Clearing Up the Confusion in COVID-19 Testing

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There are so many options available for coronavirus disease 2019 (COVID-19) testing. How do you know what test is best for your urgent care center?

The need for virus testing was and still is paramount in the fight against this COVID-19 pandemic. The American Medical Association introduced new Current Procedural Terminology (CPT) code 87635, "Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19)], amplified probe technique" on March 13, 2020, also making the code effective that same date of service.

The Centers for Medicare and Medicaid Services (CMS) then provided Healthcare Common Procedural Services (HCPCS) code U0001, "CDC 2019 novel coronavirus (2019-ncov) real-time RT-PCR diagnostic panel" to be used only by those locations where the CDC sent their test kits. The more common test code urgent care centers might see is HCPCS code U0002, "2019-nCov (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC." Both of these codes took effect April 1, 2020 for dates of service from February 4, 2020 forward. Your biller would use HCPCS code U0002 for any COVID-19 virus test not performed as described in CPT code 87635. The specimen type for all of the tests is from the nasal cavity.

The next tests we saw being developed were the severe acute respiratory syndrome (SARS) antibody tests, where serum and/or blood is collected and tested for IgG, IgM, and IgG. Again, the AMA worked quickly to update the CPT code description for 86318 to accommodate multiple antibodies, as well as create two new CPT codes to capture the tests appropriately:

- 86328, "Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])"
- 86769, "Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])"

Antibodies typically become detectable 1 to 3 weeks after the onset of symptoms. It is believed that this is the time where infectiousness is decreased and some degree of immunity from future infection has developed. However, much more data are needed to make a determination. To help minimize false positive test results, choose an assay with high specificity and also by doing what you can to make sure you are testing only those patients who have most likely been exposed to SARS-CoV-2.

As of this writing, the latest test we have seen to get approval from the Food and Drug Administration for Emergency Use Authorization (EUA) is the SARS antigen test that uses a nasal swab. There is no definitive HCPCS or CPT code for this test right now, but we were informed by the manufacturer of the only FDA-approved test that they have applied for a new CPT code to represent their product. Until that happens, our recommendation is to use HCPCS code U0002 for this particular test. This test will determine if the patient currently has the virus.

In deciding what test to purchase, you will want to consider what type of Clinical Laboratory Improvement Amendment (CLIA) waived certificate is required to perform the test in your urgent care center. CMS has stated that if the test is a point of care (POC) test and you hold a CLIA waiver certificate, you can perform and bill for the test.

Just as important in making a decision when considering the purchase of any of these tests is to make sure that the test has been approved by the FDA. You can find information on every test that has been approved by going to their website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. Here you can read the authorization letter from the FDA, including the instructions for use and the CLIA certificate required. For POC tests during the PHE period, you only need a CLIA waiver and not a certificate for moderate or high complexity as mentioned in the authorization letter. ■

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