

Chemtrue[®]
Rapid Strep A Test

For In Vitro Diagnostic Use
Product Code: 8006C

INTENDED USE

The Chemtrue[®] Rapid Strep A Test is a lateral flow, immunoassay for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs.

SUMMARY

Beta-haemolytic Group A Streptococcus is a major cause of upper respiratory infection such as tonsillitis, pharyngitis and scarlet fever. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications, such as rheumatic fever and glomerulonephritis.

Conventional methods used for the detection of the disease depend on the isolation and subsequent identification of the organism. These methods often require 24 - 48 hours to complete. Developments in immunological techniques, which can detect Group A Streptococcal antigen directly from throat swabs, allow physicians to diagnose and administer therapy immediately.

PRINCIPLE

The Chemtrue[®] Rapid Strep A Test utilizes two-site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The test device consists of plastic housing containing a membrane strip which has been pre-coated with rabbit anti-Strep A antibody on the test band region and goat anti-rabbit antibody on the control line region. A colored rabbit anti-Strep A polyclonal antibody-colloid gold conjugate pad is placed at the end of the membrane. During testing, the Strep A antigen is extracted from the throat swab using Sample Extraction Buffer and tablet. The extracted solution is then added to the sample well. The Strep A antigen reacts with colored antibody-colloidal gold conjugate to form Strep A antigen-antibody complexes. The mixture then moves chromatographically across the membrane to the immobilized rabbit anti-Strep A antibody at the test line region. If Strep A antigen is present in the specimen, a red colored sandwich of solid phase/Strep A antigen/gold conjugate is formed on the test line region. Absence of the red line at the test line region indicates a negative result. Regardless of the presence of Strep A antigen, as the extracted mixture continues to move laterally across the membrane to the immobilized goat anti-rabbit antibody test region, a red line at the control region will always appear. The presence of this colored band serves as: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained and 3) reagent control.

CONTENTS OF KIT

- 20 sealed pouches including: 1 test cassette and 1 extraction tube containing a tablet
- 1 Sample Extraction Buffer: (15ml)
- Sterile Throat Swabs

MATERIALS REQUIRED BUT NOT SUPPLIED

- Timer

STORAGE AND STABILITY

The test kit is to be stored at temperature (4-30°) in the sealed pouch for the duration of its shelf-life.

PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as swabs, Strep A test devices and extracts should be properly disposed of.
- To obtain accurate results, package insert instructions must be followed.

SPECIMEN COLLECTION AND STORAGE

- Collect throat swab specimens by standard clinical methods such as those described by Fachlam and Ross. Use only Dacron or Rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- It is recommended that swabs specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped tube or bottle and refrigerated. If liquid transport methods are employed, use Modified Stuart's Transport Media as outlined in the manufacture's instructions. Do not use transport media formulas including charcoal or agar. Swabs can be stored at room temperature up to 4 hours, or refrigerated (4-8°C) up to 24 hours.
- If a bacteria culture is desired, lightly streak the swab on a 5% sheep blood agar plate before using it in the Chemtrue[®] Rapid Strep A Test. Extraction reagents kill the bacteria on swabs and make them impossible to culture. Alternatively, a subsequent second swab sample may be taken for culture procedure.

TEST PROCEDURE

Procedural Notes

- If specimen swabs or any Chemtrue® Rapid Strep A Test reagents have been refrigerated, allow them to equilibrate to room temperature before testing.
- Label the device with patient or control identification. To avoid cross contamination, do not allow the tips of the reagent bottles to come in contact with sample swabs and Extraction Tubes.

Extraction Procedure

- Remove the cap from the Extraction Tube and add 9 - 11 drops of Extraction Buffer to the line marked on the Extraction Tube.
- Place the throat swab specimen in the Extraction Tube. Press the swab against the tablet until it is completely dissolved (about 1 - 2 minutes).
- Squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Discard the swab.

Test Procedure

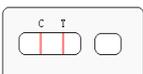
- Re-Cap the Extraction Tube with the attached dropper. **Add 3 drops of all** the extracted solution to the sample well of the test cassette.
- Read result in 5 minutes. Depending on the number of organisms on the swab, a positive result may be visible as soon as 1 minute. However, to confirm a negative result the complete reaction time of 5 minutes is required. Do not read result after 10 minutes.

INTERPRETATION OF RESULTS

Positive

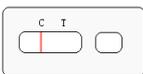
Two colored lines are observed in the Result Window. The line in the test region (**T**) is the test line; the line in the control region (**C**) is the control line, which is used to indicate proper performance of the test.

The color intensity of the test line may be weaker or stronger than that of the control line.



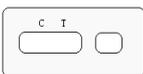
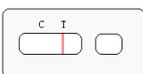
Negative

Only the control line (C) appears in the Result Window, but the test line (T) is not visible.



Invalid

No line appears in the control (C) region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not appear, the test result is inconclusive and the assay should be repeated with a new test.



LIMITATION OF PROCEDURE

- The accuracy of the test depends on the quality of the swab sample. A false negative may result from improper sample collection or storage. A negative result may be obtained from patients at the onset of the disease due to low antigen concentration. Therefore, when a patient is suspected of having infection, additional testing using the culture method is required.
- The test does not differentiate asymptomatic carriers of Group A Streptococcus from those with infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up throat culture is recommended.
- In rare cases, test specimens heavily colonized with Staphylococcus aureus can yield false positive results. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture procedure should be performed.
- Respiratory infections, including pharyngitis, can be caused by Streptococci from serogroups other than Group A, as well as by other pathogens.
- As in the case of any diagnostic procedure, the results obtained with this test should be used in conjunction with other information available to the physician.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

Sensitivity Study

To determine the analytical sensitivity of the Chemtrue® Rapid Strep A Test, Group A Streptococcus bacteria were grown in broth culture. The detection limit of the Chemtrue® Rapid Strep A Test was determined to be 2.5×10^5 organisms per test.

Specificity Study

To determine the specificity of the Chemtrue® Rapid Strep A Test to Group A Streptococcal bacteria, the following Group A Streptococcal Strains at different levels of organisms per test were examined. Positive results obtained at the level of 2.5×10^5 organisms/test for all Strep A strains indicate that Chemtrue® Rapid Strep A Test is sensitive to all Group A Streptococcal bacteria.

Group A Streptococcal Strains:

SS-091 SS-410 SS-492 SS-496
 SS-633 SS-634 SS-635 SS-721
 SS-754 SS-799 ATCC-19615

- Sensitivity: 91.3%
- Specificity: 92.1%
- Overall accuracy: 91.8%

Cross-reactivity

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also performed using the Chemtrue® Rapid Strep A Test. The following organisms were tested at 1 × 10⁸ organisms/test.

Group B Streptococcus	Group C Streptococcus
Group D Streptococcus	Group F Streptococcus
Group G Streptococcus	Pseudomonas aeruginosa
Streptococcus bovis	Staphylococcus aureus
Proteus vulgaris	Streptococcus faecalis
Staphylococcus epidermidis	Escherichia coli
Staphylococcus saprophyticus	Streptococcus mitis
Corynebacterium diphtheriae	Neisseria lactima
Neisseria gonorrhoeae	Streptococcus pneumoniae
Streptococcus mutans	Moraxella catarrhalis
Bordetella pertussis	Neisseria sicca
Neisseria meningitidis	Streptococcus sanguis
Streptococcus salivarius	Candida albicans
Neisseria subflava	Haemophilus parahaemolyticus

Negative results in all above cases indicate that the Chemtrue® Rapid Strep A Test is specific to Strep A bacteria only.

Correlation Study

- A correlation study of the Chemtrue® Rapid Strep A Test and conventional culture tests has been determined in multi-center clinical evaluations. Throat swab specimens were taken from patients exhibiting symptoms of pharyngitis. The swabs were then used to inoculate blood agar plates prior to testing with the Chemtrue® Rapid Strep A Test. Beta-hemolytic colonies from the blood agar plates were confirmed as Group A Streptococcus using serologic streptococcal grouping methods. Strep A was reported as present or not present.
- The qualitative results are summarized as follows:

		Chemtrue® Strep A		Total
		+	-	
Culture	+	21	2	23
	-	3	35	38
Total		24	37	61

Physician Office Laboratory Studies

An evaluation of Chemtrue® Rapid Strep A Test was conducted at three physician Office Laboratory sites, using a panel of coded samples containing Negative Control, Low positive, Medium Positive and High Positive specimens. One hundred percent (100%) agreement to the expected results was obtained.

REFERENCES

1. Facklam, R.R. and Carey, R.B. Streptococci and Aerococci, Manual of Clinical Microbiology, 4th ed, Lennette, E.H. Balows, A. Hausler, W.J. and Shadomy, H. J. (eds), American Society for Microbiology, 1985.
2. Levinson, M.L. and Frank P.K. Differentiation of Group A from other Beta Hemolytic Streptococci with Bacitracin, J. Bacteriol. 69,284-287(1995).
3. Edwards, E.A. Phillips, I.A. and Suiter, W.C. Diagnosis of Group A Streptococcal Infections Directly from Throat Secretions, J. Clin. Micro. 15,481-483 (1982).
4. Gupta, R. Talwar, G.P. and Gupta, S.K. Rapid Antibody Capture Assay for Detection of Group A Streptococci Using Monoclonal Antibody and Colloidal Gold-Monospecific Polyvalent Antibody Conjugate, J. Immunoassay, 13,441-445(1992).
5. Rose P.W. Throat Swabs and Swabbing Technique, The Practitioner, 207,791-796(1971).
6. Lauer, B.A. Rellar, L.B. and Mirrett, S. Effect of Atmosphere and Duration of Incubation on Primary Isolation of Group A Streptococci from Throat Cultures, J. Clin. Micro. 17,338-340.(1983).

Revised 31.03.2010
 Code: Q8496 Edition: B



Shanghai Chemtron Biotech Co., Ltd.

118 West Heli Rd., Xia Sha Industrial Park,
 Pudong New District, Shanghai 201317, P.R.C
 www.chemtronbio.com



Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany
 Tel: 0049-40-2513175
 Fax: 0049-40-255726