COVID-19 Testing – Access & Impact

June 2, 2020
A clinical advisor is currently included on Return to Work task force about half the time.

- varies significantly by size of employer

### Overall

<table>
<thead>
<tr>
<th>Status</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently in place</td>
<td>50%</td>
</tr>
<tr>
<td>Considering within the next 60 days</td>
<td>7%</td>
</tr>
<tr>
<td>Not considering within the next 60 days</td>
<td>6%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>37%</td>
</tr>
</tbody>
</table>

### % Employers with Clinical Advisor currently in place as part of Back to Work Task Force

<table>
<thead>
<tr>
<th>Employer Size (# of Employees)</th>
<th>% Employers w Clinical Advisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 or more</td>
<td>76%</td>
</tr>
<tr>
<td>5,000 - 9,999</td>
<td>64%</td>
</tr>
<tr>
<td>1,000 - 4,999</td>
<td>59%</td>
</tr>
<tr>
<td>500 - 999</td>
<td>44%</td>
</tr>
<tr>
<td>Less than 500</td>
<td>8%</td>
</tr>
</tbody>
</table>
Which of these criteria are you considering in clearing employees to come back to work

1. Positive antibody testing
   - Currently in place: 1%
   - Considering within the next 60 days: 45%
   - Not considering within the next 60 days: 54%

2. Tested & Free of COVID-19
   - Currently in place: 22%
   - Considering within the next 60 days: 39%
   - Not considering within the next 60 days: 39%

3. Daily screenings for COVID-19 symptoms
   - Currently in place: 51%
   - Considering within the next 60 days: 28%
   - Not considering within the next 60 days: 21%

4. Employee pledge to social distancing both inside and outside the workplace
   - Currently in place: 46%
   - Considering within the next 60 days: 38%
   - Not considering within the next 60 days: 16%
Speakers

Michael Thompson
MODERATOR
President & CEO
National Alliance of Healthcare Purchaser Coalitions

Mohannad Kusti, MD
Independent Medical Advisor
(Former US Steel CMO)

Madhuri Hegde, PhD
VP & Chief Scientific Officer
PerkinElmer

Rick Hennessey
CEO
Empowered Diagnostics
Background on Mohannad Kusti, M.D., M.P.H

Over 10 years of Occupational Medicine, Public Health and Population Health, & Corporate Health experience, recently completed tenue with United States Steel Corporation as the Chief Medical Officer.

• Board Member of Integrated Benefit Institute.
• Council member of the National Purchaser Leadership Council of the National Alliance of Healthcare Purchaser Coalitions.
• Published articles in scientific journals through NIOSH and West Virginia University (WVU).
• A member of the Occupational Medicine Residency Advisory Committee for Rutgers Environmental & Occupational Health Science Institute at Rutgers School of Public Health in NJ
• Member of the leadership council for WVU School of Public Health
• Founder of Optimal Workplace & Environmental Wellness Corporation: Provides CMO consultation to employers.
• Provider consultation work for Corporate Medical Advisors and CMO on Demand.
COVID-19 TESTING, SCREENING AND LIMITATIONS

- Two types of testing:
  - Molecular: looking for antigen.
  - Serological: looking for antibodies. May be helpful Contact Tracing.

- Temperature screening:
  - Self-checking at home
  - Entrance screening:
    - Infrared guns
    - Thermal Cameras (fixed or portable)
. Testing alone is not the answer!

. There are many limitation to the current testing technology for both antigen and antibody testing.

. It is still a tool that healthcare providers can use.

CXR: SE (23-99%), SP (93-96%)
EKG: SE (3-31%), SP (80-96%) PPV (40-88%)
CBC: SE (75-97%), SP (75-95%)
Back-to-Work Roadmap and Resources

Researched and Created by Dr. Mohannad Kustl, Medical Director at Pittsburgh Business Group on Health

1. PPE Resources
   - Physician Core Care
   - Med Bar

2. Testing Resources
   - Physician Core Care
   - Med Bar

3. Monitoring Resources
   - Cassian Solutions
   - MAP Health
   - Med Bar

Employee -> Risk Assessment Risk Stratification

1. Low Risk Test for Work
2. Send to Clinic for Testing OR
3. On-site Mobile Testing

Testing Ag & Ab
Temperature Screening If Mandated Locally

Telehealth Consultation
Secondary Survey

High Med Low
Medium to High Risk Stay at Home

High Med Low

Go to Work with Weekly Monitoring

Conside All Data

Work From Home or Self Isolate
Daily prescreen
Select your institution (work or school) and answer a few questions to update your health status to your workplace/school.

Prescreen Interview
Take a series of questions to determine if you need to go to the hospital for a COVID-19 test.

Return to work or school
Select your institution (work or school) and answer a few questions to find out if you can return to your workplace or school.

Other Resources
This section enlists various resources about the COVID-19 disease.

Select all of the following new symptoms you are currently experiencing:

- Fever
- Dry Cough
- Three or more consecutive days of increased weakness
- Recent sputum production (thick mucus)
- Shortness of breath
- Generalized muscle or joint aches
- Sore throat
- Chills
- Recent upset stomach or diarrhea
- None of the above

Continue
Please describe how you feel today:

- Healthy
- A little under the weather
- Quite sick

Continue

I've had close contact (within 6 feet for more than 10 minutes) with someone who has tested positive for COVID-19 in the last 14 days:

Yes  No
Daily Risk Assessment & Risk Stratification is Key!
Updates

- **Antivirals**
  - Under research protocols, promising progress with Remdesivir. Cost could be an issue for payers.
  - Chloroquine & Hydroxychloroquine should not be used for COVID-19 treatment until further studies show better results.

- **Vaccines**
  - Under research protocols – progressing as well but not yet ready.
Frequently asked questions

- **Ventilation, HVAC, Air-filter:**
  - Moving and circulating air is recommended vs. stagnant (fans, open windows, etc.)
  - Air filters need to be changed frequently as per manufacturer’s guidance.
  - No evidence to support HEPA filter can prevent the spread of SARS-CoV-2.
    - Virus is round or oval shaped with diameter of 60 – 140 nm. (1 µm = 1000 nm)
    - U.S. EPA reports that HEPA air filter can theoretically remove at least 99.97% of dust, pollen, mold, bacteria, and any airborne particles with a size of 0.3 microns (µm).
  - HEPA filter recommended in healthcare settings only at this time.

https://www.epa.gov/indoor-air-quality-iaq/what-hepa-filter-1
Frequently asked questions

Traveling:

- Avoiding non-business essential travelling goes without saying. For domestic travelling, If other means of travelling is possible such as driving, that should be the first choice.
- If travelling is absolutely necessary, contact the airline and make sure they are following the “No passenger in the middle seat rule”. Some airlines are doing that, and some are not.
- Traveler needs to be aware of the surrounding, stay away from anyone who appears to be sick wither in the plane or in the terminal.
- According to public health agencies, the primary risk factor is sitting within two rows of an infectious passenger.
- Finally, the traveler needs to avoid seats that has more chances of contact, so, window seats are preferred.
Frequently asked questions

Traveling:

- Face masks are still recommended, and many airlines will offer it to the passenger if they do not have their own.
- Since hand washing could be challenging on the plane, hand sanitizers must be used.
- Disinfectant wipes need to be used to clean the table tray, arm rests, seatbelts and anything else that may have been touched.
- Travelers needs to be up to date on all vaccination including flu-shots.
- Traveler needs to practice healthy life choices to make sure their immune system is working well, such as avoid excessive alcohol intake or avoid alcohol completely if possible, avoid smoking, eat healthy, sleep well prior to the trip, exercise if possible.
COVID-19 Solutions

Madhuri Hegde, VP & CSO PerkinElmer Global Laboratory Services
June 2, 2020
About PerkinElmer Genomics

• Madhuri Hegde, PhD, FACMG, VP and CSO, Global Lab Services
  • Over 20 years of experience in clinical genetics
  • Former Executive Director of Emory Genetic Laboratory
  • Over 125 peer-reviewed publications
• Alka Chaubey, PhD, FACMG, Head of Cytogenomics
  • Double board certified in Cytogenetics and Molecular Genetics
  • Former Director of Cytogenomics Laboratory at Greenwood Genetic Center
  • Former Scientific Director of Cytogenomics Laboratory at Augusta University

Rayna N. Kohle, MD, PhD, FACAP, FACP, 2nd Vice Chairman, Pathology, Physician | Scientist | Educator.

This week we completed COVID-19 screening for 20,000 individuals in the State of Georgia in my lab. This is part of our ongoing commitment to statewide support for COVID-19 screening.

This is a major milestone for our small lab which was not equipped or trained to take on such responsibility a few weeks ago. This would have been impossible without herculean efforts from the amazing group of people in my lab and my colleagues at Augusta University. Also thank you, Madhuri Hegde, Alka Chaubey, and PerkinElmer, Inc, for their tireless support for my lab and State of Georgia.

Testing Timeline: Nucleic Acid vs. Antibody

<table>
<thead>
<tr>
<th>Infection</th>
<th>Asymptomatic Stage</th>
<th>Onset of Symptoms</th>
<th>Patient begins to recover</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>5</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>21</td>
<td>35</td>
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</table>

**SARS-CoV-2**

Single long strand of RNA encodes five major protein regions involved in structure: spike (S), envelope (E), membrane (M), nucleocapsid (N) and replication: (ORF1ab).

**Nucleic Acid Detection**

Nucleic acid testing targets ORF1ab and N protein regions, the replicase complex and viral coat respectively.

**Antibody Detection**

Three classes of Anti-SARS-CoV-2 antibodies are being tested for: IgM, IgA, and IgG. There are two combinations for tests: IgM and IgG or IgA and IgG.

- **IgM Antibody Detectable**
  - Immediate antibody response

- **IgA/ IgM Antibody Detectable**
  - Immediate antibody response

- **IgG Antibody Detectable**
  - Sustained response, remains in blood and provides long-term immunity
# Two Distinct Focus Areas for Testing

<table>
<thead>
<tr>
<th>Diagnostic Kits &amp; Instruments</th>
<th>NUCLEIC ACID DETECTION</th>
<th>ANTIBODY DETECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Primary method for <strong>detecting SARS-CoV-2</strong>, the virus that causes COVID-19</td>
<td>Surveillance and neutralizing antibody status of a patient, potentially identifying patients that have developed <strong>immunity</strong></td>
</tr>
<tr>
<td><strong>Detection Timing</strong></td>
<td><strong>0 – 20 days</strong> after infection</td>
<td><strong>21 – 35 days</strong> after infection</td>
</tr>
</tbody>
</table>
| **Testing Type**              | **PCR** (higher sensitivity, 3-4 day to result)  
**POC** (low sensitivity, <1 day to result) | **Serology tests** using antibody detection (e.g., ELISA, ChLIA) |
| **Key Use Cases**             | Detecting virus in populations to **prevent spreading**, e.g. front line workers | Detecting immunity to allow those immune to **return to normal life**, e.g., employee screening |

## Lab Services

Service labs in both Pittsburgh (PKIG) and Taicang (ICL) quickly launched both types of testing and have quickly ramped efforts in areas such as publication submissions, validation studies, collaborations for employee-based screening, weekly webinars, and more.
Resulting in full workflow solutions for the first wave testing to detect the virus …

**NUCLEIC ACID DETECTION**

Primary method for detecting SARS-CoV-2, the virus that causes COVID-19

<table>
<thead>
<tr>
<th>PCR Testing</th>
<th>Sample Collection</th>
<th>RNA Extraction</th>
<th>Liquid Handling</th>
<th>Testing Kit</th>
<th>PCR Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PKI Offerings</strong></td>
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<tr>
<td></td>
<td>Primarily using <strong>nasal swab</strong></td>
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<td></td>
<td>First FDA EUA authorized <strong>saliva-based</strong> kit used on May 7*</td>
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<td></td>
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<td>chemagic Kit on chemagic 360 instrument (all geographies)</td>
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<td></td>
<td></td>
<td>PreNATII instrument &amp; kits (APAC)</td>
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<td></td>
<td></td>
<td>Janus G3 Workstation</td>
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<td></td>
<td>SARS-CoV-2 PCR Assay (Approved in 30+ countries, including FDA EUA Authorized)</td>
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<td>Compatible with 8-10 third party systems</td>
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<td>E.g.</td>
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<tr>
<td></td>
<td></td>
<td>EURORealTime Nucleic Acid Detection Kit (CE-IVD approved; LDT+ Available)</td>
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</tbody>
</table>

(1) Laboratory Developed Test

*Based on workflow utilized at Rutger's RUCDR Infinite Biologics
ANTIBODY DETECTION
Serological testing for surveillance and neutralizing antibody status of a patient, potentially identifying patients that have developed immunity

… as well as solutions for the second wave of testing for immunity
PerkinElmer Genomics – Service Offerings

SARS-CoV-2 RT-PCR ASSAY

• PerkinElmer Genomics has launched two laboratory developed tests (LDT) that can be used for the rapid detection of an active COVID-19 detection. Both of our SARS-CoV-2 RT-PCR assays (PerkinElmer assay and EURORealTime assay) include internal control (IC) that serve as both the extraction and amplification controls.

SEROLOGY ASSAY

• PerkinElmer Genomics serology assay utilizes the Enzyme Linked ImmunoSorbent Assay (ELISA) test that provides in vitro determination of human antibodies against the SARS-CoV-2. This test can independently detect immunoglobulin classes IgA and IgG against the SARS-CoV-2.

• The EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The positive percent agreement to PCR was 100% at and after 21 days following the onset of symptoms while the overall negative percent agreement to presumed negatives was 99%.

<table>
<thead>
<tr>
<th>RT-PCR Offerings*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay Only</td>
</tr>
<tr>
<td>Assay with Collection Pack (+/- Shipping)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serology Offerings*</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG Assay Only</td>
</tr>
<tr>
<td>IgG Assay with Collection Pack (+/- Shipping)</td>
</tr>
<tr>
<td>IgA + IgG Assay Only</td>
</tr>
<tr>
<td>IgA + IgG Assay with Collection Pack (+/- Shipping)</td>
</tr>
</tbody>
</table>

*Ability to coordinate physician order for back-to-work programs depending on the size and scope of the program

Pursuant to applicable federal and/or state laboratory requirements, PerkinElmer Genomics establishes and verifies the accuracy and precision of their testing services. Testing services may not be licensed in accordance with the laws in all countries. Please check with your local representative for availability.
EmpoweredDiagnostics.com

A World Leader in LFA Manufacturing

IgM & IgG antibodies to SARS-CoV-2, Corona Virus
The World’s Top Experts in Manufacturing LFA

Empower Diagnostics is made up of the World's top experts in Development and Manufacturing of Rapid, Point-of-Care Diagnostics and LFAs.

Our Chief Scientist, invented the one-step pregnancy test, rapid ovulation tests, early strips for glucose meters and many of the World's rapid point-of-care tests for Infectious Diseases. Over 100 in total.

We have brought over 300 diagnostic tests through FDA and manufactured 100s of millions.

For many years our team developed and manufactured point-of-care tests for the largest medical brands in the world. Now we are bringing our latest innovations directly to you.

Highest Throughput and Highest Quality Manufacturing

Be EMPOWERED.
### Highly Specific, Highly Accurate

- Newly Developed Specific Recombinant Antigens. Mammalian Antigen and produced in tissues. Highly purified (98%-100%) for extremely accurate results.
- Directly Reacts to SARS-CoV-2
- Reacts to both S and N
- Tests All forms of Patient antibodies (IgM & IgG)
- Reacts with ALL Strains of SARS-CoV-2
- Low cost to administer
- Detects recent exposure or exposure from several week prior

### Current Rapid Tests

- Either older Antigens from 2003 and 2010 OR Produced in Ecoli (Bacterial) w/ only approximately 80% purity producing many more false results.
- Cross Reaction = High Rates of False Readings
- The entire population
- Limited Antibodies Detected
- Often Limited or Outdated Strains
- More Logistics & Labor cost with higher waste
- Does not provide additional insight

© 2020 Empowered Diagnostics - Proprietary and confidential - Patent Pending
SAR-SoC-2 IS COMPLICATED FOR MANY REASONS

Empowered Distribution Channel for Covid 19 helps

Medical Hurdles
- COVID19 is highly Contagious
- Hospitals reluctant to encourage people with symptoms to come in
- Labs require expertise for validity
- Too much time for results
- Costly to Assess
- False Positives

Patient’s Perspective
- Testing is moving too slow
- Testing is expensive
- Waiting for a result creates anxiousness
- Nervous about going to hospitals
- Aren’t enough tests to go around so many just don’t try to get them
- Advised to Stay Home
Questions?

Michael Thompson
MODERATOR
President & CEO
National Alliance of Healthcare Purchaser Coalitions

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(Former US Steel CMO)

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Ph. 206.228.5990
Upcoming Events

LEADERSHIP SUMMITS 2020
JUNE 15 - 16
MOBILIZING COLLECTIVE ACTION
TOTAL PERSON HEALTH
ACHIEVING VALUE 2020
NOW A VIRTUAL EVENT