

FDA: SARS-CoV-2 antigen tests can produce false positives

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Editor's note: For the latest news on COVID-19, visit <https://www.aappublications.org/news/2020/01/28/coronavirus>.

Health authorities are warning that SARS-CoV-2 antigen tests can produce false positive results.

Antigen tests can provide rapid results but are not as sensitive as molecular tests. The Food and Drug Administration (FDA) **has notified health care providers and laboratories** that false positives can occur for a variety of reasons, including when tests are used for screening large populations with a low prevalence of infection and when users do not follow the tests' instructions.

The FDA made several recommendations for minimizing false positives.

- Follow the manufacturers' instructions for performing the tests and reading results carefully.
- Be aware of incubation time when processing multiple specimens.
- Minimize the risks of cross-contamination by carefully cleaning the workspace and using personal protective equipment.
- Keep in mind as disease prevalence decreases, the percent of false positive results increases.
- Consider positive results in combination with clinical observations and patient history.
- Report suspected false positive or false negative results to the FDA and the manufacturer.

The **AAP's interim COVID-19 testing guidance** notes antigen tests may be helpful when rapid results are required or when screening large numbers of people. However, polymerase chain reaction (PCR) tests are the "gold standard," especially when making individual clinical decisions. Clinicians may want to follow up an antigen test with a PCR test.

Children may need testing for SARS-CoV-2 infection if they have symptoms, were in close contact with a person with confirmed or probable infection or are scheduled for an invasive medical procedure such as elective surgery.

Resources

- [Centers for Disease Control and Prevention testing overview](#)
- [Food and Drug Administration \(FDA\) frequently asked questions on SARS-CoV-2 testing](#)
- [FDA information on emergency use authorizations for SARS-CoV-2 diagnostics](#)

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