

Emerging evidence supports patient-collected mid-turbinate nasal swabs as a practical alternative to nasopharyngeal swabs for COVID-19 testing.

Overview

Efforts to enact widespread testing for the COVID-19 pandemic have stressed the supply chain for critical materials needed for the collection, storage and processing of patient specimens. Specifically, severe shortages of swabs for nasopharyngeal sample collection, personal protective equipment for health care providers administering collections, and reagents for stabilizing and transporting specimens, threaten to stall increased roll out of COVID-19 testing across the country. To mitigate these supply constraints, and to better position the State for future surveillance testing of recurrent outbreaks, alternative testing workflows are urgently needed. In this white paper we review the scientific evidence supporting the diagnostic performance of patient-collected mid-turbinate (MT) nasal swabs as a promising alternative to the standard nasopharyngeal (NP) swab administered by a healthcare professional (HCP). Considering the delicate balance of test performance, supply chain constraints, and urgent need for broader testing, Verily endorses the adoption of mid-turbinate nasal swabs as an acceptable and more scalable alternative to nasopharyngeal swabs for COVID-19 testing.

Background

Testing and collection workflows for detecting the SARS-CoV-2 virus responsible for the COVID-19 pandemic have been rapidly evolving to counter supply chain constraints. However, to date, few peer-reviewed studies have thoroughly compared the diagnostic performance of alternative collection methods and sampling materials to the standard NP swab for SARS-CoV-2 testing. The most extensive comparison to date comes from a recent clinical study of 533 patients, supported by The Gates Foundation, Quest Diagnostics and UnitedHealth Group, which evaluated the testing sensitivity of patient-collected tongue, nasal, and MT samples against HCP collected NP samples. Investigators reported a sensitivity of 96.2 (95% CI: 87.7-100.0) for self administered MT sampling using nylon flocked swabs when compared to HCP administered NP sampling using polyester tipped swabs. Viral load in NP and MT samples, as determined by qPCR cycling threshold, was correlated with a Pearson correlation coefficient of 0.86 [1].

Similar evidence supporting the diagnostic utility of MT swabs is observed in several other recent, yet non-peer reviewed studies: A comparison of testing methods involving 45 patients, self-collected nasal swabs detected 85% of SARS-CoV-2-positive patients, similar to HCP collected NP swabs which detected 79% of SARS-CoV-2 infections [2]. A study comparing two different swabbing systems across

two different testing instruments with 94 patients showed concordance of >97% between MT swabs and NP swabs though this study was all HCP administered and does not capture the impact of patient self-testing [3].

These early data supporting the detectability of SARS-CoV-2 in alternative collection sites builds on our understanding of feasible sampling approaches for diagnosing other respiratory viral infections [4-7]. However concordance of diagnostic tests in different sampling sites is often dependent on the specific virus and their manifestation of symptoms [8]. While promising, larger and more quantitative, longitudinal, studies including asymptomatic patients are needed to fully understand the most optimal alternative methods for scalable and effective diagnostic testing.

Regulatory Guidance

CDC guidance updated on April 29, 2020 removed the preference for NP specimen for swab-based SARS-CoV-2 testing, and instead listed, mid-turbinate (NMT), oropharyngeal, and anterior nares swabs as an acceptable alternative [9].

As with the CDC, the FDA updated their collection guidelines on April 21, 2020 to allow for mid-turbinate specimen by onsite self-collection or HCP (using a flocked tapered swab) [10]. On April 21, 2020, the FDA authorized Pixel by LabCorp COVID-19 Test under an EUA, the first approved at home self collection option for detecting SARS-CoV-2 [11].

Recommendations

In the interest of public health which requires an increase in the scale of testing locations across the state and in light of the current supply limitations, Verily is following the recent CDC and FDA guidance,

supported by recent clinical trial data to implement self administered MT swabbing protocols in order to facilitate the necessary expansion of testing operations.

References

1. [Tu YP, Jennings R, Hart B, et al. Patient-collected tongue, nasal, and mid-turbinate swabs for SARS-CoV-2 yield equivalent sensitivity to health care worker collected nasopharyngeal swabs. medRxiv. 2020.4.6, preprint.](#)
2. [Kojima N, Turner F, Slepnev V, et al. Self-Collected Oral Fluid and Nasal Swabs Demonstrate Comparable Sensitivity to Clinician Collected Nasopharyngeal Swabs for Covid-19 Detection. medRxiv. 2020.4.15, preprint.](#)
3. [Vermeiren C, Marchand-Senécal X, Sheldrake E, et al. Comparison of Copan Eswab and FLOQswab for COVID-19 PCR diagnosis: working around a supply shortage. J Clin Microbiol. 2020 Apr 15. \[Epub ahead of print\]](#)
4. [Irving SA, vandermause MF, et al. Comparison of Nasal and Nasopharyngeal Swabs for Influenza Detection in Adults. Clin Med Res. 2012 Nov; 10\(4\):215-218](#)
5. [Larios OE, Coleman BL, et al. Self-Collected Mid-Turbinate Swabs for the Detection of Respiratory Viruses in Adults with Acute Respiratory Illnesses. PLoS One. 2011;6\(6\):e21335](#)
6. [Dhiman N, Miller RM, et al. Effectiveness of patient-collected swabs for influenza testing. Mayo Clin Proc. 2012 Jun;87\(6\):548-554](#)
7. [Blaschke, AJ, Mckevitt M, et al. A Mid-Turbinate Swab Appears Comparable to Nasopharyngeal Swabs for Quantitative Detection of RSV in Infants. Open Forum Infectious Diseases. 2017; Vol 4, Issue suppl_1: S354–S355](#)
8. [Kim C, Ahmed JA, Eidex RB, et al. Comparison of nasopharyngeal and oropharyngeal swabs for the diagnosis of eight respiratory viruses by real-time reverse transcription-PCR assays. PLoS One. 2011;6\(6\):e21610](#)
9. [CDC: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 \(COVID-19\)](#)
10. [FDA: FAQs on Diagnostic Testing for SARS-CoV-2](#)

11. [Coronavirus \(COVID-19\) Update: FDA Authorizes First Test for Patient At-Home Sample Collection, April 21, 2020.](#)