A Rapidly Evolving Landscape: Coronavirus Tests for Diagnosis, Surveillance and Vaccine Efficacy

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ICAP at Columbia University

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A RAPIDLY EVOLVING LANDSCAPE: CORONAVIRUS TESTS FOR DIAGNOSIS, SURVEILLANCE AND VACCINE EFFICACY

Yen Pottinger, PhD
Senior Technical Advisor for Laboratory Surveillance
ICAP New York
April 23rd, 2020
OVERVIEW

• Coronavirus structure, replication cycle, and immune response
• Status of tests approved by FDA
• Different tests for detecting active infection
• Different tests for detecting antibodies from previous infections or vaccination
• Test performance and testing algorithm
• Role of testing in reopening society
SARS-CoV-2 STRUCTURE & LIFECYCLE

- Single-stranded RNA virus
- 30K base pairs containing 14 ORFs, 27 proteins
- 79.6% sequence similarity to SARS, 96% to a Bat CoV RaTG13*, and only 50% to MERS#
TARGETS FOR DETECTING INFECTION

- **ACTIVE INFECTION**
  - Replicating RNA detected by **RT-PCR, CRISPR**
  - Viral proteins detected by **antigen testing**

- **PREVIOUS INFECTION**
  - Immune response aimed at the virus detected by **antibody testing**
FDA has worked with >350 test developers who will be submitting emergency use authorizations (EUA) requests for tests that detect the virus.

FDA has issued 42 individual EUAs for test kit manufacturers and laboratories.

Over 210 public and private laboratories have begun testing for SARS-CoV-2

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
DETECTING ACTIVE INFECTION

RT-PCR
CRISPR
ANTIGEN RAPID TEST
HOW DOES RT-PCR WORK?

**AMPLIFICATION**
This technique involves the amplification** of specific DNA fragments. Only a single DNA fragment is needed to generate **millions, even billions**, copies.

- **Start:** 1 Copy
- **After First Cycle:** 2 Copies
- **After Second Cycle:** 4 Copies
- **After Third Cycle:** 8 Copies
- **After Fourth Cycle:** 16 Copies

**AMPLIFICATION CURVE**
- **Threshold**
- **Ct**
- **Exponential phase**
- **Initiation phase**
- **Plateau**
- **Neg Control**

**PCR cycle number**

- **Lower the Ct, the higher the VL (inversely related)**
# HIGH THROUGHPUT RT-PCR PLATFORMS

<table>
<thead>
<tr>
<th>Platform</th>
<th>Daily Capacity</th>
<th>Gene Target</th>
<th>Machines in US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott M2000® Realtime System</td>
<td>470</td>
<td>RdRp, N</td>
<td>180</td>
</tr>
<tr>
<td>Roche Cobas® 6800/8800 Systems</td>
<td>1152 on 6800 System, 3168 on 8800 System</td>
<td>E, unspecified gene</td>
<td>33</td>
</tr>
<tr>
<td>Thermo Fisher® 7500 Fast Real-Time PCR System</td>
<td>470</td>
<td>S, N</td>
<td>?</td>
</tr>
<tr>
<td>BD MAX™ System</td>
<td>360</td>
<td>N1, N2</td>
<td>658</td>
</tr>
</tbody>
</table>
**POINT-OF-CARE RT-PCR TESTING**

<table>
<thead>
<tr>
<th><strong>ID NOW COVID-19</strong></th>
<th><strong>CEPHEID GENEXPERT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Results in 15 mins</strong></td>
<td><strong>Results in 45 mins</strong></td>
</tr>
<tr>
<td><strong>Gene Target: RdRp</strong></td>
<td><strong>Gene Target: N2, E</strong></td>
</tr>
<tr>
<td><strong>Machines in US: 18,000</strong></td>
<td><strong>Machines in US: 5000</strong></td>
</tr>
<tr>
<td><strong>Sample Types: throat, nasal, nasopharyngeal and oropharyngeal swabs</strong></td>
<td><strong>Sample types: nasopharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate specimens</strong></td>
</tr>
<tr>
<td><strong>LOD: 125 copies/mL</strong></td>
<td><strong>LOD: 250 copies/mL</strong></td>
</tr>
</tbody>
</table>
Testing Capacity in the United States

From the White House Coronavirus Task Force

Total tests performed in the US as of April 22: ~4.2 million

Nationally

New York State
AT-HOME TESTING WILL HELP EXPAND TESTING

- FDA EUA granted on April 21st
- Self-administered nasal swab
- Reduce the need to come into a doctor’s office
- Reduce exposure to health personnel
- Expand testing population to understand how widespread the disease is
Expansion of Specimen Collection Types

- First tests required nasopharyngeal (NP) swabs and viral transport media (VTM)
- FDA is now allowing synthetic spun swabs (like Q-tip) to collect sample from front of the nose and saline solution to transport sample
  - Allows for self-collection by patients and thus reducing exposure for healthcare providers
  - More comfortable for patients than NP swab
  - Can be produced at scale to meet testing needs
  - Saline solution is more widely available in most labs
- FDA approved the first oral fluid test from Curative Inc. that is being used widely in Southern California (April 17th)
- Cleveland Clinic Study (Apr 21):
  - 239 positive specimens tested on 5 different RT-PCR tests
  - Abbott ID NOW detected the virus in 85.2% of the samples, 14.8% false negative
  - Samples were collected and stored in VTM which is not indicated for the ID Now

CRISPR–CAS12-BASED DETECTION OF SARS-COV-2

ANTIGEN TESTS ARE USED FOR OTHER DISEASES

- Companies and researchers are actively working on developing a rapid antigen test for SARS-CoV-2 and have been working with FDA for approval
- SARS-CoV-2 antigen test can be used as a screening test with RT-PCR as a confirmatory test
DETECTING PREVIOUS INFECTION WITH SEROLOGY TESTING

ELISAS
POC RAPID TESTS
UNEVALUATED AND UNAPPROVED TESTS HAVE FLOODED THE MARKET

The 'game changer' that wasn’t: Company falsely claimed FDA authorization for coronavirus blood test
By Arman Aziz, CNN
Updated 10:19 AM ET, Thu April 2, 2020

Concerns rise over accuracy of coronavirus antibody testing
By MOLI LENGI / CBS NEWS - April 21, 2020, 9:22 AM

Bodysphere claimed it would distribute the first FDA-authorized coronavirus blood test, but a spokesperson later said “there was a misunderstanding.”

COVID-19 TESTING & CONSULTATION
We have stopped all new test requests. Please check back often for updates.
LEARN MORE
FDA EUA APPROVED SEROLOGY TESTS

• Only 4 serological tests have been approved for use:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test Name</th>
<th>Type of Test</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ortho Clinical Diagnostics</td>
<td>VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack</td>
<td>Luminescence detection, automated, high-throughput, lab-based</td>
<td>Total Antibody (IgM &amp; IgG)</td>
</tr>
<tr>
<td>Cellex qSARS-CoV-2 IgG/IgM Rapid Test</td>
<td>Rapid Test</td>
<td>Separate IgG and IgM detection</td>
<td></td>
</tr>
<tr>
<td>Chembio Diagnostics Systems</td>
<td>DPP COVID-19 IgM/IgG System</td>
<td>Dual Path Platform Rapid Test with Reader</td>
<td>Separate IgG and IgM detection</td>
</tr>
<tr>
<td>Mt Sinai Laboratory</td>
<td>COVID-19 ELISA IgG Antibody Test</td>
<td>ELISA, Lab-based</td>
<td>IgG</td>
</tr>
</tbody>
</table>

**FDA Key Recommendations for Health Care Providers:**

• Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.

• Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.

• Be aware that not all marketed serological tests have been evaluated by the FDA. Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.
ORTHO VITROS HIGH THROUGHPUT ASSAY

VITROS® Anti-SARS-CoV-2 Total Reagent Pack
Ortho Clinical Diagnostics

1. A patient’s blood sample is collected in a tube and transported to a lab.
2. The sample tube is centrifuged to separate serum/plasma liquids and blood cells (solid).
3. Lab technicians load the tube onto the VITROS analyzer. A small sample is taken for testing.
4. Our test contains viral proteins, detectable viral proteins mix with a patient’s sample, and the antibodies in the sample bind to the proteins and create a chemical reaction, which is measured by the analyzer.
5. Tests are processed every minute, each taking four minutes to complete.

Capacity: 150 tests/hour
Detection: Total IgG, IgM
Machines in US: 1000
AVAILABLE POINT OF CARE RAPID TESTS

- Chembio DPP COVID-19
- Cellex qSARS-CoV-2 IgG/IgM Rapid Test
MT SINAELISA USING RBD & SPIKE PROTEINS

• Received FDA EUA approval last week for using in their clinical laboratories
• Working with manufacturers to develop a commercial kit
• Working with CDC to develop DBS protocol for expanded use
• Dilution protocol to help identify high levels of Abs without the need to do a neutralizing Ab assay which takes days to complete
TESTING PERFORMANCE: IMPROVING POSITIVE PREDICTIVE VALUE WITH AN ALGORITHM

Sensitivity & Specificity
PPV & NPV & Prevalence
Antibody Testing Takes Front Stage in Coronavirus Battle, But Don’t Count on It Yet

Testing that will determine on a bigger scale the scope of Covid-19 infections is ramping up now, though it likely won’t be reliable for a few weeks.

Concerns rise over accuracy of coronavirus antibody testing

Dozens of coronavirus antibody tests on the market were never vetted by the FDA, leading to accuracy concerns.

Aggressive marketing of the tests could confuse those clamoring for the products to determine who may have developed disease-fighting antibodies.
TEST PERFORMANCE: SENSITIVITY & SPECIFICITY

• Sensitivity and specificity are inherent properties of an assay and are generally fixed for a given pathogen in a particular population

• Sensitivity may change for different strains of the pathogen (genetic or antigenic differences)

• Specificity may change when testing different population due to underlying host differences and cross-reactivity

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>True Pos Detected</th>
<th>False Neg</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>99%</td>
<td>99</td>
<td>1</td>
</tr>
<tr>
<td>98%</td>
<td>98</td>
<td>2</td>
</tr>
<tr>
<td>97%</td>
<td>97</td>
<td>3</td>
</tr>
<tr>
<td>96%</td>
<td>96</td>
<td>4</td>
</tr>
<tr>
<td>95%</td>
<td>95</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specificity</th>
<th>True Neg Detected</th>
<th>False Pos</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>99%</td>
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<td>1</td>
</tr>
<tr>
<td>98%</td>
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<td>2</td>
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<tr>
<td>97%</td>
<td>97</td>
<td>3</td>
</tr>
<tr>
<td>96%</td>
<td>96</td>
<td>4</td>
</tr>
<tr>
<td>95%</td>
<td>95</td>
<td>5</td>
</tr>
</tbody>
</table>

For every 100 true positives tested, x number will be missed
For every 100 true negatives tested, x number will be falsely reactive

POSSIBLE CUTOFF VALUES
A = 100% sensitivity cutoff value
B = practical compromise between specificity and sensitivity
C = 100% specificity cutoff value

Lowering the cutoff point:
A → B (↑ Sensitivity, ↑ NPV)
B → A (↑ FP, ↓ FN)

Raising the cutoff point:
B → C (↑ FN, ↓ FP)
C → B (↑ Sensitivity, ↓ PPV)
PREDICTIVE VALUES SIMPLIFIED: PPV & NPV

- Example: N=100 positives; N=100 negatives

- Assay sensitivity of 95% and specificity of 95%
  - 95 true positives, 5 false positives (come from negs tested)
  - 95 true negatives, 5 false negatives (come from pos tested)

- PPV = % people who are true positives among those tested positive by an assay
  - PPV = 95/100 = 95% (% true positive among all positives)
  - % false positives = 5% (among all positives by the test)

- NPV = % people who are true negatives among those tested negative by an assay
  - NPV = 95/100 = 95% (% true negative among all negatives)
  - % false negatives = 5% (among all negatives by the test)
PPV AND DISEASE PREVALENCE ARE CONNECTED

- Test with sensitivity of 95% and specificity of 95%
- Sample size = 200

50% Prevalence = True 100 pos + True 100 neg
- Test Pos = 95 TP + 5 FP = total 100; PPV = 95/100 = 95%

10% prevalence = True 20 pos + True 180 neg
- Test Pos = 19 TP + 9 FP = total 28; PPV = 19/28 = 67.9%

1% prevalence = True 2 pos + True 198 neg
- Test Pos = 2 TP + 10 FP = total 12; PPV = 2/12 = 16.7%

- PPV, NPV, prevalence, sensitivity and specificity are all connected
HOW DO YOU IMPROVE ACCURACY?

- Use of two or more tests in an algorithm
- Use the most sensitive first test (close to 100%) to detect almost all true positives

Example: Sensitivity 99%; Specificity 95% with sample size of 200
  - 99 true positives detected + 5 false positives detected
  - PPV = 99/104 = 95.2%; % false positives = 5/104 = 4.8%

- Use a second, more specific test in an algorithm can help to weed out false positives (specificity = 99%)
  - Since only 5 negatives tested (classified as false positives from first test), they will likely be detected by second test as negatives
  - Removal of 5 false positives will improve PPV from 95% to 100%
IMPROVING THE PPV BY USING AN ALGORITHM (2 OR MORE TESTS): HIV EXAMPLE

HIV Rapid Tests:
Sensitivity >99% Specificity >98%

By Country

Control line
Test line
Sample Pad

Non-Reactive
Reactive

Control line
HIV-1
Sample Pad

Non-Reactive
Reactive

PPV for T1 only
Overall PPV (Testing Algorithm)
Prevalence

0%
20%
40%
60%
80%
100%

0%
5%
10%
15%
20%
25%
30%
35%

1.4 2.8 3 3.7 4.9 5.3 6.2
10.6 12 12.6 14.1 25.6 27

0 5 10 15 20 25 30 35

By Country

Prevalence (%)

ICAP
IS TESTING THE KEY TO REOPENING OUR SOCIETY?

• Need to be able to detect community level infections and be able to do contact tracing to stop the spread

• Sentinel surveillance will require a large increase in testing levels
  • Address reagent shortages for manufacturers for test kit components
  • Address sample collection and other supply shortages

• Accurate and reliable results are needed
  • Standardized test kit evaluation approach by FDA/NIH/CDC before widespread use
  • Need for a biorepository that researchers can access for test development
  • Evaluate different testing algorithms for different scenarios/populations

• What if prevalence is only 1-5%? 10? What does this mean for restarting our economy and getting back to normal?
THANK YOU!
(Rapid) Coronavirus Tests for Diagnosis, Surveillance and Vaccine Efficacy

Samuel Sia, Ph.D.
Professor
Department of Biomedical Engineering
Columbia University

ICAP Grand Rounds
April 23, 2020
Blood test for prostate cancer in doctor’s office

OPKO Health Receives FDA Approval for the Point-of-Care Sangia PSA Test with the Claros® 1 Analyzer

MIAMI, Feb. 01, 2019 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company’s point-of-care Sangia Total Prostate Specific Antigen (PSA) Test using the Claros 1 Analyzer. The product is indicated to quantitatively measure total PSA in whole blood from a fingerstick of blood collected by a healthcare professional and is used in conjunction with a digital rectal exam as an aid in the detection of prostate cancer in men aged 50 years and older.
Columbia ICAP testing sites (School of Public Health)

Test sites:
1. Kigali (national testing center)
2. Gisenyi (regional testing center)
3. Kabaya (rural health clinic)
Microfluidics-based diagnostics of infectious diseases in the developing world

Curtis D Chin¹, Tassaneewan Laksanasopin¹, Yuk Kee Cheung¹, David Steinmiller², Vincent Linder², Hesam Parsa¹, Jennifer Wang¹, Hannah Moore¹, Robert Rouse¹, Gisele Umwiligihozo³, Etienne Karita³, Lambert Mwamarangwe⁴, Sarah Braunstein⁵, Janneke van de Wijgert⁴,⁶, Ruben Sahabo⁵, Jessica Justman⁵, Wafaa El-Sadr⁵ & Samuel K Sia¹

August 2011
Smartphone dongle for HIV/syphilis immunoassay

- **Power-free vacuum**
  - Low-power
  - Reduced price

- **Audio jack power/data**
  - Portable power source
  - Universal interface

- **Microfluidic test**
  - 15 min assay time
  - Auto-reagent handling
  - Multiplexing

- **Low-cost optics**
  - Objective readout
  - Reduced price

- **User-friendly app**
  - Low training burden

---

1. RT-PCR
2. Serology (antibody) test
3. Mobile tracking of results
Point-of-Care Diagnostics: Recent Developments in a Connected Age
Samiksha Nayak,†,§ Nicole R. Blumenfeld,†,§ Tassaneewan Laksanasopin,‡ and Samuel K. Sia*,†

microfluidics + consumer electronics

*Microfluidics: assay integration

*Assay chemistry: affinity reagents, amplification chemistry, materials

Connected instrumentation
trend: omnipresence of smart consumer electronic devices

Systems integration:
chemistry, fluidics, hardware, software
trend: systems design appropriate for specific use-case scenarios

Data analytics
trend: consumer-led health databases

*Clinical workflow
trend: decentralized testing and self-testing

Regulatory guidance
trend: FDA policies for consumer-led health

Reimbursement
trend: cost-benefit analysis with value-based framework

Legislation
trend: direct-to-consumer access for diagnostic devices and services

*Mixed focus areas of POC diagnostics

### 4 unique use cases in today’s POC ecosystem

<table>
<thead>
<tr>
<th>Use Case 1</th>
<th>Use Case 2</th>
<th>Use Case 3</th>
<th>Use Case 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital ER, OR, ICU Units</td>
<td>Self-testing (consumer devices)</td>
<td>Primary care clinics</td>
<td>Remote clinics</td>
</tr>
<tr>
<td>Private Pharmacies</td>
<td>Ambulance/EMS</td>
<td>NGO/non-profit health centers</td>
<td>Global health</td>
</tr>
<tr>
<td>Military Base Clinics</td>
<td>Military Industrial/agricultural</td>
<td></td>
<td>Self-testing (LMICs)</td>
</tr>
</tbody>
</table>

#### Infrastructure

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trained personnel</td>
<td>Untrained personnel</td>
</tr>
<tr>
<td>Portability-not important</td>
<td>Portability-very important</td>
</tr>
<tr>
<td>Minimal rough handling</td>
<td>Rough handling</td>
</tr>
<tr>
<td>Rapid analysis-moderately important</td>
<td>Rapid analysis-important</td>
</tr>
<tr>
<td>Ground electricity</td>
<td>No ground electricity</td>
</tr>
<tr>
<td>Controlled ambient conditions (temperature/humidity)</td>
<td>Ambient temperature/humidity fluctuations</td>
</tr>
<tr>
<td>Refrigeration</td>
<td>Limited Refrigeration</td>
</tr>
<tr>
<td>Cost of accessory equipment-high/low</td>
<td>Cost of accessory equipment-high/low</td>
</tr>
<tr>
<td>Cost of disposables-high/low</td>
<td>Cost of disposables-high/low</td>
</tr>
</tbody>
</table>

#### Budget

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderately trained personnel</td>
<td>Untrained personnel</td>
</tr>
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<td>Rough handling</td>
</tr>
<tr>
<td>Rapid analysis-moderately important</td>
<td>Rapid analysis-important</td>
</tr>
<tr>
<td>Ground electricity (supply fluctuations)</td>
<td>No ground electricity</td>
</tr>
<tr>
<td>Limited refrigeration</td>
<td>No refrigeration</td>
</tr>
<tr>
<td>Ambient temperature/humidity fluctuations</td>
<td>Ambient temperature/humidity fluctuations</td>
</tr>
<tr>
<td>Cost of accessory equipment-low</td>
<td>Cost of accessory equipment-low</td>
</tr>
<tr>
<td>Cost of disposables-low</td>
<td>Cost of disposables-low</td>
</tr>
</tbody>
</table>

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1. RT-PCR
2. Serology (antibody) test
3. Mobile tracking of results
**SARS-CoV-2 point-of-care molecular diagnostic tests**

Number of samples in parallel:
- 96 samples
- 24 samples
- 8 samples
- 4 samples
- 2 samples
- 1 sample

Number of samples that can be processed in a single run

Speed of analysis (time to results):
- Emergency Use Authorization (EUA) and/or CE mark
- For Research Use Only (RUO)
- In development

*(Situation as of March 31, 2020)*

(Yole Développement, April 2020)
Automated molecular test (swab or saliva)

startup company:
Rover Diagnostics

Sia Lab, unpublished results
Amplification of COVID-19 targets in plasmids
(1 second at 95ºC, 2 seconds at 60ºC)

In progress: validation with genomic target and clinical specimens

Sia Lab, unpublished results
1. RT-PCR

2. Serology (antibody) test

3. Mobile tracking of results
Coronavirus antigens
BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

Point-of-care blood test detects evidence of present or past exposure in 15 minutes

Mar 31, 2020

FRANKLIN LAKES, N.J. MORRISVILLE, N.C., March 31, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.
Applicability of a serology test for COVID-19

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Estimated Median Seroconversion Time (post-symptom onset)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM</td>
<td>5 - 12 days</td>
</tr>
<tr>
<td>IgA</td>
<td>5 - 10 days</td>
</tr>
<tr>
<td>IgG</td>
<td>14 - 15 days</td>
</tr>
</tbody>
</table>

Total antibody detection could allow for earlier detection post-symptom onset with higher sensitivity.


Rapid test printer

In progress: high-sensitivity rapid antibody tests
OPKO Health Receives FDA Approval for the Point-of-Care Sangia PSA Test with the Claros® 1 Analyzer

MIAMI, Feb. 01, 2019 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company’s point-of-care Sangia Total Prostate Specific Antigen (PSA) Test using the Claros 1 Analyzer. The product is indicated to quantitatively measure total PSA in whole blood from a fingerstick of blood collected by a healthcare professional and is used in conjunction with a digital rectal exam as an aid in the detection of prostate cancer in men aged 50 years and older.
1. RT-PCR
2. Serology (antibody) test
3. Mobile tracking of results
Real-time tracking of HIV incidences (lateral-flow test readers)

- track, analyze, and predict outbreaks
- over 2000 HIV test results tracked in Rwanda
- real-time online dashboard

Nsabimana et al, JMIR Public Health Surveill, 2018
SMARTest app: HIV and syphilis self-testing, and with partners
Overview of smartphone-based data gathering and results interpretation framework using at-home tests

Figure 1. A) App user account creation with demographic data entry. B) Video and step-by-step instructions to carry out test. C) Image capture of test kit. D) Cloud-hosted deep learning model for results interpretation. E – F) Test results delivered to user in seconds with linkage-to-care options. G) Test results with demographic data stored on cloud server for real-time surveillance and modeling.
Usability study results on the INSTI HIV + Syphilis multiplex test with smartphone app

48 high-risk participants were provided 10 INSTI test kits for a 3-month study

Results

- Acceptability of the app was high for:
  - Usability (M=4.16 of max 5, SD=0.85)
  - Helpfulness (M=6.13 of max 7, SD=1.1)
- 78% would recommend app to a friend.
- 72.7% stated app increased their comfort with testing partners for HIV/STIs
- 76.4% stated it was helpful for finding follow-up confirmatory testing or HIV/STI health care services
- 76.8% stated that the app increased knowledge of HIV and Syphilis testing.

Acknowledgments – Sia Lab
collaborations welcome!  ss2735@columbia.edu

Past members who contributed to work:
Brian Gillette, Yukkee Cheung, Hesam Parsa, Sau Yin Chin (biomaterials/implantables/cell therapy)
Curtis Chin, Wan Laksanasopin, Tiffany Guo (diagnostics/sensors)
Paolo Cadinu, Olga Ordeig, Nalin Tejavibulya, Archana Sridhar, Rafael zur Nieden, Debra Leong,
Krishna Rajaram, Robert Houghtaling, Tomoya Saito, Nikkan Das, Byron G. Weiss, Nirali Sampat,
Elizabeth Shay, Kathleen Atkatsh, Ryan Gallagher, Yaas Bigdeli, Sophie Wang, Daniel Cohen,
Douglas Onyango, Ariq Azad, Aneem Talukder, Lauren Hsu, Charlie Wu, Kathryn Lau, Claire
Duvallet
THANK YOU!