

Clinical Study Report of Strep A Rapid Test (Throat Swab)

Ref.: IST-501/IST-502 /

ISTB-501/ISTB-502

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1. Summary

122 Strep A positive specimens and 404 Strep A negative specimens confirmed by culture and clinical Symptoms were used in clinical study. Culture served as the reference method for the Strep A Rapid Test (Throat Swab). The result shows the Strep A Rapid Test has a high restive sensitivity and high relative specificity when tested with the 526 specimens.

2. Background

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.^[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.^[2] 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.^[3,4] The Strep A Rapid Test Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

3. Objective

Do clinical studies of Strep A Rapid Test (Throat Swab) with the Strep A positive specimens and negative specimens which confirmed with culture method.

4. Materials

- Strep A Rapid Test
- IST-501 Lot: STA14030001-T
- IST-502 Lot: STA14030004-T
- ISTB-501 Lot: STA14030007-T
- ISTB-502 Lot: STA14030010-T
- 122 Strep A positive specimen confirmed with Culture
- 404 Strep A negative specimen confirmed with Culture

5. Method

Totally 526 throat swab samples collected from individuals with suspected strep A infection, then tested with culture and strep A Rapid test respectively.

6. Operation Method

Operation method can be referred to package insert provided in the kits.

Test Results**Table: Clinical Study Result****IST-501**

Method		Culture		Total Results
Results		Positive	Negative	
Strep A rapid test Dipstick (Throat Swab)	Positive	116	9	125
	Negative	6	395	401
	Total Results	122	404	526
Relative Sensitivity		95.1% (95%CI*: 89.6%-98.2%)		
Relative Specificity		97.8% (95%CI*: 95.8%-99%)		
Totally accuracy		97.1% (95%CI*: 95.3%-98.4%)*Confidence Intervals		

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7. Conclusion

The relative sensitivity of strep A rapid test was 95.1% and the relative specificity was 97.8% compare with culture result.

8. References

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995, p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. *Pediatrics* (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. *Clinical Infectious Diseases* (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. *Journal of Clinical Microbiology* (Dec 1998), 36: 3468-3473.