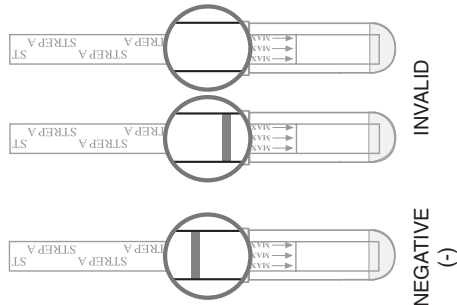


RESULTS



vigorously. Then add 1 drop of either the Positive or Negative Control to the tube. Place a sterile swab into the tube and swirl. Continue with Test Procedure Step 3.

If the controls do not perform as expected, do not interpret the test results. Repeat test or contact Technical Service.

It is recommended that both a Positive and Negative Control be tested with every new test kit. However, every laboratory should follow their local and state quality control requirements.

LIMITATIONS

The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage. A negative result may be obtained from patients at the onset of the disease due to low antigen concentration. Therefore, when a patient suspected of having Strep A infection has a negative Clearview Strep A Exact Dipstick result, additional testing using the culture method is recommended.

The test does not differentiate asymptomatic carriers of Group A Streptococcus from those with infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up throat culture method is recommended.

In rare cases, test specimens heavily colonized with *Staphylococcus aureus* can yield false positive results. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture procedure should be performed.

Respiratory infections, including pharyngitis, can be caused by Streptococci from serogroups other than Group A as well as by other pathogens.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

It is not known how the test will perform with the presence of *Fusobacterium necrophorum*.

EXPECTED RESULTS

It is estimated that approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci (ref.4). Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas.

PERFORMANCE CHARACTERISTICS

DETECTION LIMIT

To determine the analytical sensitivity of the Clearview Strep A Exact Dipstick, Group A Streptococcus bacteria were grown by standard culture technique. The detection limit of the Clearview Strep A Exact Dipstick was determined to be 5×10^4 organisms/test.

CORRELATION STUDY

A correlation study of the Clearview Strep A Exact Dipstick and the conventional culture test was carried out in multi-center clinical evaluations. Throat swab specimens were taken from children and adults exhibiting symptoms of pharyngitis. The swabs were used to inoculate blood agar plates prior to testing with the Clearview Strep A Exact Dipstick. Beta-hemolytic colonies from the blood agar plates were confirmed as Group A Streptococcus using serologic streptococcal grouping methods. Strep A was reported as present or not present.

The results are summarized in Table 1. Clinical Sensitivity and Specificity, and overall accuracy for Clearview Strep A Exact Dipstick are calculated based on this data.

Table 1

	Swab Culture	
	Positive	Negative
Clearview Exact	98	2
Strep A Dipstick	5	200

Sensitivity = $98/103 = 95.1\%$ (95% confidence interval = 90.9 – 99.3%)

Specificity = $201/203 = 99.0\%$ (95% confidence interval = 97.6 – 100%)

Accuracy = $299/305 = 97.7\%$

SITE STUDIES

An evaluation of Clearview Strep A Exact Dipstick was conducted at three sites by laboratory personnel using a panel of coded dried swab samples containing Negative Control (5×10^6 organisms/test group B streptococcus), Low Positive (5×10^4 organisms/test) and Positive (1.5×10^5 organisms/test) specimens. A total of one hundred thirty-five (135) coded specimens were tested over a period of three days at three sites. Over 99% agreement with the expected results was obtained.

SPECIFICITY STUDY

To determine the specificity of the Clearview Strep A Exact Dipstick to Group A Streptococcal bacteria, various Group A Streptococcal strains at different levels of organisms per test were examined. Positive results obtained at a level of 5×10^4 organisms/test for all strains indicate that Clearview Strep A Exact Dipstick is sensitive to all Group A Streptococcal bacteria.

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also performed using the Clearview Strep A Exact Dipstick. The following organisms were tested at 1×10^8 organisms/test.

Group B Streptococcus	<i>Candida albicans</i>
Group C Streptococcus	<i>Corynebacterium diphtheriae</i>
Group D Streptococcus	<i>Escherichia coli</i>
Group F Streptococcus	<i>Haemophilus parahaemolyticus</i>
Group G Streptococcus	<i>Moraxella catarrhalis</i>
<i>Streptococcus agalactiae</i>	<i>Neisseria gonorrhoeae</i>
<i>Streptococcus dysgalactiae</i>	<i>Neisseria lactima</i>
<i>Streptococcus faecalis</i>	<i>Neisseria meningitidis</i>
<i>Streptococcus faecium</i>	<i>Neisseria sicca</i>
<i>Streptococcus oralis</i> (formerly mitis)	<i>Neisseria subflava</i>
<i>Streptococcus mutans</i>	<i>Proteus vulgaris</i>
<i>Streptococcus pneumoniae</i>	<i>Pseudomonas aeruginosa</i>
<i>Streptococcus salivarius</i>	<i>Staphylococcus aureus</i>
<i>Streptococcus sanguis</i>	<i>Staphylococcus epidermidis</i>
<i>Arcanobacterium haemolyticum</i>	<i>Staphylococcus saprophyticus</i>
<i>Bordetella pertussis</i>	<i>Yersinia enterocolitica</i>

Staphylococcus aureus was tested at a concentration of 1×10^7 organisms/test.

Negative results were observed indicating that the Clearview Strep A to Group A Streptococcal bacteria.

PHYSICIAN OFFICE LABORATORY

An evaluation of Clearview Strep A was conducted at two Physician Office panels of coded samples containing Positive and High Positive specimens was tested in replicates of five at five days. One hundred percent (100%) expected results was obtained.

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