A negative result may be obtained if the concentration of the Strep A antigen is very low. A negative result obtained from this kit should be confirmed by culture.

This test will only indicate the presence of Strep A antigen in the specimen, and must not be used to rule out the presence of other pathogens. Avoid touching the tongue, cheeks, and teeth and any blinding areas of the mouth with the swab when collecting specimens.

With all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

**STORAGE AND STABILITY**

- Test dipsticks should not be used if they are damaged.
- Test dipsticks should be retested within 30 minutes of rehydration. Two lines must appear in the control region of the dipsticks within 30 minutes. If two lines do not appear in this time, the test result should be retested.
- Humidity and temperature can adversely affect results.
- Positive and negative controls contain sodium azide which may react with the reagents. Do not use beyond the expiration date.
- Do not freeze. The test dipstick must remain in the sealed pouch until use.
- The kit can be stored at room temperature or refrigerated (36-86°F / 2-30°C).

**EXPECTED VALUES**

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta-hemolytic Streptococcus. In school-aged children and adults, the incidence of Strep throat increases in the fall and winter months. The disease usually occurs in the winter and early spring in temperate climates.1

**PERFORMANCE CHARACTERISTICS**

Using three medical centers for evaluation, a total of 491 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, incubated for 24 hours at 36°C, and shipped to McKesson Consult® Diagnostics Strep A Dipstick. The plates were further streaked for isolation, and then incubated at 37°C with 10% CO2, and a Bactec drum for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination grouping kit. Of the 491 total specimens, 375 were found to be negative by culture and 124 were found to be positive by culture and rehydration test. Two Strep F strains were yielded positive results with the test. One of these specimens was re-tested, then rehydrated and yielded a negative result. Three additional different Strep F strains were cultured and tested for cross-reactivity and also yielded negative results.

**CROSS-REACTIVITY**

The following organisms were tested at 1.0 x 10^4 organisms per test and were all found to be negative when tested with the McKesson Consult® Diagnostics Strep A Dipstick. No mucoid-producing strains were tested.

- Streptococcus Group B
- Streptococcus Group F
- Bacillus cereus
- Neisseria sicca
- Neisseria subflava
- Streptococcus mutans
- Enterococcus faecalis
- Enterococcus faecium
- Staphylococcus aureus
- Staphylococcus epidermidis
- Candida albicans
- Kluyvera pneumoidea
- Pseudomonas aeruginosa
- Bordetella pertussis
- Neisseria meningitidis
- Neisseria gonorrhoeae
- Neisseria sicca
- Neisseria subflava

**POL STUDIES**

Three physicians’ offices were used to conduct an evaluation of the McKesson Consult® Diagnostics Strep A Dipstick. Personnel with various educational backgrounds performed the testing. Each physician’s office tested a randomly collected set of specimens consisting of negative (20), low positive (20), medium positive (20), and positive result (20) for three days. The results obtained had a 96% correlation with the expected results.

**LIMITATIONS**

1. The McKesson Consult® Diagnostics Strep A Dipstick is for professional in vitro diagnostic use only. The test can be used for the detection of Strep A antigen in throat swab specimens. Neither the sensitivity nor the specificity values nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.

2. This test only indicates the presence of Strep A antigen from both viable and non-viable Group A Streptococcus bacteria.

3. A negative result obtained from this kit should be confirmed by culture. A negative result may only be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.

4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any blinding areas of the mouth with the swab when collecting specimens.

5. With all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

**INTERPRETATION OF RESULTS**

- **NEGATIVE:**
  - One red line appears in the control region (C).
  - No apparent red or purple line appears in the test region (T).

- **POSITIVE:**
  - Two red lines appear in both control region (C) and test region (T). The result indicates the presence of Strep A antigen in throat swab specimens.

**REFERENCES**


**LIMITATIONS**

1. The McKesson Consult® Diagnostics Strep A Dipstick is for professional in vitro diagnostic use only. The test can be used for the detection of Strep A antigen in throat swab specimens. Neither the sensitivity nor the specificity values nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.

2. This test only indicates the presence of Strep A antigen from both viable and non-viable Group A Streptococcus bacteria.

3. A negative result obtained from this kit should be confirmed by culture. A negative result may only be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.

4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any blinding areas of the mouth with the swab when collecting specimens.

5. With all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

**INTERPRETATION OF RESULTS**

- **NEGATIVE:**
  - One red line appears in the control region (C).
  - No apparent red or purple line appears in the test region (T).

- **POSITIVE:**
  - Two red lines appear in both control region (C) and test region (T). The result indicates the presence of Strep A antigen in throat swab specimens.

**REFERENCES**

of the test. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a red line must always appear in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample. The intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A present in the sample. Therefore, any shade of red in the test line region (T) should be considered positive.

INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink lines appear in the test region (T). A negative result indicates that Strep A is not present in the sample, or is present below the detectable level of the test. In these instances, further testing is required to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.

VALID/NONEVALID: Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test dipstick. If the problem persists, discontinue using the test kit immediately and contact Technical Support at (866) 216-0094.

**QUALITY CONTROL**

**INTERNAL QUALITY CONTROL:** Internal procedural controls are included in the test. A negative appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white.