Stereotactic navigation in sinus surgery Testing for coronavirus (COVID-19)

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Policy contains: Coronavirus; COVID-19; testing.

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Coverage policy

Testing for Coronavirus, or SARS-Co-V-2 COVID-19) is clinically proven, and therefore medically necessary, for persons who are symptomatic; with a known exposure to someone with suspected or confirmed COVID-19; (if vaccinated) when prioritized for expanded community screening; or (if not vaccinated) when referred by a school, workplace, provider, or health department s (Centers for Disease Control and Prevention, 2020b).

Limitations

A positive nucleic acid amplification test for SARS-CoV-2 should not be repeated within 90 days, since ribonucleic acid may be detectable after risk of transmission has passed, and infectiousness is unlikely (Centers for Disease Control and Prevention, 2021e).

Tests for antibodies to COVID-19 are to detect past infections, and should not be used to identify current infections.

Alternative covered services

None.

Background

A new virus known as SARS-CoV-2, or COVID-19, originated in Wuhan, China late in 2019, and had spread to most nations in the world by mid-March 2020. The pandemic makes testing for the new virus a critical component of controlling and treating the disease.

The virus is transmitted relatively easily between humans, by coughing, sneezing, or other airborne vectors, and in symptomatic cases, symptoms can appear 2 – 14 days later. Symptoms can include fever/chills, shortness of breath/difficulty breathing, fatigue, muscle/body aches, headache, new loss of taste/smell, sore throat, congestion/runny nose, nausea/vomiting, and diarrhea (Centers for Disease Control and Prevention, 2021a).

Elderly persons and/or those who have severe comorbid conditions such as heart disease, lung disease, or diabetes, appear to be at elevated risk for developing serious complications from COVID-19 (Centers for Disease Control and Prevention, 2021a).

A viral test analyzes specimens from the nose or mouth for current infection. Tests are performed in a laboratory, testing site, home, or other sites. The two types of tests are:

- Nucleic acid amplification tests. These tests detect viral ribonucleic acid genes indicating current or recent infection. Most are processed in labs. Turnaround for results are often 1 – 3 days, but some point-of-care tests require 15 – 45 minutes. Results are mostly qualitative. Prolonged detection of viral ribonucleic acid means results are not always evidence of virus capable of replicating or being transmitted to others
- Antigen tests. These tests are immunoassays that detect a specific viral antigen, and are less sensitive than most nucleic acid tests. Results are often available in minutes (Centers for Disease Control and Prevention, 2021b).

After December 31, 2021, the Centers for Disease Control will withdraw the request to the U.S. Food and Drug Administration for Emergency Use Authorization of the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel, used beginning February 2020. This notice allows clinical laboratories time to select alternatives approved by the Food and Drug Administration (Centers for Disease Control and Prevention, 2021f).

The Centers for Disease Control and Prevention advises COVID-19 testing for the following:

- Persons with symptoms of COVID-19, regardless of prior infection.
- Persons who have a known exposure (within six feet for a total of 15 minutes or more) to someone with suspected or confirmed COVID-19.
    - For vaccinated persons, testing should occur 3 – 5 days after exposure, while wearing a mask in public indoor settings for 14 days or until a negative test results is received.
    - For persons not fully vaccinated who have taken part in activities that put them at higher risk for COVID-19 because they cannot physically distance as needed, testing should occur immediately (while quarantined); testing should occur again 5 – 7 days after last exposure or immediately if symptoms develop during quarantine.

- Persons not fully vaccinated who are prioritized for expanded community screening for COVID-19.
- People not fully vaccinated who have been asked or referred to get testing by their school, workplace, healthcare provider, state, tribal, local, or territorial health department.

For international travelers, those who are fully vaccinated do not need to get tested before leaving the United States unless required by their destination. After travel and return to the United States a SARS-CoV-2 viral test is recommended 3-5 days after travel regardless of vaccination status.

Persons who have been exposed to someone with COVID-19 who has tested positive for COVID-19 within the past three months and recovered, and do not develop new symptoms, do not need to get tested (Centers for Disease Control and Prevention, 2021b).

As of September 3, 2021, a total of 528,875,293 COVID-19 tests had been administered in the U.S. These tests have confirmed 39,488,866 cases, representing 12% of U.S. residents (Centers for Disease Control and Prevention, 2021).

Findings

Nucleic acid amplification tests are the gold standard for accurate detection of active SARS-CoV-2. Sensitivity is greater than in antigen tests (specificity is equal for both). However, nucleic acid amplification tests can remain positive for weeks to months following infection and can detect viral nucleic acid even when virus cannot be cultured; thus, results may not always indicate contagiousness.

Antigen tests are used frequently within days of symptom onset. Antigen tests also may be informative in testing persons with a known exposure to someone with COVID-19. Nucleic acid amplification tests (with the exception of some point-of-care tests) are used to confirm a positive result with antigen testing (Centers for Disease Control and Prevention, 2021d).

A Cochrane review included 64 studies (n = 24,087 samples, 7,415 with confirmed SARS-CoV-2) of rapid, point-of-care or molecular COVID-19 tests, versus a single reverse transcriptase-polymerase chain reaction result. Sensitivity varied between symptomatic and asymptomatic subjects (72.0% and 58.1%); first and second week after symptom onset (78.3% and 51.0%); and cycle threshold ≤25 or >25 (94.5% and 40.7%) (Dinnes, 2021).

A large (n = 17,171) systematic review/meta-analysis of patients with suspected COVID-19 due to a positive rapid antigen test determined sensitivity and specificity to be 68.4% and 99.4%, respectively. Sensitivity ranged from 56.8% in African nations to 74.1% in American nations, and was higher in symptomatic persons (78.5%) than asymptomatic persons (54.5%) (Khandker, 2021).

A systematic review/meta-analysis of 133 studies (n = 112,323) determined the sensitivity and specificity for rapid antigen tests for COVID-19, compared with reverse transcription polymerase chain reaction, were 71.2% and 98.9%, respectively. Sensitivity was markedly better on samples with lower rapid testing-polymerase chain reaction cycle thresholds (96.5% for <20 versus 20.9% for ≥30). Testing in the first week from symptom onset had higher sensitivity compared to testing after one week (83.8% versus 61.5%) (Brummer, 2021).

In a systematic review/meta-analysis of 13 studies (n = 4,092), sensitivity and specificity of diagnosing COVID-19 by computerized tomography, versus reverse transcription polymerase chain reaction blood tests were 91.0% and 77.5%, respectively. Authors note the “relatively high” false positive rate, but contend tomography might be helpful in cases with suspicious COVID-19 presentation with a negative blood test (Karam, 2021).

A meta-analysis of 12 studies of seven commercial COVID-19 molecular *in vitro* diagnostic tests had sensitivity and specificity of 95.9% and 97.2%. Two of the tests had lower sensitivity (91.6% and 92.0%) (Ulhaq, 2021).

A systematic review/meta-analysis of 23 studies (n = 7,393, with 16,762 samples) revealed that, compared with the gold standard of nasopharyngeal swabs, ability to diagnose COVID-19 varied by sampling method. Sensitivity was 97% for nasal and throat swabs, 85% for saliva, and 68% for throat swabs (Tsang, 2021).

References

On September 10, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “coronavirus,” “COVID-19,” and “testing.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

3/2020: initial review date and clinical policy effective date: 3/2020.

12/2021: Policy references updated, coverage modified.