

## Instructions for Use

Version: 1.0.1

Revision date: 4-Jul-25

### Streptococcus A Rapid Test Kit

**Catalog No:** abx472048

**Size:** 20 tests

**Storage:** Store all reagents at 2 — 30°C. Keep dry.

**Application:** For qualitative detection of Streptococcus A in throat swabs.

#### Introduction and assay principle

Abbexa's Streptococcus A Rapid Test Kit detects Streptococcus A through visual interpretation of color development on the internal strip. Streptococcus A (whole cell Lancefield) carbohydrate antigen-specific antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti- Streptococcus A carbohydrate antigen antibodies which are conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient Streptococcus A carbohydrate antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that sufficient volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

#### Kit Components

- Test cassettes: 20
- Extraction tubes: 20
- Polyester swabs: 20
- Positive Control (contains NaN3): 1 ml
- Negative Control (contains NaN3): 1 ml
- Reagent A (2 M sodium nitrate): 10 ml
- Reagent B (0.2 M acetic acid): 10 ml

#### Material Required But Not Provided

- Timer

#### A. Sample preparation

It is recommended that specimens be tested immediately after collection. If this is not possible, place swab specimens in a dry transport tube for storage or transport. The swabs may be stored for 8 hours at room temperature (15-30°C) or for up to 3 days at 2-8°C. Transport swabs containing modified Stuart's or Amies medium can be used with this product. Do not freeze.

- **Throat swabs:** Insert the fabric end of the swab into the mouth, avoiding contact with the tongue, cheeks and teeth. Rub the swab against the tonsils, posterior pharyngeal wall, or any inflamed areas, with firm contact.

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### B. Assay procedure

#### 1. Throat swab specimens:

Allow all components to equilibrate to room temperature before testing.

1. Remove the test device from the foil pouch and perform test immediately.
2. Hold Reagent A vertically and add 4 drops to a clean extraction tube. Hold Reagent B vertically and add 4 drops to the same extraction tube. Reagent A is red, and Reagent B is colorless.
3. Mix the solution gently by swirling the extraction tube. The solution will change from red to yellow.
4. Immediately insert the swab into the extraction tube, and agitate the swab 10 times. Leave the swab to stand in the tube for 1 minute.
5. Press the swab against the side of the tube and withdraw the swab whilst squeezing the tube. Fasten the dropper tip on top of the extraction tube and discard the swab.
6. Take a test cassette and lay it flat on a clean table. Holding the extraction tube vertically, slowly add 3 drops of extracted sample to the sample well (S) on the test cassette. *Avoid trapping air bubbles in the sample well. Do not add solution to the result window.*
7. Leave at room temperature for 5 minutes, then analyze the result. Results should not be interpreted after 10 minutes.

#### 2. Positive and Negative Controls:

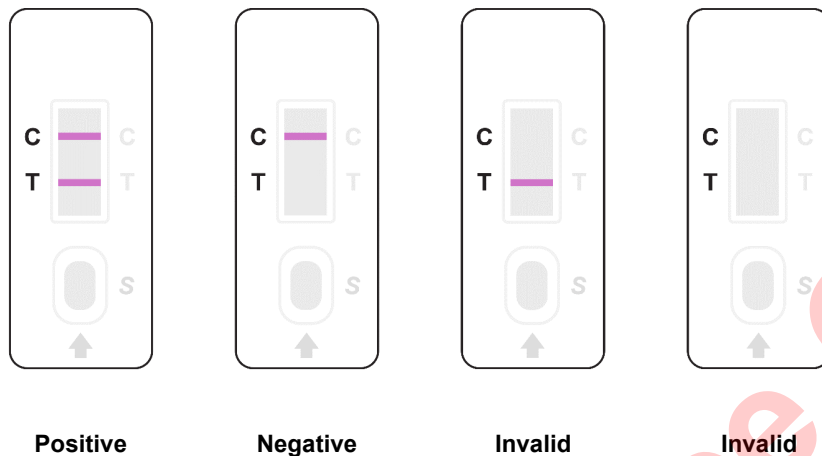
1. Remove the test device from the foil pouch and perform test immediately.
2. Hold Reagent A vertically and add 4 drops to a clean extraction tube. Hold Reagent B vertically and add 4 drops to the same extraction tube. Reagent A is red, and Reagent B is colorless.
3. Mix the solution gently by swirling the extraction tube. The solution will change from red to yellow.
4. Add 1 drop of Positive or Negative Control solution to the extraction tube.
5. Place a clean swab into the extraction tube, and agitate 10 times. Leave the swab to stand in the tube for 1 minute.
6. Press the swab against the side of the tube and withdraw the swab whilst squeezing the tube. Fasten the dropper tip on top of the extraction tube and discard the swab.
7. Take a test cassette and lay it flat on a clean table. Holding the extraction tube vertically, slowly add 3 drops of extracted control solution to the sample well (S) on the test cassette. *Avoid trapping air bubbles in the sample well. Do not add solution to the result window.*
8. Leave at room temperature for 5 minutes, then analyze the result. Results should not be interpreted after 10 minutes.

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### Results analysis

- **Positive result:** A colored line is observed in both the control (C) section and the test (T) section.
- **Negative result:** A colored line is observed in the control (C) section but not the test (T) section.
- **Invalid result:** No colored line is observed in the control (C) section.



### Notes:

1. Read the entire procedure carefully prior to testing.
2. The test cassettes should be brought to room temperature before use.
3. After opening the aluminium foil, use the test cassette as soon as possible.
4. Samples should be clear with no visible particles, turbidity, or bacterial pollution.
5. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
6. Avoid touching the cassette membrane through the sample well or test result window.
7. This kit is for the qualitative detection of Streptococcus A in throat swab specimens. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
8. This test will determine the presence of Streptococcus A in both viable and non-viable Group A Streptococcus bacteria.
9. A negative result may be obtained if the concentration of Streptococcus A in the throat swab is below the detectable level of the test. Therefore negative test results should be confirmed by culture.
10. Excess blood or mucus on the swab can cause a false positive result. Avoid touching the tongue, cheeks, teeth, and any bleeding areas when collecting samples.
11. Only the sterile swabs provided in this kit should be used for sample collection.
12. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
13. All waste should be disposed of appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.
14. No meaning should be inferred from the color intensity or width of any apparent bands.

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15. Do not eat, drink or smoke in any area where specimens and kits are handled.
16. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
17. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
18. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately.
19. Humidity and temperature can adversely affect results.

### Technical Support

For troubleshooting and technical assistance, please contact us at [support@abbexa.com](mailto:support@abbexa.com).

For Reference Only