The Clearview Strep A Exact Cassette is a rapid qualitative test for the detection of Group A Streptococcal antigen directly from throat swabs.

**INTENDED USE**

The Clearview Strep A Exact Cassette is a rapid test for the visual, qualitative detection of Group A Streptococcal antigen directly from throat swabs. The test is intended for use as an aid in the diagnosis of Group A Streptococcal infection and is for professional and laboratory use only.

**SUMMARY AND EXPLANATION**

Beta-hemolytic Group A Streptococcus is a major cause of upper respiratory infections 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 (ref.2).

Conventional methods used for the detection of the disease depend on the isolation and subsequent identification of the organism (ref.2,5). These methods often require 24-48 hours to complete. Recent developments of immunological techniques (ref.1,3) which can detect Group A Streptococcal antigen directly from throat swabs allow physicians to diagnose and administer therapy immediately.

**TEST PRINCIPLE**

The Clearview Strep A Exact Cassette utilizes a two-site sandwich immunosassay technology for the detection of Group A Streptococcal antigen. The test consists of a membrane strip which was precoated with rabbit anti-Strep A antibody and a colored rabbit anti-S. pyogenes conjugate pad that is placed at the end of the membrane.

During testing, the Strep A antigen is extracted from the throat swab specimen by a coated rayon swab. The extraction solution is then added to the cassette’s sample well. The Strep A antigen reacts with coated 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 (T) region. If Strep A antigen is present in the specimen, a colored sandwich of antibody/Strep A antigen/gold conjugate antibody complexes is formed on the test line region. Absence of the colored line at the test (T) 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 control (C) region, a colored line at the control region will always appear. The presence of this colored line serves as verification that sufficient volume has been added and that proper flow was obtained.

**REAGENTS AND MATERIALS SUPPLIED**

- Thirty (30) Test Cassette.
- Extraction Reagent 1 (12ml): 5M Sodium Nitrite.
- Extraction Reagent 2 (12ml): 0.03M Citric Acid.
- Thirty (30) Extraction Tubes.
- Thirty (30) sterile polyester throat swabs.
- Positive Control (2 ml): Heat-killed Group A Streptococcus in solution (1 x 10⁹ organisms/ml) with 0.1% sodium azide as a preservative.
- Negative Control (2 ml): Heat-killed Group B Streptococcus in solution (1 x 10⁹ organisms/ml) with 0.1% sodium azide as a preservative.
- Two directional inserts: one waived and one moderately complex.
- One procedure card.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timing device.
- Alternate swabs (see specimen collection & handling).

**STORAGE AND STABILITY**

The Clearview Strep A Exact Cassette should remain in sealed pouch and may be stored either refrigerated or at room temperature 2°-30°C (36°-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.
- Discard the test device if package is torn, ripped or if device itself is damaged.
- Do not mix reagent or control bottle caps.
- Do not mix reagents from different lots.
- To obtain accurate results, the package insert instructions must be followed.
- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures.
- Extraction Reagents 1 and 2. The solution should be purple to pink in color.
- Extraction Reagents 1 and 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.

**TEST PROCEDURE**

1. Open the test package and place the Extraction Tube in the designated area of the workstation. Add 4 drops of Extraction Reagent 1 to the Extraction Tube. The solution should be purple to pink in color.
2. Add 4 drops of Extraction Reagent 2 to the Extraction Tube. The solution must turn yellow in color.
3. Place the throat swab specimen in the Extraction Tube. Rotate the swab inside the tube using a circular motion to roll the side of the Extraction Tube so that liquid is expressed and reabsorbed from the swab. Let stand for a minimum of 1 minute. You may leave the Extraction Tube for 15 minutes at room temperature.
4. Gently squeeze the swab firmly against the Extraction Tube to expel as much liquid as possible from the swab. Discard the swab.
5. Cap the Extraction Tube with the provided dropper. Add all the extraction solution to the sample well of the test device. Start the timing device.
6. 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.

**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.

**HOW TO PERFORM TEST**

1. Add 4 drops of the Extraction Reagent 1. The solution should be purple to pink in color.
2. Add 4 drops of the Extraction Reagent 2. The solution should turn yellow.
3. Squeeze the swab firmly against the tube to expel as much liquid as possible.
4. Cap the Extraction Tube with the provided dropper. Dispense all the extraction solution. Read the results in 5 minutes.
5. Rotate the swab inside the tube. Wait for at least 1 minute.

**CLIA COMPLEXITY:**

Moderate
The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage. A negative result may be obtained following the onset of the disease due to low antigen concentration. Therefore, when a patient suspected of having Strep A infection has a negative Clearview Strep A Exact Cassette result, additional testing using the culture method is recommended.

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 method is recommended.

In rare cases, test specimens heavily colonized with Staphylococcus aureus and group A Streptococcus may result in a false negative result. 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 Streptococcus or serogroups other than Group A as well as by other pathogens.

As with all diagnostic tests, a definitive clinical diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.

It is not known how the test will perform in the presence of Fusobacterium necrophorum.

The results are summarized in the following tables. Clinical Sensitivity and Specificity, and overall accuracy for Clearview Strep A Exact Cassette are calculated based on this data.

**Sensitivity** = 99/104 = 95.2% (95% confidence interval = 92.8 – 97.3)
**Specificity** = 199/201 = 99.0% (95% confidence interval = 97.0 – 100.0)
**Accuracy** = 299/305 = 97.7%

**Site Studies**

An evaluation of Clearview Exact Strep A Cassette was conducted at three sites by laboratory personnel using a panel of coded dried swab samples containing Positive Control (5 x 10^5 organisms/test) and Negative Control (5 x 10^3 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.

**Specificity Study**

To determine the specificity of the Clearview Strep A Exact Cassette 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 10^6 organisms/test for all strains indicate that Clearview Strep A Exact Cassette is sensitive to all Group A Streptococcal bacteria.

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also conducted using the Clearview Strep A Exact Cassette. The following organisms were tested at 1 x 10^6 organisms/test:

- Group B Streptococcus
- Group D Streptococcus
- Group F Streptococcus
- Group G Streptococcus
- Streptococcus agalactiae
- Streptococcus dysgalactiae
- Streptococcus faecalis
- Streptococcus faecium
- Streptococcus faecalis
- Streptococcus oralis (formerly milis)
- Streptococcus mutans
- Streptococcus pneumoniae
- Streptococcus salivarius
- Streptococcus sanguis
- Arcanobacterium haemolyticum
- Haemophilus parahaemolyticus
- Neisseria catarrhalis
- Neisseria gonorrhoeae
- Neisseria meningitidis
- Neisseria sicca
- Neisseria subflava
- Proteus vulgaris
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus saprophyticus
- Yersinia enterocolitica
- Veronella meningococcal

**REFERENCES**