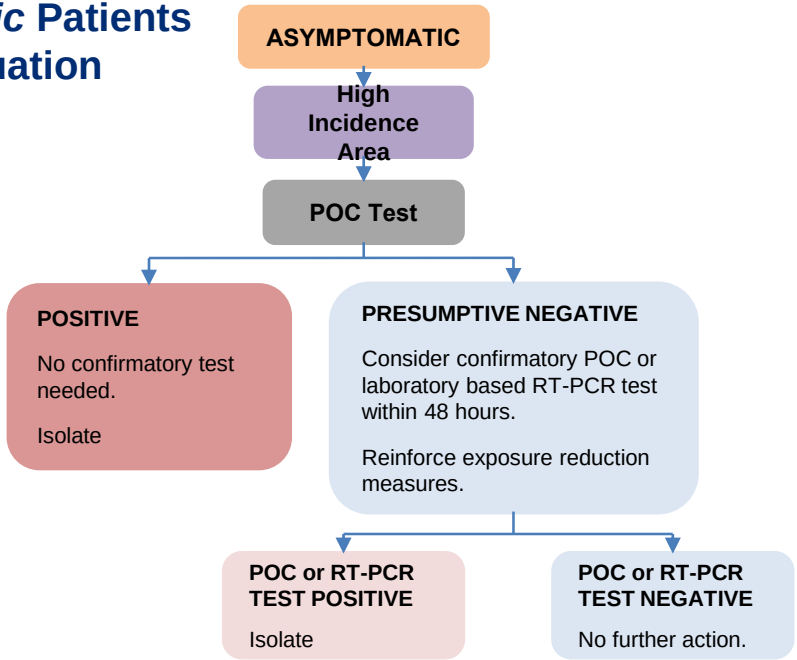
Algorithm for Responding to POC Test Results:

- ***Asymptomatic*** **Patients**
- **Outbreak situation**



Healthcare providers should consider negative results in the context of:

- **Limitations of the test**
- **Clinical observations**
- **Patient history (exposure)**
- **Epidemiology information (prevalence)**

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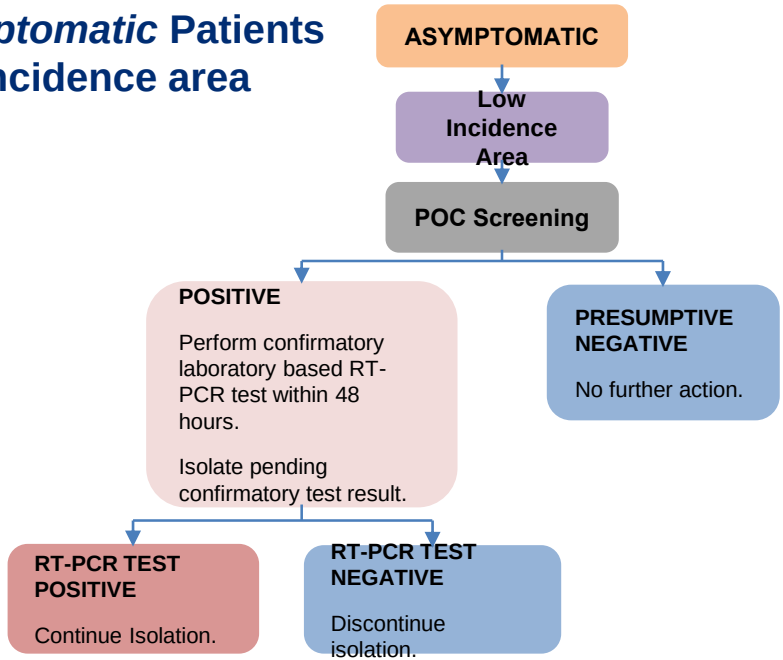
Algorithm for Responding to POC Test Results:

- ***Asymptomatic*** **Patients**
- **Low incidence area**



Healthcare providers should consider negative results in the context of:

- **Limitations of the test**
- **Clinical observations**
- **Patient exposure history**
- **Epidemiology information (prevalence)**

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Thank you!

Questions?