



**INVALID: 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

**Internal Quality Control,** Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

**External Quality Control,** In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each 25-test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure. External positive and negative controls are supplied in the kit.

### CLINICAL SIGNIFICANCE

*Streptococcus pyogenes* is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.<sup>1</sup> Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.<sup>2</sup> Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.<sup>3</sup> Rapid diagnosis and early antibiotic therapy of Group A Streptococcal infection appear to be the best means of preventing medical complications and reducing the spread of the disease.

### 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 infection is about 40%. This disease usually occurs in the winter and early spring in temperate climates.

### ANALYTICAL PERFORMANCE

#### Sensitivity and Specificity

To determine the analytical sensitivity of the test, Group A *Streptococcus* bacteria organisms were grown by standard culture techniques. The detection limit of the Strep A Rapid Test Strip (Swab) was determined to be  $1 \times 10^5$  organisms / test.

#### Correlation Study

**Table: Strep A Rapid Test vs. Culture**

	Strep A Rapid Test		Total
	+	-	
Culture +	82	2	84
Culture -	4	156	160
	86	158	244

**Relative Sensitivity:**  
95.35% (88.51-98.72)\*  
**Relative Specificity:**  
98.7% (95.50 - 99.85)\*  
**Overall Agreement:**  
97.5% (94.72 - 99.09)\*  
**\*95% Confidence Interval**

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also performed using the test. The following organisms were tested at  $1 \times 10^7$  organisms/test, and all yielded negative results.

Group B <i>Streptococcus</i>	Group C <i>Streptococcus</i>	<i>Pseudomonas aeruginosa</i>
Group F <i>Streptococcus</i>	Group G <i>Streptococcus</i>	<i>Proteus vulgaris</i>
<i>Streptococcus bovis</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>
<i>Streptococcus faecalis</i>	<i>Staphylococcus epidermidis</i>	<i>Corynebacterium diphtheria</i>
<i>Streptococcus mitis</i>	<i>Neisseria gonorrhoeae</i>	<i>Bordetella pertussis</i>
<i>Streptococcus mutans</i>	<i>Neisseria lactima</i>	<i>Moraxella catarrhalis</i>
<i>Streptococcus faecium</i>	<i>Neisseria meningitidis</i>	<i>Candida albicans</i>
<i>Streptococcus salivarius</i>	<i>Neisseria sicca</i>	<i>Neisseria subflava</i>
<i>Streptococcus sanguis</i>		
<i>Streptococcus pneumoniae</i>	<i>Staphylococcus saprophyticus</i>	<i>Haemophilus parahaemolyticus</i>

### POL Studies

An evaluation of the test was conducted at three physician office laboratory sites, using a panel of coded samples containing negative control, low positive and medium positive specimens. Each specimen level was tested at each site in replicates of five over a period of five days. The study showed >99.9% agreement with the expected results.

### NOTES

- The Linear Strep A Test is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
- A negative result obtained from this kit must be confirmed by culture. A negative result may 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.
- The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
- 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<sup>5</sup> and any bleeding areas of the mouth with the swab when collecting specimens.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

### PRECAUTIONS

- Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Use only dacron or rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- Reagents A & B are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- The positive and negative controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions always flush with copious amounts of water to prevent azide buildup.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

### REFERENCES

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