Compendium on rapid tests for COVID-19 offers insights

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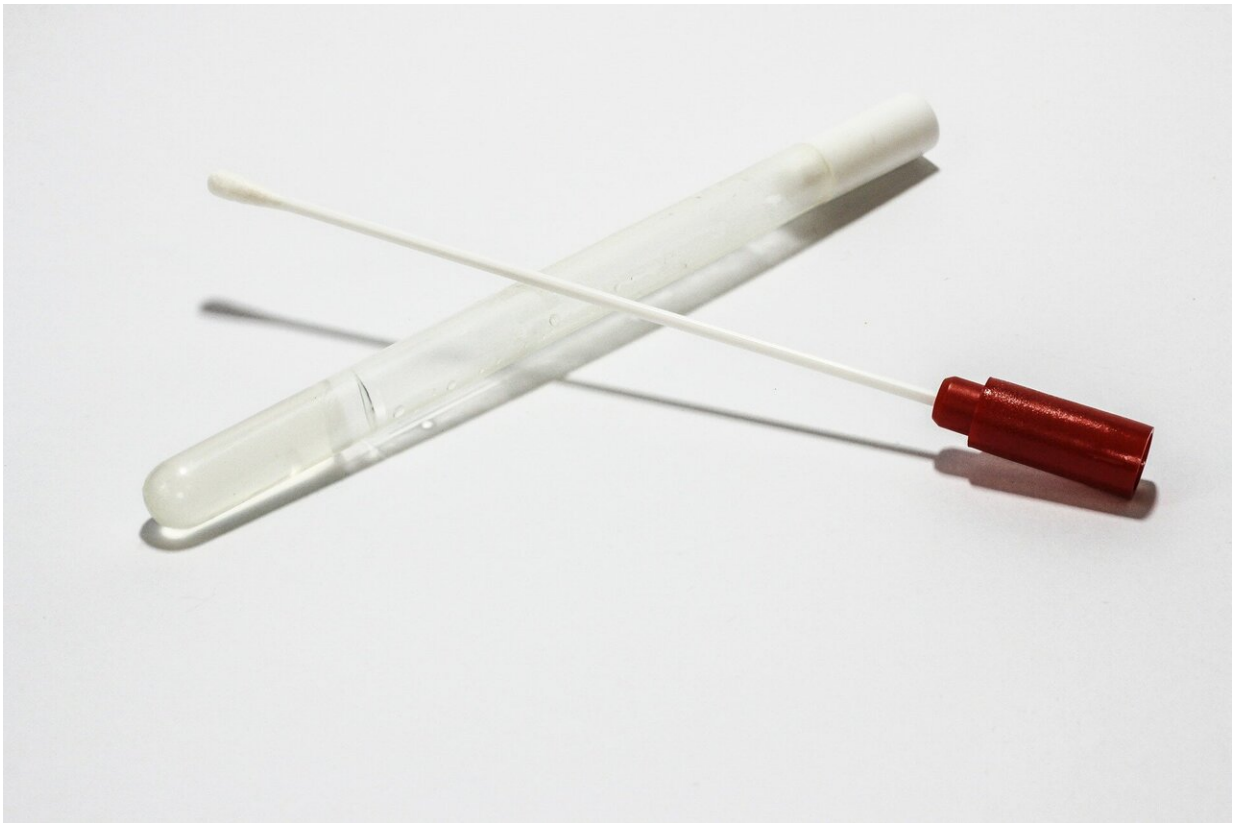

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A clinical practice article in the *New England Journal of Medicine* distills available data and clinical experience into a compendium about rapid diagnostic tests for SARS-CoV-2, the virus that causes COVID-19. The

appendix identified nearly all FDA-approved rapid diagnostic tests and their efficacy. The list is divided into home-based tests and those for use at designated testing sites (drive-through sites, schools, churches, etc.).

Dr. Paul Drain, associate professor of medicine and global health at the University of Washington School of Medicine, leads a clinical research group in the International Clinical Research Center to develop and evaluate rapid diagnostic tests for various infectious diseases.

More than 1,000 COVID-19 diagnostic tests (molecular and antigen) have been commercially developed globally. As of December 2021, the U.S. Food and Drug Administration had granted emergency use authorization to just 28 rapid diagnostic tests, while in the European Union, more than 140 were in use.

For a rapid diagnostic test to receive temporary authorization by the FDA, the World Health Organization and European Union regulatory agencies, it must have at least 80% sensitivity and 98% specificity. Approval by the FDA is also based on a prospective cohort study involving at least 30 people with SARS-CoV-2 infection and 30 people without.

Key points:

- Rapid diagnostics authorized by the FDA are either nucleic acid amplification tests to detect genes or antigen-based immunoassays to detect proteins of SARS-CoV-2.
- Rapid diagnostic tests are approved for use in people with symptoms of COVID-19 and in asymptomatic people who are close contacts of a person with COVID-19 or who have been in a potential high-risk transmission setting.
- Symptomatic people should undergo testing as soon as possible, quarantine while awaiting testing results, and consider retesting if

they had a negative rapid diagnostic test, particularly if they have a high probability of infection.

- Asymptomatic people with a known exposure to COVID-19 should undergo testing five to seven days after the exposure. If the rapid diagnostic test is negative, they should undergo testing again two days later.
- People with a known exposure to COVID-19 who are not fully vaccinated should quarantine while awaiting test results. People who test positive should isolate, contact a health provider or public health department, and inform close contacts about the infection.

"Often, when people get exposed to a person with COVID-19, they think they should get tested right away," said Drain. "In reality, they shouldn't undergo testing within 48 hours of exposure because it's not enough time for the virus to replicate and be picked up by a molecular test or antigen test."

Drain said it's imperative that rapid tests become much more available. Diagnostic companies and government officials are working to make them more accessible. People who use rapid diagnostic tests must be able to follow the test instructions and understand how to interpret the results.

While FDA guidelines stipulate that tests must show a false-positive rate of no more than 2%, that still allows one out of every 50 people to have a false-positive result. So it's important to get retested if you get a positive result and have low risk.

Weakness in evaluating home-based tests

Test manufacturers provided data to the FDA on the performance of their own diagnostics. Validation of most rapid diagnostic tests has not

been independently verified.

Clinical example

A 38-year-old woman with type 2 diabetes found out she had been exposed to COVID-19 at an indoor wedding three days earlier. The woman is asymptomatic and has had two vaccinations. She attended the wedding with her husband, who is also vaccinated, and her two unvaccinated children, five and eight. Her husband had a cough and nasal congestion.

The woman and her family are at moderate risk. All family members should be tested for COVID-19. The woman is at higher risk because she has type 2 diabetes. If the woman and her children remain asymptomatic, testing is appropriate five-seven days after exposure and can be done with a rapid diagnostic test that has received FDA approval. Quarantine is not recommended for asymptomatic people who have been vaccinated. But given the woman's unboosted vaccination status and the surge of the omicron variant, she should minimize contact with others. If the rapid test is negative, it should be repeated in two days.

The woman's husband should quarantine and be tested promptly with any FDA-approved home-based rapid diagnostic test. If the test is negative, a second test should be considered, particularly if his condition worsens. The children's return to day care or school should be guided by local regulations.

More information: Paul K. Drain et al, Rapid Diagnostic Testing for SARS-CoV-2, *New England Journal of Medicine* (2022). DOI: 10.1056/NEJMcp2117115

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