Clarity Strep A is a rapid immunochromatographic assay for the qualitative detection of group A streptococcal antigen directly from throat swab specimens. It is intended for use in the physician’s offices, hospitals, and clinical laboratories as an aid in the clinical diagnosis of group A streptococcal infection (1).

Summary and Explanation
Group A streptococci are one of the most significant human pathogens causing acute pharyngitis, tonsillitis, and scarlet fever (1). It is very important to differentiate streptococcal infection from other etiologic agents (e.g., viral, mycoplasmal, and chlamydial) so that appropriate therapy may be initiated. Classical methods for identification require 18–48 hours culture time for throat swabs or other clinical samples to produce results showing bactricum susceptible beta-hemolytic streptococci. Rapid diagnostic and timely treatment of group A streptococcal pharyngitis infections will reduce the severity of disease, and further complications such as rheumatic fever and glomerulonephritis (2–6).

Materials and Reagents
Each Clarity Strep A test kit contains all necessary reagents and materials for 25 tests. 

1. Strep A test strip: Contains a membrane coated with rabbit anti-group A streptococcal antibody for the test line and a secondary control antibody, and a conjugate pad impregnated with the rabbit anti-Strep A antidote-body-dye complex.
2. Extraction Reagent A (6 mL): 2.0 M sodium nitrite solution. (Warning: Avoid contact with eyes or skin.)
3. Extraction Reagent B (6 mL): 0.2 M phosphoric acid solution. (Warning: Avoid contact with eyes or skin.)
4. Positive Control (1 mL): Extracted (non-infective) group A streptococcal suspension spiked to a positive strep A control (3 x 10^5 CFU/mL) in phosphate buffered saline containing 0.1% sodium azide.
5. Negative Control (1 mL): Extracted (non-infective) group B streptococcal suspension spiked to buffered saline containing 0.1% sodium azide.
6. Extraction Tubes (25)
7. Throat Swabs (25): Rayon swab with plastic shaft (use only the swabs supplied with the kit).
8. Instructions for Use
9. Reaction tube rack

Materials Required but Not Provided
1. Timer
2. Precautions
   - For in vitro diagnostic use only.
   - Do not interlace materials from different product lots.
   - Do not use after the expiration date indicated.
   - The test kit should be used only with the swabs supplied with the kit.
   - Do not interchange kits between reagents.
   - Reagents A and B are slightly caustic. Avoid contact with eye, skin, or mucous membranes, cuts, abrasions, etc.
   - If these reagents come in contact with the skin or eyes, flush with a large volume of water.
   - Do not smoke, eat or drink in areas where the specimens or kit reagents may be handled.
   - Wear disposable gloves while handling the kit reagents or specimens and wash hands thoroughly afterwards.
   - All patient samples should be handled as if capable of transmitting disease.
   - Observe established precautions against microbial hazards throughout the procedures and follow standard procedures for proper disposal of specimens.

Clarity Strep A should remain in its canister until ready for use. The control solutions contain sodium azide, which, on contact with lead or copper plumbing, may react to form explosive metal azides. Use a large volume of water to flush reagents on disposal.

Storage and Stability
Clarity Strep A should be stored at 2–30 °C (35–86 °F) in its canister, out of direct sunlight. Kit contents should remain in their canister until ready for use.

Specimen Collection and Preparation
Collect throat swab specimens following standard clinical procedures, using the sterile swab or swabs supplied with this kit. Throat swab specimens should be collected by health care professionals only.

1. Collect throat swab specimens following standard clinical procedures using the swabs supplied in this kit.
2. Swabs should be processed within 4 hours after collection, unless they are stored in phosphate buffer (5°C). If stored in a refrigerator, swab should be processed within 24 hours from collection.
3. If a culture is required, it is recommended that two swab samples be collected. The first swab sample should be used for testing with Clarity Strep A as soon as possible after collection. The second swab may be stored in a liquid medium (about 200 µL) such as Modified Staur's, or equivalent, for up to 24 hours in the refrigerator.

Manufactured for:
Diagnostic Test Group
http://www.diagnosticsetgroup.com
1-877-722-6339

P-3571-A
121707bl
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SBA Culture
No. of Positive
Colony Count
Culture
Confirmed Status
A
% Sensitivity for Clarity Strep A
L (10^2 colonies)
11
11
10^a
90.9^b
M (>10^2 and <10^3 colonies)
28
28
100
H (>10^3 colonies)
80
70
70^a
94.9^b
TOTAL
98.3^a

* The lower sensitivity was probably due to the presence of culture plates with the colony count of less than 5.
** One high positive sample was found negative in the initial testing of the swab. However, testing the colony collected from the plate by Clarity Strep A confirm the positive result. There might have been the operator error in the initial testing; however, not confirmed.

Sensitivity
The analytical sensitivity of the test is 1.5 x 10^4 CFU/mL. This was established by testing a known number of organisms, ATCC 49230 or ATCC 19615, using Todd Hooe Broth from BBL. The cultured organisms were diluted in culture medium and tested by Clarity Strep A and Becton-Dickinson® Strep A. The same dilutions were cultured overnight on sheep blood agar plates from BBL for 24 hours and enumerated in the assay. The results are as follows:...
**Procedures**

**Proper Throat Swabbing**

- Care should be taken in collecting the throat swab specimens to avoid touching sides of the mouth while sampling inflamed or exudative areas.
- Presence of excess amount of saliva or blood in the collected sample would interfere with test results.

**Test Procedure**

1. Just before testing, add 4 drops of Reagent A (yellow) and 4 drops of Reagent B to the extraction tube. Mix solution by shaking the tube gently. (The solution should turn pink.)
2. Immediately put the swab into the tube.
3. Rotate the swab vigorously in the extraction solution to extract specimen thoroughly.
4. Let stand for 1–2 minutes.
5. Squeeze out as much liquid as possible from the swab by pressing the swab firmly against the side of the tube with two fingers.
6. Discard the swab.
7. Take out the Strept A test strip from the cannister. Recap the cannister immediately.
8. Insert the Strept A test strip into the tube of extracted solution and allow the migration to begin.
9. Read the result in 5 minutes, after which a distinct color line has formed in the reading window, but no later than 10 minutes after the test strip has been dipped in the extracted solution.

**Interpretation of Results**

**POSITIVE**

Two reddish-purple colored lines, both a Control line and Test line, indicate that group A streptococcal antigen has been detected.

**NEGATIVE**

Only one colored line in the Test line area indicates that the specimen does not contain detectable levels of group A streptococcal antigen and is considered as presumptive negative. It is recommended by the American Academy of Pediatrics (7) that presumptive negative results be confirmed by culture.

**INVALID**

A distinct colored line in the Control line area (C) should always appear. The test is invalid if no Control line forms in 5 minutes. When the test shows an invalid result, the test should be repeated with a new test strip and a new swab sample.

**Limitations**

- **As is the case with any other diagnostic procedure, the results obtained with this kit must be used only as an adjunct to information available to the practitioner.**
- **This test should be used only for the qualitative detection of group A antigen. Use of the kit for the semiquantitative determination of group A streptococci has not been reported.**
- **This test will not differentiate between a carrier and an infected individual.**
- **Clarity Strept A can detect non-viable as well as viable organisms.**
- **The test must not be performed on patient specimens which cannot be demonstrated in culture.**
- **This test is not intended as a substitute for bacteriological culture testing; test results should be compared with culture identification until each laboratory establishes its own equivalences of performance.**
- **Additional follow-up testing using the culture method is recommended if Clarity Strept A test result is negative and group A streptococcal infection is suspected.**
- **Test specimens heavily colonized with Streptococcus pyogenes (> 10^6 CFU/mL) can yield false positive results.**
- **Proper throat swabs must be obtained for good quality tests.**
- **Pharyngitis can be caused by organisms other than group A streptococci.**
- **This test does not provide any further information about pharyngitis other than the possibility of strep A infection.**
- **Clinical correlation:**
  - The Positive and Negative controls provided with the kit do not monitor the performance of the test. The test has been performed correctly and the test strip is working properly, the background in the result area should be clear, providing a distinct negative result.

**Expected Results**

Group A streptococcus infection exhibits a seasonal variation and is most prevalent in the winter and early spring. Approximately 10% of all upper respiratory infections are due to group A streptococci (7). The highest incidence of this disease is found in high density populations, such as school aged children and military bases. Males and females are equally affected by the disease (8).

**Performance Characteristics**

**Clinical Correlation:**

- The performance of Clarity Strept A—Direct Strep A Antigen Test was compared to that of BioSign™ Strep A test and the conventional plate culture techniques in a prospective evaluation of clinical specimens. Throat swab specimens were collected from 505 children and adult patients with pharyngitis symptoms. Each swab was first used to inoculate a sheep blood agar plate containing a bacitracin disk, and the swab was then assayed with Clarity Strept A to record Strept A test results. The plates were incubated at 37°C in 5% CO₂ for 18-24 hours to detect b-hemolytic colonies typical of group A streptococci. If the plates were negative, they were held for additional 18-24 hours. All samples were collected from cultured plates and assayed by a strep A confirmatory latex agglutination test (Streptex A). All presumptive positive hemolytic colonies were typed by four different Strepex test kits (A, B, C, F, and G). Sensitivity by five kinds of Strepex test kits (A, B, C, F, and G) was also performed when the hemolytic b-hemolytic results were obtained. These results constitute the confirmed 18-24 hour culture test results. The results are summarized below.

**Clarity Strept A**

<table>
<thead>
<tr>
<th>Test Procedure</th>
<th>Confirm (18/24 hour)</th>
<th>Culture Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid</td>
<td>(+) 127 (96.2%)</td>
<td>5 368 (98.0%)</td>
</tr>
<tr>
<td>Invalid</td>
<td>(-) 365 (98.0%)</td>
<td>373 (97.5%)</td>
</tr>
</tbody>
</table>

Total Sensitivity: 96.2%

Specificity: 98.7%

Overall Accuracy: 99.5%

All of 375 specimens that were BioSign® Strep A negative were also negative by Clarity Strept A for a relative sensitivity of 100%. All of 132 specimens that were BioSign® Strep A positive were also positive by Clarity Strept A for a relative sensitivity of 100%. The overall agreement of both assays was 100%. The following table compares the sensitivity of Clarity Strept A to the semi-quantitative of SBA culture.