



Strep A Rapid Test Fact Sheet for Healthcare Professionals

**All individuals who use this assay should carefully review the
Flowflex Plus Strep A Rapid Test Instructions for Use before they use the test.**

This Fact Sheet informs you of the significant known and potential risks and benefits of the Flowflex Plus Strep A Rapid Test Cassette and Flowflex Plus Strep A Rapid Test Strip.

WHERE CAN I GO FOR GENERAL INFORMATION ON GROUP A STREPTOCOCCUS (STREP A)?:

For general information on Strep A, including symptoms, infection control precautions, and other relevant information please check the CDC Strep A webpages (see links provided in “*Where can I go for updates and more information?*” section at the end of this document).

WHAT DO I NEED TO KNOW ABOUT STREP A TESTING WITH THIS PRODUCT?

- The Flowflex Plus Strep A Rapid Test Cassette and the Flowflex Plus Strep A Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of Group A Streptococcus antigen from throat swab specimens from symptomatic patients. The test is used to aid in the diagnosis of Group A Streptococcal infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacterium.
- Test results must always be evaluated with other data available to the physician. A negative test result might occur if the level of extracted antigen in a specimen is below the detectable level of the test. Additional follow-up testing by culture is required if the test result is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF).

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR STREP A?

A positive test result for Strep A indicates that antigens from Group A Streptococcus (Strep A) were detected in the sample, suggesting that the individual tested is infected with the bacterium and may be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak) in determining individual diagnosis and patient management decisions.

The Flowflex Plus Strep A Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, unnecessary prescription of antibiotic treatment, needless monitoring of close contacts for symptoms, or other unintended adverse effects.



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WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR STREP A?

A negative test result for Strep A indicates that antigens from Group A Streptococcus (Strep A) were not detected in the sample or the levels of antigen in the sample were below the detectable level of the test. If clinical symptoms are not consistent with results, obtain another sample for culture. It is recommended that a negative patient sample be cultured to confirm the absence of Strep A infection.

False negative results may occur if bacteria are present at levels below the test's limit of detection or if mutations are present in the regions targeted by the test. When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that Strep A is likely, and diagnostic tests for other causes of illness are negative.

Risks of a false negative test result include delayed or missed treatment, insufficient monitoring of the patient and their household or close contacts, and other unintended adverse events. For additional recommendations regarding infection control and prevention, refer to CDC's Group A Strep Infection webpage (see links provided in "*Where can I go for updates and more information?*" section).

The performance of this test was established for the 2022-2024 season. Performance may vary depending on the prevalence and the population tested, which may change over time.

WHERE DO I REPORT ADVERSE EVENTS?

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC WEBPAGES

General: <https://www.cdc.gov/group-a-strep/about/index.html>

Healthcare Professional: <https://www.cdc.gov/group-a-strep/site.html#hcp>

Public Health: <https://www.cdc.gov/group-a-strep/site.html#php>



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