URGENT UPDATE DIAGNOSTIC TESTING

Information for Healthcare Providers, Healthcare Systems, and Laboratories Following Updated FDA Recommendations for SARS-CoV-2 Diagnostic Testing

As part of our COVID-19 response efforts, the US government continues to prioritize efforts to expedite patient testing. Experts continue to work tirelessly during this dynamic and evolving situation. This includes adapting to supply chain pressures and continuing to evaluate options for sample collection as well as working with stakeholders on efforts to facilitate greater access to these critical medical products.

On March 23, 2020, additional types of swabs were added to the FDA's recommendations for SARS-CoV-2 diagnostic processes. These recommendations provide additional options for sampling that, based on industry data, are more readily available and may also lessen exposure risks by facilitating self-collection in an appropriate clinical setting, such as "drive-thru" testing sites.

The self-collected nasal swab was recently determined to be equivalent to a nasopharyngeal swab in detecting coronavirus through a study performed by the United Health Group. As a result of these data, the FDA is recommending a self-collected nasal swab (using a round foam swab) or self-collected mid-turbinate swabs (using a flocked tapered swab) for use when a nasopharyngeal (NP) swab is not performed. Based on available data, the FDA recommends that, for symptomatic patients, nasal swabs could be used that access just the front of the nose rather than the depth of the nasal cavity. This would provide COVID-19 testing that is more comfortable for patients, allows self-collection of samples at collection sites, and that can be performed with a simpler and more readily available swab.

The use of a nasal swab versus a nasopharyngeal swab includes the following benefits:

- Increases the total volume of available sample collection materials, since the recommendations are broadened to include flocked and foam swabs, which are available in large quantities
- Collection of nasal swab samples is less technically complex, so can reduce the risk of the spread of infection to healthcare providers, by (1) reducing the duration of the procedure, and (2) allowing the patient to perform self-collection under supervision
- Helps lessen the impact of PPE utilization, given that the patient can perform self-collection under supervision (versus the health care provider performing the collection)

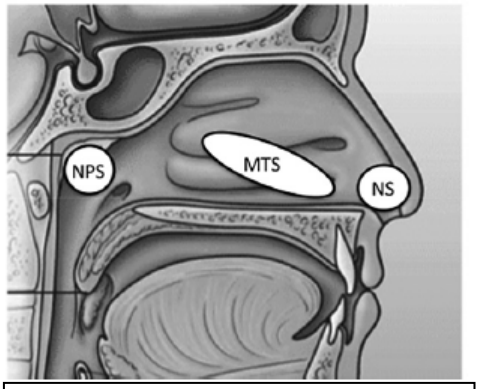
In practice, supervised nasal swab self-collection will occur at at a drive-thru testing site or a healthcare clinic.

Home self-collection is **NOT** recommended.

Background

The FDA identifies preferred preferences for diagnostic sample collections for swab-based SARS-CoV-2. The nasopharyngeal sample is the FDA-preferred sample. In the event that this specimen is not available, the FDA identifies the following alternatives as acceptable:

- oropharyngeal sample collected by a healthcare professional (HCP);
- mid-turbinate sample by onsite self-collection or HCP (using a flocked tapered swab); or
- *anterior nares sample by onsite self-collection or HCP (using a round foam swab).*
- For patients with productive cough, a sputum sample is an acceptable lower respiratory sample.



Sampling Locations: NPS, Nasopharyngeal swab; MTS, midturbinate swab; NS, nasal swab. (From Frazee et al., 2018)

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Learn More

HHS continues to support efforts to expand testing while basing our recommendations on scientific data.

For updates and information on serological testing Healthcare professionals, laboratories, and diagnostic test developers can review the FDA's Frequently Asked Questions on Diagnostic Testing for SARS-CoV-2: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

The U.S. Department of Health and Human Services has created a resource for stakeholders, COVID-19 testing Diagnostics, to serve as a reference that can be used to facilitate purchasing of Diagnostic materials that have received an Emergency Use Authorization from the FDA.

Coronavirus COVID-19 Diagnostic Tests Hotline

For test developers and labs who have questions about the EUA process or spot shortages of testing supplies.

Contact our toll-free line 24 hours a day: 1-888-INFO-FDA, choose option *.

Additional References

1. Frazee, B. W., et al. (2018). "Accuracy and Discomfort of Different Types of Intranasal Specimen Collection Methods for Molecular Influenza Testing in Emergency Department Patients." Ann Emerg Med 71(4): 509-517 e501.
2. Heikkinen T, Salmi AA, Ruuskanen O. Comparative study of nasopharyngeal aspirate and nasal swab specimens for detection of influenza. BMJ. 2001;322:138.
3. Heikkinen T, Marttila J, Salmi AA, et al. Nasal swab versus nasopharyngeal aspirate for isolation of respiratory viruses. J Clin Microbiol. 2002;40:4337-4339.
4. Sung RY, Chan PK, Choi KC, et al. Comparative study of nasopharyngeal aspirate and nasal swab specimens for diagnosis of acute viral respiratory infection. J Clin Microbiol. 2008;46:3073-3076.
5. Spencer S, Gaglani M, Naleway A, et al. Consistency of influenza A virus detection test results across respiratory specimen collection methods using real-time reverse transcription-PCR. J Clin Microbiol. 2013;51:3880-3882.
6. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#troubleobtainingviraltransport