

STREP A CARD

For *in Vitro* diagnostic use only

Immunochromatographic test for detection of Group A Streptococcus from throat swabs

I. INTENDED USE

Strep A Card is a lateral flow, immunoassay for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs. Beta-haemolytic Group A Streptococcus is a major cause of upper respiratory infection such as tonsillitis, pharyngitis and scarlet fever in kids.

II. PRINCIPLE

The Strep A Card utilizes two site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The method utilizes a combination of specific antibody conjugate with colloidal gold on solid surface. During testing, the Strep A antigen is extracted from the throat swab using Extraction Reagents 1 and 2. The extracted solution is then added to the sample well. The Strep A antigen reacts with colored antibody-colloidal gold conjugate to form Strep A antigen-antibody complexes. The mixture then moves chromatographically across the membrane to the immobilized rabbit anti-Strep A antibody at the test line region. If Strep A antigen is present in the specimen, a red colored sandwich of solid phase/Strep A antigen/gold conjugate is formed on the test line region (T). Absence of the red line at the test line region indicates a negative result. Regardless of the presence of Strep A antigen, as the extracted mixture continues to move laterally across the membrane to the immobilized goat anti-rabbit antibody test region, a red line at the control region will always appear (C). The presence of this colored band serves as: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained and 3) reagent control.

III. REAGENTS AND MATERIALS

Each kit contain:

- 1) **Strep-A Cards**: sealed pouch containing the device, an essicant and a tube for sample extraction, with dropper tip
- 2) **Extraction solution 1**
- 3) **Extraction solution 2**
- 4) **Sterile Swabs**
- 5) **Extraction tube**
- 6) **Instructions leaflet**

IV. STORAGE AND STABILITY

The test kit is to be stored at temperature (4-30°C) in the sealed pouch for the duration of the shelf-life.

V. PRECAUTIONS

- 1) For *in vitro* diagnostic use only.
- 2) For professional use only.
- 3) Read the package insert instruction before use the kit.
- 4) Do not use beyond the expiration date which appears on the package label.
- 5) 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 the physician after all clinical and laboratory findings have been evaluated.

VI. SPECIMEN COLLECTION

To obtain optimal results use only swabs in rayon or dracon. Do not use calcium alginate, cotton tipped swabs.

It is recommended that swabs specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped tube or bottle and refrigerated. Swabs can be stored at room temperature up to 4 hours, or refrigerated (4-8°C) up to 5 days.

VII. TEST PROCEDURE

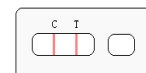
- 1) Remove the test card from the sealed pouch.
- 2) Place the specimen swab in the plastic tube supplied. Add 6 drops of Extraction Reagent 1 (300 µl) and 6 drops of Extraction Reagent 2 (300 µl). Swirl vigorously to mix the reagents. Then incubate the mixture at room temperature for 2-5 minutes.
- 3) After this time, expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab.
- 4) Put the dropper tip on to the extraction tube. Holding the sample dropper above the card, squeeze a total of 4 drops (200 µl) of the mixed specimen into the sample well (S).
- 5) Interpret test results at 10 minutes. Do not interpret test after 10 minutes.

VIII. INTERPRETATION OF RESULTS

Negative: The control line appears in the test window, but the test line is not visible.



Positive: Two colored lines should be observed in the viewing region. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to indicate proper performance of the test.



Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.



IX. PERFORMANCE CHARACTERISTICS

Analytical Sensitivity: To determine the analytical sensitivity of the Strep A Card, Group A Streptococcus bacteria were grown in broth culture. The detection limit of the Rapid Strep A Test was determined to be 2.5×10^5 organisms per test. Sensitivity: **2.5×10^5 org/test.**



Specificity: To determine the specificity of the Strep A Card to Group A Streptococcal bacteria, the following Group A Streptococcal Strains at different levels of organisms per test were examined. Positive results obtained at the level of 2.5×10^5 organisms/test for all Strep A strains indicate that Strep A Card 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 Strep A Card. The following organisms were tested at 1×10^8 organisms/test.

ORGANISMS	RESULT
Strep-A (2.5×10^5 org/test) strains: SS-091; SS-410; SS-492; SS-496; SS-633; SS-634; SS-635; SS721; SS-754; SS-799; ATCC-19615	+
Strep-B, -C, -D, -F, -G	-
<i>Pseudomonas aeruginosa</i>	-
<i>Streptococcus bovis, faecalis, mitis, mutans, salivarius, pneumoniae, sanguis</i>	-
<i>Staphylococcus aureus, epidermidis, saprophyticus</i>	-
<i>Proteus vulgaris</i>	-
<i>Escherichia coli</i>	-
<i>Corynebacterium diphtheriae</i>	-
<i>Neisseria lactima, gonorrhoeae, meningitidis, sicca, subflava</i>	-
<i>Bordetella pertussis</i>	-
<i>Moraxella catarrhalis</i>	-
<i>Candida albicans</i>	-
<i>Haemophilus parahaemophyticus</i>	-

Accuracy

A correlation study of the Strep A Card and the conventional culture tests has been determined in multi-center clinical evaluations. Throat swab specimens were taken from patients exhibiting symptoms of pharyngitis.

The qualitative results are summarized as follows:

		Culture		Total
		Positive	Negative	
Strep A Card	Positive	21	3	24
	Negative	2	35	37
	Total	23	38	61

Sensitivity: $21/23 = 91.3\%$

Specificity: $35/38 = 92.1\%$

Accuracy: $(21+35)/61 = 91.8\%$

X. EXTERNAL QUALITY CONTROL

Positive and negative control are available in Catalogue Mascia Brunelli (UD80025).

XI. LIMITATION OF PROCEDURE

The accuracy of the test depends on the quality of the swab sample. False negative 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 infection, additional testing using the culture method is required.













The test does not differentiate asymptomatic carriers of Group A Streptococcus from those with infection.

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

As for any diagnostic procedure, the results obtained with this test should be used in conjunction with other information available to the physician. Strep A Card is a test for the qualitative detection of Group A Streptococcal antigen.

XII. REFERENCES

1. Facklam RR and Carey RB "Streptococci and Aerococci, Manual of Clinical Microbiology" 4th ed, Lenette EH, Balows A, Hausler WJ and Shadomy H, *American Society for Microbiology*, 1985.
2. Levinson ML and Frank PK "Differentiation of Group A from other Beta Hemolytic Streptococci with Bacitracin" *J. Bacteriol* 69,284-287 (1995).
3. Edwards EA, Phillips IA and Suiter WC "Diagnosis of Group A Streptococcal Infections Directly from Throat Secretions" *J. Clin. Micro.*, 15,481-483 (1982).
4. Gupta R, Talwar GP and Gupta SK "Rapid Antibody Capture Assay for Detection of Group A Streptococci Using Monoclonal Antibody and Colloidal Gold-Monospecific Polyvalent Antibody Conjugate" *J. Immunoassay*, 1992, 13, 441-445.
5. Rose PW "Throat Swabs and Swabbing Technique" *The Practitioner*, 207,791-796 (1971).
6. Lauer BA, Rellar LB and Mirrett S "Effect of Atmosphere and Duration of Incubation on Primary Isolation of Group A Streptococci from Throat Cultures" *J. Clin. Micro* 17,338-340 (1983)

 In Vitro Diagnostic Medical Device	 Temperature limitation	 Batch code (EXXX)	 Manufacturer	 Keep dry	 Non-sterile
 Consult Instructions for use	 Use by (year/month)	 Catalogue number	 Do not reuse	 Fragile, handle with care	 Keep away from heat

CONTENTS

- 1) Strep-A Cards
- 2) Extraction solution 1
- 3) Extraction solution 2
- 4) Sterile Swabs
- 5) Instructions leaflet

REF. VQ81210 (50 test)

- 50 items
- 1 x 16,5 mL
- 1 x 16,5 mL
- 50 items
- 1 item

REF. VQ81209 (20 test)

- 20 items
- 1 x 7 mL
- 1 x 7 mL
- 20 items
- 1 item

EDMA Code 15 70 01 03 00

