

## What are rapid diagnostics?

Rapid diagnostics are tools that help to quickly identify or diagnose health conditions, such as infectious diseases. Conducted close to the site of patient care (often referred to as the point-of-care, or POC), rapid diagnostic tests can be performed at home or in a doctor's office/clinic setting. Rapid diagnostic tests are designed to provide results using patient samples that are easy to collect and can enable immediate treatment in the case of a positive test. Key characteristics of rapid diagnostics are:

- **Speed:** Results from rapid diagnostics are available usually within an hour or less, which is crucial in acute or emergency situations and allow for immediate treatment, in the case of a positive test, often during a single visit with a health care professional.
- **Convenience:** Rapid diagnostics are designed to be easy for the patient or clinician to perform, often requiring only a biological sample such as a few drops of blood, urine, or saliva.
- **Portability:** Rapid diagnostics are typically small, lightweight, and do not require complex storage conditions, making them ideal for use in a variety of locations like at home, in the clinic, or in remote areas without electricity or major medical equipment.



*At-home lateral flow immunoassays for COVID-19.  
Shutterstock Image*

Common examples of rapid diagnostics include COVID-19 antigen tests, glucose tests for diabetes, and pregnancy tests.

### *Are rapid diagnostics accurate?*

Rapid tests approved to diagnose a patient are very accurate and have appropriate sensitivity and specificity upon which to make a diagnosis and begin treatment. Sensitivity—the ability of the test to correctly identify those with the disease or condition, and specificity—the ability of the test to correctly identify those without the disease or condition—are vital for correct diagnosis. Tests are generally measured in terms of sensitivity and specificity to determine clearance from the U.S. Food & Drug Administration (FDA).

## How are rapid diagnostics used in current medical practice?

Rapid diagnostics have become more common in clinics and homes over the past decade based on technology advancements that improved the speed, accuracy, and ease of use, all while lowering cost and improving convenience. In particular, the COVID-19 pandemic drove innovation for rapid diagnostics and new expectations for how individuals access testing.

Rapid diagnostics are used commonly as a first-line diagnostic tool. Due to their speed and low cost, these tests are perfectly placed to help rule out potential conditions as clinicians work to diagnose patients. In the event of a positive test, doctors can start treatment immediately, reducing transmission of infectious diseases. For stigmatized populations or diseases, individuals can learn of their health status in private or directly with their provider, increasing support for the individual and treatment uptake both of which may be lost if the diagnostic result is delayed. Overall, rapid diagnostics empower patients and clinicians alike with more information about a patient's health.

## How does NIBIB support the development of rapid diagnostics?



*Point-of-care hemoglobin analysis test. Shutterstock Image*

**Over-the-counter COVID-19/flu multiplex tests:** NIBIB, via the Rapid Acceleration of Diagnostics (RADx<sup>®</sup>) Tech program, has supported the development of numerous Emergency Use Authorized COVID-19 tests and has expanded this effort to multiplex COVID-19/flu A&B tests. These tests are at-home (also known as over-the-counter, or OTC) lateral flow immunoassays that test for COVID-19 and both influenza A and B at the same time, improving ease of use and convenience. These tests received clearance from the FDA, including non-emergency approvals.

**Hepatitis C POC test:** Under RADx Tech, NIBIB has supported the development of the first POC diagnostic test for hepatitis C virus (HCV). Current HCV diagnosis and treatment requires three visits to the clinic: 1) screening for exposure to HCV, 2) drawing blood and sending it to a lab for testing, and 3) returning to learn the results of the test and receive

treatment. This new POC test allows the possibility for anyone to walk into a clinic or physician's office to get tested, get results in under an hour, and start a simple oral antiviral treatment at the same visit. This test received marketing authorization from the FDA and is now available for use.

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