COMPLIMENTARY ACCREDITED WEBINAR

COVID-19 VARIANTS, VACCINES AND THE VALUE OF RAPID TESTING

July 27, 2021

10:00 – 11:00 a.m. ET
4:00 – 5:00 p.m. CET

This webinar is sponsored by:

Abbott

The speakers are presenting on behalf of Abbott.
The information presented is consistent with applicable FDA guidelines.
This program does not provide continuing medical education (CME) credits.

COL-05925-01 07/21

MODERATOR

Norman Moore, PhD

Director, Infectious Diseases,
Scientific Affairs
Abbott Rapid Diagnostics

United States

SPEAKERS

John R. Hackett Jr., PhD

Divisional VP of Applied
Research and Technology
Abbott Diagnostics

United States

Sheldon Campbell, MD, PhD

Prof. of Lab Medicine
Yale School of Medicine

Assoc. Chief of
Pathology and Lab
VA CT Healthcare System

United States

Mohammad Raza, MBBS, BSc, FRCP, FRCPath (Virology)

Consultant Virologist
Sheffield Teaching Hospital
NHS Trust

United Kingdom

Learning Objectives

- Gain expert insight on virus surveillance from the Abbott Virus Hunters, an expert team that is identifying, cataloging, and tracking evolving COVID-19 strains
- Learn the latest on the critical role of routine rapid testing in reducing the spread of SARS-CoV-2 and tracking highly contagious variants
- Review practical considerations for testing protocols and use cases in the selection of rapid antigen and molecular testing
- Discover ways to manage simultaneous diagnostic demands of COVID-19 and Influenza

Meeting the Challenge of Viral Diversity: The Abbott Global Viral Surveillance Program

John R. Hackett Jr., PhD

Divisional VP of
Applied Research and Technology
Abbott Diagnostics

United States

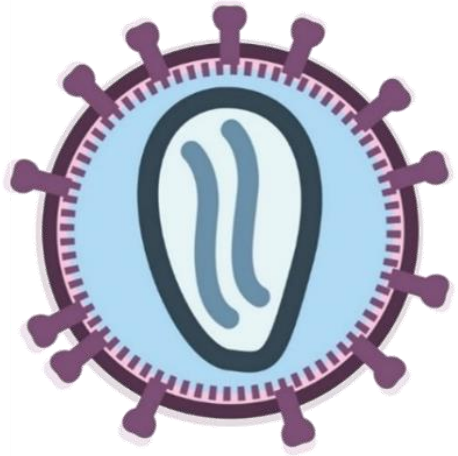
Disclosures

Abbott Diagnostics

Virus Diversity Can Impact Performance of Diagnostic and Screening Tests

Diagnostic and blood screening tests fundamentally rely upon sequence conservation

Serology



Molecular

Primer/probe binding site

ATGCCCAGCTTTAGCTAGATACC

mutation

ATGCCCAGATTTAGCTAGATACC

Meeting The Challenge of Viral Diversity

THE ABBOTT GLOBAL VIRAL SURVEILLANCE PROGRAM

For 26 years studying Hep/Retro virus variation together with collaborators

- Monitor emergence of new viral strains
- Establish well characterized specimen panels representing all viral genotypes and common mutations from broad geographical locations for regulatory submissions, etc.
- Characterize unique specimens with discordant testing results/clinical status

Benefits

- Use circulating strains on an ongoing basis for serological and molecular assay development
- Provide assays that reliably detect and monitor ALL infections
- Advance knowledge: >140 peer-reviewed publications; numerous sequence contributions

Archived >82,000 specimens from 45 countries, 6 continents

Abbott Global Surveillance Program

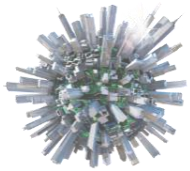
- **LEGACY**

Abbott Global Surveillance Program

- **LEGACY**
- **EXPANDING GEOGRAPHIES**

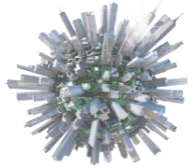
Abbott Surveillance Program Milestones

HBV



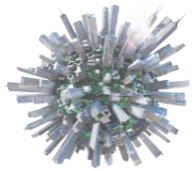
2009

HCV



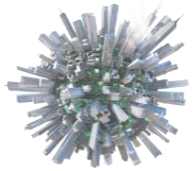
2014

HPgV-2 Discovery



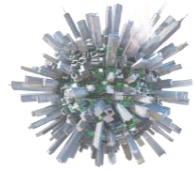
2015

HDV



2016

SARS-CoV-2



2020

2011

Discovered 2nd HIV Group P

2016

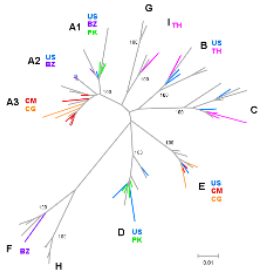
Surveillance database

2017

Discovered 10th & 11th HIV Group N

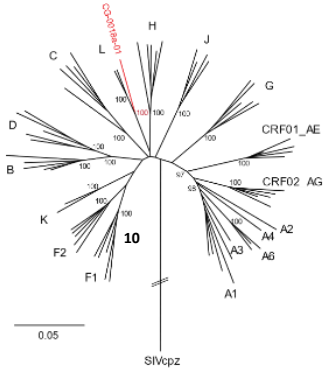
2018

Discovered 1st HBV-I strain in Thailand



2019

HIV-Subtype L



2021

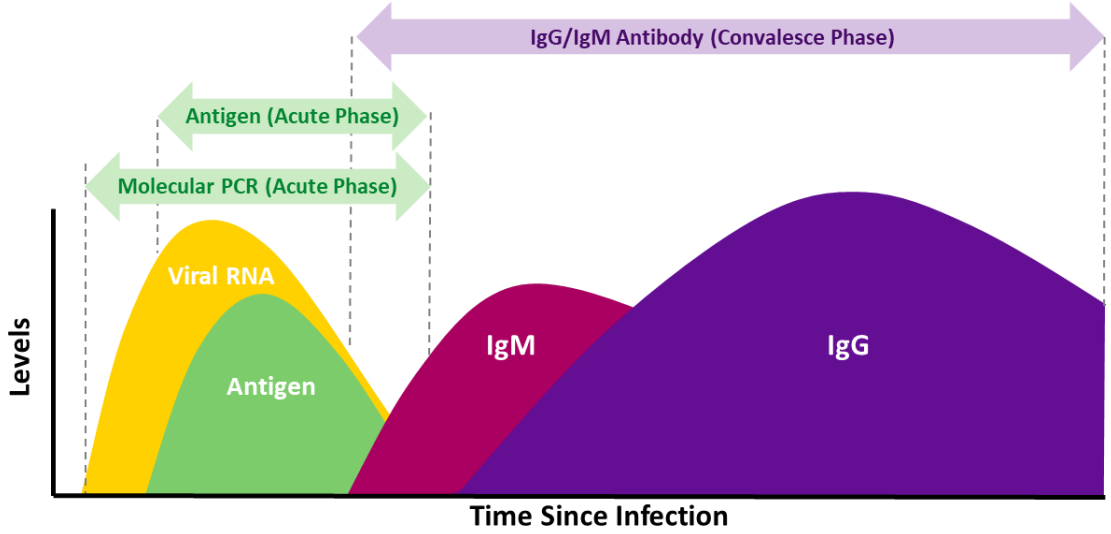
HIV Controllers

Whole Genome Next Gen Sequencing Implementation

Abbott Global Surveillance Program: SARS-CoV-2 Variants

- ***In silico* sequence analysis** – as new variants emerge, these sequences are compared to Abbott assay target regions to identify possible mismatches, no impact to detection predicted for any variants analyzed yet to date
- **Proactive surveillance –** collaborator network to acquire clinical specimens for sequence analysis and evaluation of Abbott test performance (on site and externally)
- **Virus culture –** Abbott, BEI, collaborators
- **Evaluate performance of Abbott COVID-19 tests**
- **Current geographies monitored to date**
  - South Africa
  - United Kingdom
  - Senegal
  - Brazil
  - Canada
  - France
  - Italy
  - India
  - USA
    - Illinois
    - California
    - Wisconsin
    - Michigan
    - New York
    - Ohio
    - South Carolina
    - Texas
    - Florida

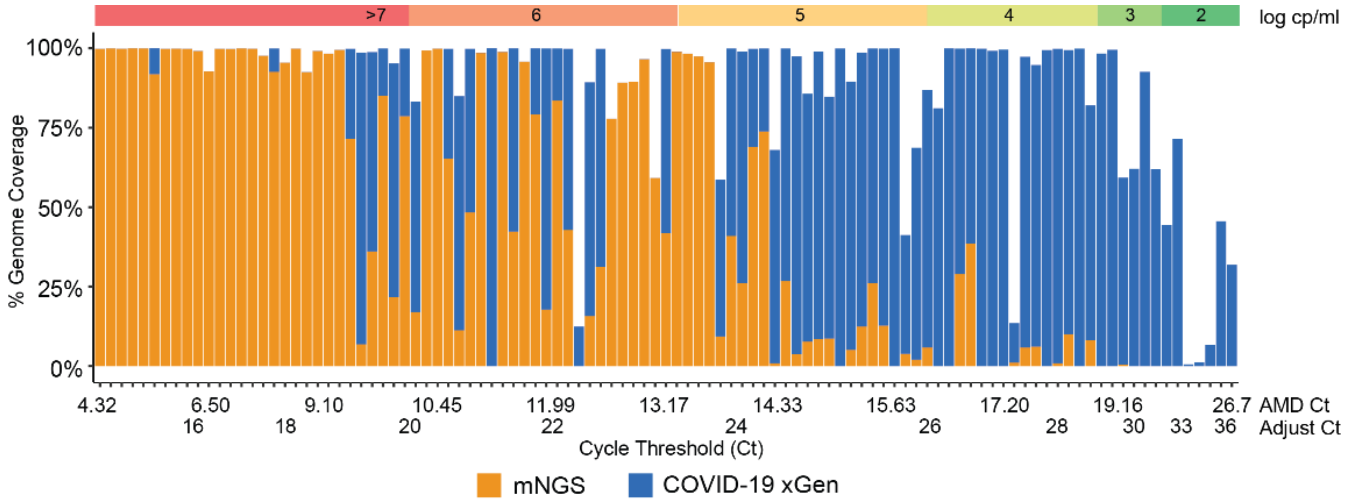
Vigilance to ensure detection of infections with all circulating strains by each diagnostic marker



NOTE: this is a typical viral patient response and is not specific to COVID-19

SARS-CoV-2 Genome Sequences Generated at Abbott

- Next-generation sequencing
  - Metagenomic (random-primed) sequencing
  - Target-enriched (X-gen) sequencing
- Pangolin/NextClade sequence classifications
- Phylogenetic analysis
- *In silico* analyses of Abbott test target regions



SARS-CoV-2 pipeline

Trim adapters

↓

Remove short and low qual reads

↓

Align to Wuhan reference (blast → sam file)

↓

Tabulate variation from reference

↓

Apply R-language variant caller

↓

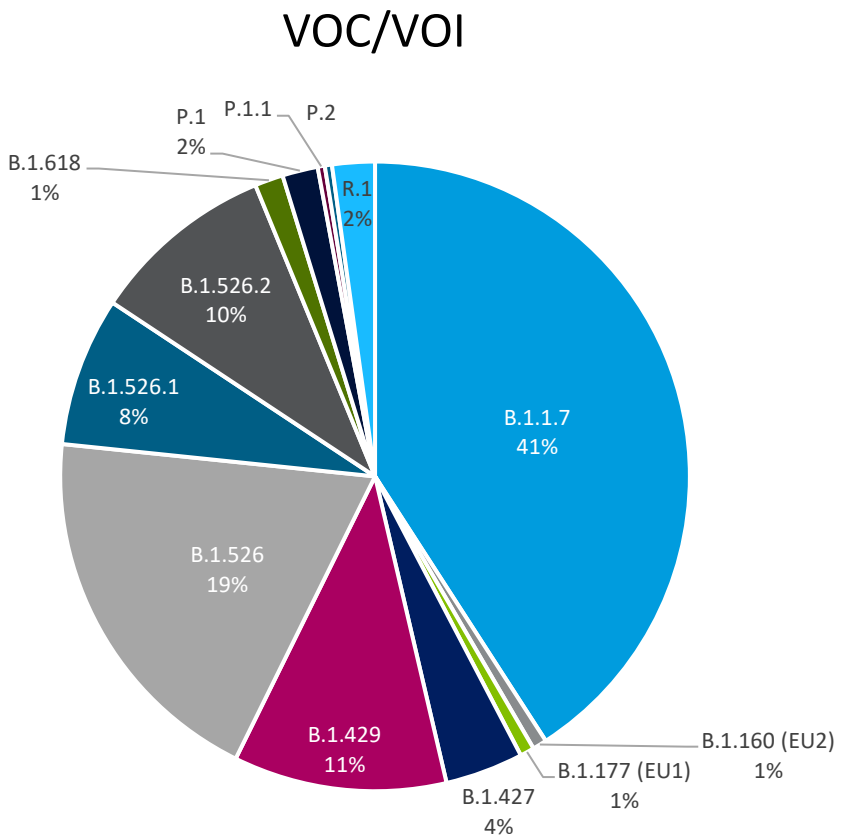
Output consensus sequence, metrics, bam file

Abbott Bioinformatics

Forberg and Orf et al *Frontiers in Microbiology* 2021 *submitted*

Identification of SARS-CoV-2 Variant Lineages

- 830 specimens sequenced and classified to date
- 355 variant infections identified in US and SN
  - B.1.1.7 *Alpha* (UK)
  - B.1.526, B.1.526.1, B.1.526.2 *Eta* (NY strains)
  - B.1.427, B.1.429 *Epsilon* (CA strains)
  - P.1, P.2, P.1.1, B.1.1.28 *P.1.x Gamma, P.2 Zeta* (Brazil strains)
  - B.1.351 *Beta* (South Africa)
  - B.1.618 (India strain)
  - R.1 (Japan/US strain)
  - Spike mutations of concern (MOC) in common lineage backgrounds at positions E484, L452, N501, S477
- Virus cultures

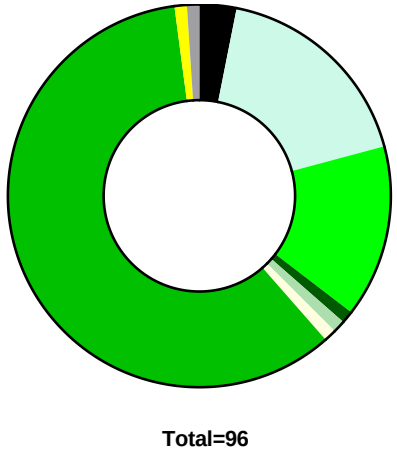


*WHO, Variants of Concern, https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/, accessed July 19, 2021

Viral Diversity Differs Between Waves of COVID-19 Infections

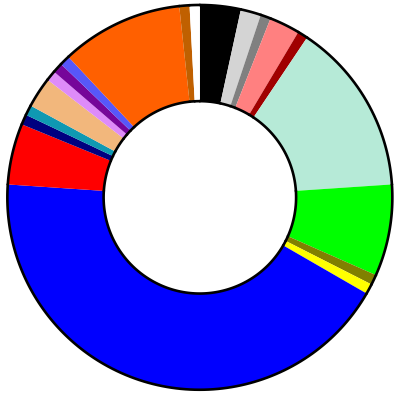
SENEGAL

WAVE 1



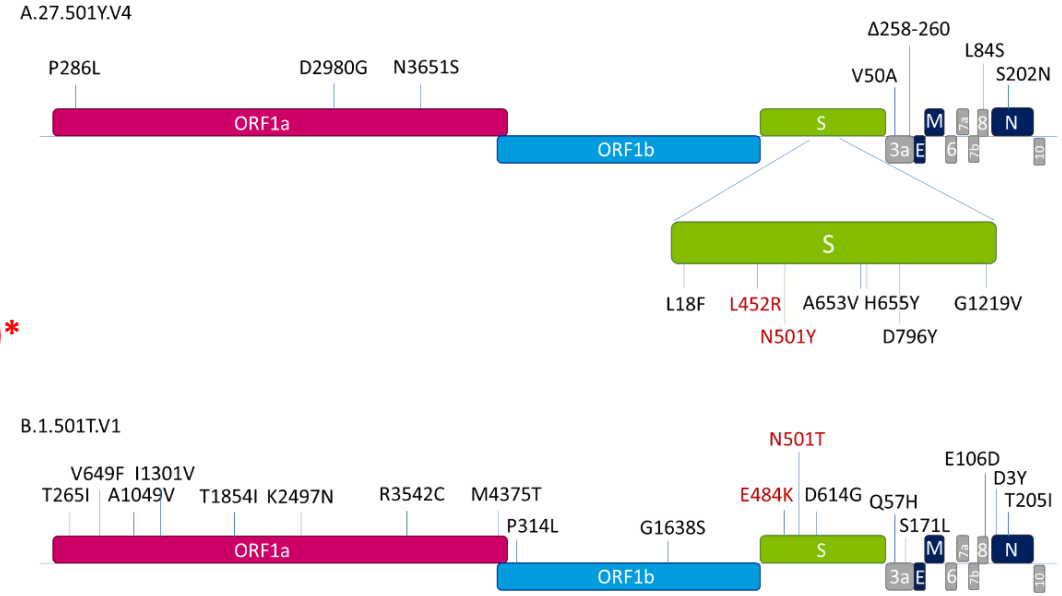
A
B.1
B.1.1
B.1.221
B.1.237
B.1.265
B.1.416
B.1.541
B.1.610

WAVE 2



A
A.21
A.23.1
A.27.501Y.V4
B.1.501T.V1
B.1
B.1.1
B.1.1.28
B.1.1.348
B.1.1.420
B.1.1.7
B.1.160
B.1.177
B.1.2
B.1.214.3
B.1.338
B.1.398
B.1.416
B.1.596
C.36

Alpha* (UK)



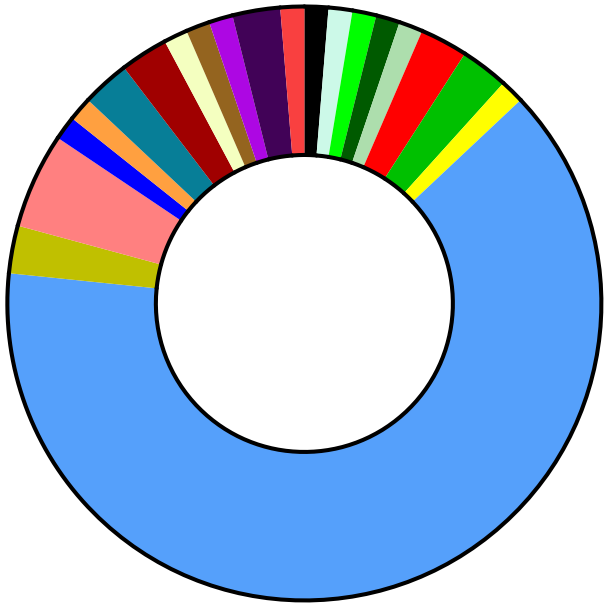
Souleymane Mboup
Ambroise Ahouidi
IRESSEF, Dakar

*WHO, Variants of Concern, https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/, accessed July 19, 2021
Ahouidi and Rodgers et al *Scientific Reports* 2021 *submitted*

Viral Diversity: Differences Between Cities 90 Miles Apart

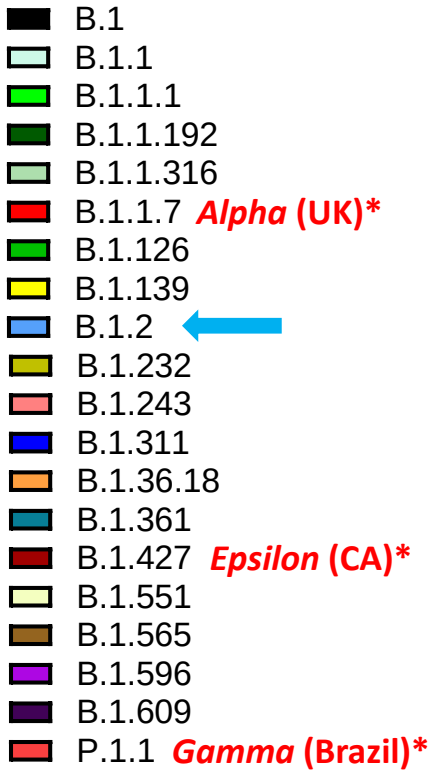
JAN-MARCH 2021

CHICAGO, IL

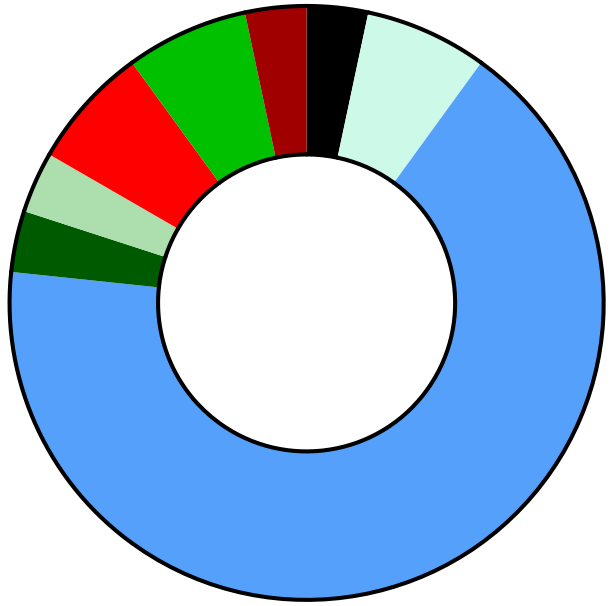


Total=77

Alan Landay
James Moy
Rush

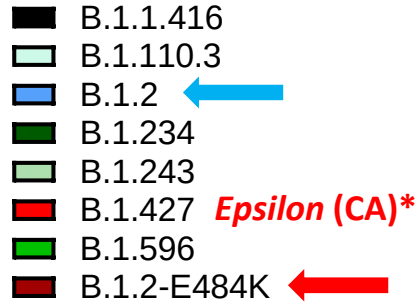


MILWAUKEE, WI



Total=30

Matt Faron
MCW



*WHO, Variants of Concern, https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/, accessed July 19, 2021

The Abbott Pandemic Defense Coalition

A SCIENTIFIC AND PUBLIC HEALTH PARTNERSHIP DEDICATED TO THE EARLY DETECTION OF AND RAPID RESPONSE TO *FUTURE PANDEMIC THREATS*

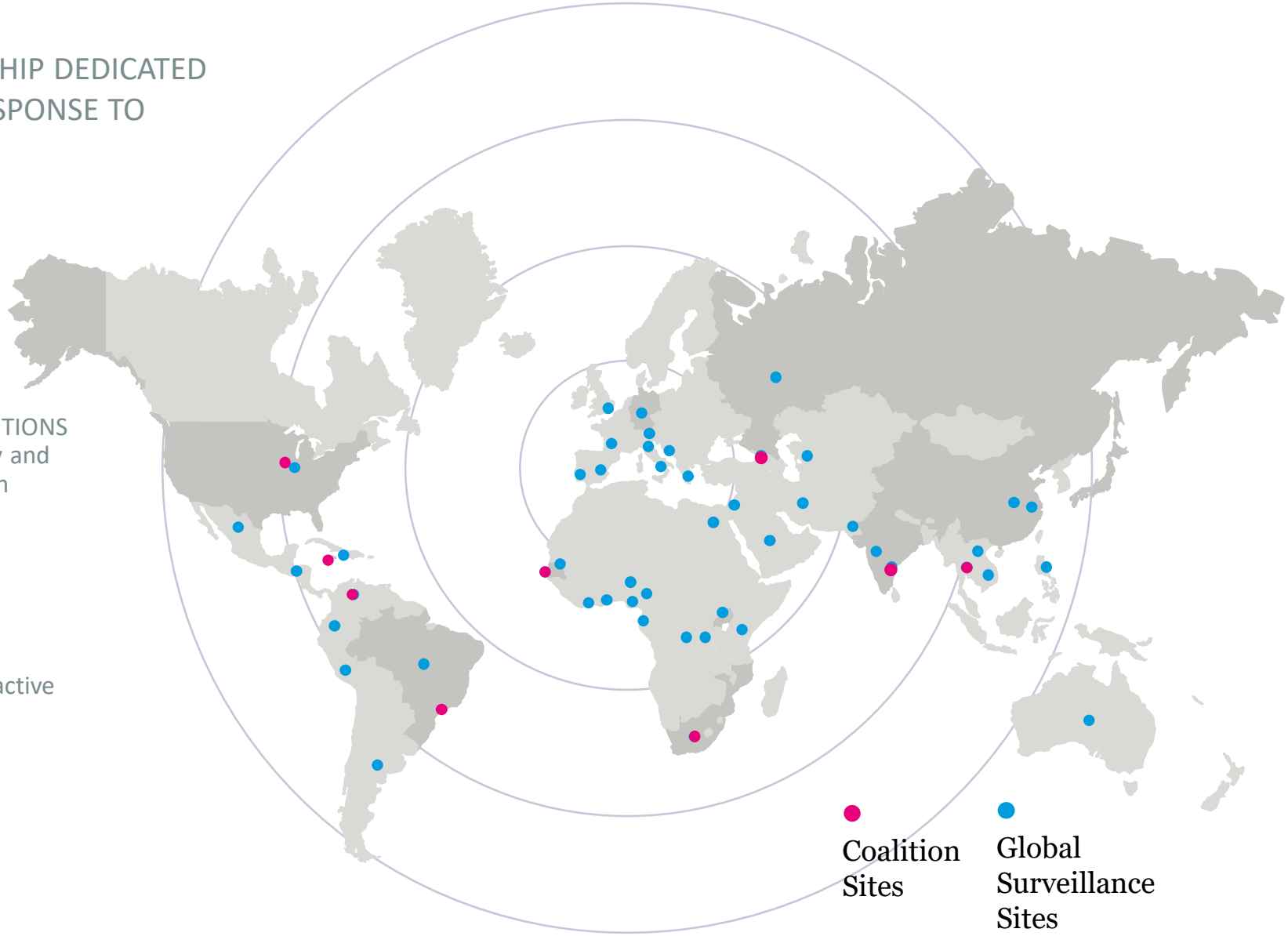
COMMON SPECIMEN REPOSITORY
and access to state-of the art technologies

BIOINFORMATIC SOLUTIONS
that support discovery and accelerated test design

CREATION
of prototype tests to evaluate potential pandemic threat

RAPID DEPLOYMENT
of tests to enable proactive response

REAL-TIME ACTION
through engagement with the global health community



Colleagues, Collaborators, and Resources

ADD ID Research

Dr. Gavin Cloherty
Dr. Mary Rodgers
Dr. Michael Berg
Ana Vallari
Ana Olivo
Xinxin Luo
Chris Lark
Barbara Harris
Dr. Mark Anderson
Dr. Greg Orf
Dr. Lester Perez
Dr. Ka-Cheung Luk
Julie Yamaguchi
Kenn Forberg
Vera Holzmeyer
Priscilla Swanson
Megha Patel

US Studies

Dr. Matt Faron - MCW
Dr. Rick Nolte – MUSC
Dr. Julie Hirshhorn – MUSC
Dr Yitz Goldstein – Montefiore
Dr Amy Fox – Montefiore
Dr Alan Landay – Rush
Dr James Moy – Rush

Senegal Studies

Dr Souleymane Mboup – IRESSEF
Dr Ambroise Ahouidi – IRESSEF

UK Studies

Dr Rahul Batra – GSTH
Dr Gaia Nebbia – GSTH
Dr Sam Douthwaite – GSTH

BEI

The following reagent was deposited by Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA/CA_CDC_5574/2020, NR-54011.

The following reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/South Africa/KRISP-EC-K005321/2020, NR-54008, contributed by Alex Sigal and Tulio de Oliveira.

The following reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/South Africa/KRISP-K005325/2020, NR-54009, contributed by Alex Sigal and Tulio de Oliveira.

The following reagent was obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate hCoV-19/Japan/TY7-503/2021, NR-54982, contributed by M Takayama-Ito.

GISAID (used for *in silico* analysis)

Data, including metadata and sequence information was obtained from the GISAID database as a result of the work of data contributors, i.e., the Authors, the Originating laboratories responsible for obtaining the specimens, and the Submitting laboratories for generating the genetic sequence and metadata and sharing via the GISAID Initiative, on which this research is based. GISAID data are subject to GISAID's Terms and Conditions that can be accessed via www.gisaid.org.

Polling Question #1

We CURRENTLY use **RAPID COVID-19 TESTING** for the following populations: (select all that apply)

A. Emergency room
B. Inpatient
C. Pre-surgical
D. Outpatient/Clinic
E. Skilled Nursing/Long Term Care
F. Other
G. None of our testing is rapid

Sheldon Campbell, MD, PhD

Prof. of Lab Medicine
Yale School of Medicine

Assoc. Chief of Pathology and Lab
VA CT Healthcare System

United States

Disclosures

Receiving honorarium, Abbott

No conflicts

Why Test for SARS-CoV-2 in our Health System?

> “ WHAT A STUPID QUESTION, CAMPBELL! IT’S THE BIGGEST THING THIS CENTURY. ”

3 (SOMEWHAT CONFUSING AND OCCASIONALLY-OVERLAPPING, BUT STILL USEFUL) BINS:

Diagnostic
Symptomatic, high-risk exposure, or otherwise high suspicion of active infection

Screening
Asymptomatic, tested related to a discrete event (e.g., admission, high-risk procedure)

Monitoring
Pre-, a-, or paucisymptomatic; used periodically, at intervals, for all eligible members (or a sample) of a defined population

WHAT TEST DO YOU USE FOR WHICH? DECISION DRIVEN BY:

- **Clinical Question:** presence of pathogen or infectivity?
- **Test Characteristics:** sensitivity/specificity
- **Operational Issues:** turnaround time, labor, cost, reagent availability

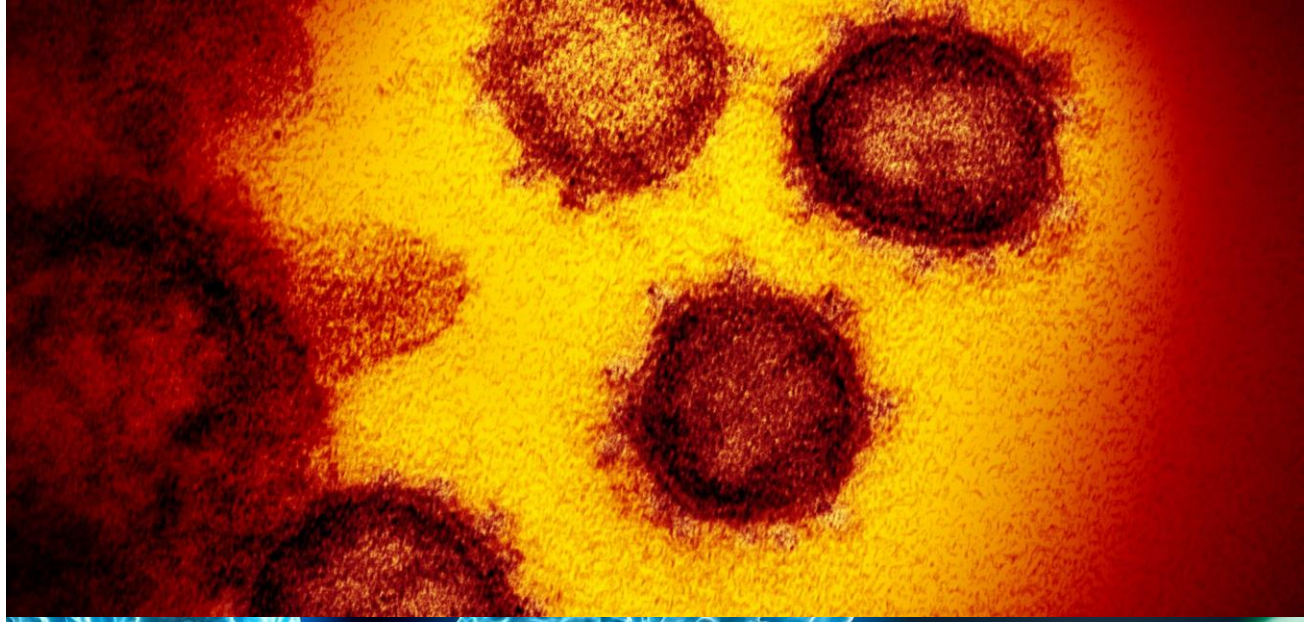
Types of COVID Tests

DIRECT TESTS FOR VIRUS

- RT-PCR and other molecular tests
- Antigen tests

SEROLOGICAL TESTS

- Antibody tests (IgG, IgM)
- Neutralizing antibody tests

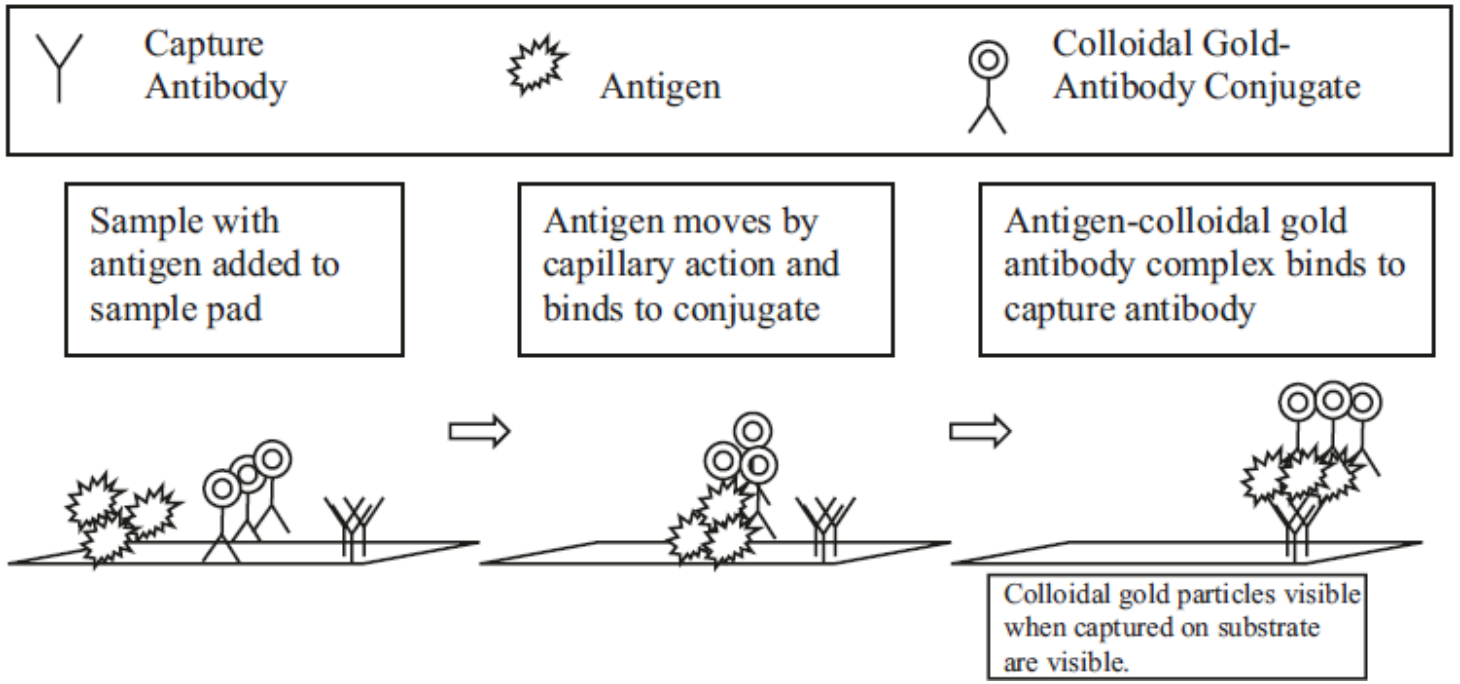


DIRECT TEST FOR VIRUS

Antigen or Molecular?

Antigen ("Lateral Flow") Tests – Immunoassays

React antigen with antibody and detect the reaction.

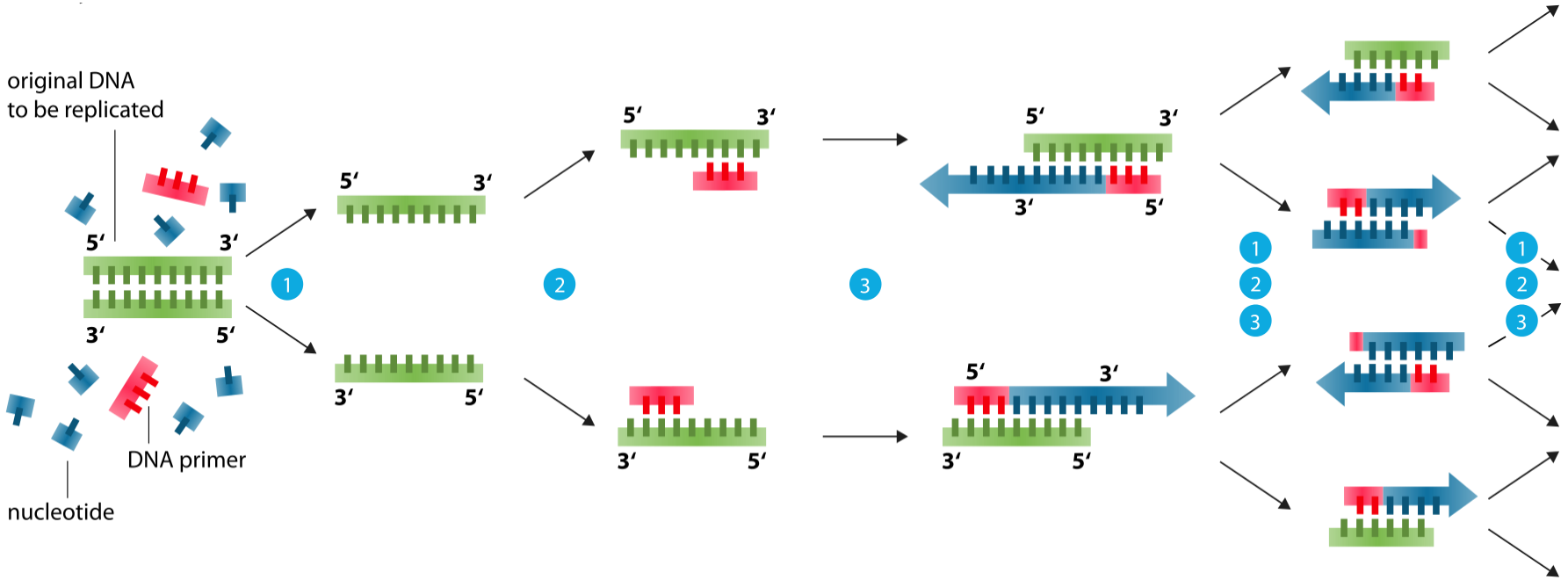


Depending on format, detect microbes (by looking for their antigens) or specific antibodies.

Polymerase Chain Reaction (PCR)

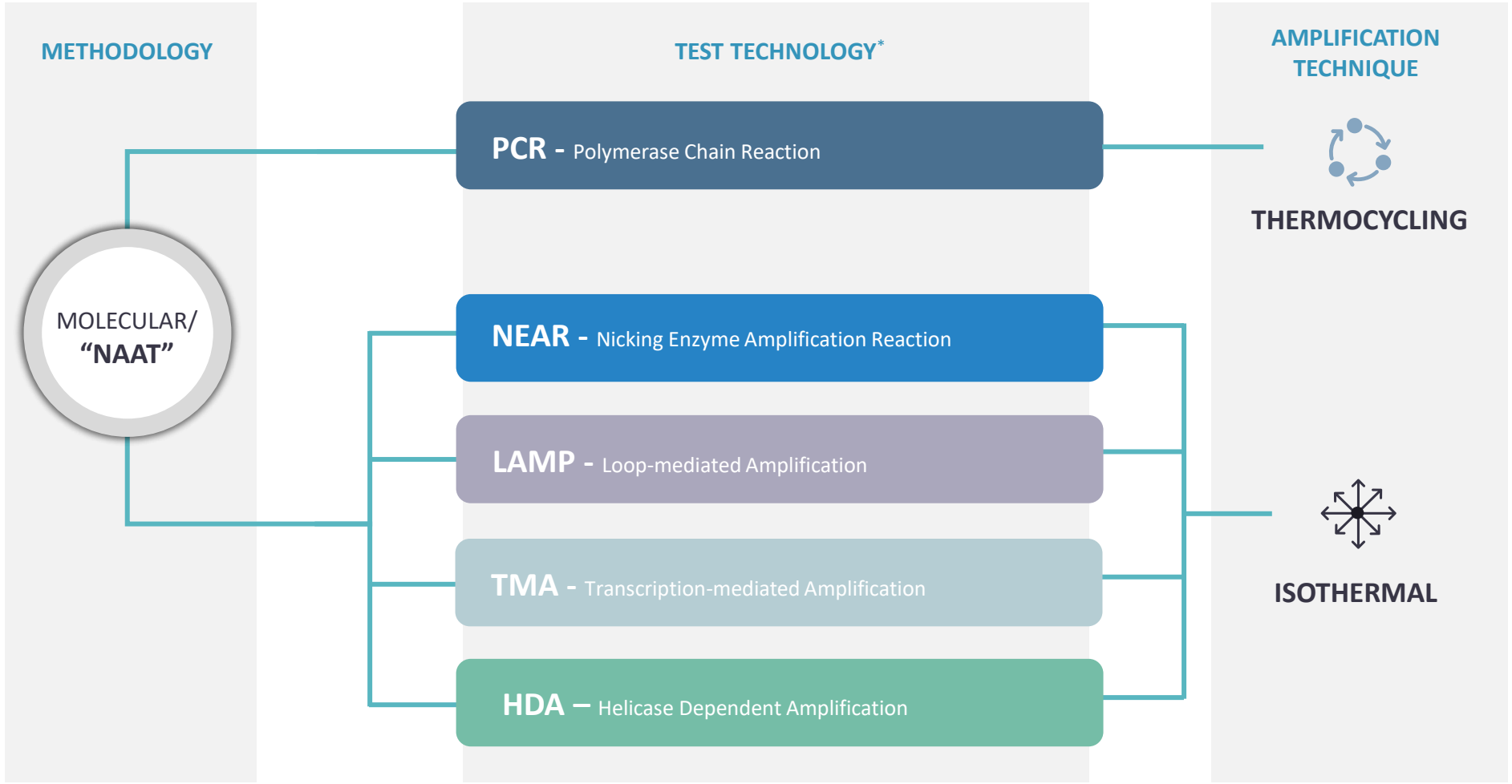
IT ALL STARTED WITH PCR…

Basically, you pick a target sequence out of a bunch of other DNA and make a jillion copies of it, then detect those copies.



BUT THERE ARE MANY OTHER AMPLIFICATION TECHNOLOGIES.

Molecular (NAAT) COVID-19 Tests (By Methodology)

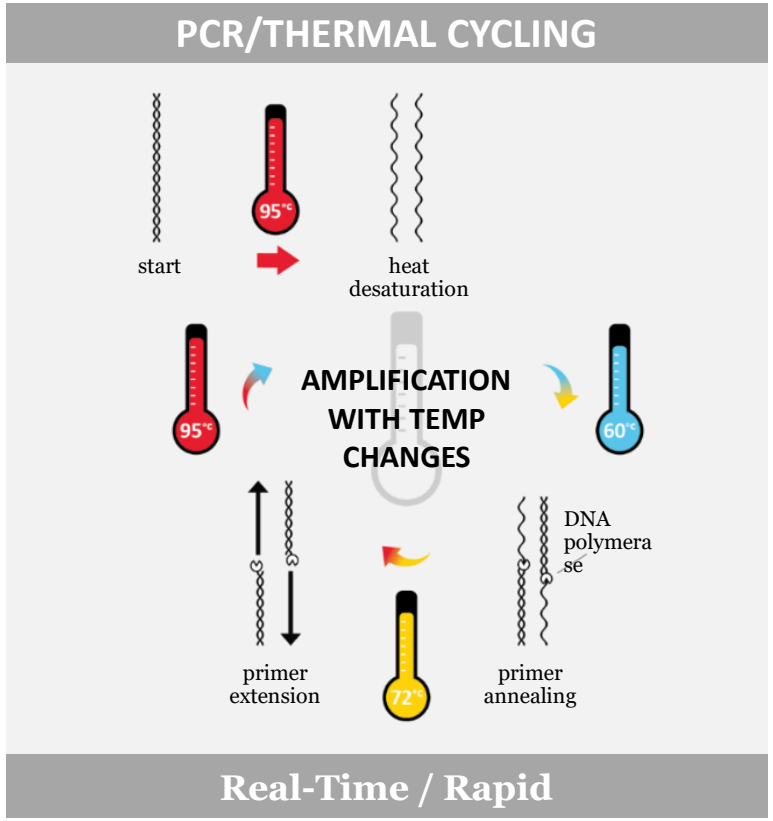


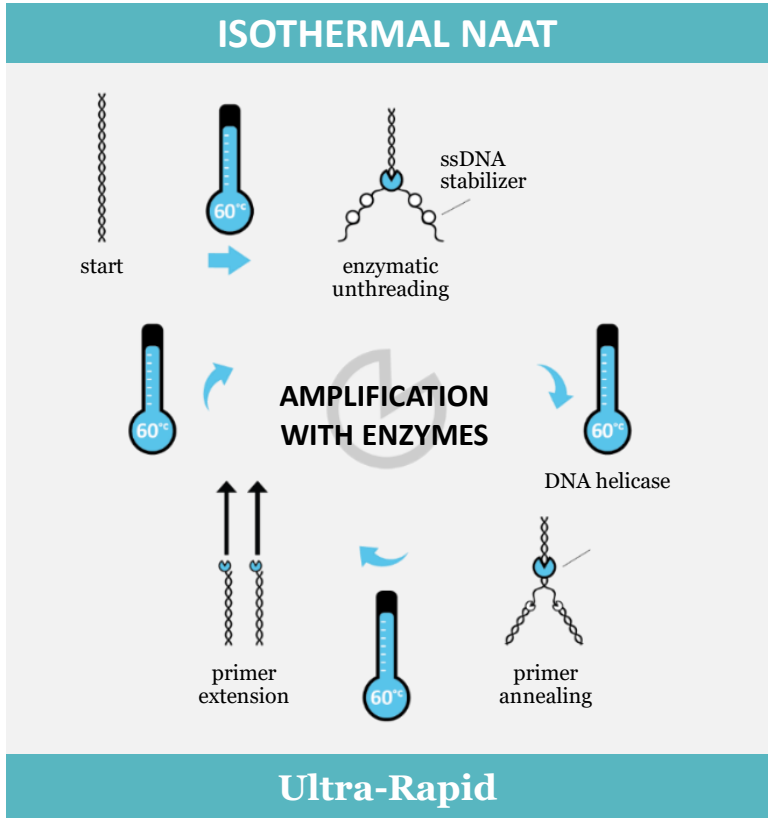
NAAT, nucleic acid amplification test.
*Multiple NAATs amplify nucleic acids, not a comprehensive list.
CDC, Nucleic Acid Amplification Tests (NAATs), updated June 16, 2021. Accessed July 21, 2021.

PCR and Isothermal–Molecular, with a Key Difference

PCR tests require thermocycling, a series of **temperature changes** for pathogen amplification, which increases time to result. [1]

Isothermal tests may use enzymes and **consistent temperature** to reduce the time of the reaction.





Both technologies **amplify** the target

1. RT-PCR, real-time or reverse transcriptase polymerase chain reaction. Adapted from, https://www.frontiersin.org/articles/10.3389/fbioe.2015.00029/full

Molecular Diagnostic Workflow

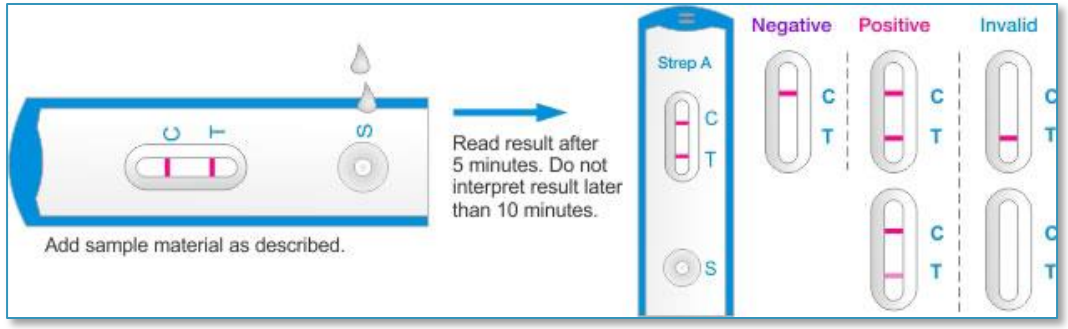
Antigen vs. Molecular

Antigen/Immunoassay

- Rapid; typically minutes
- May not need instrumentation (though some do)
- Usually highly specific; tend to lack sensitivity vs gold standard methods
- Usually relatively inexpensive

Molecular/NAAT

- Rapid; minutes to 1h or so, or batched
- Require instrumentation
- Can be highly sensitive and specific
- Detect only target nucleic acid, not host response
- Relatively costly



Polling Question #2

We would like/plan to expand **RAPID COVID-19 TESTING** for the following populations: (select all that apply)

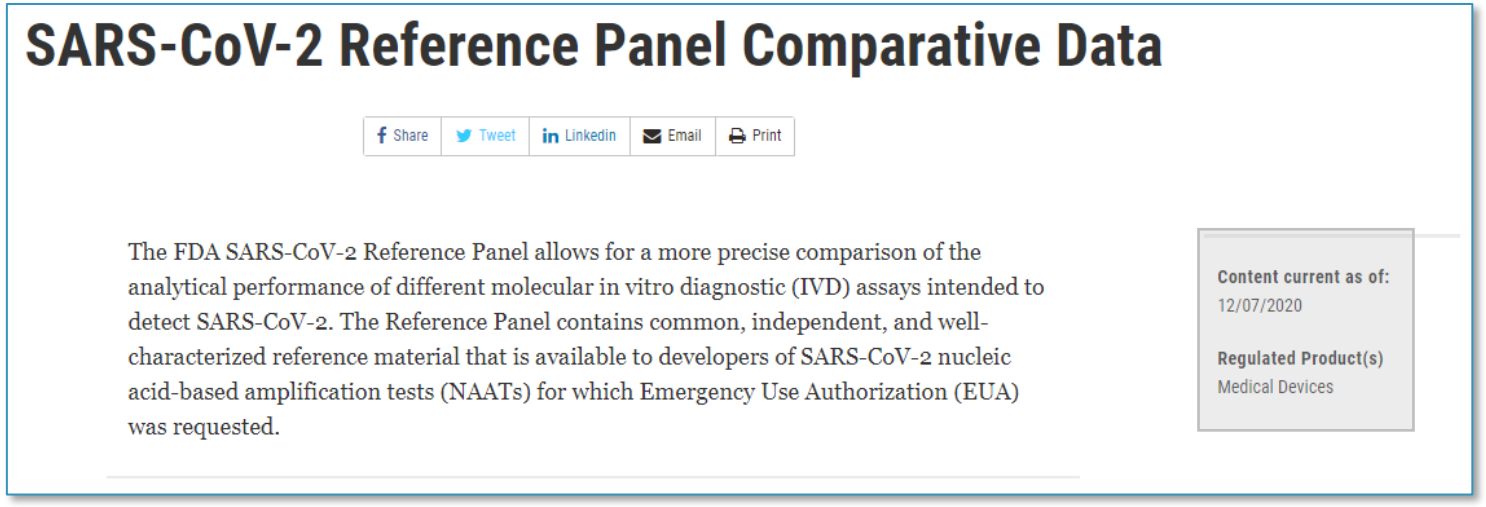
A. Emergency room
B. Inpatient
C. Pre-surgical
D. Outpatient/Clinic
E. Skilled Nursing/Long Term Care
F. Other
G. No plans to change current testing

How sensitive are molecular tests for diagnosis?

All highly sensitive; can detect smallish numbers of viral copies

FDA lists limit of detection with standard materials for many assays:[1]

These numbers (for most tests 180-18,000 copies/ml but occasionally *much* higher) don't translate well to clinical sensitivity.



SARS-CoV-2 Reference Panel Comparative Data

Share Tweet Linkedin Email Print

The FDA SARS-CoV-2 Reference Panel allows for a more precise comparison of the analytical performance of different molecular in vitro diagnostic (IVD) assays intended to detect SARS-CoV-2. The Reference Panel contains common, independent, and well-characterized reference material that is available to developers of SARS-CoV-2 nucleic acid-based amplification tests (NAATs) for which Emergency Use Authorization (EUA) was requested.

Content current as of:
12/07/2020

Regulated Product(s)
Medical Devices

Clinical sensitivity: In symptomatic patients, sensitivity of a single RT-PCR test is well under 100%, but I haven't seen a well-conducted study saying what it is.

- Keep testing 'till you get the answer you want…that's what everyone else does.
- Just kidding…sort of.

1. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

Testing Scenarios

EARLY OUTBREAK (SPRING 2020)

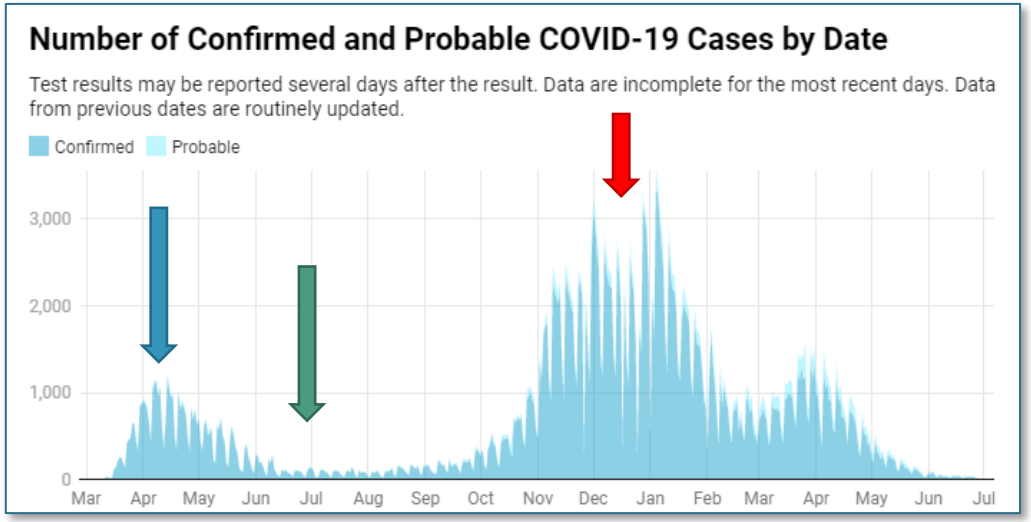
'We have six patients in the **ED** with fever and respiratory distress, **how long 'till the COVID tests are done**?'

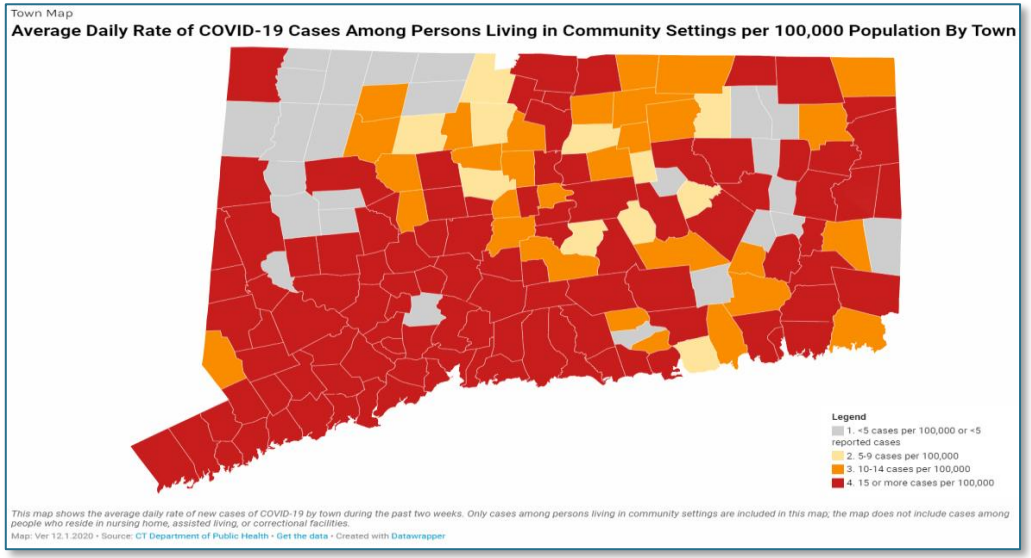
EARLY RE-OPENING (SUMMER-FALL 2020)

'How many COVID tests can you do in a day? We're trying to re-open the **colonoscopy** service. And can you turn them around **within 30 minutes** of the patient arriving?'

RESURGENCE (WINTER-2020)

'We have six patients in the **ED** with fever and respiratory distress and twelve in the **MICU** and we need to repeat four of those, and also the **nursing home** wants to test their entire population and staff **twice a week** and they really need those **within an hour** of collection. And the pulmonary people are doubling their outpatient **bronchoscopies,** too. And we're opening a new **community drive-through testing site**, can you work out the transportation?

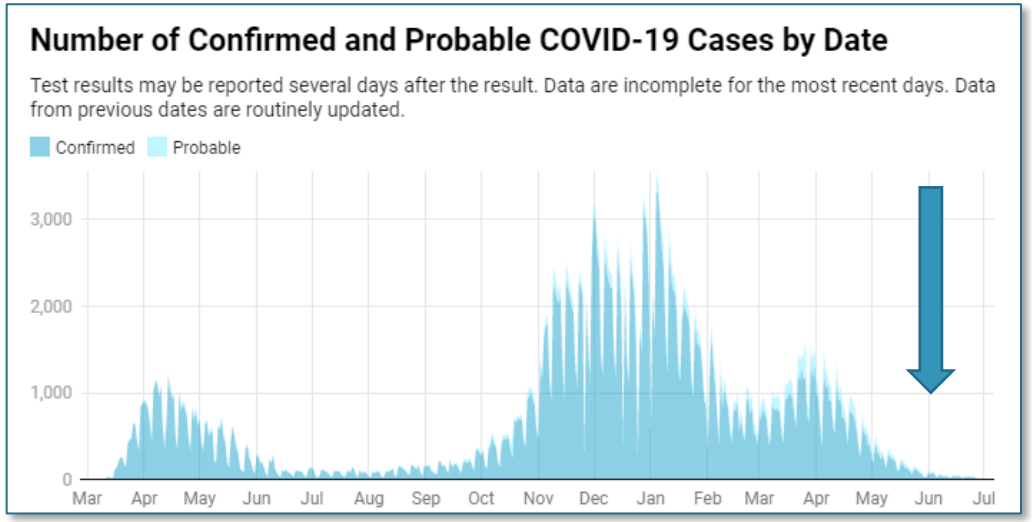


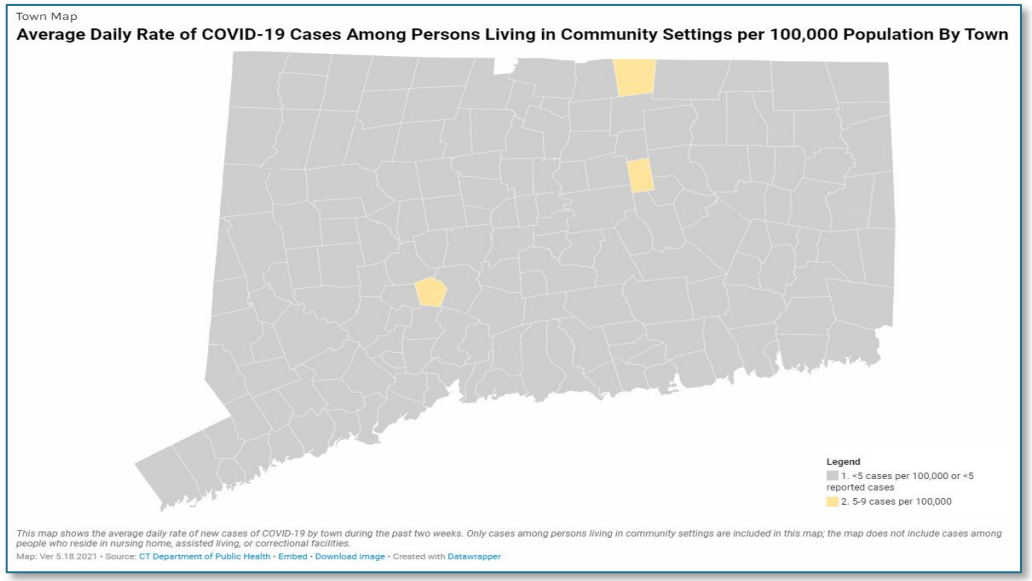


Case from Last Month…

‘Patient tested positive pre-procedure. They were vaccinated in March. Can you investigate?’

WHAT WOULD YOU DO?





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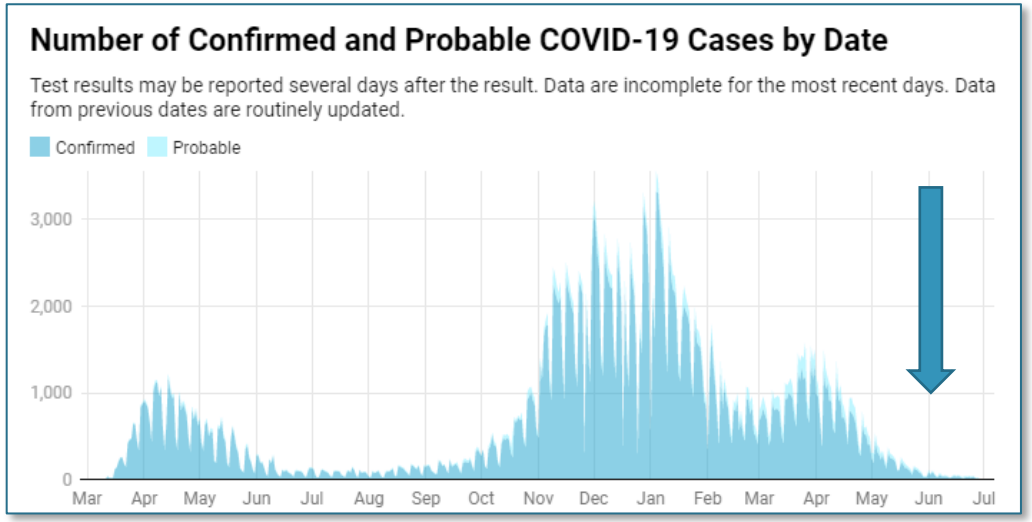
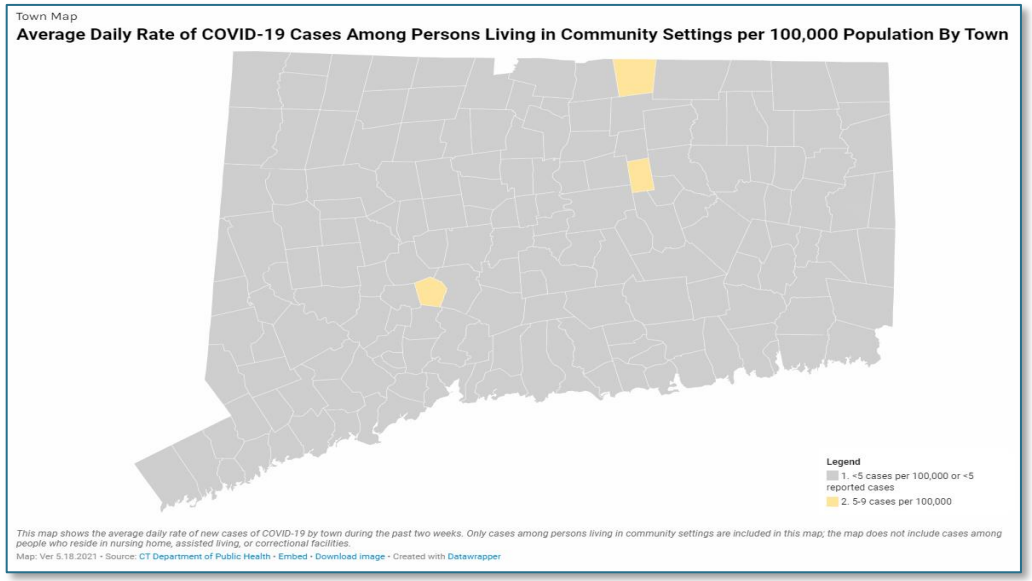
WHAT WOULD YOU DO?

- Note community case rates
  - 200 tests/d, 0-2 positives.
- Check Ct value
  - High (note no number here)
- Re-test on same platform
  - Negative
- Re-test x2 on another (good) platform:
  - Negative





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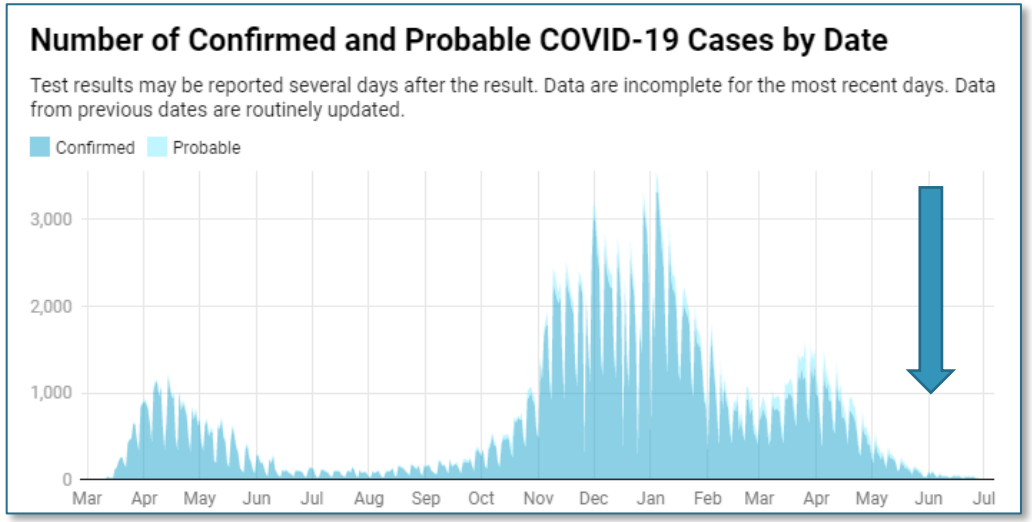
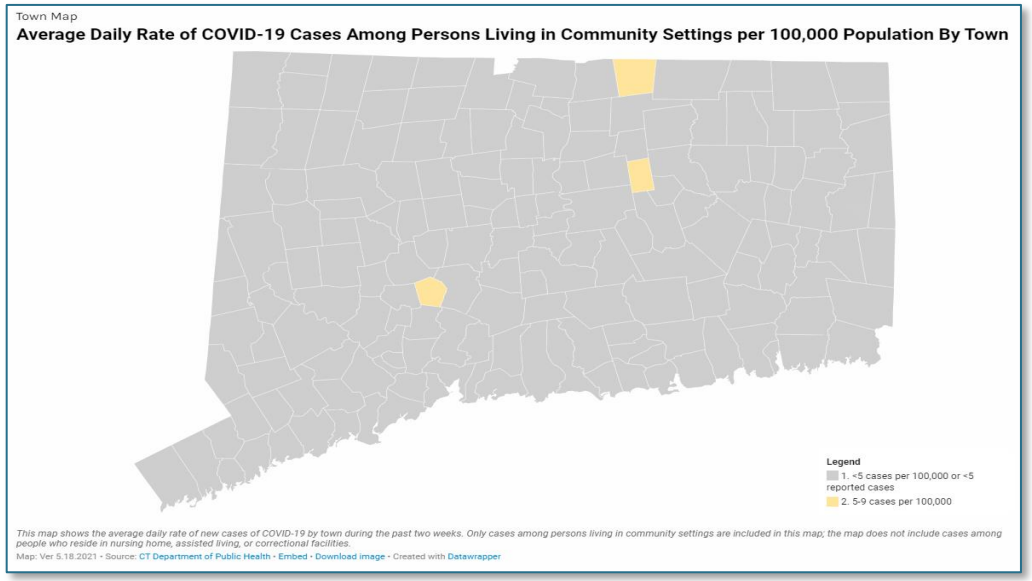
NOW WHAT? CONSIDER:





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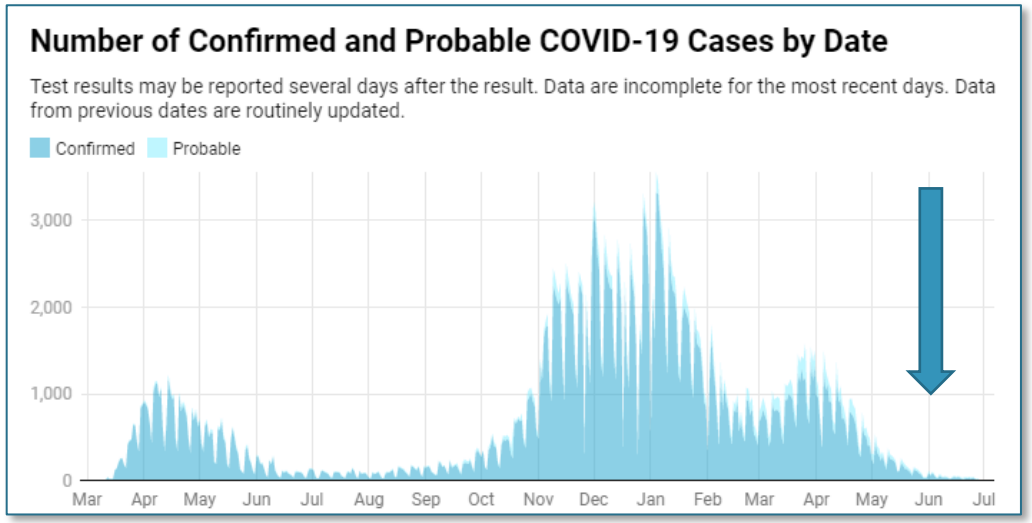
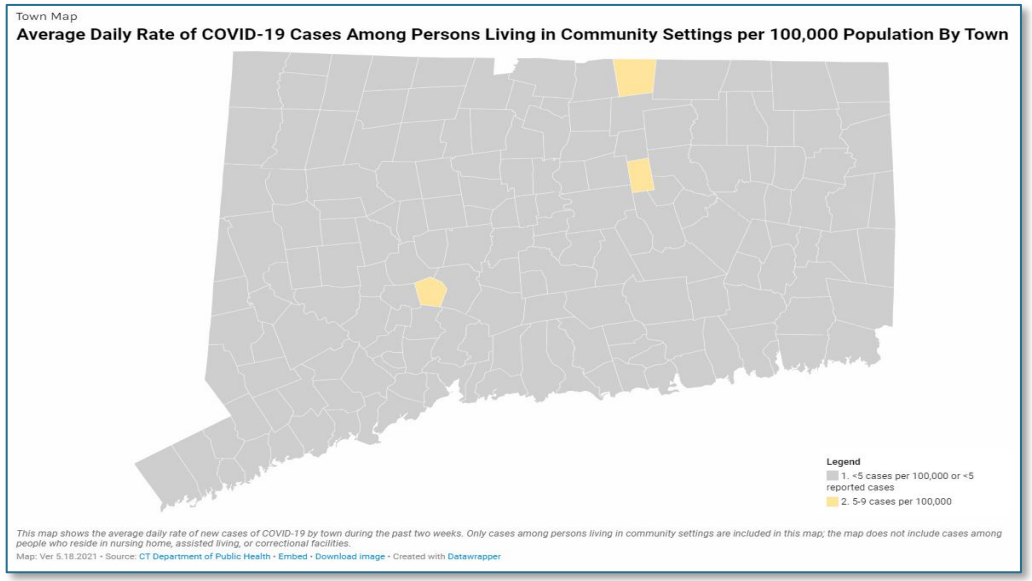
NOW WHAT? CONSIDER:

- S and NC antibodies
- Recollect tomorrow



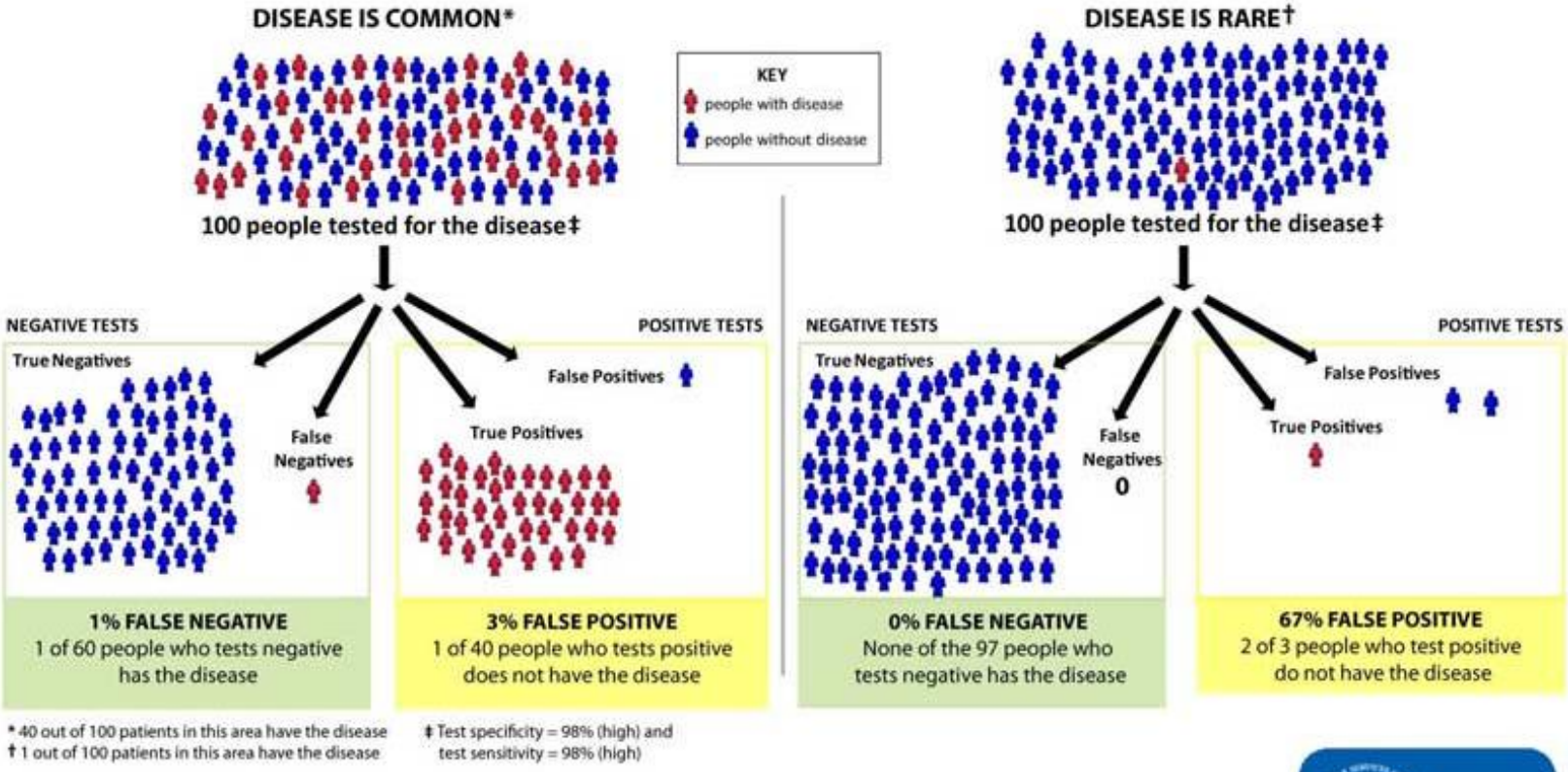


Understanding Test Results for Infectious Diseases

Consider the likelihood of disease ***before*** performing Laboratory testing

The likelihood that a patient has a disease depends on many factors:

- Has the patient been in an area where the disease is found?
- Does the patient have signs and symptoms typical of the disease?
- Does the patient have risk factors for contracting or developing the disease?



Summary

Tests include antigen, nucleic acid, and serology, each testing slightly (or markedly) different things, each with specific characteristics, even within a methodology.

Reasons to test include diagnosis, screening, and monitoring.

Test strategy and interpretation may vary not only with test type and clinical question, but by background epidemiology.

Be available for consultation and recommendations.

Polling Question #3

Overall, in 2021-2022, we anticipate **RAPID/POINT-OF-CARE COVID-19 TESTING** in our institution/health system to:

A. Increase
B. Not change
C. Decrease

To NAAT or not to NAAT?

Mohammad Raza, MBBS, BSc, FRCP, FRCPath (Virology)

Consultant Virologist
Sheffield Teaching Hospital
NHS Trust

United Kingdom

Disclosures

Receiving honorarium, Abbott

An Interesting Case

- **32 years old Male**
- **Hodgkin's Lymphoma, received multiple chemotherapy courses**

OCTOBER 2020:
Develops COVID symptoms and was found to be positive for SARS-CoV-2 infection

→

OVER THE NEXT MONTH:
Cancer fails to settle
Patient referred for stem cell transplant

→

ROUTINE ADMISSION:
Tertiary care teaching hospital
2-Days Pre-Stem Cell Transplant

Hologic Panther:
RNA detected (ORF1 target)
Local In-house PCR:
Negative (E gene, RdRP)

- **Patient has been double vaccinated and asymptomatic**
- **Is this an active infection?**
  - If true, patient may die of COVID complications
  - If false, treatment may have to be delayed risking an acute relapse of cancer
  - Had 7 negatives at Barnsley since he tested positive in October 2020

Similar Other Examples

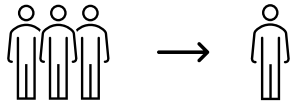
TEST 1 = DAY OF FIRST POSITIVITY

PATIENT Test results & Days from initial test	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10	Test 11	Test 12	Test 13	Test 14	Test 15
1	+ 0	- 20	- 28	- 49											
2	+ 0	- 67	+ 93	- 93	- 96										
3	+ 0	- 29	+ 41	+ 41	+ 44	+ 47									
4	+ 0	+ 23	+ 24	- 25	+ 27	+ 28	- 29	+ 30	+ 31	+ 32	+ 33	+ 34	+ 35	+ 36	- 42
5	+ 0	- 15	- 22	+ 22	- 77	- 91	- 45	+ 48	- 60	- 68					

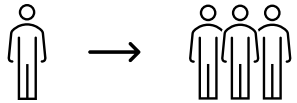
Importance of Accurate Results

Result Implications

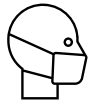
POSITIVE PATIENTS



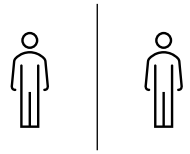
Isolated into side rooms



Moved to cohort bay



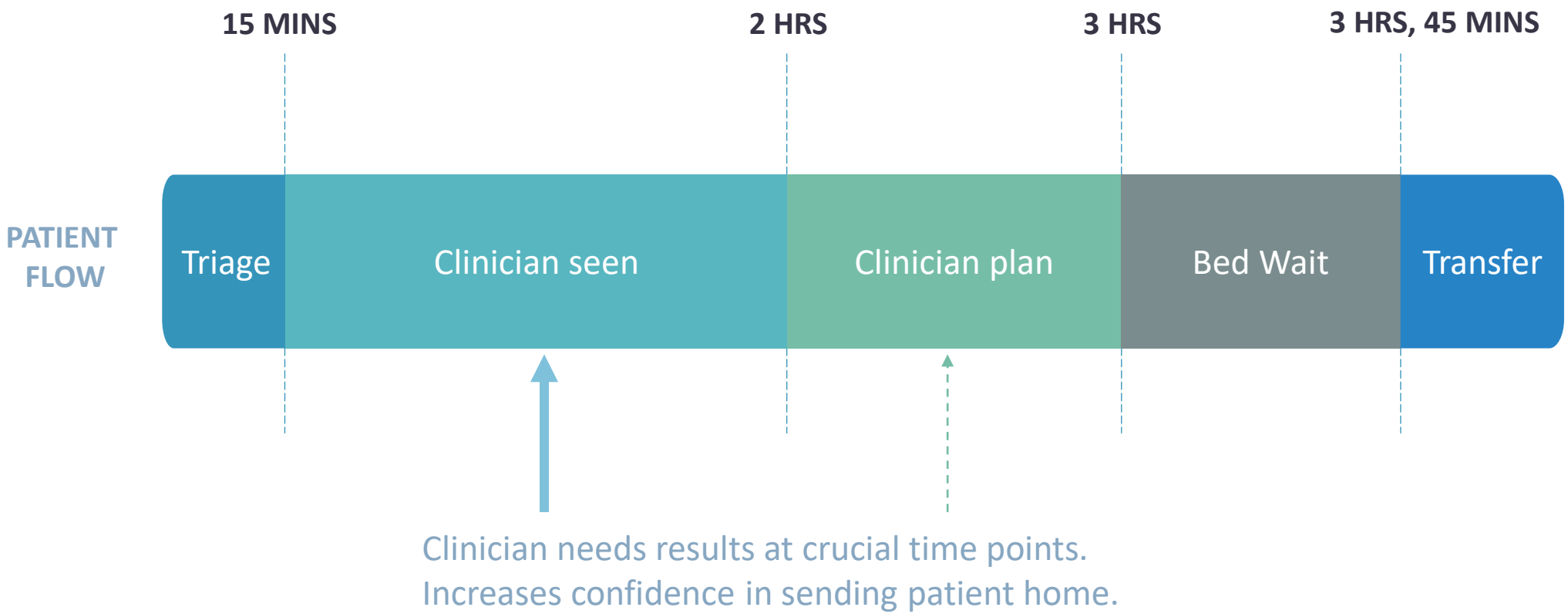
Additional PPE



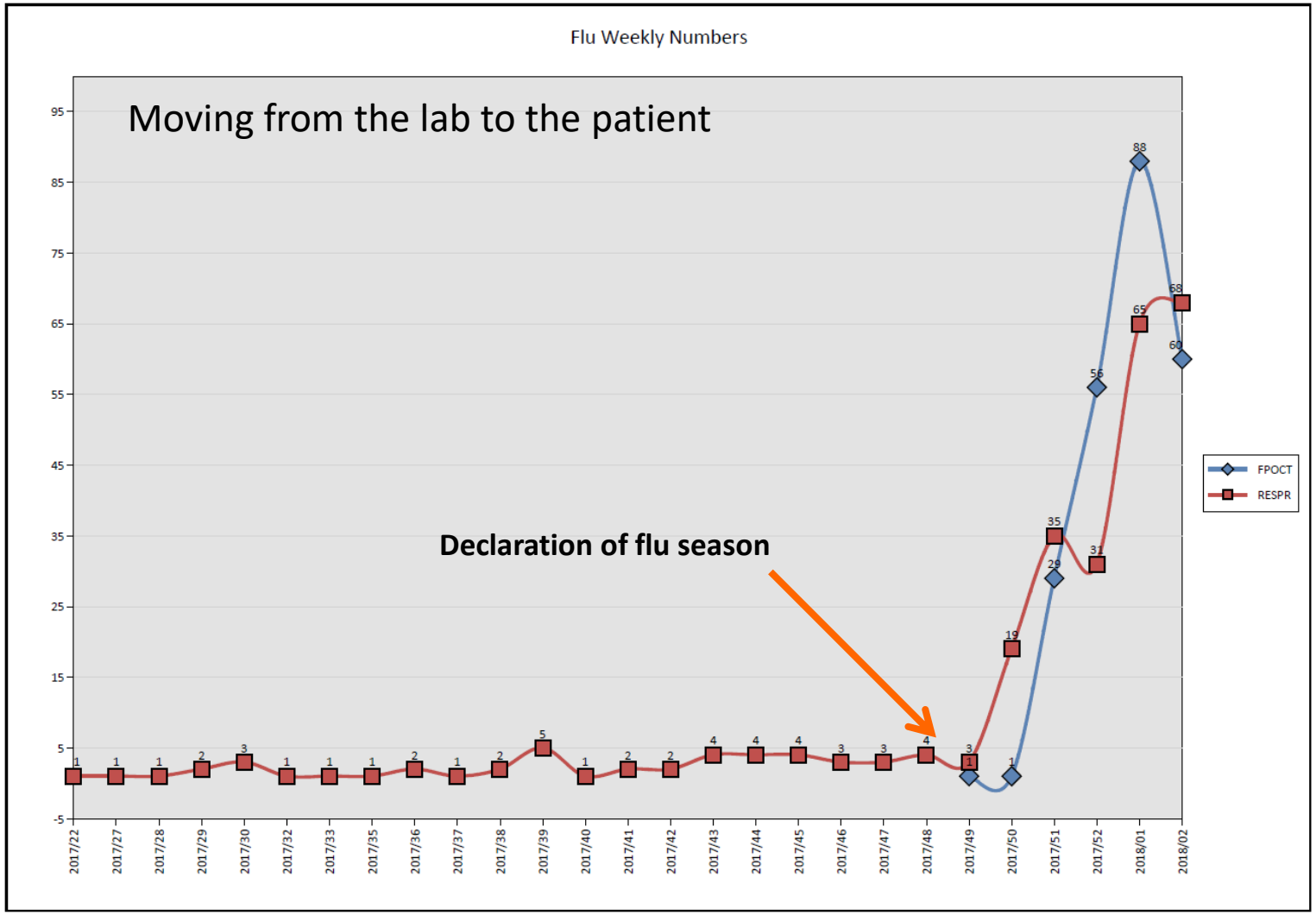
No staff crossover

Home isolation for 10 days

Rapid Test Results Reduces Emergency Demand, Maintains Flow in Accident & Emergency



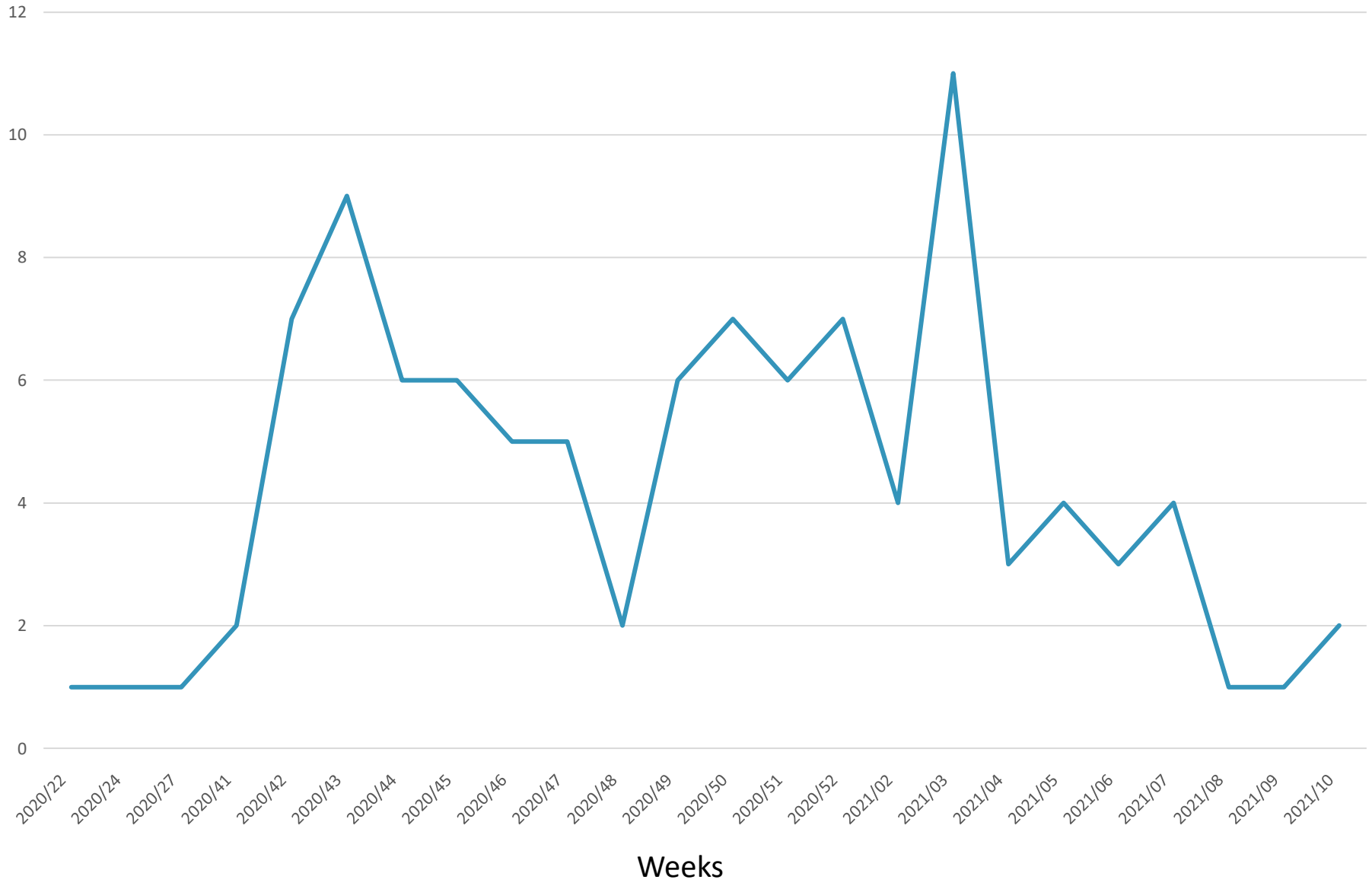
Increased reliance on POCT during peak seasons and holidays



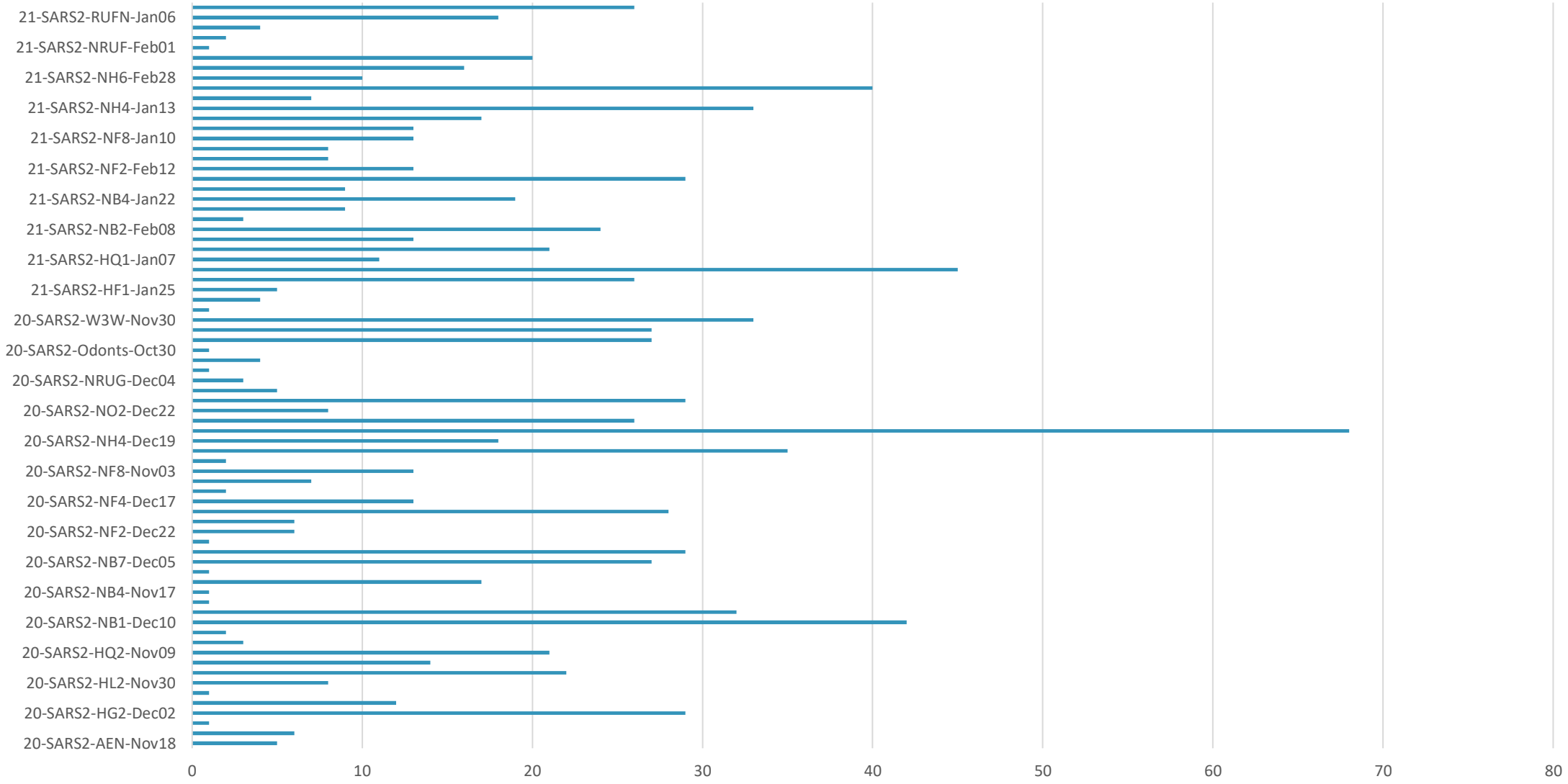
> …diagnosing 60% of patients with Ebola **within ONE day instead of FIVE days** could have dropped the population attack rate **from 80% to nearly 0%.**

Perkins M, et al. Diagnostic preparedness for infectious disease outbreaks. The Lancet VOLUME 390, ISSUE 10108, P2211-2214, NOVEMBER 11, 2017.

Hospital Outbreaks



Patients & Staff for Each Outbreak



Average Length of Stay (LOS)

LABORATORY POSITIVE CASES OF INFLUENZA

SWAB COLLECTED < 3 DAYS OF ADMISSION

n=540	POCT PERFORMED (Pathway followed)		POCT NOT DONE (Pathway not followed)
AGE GROUPS	POCT +	POCT -	No POCT
ALL	5.8 n=235	7.9 n=106	7.6 n=199
<65	3.6 n=96	4.2 n=45	5.9 n=88
>65	7.3 n=139	10.7 n=61	8.9 n=111

26%
reduction in LOS with POCT

Local Sheffield Usage Data (Abbott ID NOW™ Influenza A&B)
Excludes patients with Influenza + results > 3 days from admission (potential nosocomial infections)

Importance of Accurate Results

CONTAMINATION INCIDENT

- 96 well extraction plate of mostly positive samples (Sequencing), with others
- An automated commercial platform's pipette caused mayhem
- Recognised AFTER reports had been issued

21 Samples Implicated

PATIENTS IMPACTED

10 Inpatients
3 Pre-surgery
6 Staff
1 Community
1 Post-mortem

Inpatient	Subsequent 2 negs
Inpatient	Subsequent 2 negs
Inpatient	Repeat sample negative
Inpatient	Repeat sample negative
Inpatient	Pos 3 days later
Surgical admission	Repeat sample negative
Surgical admission	Previous Positive 5 weeks earlier
Surgical admission	Pos 2 days later
Surgical admission	Repeat sample negative
Surgical Admission	Pos 5 days later
Pre Surgery Sample	Repeat sample negative
Pre Surgery Sample	No further samples
Pre Surgery Sample	Subsequent 2 negs
Staff Sample	No further samples
Staff Sample	Further samples negative
Staff Sample	No further samples
Staff Sample	Further samples negative
Staff Sample	Repeat sample negative
Staff Sample	No further samples
Community Patient	Repeat sample negative
Post mortem	No further samples

DOWNSTREAM IMPACT

5 moved to cohort ward with other positive patients

Followed up with daily PCRs

Three developed infection at days 2, 3 & 5

Upcoming challenges

Virus Seasonality

ADENOVIRUS

FLU

SARS-COV-2

WILL SARS-COV-2 CONTINUE INTO WINTERS?

RSV / METAPNEUMOVIRUS

PIV3

PIV1, PIV2

RHINO 1ST PEAK (MARCH/APRIL)

RHINO 2ND PEAK (ESP SEPT)

VZV

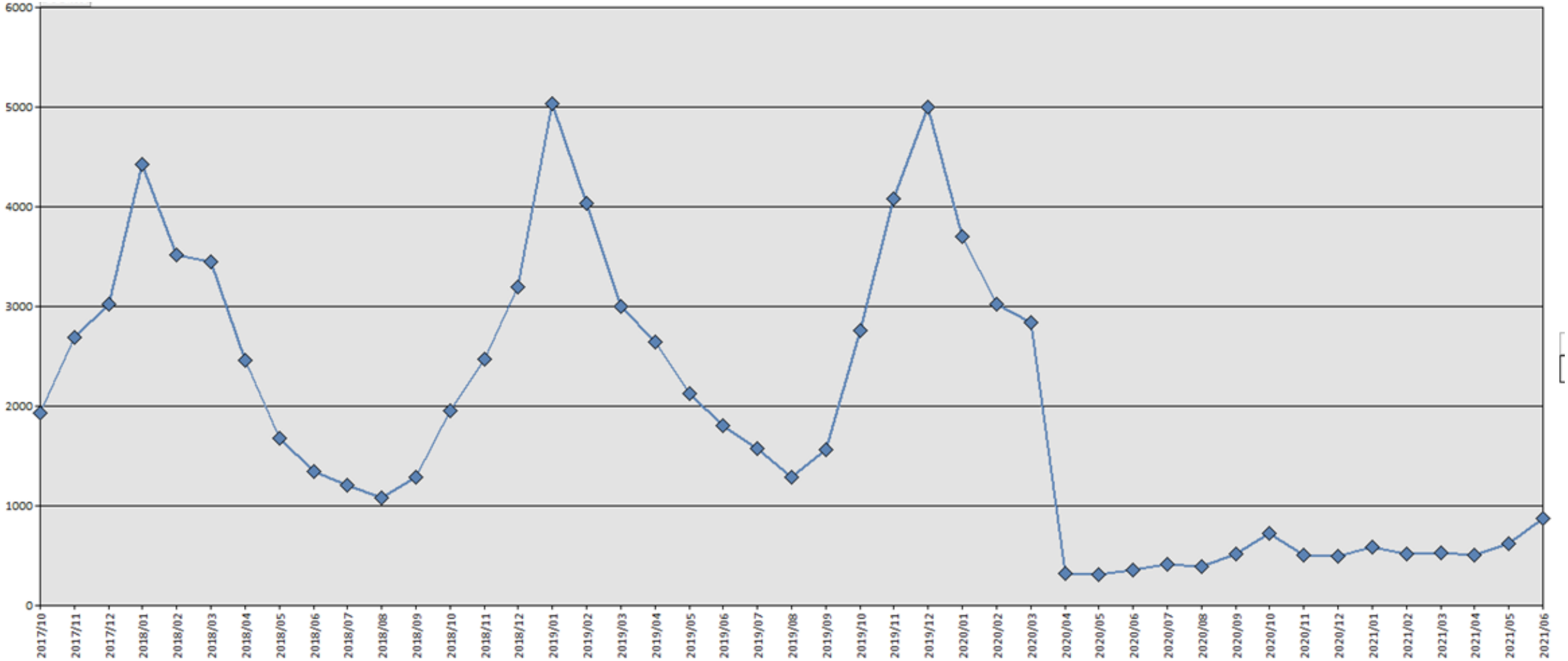
PARVOVIRUS B19

ENTEROVIRUS

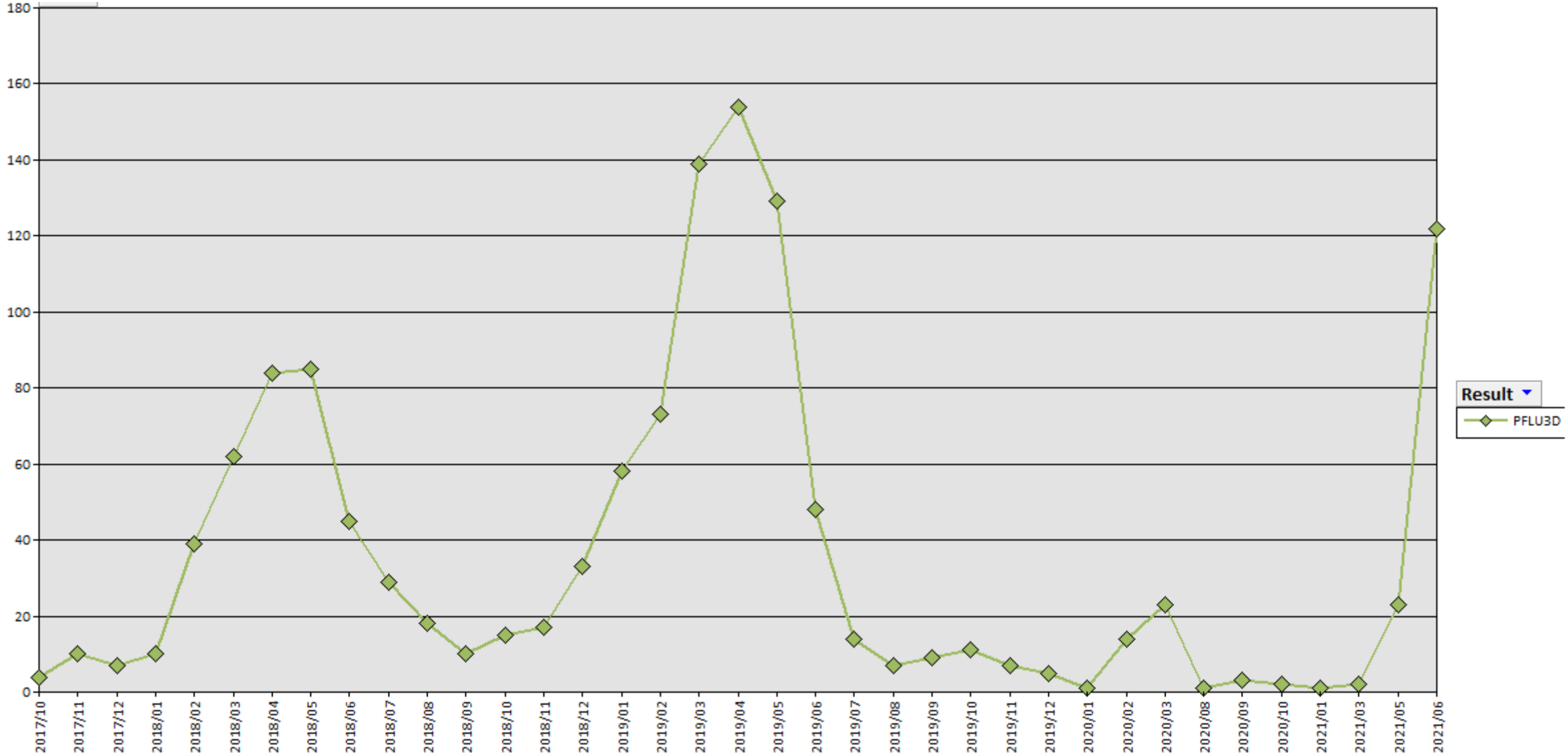
WINTER SPRING SUMMER AUTUMN

NOV OCT

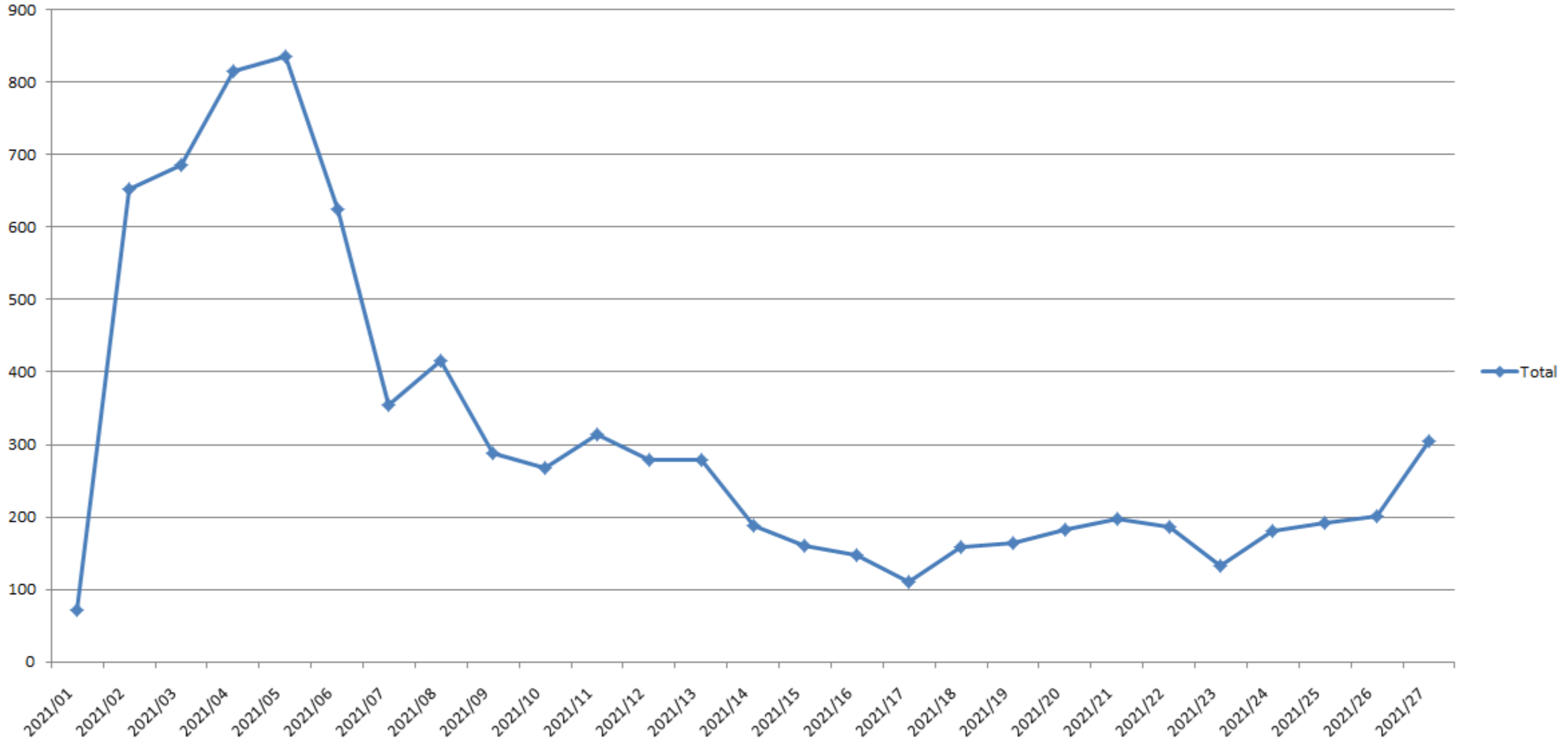
Number of Respiratory Virus PCRs Done Over Last 5 Years



Number of Parainfluenza Cases Over Last 5 Years



Staff Attending COVID Testing Facility (Total)



Expected Scenario

- **UK Reopening**
  - COVID-19 cases will plateau for a bit and then shoot up
  - Other respiratory viral infections will increase; may be randomly then catch up
  - May result in cocktail of infections and overload the healthcare systems
  - Hidden, undiagnosed infections masquerading as COVID
- **Look for other patterns**
  - Why are we worried only about influenza, RSV and SARS-CoV-2? Does the situation not call for looking for similar causes?
  - Broader panel testing only available at larger laboratories and not likely to provide capacity and turn around times

Change in Direction Needed?

- **Focus at start of pandemic was correctly on diagnosis of new infections**
- **PCR can no longer be taken at face value; persistent shedding is more common than we think**
- **After 14 days, patients are considered non-infectious**
- **Should capture syndrome, not just diagnosis of 'COVID'**
  - Acute Primary COVID
  - Pre-symptomatic or Asymptomatics
  - Recovered Primary Infection
  - Susceptible to Primary COVID infection
  - Persistent Shedder

Summary and Current Challenges

- **Question is "Do we really want to know about all COVID +ve results"**
  - Classify results into 'COVID groups'
  - Antibody testing at admission, but is there a reliable rapid assay available?
- **Clinical challenges, e.g., lack of treatment, case definition shortcomings**
- **Diagnostics**
  - Traditional PCRs: not suitable for all settings
  - Antibody testing: not a supporter for acute diagnosis
  - Antigen/Lateral Flow testing: higher clinical specificity but lacks required sensitivity for screening
  - Can diagnostic companies give us rapid sequencing solution?
- **Infection control, vaccines, public health related**