

CLIA WAIVED

Strep A Detection Strip

(Throat Swab)

INFECTIOUS DISEASES

CLIA WAIVED

 For prescription, *in vitro* diagnostic use only.


The Rapid Response™ Strep A Detection Strip is a rapid test for the qualitative detection of *Streptococcus pyogenes* (Group A β -hemolytic *Streptococcus*, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A *Streptococcus* bacterial infection, providing results within 5 minutes.

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Kit Content

- 25 Test Strips
- 25 Sterile Swabs
- 25 Disposable extraction tubes (One tube for each test strip)
- 1 Reagent A (10mL; 2M Sodium Nitrite)
- 1 Reagent B (10mL; 0.2M Acetic Acid)
- 1 Positive Control (1mL: Non-viable Strep A; 0.05% ProClin™ 300)
- 1 Negative Control (1mL: Non-viable Strep C; 0.05% ProClin™ 300)
- 2 Tube Holders
- 1 Instructions for Use
- 1 Quick Reference Instructions

Details

Sample: Throat swab

Format: Strip

Time-to-Result: 5 minutes

Storage Condition: 36-86°F/ 2-30°C

Test Principle: Lateral Flow Assay

\$16.53*

Medicare Reimbursement

*Estimate was determined based on previous Medicare Reimbursements for infectious agent antigen detection immunoassay with direct optical observation; *Streptococcus*, group A. Actual reimbursements may vary.

CPT Code
87880-QW


Detects Strep A Antigen

Detects antigens from *Streptococcus pyogenes* from throat swab specimens of symptomatic patients.



Rapid Testing

In just 5 minutes, test from a single swab sample and quickly determine the appropriate course of treatment.



Easy & Convenient

No specialized training or equipment required and Includes all materials needed to run the test.

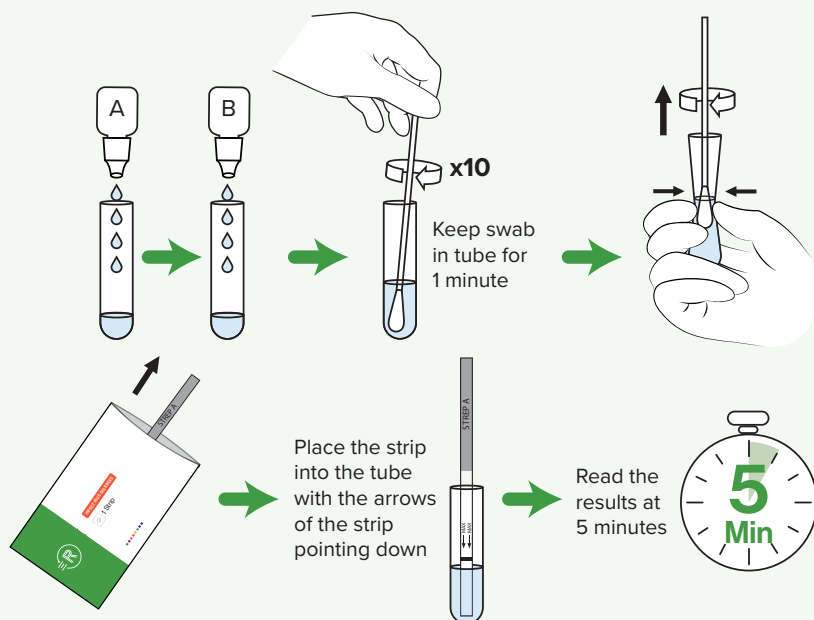


High Performance

The precision of the test results showed >90% agreement, sensitivity of 96.5%, and a specificity of 99.5%*

* Clinical study from product insert.

Strep A Detection Strip



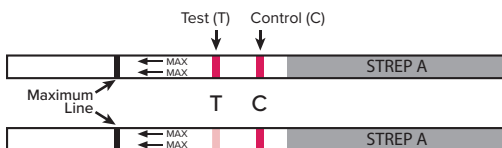
These instructions are for illustrative purposes only. Please read the instructions supplied with the test before use.

Testing Procedure

1. Place an extraction tube in the tube holder.
2. Add 4 drops of Reagent A and add 4 drops of Reagent B in the tube. Gently mix the solution.
3. Place the throat swab into the extraction tube. Mix well by rolling the swab and pressing the tip against the sides. Leave in the tube for 1 minute.
4. Remove and discard the swab while squeezing the tube.
5. Remove the test strip from the foil pouch and place the test strip into the tube with the arrows pointing down.
6. Start a timer for 5 minutes and do not touch or move the strip until the test is ready for reading.
7. After 5 minutes, read the test results.

Result Interpretation

Positive



If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive.

Negative



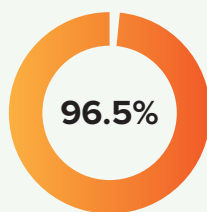
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that Strep A was not detected in the sample.

Invalid



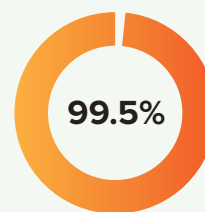
If a Control (C) line is not visible, the test is not valid. Invalid tests should be repeated with a new test.

Accuracy



Sensitivity

95% C.I. = 91.3 – 98.6%



Specificity

95% C.I. = 98.3 – 99.9%

C.I. = Confidence Interval

Ordering Information

Product Code	Product Name	Contents
STR-15SGPU-25	Rapid Response™ Strep A Detection Strip	25 Tests / Kit

To learn more contact your local **Sales Representative**, call us at **+1 888 506-2658**, or email us at **orders@lochnessmedical.com**