Ref 337 Strep A Test Kit (20t)

CYPRESS DIAGNOSTICS

STREP A

A qualitative test kit for the detection of streptococcal group A antigen from throat swabs

**Intended Use**
The Cypress Diagnostics’ Strep A test is a rapid immunochromatographic screening test for the detection of group A streptococcus antigen from throat swab specimens.

**Summary and Explanation**
Beta-hemolytic group A streptococcus (S. pyogenes) is the most common bacterial agent associated with upper respiratory tract infections in humans. The most commonly occurring group A streptococcal disease is pharyngitis. Males and females are equally affected by group A streptococcus. Seasonal increases in the prevalence of group A streptococcus occur. Streptococcal pharyngitis is most prevalent in winter and early spring with the higher incidence of disease occurring in crowded populations such as school children. A severe form of streptococcal infection causes streptococcal toxic shock syndrome (STSS) which is associated with invasive soft tissue infections and the early onset of shock and organ failure. Invasive group A streptococcal infection and STSS have increased the cause of morbidity and mortality among children and adults.

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.

The conventional methods used for identification of group A streptococci depend on the isolation and identification of the organism on blood agar plates. These methods usually require 18-24 hours of incubation at 37°C. This delay in identifying group A streptococcus often caused physicians to administer therapy without first knowing the etiological agent.

With the development of immunologic tests capable of detecting group A streptococcal antigen directly from throat swabs rapid test results can now be achieved for better patient treatment.

**Principle of the Test**
The method employs a unique combination of anti-Strep A antibody using a colloidal gold dye conjugate and solid phase anti-Strep A antibodies to selectively identify group A streptococcus with high degree of sensitivity and specificity.

During testing, the Strep A antigen is extracted from the throat swab using Extraction Reagents A, B and C. The extracted solution is then added to the sample well.

As the extracted sample flows through the sample pad, the labelled antibody-dye conjugate binds to the Strep A antigen forming an antibody antigen complex.

This complex binds to the anti-strep A antibody in the TEST area (T) of the device producing a pink colored line.

In the absence of Strep A antigen there is no line visible in the TEST area (T). The extracted sample continues to migrate along the membrane past the TEST area and to the CONTROL area (C) on the test device.

The unbound conjugate binds to the reagents in the CONTROL area (C) producing a pink colored line demonstrating that the reagents are functioning properly, sufficient volume has been added and a proper flow is obtained.

**Content of the Kit**
Each kit contains items to perform 20 tests:
1. test device and extraction tube in sealed pouch - 20
2. Reagent A : NaOH (5 ml).
   Reagent B : Acid (5 ml).
   Reagent C : Oxidation reagent (5 ml).
4. Instruction leaflet

Additional material required : Timer.

**Storage and Stability**
The Strep A test devices should be stored at any temperature between 4-30°C in the original sealed pouch.

The extraction reagents should be stored at 4-30°C in the original vials. The kit is stable until the date imprinted on the box label and/or pouch.

NOTE : Do not use expired test kits.
CAUTION: DO NOT FREEZE TEST KITS
**Precautions**

1. The test is designed for IN VITRO DIAGNOSTIC. Use only. For PROFESSIONAL USE only. Use the test only in accordance with instructions supplied with the kit.
2. Handle all specimens as recommended for any potentially infectious specimen.
3. Use suitable protective clothing (gloves, lab coat, safety glasses) when handling the kit or samples before performing the assay. Avoid any contact between hands, eyes, nose or mouth during specimen collection and testing.
4. Extraction Reagent B is slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with large volumes of water.
5. Do not mix reagents from different lots of test kits and do not mix vial caps.
6. Proper disposal of contaminated waste such as swabs, extract and reaction device should be performed in biohazard bags.

**Specimen collection and storage**

To obtain the best results, specimens should be collected using standard throat swab collecting methods such as those described by Facklam and Ross. Use only Dacron or Rayon tipped sterile swabs with plastic shafts such as those provided. Do not use swabs with cotton or calcium alginate tips or wooden shafts.

Patient samples perform best when tested immediately after collection. If immediate testing is not possible, the patient sample should be placed in a dry plastic tube or bottle and refrigerated. If a liquid transport methods is 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 (10-30°C) 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 Cypress 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**

**Extraction procedure**

1. Allow test device, buffers and samples to equilibrate to room temperature before testing.
2. Remove the required number of test devices from their wrappers by tearing along the notched area and place on a flat surface area.
3. Label the test unit with patient name or identification number.
4. To avoid cross contamination, do not allow the tips of the reagent bottles to come in contact with sample swabs and Extraction Tubes.
5. Take an Extraction Tube and add 4 drops of Extraction Reagent A to the Extraction Tube.

6. Add 4 drops of Extraction Reagent B to the tube. Immediately place the throat swab specimen in the tube. Use a circular motion to roll the swab against the side of the Extraction Tube so that the liquid is expressed from the swab and reabsorbed. Let stand for a minimum of 1 minute at room temperature and maximum of 15 minutes.

7. Add 4 drops of Extraction Reagent C to the tube. Squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Discard the swab.

**Test procedure**

1. Cap the Extraction Tube with the attached dropper. Add 3 drops of all the extracted solution to the sample well of the test device.
2. 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**

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<tr>
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<th>S</th>
<th>C</th>
<th>T</th>
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<tbody>
<tr>
<td><strong>Positive</strong></td>
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<td>X</td>
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</tr>
<tr>
<td><strong>Negative</strong></td>
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<td></td>
<td>X</td>
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<tr>
<td><strong>Invalid</strong></td>
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**Positive**

Two pink colored lines, one in the CONTROL area (C), and a clearly distinguishable pink colored line in the TEST area (T) indicates a positive result.

**Negative**

Only one pink colored line in the CONTROL area (C), with no colored line in the TEST area (T) indicates a negative result.

**Invalid**

A pink colored line should always appear in the CONTROL area (C), no matter if the TEST LINE appears or not. If there is no distinct pink/purple line visible in the CONTROL area (C), the test is inconclusive. In that case, it is recommended that the test be repeated.

**Quality Control**

A pink colored line should always appear in the control area if the test is performed correctly and the device is working properly. It serves as an internal procedural positive control.

Good laboratory practice recommends the use of control materials along with the test samples to ensure proper performance of test kit. Commercial positive and negative controls should be used for this purpose.
Limitations of the test

- The accuracy of the test depends on the quality of the swab sample. 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 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 auras 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.

Performance Characteristics

Sensitivity

The sensitivity of this Strep A test was determined to be 2.5 x 10^5 organism/ml.

Specificity

- To determine the specificity of the Cypress Diagnostics’ 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 x 10^5 organisms/test for all Strep A strains indicate that Cypress Diagnostics’ 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

Cross-reactivity

Studies with organisms likely to be found in the respiratory tract were also performed using the Cypress Diagnostics’ Strep A Test. The following organisms were tested at 1 x 10^6 organisms/test.

Group B Streptococcus  Group C Streptococcus  Group D Streptococcus
Group G Streptococcus  Pseudomonas aeruginosa  Group F Streptococcus
Streptococcus bovis  Staphylococcus aureus
Proteus vulgaris  Streptococcus faecalis
Staphylococcus epidermidis  Escherichia coli
Staphylococcus saprophyticus  Streptococcus mitis
Corynebacterium diphtheriae  Neisseria lactam
Neisseria gonorrhoeae  Streptococcus pneumoniae

Negative results in all above cases indicate that the Cypress Diagnostics Strep A Test is specific to Strep A bacteria only.

Correlation Study

- A correlation study of the Cypress Diagnostics Strep A Test and the 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 Cypress Diagnostics’ 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:

<table>
<thead>
<tr>
<th>Culture</th>
<th>Cypress Diagnostics Strep A</th>
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<tbody>
<tr>
<td>+</td>
<td>+  21 2 23</td>
</tr>
<tr>
<td>-</td>
<td>3 35 38</td>
</tr>
<tr>
<td>Total</td>
<td>24 37 61</td>
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Sensitivity: 91.3%
Specificity: 92.1%
Overall accuracy: 91.8%

Evaluation Studies

An evaluation of Cypress Diagnostics’ 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.

Bibliography


Langdorp, 10.2009