



Strep A Rapid Test Cassette Frequently Asked Questions (FAQ)

Q: How does the test work?

A: The Flowflex Plus Strep A Rapid Test Cassette 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.

Q: What can this test help diagnose?

A: The test is used to aid in the diagnosis of Group A Streptococcal infection.

Q: Are there any limitations to this test?

A:

1. The Strep A Rapid Test Cassette is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacterium.
3. The accuracy of the test depends on the quality of the throat sample. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.
4. 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).
5. False negative results may occur if bacteria are present at levels below the test's limit of detection.
6. False negative results may occur if mutations are present in the regions targeted by the test.
7. Positive and negative predicted values are dependent upon prevalence. The performance was established for the 2022-2024 season. Performance may vary depending on the prevalence and the population tested.
8. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
9. Do not interchange materials from different lots of products.

Q: How accurate is the test?

A: The Strep A Rapid Test Cassette was evaluated against bacterial culture at a CLIA-certified laboratory. The test correctly identified 98.2% of positive specimens and 95.1% of negative specimens.

Q: How do I know that the test was run properly?

A: A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Q: What does it mean if a blue color appears on the test strip and sample well after sample application?

A: The appearance of a blue color on the test strip and in the sample well after the processed sample is added is normal and does not impact the test results, as this coloration is caused by the reagent dye.



[aconlabs.com](https://www.aconlabs.com)

ACON Laboratories, Inc.
9440 Carroll Park Drive
San Diego, CA 92121, USA
Tel: 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com