**Strep A Exact Dipstick**

A rapid qualitative test for detection of Group A Streptococcal antigen directly from throat swabs.

**HOW TO PERFORM TEST**

1. Open the test package and place the Extraction Tube in the designated area of the plastic workstation. Add 3 drops of Extraction Reagent 1 to the Extraction Tube. The solution must turn yellow in color.
2. Gently squeeze the swab firmly against the Extraction Tube to expel as much liquid as possible from the swab. Discard the swab.
3. Immerse the test strip into the Extraction Tube with the arrows pointing toward the extracted sample solution. Leave the test strip in the Extraction Tube. Start the timing device.
4. Read results in 5 minutes. Depending on the number of organisms on the swab, positive results 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 results after 10 minutes.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timing device.
- Test strips and reagents to room temperature prior to testing. Do not open test packs until ready to perform the test to avoid condensation of moisture on the membrane.
- Do not mix reagent or control bottle caps.
- Do not mix reagents from different lots.
- To obtain accurate results, package insert instructions must be followed.

**STORAGE AND STABILITY**

The Clearview Strep A Exact Dipstick should remain in sealed pouch and may be stored either refrigerated 2-8°C (36°-46°F) or at room temperature 20-30°C (68°-86°F) until use or the expiration date printed on the kit box.

**PRECAUTIONS**

- For in vitro diagnostic use only.
- For professional and laboratory use only.
- Do not use after stated expiration date on the kit box.
- Do not reuse the test.
- Do not mix reagents and reagent bottle caps.
- Do not mix reagents from different lots.
- Do not mix reagents from different lots.
- To obtain accurate results, package insert instructions must be followed.

**SPECIMEN COLLECTION AND HANDLING**

Follow standard clinical methods described by Facklam (ref.2) and Ross (ref.6). Use only polyester tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped or wooden shafted swabs. To collect throat specimens, hold down the tongue with a depressor and rub the swab on the tonsils, or any areas of inflammation with the signs of pus or redness in the back of the throat. Avoid contact with the tongue or sides of the mouth 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 into a dry, sterile and tightly sealed plastic tube for storage. Swab specimens can be stored at room temperature 20-30°C (68°-86°F) for up to 4 hours or refrigerated 2-8°C (36°-46°F) for up to 24 hours.

If a bacteria culture is desired, gently streak the swab on a 5% sheep blood agar plate before using it in the Clearview Strep A Exact Dipstick. The Extraction Reagents kill the bacteria on the swab and make it impossible to culture. Alternatively, a dual swab procedure or a subsequent second swab specimen may be collected for culture. If a second swab sample is collected, rub the swab ends together to ensure even distribution of bacteria before performing the Clearview Strep A Exact Dipstick test and the bacteria culture.

**EXTRACTION**

Shake the Extraction Reagent and Control bottles before use.

1. Open the test package and place the Extraction Tube in the designated area of the plastic workstation. Add 3 drops of Extraction Reagent 2 to the Extraction Tube. The solution must turn yellow in color.
2. Add 3 drops of the Extraction Reagent 2. The solution must turn yellow.
3. Squeeze the test strip firmly against the Extraction Tube to expel as much liquid as possible from the swab. Discard the swab.
4. Immerse the test strip into the Extraction Tube with the arrows pointing toward the extracted sample solution. Leave the test strip in the Extraction Tube. Start the timing device.
5. Read results in 5 minutes. Depending on the number of organisms on the swab, positive results 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 results after 10 minutes.

**MATERIALS SUPPLIED**

- Each pack includes one test strip, 12ml): 5M Sodium Nitrile and one Extraction Tube.
- Add 3 drops of the Extraction Reagent 2. The solution must turn yellow.
- Cotton swab, calcium alginate, cotton tipped or wooden shafted swabs.
- To collect throat specimens, hold down the tongue with a depressor and rub the swab on the tonsils, or any areas of inflammation with the signs of pus or redness in the back of the throat. Avoid contact with the tongue or sides of the mouth with the swab.

**EXTRACTION**

- Positive Control (2 ml): Heat-killed Group A Streptococcus in solution (1 x 10⁶ organisms/ml) with 0.1% sodium azide as a preservative.
- Negative Control (2 ml): Heat-killed Group B Streptococcus in solution (1 x 10⁶ organisms/ml) with 0.1% sodium azide as a preservative.
- Two directional inserts: one waived and one moderately complex.
- One procedure card.
An evaluation of Clearview Strep A Exact Dipstick was conducted at three sites by laboratory personnel using a panel of coded dried swab samples containing Negative Control (5 x 10^4 organisms/test) and Positive (5 x 10^6 organisms/test) specimens. A total of one hundred thirty-five (135) coded specimens were tested over a period of three days at three sites. Over 99% agreement with the expected results was obtained.

### Table 1

<table>
<thead>
<tr>
<th>Swab Culture</th>
<th>Positive</th>
<th>Negative</th>
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<tbody>
<tr>
<td></td>
<td>99</td>
<td>2</td>
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<tr>
<td></td>
<td>200</td>
<td>5</td>
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### SPECIFICITY STUDY

To determine the specificity of the Clearview Strep A Exact Dipstick to Group A Streptococcal bacteria, various Group A Streptococcal strains at different levels of organisms per test were examined. Positive results obtained at a level of 5 x 10^4 organisms/test for all strains indicate that Clearview Strep A Exact Dipstick is sensitive to all Group A Streptococcal bacteria. In rare cases, test specimens heavily colonized with Group A Streptococcus from serogroups other than Group A as well as by other pathogens may give a discernible result. It is not known how the test will perform with the presence of other Respiratory infections, including pharyngitis, can be caused by Streptococci from serogroups other than Group A as well as by other pathogens. A definitive clinical diagnosis should be based on the results of a single test but should find be repeated after clinical and laboratory analysis. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture procedure should be performed.

### EXPECTED RESULTS

It is estimated that approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas. In rare cases, test specimens heavily colonized with Group A Streptococcus from serogroups other than Group A as well as by other pathogens may give a discernible result. It is not known how the test will perform with the presence of other Respiratory infections, including pharyngitis, can be caused by Streptococci from serogroups other than Group A as well as by other pathogens. A definitive clinical diagnosis should be based on the results of a single test but should find be repeated after clinical and laboratory analysis. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture procedure should be performed.

### PERFORMANCE CHARACTERISTICS

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should find be repeated after clinical and laboratory analysis. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture procedure should be performed.

### CORRELATION STUDY

A correlation study of the Clearview Strep A Exact Dipstick was performed to determine the analytical sensitivity. The detection limit of the Clearview Strep A Exact Dipstick was determined to be 5 organisms/test. The test results are summarized in Table 1.

### REFERENCES


