



AMERICAN  
COLLEGE *of*  
CARDIOLOGY

**COVID-19**

# First Do No Harm: Approaches to PPE and Testing

Presenters and Panelists:

Dr. Judy Tingley, DNP, MPH, BSN, RN, AACC

Dr. George Diaz, MD

Dr. Dipti Itchhaporia, MD, FACC

Moderated by Dr. Tyler Gluckman, MD, FACC





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# COVID-19 Hub

## Speakers

**Judy Tingley, DNP, MPH, RN, AACC** - Vice President, Chief Nursing Officer, Hackensack University Medical Center, Hackensack Meridian Health

**George Diaz, MD** - Infectious Diseases Hospitalist, Medical Director, Antimicrobial Stewardship; Section Chief, Infectious Diseases, Providence Regional Medical Center Everett

**Dipti Itchhaporia, MD, FACC** - Vice President, American College of Cardiology; Hoag Memorial Hospital Presbyterian, University of California, Irvine

**Moderator: Tyler Gluckman, MD, FACC** - Medical Director, Center for Cardiovascular Analytics, Research and Data Sciences (CARDS), Providence St. Joseph Health



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# COVID-19

Judy Tingley DNP, MPH, BSN, RN, AACC  
VP, Chief Nursing Officer  
Hackensack University Medical Center



## Hackensack Meridian Health

- New Jersey's largest and most comprehensive health network, offering a complete range of medical services, innovative research and life-enhancing care.
- Includes three academic medical centers:
  - Hackensack University Medical Center
  - Jersey Shore University Medical Center
  - JFK Medical Center



Our journey to Magnet recognition began in 1995 when HUMC became the 2<sup>nd</sup> institution in the US (1<sup>st</sup> outside of the pilot program) to receive the Magnet honor form the ANCC for nursing excellence.





# COVID-19 United States Cases by County Johns Hopkins University

States/Territories Please select

## Top 50 Confirmed Cases by County

- 21,234 confirmed Philadelphia
- 20,437 confirmed Middlesex
- 19,771 confirmed Wayne
- 18,879 confirmed Hudson
- 17,804 confirmed Bergen
- 17,417 confirmed Suffolk
- 17,214 confirmed Essex
- 16,845 confirmed Miami-Dade
- 15,686 confirmed Passaic
- 15,351 confirmed Middlesex
- 15,169 confirmed Union
- 15,114 confirmed Fairfield
- 13,521 confirmed Prince George's
- 13,457 confirmed Essex
- 13,165 confirmed Richmond

### Bergen, New Jersey

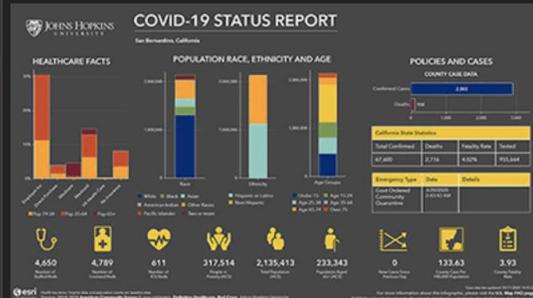
Showing 1

Confirmed by 1,900.73  
100k Population

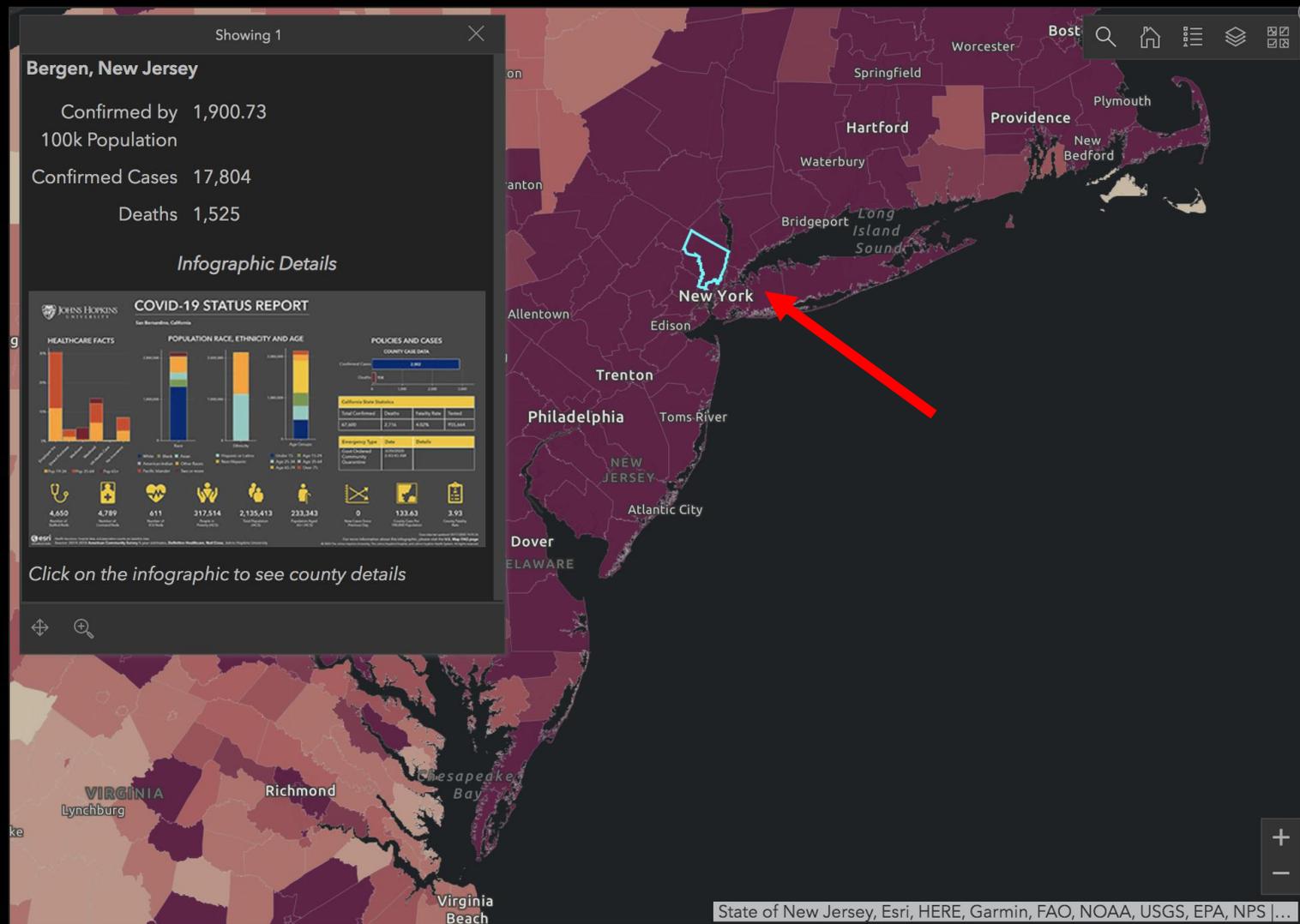
Confirmed Cases 17,804

Deaths 1,525

#### Infographic Details



Click on the infographic to see county details



# Capacity Expansion for Surge



As part of a rapid-response expansion project, the hospital converted cafeteria space into a 74-bed unit to treat COVID-19 patients in non-intensive care beds.

# Surge Response Management

- HUMC, which typically operates 48 adult Intensive Care Unit (ICU) beds, converted medical surgical units into ICU beds. Facility crews working around the clock converted unused spaces into intensive care units to expand total capacity to over 200 critical care beds, more than a four-fold increase vs. original capacity.
- Emergency Management Staffing Office was established as part of the Command Center structure which brought staffing and capacity together to collaborate and optimize resource utilization.
- Clinical Education was **key** to safety and frontline caregiver confidence.

# Innovation





# Build Confidence

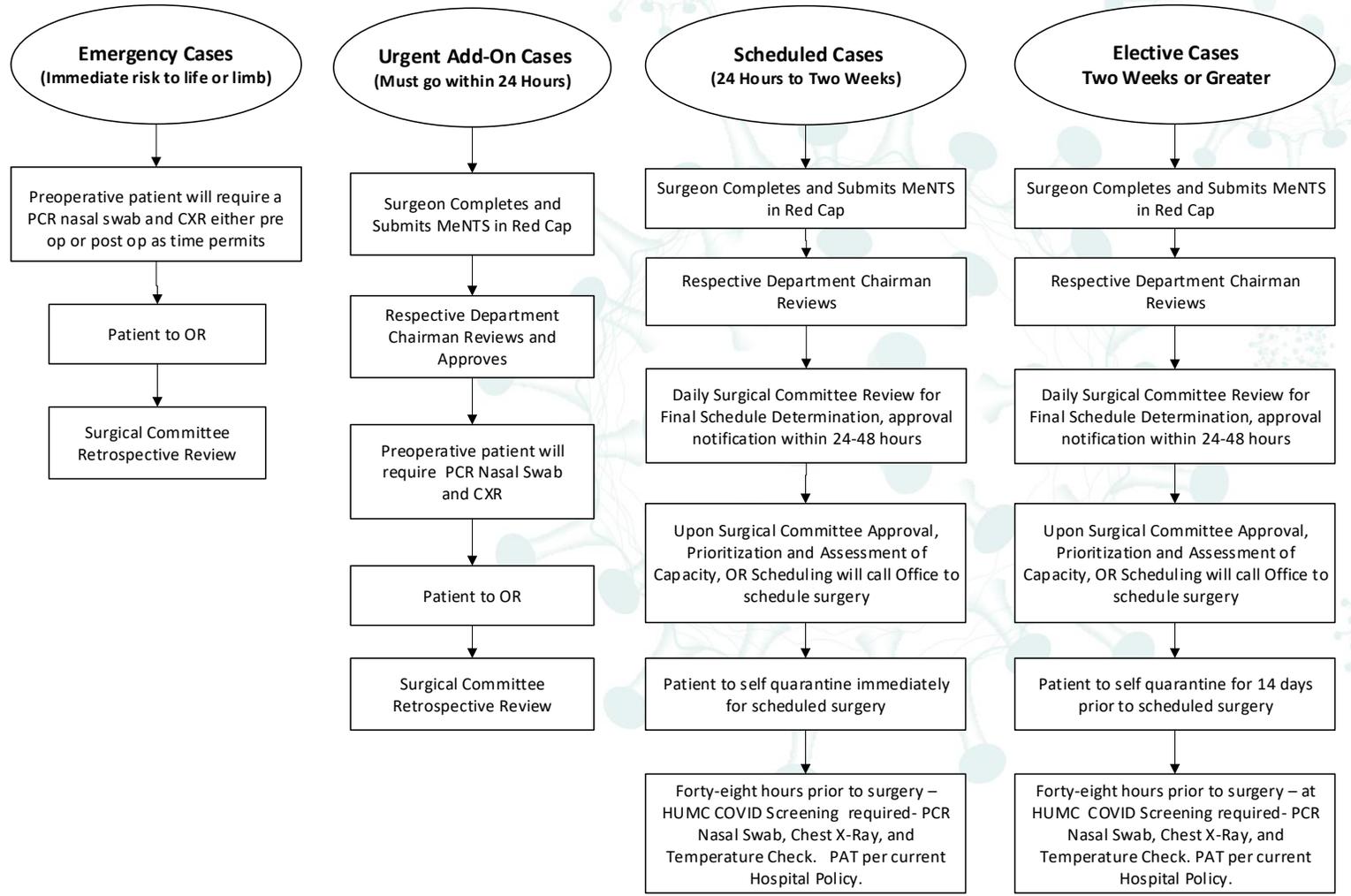
Safety measures were based on CDC guidelines and aligned with the Network. PPE education was a major initiative for all the team members.

Methods of education included:

- Classroom based drop in sessions for all team members on all shifts
- Rounding to reinforce proper donning/doffing of PPE
- “Just in time” educators focused on PPE education 24/7; 7 days a week
- Donning and doffing checklists for use on the units, updated based on HMM guidelines



- **Patient Flow created to address:**
  - Emergency Cases (immediate risk to life or limb)
  - Urgent Add-on Cases (must go within 24 hours)
  - Scheduled Cases (in 24 hours to two weeks)
  - Elective Cases (in two weeks or greater)
- Medically-Necessary and Time Sensitive (MeNTS) form completed in RedCap for approval by respective Department Chairman





# Guideline: cardiovascular care in the era of COVID-19 pandemic with widespread community transmission

- **HVH Policy on the Management of STEMI in the COVID 19 Pandemic**
  - STEMI treatment strategies and performance targets for COVID-19 patients are unchanged from our standard protocol.
  - All patients admitted to the cath lab will be assumed to have COVID and therefore, full PPE precautions will be implemented. Thus, the presence or absence of COVID testing results will not impact the cath lab isolation precautions for patients presenting with STEMI.
  - COVID testing will be performed in the cath lab in order to determine whether isolation is required post procedure.



## **Guideline: cardiovascular care in the era of COVID-19 pandemic with widespread community transmission (continued)**

- All personnel who will be within six feet of the patient should wear full PPE (including N95, gown, gloves, face shield/goggles for eye protection), as the COVID-19 infection status of the patient is not known.
- Personnel who will remain in the control room throughout the procedure should wear a surgical mask in accordance with universal surgical masking recommendations for all hospital personnel.
- Additionally, in accordance with universal masking protocol for patients, all patients should be provided with a surgical mask upon arrival.



# Elective cardiovascular care

- Maintain universal masking for all team members and patients.
- Social (physical) distancing should be reinforced for all patients, until such time as public health authorities determine that this may be relaxed. Frequent handwashing and respiratory etiquette is always recommended.
- Routine in-person visits for stable patients, including medication renewals, should be rescheduled for after pandemic has peaked, as indicated by public health officials.
- Conduct appointments via tele-health visits using Convenient Care Now, or by telephone.



# Indications for COVID-19 testing prior to outpatient elective procedures or diagnostic testing

- COVID-19 testing via PCR is required to be done 48 hours before all outpatient elective procedures or diagnostic tests which require close extended patient contact, including:
  - Any procedure or diagnostic test which requires anesthesiology services for sedation, or which may require general anesthesia during the course of care
  - Any procedure or diagnostic test which may cause the production of aerosolized respiratory secretions
  - Any procedure or diagnostic test involving the airway, mouth, sinuses, throat, or stomach
  - Any procedure or diagnostic test which may require invasive specimen collection or extended post-procedural recovery
- Patients testing positive for COVID-19 should be reviewed for urgency of the procedure or diagnostic test with the provider and the appropriate procedural area or department as part of pre-admission testing protocols, and may be deferred or rescheduled based on the clinical situation.



# Contraindications to COVID-19 testing prior to outpatient elective procedures or diagnostic testing

- COVID-19 testing via PCR is not required before outpatient elective procedures or diagnostic tests which do not require close extended patient contact, are not invasive in nature, and are not considered high-risk for virus aerosolization.
- This includes:
  - Trans-thoracic echo
  - Non-exercise stress testing
  - Vascular duplex
  - Holter monitoring
  - EKGs



# Visitation

- All visitation is in accordance with the HMM Visitation Policy and guidelines and NJ Department of Health guidance
- Office of Patient Experience leading patient and family engagement
- In-person visitation for inpatients suspended, except in special circumstances, such as end-of-life situations
- Intentional scheduling of family communications done at the unit level
- Phone and video calls to patients are always welcome
- For same-day surgeries/procedures, one family member can accompany the patient
- Continuously reassessing



# KEY TAKEAWAYS

- Change is the new normal
- Communicate, communicate, communicate
- Multidisciplinary/specialty collaboration
- Robust Clinical Education strategy



***Thank you***

***Judith.tingley@hackensackmeridian.org***



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# COVID-19

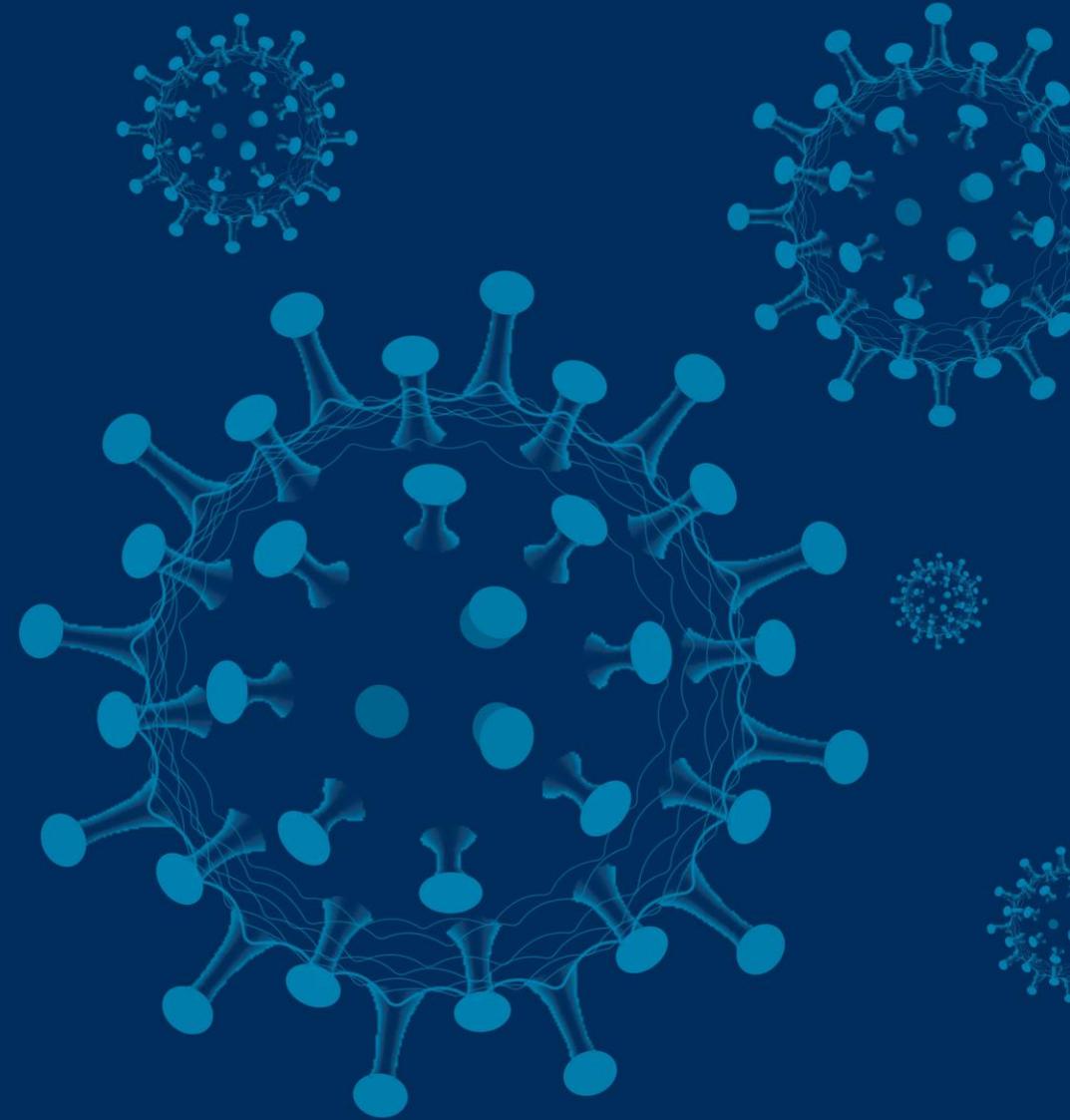
COVID testing

George Diaz, MD

Special thanks to Dr. Kirstine Oh

Lab director PRMCE

Disclosures: Support from Gilead  
and Regeneron for COVID  
therapeutics clinical trials





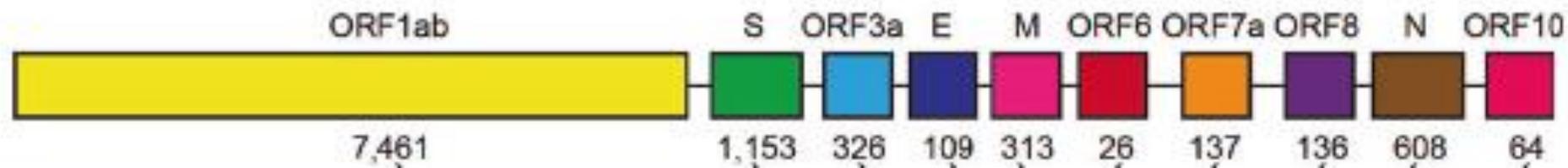
# Test evaluation

- PCR testing: specimen type and timing
- IgM and IgG serologic response
- Point of Care serologic testing

## Overarching questions

1. Who are you testing?
2. When are you testing?
3. What are you testing?

# SARS-CoV-2 virus genes



- Open reading frame (ORF)
- Spike protein region (S) with receptor binding domain (RBD)
- Envelope protein region (E)
- Membrane protein region (M)
- Nucleocapsid protein region (N)

# Clinical sample type for RT-PCR



- Possible sample types from the literature:

Nasopharyngeal or nasal wash	Nasal
Saliva	Sputum
Sputum	Bronchoscopy-obtained
Blood	Stool/anal swab

- PCR testing: Samples undergo successive cycles of amplification of transcript. The transcript targets are labeled with a fluorescent label.
- Cycle threshold (Ct) = number of cycles required for the sample's fluorescent signal to exceed the background level. A high Ct value means there is less transcript in the sample because it requires more cycles to be seen above background.
- Copies per mL = viral genome copies per mL as determined by WHO protocol. The lower limit of detection is how many copies/mL the assay can detect. Eg. The lower the limit of detection (copies/mL), the more sensitive the test.

# Viral kinetics and antibody responses in patients with COVID-19. Preprint Tan et al.

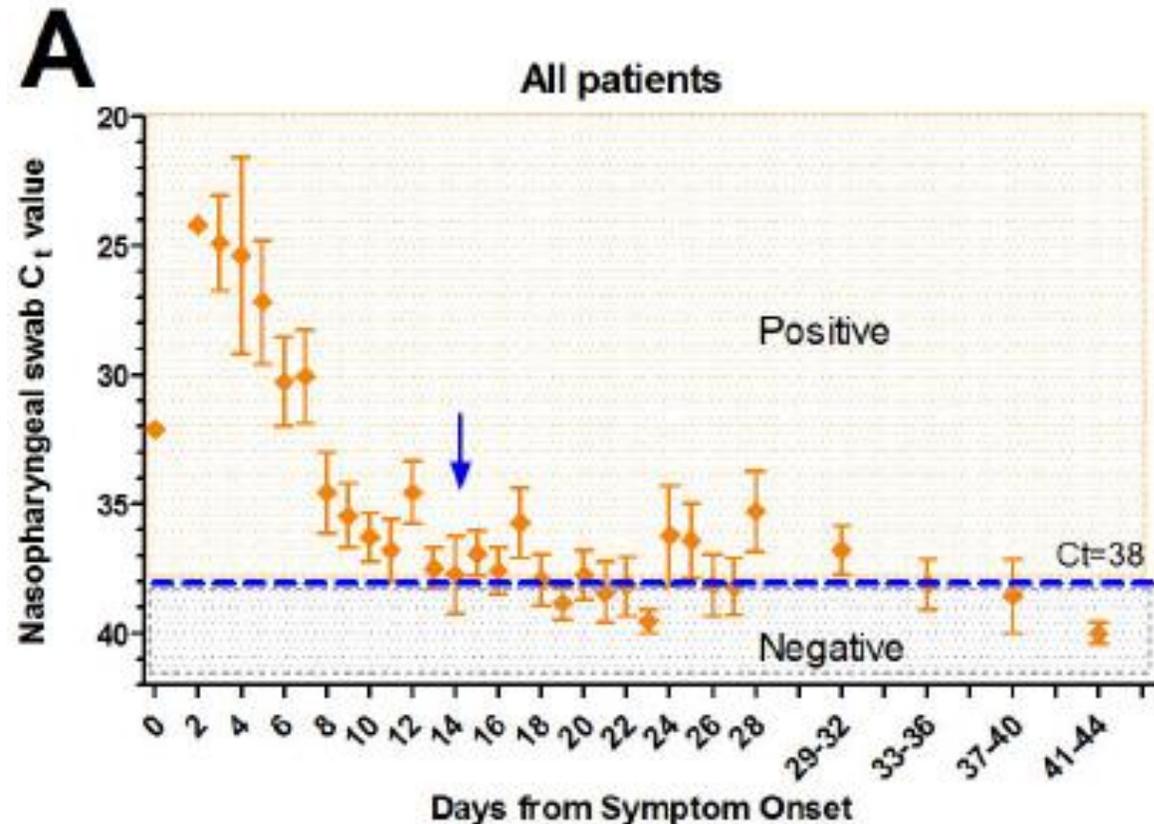


N=67, serial testing of nasopharyngeal, sputum and stool

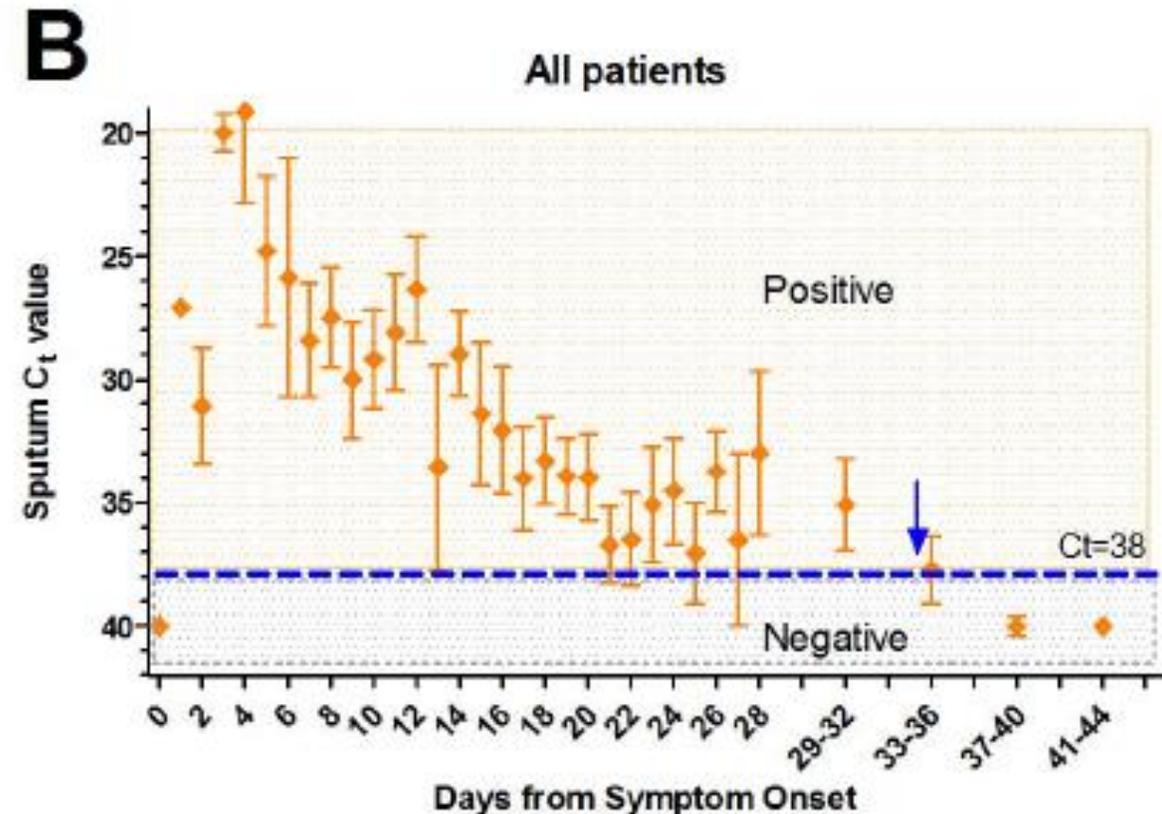
Time to negative	Median = 12 days
	Mean = 16.2 days

Time to negative	Median = 19 days
	Mean = 22 days

## Nasopharyngeal swab



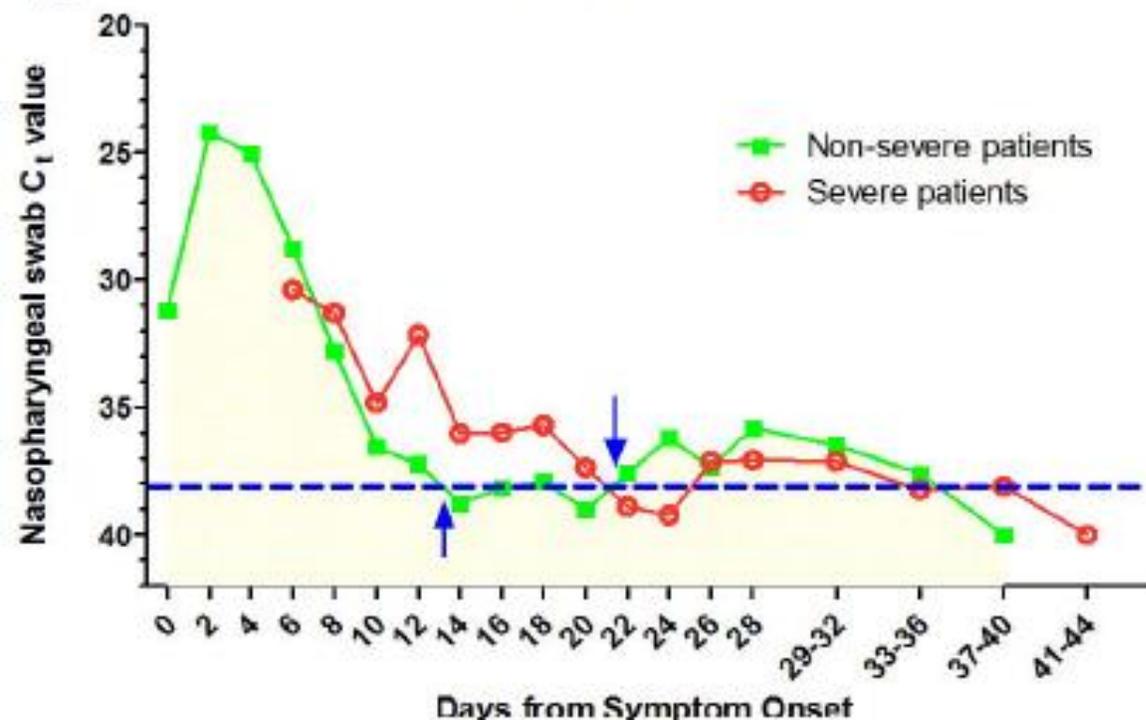
## Sputum



## Nasopharyngeal swab

**D**

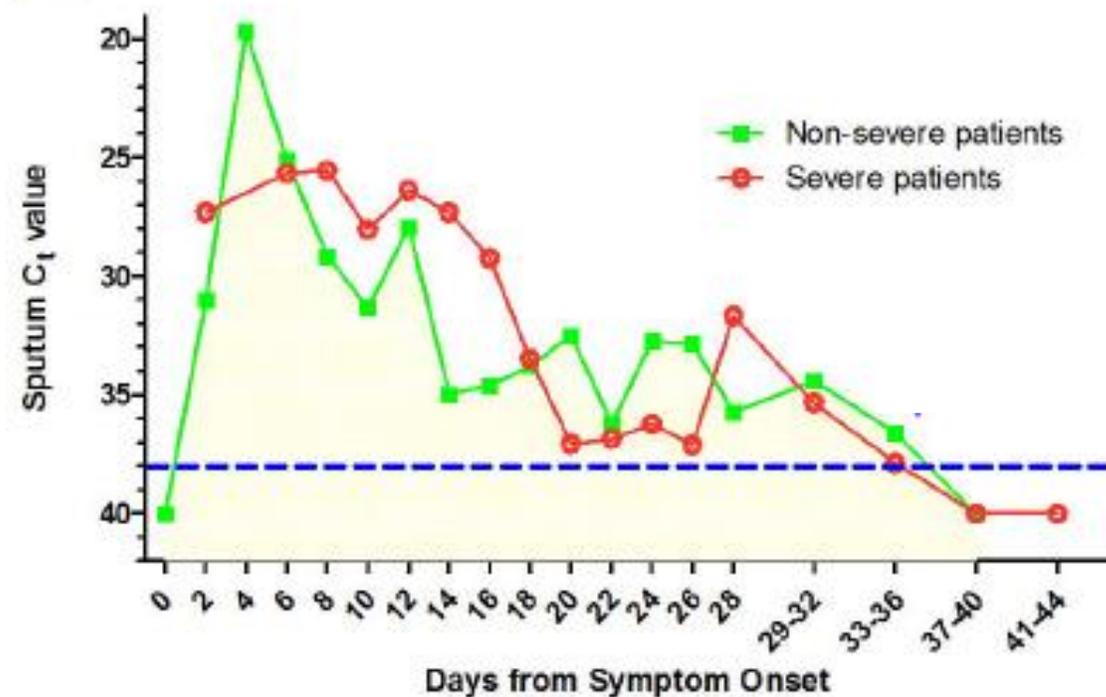
Severe vs. Non-severe



## Sputum

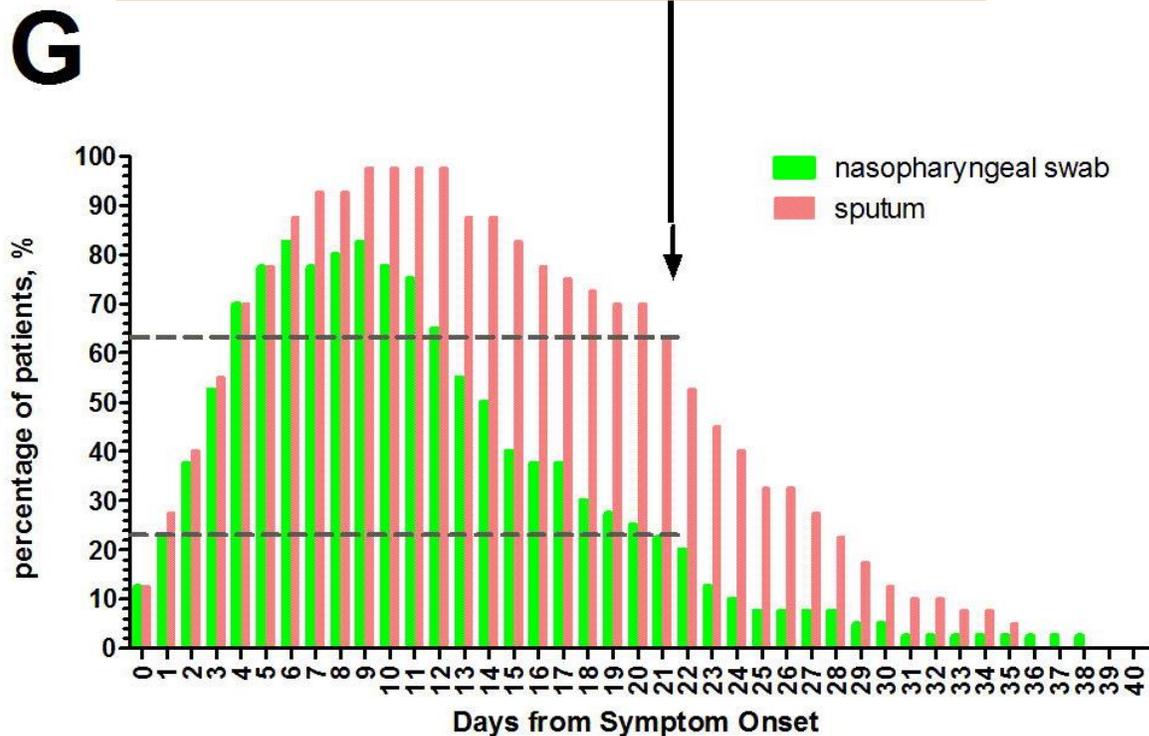
**E**

Severe vs. Non-severe

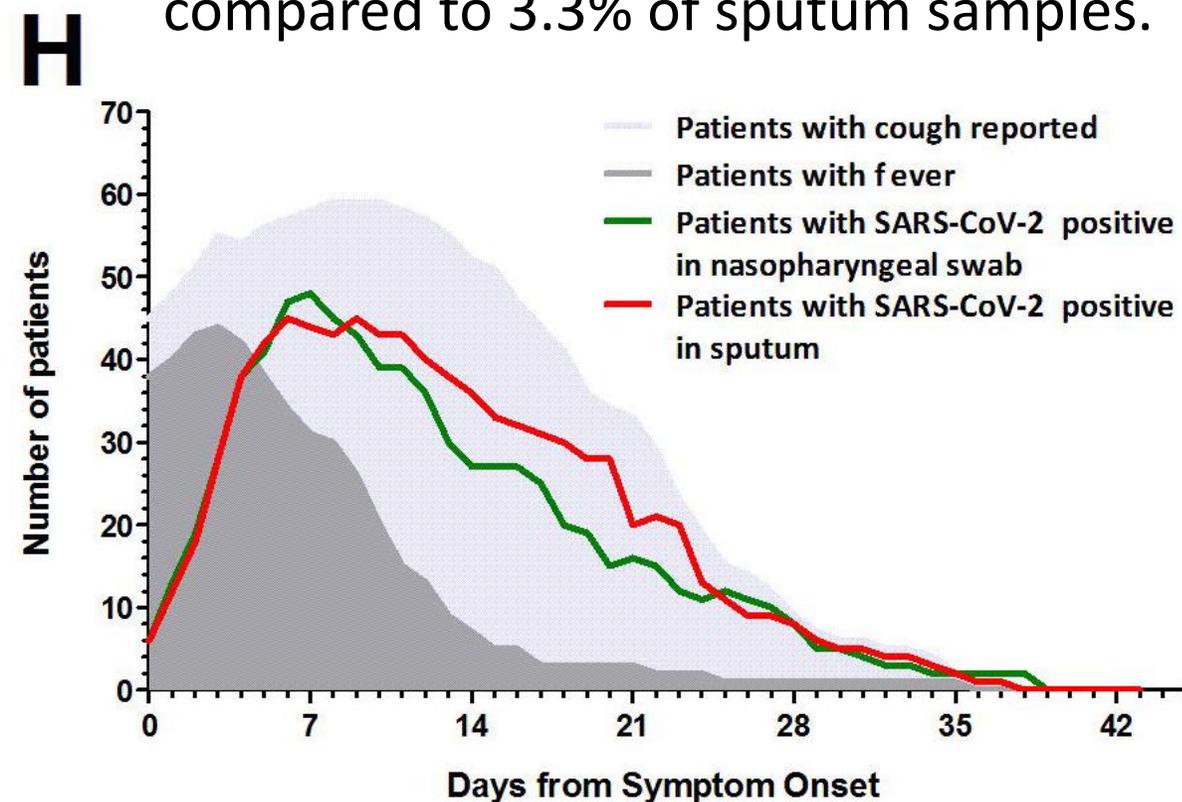


- Patients with clinically more severe disease had a higher viral burden

21 days after symptom onset,  
62.5% of patients had positive  
sputum compared to 22.5%  
positive NP swab. N = 40.



- In 46 patients, at the time their NP swabs were negative, 60.9% still had positive sputum and 30.4% were positive in stool.
- NP swabs shows fluctuating positive and negative results in 40.3% of patients compared to 3.3% of sputum samples.





# The big questions for testing

1. Does a negative RT-PCR mean the person is free of SARS-CoV-2?
2. Does it matter how sensitive the RT-PCR test is?
3. How long is a person infectious?
4. Are antibodies to SARS-CoV-2 protective and do all infected people make them?

# 1. Does a negative RT-PCR mean the person is free of SARS-CoV-2?

**What is the estimated overall sensitivity of the PCR test in the context of clinical findings and disease course combined with the analytic sensitivity of the test?**

## **What are you testing?**

- Nasopharyngeal swab is very reliable and is preferred.
- Other specimens (oropharyngeal, nasal, mid-turbinate, saliva) have varied reports in literature in sampling sensitivity, likely due to inadequate specimen collection or timing of sampling.

Kinloch et al. Suboptimal biologic sampling as a probable cause of false-negative COVID-19 diagnostic test results

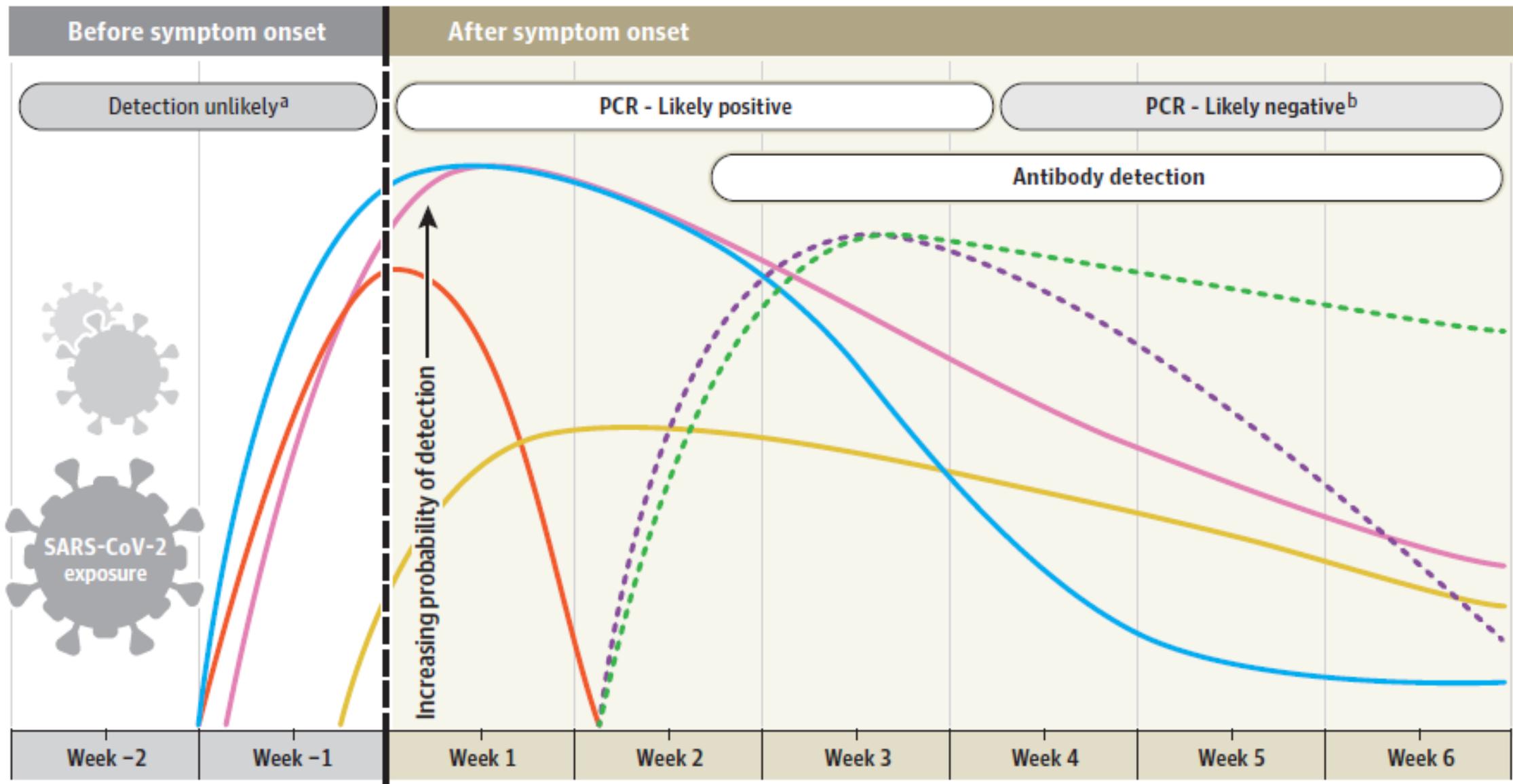
# 1. Does a negative RT-PCR mean the person is free of SARS-CoV-2?

## When are you testing?

- The slope of the viral load increase immediately after infection and before symptoms is not known yet. In contact-tracing studies, the viral load is high within 5 days after exposure and infection, but the timing of initial rise is unclear.
- The data in the literature suggests that peak viral detection is at around 80% max at days 5-12 after symptom onset using upper respiratory specimens.

## How are you testing?

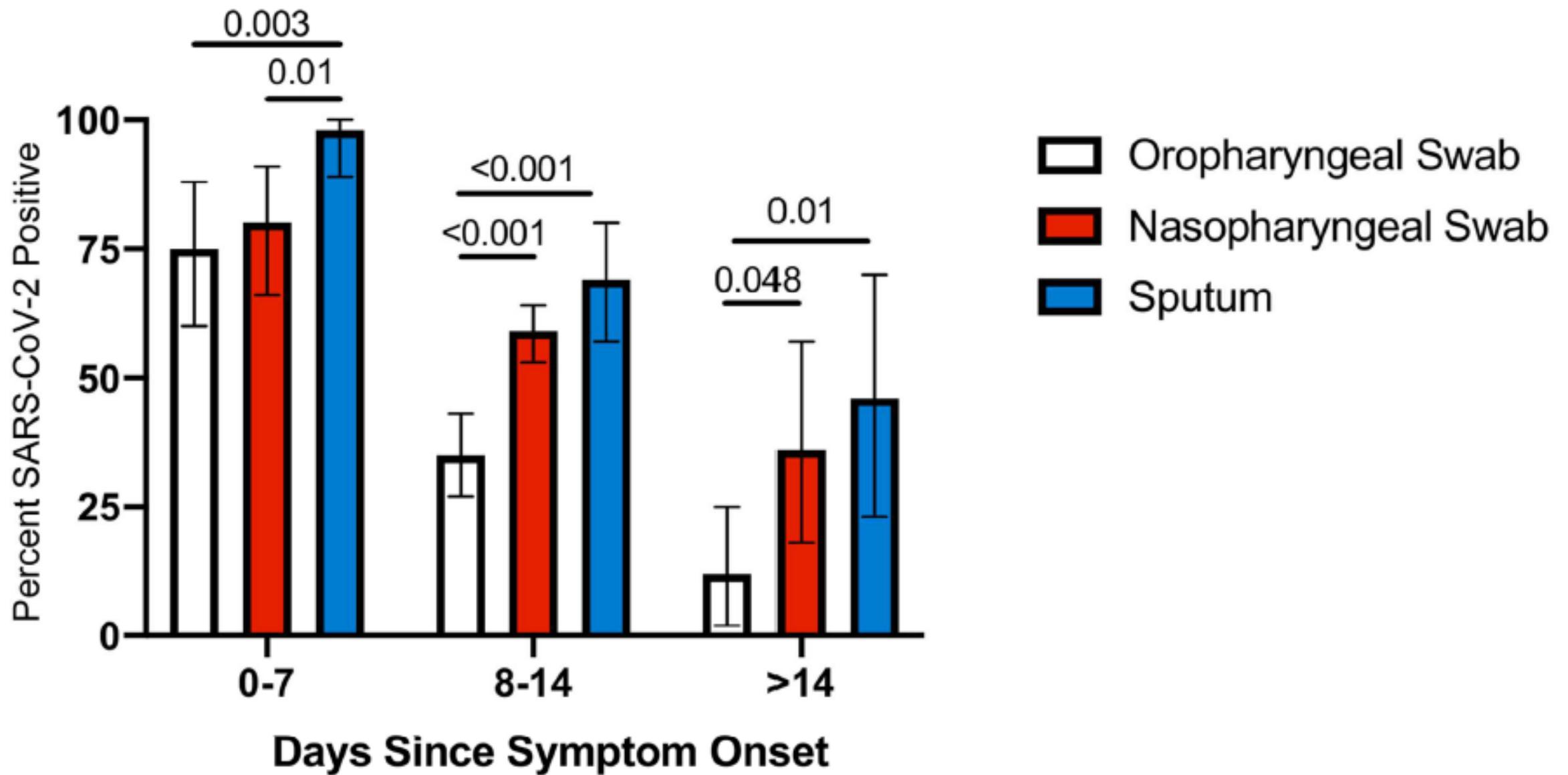
- Different test platforms have different viral gene targets and sensitivities.
- One test platform is suggested to have an RNA probe that cannot detect a SARS-CoV-2 strain with a specific mutation. Failure of the cobas SARS-CoV-2 (Roche) E-gene assay is associated with a C-to-T transition at position 26340 of the SARS-CoV-2 genome. Artesi et al.



Symptom onset

Sethuraman et al. Interpreting diagnostic tests for SARS-CoV-2 JAMA 2020

- Nasopharyngeal swab PCR
- Virus isolation from respiratory tract
- Bronchoalveolar lavage/sputum PCR
- Stool PCR
- IgM antibody
- IgG antibody



SARS-CoV-2 detection in different respiratory sites: as systemic review and meta-analysis. Mohammadi et al.



## 2. Does it matter how sensitive the RT-PCR test is?

### Who are you testing?

- Asymptomatic
- Pre-symptomatic
- Symptomatic
- Convalescent

Even if there is a test platform with a lower sensitivity or a sample type with lower sensitivity, at low prevalence, the NPV changes very little.

Prevalence %	Sensitivity %	Specificity %	PPV %	NPV %
1	80	100	100	99.80
3	80	100	100	99.39
6	80	100	100	98.74
15	80	100	100	96.59

Prevalence %	Sensitivity %	Specificity %	PPV %	NPV %
1	50	100	100	99.50
3	50	100	100	98.48
6	50	100	100	96.91
15	50	100	100	91.89



## Preprocedural surveillance testing for SARS-CoV-2 in an asymptomatic population shows low rates of positivity. Mays et al.

March 30, 2020: begin screening of asymptomatic patients before surgery and aerosolizing procedures.

April 30, 2020: begin universal surveillance all admissions

Indication	Total Patients	Positive (%)	Inconclusive (%)	Negative (%)
Asymptomatic Admission Surveillance	349	3 (0.9)	2 (0.6)	344 (98.6)
Asymptomatic (Other)	157	12 (7.6)	1 (0.6)	144 (91.7)
Pre-procedural Surveillance	350	3 (0.9)	0	347 (99.1)
Symptomatic	473	68 (14.3)	0	405 (85.6)



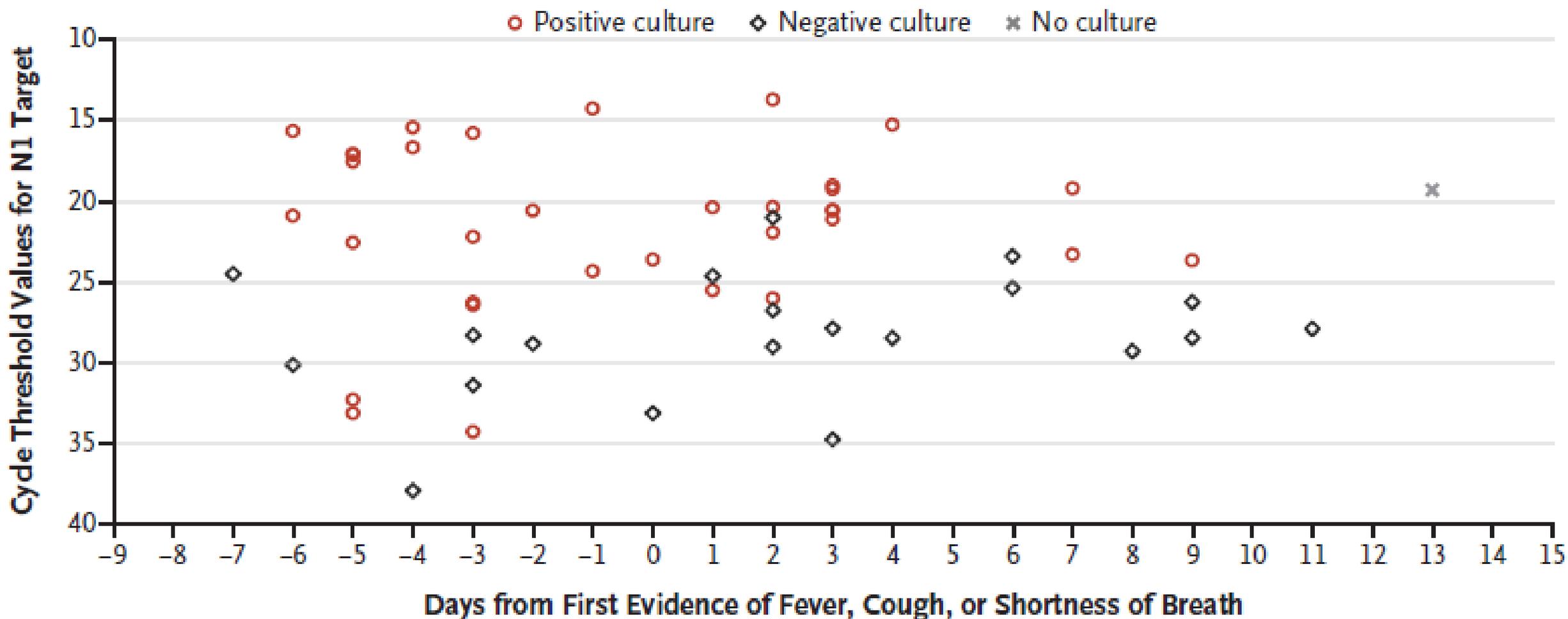
### 3. How long is a person infectious?

CDC May 3, 2020: Symptom-based strategy to discontinue isolation for persons with COVID-19, Decision Memo:

[https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html#\\_ftn2](https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html#_ftn2)

- Recommendation: For persons recovered from COVID-19 illness, CDC recommends that isolation be maintained for at least 10 days *after illness onset* and at least 3 days (72 hours) *after recovery*. Illness onset is defined as the date symptoms begin. Recovery is defined as resolution of fever without the use of fever-reducing medications with progressive improvement or resolution of other symptoms. Ideally, isolation should be maintained for this full period to the extent that it is practicable under rapidly changing circumstances.

## Presymptomatic SARS-CoV-2 infections and transmission in a skilled nursing facility. Arons et al. NEJM 2020 • N= 47 patients





# What to remember about CDC statements:

1. A good sample in the upper respiratory tract and good testing technique are very important.
2. The CDC studies were not based on sputum or lower respiratory tract specimens.
3. Viral culture is not simple and the culture results may not truly reflect virus ability to infect.
  - Prolonged (>20 days) viral shedding is seen in sicker patients and patients with compromised immune systems.

Hartman et al. Prolonged viral RNA shedding after COVID-19 symptom resolution in older convalescent plasma donors.

## 4. Are antibodies to SARS-CoV-2 protective and do all infected people make them?

- Initial antibody results showed a deficit in seroconversion.
  - How many people truly don't seroconvert vs. some tests are just not very good at detecting the antibodies?
  - Kits vary in specificity for antibodies against SARS-CoV-2 compared to other coronaviruses (e.g anti-spike, anti-nucleocapsid).
  - Some kits are more sensitive and show 100% seroconversion (newer automated instruments).
- Immunocompromised patients (e.g. patients with cancer and on chemo) are a subset that are shown to have lower conversion rates.

Solodky et al. Lower detection rates of SARS-CoV-2 antibodies in cancer patients vs. healthcare workers after symptomatic COVID-19.
- Patients with less severe symptoms and faster recovery have lower antibody titers.



# SARS-CoV-2 antigens for antibody generation

- There are 4 different coronavirus structural proteins:
  - Spike protein with receptor binding domain (S), (RBD)
  - Envelope protein (E)
  - Membrane protein (M)
  - Nucleocapsid protein (N)
- S1 protein RBD show more specificity for SARS-CoV-2 compared to other protein sequences (MERS-CoV, SARS-CoV [2003])
  - SARS-CoV-2 N protein has 90% homology to SARS-CoV [2003] N protein.

SARS-CoV-2 specific antibody responses in COVID-19 patients. [Emerg Infect Dis.](#) 2020 Apr 8;26(7).

Evaluation of recombinant nucleocapsid and spike proteins for serologic diagnosis of novel coronavirus disease 2019 (COVID-19). Preprint Zhang et al.

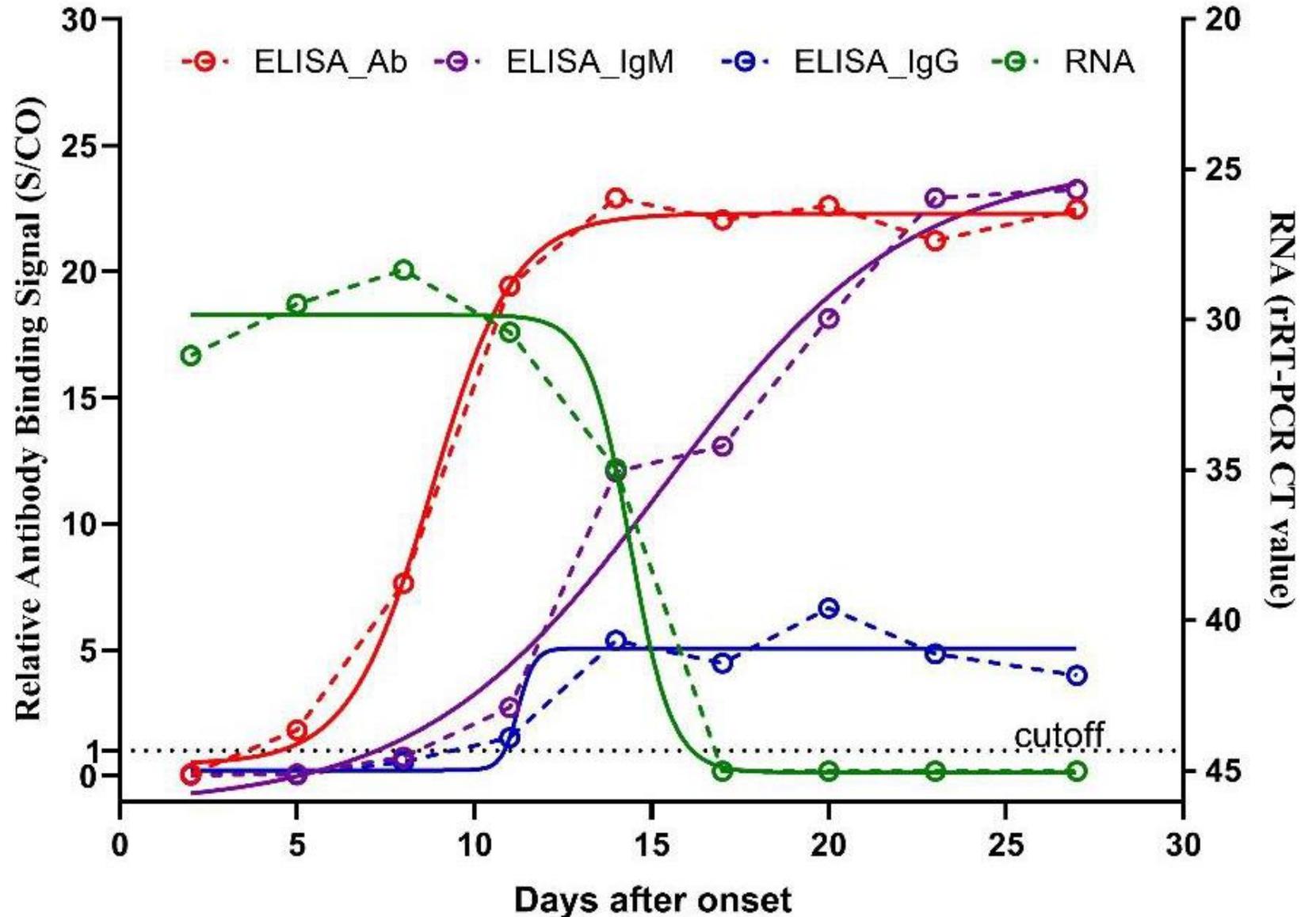
# Serologic tests for SARS-CoV-19 overview

- IgG vs IgM in SARS-CoV-19:
  - IgM and IgG does not appear in all patients.
  - Antibody response may be low in patients with mild symptoms and may be absent in immunocompromised patients.
  - IgG and IgM may appear concurrently or IgG may appear before IgM
  - Antibody production has been seen in patients with persistently positive RT-PCR testing of the nasopharynx (approximately 15%, N=26).
- Different manufacturers of antibody proteins and different methods of antibody measurement.
- Disease prevalence matters for false positives and cross reactivity with endemic coronaviruses.

# Serology characteristics of SARS CoV-2 infection since exposure and post symptom onset. Preprint Lou et. al



- N=80 patients
- Deep sputum sample PCR
- IgM and total antibody to spike region receptor binding domain
- IgG antibody to nucleoprotein

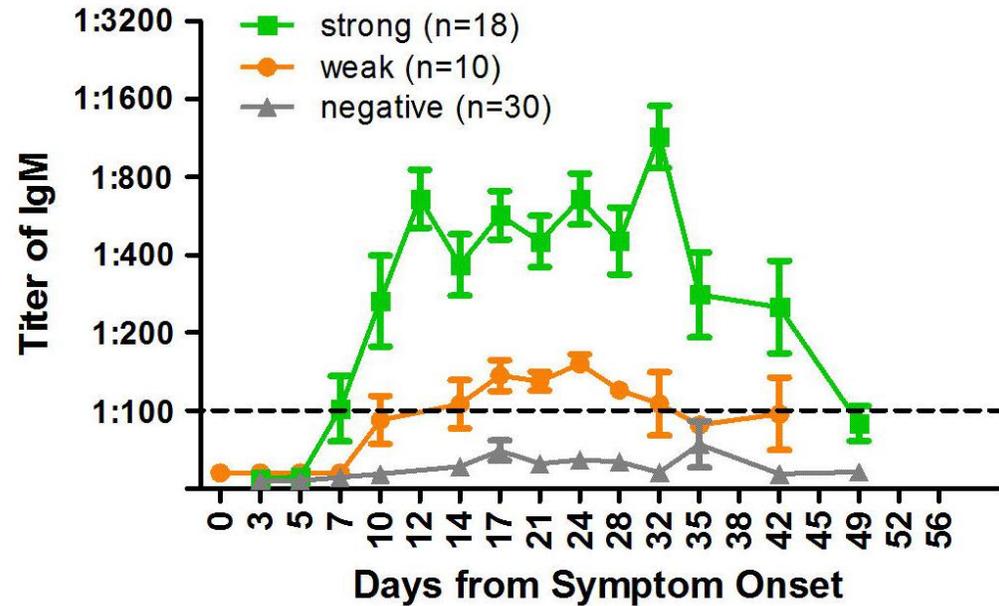


# Viral kinetics and antibody responses in patients with COVID-19. Preprint Tan et al

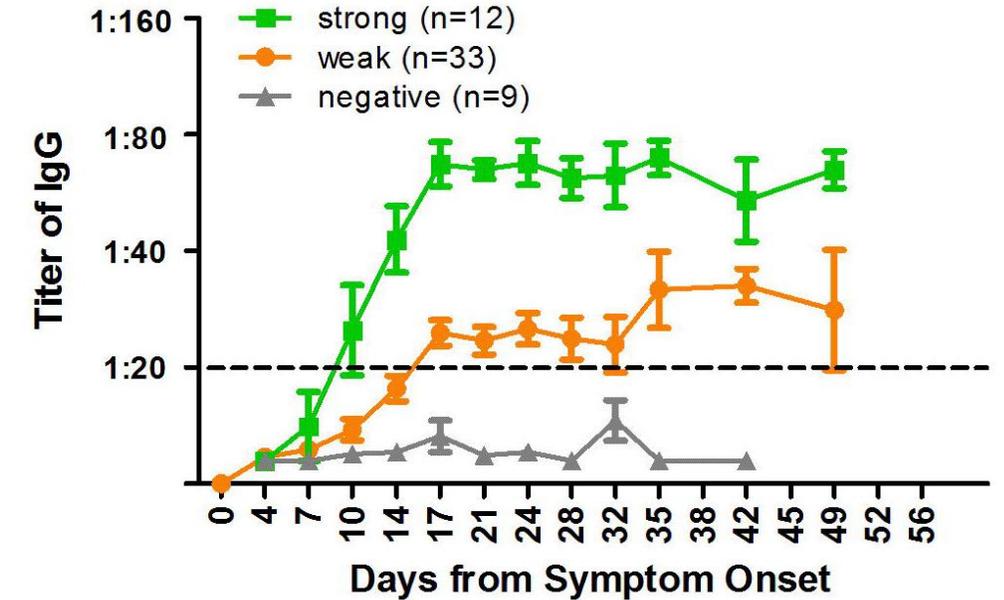


**A**

Nucleocapsid protein antigen for antibody specificity IgG and IgM



**B**



- 3 tiers of antibody response seen, with higher titers seen in patients with more severe disease for both IgM and IgG, with similar time of appearance; N=65
  - Strong responders: peak >2x cutoff value (31% IgM, 22.2% IgG)
  - Weak responders: peak 1 – 2x cutoff value (17.2% IgM, 61.1% IgG)
  - Negative responders: peak titer below cutoff value (51.7% IgM, 16.7% IgG)
- Weak responders for IgG had a higher viral clearance rate than strong responders; weak antibody response means faster viral clearance.

## 4. Are antibodies to SARS-CoV-2 protective and do all infected people make them?

- Neutralization:
  - Initial studies show varied ability for neutralization by various antibody types against specific viral protein targets.
  - The CDC has an ongoing study.
- Resources for interpretation of serologic testing:
  - <https://www.idsociety.org/news--publications-new/articles/2020/emphasizing-need-for-more-information-idsa-releases-antibody-testing-primer2/>
  - <https://www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf>
  - <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers>



# Panel Discussion

- **Moderator:** Tyler Gluckman, MD, FACC
- Dipti Itchhaporia, MD, FACC
- George Diaz, MD
- Judy Tingley, DNP, MPH, RN, AACC



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