

## A Closer Look at Coronavirus Disease 2019 (COVID-19) Diagnostic Testing

The FDA has been working around the clock to help increase the availability of critical medical products, including diagnostic tests, to fight the coronavirus disease 2019 (COVID-19) pandemic.

A patient and consumer overview<sup>1</sup> of COVID-19 testing has plain language information about both diagnostic and antibody testing for COVID-19. This comparison resource takes a closer look at diagnostic testing for COVID-19 and may be of interest to health care providers, test purchasers, and other public health professionals.

### COVID-19 Diagnostic Tests

In emergency circumstances, the FDA can issue an emergency use authorization (EUA) to provide early access to critical medical products



including medicines and tests that may help during the emergency period.

Work are to identify, screen, and monitor alternative systems that may be authorized

for emergency use that **work** that cut diagnostic selection with the virus that causes COVID-19 among acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

#### Emergency Use Authorization

The EUA process is different than the approval, clearance, or licensure because the EUA standard is more flexible than normal approval, clearance, or licensure standards. Under an EUA, the FDA must show that a product may be effective and that the known and potential benefits outweigh the known and potential

risks. The studies the FDA approves for emergency use of these products that must be either either **type** or **randomized** than **double-blind**.

The FDA has granted EUA of tests to assist for tests that performance level (sensitivity and specificity) of most rapidly receive testing capacity. As a result, the FDA grants EUA of EUA requests for point-of-care (POC) tests, home collection tests, at-home tests, tests of which had been submitted as of October 2020, tests that utilize reference test systems, and high-throughput, widely distributed tests.

#### Test performance

Sensitivity is 100% accurate, and test performance summary based on the prevalence of disease in the population being tested. COVID-19 diagnostic testing may be less accurate if you are at risk of a low prevalence of disease and if asymptomatic individuals, individuals who shed the virus, or individuals who are early in the course of illness.

Tests are assessed based on their sensitivity and specificity at two sensitivity or specificity of positive results that the test correctly identifies as positive, and a test's specificity is the fraction of negative results that the test correctly identifies as negative.

- A highly sensitive test will generally have a low false negative rate but will for some false positives if the test's specificity is low.
- A highly specific test will generally have a low false

<sup>1</sup> Visit <https://www.fda.gov/medical-products/updates/coronavirus-diagnostics>.

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