

Respiratory



COVID-19

FLU A/B

RSV

STREP A

COMBO

Accurate, Simple, Rapid

Rapid Strep A Antigen Test



For Prescription Use Only



510(k) cleared



CLIA Categorization: Waived

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.

► **Fast, Reliable Results**

- **96.5% Sensitivity and 99.5% Specificity vs. Culture**
- Results in 5 minutes

► **Easy To Use**

- CLIA-waived
- Includes all necessary components to perform the test
- External positive and negative controls included

► **Storage & Stability**

- Room-temperature storage
- 24 months expiry from date of manufacture

► **Point-of-Care**

- Aid in the diagnosis of Group A Streptococcal infection
- Specimen: human throat swab

Rapid Strep A Antigen Test

KIT CONTENTS

MATERIALS PROVIDED

- 25 Test Strips
- 25 Sterile swabs
- 25 Disposable extraction tubes
- 1 Reagent A
- 1 Reagent B
- 1 Positive Control
- 1 Negative Control
- 1 Instructions for Use
- 1 Quick Reference Instructions
- 2 Tube Holders

MATERIALS REQUIRED BUT NOT PROVIDED

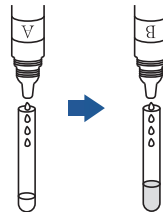
Timer, clock, or watch for specimen collection and test procedure.

TEST PROCEDURE

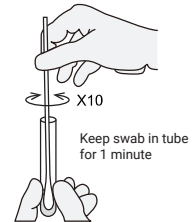
- 1** Collect throat swab sample with sterile swab



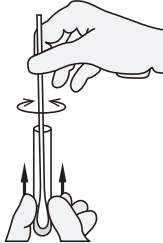
- 2** Add 4 drops of Reagent A and Reagent B to extraction tube. Swirl the tube to mix solution.



- 3** Place swab into the tube and agitate for 10 times, then wait 1 minute.



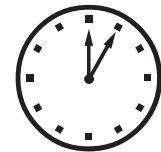
- 4** Press swab against the tube side, withdraw the swab to squeeze out liquid inside the swab. Discard the swab.



- 5** Remove test strip from pouch. Insert test strip into the extraction tube and start the timer



- 6** Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



5 minutes

INTERPRETATION OF RESULTS

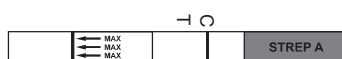
POSITIVE TEST RESULT

BOTH 'C' and 'T' are visible



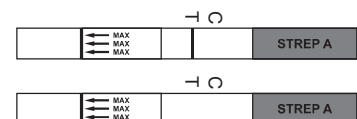
NEGATIVE TEST RESULT

ONLY 'C' Line is visible



INVALID TEST RESULT

Missing 'C' line



ORDERING INFORMATION

DESCRIPTION	REF/Catalog Number	KIT SIZE	CERTIFICATION
Healgen® Rapid Strep A Antigen Test	GCSTR-501Ca	25 Tests/Kit	510(k) CLIA Waived

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