Covid 19 TESTING Overview

Mount Sinai Health Partners

SARS CoV-2 Viral Testing with FDA EUA (as of 8/15/2020)

- **Rapid Point of Care Testing (15 minute tests)**
  - 1 PCR based (Abbott ID Now-used at White House); 2 Antigen Based (Qudel Sofia & Becton Dickenson – both recently purchased by multiple states including New York)
  - From Nasopharyngeal/Nasal swab - For Symptomatic individuals
  - **NYS DOH Suggestion: work with smaller local labs – for more rapid turnaround time and also will report positive results to DOH for follow up contact tracing**

- **Saliva Direct (approved for CLIA labs 8/15/20)**
  - Rutgers saliva test – piloted with practices and the Yale NBA study
  - Stable in saliva for 2-25 days, at room temperature
  - Efficacy comparable to NP/Nasal swab
  - Can collect saliva at home but test conducted in CLIA approved labs
  - **Opens the door for At-Home Testing & Result -** laminar flow technology being developed (similar to home pregnancy test)

- **Combined Testing for Collection at the Point of Care**
  - 3 tests with FDA EUA for Covid 19, Influenza A & B
  - Collection of Nasopharyngeal or Nasal Swab specimen
  - Performed by CLIA approved laboratories – what will the turnaround time be?!

Currently Available Rapid testing with FDA EUA - August 2020

NAAT- Nucleic Acid Amplification Test - Whole gene detection

- Abbott ID Now
- Requires specialized machines that are not easy or cheap to produce in bulk
- Is what the White House is using for its daily testing

Antigen Detection – Detects surface Spike Protein

- Quidel Sofia 2 SARS Antigen FIA test - Result in 15 minutes
  - Sensitivity/Specificity 87.5% sensitivity (ability to exclude false negatives) and 100% specificity (ability to exclude false positives).
  - On August 7, 2020 announced **Sensitivity of 96.7% on par with PCR testing**
- Becton Dickinson Antigen Test – Result in 15 minutes
  - 84% sensitivity and 100% specificity.
- Seven states (including NY) have announced a joint bid to purchase 3.5 million Antigen tests from BD & Quidel
- Practical for Community Surveillance use

Local COVID-19 Testing Availability

- **Spoke with Bioreference, Sherman Abrams, and Lenco**

- **They will not be offering any of the Rapid Tests**
  - Rationale:
    - Rapid test is for large venues (e.g. sports/large hospital settings) –15 minute turnaround is otherwise useless
    - They have no plans to use it for local practices/physicians

- **The Saliva test is more promising and is being assessed**
  - Reviewing Sensitivity/Specificity
  - Awaiting NYS guidelines for their ability to perform this test
  - Will need to develop the infrastructure: codes, etc
  - Understand they could collect it at their patient service centers - with NYS DOH approval

Local COVID-19 Testing Availability

Bottom Line:

- For now it is still the PCR test on Nasopharyngeal/Nasal Swabs
- Collected by the Provider
- Processed in their lab
- Usually a 2-3 day turnaround for all three labs

At-home COVID-19 Collection Tests (July-August 2020)

- FDA EUA; Test kits now include collection device to collect your saliva (instead of deep nose or throat swabs) and the sample is then mailed to lab for processing.

- Some require video consultation to supervise sample collection.

- Examples of at-home collection tests :
  - Pixel of Labcorp (nasal swab): results within 2 to 3 days from when sample is received
  - Everlywell (nasal swab): results within 72 hours
  - LetsGetChecked (nasal swab): results within 2 to 5 days
  - Hims (saliva): results within 3–5 days from when sample is shipped
  - Vault Health (saliva): results within 2–3 days

- Most require up front payment (Pixel of Labcorp will take insurance reimbursement)

- Cost may vary from $109-$155 per sample

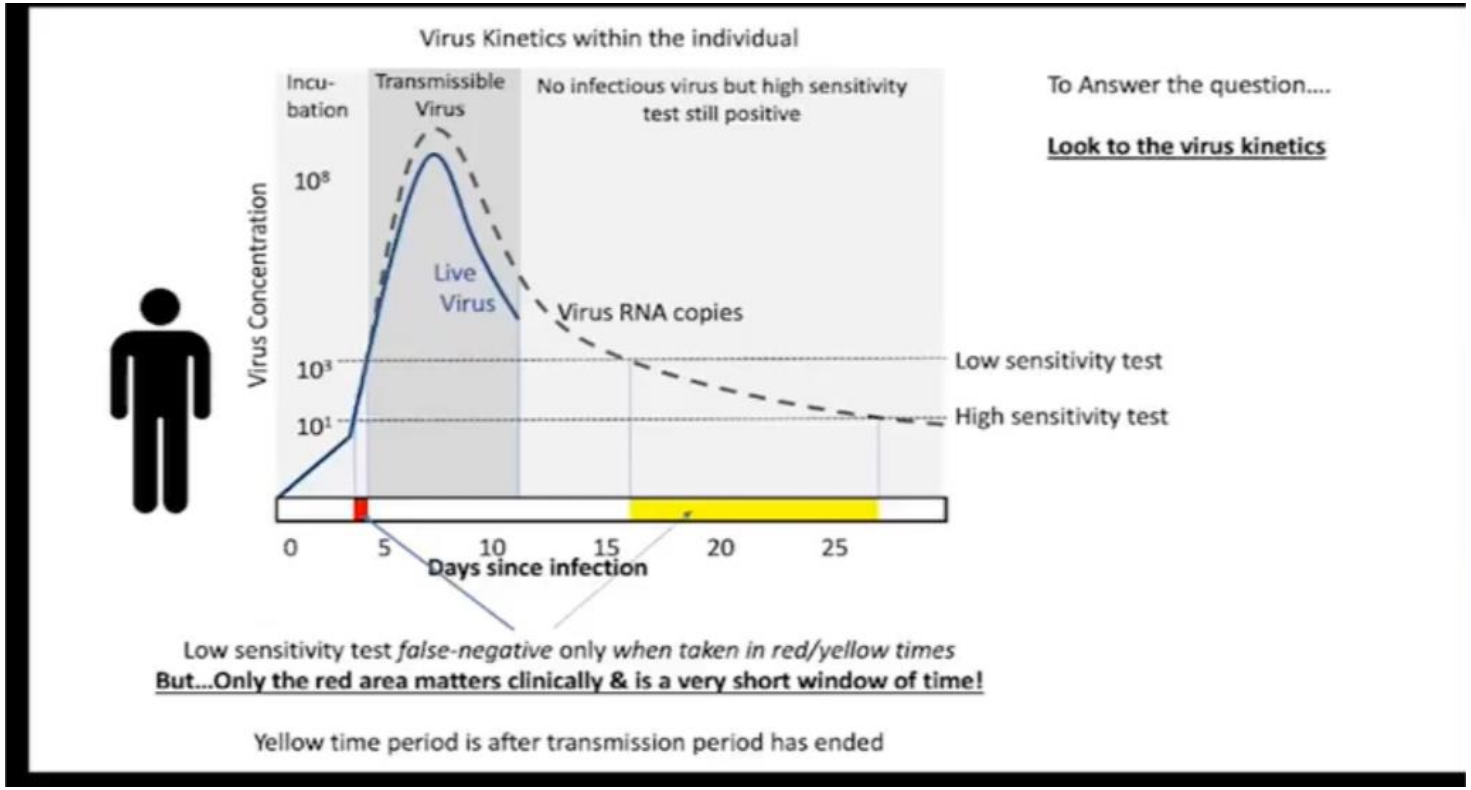
COMBINED Test: SARS CoV2 Coronavirus, influenza A & B

(For CLIA authorized labs - 7/1/2020)

- Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC produced)
- A nucleic acid test for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids
- From upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate)
- From individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider
- Emergency use of this test is limited to authorized CLIA laboratories
- Collect at the POC but performed by the laboratory

Appendix

The Viral Kinetics: Making the Case for Sensitive Testing with Rapid Reporting vs Very Sensitive Testing with long (>48 hours) delay



FREQUENT Less sensitive Testing (q 3 days) with RAPID Result would be MORE useful than VERY sensitive (PCR) testing with result after 48 hours
Detecting Viral fragments that are NOT infectious is not useful for Community Surveillance
No value in identifying these fragments

Sources

- COVID-19 & Testing: Can More Frequent and Faster Testing With Cheaper, Less Sensitive Tests Control The Pandemic? When Do We Need It? Can Pool Testing Increase Capacity?Dr. Chaz Langelier, UCSF, San Francisco, CA. VuMedi July 31, 2020

- Click here to view: Rapid Testing for COVID-19: What is the Evidence Supporting the Move From Highly Sensitive PCR-based Viral Tests to More Rapid, Cheaper, and Less Sensitive Tests? Dr. Michael Mina, Harvard T.H. Chan School of Public Health, Boston, MA August 2020