**The lower sensitivity was probably due to the presence of culture plates with the colony count of less than 5.**

**% sensitivity for Accustrip® Strep A was calculated using the confirmed culture result.**

### Analysed Sensitivity

The analytical sensitivity of the test is 1.5 x 10^6 CFU/mL. This was established by testing a known number of organisms, ATCC 14285 or ATCC 19615, using Todd Hewette Broth from BBL. The cultured organisms were serially diluted in culture medium and tested by Accustrip® Strep A. The same dilutions were cultured overnight on sheep blood agar plates from BBL for cell enumeration in CFU/mL. The assay results are as follows:

<table>
<thead>
<tr>
<th>CellNumber in CFU/mL</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0 x 10^5</td>
<td>+ (medium positive)</td>
</tr>
<tr>
<td>3.0 x 10^5</td>
<td>+ (low positive)</td>
</tr>
<tr>
<td>1.5 x 10^5</td>
<td>+ (low positive)</td>
</tr>
<tr>
<td>7.7 x 10^4</td>
<td>+ (medium positive)</td>
</tr>
<tr>
<td>3.8 x 10^4</td>
<td>− (negative)</td>
</tr>
</tbody>
</table>

### Cross- Reactivity

To confirm the specificity of Accustrip® Strep A, organisms likely to be found in the respiratory tract, as listed below, were tested at 1 x 10^5 organisms per ml. The results were all negative. Each organism [1 x 10^5 CFU/ml] was also spiked to a positive strep A control [3 x 10^5 CFU/mL] to confirm that the test results are the same as expected.

### Accustrip® Strep A

**Organism Tested**

- Escherichia coli (ATCC 11775)
- Klebsiella pneumoniae (ATCC 13883)
- Pseudomonas aeruginosa (ATCC 19455)
- Candida albicans (ATCC 14053)
- Neisseria gonorrhoeae (ATCC 9347)
- Neisseria lactamica (ATCC 23879)
- Neisseria meningitidis serogroup B (ATCC 13090)
- Neisseria sicca (ATCC 9915)
- Cornebacterium diphtheriae (ATCC 296)
- Proteus vulgaris (ATCC 6045)
- Staphylococcus aureus (ATCC 12600)
- Streptococcus pneumoniae (ATCC 6030)
- Streptococcus Group B (ATCC 12886)
- Streptococcus Group C (ATCC 12888)
- Streptococcus Group D (ATCC 12798)
- Streptococcus Group F, Type 2 (ATCC 12392)
- Streptococcus Group G (ATCC 12399)
- Streptococcus gallolyticus subspecies infantarius (ATCC 14990)
- Haemophilus influenzae (ATCC 49244)
- Branhamella catarrhalis (ATCC 25581)
- Streptococcus saprophyticus (ATCC 10556)
- Streptococcus mutans (ATCC 10449)

### Negative Control

- Positive Control

| *A* = 1 x 10^5 CFU/mL without strep A | *B* = 1 x 10^5 CFU/mL spiked with 3 x 10^5 CFU/mL strep A |

### Distribution of Random Error

Twenty blind samples prepared by spiking 4 different concentrations of group A streptococcal antigen, prepared from a known live culture of ATCC strain 19615, were separately tested by two operators. Five (5) replicate samples were prepared for each concentration: high positive samples containing approximately 4 x 10^8 CFU/mL, medium positive samples containing approximately 1.2 x 10^7 CFU/mL, low positive samples containing approximately 3 x 10^6 CFU/mL, and negative samples containing approximately 1.2 x 10^5 CFU/mL, prepared from a known live culture of ATCC strain 19615. The results obtained at each site agreed 100% with the expected results.

### Reproducibility Study

Reproducibility of Accustrip® Strep A test results was examined at two POL (physician's office laboratory) sites and a clinical laboratory, using a total of 15 blind control samples for total 90 tests. The panel consisted of 5 negative samples, 5 low positive samples containing approximately 3 x 10^5 CFU/mL, and 5 medium positive samples with approximately 1.2 x 10^6 CFU/mL, prepared from a known live culture of ATCC strain 19615. The results obtained at each site agreed 100% with the expected results.

### References


### Symbols Key

<table>
<thead>
<tr>
<th>Instruction Per Use (Read)</th>
<th>Procedure Card</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog Number</td>
<td>Do Not Reuse</td>
</tr>
<tr>
<td>Store at</td>
<td>For In Vitro Diagnostic Use</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>Lot Number</td>
</tr>
<tr>
<td>Contents</td>
<td>Manufactured Per</td>
</tr>
<tr>
<td>Ethanol Swab</td>
<td></td>
</tr>
<tr>
<td>Test Device</td>
<td></td>
</tr>
</tbody>
</table>

### Principle

**Accustrip® Strep A** is a rapid immunochromatographic assay for the qualitative detection of group A streptococcal antigen directly from throat swab specimens. The test 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.

### Summary and Explanation

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

### Intended Use

**Accustrip® Strep A**—Value Group A Streptococcus Antigen Test Strip is a single-instrument immunochromatographic assay for the qualitative detection of group A streptococcal antigen directly from throat swab specimens. The test 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.

### Jant Pharmacal Corp.

**CLIA Complexity:** Waived
**CDC Analyte Identifier Code:** 5810

Catalog No. ID513 25 Test Kit

### Materials Required but Not Provided

- **Timer**
- **Reagent tube rack**

### Warning and Precautions

- **For in vitro diagnostic use only.**
- **Do not interchange 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 caps between reagents.**
- **Reagents A and B are slightly caustic. Avoid contact with eyes, sensitive 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 are 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 microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.**
- **The Accustrip® Strep A test strip should remain in its original sealed pouch until ready for use. Do not use if the pouch is damaged or the seal is broken.**
- **The control solutions contain sodium azide, which, on contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents come in contact with the skin or eyes, flush with a large volume of water.**

### Storage and Stability

**Accustrip® Strep A** test strip should be stored at 2–30°C (35–86°F) in its original sealed pouch, out of direct sunlight. Do not freeze. Kit contents are stable until the expiration date printed on the outer box.
Specimen Collection and Preparation
Collect throat swab specimens following standard clinical procedures, using sterile rayon swabs supplied with this kit. Throat swab specimens should be collected by health care professionals only.
- Collect throat swab specimens following standard clinical procedures using the swabs supplied in this kit.
- Swabs should be processed within 4 hours after collection, unless they are stored in a refrigerator (2–8°C). If stored in a refrigerated swab, specimens should be processed within 24 hours from collection.
- If a culture is required, it is recommended that two swab samples be collected. The first sample should be used for swabbing with Accustrip® A as soon as possible after collection. The second swab may be stored in a liquid medium (about 200 μL) such as a Modified Stuart’s or equivalent, for up to 24 hours in the refrigerator.
- Care should be taken in collecting the throat swab specimens to avoid touching sides of the mouth while swallowing inflamed or erosive areas. Presence of excess amount of saliva or blood in the collected sample will interfere with test results.

Procedure
Procedural notes
These instructions must be followed carefully to achieve optimal test results. Follow the assay procedure and always perform the test under carefully standardized conditions.
- If specimens, kit reagents or Accustrip® Strep A have been stored in the refrigerator, allow them to reach room temperature before use.
- Do not open the foil pouch until you are ready to perform the test.
- Several tests may be run at one time.
- To avoid contamination of reagents, do not allow the tips of the reagent bottles to come in contact with the extraction tubes.
- To add Reagents A and B, hold the bottles in a vertical position under carefully standardized conditions.
- Swabs transported in liquid media prior to testing may result in reduced sensitivity due to dilution of organisms.

Test Protocol
1. Just before testing, add 4 drops of Reagent A (yellow) and 4 drops of Reagent B to the extraction tube. Mix gently by swirling the solution. (The solution 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 Accustrip® Strep A test strip from the sealed pouch.
8. Insert the Accustrip® Strep A test strip into the tube of extracted solution and allow the migration to begin.
9. Read the result in 5 minutes, after 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
Two reddish-purple colored lines, both a Control line and Test line, indicate that group A streptococcal antigen has been detected.
- The Test line may have a color shade of varying intensity depending on the concentration of antigen detected (weak to strong). The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.
- Only one colored line in the Control line area and no distinct 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 that the Accustrip® A kit be used for presumptive negative results to confirm by culture.
- A distinct colored line in the Control line area (shaded) always should 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.

Test Limits
- As is the case with any other diagnostic procedure, the results obtained with this kit must be used only as an adjunct to other information available to the physician.
- The test should be used only for the qualitative detection of strep A antigen. Use of the kit for the semi-quantitative determination of group A strep has not been established.
- This test will not differentiate between a carrier and an infected individual.
- The Accustrip® Strep A test can detect non-viable as well as viable organisms. The test may therefore detect organisms which cannot be demonstrated in culture.

Internal Procedural Controls
- A colored line in the Control line area can be considered an internal procedural control. A distinct pink-purple control line will always appear if the test has been performed correctly. If the control line does not appear, the test is invalid and a new test should be performed. If the problem persists, contact Just Pharmaccorp. for technical assistance.

External quality Control
Group A streptococcus infection exhibits a seasonal variation and is most prevalent in the winter and early spring. Approximately 90% of all upper respiratory tract infections are caused by group A streptococcus. The highest incidence of this disease is found in high density populations, such as school aged children and military bases.

Expected Values
Sensitivity (127/132): 96.2%
Specificity (368/573): 97.9%
Overall Accuracy (495/595): 98.0%

All of 373 specimens that were negative by the commercially available Strep A test were also negative by Accustrip® Strep A. No specimens were positive by the commercially available Strep A test were also negative by Accustrip® Strep A for a relative specificity of 100%. All of 132 specimens that were positive by the commercially available Strep A test were also positive by Accustrip® Strep A for a relative sensitivity of 100%. The overall agreement of both assay was 100%. The following table compares the sensitivity of the Accustrip® Strep A test to a semi-quantitative SBA culture.

Performance Characteristics

Clinical Correlation:
- The performance of the Accustrip® Strep A, a Value® Strep A Antigen Test was compared to that of a commercially available Strep A test and the conventional plate culture technique in a prospective evaluation of clinical specimens. Throat swab specimens were collected from 505 children and adult patients with pharyngitis symptoms. Each specimen was first used to inoculate a sheep blood agar plate containing a bacitracin disk, and the swab was then assayed with Accustrip® Strep A to record Accustrip® Strep 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 streptococcus. If the plates were negative, they were held for additional 18-24 hours. All samples were collected from cultured plate with a by a streaking loop and/or laterally adjacent areas. The frequency of additional Q.C. tests should be determined according to your laboratory’s standard Q.C. procedures. Upon confirmation of the external quality controls, the kit is ready for use with patient samples.
- The Negative control will yield a negative result (Control line only) when the test has been performed correctly and the test device is functioning properly. Add 4 drops of each Reagents A and B into an extraction tube, then add one drop of Negative Control and mix thoroughly. Process the extraction in the same manner as you would for a patient specimen according to the Test Procedure. The Negative control will produce a moderate positive result (two lines) when the test has been performed correctly and the test strip is functioning properly. Add 4 drops of each Reagents A and B into an extraction tube, then add one drop of Positive Control and mix thoroughly. Process the extraction in the same manner as you would for a patient specimen according to the Test Procedure. In addition to the external positive control provided with the kit, a known culture positive, 127, of ATCC strain 19615 can be used for quality control testing. Live culture from an agar plate may be collected by swab and tested the same way as described by unknown samples in the Test Procedure. Negative control can be used to dilute the culture organism to make a 10% dilution.
- A known live culture of group C streptococcus such as ATCC strain 12838 can be used for negative quality control testing at a minimum concentration of 10^5 CFU/mL. Process the extraction in the same manner as you would for a patient specimen according to the Test Procedure.
- The Positive and Negative controls provided with the kit do not meet the criterion of the Q.C. of the controls do not perform as expected, do not report patient results.
- The use of positive and negative controls from other commercial kits has not been established with Accustrip® Strep A.

Limitations
- This test is not intended as a substitute for bacterial culture testing technique and should be compared with culture identification until each laboratory establishes its own equivalents of performance.
- Additional follow-up testing using the culture method to confirm the negative test result obtained with Accustrip® Strep A is recommended.
- The test results should be clear, providing a distinct negative result.