

# Cleveland Clinic COVID Testing

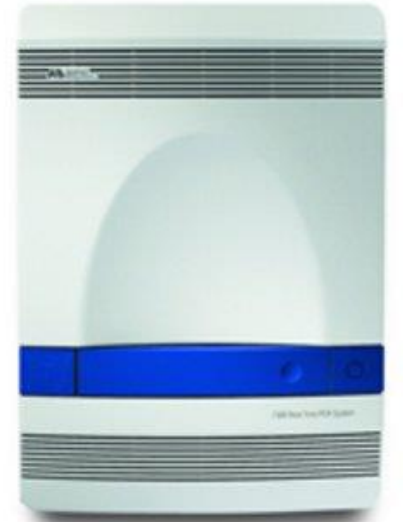
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Chairman, Robert J. Tomsich  
Pathology and Laboratory Medicine Institute



# COVID-19 accomplishments

- Launched nucleic acid-based test for SARS-CoV-2 in 10 days
- Staffed 3 shifts/day – 7 days/week continuously without any hiring for first 7 months
- Currently use six different testing platforms
  - 4,733 Standard TAT (24 hr TAT) and 266 Rapid Tests per day (1.5 - 6 hr TAT)
  - EUA for Cleveland Clinic SARS-CoV-2 assay
- Pivotal role in communication and educating colleagues
  - Many media presentations and many academic publications
- Management and staffing of outpatient swabbing enterprise linked to COVID testing
  - Observed self swabbing

# CDC Assay



# SARS-CoV-2 currently in use



Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) (PDF)	Technology <sup>3</sup>	Authorized Setting(s) <sup>1</sup>
+ 08/03/2020	Wren Laboratories LLC	<a href="#">Wren Laboratories COVID-19 PCR Test (114KB)</a>	Molecular	H
+ 08/03/2020	Ethos Laboratories	<a href="#">Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay (124KB)</a>	Molecular, Home Collection	H
+ 08/03/2020	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	<a href="#">Cleveland Clinic SARS-CoV-2 Assay (116KB)</a>	Molecular	H
+ 08/03/2020	Poplar Healthcare	<a href="#">Poplar SARS-CoV-2 TMA Pooling assay (118KB)</a>	Molecular, Sample Pooling	H
+ 08/03/2020	ISPM Labs, LLC dba Capstone Healthcare	<a href="#">Genus SARS-CoV-2 Assay (292KB)</a>	Molecular	H
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	<a href="#">Atellica IM SARS-CoV-2 IgG (COV2G) (244KB)</a>	IgG, Semi-quantitative	H, M
+ 07/31/2020	Siemens Healthcare Diagnostics Inc.	<a href="#">ADVIA Centaur SARS-CoV-2 IgG (COV2G) (156KB)</a>	IgG, Semi-quantitative	H, M
+ 07/31/2020	Xiamen Zeesan Biotech Co., Ltd.	<a href="#">SARS-CoV-2 Test Kit (Real-time PCR) (134KB)</a>	Molecular	H
+ 07/31/2020	University of California San Diego Health	<a href="#">UCSD RC SARS-CoV-2 Assay (107KB)</a>	Molecular, Pooling	H
+ 07/30/2020	Clinical Reference Laboratory, Inc.	<a href="#">CRL Rapid Response (110KB)</a>	Molecular, Home Collection	H

Showing 1 to 10 of 168 entries

# SelfCheck Covid Testing Kit (patent pending)

Capacity: 800-1000 / day

\*(can only use one instrument for testing due to FDA requirements)

Assembled by: Aeromed/ Cardinal

Distributed by: **CC Pharmacy**

Used by: Pre-procedure, adult patients

Dropped off at: CC Express Care, Labs and Pharmacy

Locations

Tested by: CC lab



## COVID-19 Self-Collection Kit

This kit is used to collect a sample from your nose to test for Coronavirus 2019 (COVID-19). Every patient with an upcoming procedure at an ambulatory surgery center or in an operating room at Cleveland Clinic will be tested before their appointment.

If you have any questions or concerns, please contact your primary healthcare provider.

After Cleveland Clinic receives your sample, your test results will be available in MyChart within 24 to 48 hours.



3 days

Collect & deliver your sample **as soon as possible.**

*If you are having surgery, use this kit three days before your procedure.*



68-77°F

Store the kit **at room temperature** before and after using it.



Be sure to follow this instruction sheet carefully.

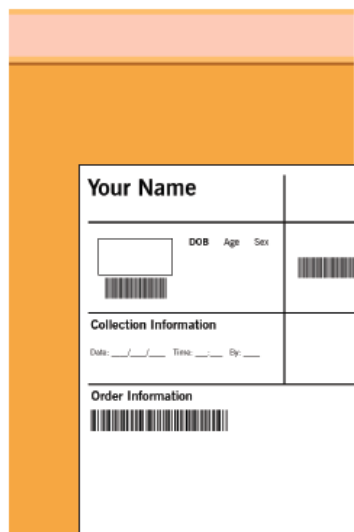
**If your specimen is not collected properly, incorrect results could occur.**

*Pre-Surgical/Pre-Procedural Patients:*

**If your sample is not received in time, your procedure may be postponed or canceled.**

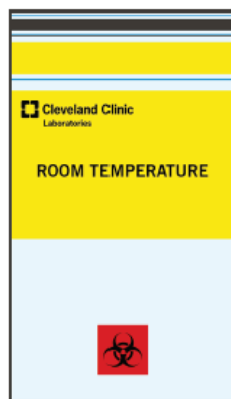
### What's inside the kit:

Padded envelope



Order for COVID-19 Testing

Biohazard bag



Absorbent sheet

Labeled tube with saline



Nasal swab



Step 1: Wash your hands.

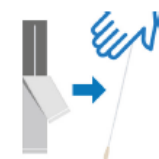


Step 2: Open the large padded envelope and lay the items on a clean surface.



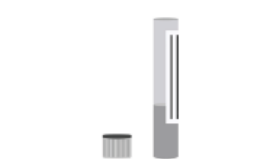
Step 3: Verify your name and date of birth on the tube's label.

*If the information on the label is incorrect, please call the location that provided this kit to you.*



Step 4: Remove the swab from the wrapper.

*Do not touch the tip of the swab.*



Step 5: While holding the swab in your hand, open the tube and set the cap down.



Step 6: Place the swab inside your nostril until the tip is no longer visible, then rub the inside of your nose three times in a circular motion.



Step 7: Repeat Step 6 using the same swab with your other nostril.



Step 8: Place the tip of the swab down into the tube.



Step 9: Bend the swab against the top of the tube until the handle snaps at the swab's breakpoint.



Step 10: Tighten the cap back on the tube so it does not leak.

*Your test will be cancelled if the tube leaks.*



Step 11: Write the date and time of when you swabbed your nose in the *Collection Information* section on the test order.

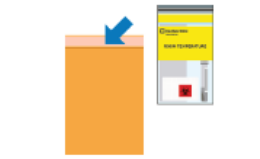


Step 12: Place the tube and the white absorbent sheet into the biohazard bag, then seal the bag closed.



Step 13: Slip the test order into the front pouch of the biohazard bag.

*Do not put the paperwork in the same part of the bag as the tube.*

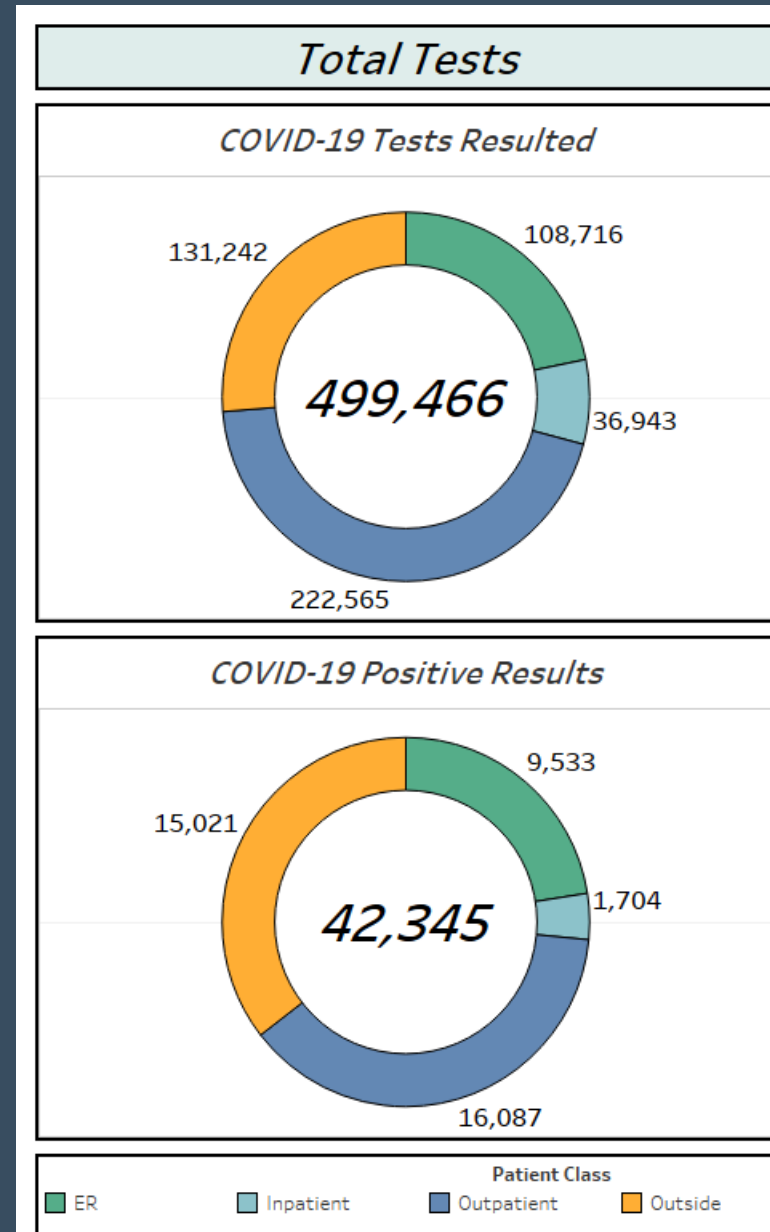


Step 14: Insert the biohazard bag into the large padded envelope, then seal the envelope closed.



Step 15: Deliver the padded envelope to a Cleveland Clinic COVID-19 Kit Drop-Off location as soon as possible.

# Almost 500,000 COVID tests resulted

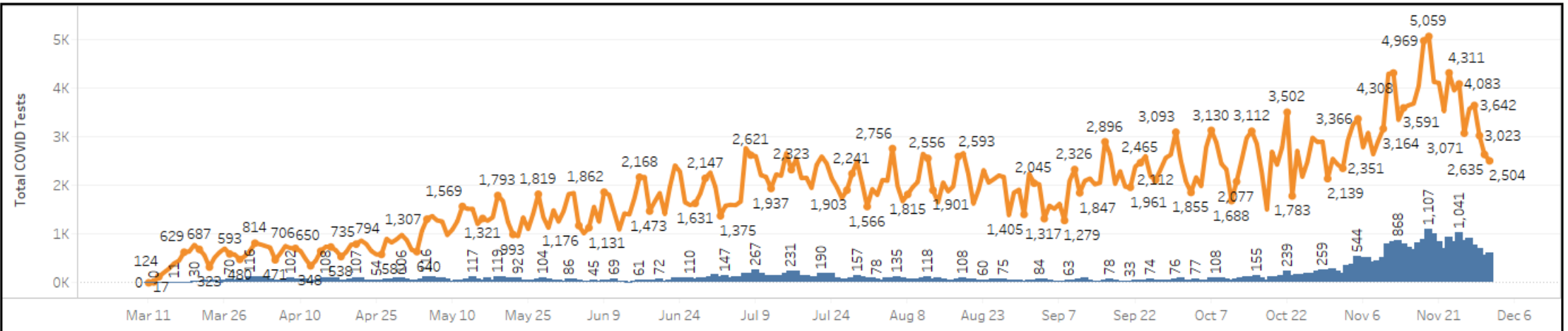


8.5% overall  
positivity rate

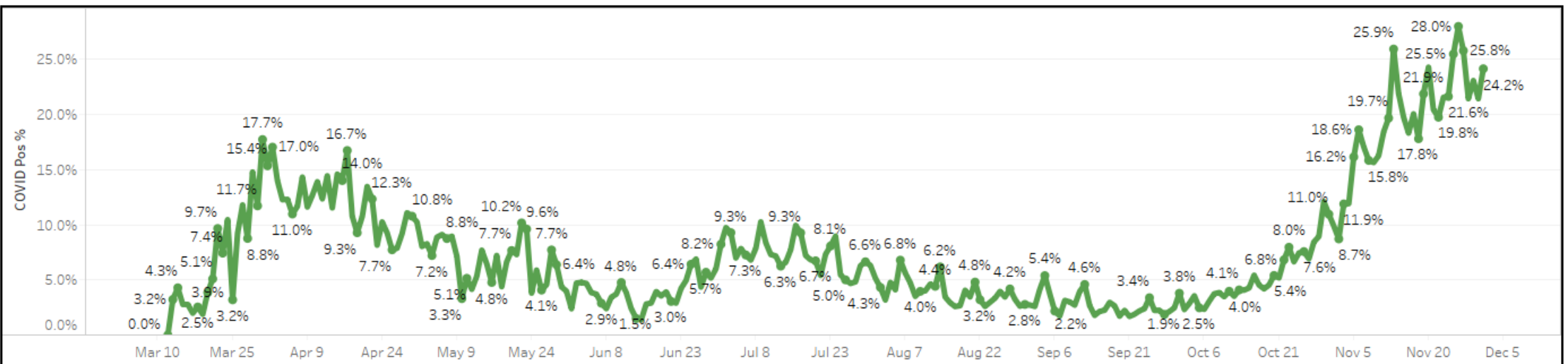


# Constant increases in testing capacity to meet clinical volumes

*COVID-19 Total Tests by Day*

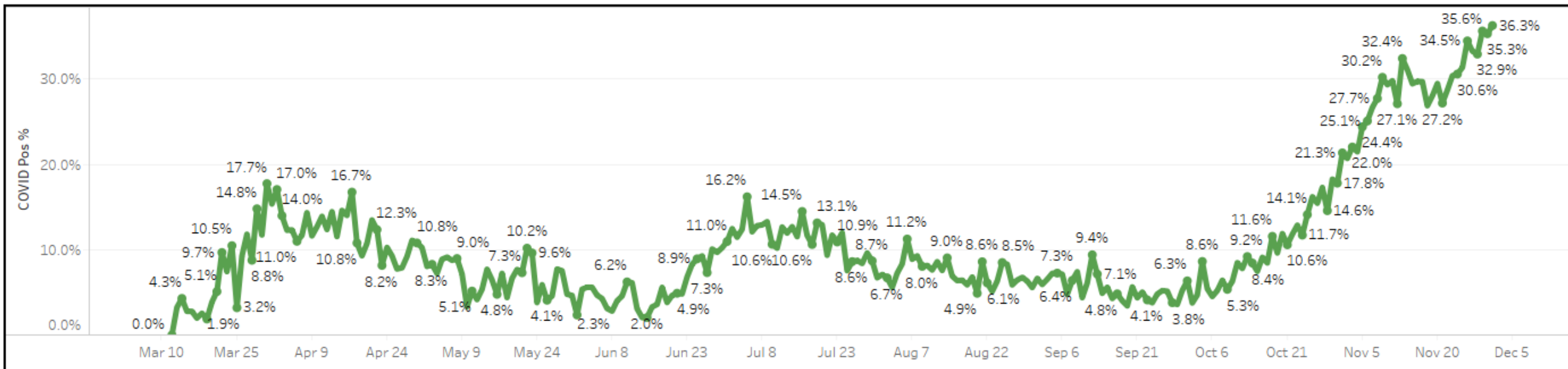


*COVID-19 Positive Tests % by Day*



# Current positivity rate of symptomatic patients

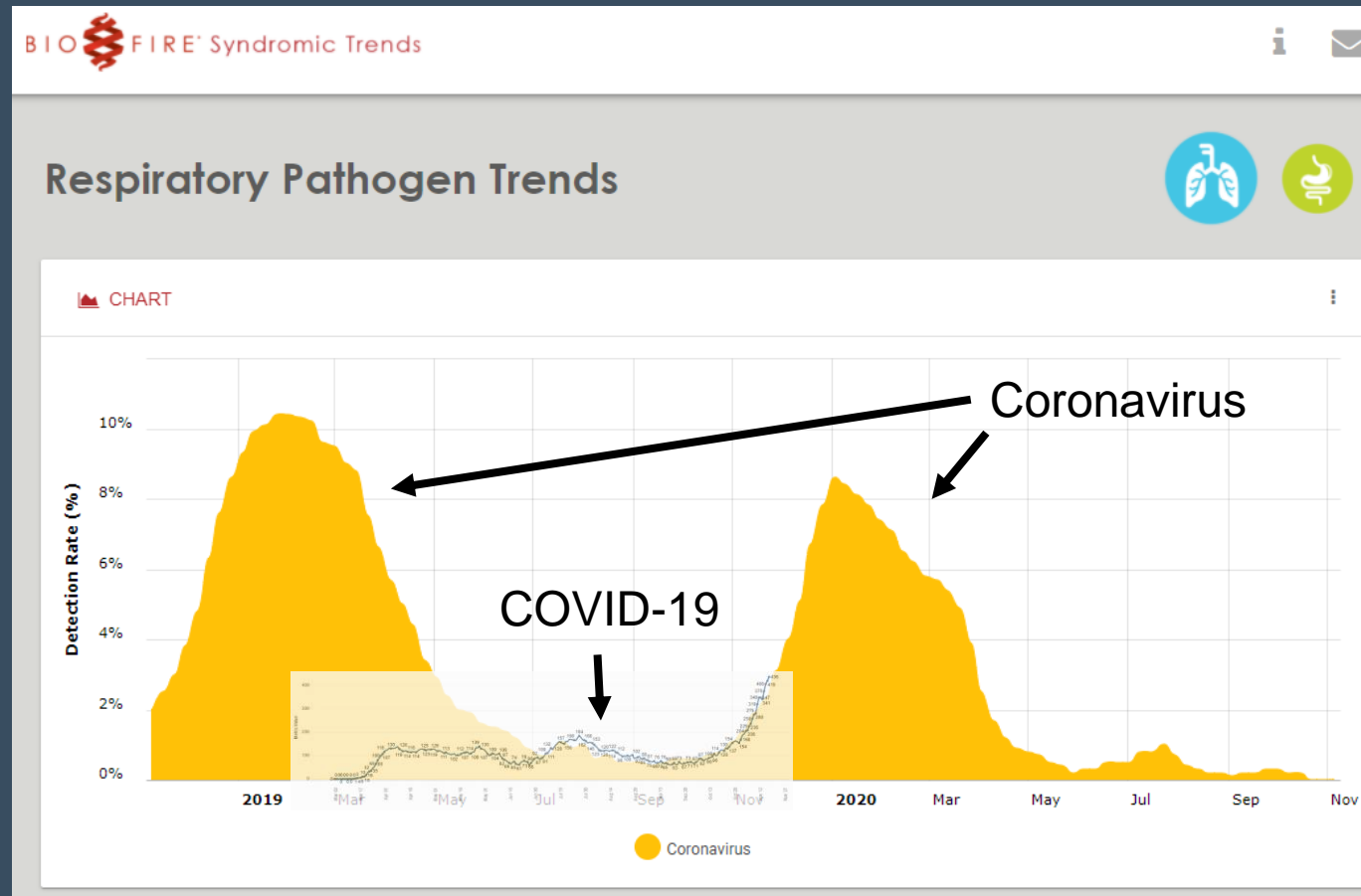
*COVID-19 Positive Tests % by Day*



# Antigen and Antibody Testing

- We have not used antigen testing of any type
  - Lower specificity than NAT
  - False Positives are a major problem
- Antibody testing/serology is not useful in managing individual patients
  - Unclear what antibody titers mean in terms of history of infection
  - Correlates of protection unknown

November is the beginning of the traditional season for coronaviruses, which has peaked the last two years in January. This is our first winter with SARS-CoV-2.



# Caregiver COVID Testing

- CC Tests Symptomatic Caregivers Only
- Negative
  - Return to work when afebrile for 24 hrs without fever reducing medications AND improvement of symptoms
- Positive
  - Ambulatory caregivers isolate at home
  - Back to work
    - At least 10 days have passed since symptoms appeared AND at least 24 hrs have passed since last fever without need for fever reducing medications AND improvement of symptoms (cough, shortness of breath)

# Procedure Related Testing

- Elective pre-procedure testing 2-3 days before procedure
- We do accept outside results if tested within 2-3 days with documentation of results
- If positive, surgery is permitted 28 days after positive test result with improved symptoms and 3 days of rest
- Patients do not require an additional test
- Non-urgent surgeries need an ID consult and appropriate COVID PPE if prior to 28 days
- Urgent surgeries need appropriate COVID PPE if prior to 28 days



**Every life deserves world class care.**

# Procedures requiring pre-procedure COVID test

All surgeries and procedures occurring within an Operating Room or Ambulatory Surgery Center

- ☒ Electro-physiology procedures
- ☒ Cardiac Catheterizations
- ☒ TEE - Transesophageal Electrocardiograph
- ☒ Stress echo, regular exercise stress, metabolic stress, exercise nuclear
- ☒ Pain management occurring at Walker, Hillcrest, and Euclid
- ☒ Scheduled C-sections, Scheduled Inductions, or egg retrieval for IVFs
- ☒ Select Interventional Radiology (AGP, requiring general anesthesia)
- ☒ Dental procedures and cleaning
  - Dental extractions, implants, fillings, crowns, cleaning
  - Periodontal osseous surgery, Periodontal crown lengthening
  - Root canal therapy
  - Alveoloplasty
  - Debridement/Ultrasonic Scaling
- ☒ Nasal and oral procedures excluding routine nasal endoscopy and laryngoscopy
- ☒ Bronchoscopy
- ☒ Endoscopy
- ☒ Sleep lab procedures