**Strep A cassette**

**CONTENTS**

<table>
<thead>
<tr>
<th>REF</th>
<th>4280225</th>
<th>Strep A</th>
<th>25 tests</th>
</tr>
</thead>
</table>

For professional in vitro diagnostic use only

---

**Strep A**

A rapid test for the qualitative detection of Strep A antigen in throat swab specimens.

**ONE STEP**

**PRINCIPLE**

The Linear Strep A Test is a rapid qualitative, lateral flow immunoassay for the detection of Strep A antigen in a throat swab. In this test, antibody specific to Strep A antigen is coated on the test line region of the strip. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a red line in the test region. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a red line will always appear in the control region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENT COMPOSITION AND PACKAGING CONTENTS**

- Individually packed test cassette
- Reagent A 1.0 M sodium nitrite
- Reagent B 0.4 M acetic acid
- Positive control Non-viable Strep A; 0.09% sodium azide
- Negative control Non-viable Strep A; 0.09% sodium azide
- Sterilized swabs For specimen collection
- Extraction tubes For specimen preparation
- Workstation For specimen preparation

Reagent A and Reagent B, T: Toxic; R25 Toxic if swallowed

**STORAGE AND STABILITY**

Store at 2-30°C.

The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

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.

It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed in a sterile, dry, tightly capped tube or bottle and refrigerated. Do not freeze. Swabs can be stored at room temperature (15-30°C) up to 4 hours, or refrigerated (2-8°C) up to 24 hours. All specimens should be allowed to reach room temperature (15-30°C) prior to testing.

**MATERIALS REQUIRED**

- Timer (not provided)

**PROCEDURE**

Allow the test device, reagents, and/or controls to reach room temperature (15-30°C) prior to testing.

Prepare swab specimens:
1. Place a clean extraction tube in the designated area of the workstation. Add 4 drops of reagent A (approximately 280 μL) to the extraction tube, then add 4 drops of reagent B (approximately 280 μL). Mix the solution by gently swirling the extraction tube.
2. Immediately immerse the swab into the extraction 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 can reabsorb.
3. Let stand for 1-15 minutes at room temperature, then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Cap the extraction tube with the attached dropper tip. Discard the swab following guidelines for handling infectious agents.

Test:
2. Fit the dropper tip on top of the extraction test tube. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch, and place it on a clean, level surface.
3. Add 3 drops (approximately 100 μL) of extracted solution to the sample well on the test device. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the observation window.
4. As the test begins to work, color will migrate across the membrane.
5. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

POSITIVE:* Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). A negative result indicates that Strep A antigen is not present in the sample, or is present below the detectable level of the test. The patient’s sample should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.

---

**QUALITY SYSTEM CERTIFIED**

ISO 9001 ISO 13485

LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es
INVALID: Control line fails to appear. Insufficient sample 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control, Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Quality Control, In addition to your laboratory’s standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each 25-test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure. External positive and negative controls are supplied in the kit.

CLINICAL SIGNIFICANCE

Streptococcus pyogenes is a non-motive gram-positive coccus, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and pansensitivis abscesses. Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer. Rapid diagnosis and early antibiotic therapy of Group A Streptococci infection appear to be the best means of preventing medical complications and reducing the spread of the disease.

EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta-hemolytic Streptococcus. In school-aged children and adults, the incidence of Strep throat infection is about 40%. This disease usually occurs in the winter and early spring in temperate climates.

ANALYTICAL PERFORMANCE

Sensitivity and Specificity

To determine the analytical sensitivity of the test, Group A Streptococcus bacteria organisms were grown by standard culture techniques. The detection limit of the Strept A Rapid Test (Swab) was determined to be 1×10⁷ organisms / test.

Correlation Study

<table>
<thead>
<tr>
<th>Table: Strept A Rapid Test vs. Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strept A Rapid Test</strong></td>
</tr>
<tr>
<td>Culture</td>
</tr>
<tr>
<td>1×10⁴</td>
</tr>
<tr>
<td>5×10³</td>
</tr>
<tr>
<td>Overall:</td>
</tr>
</tbody>
</table>

95% Confidence Interval

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also performed using the test. The following organisms were tested at 1×10⁷ organisms/test, and all yielded negative results.

- **Group B Streptococcus**
- **Group C Streptococcus**
- **Group D Streptococcus**
- **Streptococcus bovis**
- **Streptococcus faecalis**
- **Streptococcus mitis**
- **Streptococcus mutans**
- **Streptococcus faecium**
- **Streptococcus salivarius**
- **Streptococcus sanguis**
- **Streptococcus pneumoniae**
- **Pseudomonas aeruginosa**
- **Proteus vulgaris**
- **Staphylococcus aureus**
- **Staphylococcus epidermidis**
- **Corynebacterium diphtheriae**
- **Bordetella pertussis**
- **Moraxella catarrhalis**
- **Candida albicans**
- **Haemophilus parahaemolyticus**

POL Studies

An evaluation of the test was conducted at three physician office laboratory sites, using a panel of coded samples containing negative control, low positive and medium positive specimens. Each specimen level was tested at each site in replicates of five over a period of five days. The study showed >90.9% agreement with the expected results.

NOTES

1. The Linear Strept A Test is for in vitro diagnostic use only. The test should be used for the detection of Strept A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strept A antigen concentration can be determined by this qualitative test.

2. This test will only indicate the presence of Strept A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.

3. A negative result obtained from the kit must be confirmed by culture. A negative result may be obtained if the concentration of the Strept A antigen present in the throat swab is not adequate or is below the detectable level of the test.

4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.

5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.

6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PRECAUTIONS

- Do not use the test if the foil pouch is damaged. Do not retest tests.
- This kit contains products of animal origin. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Avoid exposure to 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.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- 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.
- Reagents A & B are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- The positive and negative controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions always flush with copious amounts of water to prevent azide buildup.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

REFERENCES


42802-4/1201 R1.1ng