



Strep A Rapid Test Cassette

A rapid test for the qualitative detection of Strep A antigen in throat swab specimens.



Rapid Testing



Easy to Use



Reliable Results

Flowflex Plus Strep A Rapid Test Cassette

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.

- Throat swab specimens
- 24 months shelf life
- Excellent performance compared to lab-based throat cultures
- CLIA waived
- Result in 5 minutes
- Store between 36 to 86°F
- Includes 2 additional test cassettes for QC testing

Clinical Performance

The performance of the Flowflex Plus Strep A Rapid Test Cassette was evaluated in a multi-center field evaluation, two swabs were collected from each patient presenting symptoms of pharyngitis. One swab was used for the Flowflex Plus Strep A Rapid Test Cassette, and the other was used for a Strep A bacterial culture. Testing with the Flowflex Plus Strep A Rapid Test Cassette was performed by operators who had no prior experience in the laboratory, and were representative of the intended users. The culture plates were incubated by a CLIA-certified laboratory following standard procedures for the routine culture of Group A Streptococcus (GAS). The presence of beta-hemolytic colonies confirmed a positive result for Group A streptococci. A total of 396 patients participated in the evaluation. The results are summarized below.

Clinical Study Test Results		Lab Culture	
		Positive	Negative
Flowflex Plus Strep A Rapid Test Cassette	Positive	107	14
	Negative	2	273
	Total	109	287

Sensitivity: 107/109 = 98.2% (95% confidence interval: 93.6% - 99.5%)

Specificity: 273/287 = 95.1% (95% confidence interval: 92.0% - 97.1%)

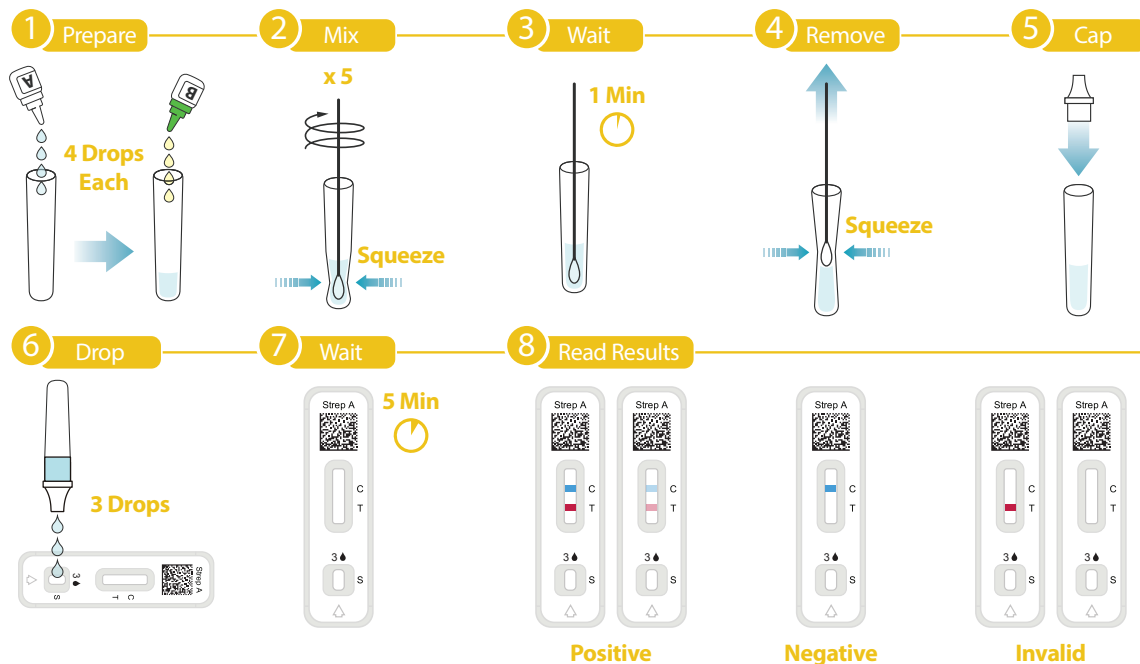
Analytical Sensitivity: Limit of Detection (LoD) :

The Limit of Detection (LoD) of the Flowflex Plus Strep A Rapid Test Cassette is 7.4×10^5 CFU/mL (3.7×10^4 CFU/swab). This was established by testing limiting dilutions of Streptococcus pyogenes (ATCC 49399) spiked into negative clinical matrix and added to swabs. The LoD was confirmed by testing 20 replicates at a specific concentration.

Materials Provided

- Test Cassettes
- Throat Swabs
- Reagent A (2M Sodium Nitrite)
- Positive Control (Heat-inactivated Group A Streptococcus)
- Test Tubes
- Package Insert
- Reagent B (0.2M Acetic Acid)
- Negative Control (Heat-inactivated Group C Streptococcus)
- Dropper Tips
- Quick Reference Instructions

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex Plus Strep A Rapid Test Cassette	L03A-R0115	Cassette	Throat Swabs	25 Tests/Kit



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