Testing for HIV and COVID-19: It is what it is.

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Principal Consultant
Scientific Affairs LLC

This activity is jointly provided by Physicians’ Research Network and the Medical Society of the State of New York.
Background and Disclosure of Financial Relationships

Dr. Branson previously served as Associate Director for Laboratory Diagnostics in CDC’s Division of HIV/AIDS Prevention until October 2014.

Dr. Branson currently serves as consultant to the Gilead Sciences FOCUS Program
Use of Brand Names

This presentation may refer to individual HIV tests by brand name for the purposes of identification and clarity.

No endorsement of any specific test is intended.
Learning Objectives

Understand the fundamentals of laboratory tests for COVID-19.

Appreciate the role for serology tests in identifying exposure to COVID-19.

Review new developments in HIV tests and their utility for a new diagnostic algorithm

Describe how similar parameters affect the accuracy of tests for COVID-19 and HIV.
Question 1: Which COVID-19 tests have received FDA-approval?

- PCR tests
- Antigen tests
- Antibody tests
- All of the above
- None of the above
FDA Regulation of Devices: a Quick Primer

License: Biologics (tests for blood screening)

Approval: high-risk devices (HIV Ag, Ab, RNA tests
  - Pre-market approval application

Clearance: most diagnostic tests
  - 510(k) application

Emergency Use Authorization: not approval
A few more regulations apply...

CLIA: Clinical Laboratory Improvement Amendments (of 1988)

- Part of CMS (Center for Medicare and Medicaid Services) classifies devices and certifies laboratories to perform tests based on complexity:
  - High
  - Moderate
  - Waived

LDTs: Laboratory-developed tests (FDA requirements suspended)

- For use only by laboratory that developed the assay
- Can be for novel assay (SARS-CoV-2) or one for which assays exist (Vitamin D)
How Confident? Depends.

<table>
<thead>
<tr>
<th></th>
<th>No. of Specimens</th>
<th>Sensitivity/PPA (95% CI)</th>
<th>Specificity/NPA (95% CI)</th>
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<tr>
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<td>Positive</td>
<td>Negative</td>
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<td>3515</td>
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<td>7000</td>
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<td></td>
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<td>100 (99.7-100)</td>
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<td>COBAS Flu A</td>
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<td>1308</td>
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<td></td>
<td>95.2 (84.2-98.7)</td>
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<td>Rapid Ag</td>
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<td>266</td>
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<td>80 (71-87)</td>
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<td>Abbott SARS-CoV-2</td>
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<tr>
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<td>Rapid Ag</td>
<td>35</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>97 (85-99)</td>
</tr>
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Current Status, SARS-CoV-2 Tests

Emergency Use Authorizations

- **RT-PCR:**
  - 158 Individual Use EUAs
  - 35 Umbrella EUAs for Laboratory Developed Tests (LDTs), all for high-complexity testing labs

- **Antigen:**
  - 4 Individual Use EUAs; all for high, moderate complexity and waived labs

- **Antibody:**
  - 35 currently with Individual Us EUAs, initial 3 withdrawn
Initial Steps: RT-PCR for SARS CoV-2 RNA

- Sample tissue
- Extract RNA
- Use reverse transcriptase to form complementary DNA
- Real-time PCR amplification

<table>
<thead>
<tr>
<th>Sampling Method</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchial lavage</td>
<td>44/15 (93%)</td>
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<tr>
<td>NP swab</td>
<td>8/5 (63%)</td>
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<tr>
<td>Throat swab</td>
<td>126/398 (32%)</td>
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<tr>
<td>Sputum</td>
<td>75/104 (72%)</td>
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<tr>
<td>Feces</td>
<td>44/153 (29%)</td>
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</tbody>
</table>

Wong et al, JAMA March 2020
Heat to denature cDNA to create two single DNA strands

Add DNA polymerase to create 2 new cDNA molecules

Repeat thermocycle

Lower temp, primers bind to 3’ and 5’ ends of single-stranded DNA

cDNA from viral RNA
Chain Reaction: Exponential Amplification

Number of copies in 1st cycle determined by number of copies in specimen

"Cycle threshold" for negative specimen

$2^2 = 4$ copies
$2^3 = 8$ copies
$2^4 = 16$ copies
$2^5 = 32$ copies

$2^{21} = 1$ million copies
$2^{31} = 2$ billion copies
## Comparative Analytical Sensitivity

**FDA Performance Panel**

<table>
<thead>
<tr>
<th>Product LOD (NDU/mL*)</th>
<th>Developer</th>
<th>Test</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Perkin Elmer</td>
<td>P.E. New Coronavirus Nucleic Acid Detection Kit</td>
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<tr>
<td>0</td>
<td>Hologic, Inc.</td>
<td>Panther Fusion/Aptima SARS-CoV-2 Assay *                (2.4 hours)</td>
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<tr>
<td>100</td>
<td>Roche Molecular</td>
<td>cobas SARS-CoV-2</td>
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<tr>
<td>100</td>
<td>Becton Dickenson</td>
<td>BD SARS-CoV-2 Reagents for BD MAX System</td>
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<tr>
<td>100</td>
<td>Quest Diagnostics</td>
<td>Quest SARS-CoV-2 rRT-PCR</td>
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<tr>
<td>100</td>
<td>Abbott Molecular</td>
<td>Abbott RealTime SARS-CoV-2 assay *                      (2.4 hours)</td>
</tr>
<tr>
<td>100</td>
<td>CDC</td>
<td>Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay</td>
</tr>
<tr>
<td>100</td>
<td>Cepheid</td>
<td>Xpert Xpress SARS-CoV-2 *                                (45 minutes)</td>
</tr>
<tr>
<td>10,000</td>
<td>CDC</td>
<td>CDC2019-nCoV Real-Time RT-PCR Dx Panel</td>
</tr>
<tr>
<td>5,400</td>
<td>Abbott Diagnostics</td>
<td>ID NOW COVID-19 *                                       (13 minutes)</td>
</tr>
<tr>
<td>5,400</td>
<td>Quidel Corporation</td>
<td>Lyra Direct SARS-CoV-2 Assay *                           (70 minutes)</td>
</tr>
</tbody>
</table>

* - FDA.gov/medical-devices as of 9/15/2020
Saliva Test: EUA for SalivaDirect Protocol

- EUA issued to Yale School of Public Health August 15, 2020
- Uses unprocessed saliva, collected into sterile urine cup or test tube
- No extraction step required
SalivaDirect Protocol for SARS-CoV-2 RT-PCR

Eliminates need to collect NP swab, so no swab or transport medium
Eliminates need for RNA extraction kit (supply issues)
Validated for use with reagents, primers and instruments from several different diagnostics manufacturers – and counting
Distributed free to individual laboratories
Commercial laboratories must obtain a license (free) that negotiates retail price they can charge
Paired specimens from 70 hospitalized patients with swabs positive for SARS-CoV-2 on hospital admission

-Wyllie et al, Yale University
Simplified, sensitive, economical SalivaDirect method

**Stability w/o preservatives**

Conditions for 7 days:
- Fresh
- 4°C
- RT
- 30°C

**Extraction-free**

Total minimum reagent cost per sample: $1.29 - $4.37
COVID-19 Genome

80% sequence identity with SARS-CoV
50% sequence identity with MERS-CoV

90% sequence identity with 2 bat coronaviruses
SARS-CoV-2 viral antigens and RNA

CDC Flu SARS-CoV-2 Multiplex (Flu SC2)
- SARS CoV-2: N gene
- Influenza A: Matrix gene
- Influenza B: NS2 gene
- Internal Control: RNAse P
- Positive Control: FluSC2PC
Mechanism of COVID-19 entry into cell
COVID-19 binding to ACE2 receptor

- Angiotensin I + ACE → Angiotensin II
- ACE inhibtor drugs block conversion of angiotensin I to II
- ACE2 receptor binds to SARS-CoV-2 spike protein
- Viral entry, replication, and ACE2 normal function blocked
Testing strategies

Symptomatic persons only ("revised" CDC guidelines)
Test symptomatic persons and known contacts

Test anyone on demand

Test everyone twice a week (Saliva: University of Illinois)
Focused testing after sentinel testing of sewage from specific locations (e.g., dorms – U of Arizona)
What about antibody tests?
HIV-1: viral antigens and RNA

- gp120
- gp 41
- p24
- RNA

pol: Protease, RT, polymerase, integrase
Which HIV antibodies do rapid tests detect?

- quick Advance: gp41
- DPP HIV 1/2: gp41, gp120
- Chembio Sure Check: gp41, gp120
- Chembio Stat Pak: gp41, gp120
- INSTI HIV 1/2: gp41
- Uni-Gold Recombigen: gp41, gp120
- Determine Combo Ag/Ab: gp41, gp120
Antigens used by instruments to detect HIV-1

<table>
<thead>
<tr>
<th>“3rd generation” instrumented antibody tests</th>
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<tbody>
<tr>
<td>Bio-Rad GS HIV-1/2 Plus O</td>
<td>p24, gp160</td>
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<tr>
<td>Ortho Vitros Anti-HIV 1+2</td>
<td>p24, gp41, gp41/120</td>
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<tr>
<td>Siemens Advia Centaur HIV 1/O/2</td>
<td>p24, gp41/120</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“4th generation” instrumented Ag/Ab combo tests</th>
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<tbody>
<tr>
<td>Abbott Architect HIV Ag/Ab Combo</td>
<td>gp41</td>
</tr>
<tr>
<td>Bioplex 2200 HIV Ag-Ab</td>
<td>gp160</td>
</tr>
<tr>
<td>Bio-Rad GS HIV Combo Ag/Ab</td>
<td>gp41, gp160</td>
</tr>
<tr>
<td>Ortho Vitros combi</td>
<td>gp41, gp41/120</td>
</tr>
<tr>
<td>Siemens Advia</td>
<td>gp41/120</td>
</tr>
<tr>
<td>Roche Elecsys</td>
<td>gp41, RT</td>
</tr>
</tbody>
</table>

Just like single-use rapid tests
Antibody Response to HIV (without treatment)

- Keating et al CID, 2016
Effect of ART during Acute HIV

- Keating et al. CID, 2016
Initiation of ART During Acute HIV Infection Leads to a High Rate of Nonreactive HIV Serology

De Souza et al. CID, 2016
Antigens in 3rd gen and 4th gen antibody assays differ.

- **Second-generation immunoassay**
  - Time after treatment (weeks): 0, 12, 24
  - * indicates gp41, p24 antibodies

- **Third-generation immunoassay**
  - Time after treatment (weeks): 0, 12, 24

- **Fourth-generation immunoassay**
  - Time after treatment (weeks): 0, 12, 24
  - gp41 antibodies
Seroconverions during PrEP trials

Partners PrEP:
- Dual blood rapid test during visit; blood drawn for central lab testing
  - Study drug withheld for reactive HIV test, discontinued for seroconversion

In seroconverters on PrEP:
- Time to reach each Fiebig stage elongated
- Delay of ≥100 days from first infected visit to detection by rapid HIV test:
  OR 7.8, as-treated vs placebo

False-positive: 110/65,945 visits (0.1%)

- Donnell et al, AIDS 2015
- Ndase PLOS One 2015
Seroconverions during PrEP trials

Bangkok Tenofovir study:
- Monthly Oraquick oral fluid test, NAT on blood every 3 months
- Median time from positive NAT to reactive OraQuick among seroconverters:
  - Participants receiving tenofovir: 191.8 days
  - Participants receiving placebo: 16.8 days

- Suntharasamai et al, PLOS One 2015
Seroconversions during PrEP trials!

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Median time from positive NAT to reactive OraQuick among seroconverters:

- Participants receiving tenofovir: 191.8 days
- Participants receiving placebo: 16.8 days

"anti-gp41 seroreversion in patients treated early and effectively as a consequence of early and prolonged suppression of viremia."

- Suntharasamai et al, PLOS One 2015
Quick Case Study

25 year old MSM in an HIV-discordant relationship, on PrEP since 12/2015. Perfect adherence by history. Also had 2 other sex partners.

4th generation testing repeatedly negative until May 2016:

- Positive 4th gen, negative Multispot, HIV RNA<20, signal detected

Repeat 2 and 4 weeks later: same results.
Poll question 2: **What would you do next?**

- Repeat tests in 6 weeks
- Order a Western blot
- Stop PrEP
- Add an additional antiretroviral
- All of the above
- Dolutegravir added to regimen

Genotype: Multiple drug resistance mutations (including TDF/FTC), virus not related to that of his virally suppressed partner.
Acquisition of wild-type HIV-1 infection in a patient on pre-exposure prophylaxis with high intracellular concentrations of tenofovir diphosphate: a case report

Elske Hoornenborg, Maria Prins, Roel C A Achterbergh, Lycke R Woittiez, Marion Cornelissen, Suzanne Jurriaans, Neeltje A Kootstra, Peter L Anderson, Peter Reiss, Henry J C de Vries, Jan M Prins, Godelieve J de Bree, on behalf of the Amsterdam PrEP Project team in the HIV Transmission Elimination AMsterdam Consortium (H-TEAM)

www.thelancet.com/hiv  Published online September 14, 2017

50 y/o MSM on PrEP for 8 months
Ag/Ab assay reactive; Western blot indeterminate (gp 160 only)
RNA undetectable; DNA undetectable
PrEP stopped; viral load became elevated after 3 weeks
Recommended Follow-up Testing: Persons on PrEP

Every 3 months:
- HIV Ag/Ab Combo test
- STI testing

But: Test positivity after infection while on PrEP (resistance or poor adherence) might be delayed or indeterminate

HIV-1 RNA not always detectable
Options for confirming HIV status in the presence of PrEP:

- Testing for (1) HIV RNA in plasma, (2) total HIV-1 nucleic acids (RNA and DNA) in plasma, peripheral blood mononuclear cells (PBMCs), or whole blood, and/or (3) proviral DNA enriched from CD4+ T cell

- Repeat Ag/Ab test from different manufacturer
  - Two positive antibody tests are indicative of infection, regardless of undetectable RNA.
From CDC: Transmission electron micrograph of isolate from first U.S. case of COVID-19

Virus particles (blue) with cross-section through viral genome (black dots)
PCR vs Antibody tests

PCR tests detect the presence of viral material, but cannot determine whether a person has been infected previously and recovered.

Serology tests determine whether a person has been previously exposed to a pathogen

Serology tests provide insight into the prevalence of a disease in the population by identifying those with specific antibodies
FDA Regulation: Lessons from HIV testing

Antibody tests came first.

- Intended for screening the blood supply so...
- “High risk” designation by FDA (= PMA); CBER vs CDRH
- First quantitative HIV-1 viral load monitoring test approved in 1996
- First HIV-1 RNA diagnostic test (qualitative) in 2006

FDA (CBER & CDRH) proposed “down-classification” of HIV and HCV tests to class II (recommended by Advisory Committee in March 2018) – public comment spring 2020
Lessons from HIV testing?

FDA required COVID-19 LDTs to obtain Emergency Use Authorizations, then

FDA granted blanket EUAs, first to LDT PCRs

FDA first granted waiver from EUAs for antibody tests

- CLIA waiver also OK’d

FDA issued EUAs for several antibody tests, then later rescinded them and required EUAs for the others
Types of SARS CoV-2 antibody tests

Lateral flow assays (LFAs) ✧ Rapid, point of care

ELISA ✧ Chemiluminescent, electrochemiluminescent
Potential for high throughput

Neutralizing antibody assays ✧ Serial dilutions of serum added to viral cultures to look for areas of inhibition
COVID-19: Dynamic Changes in IgG Levels

- 85 patients with COVID-19:

- 100% tested positive within 19 days after symptom onset

- Seroconversion for IgG and IgM occurred simultaneously or sequentially

- Long *et al.*, *Nature Medicine* 2020
## Heterogeneous Performance: False Positives

### Table: Percentage of positive specimens from individuals who were positive for non-SARS-CoV-2 viral infections and/or tested negative for SARS-CoV-2 by RT-PCR

<table>
<thead>
<tr>
<th>Assay</th>
<th>Total N</th>
<th>IgM positive</th>
<th>%</th>
<th>95% CI</th>
<th>Total N</th>
<th>IgG positive</th>
<th>%</th>
<th>95% CI</th>
<th>Total N</th>
<th>IgM or IgG positive</th>
<th>%</th>
<th>95% CI</th>
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<tr>
<td>Immuno</td>
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<td>Immunochromatographic Lateral Flow Assays</td>
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<td>Biomedomics</td>
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<td>8</td>
<td>15.4</td>
<td>6.9 - 28.1</td>
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<td>4</td>
<td>7.7</td>
<td>2.1 - 18.5</td>
<td>52</td>
<td>11</td>
<td>21.2</td>
<td>11.1 - 33.2</td>
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<td>11.1</td>
<td>3.7 - 24.1</td>
<td>45</td>
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<td>13.3</td>
<td>5.1 - 26.8</td>
<td>45</td>
<td>8</td>
<td>17.8</td>
<td>8.0 - 33.3</td>
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<td>9.6</td>
<td>3.2 - 21.0</td>
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<td>3.8</td>
<td>0.5 - 13.2</td>
<td>52</td>
<td>6</td>
<td>11.5</td>
<td>4.4 - 21.2</td>
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<td>26.9</td>
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<td>7</td>
<td>13.5</td>
<td>5.6 - 25.8</td>
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<td>14</td>
<td>26.9</td>
<td>15.6 - 41.0</td>
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<td>7.1</td>
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<td>7.1</td>
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<td>28</td>
<td>3</td>
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<td>3.8</td>
<td>0.5 - 13.2</td>
<td>52</td>
<td>3</td>
<td>5.8</td>
<td>1.2 - 15.9</td>
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<td>VivaChek</td>
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<td>4</td>
<td>8.2</td>
<td>2.3 - 19.6</td>
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<td>1</td>
<td>2.0</td>
<td>0.1 - 10.9</td>
<td>49</td>
<td>4</td>
<td>8.2</td>
<td>2.3 - 19.6</td>
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<td>WondFo</td>
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<td>0.0 - 6.8</td>
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<td>41</td>
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<td>6.9 - 28.1</td>
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<td>9</td>
<td>17.3</td>
<td>8.2 - 30.3</td>
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<tr>
<td>In-House</td>
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<td>7</td>
<td>13.5</td>
<td>5.6 - 22.1</td>
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<td>7</td>
<td>13.5</td>
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- Whitman et al, Preprint, Medrxiv May 17 2020
Heterogeneous Performance: Sensitivity

<table>
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<th>Assay</th>
<th>IgM</th>
<th>IgG</th>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>Positive</td>
<td>%</td>
</tr>
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- Whitman et al, Preprint, Medrxiv May 17 2020
Comparing Nucleoprotein vs Spike Protein targets

214 patients with PCR-confirmed COVID-19 infection

rS (spike) ELISA for IgM significantly more sensitive than rN (nucleoprotein) ELISA

IgM waned after 35 days

-Liu et al (Peoples Liberation Army), J Clin Micro 2020
Interpreting antibody test results

For a laboratory test:

**Sensitivity:** Probability test=positive if patient=positive

**Specificity:** Probability test=negative if patient=negative

For COVID tests:

**Positive Percent Agreement:** Probability test2=positive if test1=positive

**Negative Percent Agreement:** Probability test2=negative if test1=negative

**Predictive value:**

Probability patient=positive if test=positive

Probability patient=negative if test=negative
### Specificity of SARS CoV-2 antibody tests

<table>
<thead>
<tr>
<th>Assay</th>
<th>Total N</th>
<th>IgM positive</th>
<th>95% CI</th>
<th>IgG positive</th>
<th>95% CI</th>
<th>IgM or IgG positive</th>
<th>95% CI</th>
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</table>

**Mean**: 94.23
poll question: What happens with results of tests when the prevalence of disease is low?

The number of false-positive tests is higher.
There is a higher likelihood that a positive result is really false-positive.
Chance of false-positive results are much reduced.
Nothing False-positive results are unaffected by prevalence.
Example: Test 10,000 persons

Test Specificity = 94.2% (58/1000)

HIV prevalence = 10.5%

True positive: 1050 False positive: 580

Positive predictive value: 1050/1630 = 65%
Example: Test 10,000 persons

Test Specificity = 94.2% (58/1000)

SARS-CoV-2 positivity = 10%

True positive: 1050 False positive: 580
Positive predictive value: 1050/1630 = 65%

SARS-CoV-2 positivity = 1.3%

True positive: 130 False positive: 580
Positive predictive value: 130/710 = 18%
Example: Test 10,000 persons

Test Specificity = 94.2% (58/1000)

SARS-CoV-2 positivity = 1.3%
True positive: 130  False positive: 580
Positive predictive value: 130/710 = 18%

Test Specificity = 98.5% (15/1000)

SARS-CoV-2 positivity = 1.3%
True positive: 130  False positive: 150
Positive predictive value: 130/280 = 46%
Choosing antibody tests for your community

Enter the following into the FDA Calculator to calculate the positive predictive value (PPV) and negative predictive value (NPV) for 1 antibody test or 2 independent tests.

- % prevalence of SARS-CoV-2 in your community
- Sensitivity of EUA antibody test(s)
- Specificity of EUA antibody test(s)

- Positive predictive value (PPV)
- Negative predictive value (NPV)

- Lower sensitivity and specificity = lower PPV and NPV
- Lower disease prevalence = more false positive results and fewer false negative results
- Higher disease prevalence = fewer false positive results and more false negative results
### FDA calculator: Tests used in combination: “EUA Authorized Serology Test Performance”

<table>
<thead>
<tr>
<th>Test 1</th>
<th></th>
<th>Test 1</th>
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<tbody>
<tr>
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<td>PPV1 for (Test1=pos)</td>
<td>%Neg1</td>
<td>NPV1 for (Test1=neg)</td>
</tr>
<tr>
<td>%Pos1</td>
<td>(Test1=pos)</td>
<td></td>
<td>%Neg1</td>
<td>NPV1 for (Test1=neg)</td>
</tr>
<tr>
<td>%Pos1</td>
<td>(Test1=neg)</td>
<td></td>
<td>%Neg1</td>
<td>NPV1 for (Test1=neg)</td>
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<tr>
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<td>(Test1=pos)</td>
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<td>%Pos2</td>
<td>(Test1=neg)</td>
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<td>%Neg1</td>
<td>NPV1 for (Test1=neg)</td>
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### Test 2

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<td>%Neg2</td>
<td>NPV2 for (Test2=neg)</td>
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<tr>
<td>%Pos2</td>
<td>(Test2=neg)</td>
<td></td>
<td>%Neg2</td>
<td>NPV2 for (Test2=neg)</td>
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### Combined

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<tr>
<th></th>
<th>%Pos</th>
<th>PPV for (Test1=pos, Test2=pos)</th>
<th>%Discordant (Test1=pos, Test2=neg)</th>
<th>NPV for (Test1=pos, Test2=neg)</th>
<th>%Neg</th>
<th>NPV for (Test1=neg, Test2=pos)</th>
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<td>NPV for (Test1=pos, Test2=neg)</td>
<td>%Neg</td>
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<tr>
<td>%Pos</td>
<td>(Test1=neg, Test2=neg)</td>
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<td>%Discordant (Test1=neg, Test2=neg)</td>
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<td>NPV for (Test1=neg, Test2=pos)</td>
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<td>8.9%</td>
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</table>
HIV-1/2 antigen/antibody immunoassay

(+)

(-)

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+)  
HIV-1 antibodies detected

HIV-2 (-)  
HIV-2 antibodies detected

HIV-2 (+)  
HIV antibodies detected

HIV-1 (-) or indeterminate

HIV-1 NAT

HIV-1 NAT (+)  
Acute HIV-1 infection

HIV-1 NAT (-)  
Negative for HIV-1

(-) indicates non-reactive test result
(+) indicates reactive test result
NAT: nucleic acid test

Negative for HIV-1 and HIV-2 antibodies and p24 Ag
HIV-1/2 antigen/antibody immunoassay

- (+) HIV-1 (+) HIV-2 (-)
- (-) HIV-1 (-) HIV-2 (+)
- (-) Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1 RNA viral load
- Detectable (99.6%)
- Undetectable

HIV-1/2 antibody differentiation immunoassay
- HIV-1 (+) HIV-2 (-)
- HIV-1 (-) HIV-2 (+)
- HIV-1 (+) HIV-2 (+)

HIV-1 (-) or ind
HIV-2 (-) or ind

Undetectable (99.6%)

HIV infected

Treat

2nd Ag/Ab assay
- (+) Add’l NAT
- (-) Uninfected
“Point-of-Care” Nucleic Acid Tests

- Xpert HIV-1 viral load
  - 1 ml plasma
  - Results in 90 minutes
  - LOD 32 copies/mL
  - CE-marked December 2014

Not yet available in U.S.
“Point-of-Care” Nucleic Acid Tests

m-PIMA

SAMBA II
Antibody tests: HIV versus COVID-19

Positive HIV antibody tests indicate active HIV infection

Positive COVID-19 antibody tests:
- Single test has low positive predictive value in most populations
- Indicative of past exposure, not necessarily active infection
- Unknown whether antibodies indicate immune protection
- If antibodies confer immunity, not certain how long it will persist
Summary

Regulation of COVID-19 tests is substantially different than that for HIV tests – and it shows!
RNA & viral load will play an increasingly important role in HIV diagnosis

Most covid-19 diagnoses depend on PCR testing of NP swabs, but saliva specimens offer an attractive alternative
Antibody testing will help to identify persons who have already been infected.
It is as yet unknown whether antibody-positivity correlates with immunity.
Thank You for Your Attendance!

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www.prn.org