

Strep A Plus Rapid Test Kit

QUICK REFERENCE INSTRUCTIONS

CLIA Categorization: Waived

[ND] [R only]

A Certificate of Waiver is required to perform this test in a CLIA Waived environment. Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test 42 CFR 493.15(e)(1). Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

These are not the full instructions For Use.

Carefully read the instructions for Use (IFU) before performing the test. Failure to follow the instructions may result in inaccurate test results.

Collect the specimen using the sample collection procedure, prior to starting the Test Procedure. More detailed instructions can be found in the **SPECIMEN COLLECTION** section of the IFU.

SAMPLE COLLECTION

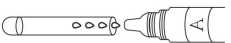
Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.



- Only use the reagents and sterile swabs provided in the kit.
- For best results, throat swabs should be tested immediately after collection. If immediate testing is not possible, a direct throat swab may be stored in a clean, dry plastic tube for 2-4 hours at room temperature (15-30°C/59-86°F) or 24 hours at 2-8°C (36-48°F).
- If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Rapid Strep A Antigen Test.

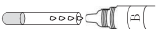
TEST PROCEDURE

- Place an empty extraction tube in the tube holder. Hold the Reagent A bottle vertically over an empty extraction tube and add 4 full drops of Reagent A. Reagent A is light red in color.

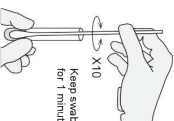


TEST PROCEDURE

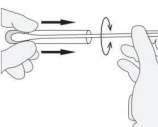
- Hold the Reagent B bottle vertically over the same tube and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube.



- Immediately place the throat swab into the extraction tube. Mix well by rolling the swab in a circular motion at least 10 times. Press the swab tip against the bottom and sides of the tube while rolling. Leave the swab in the tube for 1 minute.



- Remove the swab while pressing the swab against the side of the tube and squeezing the bottom of the tube as the swab is withdrawn. Discard the swab.



- Remove the test strip from the foil pouch. Do not touch the bottom of the strip. Place the test strip into the tube with the arrows of the strip pointing down. Start a timer for 5 minutes. Do not handle or move the strip until the test is complete and ready for reading.

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- After 5 minutes, read the tests results visually in the results window, labeled as "C" and "T" on the test strip.



Do not read the results before 5 minutes or after 10 minutes.

POSITIVE TEST RESULT

BOTH 'C' and 'T' are visible



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 TEST RESULT

ONLY 'C' Line is visible



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.

NOTE: Negative results are presumptive and should be confirmed by bacterial culture.

INVALID TEST RESULT

Missing 'C' line



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

NOTE: Insufficient specimen volume, incorrect operation procedure, or the use of expired tests are the most likely reasons for control band failure.

EXTERNAL QUALITY CONTROL

In addition to your laboratory's standard quality control procedures, it is recommended that positive and negative external controls be tested at least once per kit lot for number and by each new untrained operator. This will verify that the reagents and test strips are working properly, and the operator is able to correctly perform the test procedure.

Procedure for External Quality Control Testing

- Hold the Reagent A bottle vertically over an empty extraction tube and add 4 full drops of Reagent A. Reagent A is light red in color.
- Over the same tube and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube.
- Add 1 full drop of positive or negative control solution into the tube, holding the bottle vertically.
- Place a clean swab into the extraction tube. Mix well by rolling the swab in a circular motion at least 10 times. Press the swab tip against the bottom and sides of the tube while rolling. Leave the swab in the tube for 1 minute.
- Remove the swab while pressing the swab against the side of the tube and squeezing the bottom of the tube as the swab is withdrawn. Discard the swab.
- Continue with Step 5 in the TEST PROCEDURE Section. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact Technical Services or Customer Support.

WARNINGS & PRECAUTIONS

- Do not use the test kit beyond the expiration date printed on the pouch.
- This test is only for use in patients with symptoms.
- Negative results are presumptive and should be confirmed by culture.
- Store as packaged in the original sealed pouch either at room temperature or refrigerated (2-30°C/36-86°F). **DO NOT FREEZE** any of the test kit components [below 0°C(32°F)]. The test strip is stable through the expiration date printed on the sealed pouch. Do not use the test device or reagents after the expiration date. The test strip must remain in the sealed pouch until use.



For Symbol Glossary, refer to Instructions for Use.

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