

iStrep™

Strep A - Rapid Tests



iStrep™ A - Rapid Tests

Simple, point-of-care detection of Group A Strep

- High sensitivity at low levels of colony count
- CLIA Waived and Moderate procedures
- On board procedural control
- Results in minutes

Brands You Can Trust™



iStrep™

Strep A - Rapid Tests

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Simple, point-of-care detection of Group A Strep



iStrep™ A kit shown above.

Features

- Variety of formats..... Flexible testing
- High sensitivity and specificity..... Confidence in results
- Room temperature storage..... Convenient handling
- Results in minutes..... Rapid results for early diagnosis

Benefits

Product Code:	Kit Size:	Description:	Complexity:
I-ST-501.....	25/BX.....	Dip stick.....	CLIA Waived
I-ST-502T.....	25/BX.....	One Step.....	CLIA Waived
I-ST-502.....	25/BX.....	Cassette.....	Moderate

Instructions for iStrep™ A - Rapid Tests

Sensitivity 97%
Specificity 95%

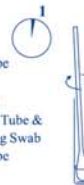
- Kit components
- 25 Test devices
- 25 Extraction tubes
- 25 Swabs
- 1 Procedure card
- 1 Reagent A
- 1 Reagent B
- 1 Positive control
- 1 Negative control

I-ST-501 iStrep™ A Dipstick - Waived

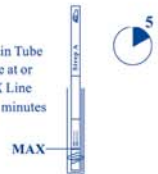
- Holding bottles upright, add **4 Drops** of Reagent A, then **4 Drops** of Reagent B to Tube
 - Tap bottom of Tube to mix



- 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



- Place Test Strip in Tube
 - Liquid should be at or just below MAX Line
 - Read result at **5** minutes



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-502 iStrep™ A Cassette - Moderate

- Holding bottles upright, add **4 Drops** of Reagent A, then **4 Drops** of Reagent B to Tube
 - Tap bottom of Tube to mix



- 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



- Add **3** drops
 - 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

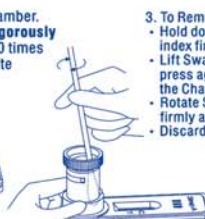
- Holding bottles upright, add **5** drops of Reagent A, then add **5** drops of Reagent B to Chamber.



- Add Swab to Chamber. **Agitate Swab vigorously** in the solution **10** times
- Let stand **1** minute



- 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.

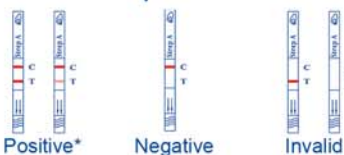


- Hold down device on a flat surface. Open Valve by twisting ribbed part of Valve clockwise until it stops (Open Valve Position).

- Begin timer. Read results at five (5) minutes.



I-ST-501 Interpretation of Results



I-ST-502 Interpretation of Results



I-ST-502T Interpretation of Results



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