Key Summary of Published Article

SARS-CoV-2 PCR Testing
Performance of Self-Collected Nasal Swabs

Is unobserved self-collection of nasal swabs reliable for SARS-CoV-2 PCR testing, and is pooling affected?

Background

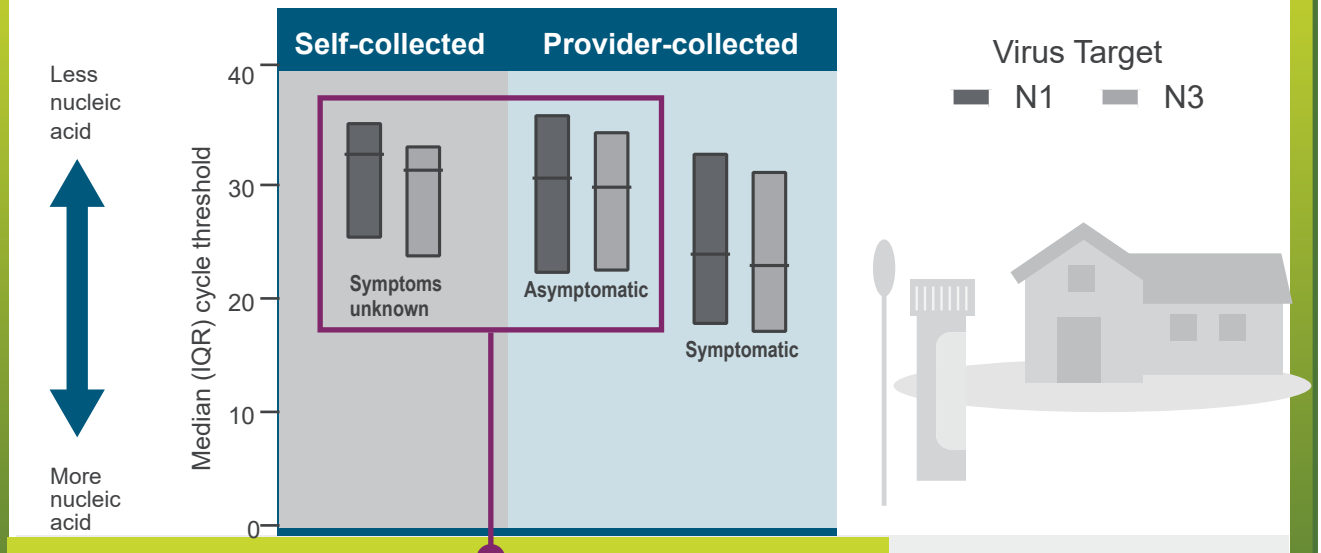
Unobserved self-collection of nasal swabs by patients would help reduce exposure risk and use of personal protective equipment.

Methods and Results

SARS-CoV-2 PCR results were compared between anterior nasal swabs that were 1) self-collected remotely (outside a clinical setting) as part of a voluntary employee screening program; or 2) collected from patients by healthcare providers.

Over 99% of 115,435 specimens had adequate quality, based on control target (RNase P) amplification.

SARS-CoV-2 positive specimens self- vs provider-collected



Self-collected specimens demonstrated similar Ct values to those collected by healthcare providers from asymptomatic patients.

Based on real-world data, pooling would have resulted in rare false negatives (0.08%).

Unobserved self-collected specimens provide adequate material for SARS-CoV-2 PCR testing, even when pooling specimens, which should alleviate concerns about false-negative results.

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SARS-CoV-2 PCR Testing
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Article Title: Performance of Unobserved Self-Collected Nasal Swabs for Detection of SARS-CoV-2 by RT-PCR Utilizing a Remote Specimen Collection Strategy

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Background

- The COVID-19 pandemic has placed unanticipated demands on the US healthcare system, including laboratory testing in which healthcare providers (HCPs) carry out specimen collection with risks of exposure.
- Self-collection (SC) of specimens at home could reduce the risk of exposure to patients, as well as the need for personal protective equipment. Testing efficiency may also be improved by pooled testing, which in 1 study demonstrated 100% agreement with individual testing of specimens positive for SARS-CoV-2.[1]
- **Objective:** In this retrospective study, investigators assessed (1) the adequacy of unobserved SC nasal swabs for detection by RT-PCR; and (2) the theoretical effect of pooled testing on test results.

Methods

- FDA emergency use authorization (EUA) SC nasal swab kits were mailed to participants in a voluntary employee return-to-work screening program. Returned specimens were tested using the Quest Diagnostics EUA SARS-CoV-2 RT-PCR.
  - N1 and N3 regions of the SAR-CoV-2 nucleocapsid gene were amplified as viral targets.
  - To determine if adequate specimen was self-collected, the human RNAse P gene was amplified from each specimen as a control.
  - Results were defined as follows:
    - Positive: cycle threshold (Ct) <40 for both targets
    - Negative: Ct ≥40 for both targets and Ct <40 the control
    - Inconclusive: Ct <40 for 1 target, Ct ≥40 for the other, and Ct <40 the control
    - Invalid: Ct ≥40 for both targets and the control, in initial test and upon repeat
- The study included specimens tested between June 3 and August 12, 2020.
- Ct values from SC specimens were compared to those of HCP-collected specimens from the same period and age range.
- The effect of pooling on positivity rates was evaluated using Ct cutoffs for pooled testing ($40 - Ct_{shift}$).

Results

- A total of 115,435 SC specimens were returned from 47,923 patients; 1,268 (1.8%) specimens were positive.
- Nearly all SC specimens had adequate sampling; the control failed to amplify in only 0.011% (13 of 115,435) of SC specimens.
- Interpatient variability was low, as indicated by the similar median control Cts for each group of positive, negative, and inconclusive specimens (23 cycles; interquartile range, 21.8-24.7 depending on specimen group).
- Amplification of viral genes was adequate, as indicated by the similar distributions of Ct values for virus targets from SC and HCP-collected specimens.
- Pooling would have resulted in only 1 false-negative result and 67 inconclusive results.

Conclusions

- The findings of this study demonstrate that unobserved SC may be adequate for RT-PCR testing and that pooling can be used to test the specimens.

References

1. Borillo GA, Kagan RM, Baumann RE, et al. Pooling of upper respiratory specimens using a SARS-CoV-2 real-time RT-PCR assay authorized for emergency use in low-prevalence populations for high-throughput testing. *Open Forum Infect Dis*. 2020;7(11):ofaa466. doi:10.1093/ofid/ofaa466