Diagnostic Testing Options for Sars-CoV-2

The U.S Food and Drug Administration (FDA) currently reviews diagnostic tests for SARS CoV-2, and has been issuing EUA, or Emergency Use Authorization, for those tests it determines are sufficiently reliable. A list of tests which have been granted EUA by the FDA can be found here. The value of each individual test can be most appropriately assessed after gaining an understanding of the different types of tests available and determining which test may be most useful in a particular situation.

Accuracy of a particular test is critical. This data, which is submitted to the FDA as part of the review process, describes test accuracy in terms of both sensitivity and specificity:

- Sensitivity measures the test's ability to identify persons who actually have the disease (true positives).
- Specificity measures the test's ability to correctly identify persons without disease (true negatives).

The FDA will not consider a test for EUA unless Sensitivity is ≥ 95%, and Specificity is ≥ 98% with a lower bound of the two-sided 95% confidence interval > 95%.

QUESTION/TOPIC	ANSWER		
How is information from the test used?	To diagnose acute infection		As proof-of-prior infection
What is measured?	Viral RNA/Polymerase chain reaction (PCR)	Viral proteins	Antibodies against the virus
What type of sample is needed to conduct the test?	Nasopharyngeal specimen or throat swab* Nasal swab specimen Collected saliva	Nasopharyngeal or nasal swab specimen	Assay dependent; may require serum, plasma, or whole blood
What type of instrumentation is needed to run the test?	Thermocyler PCR machine	Fluorescent immunoassay reader	Assay dependent
What are the laboratory setting requirements?†**	CLIA-certified for high and moderate complexity; or non-prescription, at home test	CLIA-certified for high and moderate complexity; or CLIA registered point-of-care testing facility with a Certificate of Waiver; or point-of-care; or prescription or non-prescription home test	CLIA-certified for high and moderate complexity; or CLIA registered point-of-care testing facility with a Certificate of Waiver
How much time is required to process the sample in assay (excludes transit time)?	7-24 hours	15 minutes	15 minutes up to 1-3 days
Positive test results (sensitivity)	Accurate, highly sample technique sensitive but further scientific evaluation required; sensitivity may vary by specimen source	Acceptable and well-validated, but typically with lower sensitivity than PCR tests	Accurate but further scientific evaluation required
Limitations	May not detect very early infection	Can only detect current active viral infection (not past infection); antigen test results need to be verified using PCR testing	May not detect active and/or very early infection

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**Dentists who plan to incorporate testing for COVID-19 into their screening protocol will be considered a laboratory under the Clinical Laboratory Improvements Act (CLIA) and must request a Certificate of Waiver from CMS prior to administering the tests. Some states require additional registration.

Dental practices interested in securing CLIA approval must specify in their registration application the name of the test(s) that will be used in the practice. Be sure to verify that each test listed in the application has been authorized for use in a CLIA-waived setting by consulting the FDA's list of emergency use authorized tests on the FDA website and verifying that there is a "W" in the column titled "Authorized Setting(s)".

† Though not widely available, there are home use tests, with EUA from FDA for viral proteins and viral mRNA.