The ColorQuick™ Strep A Test is a lateral flow, one-step immunoassay for the rapid, 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.

**PRINCIPLE**

The ColorQuick Strep A Test utilizes a two site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The test is performed by placing rabbit anti-Strep A antibody coated membrane and colloidal gold conjugate on the test device. The Strep A antigen is extracted from the throat swab using Extraction Reagent 1 and 2. The extracted solution is added to the sample well of the test device. The Strep A antigen reacts with the color antibody colloidal gold conjugate to form Strep A antigen colloidal gold conjugate. The color conjugate then migrates laterally across the membrane to the test line region. A pink colored line at the test line region indicates a positive result. Regardless of the presence of Strep A antigen, the extracted mixture will flow laterally across the membrane to the control region, and a pink control line will always be visible. The positive line and control lines are proportional to the amount of Strep A antigen present in the sample. A negative result will show only one pink control line at the control region. Improper flow may cause the control line to remain pink longer than the test line.

**SUMMARY**

The ColorQuick Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen directly from throat swabs. Yes, this group A streptococcal antigen immunoassay may be used for professional and laypersons use only for in vitro diagnostic use only.

**INTENDED USE**

The ColorQuick Strep A Test is a qualitative test for the differentiation of the 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.

**PRECAUTIONS**

- Follow all standard precautions throughout all procedures. All contaminated waste such as swabs, Strep A Test cassettes and extracts should be properly disposed.
- Study the instructions carefully. Test device and procedural notes must be followed.
- Read results in 5 minutes.
- Discard any unopened test cassette if the expiration date has passed.
- Do not re-use opened test cassettes.
- Use only test reagents included in the kit.
- Do not use reagents from different kits.
- Do not mix reagents from different lots.
- Extracted reagents should be observed throughout all procedures. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.

**REAGENT MATERIALS SUPPLIED**

- Extraction Reagent 1 (12 ml)
- Extraction Reagent 2 (12 ml)
- Extraction Control: (2 ml)
- Positive Control: Heat-killed Group A Streptococcus in preservative (2 ml)
- Negative Control: Heat-killed Group B Streptococcus in preservative (2 ml)

**TEST PROCEDURE**

1. **Prepare specimens**

   - Collect at least 1.0 ml of throat secretion from each subject.
   - Place the sample in the Extraction Tube. Rotate the tube in a circular motion for 30 seconds. Discard the swab.
   - To avoid cross-contamination, do not allow the tips of the reagents to come in contact with sample swabs or the Extraction Tubes.

2. **Add all the reagents to the Extraction Tube**

   - Add 4 drops of Extraction Reagent 2 to the Extraction Tube. The buffer should be red in color.
   - Add 4 drops of Extraction Reagent 1 to the Extraction Tube. The buffer should be red in color.
   - Place the Extraction Tube on a flat surface and let it sit for 1 minute.

3. **Read results**

   - Place the Extraction Tube on the work area of the test device.
   - Add 1 drop of the swab to the sample well of the test device.
   - Read results in 5 minutes.

4. **Interpret results**

   - A pink colored line at the test line region indicates a positive result. A pink control line at the control region indicates a negative result.
   - If a pink control line is not visible, the test is invalid.

5. **Procedural Notes**

   - Don't mix reagents from different lots.
   - Do not use reagents from different kits.
   - Do not re-use opened test cassettes.
   - Use only test reagents included in the kit.
   - Do not mix reagents from different lots.
A correlation study between the ColorQuick Strep A Test and the culture method was performed to determine the specificity of the ColorQuick Strep A Test. The study included a panel of coded samples containing various levels of Group A Streptococcus bacteria. The results showed that the ColorQuick Strep A Test had a specificity of 97.5%.

In summary, the ColorQuick Strep A Test is a rapid diagnostic test for the detection of Group A Streptococcus bacteria. It is easy to use and provides accurate results within minutes.

**Expected Results:**

- **Positive:** A pink colored line appears in the test (T) region. A negative result indicates the presence of Group A Streptococcus bacteria.
- **Negative:** Only one pink colored line appears in the control (C) region.
- **Invalid:** No pink colored line appears in the control (C) region.

**Limitations:**

- The test may yield false positive results if the sample is heavily colonized with other pathogens.
- False negative results may result from improper sample collection or storage.
- The test does not differentiate asymptomatic carriers from symptomatic individuals.

**Conclusion:**

The ColorQuick Strep A Test is a useful tool for the rapid diagnosis of Group A Streptococcus infections. It is recommended for use in clinical settings where prompt results are necessary.

**References:**