

# COVID-19 Testing – Access & Impact

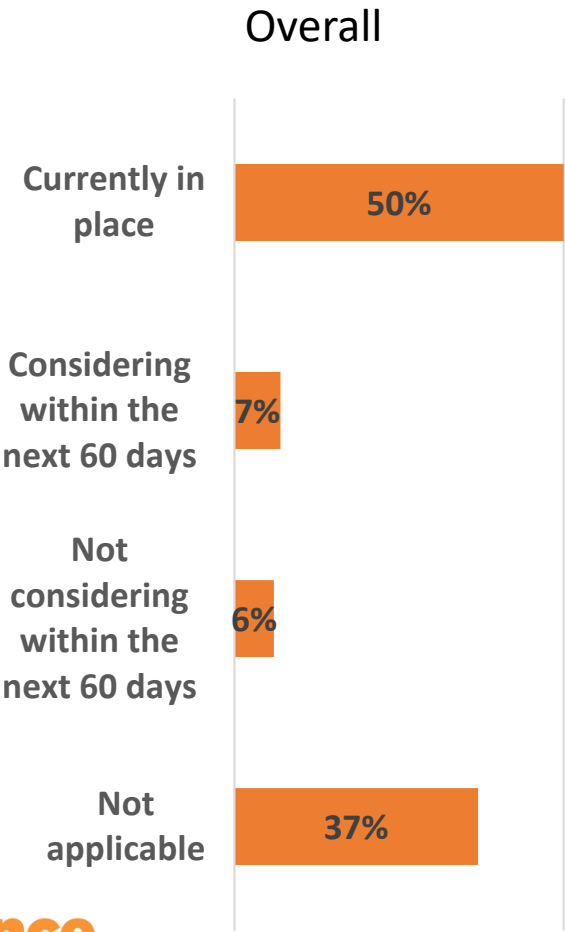
June 2, 2020



# Is a Clinical Advisor included on Return to Work Task Force?

A clinical advisor is currently included on Return to Work task force about half the time

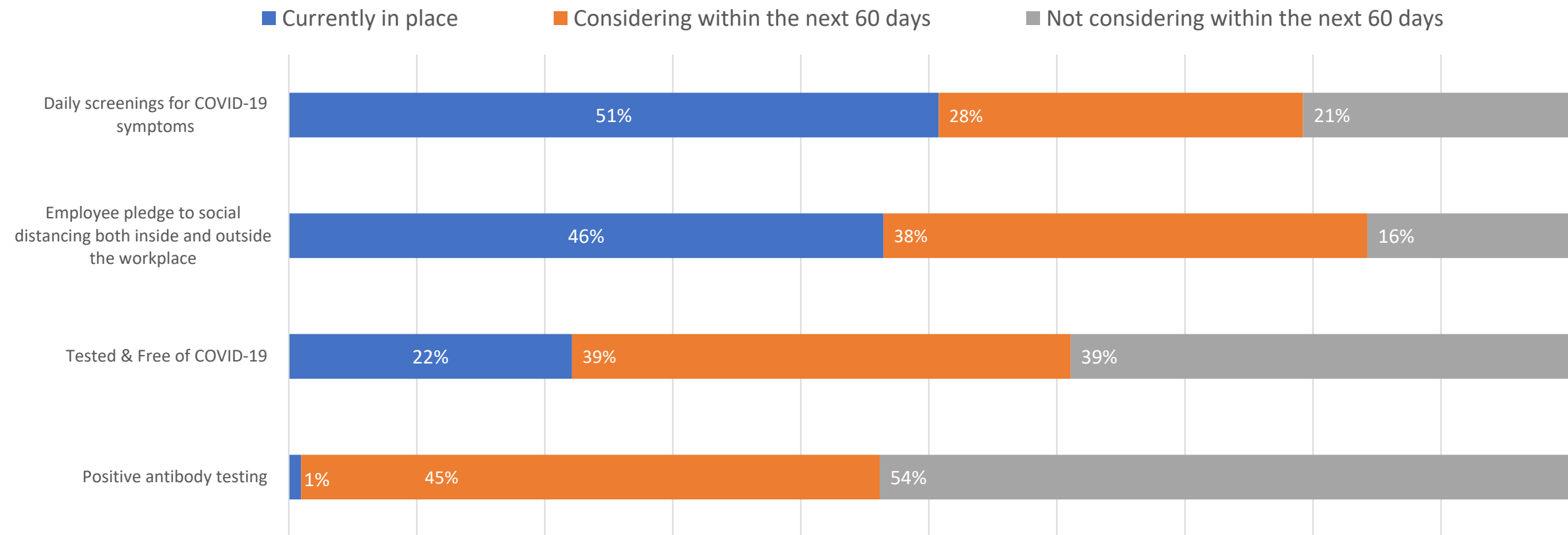
- varies significantly by size of employer



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

Employer Size (# of Employees)	% Employers w Clinical Advisor
10,000 or more	76%
5,000 - 9,999	64%
1,000 - 4,999	59%
500 - 999	44%
Less than 500	8%

# Which of these criteria are you considering in clearing employees to come back to work



# 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 tenure 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.

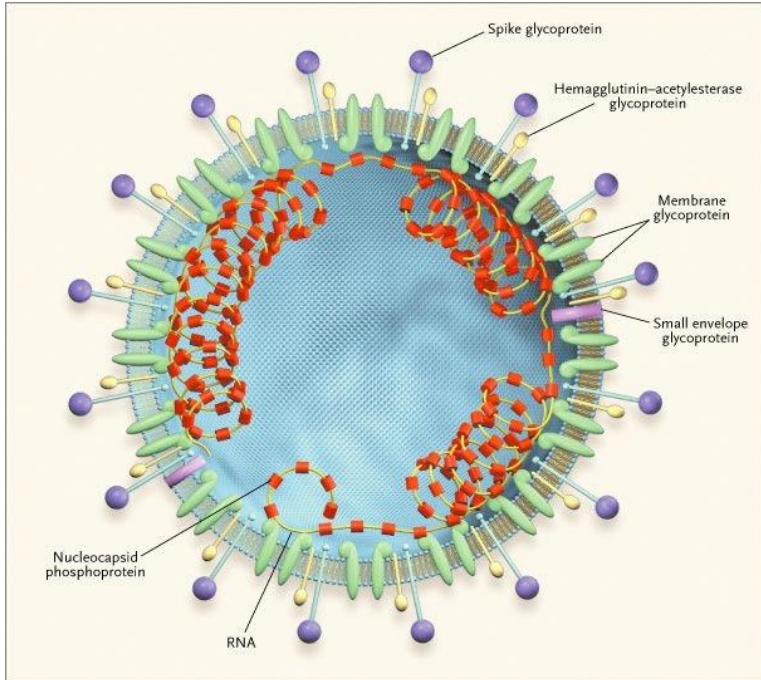


Pittsburgh  
Business Group  
ON HEALTH

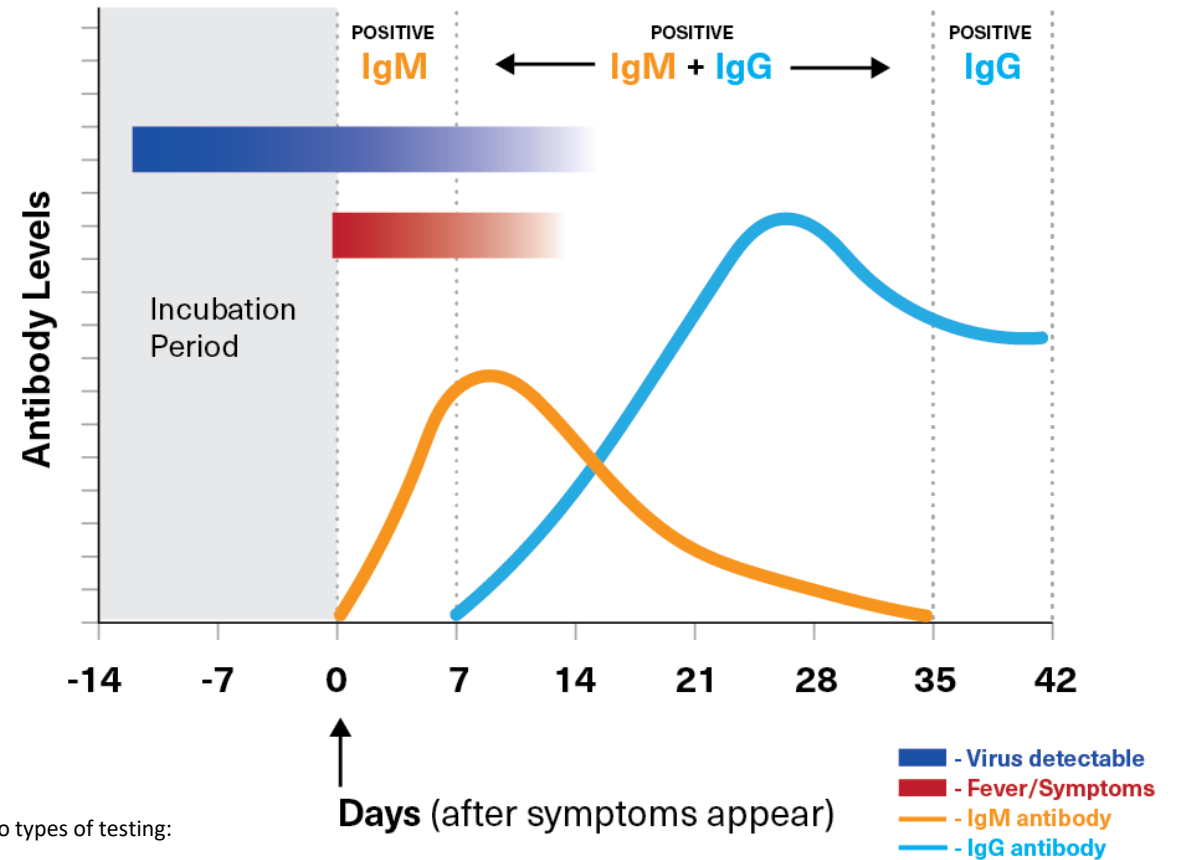


CORPORATE MEDICAL ADVISORS





## 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%)

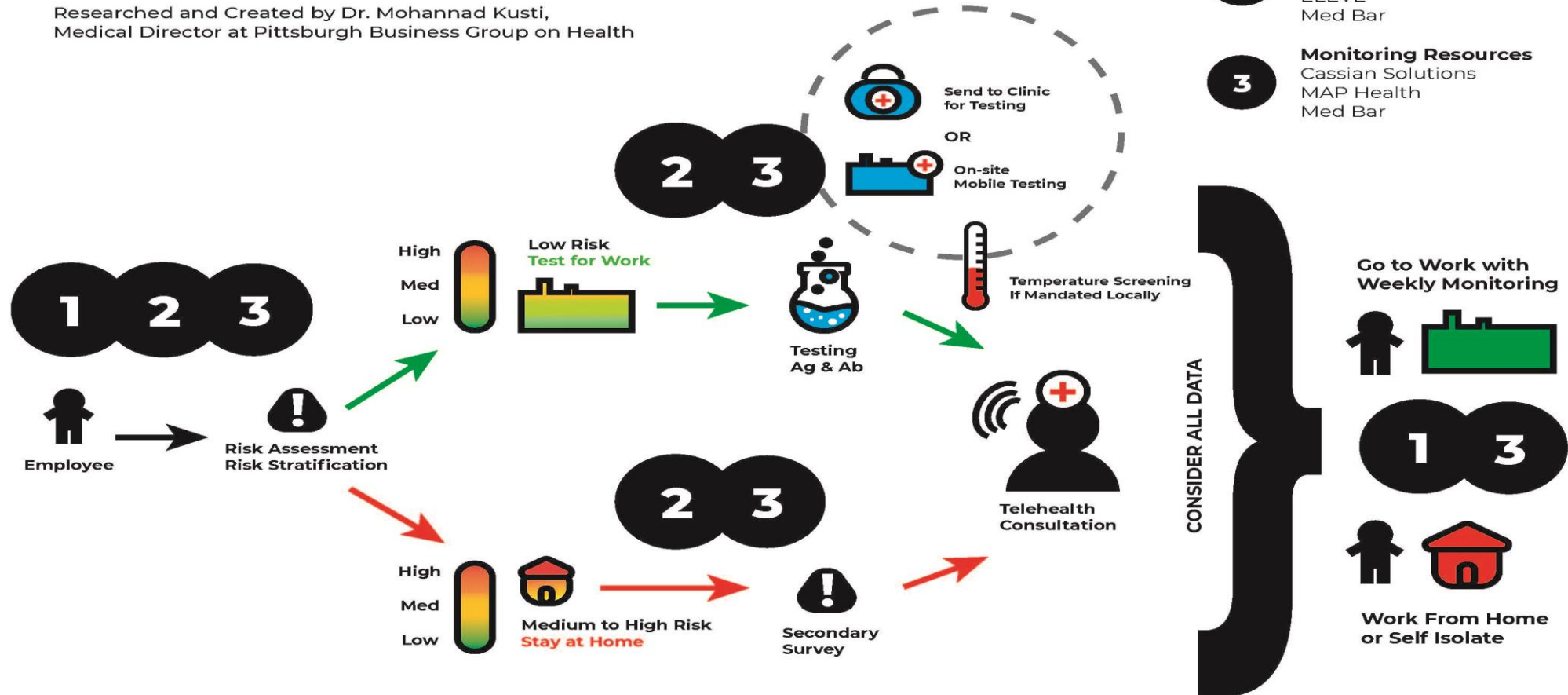
CBC: SE (75-97%), SP (75-95%)





# BACK-TO-WORK ROADMAP AND RESOURCES

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





covidprescreen.com

Prescreen

**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

covidprescreen.com

< Back Prescreen

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

covidprescreen.com

< Back Prescreen

Please describe how you feel today:

☐ Healthy

☐ A little under the weather

☐ Quite sick

Continue

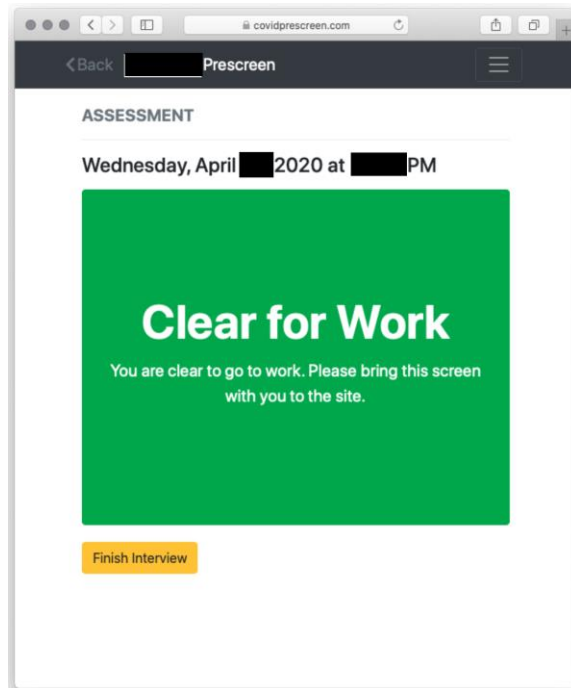
covidprescreen.com

< Back Prescreen

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!



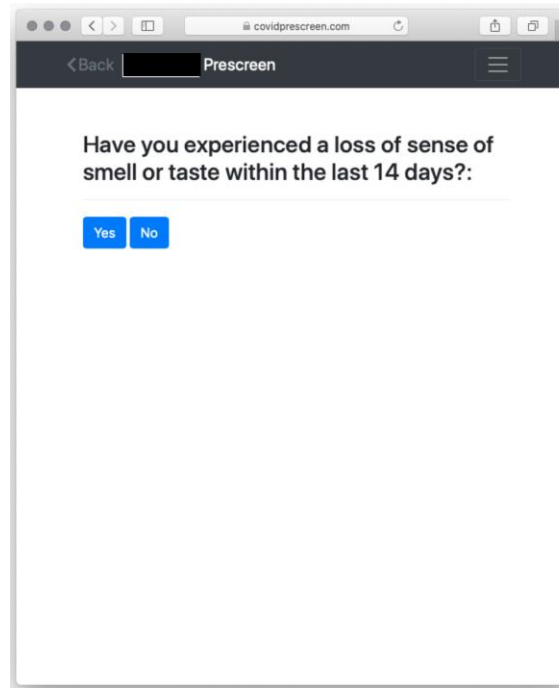
ASSESSMENT

Wednesday, April 2020 at PM

**Clear for Work**

You are clear to go to work. Please bring this screen with you to the site.

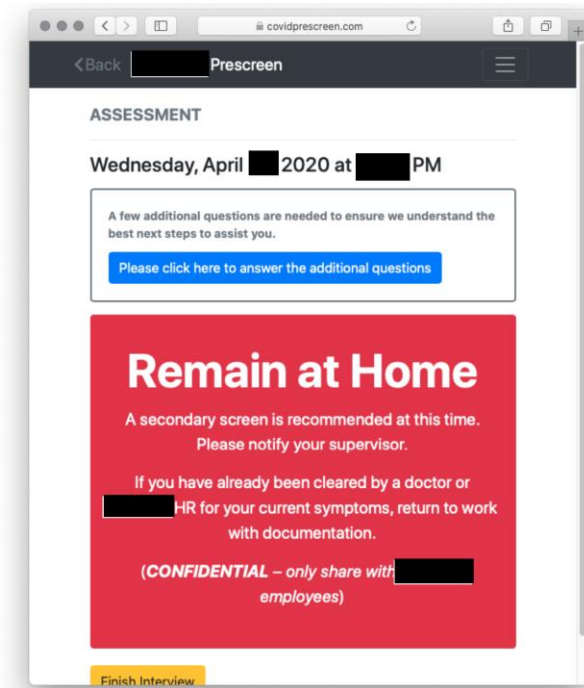
Finish Interview



ASSESSMENT

Have you experienced a loss of sense of smell or taste within the last 14 days?:

Yes No



ASSESSMENT

Wednesday, April 2020 at PM

A few additional questions are needed to ensure we understand the best next steps to assist you.

Please click here to answer the additional questions

**Remain at Home**

A secondary screen is recommended at this time. Please notify your supervisor.

If you have already been cleared by a doctor or HR for your current symptoms, return to work with documentation.

(CONFIDENTIAL – only share with employees)

Finish Interview

# 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 needs 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  $\mu\text{m}$  = 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 ( $\mu\text{m}$ ).
    - HEPA filter recommended in healthcare settings only at this time.

# 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

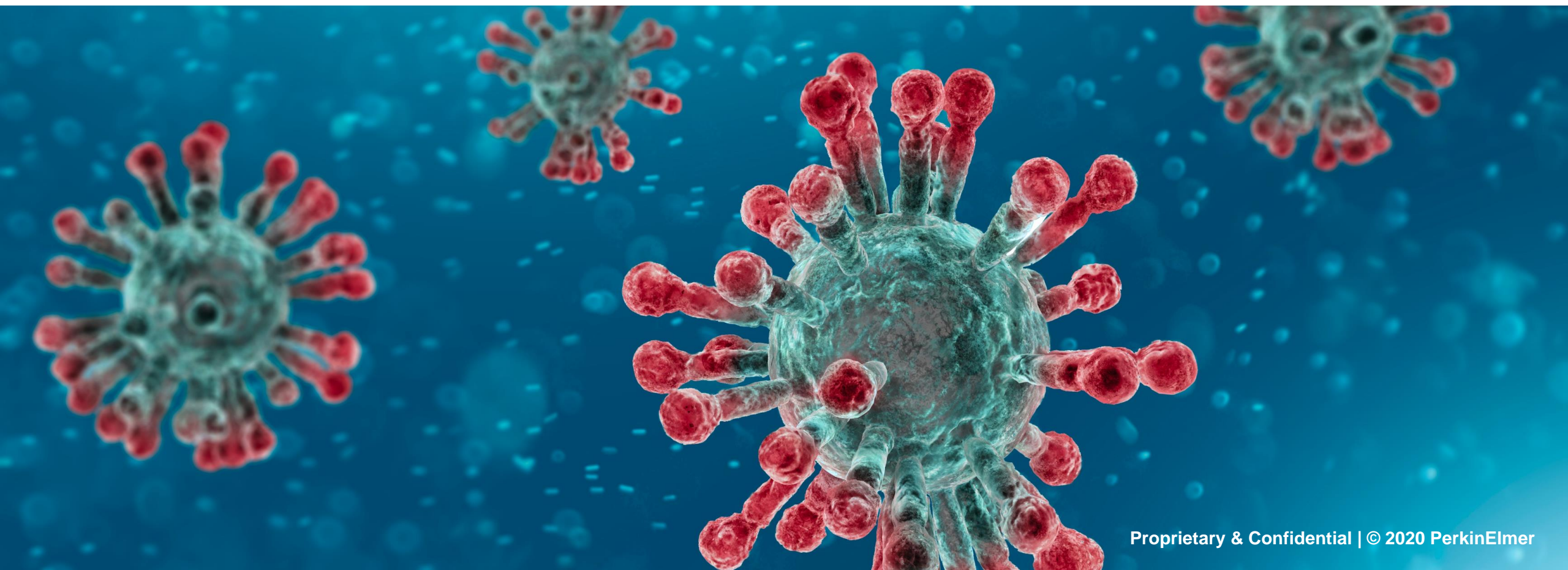
## Traveling:

- 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

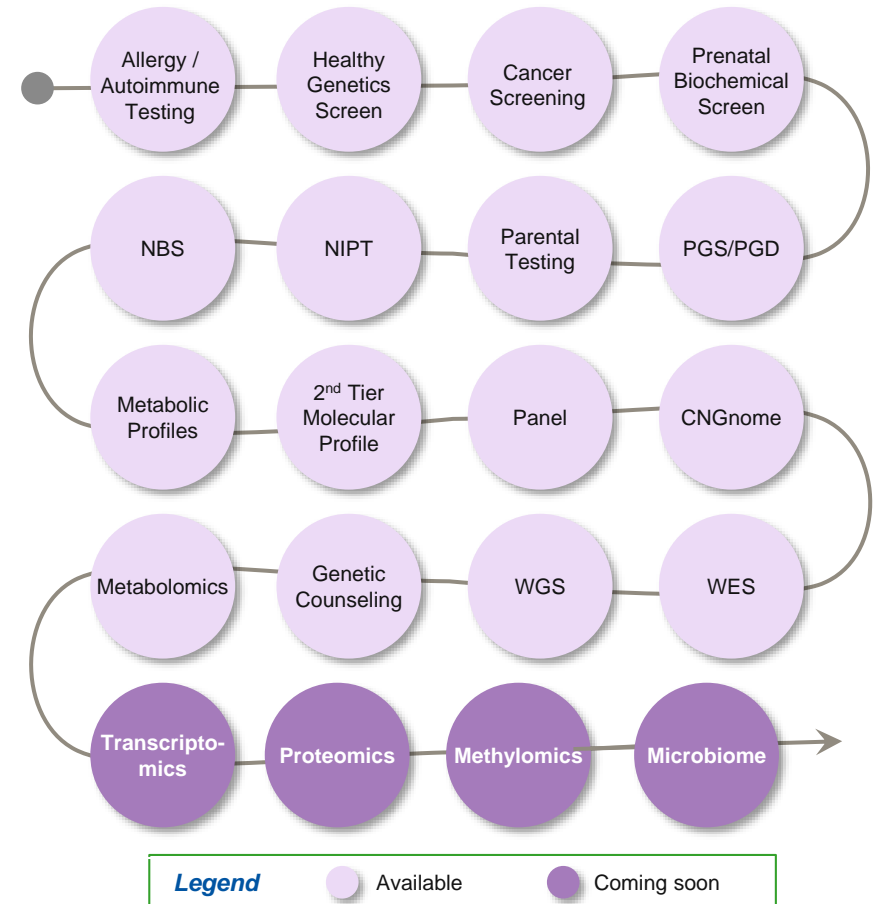


**Ravindra Kolhe MD. PhD. FCAP.** • 2nd  
Vice Chairman, Pathology. Physician | Scientist | Educator.  
2w • 🌐

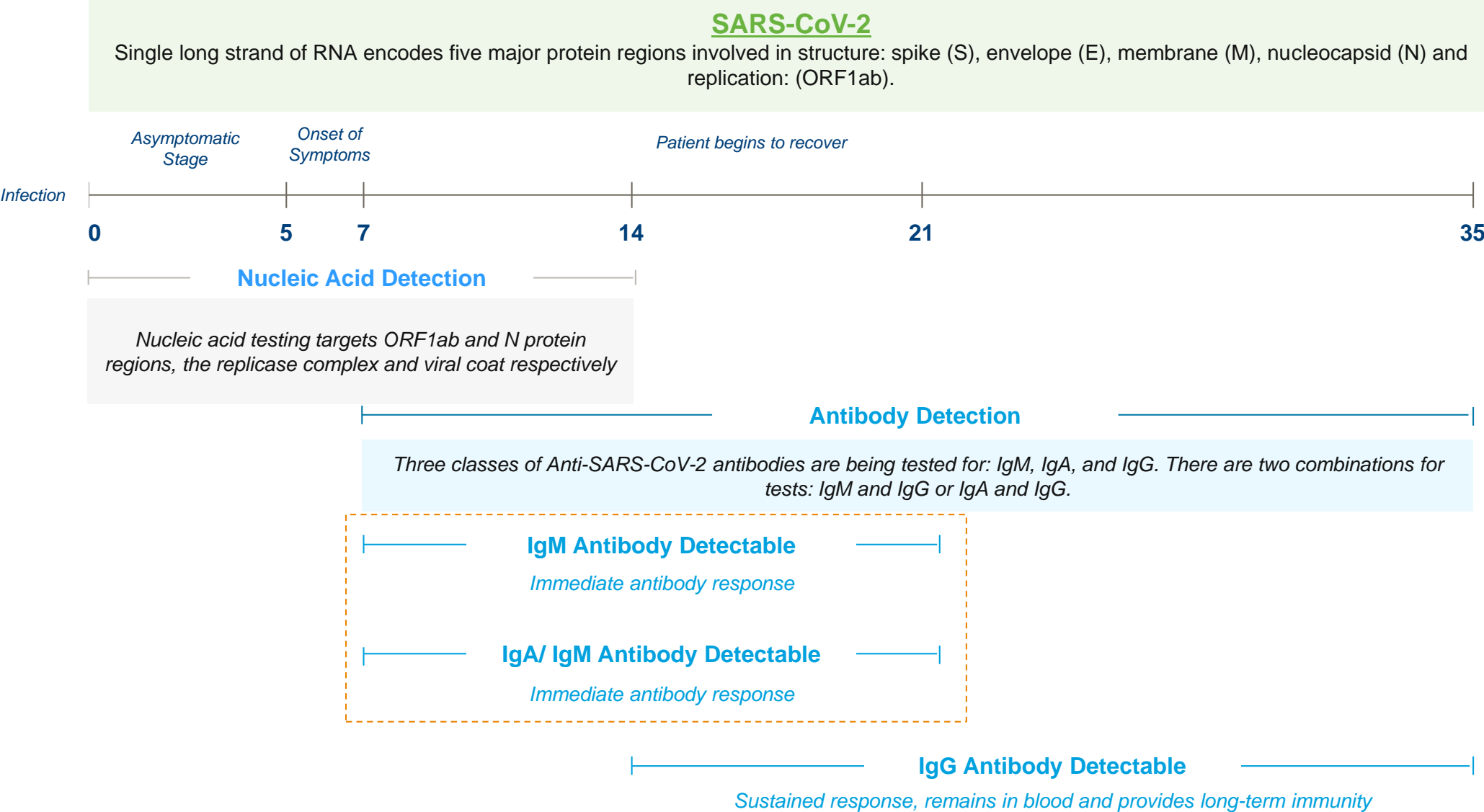
This week we completed COVID-19 screening for 20,000 individuals in the State of Georgia in my Lab. This is part of our ongoing commitment to statewide support for COVID-19 screening.

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.

## Complete 'Omics Capabilities



# Testing Timeline: Nucleic Acid vs. Antibody



# Two Distinct Focus Areas for Testing

## Diagnostic Kits & Instruments

### NUCLEIC ACID DETECTION

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

**0 – 20 days** after infection

**PCR** (higher sensitivity, 3-4 day to result)  
**POC** (low sensitivity, <1 day to result)

Detecting virus in populations to **prevent spreading**, e.g.  
**front line workers**

### ANTIBODY DETECTION

Surveillance and neutralizing antibody status of a patient, potentially identifying patients that have developed **immunity**

**21 – 35 days** after infection

**Serology tests** using antibody detection (e.g., ELISA, ChLIA)

Detecting immunity to allow those immune to **return to normal life**, e.g., **employee screening**

### Lab Services

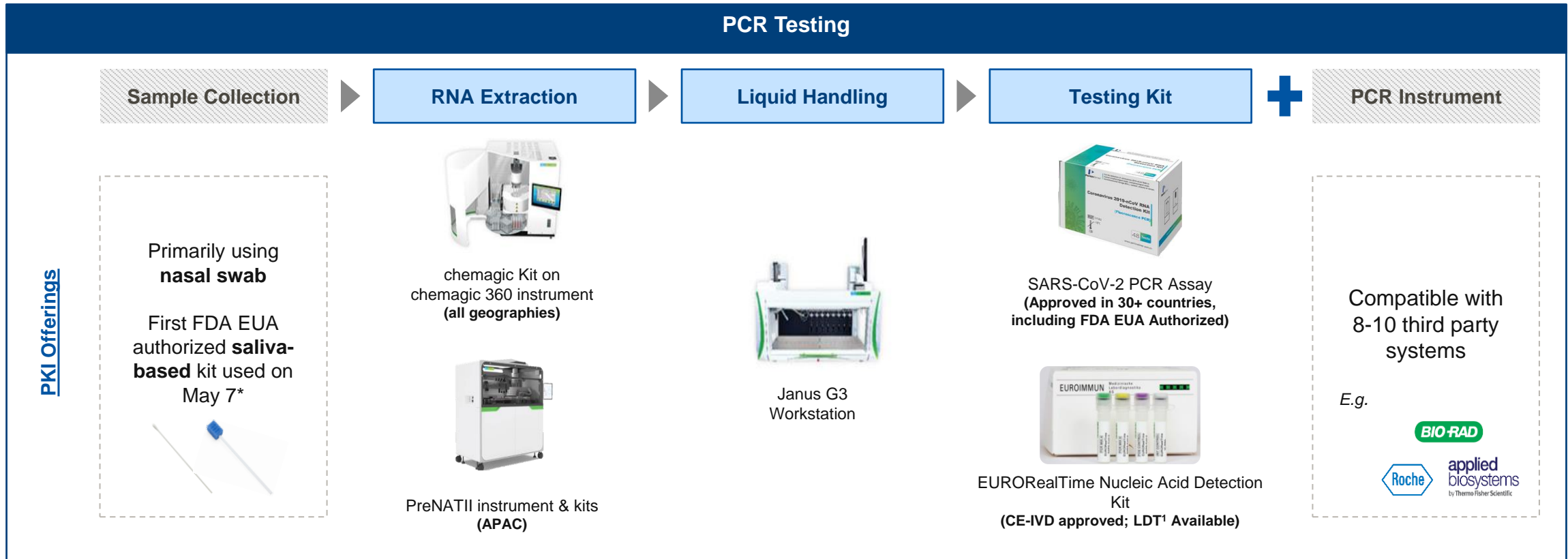
Service labs in both Pittsburgh (PKIG) and Taicang (ICL) quickly **launched both types of testing** and have quickly ramped efforts in areas such as **publication submissions**, **validation studies**, collaborations for **employee-based screening**, weekly webinars, and more

# 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

### PCR Testing



(1) Laboratory Developed Test

\*Based on workflow utilized at Rutgers' RUCDR Infinite Biologics

## ... as well as solutions for the second wave of testing for immunity

### ANTIBODY DETECTION

Serological testing for surveillance and neutralizing antibody status of a patient, potentially identifying patients that have developed immunity

#### ELISA Testing

Sample Collection

Test

Automation

PKI Offerings



Blood



Dried Blood Spots

ELISA



Anti-SARS-CoV-2 antibodies of  
classes IgA and IgG  
(CE Marked)



EUROIMMUN  
Analyzer I



EUROLabWorkstation  
ELISA



DynexDsX



Sprinter XL



# 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%.

RT-PCR Offerings*
Assay Only
Assay with Collection Pack (+/- Shipping)
Serology Offerings*
IgG Assay Only
IgG Assay with Collection Pack (+/- Shipping)
IgA + IgG Assay Only
IgA + IgG Assay with Collection Pack (+/- Shipping)

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



**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.**

# SARS-CoV-2 – ONLY RAPID WITH VISUAL RESULTS



## Highly Specific, Highly Accurate

**VS**

## Current Rapid Tests

Newly Developed Specific Recombinant Antigens. Mammalian Antigen and produced in tissues. Highly purified (98%-100%) for extremely accurate results

Either older Antigens from 2003 and 2010 OR Produced in Ecoli (Bacterial) w/ only approximately 80% purity producing many more false results.

Directly Reacts to SARS-CoV-2

Cross Reaction = High Rates of False Readings

Reacts to both S and N

The entire population

Tests All forms of Patient antibodies (IgM & IgG)

Limited Antibodies Detected

Reacts with ALL Strains of SARS-CoV-2

Often Limited or Outdated Strains

Low cost to administer

More Logistics & Labor cost with higher waste

Detects recent exposure or exposure from several week prior

Does not provide additional insight

## 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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# Upcoming Events

