



## Strep A Rapid Test Strip

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 Strip

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.

- 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 strips for QC testing

## Clinical Performance

The performance of the Flowflex Plus Strep A Rapid Test Strip 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 Strip and the other was used for a Strep A bacterial culture. Testing with the Flowflex Plus Strep A Rapid Test Strip 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 397 patients participated in the evaluation. The results are summarized below.

| Clinical Study Test Results            |          | Lab Culture |          |
|----------------------------------------|----------|-------------|----------|
|                                        |          | Positive    | Negative |
| Flowflex Plus Strep A Rapid Test Strip | Positive | 106         | 12       |
|                                        | Negative | 3           | 276      |
|                                        | Total    | 109         | 288      |

Sensitivity:  $106/109 = 97.2\%$  (95% confidence interval: 92.2% - 99.1%)

Specificity:  $276/288 = 95.8\%$  (95% confidence interval: 92.9% - 97.6%)

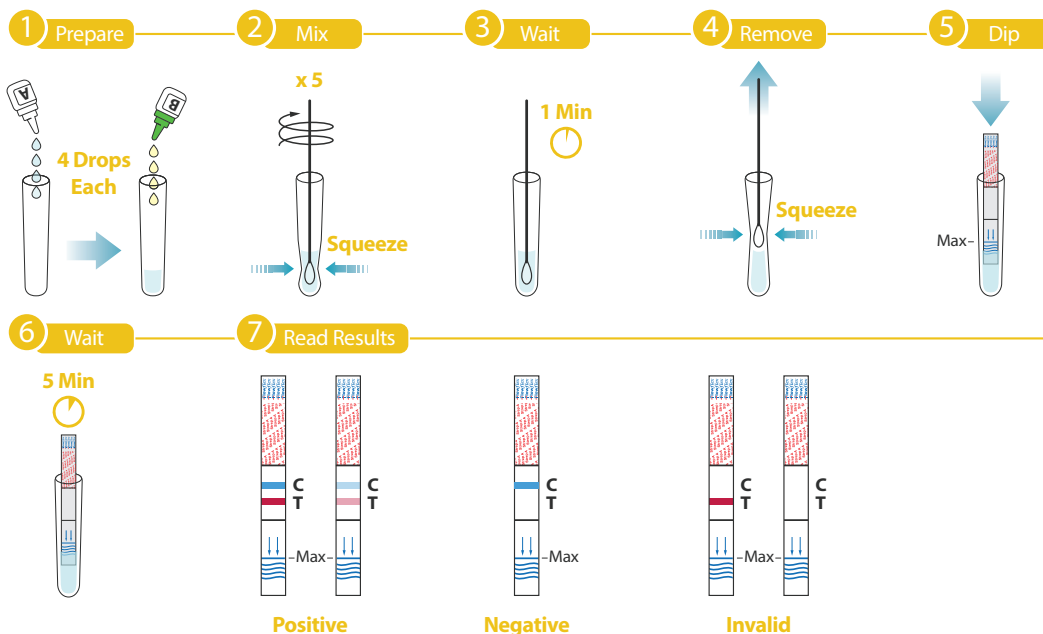
### Analytical Sensitivity: Limit of Detection (LoD) :

The Limit of Detection (LoD) of the Flowflex Plus Strep A Rapid Test Strip is  $7.4 \times 10^5$  CFU/mL ( $3.7 \times 10^4$  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 Strips
- Test Tubes
- Throat Swabs
- Package Insert
- Quick Reference Instructions
- Reagent A (2M Sodium Nitrite)
- Reagent B (0.2M Acetic Acid)
- Positive Control (Heat-inactivated Group A Streptococcus)
- Negative Control (Heat-inactivated Group C Streptococcus)

## Test Procedure and Interpretation



## Ordering Information

| Product Name                           | Catalog No. | Format           | Specimen     | Package      |
|----------------------------------------|-------------|------------------|--------------|--------------|
| Flowflex Plus Strep A Rapid Test Strip | L03A-R0125  | Strip - Pouch    | Throat Swabs | 25 Tests/Kit |
| Flowflex Plus Strep A Rapid Test Strip | L03A-R0135  | Strip - Canister | Throat Swabs | 25 Tests/Kit |



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