

# Symptom-based strategy for discontinuing Special Airborne Contact isolation

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# Overview

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- **Part I: What's changing?**

- Changes to CDC guidance from a test-based to symptom-based strategy for discontinuing Special Airborne Contact isolation
- Revised Duke Health criteria
- Why change is beneficial
  - Unintended negative consequences of prolonged isolation
  - Benefits of symptom-based strategy

- **Part II: Why the change?**

- Review of data that informed the change in CDC guidance and Duke Health criteria

# Part I: What's changing?

## Updated CDC guidance

- Due to prolonged patient isolation resulting from using a test-based strategy, the CDC now recommends using a **symptom-based strategy alone** to discontinue Special Airborne Contact isolation for patients with COVID-19 infection.
- Enough evidence has accumulated to show that patients are no longer shedding live, infectious virus **after a specified amount of time** from symptom onset.

# Brief summary of evidence

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- Positive PCR ≠ infectiousness
  - Replication-competent virus not detected beyond 10 days (mild/moderate illness) or 20 days (severe/immunocompromised)
  - Many patients will continue to have positive PCR long after recovery from COVID illness – this represents shedding of non-replication-competent virus
- Large epidemiologic study did not detect secondary cases of COVID-19 among close contacts of patients after day 6 of illness onset

# Changes to Duke Health guidance

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- **Duke Health will begin using the symptom-based strategy** outlined to discontinue Special Airborne Contact isolation for patients with COVID-19 infection.
- **We will no longer use the test-based strategy** (i.e. 2 negative tests) to determine if a patient is COVID-19 positive.
- **This guidance applies to all areas of Duke Health**, including **adult** and **children's** inpatient, outpatient, surgical, procedural and other care areas.

# Revised criteria for discontinuing Special Airborne Contact isolation

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- **Three pieces of information are needed** to determine when it is safe to discontinue Special Airborne Contact isolation for a patient infected with COVID-19:
  1. Date of illness onset
  2. Illness severity
  3. Immunocompromised status
- These factors will determine whether a patient meets the new **10-day or 20-day criteria** for discontinuing Special Airborne Contact isolation.

# 1. Date of illness onset

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- Duke Health considers the date of illness onset to be the date of the **first positive test**.
- This approach is even more conservative than CDC guidance.
- This information is readily available in the chart and is not subject to change. Therefore, it will be **used to determine the duration of infectivity and timing for discontinuing isolation** within Duke Health.

# 1. Date of illness onset (continued)

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- **Test results from outside sources are acceptable** if they can be scanned in the chart or are visible through Care Everywhere.
- **NOTE: Date of symptom onset** may be used for determining home isolation and return to work for the purposes of counseling individual patients who are:
  - not currently hospitalized
  - attending clinic visits
  - undergoing procedures
  - receiving other care within the health system



## 2. Illness severity

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- Duke Health has made minor modifications to the CDC's definition of illness severity.
- The highest level of illness severity during the patient's clinical course should be used when determining illness severity.
  - **Asymptomatic infection**
  - **Mild/moderate illness**
    - Individuals with any signs/symptoms of COVID-19 who require less than 6L of oxygen.
  - **Severe/critical illness**
    - Individuals with any signs/symptoms of COVID-19, accompanied by significant respiratory compromise, who require  $\geq 6$ L of oxygen or ICU-level care.

# 3. Immunocompromised status or Pregnancy

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- **Severe immunocompromising conditions:**
  - Primary immunodeficiency
  - Active solid organ cancer on chemotherapy
  - Hematologic malignancy
  - Hematopoietic stem cell transplant recipient
  - Solid organ transplant recipient
  - Poorly controlled HIV (CD4 < 200)
  - Steroids >20mg per day for >2 week
  - Other immunosuppressive medications (e.g. infliximab, etc.)

# 10-day criteria for discontinuing isolation

- For “immunocompetent” patients who are asymptomatic or have mild/moderate illness

10-day criteria	Met?
• Patient required <b>&lt;6L oxygen</b> during their illness <b>AND did not require ICU care</b> for COVID-19 infection	
• Patient <b>does not have a severe immunocompromising condition</b>	
• At least <b>10 days</b> have passed since the date of the positive test	
• At least 24 hours have passed since last fever without fever-reducing medications	
• Symptoms (e.g., cough, shortness of breath) have improved	

If all of the above criteria are met, Special Airborne Contact isolation can be safely discontinued for this patient population.

# 20-day criteria for discontinuing isolation

- For severely immunocompromised patients or pregnant patients with any level of disease (including asymptomatic infection), or an immunocompetent patient with severe or critical illness

20-day criteria	Met?
• Patient required <b>≥6L oxygen</b> during their illness, <b>required ICU care</b> for COVID-19 infection, <b>OR is severely immunocompromised</b> , <b>OR pregnant</b>	
• At least <b>20 days</b> have passed since the date of the positive test	
• At least <b>24 hours</b> have passed since last fever without fever-reducing medications	
• Symptoms (e.g., cough, shortness of breath) have improved	

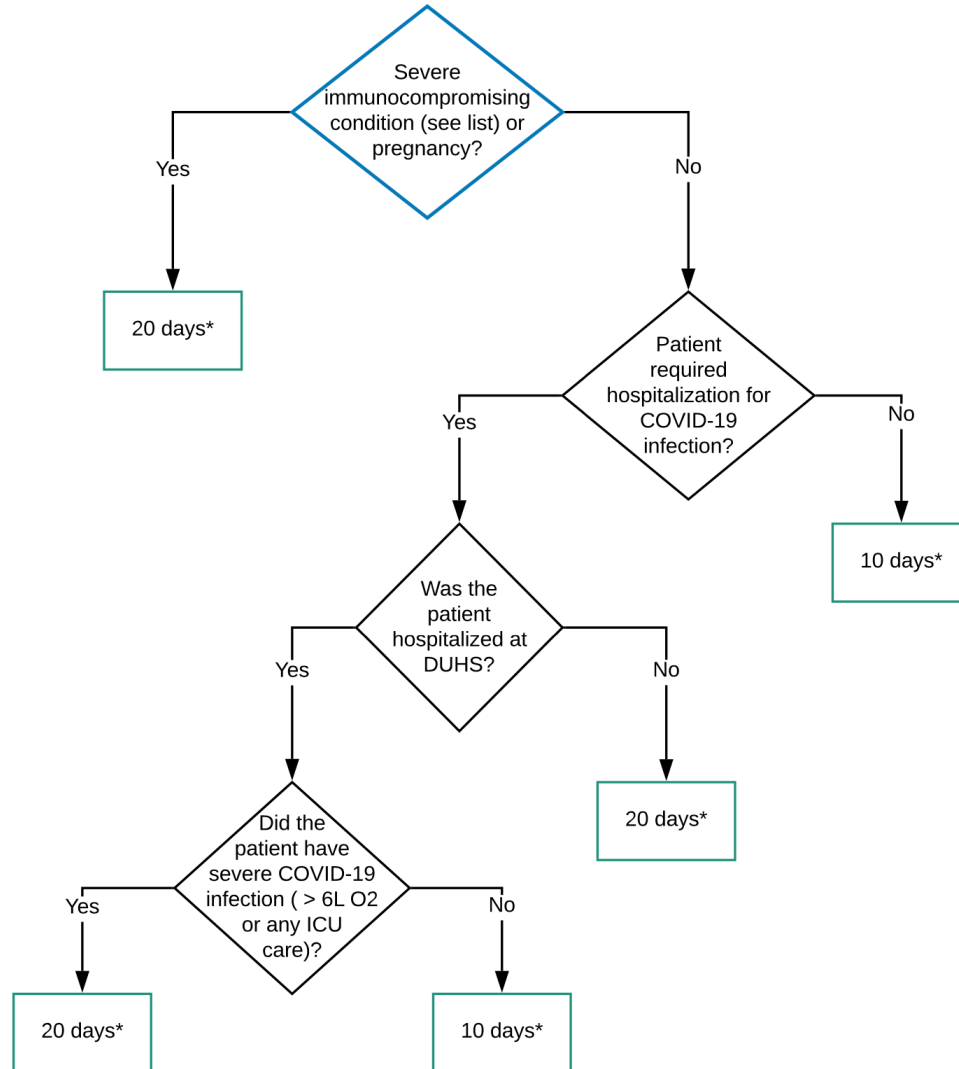
If all of the above criteria are met, Special Airborne Contact isolation can be safely discontinued for this patient population.

# Maestro Care default settings

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- Maestro Care will be set to automatically discontinue the COVID-19 infection status **after 20 days from the first positive test** in a 90-day window.
  - Inpatients: infection prevention will remove COVI-19 status
  - Outpatients: defaults to 20 days from date of positive test
- If primary teams have patients who meet criteria for discontinuing isolation after 10 days, they will need to page Infection Prevention to assist with manually removing the status based on the criteria outlined.

## Discontinuing SAC



### Severe Immunocompromising Conditions:

- Primary immunodeficiency
- Active solid organ cancer on chemotherapy
- Hematologic malignancy
- Hematopoietic stem cell transplant recipient
- Solid organ transplant recipient
- Poorly controlled HIV (CD4 < 200)
- Steroids >20mg per day for >2 week
- Other immunosuppressive medications (e.g. infliximab, etc.)

\*Earliest date of eligibility for discontinuing Special Airborne Contact isolation. Note, the date of the first positive test = Day 1. Patients must also be clinically improving and must be fever-free for at least 24 hours without fever-reducing medications.

# Impact on Admission and Preprocedural Testing

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- Admission and pre-procedural testing will **NO LONGER BE RECOMMENDED** for patients who have had a positive COVID test within the last 90 days
  - Use the symptom-based criteria to determine whether SAC is required
  - Reinfection is not expected to occur within this timeframe
  - A repeat positive test represents prolonged shedding of non-viable virus, but puts the patient at risk for unnecessary re-isolation
- **We are building a BPA to fire to alert clinicians that patient has had a positive result within 90 days and testing is not recommended**

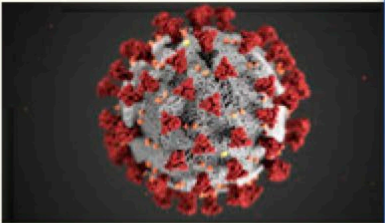
# BPA preview

BestPractice Advisory - Return, Covid

**Important (1)**

**Recent Positive COVID-19 Test**

[Provide Feedback](#)



Covid Return has had a **prior positive COVID-19 test** in the last 90 days. The CDC no longer recommends repeat COVID testing within 90 days of a positive test, because PCR test results are no longer used to determine when it is safe to remove isolation and reinfection is unlikely during this timeframe.

Last SARSCOV2, Collected: 7/20/2020 9:48 AM = DETECTED (confirmed)  
Prev SARSCOV2, Collected: 6/23/2020 6:03 PM = DETECTED  
Prev SARSCOV2, Collected: 6/11/2020 10:28 AM = DETECTED

**Acknowledge Reason**



# Anticipated pitfalls

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- Duke Health cannot control policies outside of our system, and we anticipate that other facilities may still require testing
- If an administrative test is performed per the requirement of an accepting facility and is POSITIVE but the patient has already met criteria for discontinuation of Special Airborne Contact Isolation, the patient will not be re-isolated and a staff exposure investigation will not be performed

# Unintended negative consequences of prolonged isolation

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- Mental health effects
  - Reduced care provider visits due to PPE conservation and bundling of care
  - Visitor restrictions and social isolation
  - Inability to leave inpatient room
- Delays in procedures
- Delays in rehab: PT/OT/Speech Therapy
- Additional PPE utilization
- Extended length of stay in ICU
- Multiple additional tests needed (nasopharyngeal swabs)

# Benefits of the symptom-based strategy

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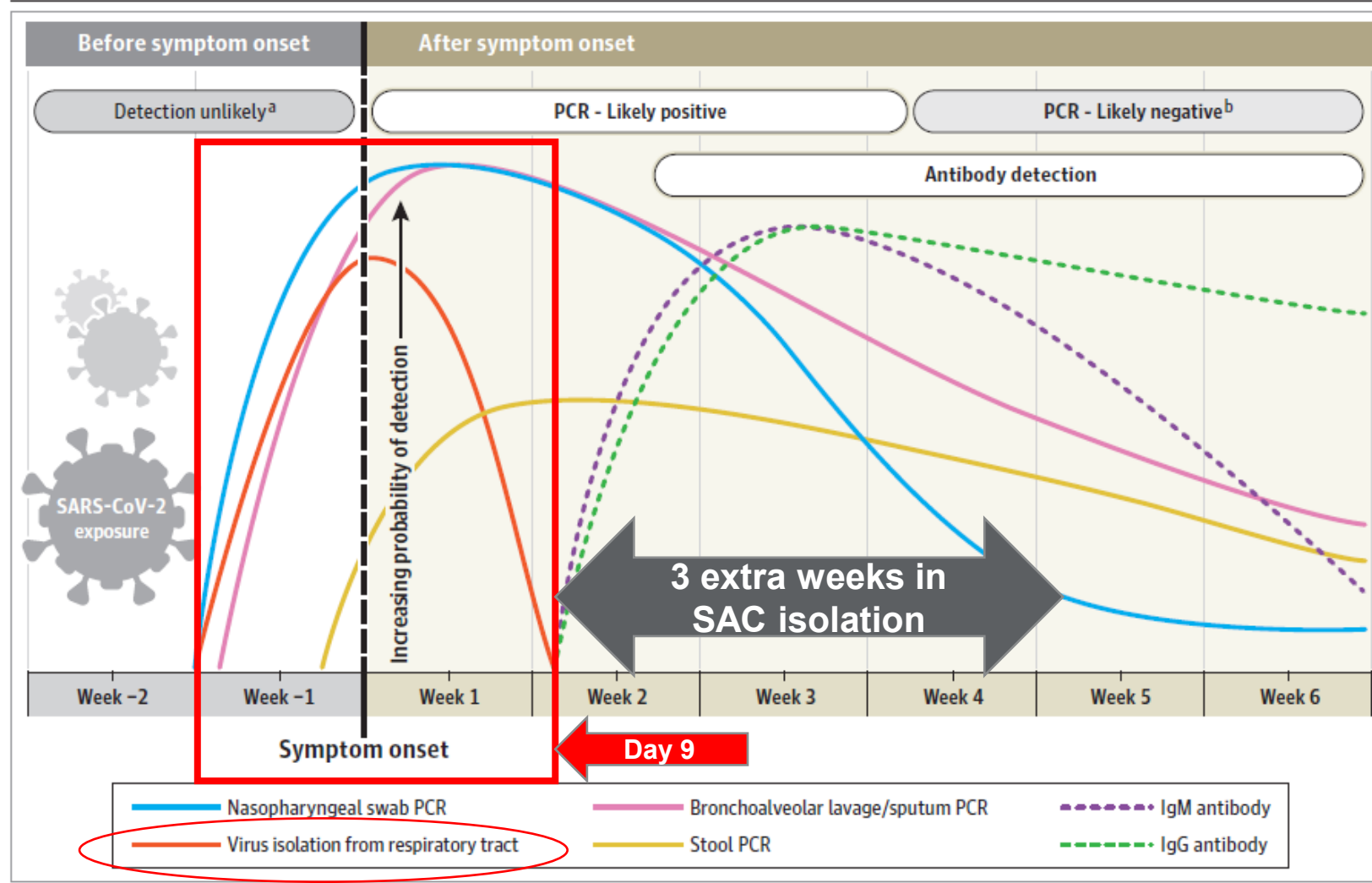
- **Decreases length of isolation**
  - Default will be set to 20 days in EPIC
  - Some patients can come off isolation at 10 days
- **Removes requirement for repeat tests after a positive test** (with the exception of SNF/LTACHs that request) during 90-day window
- **Improves overall patient care experience**
- **Conserves PPE**

# Part II: Why the change?

A summary  
of new data  
on SARS-  
CoV-2  
duration of  
infectivity

- A new study provides a timeline of diagnostic markers for COVID-19 detection:
  - Even though a PCR can stay positive 6 weeks beyond the date of the first test, **it cannot detect positive culture with infectious virus after Day 9.**
  - Patients who are no longer shedding active, infectious virus can remain on isolation unnecessarily for an **additional 3 weeks** using the test-based strategy.

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset



**Red line:**  
Shows that virus is no longer contagious by **Day 9** after symptom onset

**Blue line:**  
Shows virus detection—**NOT active, infectious virus detection**

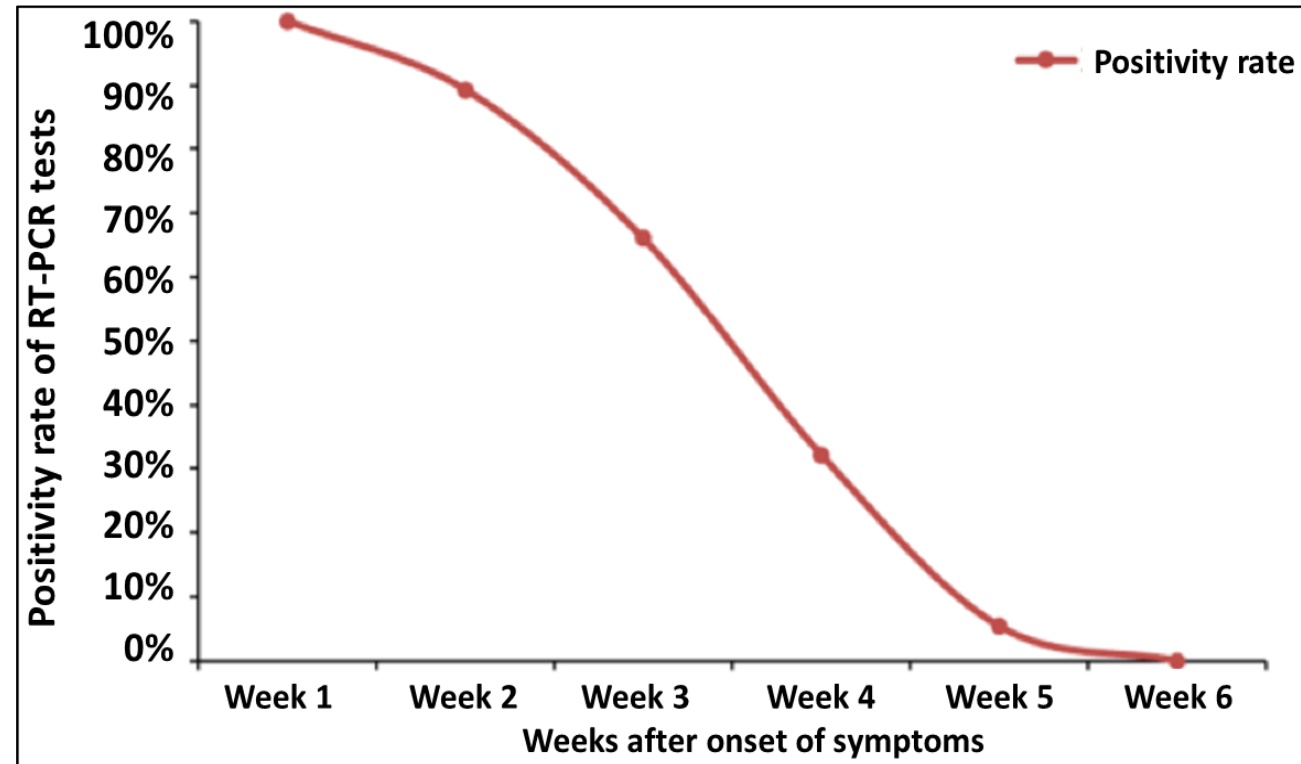
Estimated time intervals and rates of viral detection are based on data from several published reports. Because of variability in values among studies, estimated time intervals should be considered approximations and the probability of detection of SARS-CoV-2 infection is presented qualitatively. SARS-CoV-2 indicates severe acute respiratory syndrome coronavirus 2; PCR, polymerase chain reaction.

<sup>a</sup> Detection only occurs if patients are followed up proactively from the time of exposure.

<sup>b</sup> More likely to register a negative than a positive result by PCR of a nasopharyngeal swab.

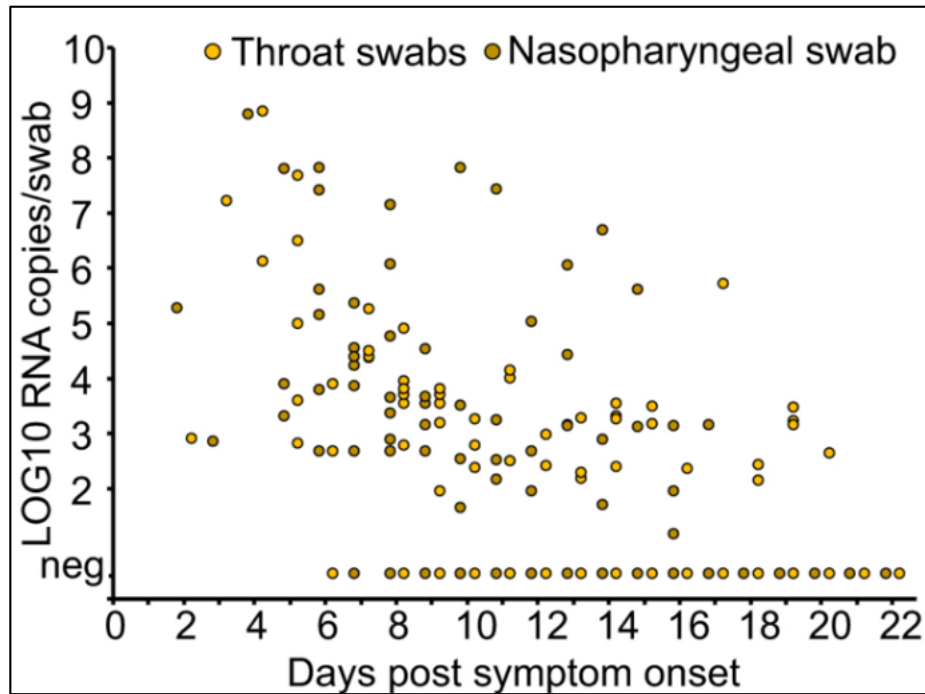
# Persistence of PCR-positive nasopharyngeal swabs

- This study noted the persistence of PCR-positive NP swabs in 56 patients who experienced mild to moderate COVID-19 infection (as defined by Chinese guidelines).
- **Results:**
  - **Week 1: 100% (highest positive rate)**
  - Week 2: 89.3%
  - Week 3: 66.1%
  - Week 4: 32.1%
  - Week 5: 5.4%
  - **Week 6: 0%**
- **Meaning:** Virus shedding can continue up to 6 weeks after symptom onset.

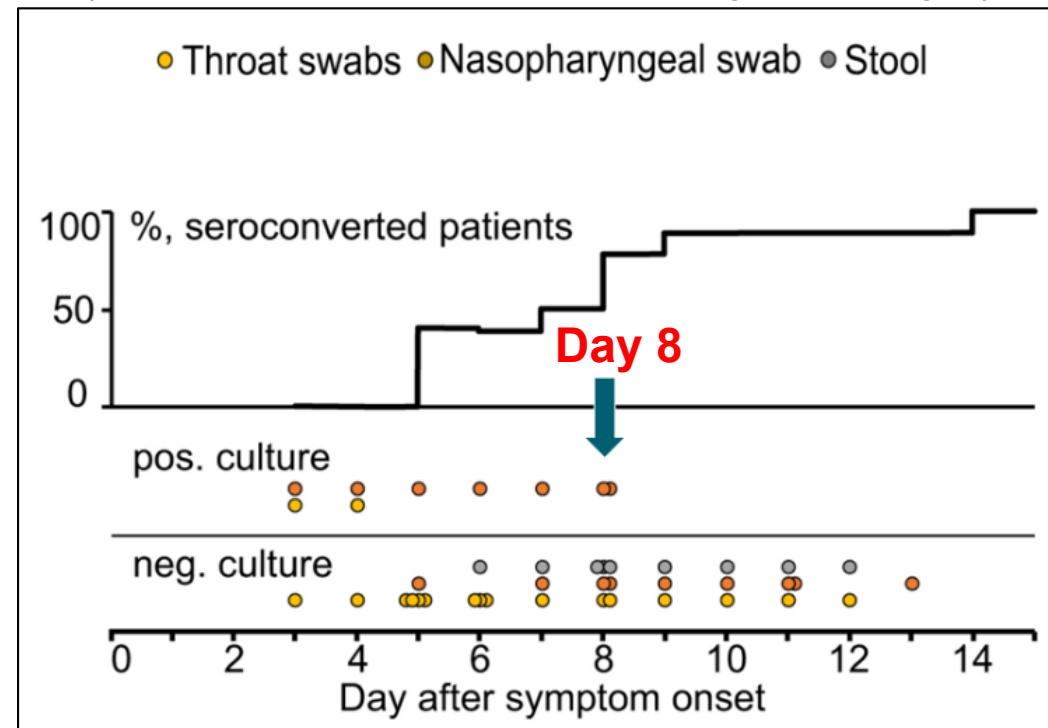


# Demonstration of decline in viral load and viable virus in upper respiratory specimens over time

- **Viral load (RNA copies/swab) declines** in upper respiratory specimens as illness progresses over time.

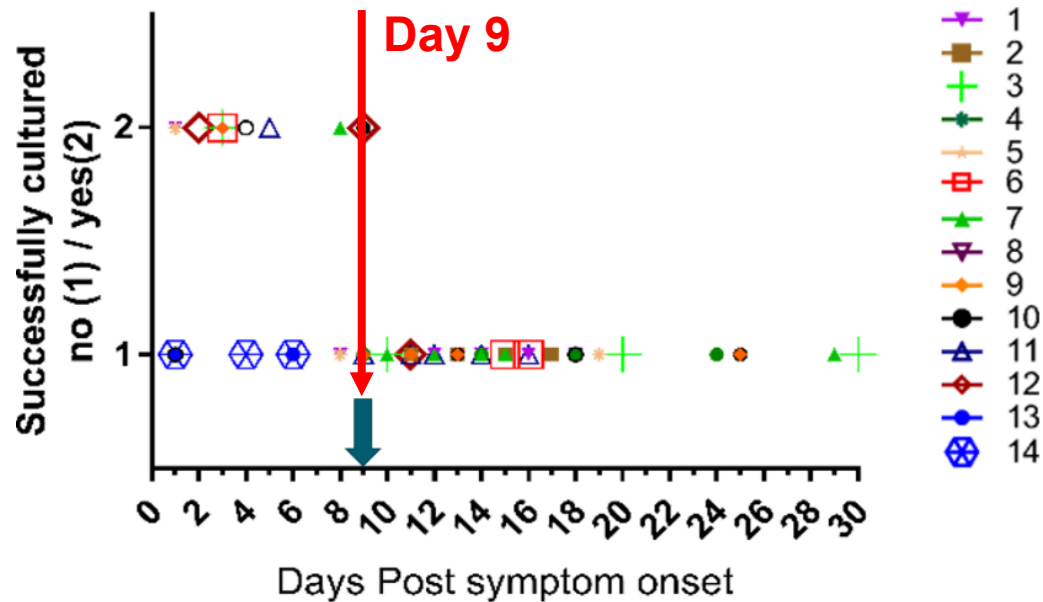


- The **capacity to isolate** replication-competent virus from same specimens **decreases** as number of patients with detectable IgM and IgG increases (i.e., **pos. culture is detected only until Day 8**).

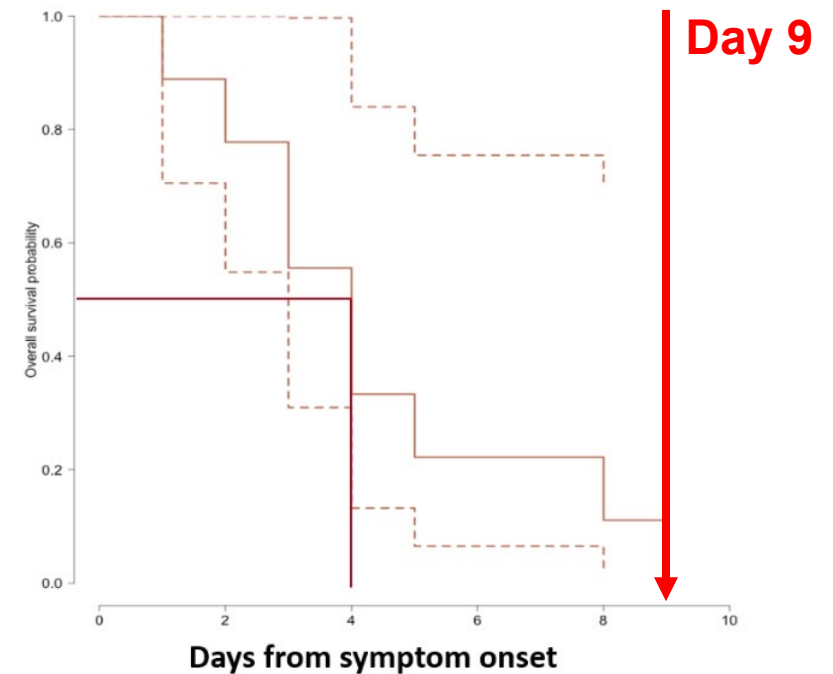


# Inability to recover viable virus after 9 days

- PCR tests are unable to recover replication-competent virus from specimens collected more than 9 days after illness onset (i.e., **no culture of infectious virus** after Day 9).



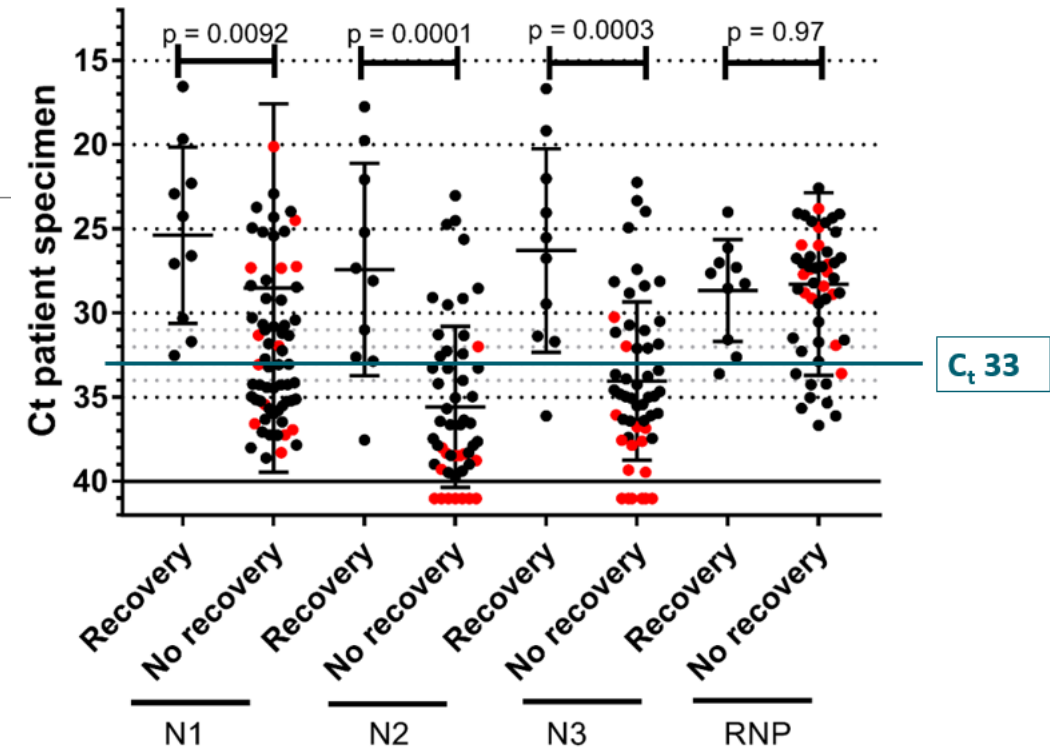
- This Kaplan-Meier analysis shows time to inability to recover replication-competent SARS-CoV-2 from 14 U.S. patients. The last probability of successful isolation falls to 50% at day 4 after illness onset and to 20% at day 8. **After Day 9, probability of culturing virus approaches zero.** (Unpublished CDC data.)





# CDC data on Ct values

- The **Ct value**, or threshold cycle, is the cycle number at which the fluorescent signal of the reaction crosses the threshold (i.e., turns positive).
- The **Ct value** is inversely related to the starting amount of our target nucleic acid – in this case, SARS-CoV-2 RNA.
  - **Higher** Ct value means **less** target nucleic acid present.
  - **Lower** Ct value means **more** target nucleic acid present.
- **GRAPH (right):** The correlation between Ct values and the ability to recover replication-competent virus is presently only applicable to upper respiratory specimens (mostly nasopharyngeal swabs) that have been assayed at the CDC.
- **INTERPRETATION:** This relationship should *not* be inferred to apply to Ct values obtained by other laboratories or used to define a strict Ct cutoff. At this time, **Ct values should not be used to define infectiousness or demonstrate the absence of risk for transmission.**



Median Ct values and their 95% confidence intervals among specimens from which replication-competent virus was recovered and not recovered according to the Ct value for the amplification target (N1, N2, or N3) in the CDC RT-PCR assay. RNP = human RNase P, a positive control for the presence of adequate human sample. Red dots indicate specimens with inconclusive RT-PCR amplification according to their corresponding Ct values and culture results.

“Recovery” = Positive culture

“No Recovery” = Negative culture

# Persons with repeat positive PCR tests are not thought to be infectious based on Korea CDC report (May 15)

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- Investigated 285 (63.8%) of 447 repeat-positive cases
  - 9.6% were tested as a screening measure.
  - 37.5% were tested because of new symptom onset.
  - Of the 284 cases for which symptoms were investigated, 126 (44.7%) were symptomatic.
- From the 285 re-positive cases, a total of 790 contacts were identified (351=family; 439=others).
  - **No secondary infections were found among the 790 contacts.**

# Summary of CDC key findings (1)

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- Concentrations of SARS-CoV-2 RNA measured in upper respiratory specimens decline after symptom onset.
- The likelihood of recovering infectious virus also declines after symptom onset.
  - For patients with **mild to moderate COVID-19**, infectious virus has not been recovered **after 10 days** following symptom onset.
  - Recovery of infectious virus **between 10 and 20 days** after symptom onset has been documented in some persons with **severe COVID-19** that, in some cases, was complicated by **immunocompromised state**. However, in this series of patients, it was estimated that 88% and 95% of their specimens no longer yielded replication-competent virus after 10 and 15 days, respectively, following symptom onset.

# Summary of CDC key findings (2)

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- A large contact-tracing study demonstrated that high-risk household and hospital contacts did not develop infection **if their exposure to a case patient started 6 days or more** after the case patient's illness onset.
- Although infectious virus was not isolated 3 weeks after symptom onset, recovered patients can continue to have **SARS-CoV-2 RNA detected in their upper respiratory specimens for up to 12 weeks**.
  - Investigation of 285 “persistently positive” persons, which included 126 persons who had developed recurrent symptoms, found **no secondary infections** among 790 contacts attributable to contact with these case patients.
  - Efforts to isolate replication-competent virus from 108 of these case patients were unsuccessful.

# Summary of CDC key findings (3)

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- Specimens from patients who recovered from an initial COVID-19 illness and subsequently developed new symptoms and retested positive by RT-PCR did not have **infectious virus** detected.
- **The risk of reinfection may be lower in the first 3 months after initial infection.**
  - This is based on limited evidence from another beta coronavirus (HCoV-OC43), the genus to which SARS-CoV-2 belongs.

# Summary of CDC key findings (4)

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- Currently, 6 months after the emergence of SARS-CoV-2, there have been **no confirmed cases of SARS-CoV-2 reinfection.**
  - However, the number of areas where sustained infection pressure has been maintained, and therefore reinfections would be most likely observed, remains limited.
  - This led to the 90 day, “re-test if symptoms” recommendation.
- Serologic or other correlates of immunity have not yet been established.

# We are here to support you

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- Contact Infection Prevention
  - If you think an Inpatient may meet criteria for discontinuation of SAC isolation
  - If you have a question about interpretation of a positive administrative test on a patient who previously tested positive for COVID
  - IP will review the chart to verify that the patient does not require re-isolation and remove the “COVID-19” Infection Status

# Questions?

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- Contact Infection Prevention or Hospital Epidemiologist on Call
- Sarah Lewis MD, MPH [sarah.stamps@duke.edu](mailto:sarah.stamps@duke.edu)
- Becky Smith, MD [becky.a.smith@duke.edu](mailto:becky.a.smith@duke.edu)