

iStrep™ Strep A Rapid Test Strip

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The iStrep™ Strep A Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection. Providing results within 5 minutes, the test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

BENEFITS:

- Variety of formats for flexible testing
- On board procedural control
- High sensitivity and specificity
- Room temperature storage
- Results in 5 minutes
- FDA-Cleared / CLIA Waived

Ordering Information:

Product Description	Catalog #
iStrep™ Strep A Rapid Dipstick Test Strip (25 tests)	I-ST-501
iStrep™ Strep A Rapid One-Step Test Strip (25 tests)	I-ST-502T

Reimbursement Information:

CPT Code #	National Limit Amount
87880QW	\$16.76

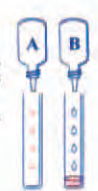
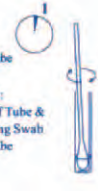
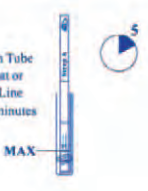
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iStrep™ Strep A Rapid Test Strip Instructions

Sensitivity 97%
Specificity 95%

Kit components
25 Test devices
25 Extraction tubes
25 Swabs
1 Procedure card
1 Reagent A
1 Reagent B
1 Positive control
1 Negative control

I-ST-501 iStrep™ A Dipstick - Waived

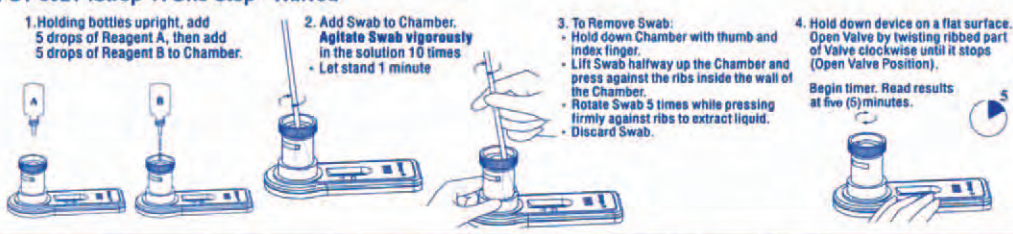
- 1**
 - Holding bottles upright, add **4 Drops** of Reagent A, then **4 Drops** of Reagent B to Tube
 - Tap bottom of Tube to mix
- 2**
 - Add Swab to Tube
 - Rotate Swab **10** times in Tube
 - Let stand **1** minute
 - To remove Swab from Tube: Press Swab against inside of Tube & squeeze Tube while removing Swab so most of liquid stays in Tube
- 3**
 - Place Test Strip in Tube
 - Liquid should be at or just below MAX Line
 - Read result at **5** minutes

Sensitivity 90%
Specificity 94%


Kit components
25 Test devices
25 Swabs
1 Procedure card
1 Reagent A
1 Reagent B
1 Positive control
1 Negative control

I-ST-502T iStrep™ A One Step - Waived

- 1.** Holding bottles upright, add **5** drops of Reagent A, then add **5** drops of Reagent B to Chamber.
- 2.** Add Swab to Chamber. **Agitate Swab vigorously** in the solution **10** times
• Let stand **1** minute
- 3.** To Remove Swab:
 - Hold down Chamber with thumb and index finger.
 - Lift Swab halfway up the Chamber and press against the ribs inside the wall of the Chamber.
 - Rotate Swab **5** times while pressing firmly against ribs to extract liquid.
 - Discard Swab.
- 4.** Hold down device on a flat surface. Open Valve by twisting ribbed part of Valve clockwise until it stops (Open Valve Position).
Begin timer. Read results at five (5) minutes.




I-ST-501 Interpretation of Results




Positive* Negative Invalid

I-ST-502 Interpretation of Results



Positive* Negative Invalid

I-ST-502T Interpretation of Results



Positive* Negative Invalid

*Any shade of red in the test region (T) should be considered positive. *Any shade of red in the test region (T) should be considered positive. *Any shade of red in the test region (T) should be considered positive.