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SARS-CoV-2 Molecular Testing: Frequently Asked Questions (July 4, 2020)
SPECIMEN TYPES

Background:
1) SARS-CoV-2 viral shedding can be detected in upper and lower respiratory sites with peak viral loads within the first week of symptom onset.[1-3]
2) For initial diagnostic testing for SARS-CoV-2, the CDC recommends collecting and testing an upper respiratory specimen.[4]   The following are acceptable specimens:
   • A nasopharyngeal (NP) specimen collected by a healthcare provider; or
   • An oropharyngeal (OP) specimen collected by a healthcare provider; or
   • A nasal mid-turbinate swab collected by a healthcare provider or by a supervised onsite self-collection (using a flocked tapered swab); or
   • An anterior nares (nasal swab) specimen collected by a healthcare provider or by onsite or home self-collection (using a flocked or spun polyester swab); or
   • Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a healthcare provider.

Q: What are the detection rates of SARS-CoV-2 by respiratory specimen?
A: In two studies comparing the same group of patients, the detection rates by nucleic acid amplification testing were reported as: [5-6]
   • "Nasal":   63-73.3% (did not specify location in nasal cavity)
   • Oropharynx: 32-61.3%
   • Sputum: 72-88.9%
   • Bronchoalveolar lavage fluid: 80-93%

Q: What is the sensitivity of non-nasopharyngeal specimens in detecting SARS-CoV-2?
A: For patients that were diagnosed with SARS-CoV-2 by NP swabbing, the corresponding detection sensitivities for other specimen types have been reported as:
   • Saliva: 84.6-91.7%[7-9]
   • Tongue: 89.8%[10]
   • Anterior nares: 94%[10]
   • Mid-turbinate: 96.2%[10]

It should be noted that were minor subsets of saliva, tongue, and anterior nares specimens that did detect virus while NP swabbing did not. [10-12]

Q: *Can you improve the detection sensitivity of SARS-CoV-2 for non-nasopharyngeal specimens?*

A: One group reported that combined oropharyngeal / nares (OP/Na) swabbing is comparable to nasopharyngeal (NP) swabbing. (In their study, NP swabbing had a sensitivity of 94.4-100% while OP/Na swabbing had a sensitivity of 88.9-91.7%. However, these findings were not statistically different.[13])

Another group reported that combining nasal swab specimens and saliva specimens increased the viral detection sensitivity from 87.1% to 94.6%.[14]

Q: *What are some factors that might affect the test results?*

A. The diagnostic sensitivity of the molecular assay is likely dependent on different factors:
1) Ability to obtain an adequate, representative specimen.
    - Inadequate sampling will yield false negative results.
2) Timing of sample retrieval during the infection course.
    - Viral shedding may begin 2 to 3 days before the appearance of the first symptoms.[15] After symptom onset, viral loads decrease with time.[16-17]
    - The greatest detection of the virus appears to be within one week from the onset of symptoms.
3) Type of specimen (see earlier discussion)
4) Specimen integrity during transport

Conclusions:
1) Detection of the virus depends on when sampling occurs during the infection course and the anatomic location.
2) If viral infection is clinically suspected and an initial test is negative, consider re-testing using another specimen type.

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