

# STREP A CARD

Qualitative Determination of Antigen  
of Streptococcus  $\beta$ -hemolytic  
Group A from Throat Swab

20 tests

REF 4011

## PRINCIPLE

Among the pathogenic beta-hemolytic streptococci causing infections in human, the A, B, C and G groups most prominently. Group A streptococci continue to be a focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with poststreptococcal sequelae, specifically acute rheumatic fever and acute glomerulonephritis.

In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent.

For the screening of group A streptococcal infection several methods are currently used including susceptibility of the organism to a bacitracin disc placed on a sheep blood agar plate, latex agglutination and enzyme immunoassay (EIA).

The Strep A card test is a rapid qualitative one-step assay for the detection of streptococcus Group A antigen from throat swab specimens. The method employs a unique combination of monoclonal-dye conjugate and polyclonal solid phase antibodies to selectively identify streptococcus-A with a high degree of sensitivity.

As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the Strep-A antigen forming an antibody antigen complex. This complex binds to the Anti-strep-A antibody in the positive reaction zone producing a pink coloured band. In the absence of Strep-A, there is no line in the positive reaction zone and control zone. Unbound conjugate binds to the reagents in the control zone producing a pink coloured band demonstrating that the reagents are functioning correctly.

## REAGENTS

Kit components:

<b>Cards</b>	20
<b>Swabs</b>	20
<b>Plastic Tubes</b>	20
* <b>Extraction solution 1</b>	1 x 6,5 ml
* <b>Extraction solution 2</b>	1 x 6,5 ml

WARNING: Extraction solution 1 contain Sodium Nitrite >5%, while Extraction solution 2 contain acetic acid < 1%. Wash off immediately if extraction reagent came in contact with skin.

STABILITY: the card and reagents are stable up to stated expire date when stored at 4-30°C. Do not freeze the kit.

## SAMPLE

### Throat swab

To obtain the best results, specimens should be collected using standard throat swab collection methods. Plastic shafted swabs with rayon or dacron tips may be used. Do not use swabs with cotton or calcium alginate tips with wooden shafts or impregnated with charcoal or transport media containing agar or gelatin.

STABILITY: patients samples are best performed immediately following specimen collection. If immediate testing is not possible, the patient samples should be placed in a dry plastic tube and stored refrigerated at 2-8°C.

## TEST PROCEDURE

1. Remove the card from the pouch.
2. Label each card with patient's name.

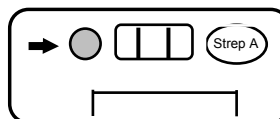
3. Place the specimen swab in a plastic tube. Add 6 drops of extraction reagent 1 (250  $\mu$ l) and 6 drops of extraction Reagent 2 (250  $\mu$ l). Twirl swab to mix the extraction reagents thoroughly. Incubate at room temperature for 3 min.

4. At the end of incubation time, squeeze the swab firmly against the side of the tube in order to remove as much liquid as possible from the swab. Discard the swab.

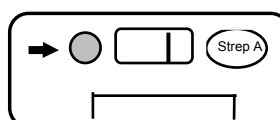
5. Add 100  $\mu$ l (4 full drops) of the extract solution into the sample well on the card ( → ).

6. Read the results of the test 5 min after addition of sample on the card. DO NOT INTERPRET THE RESULT AFTER 10 MINUTES.

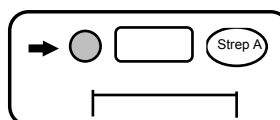
WARNING: a procedure performed non correctly or a damaged card can give an inconclusive result. Verify if the inconclusive result it caused by an expired card or a not correctly stored card. Repeat the test with a fresh card.



POSITIVE: 2 bands



NEGATIVE: 1 band



INCONCLUSIVE: no band

## CHARACTERISTICS

Comparing the results obtained with Strep A Card with classical method (cellular culture) on two different swabs we have found the following results (duplicate measure):

1. Specificity: 97.70%
2. Sensitivity: 91.80%

		cellular culture		
		(+)	(-)	total
Strep A card	(+)	56	5	61
	(-)	5	212	217

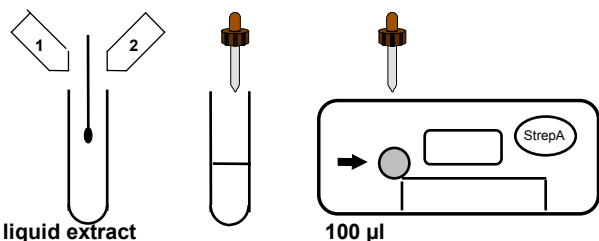
Samples contains the following micro-organisms culture: Strep-B CDC-1073 strain, Strep-C CDC-660 strain, Ungrouped CDC-763 strain, S.mutans ATCC-27351 strain, Staph. epidermitis ATCC-155 strain, are analysed. The negative results obtained confirm the specificity of the StrepA card.

## NOTE

(\*) Dangerous reagents are marked by an asterisk. Refer to MSDS.

## REFERENCE

Available on request.



IVD

CE

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Manufactured by: FAR srl

Via Fermi, 12 - 37026 Pescantina - VERONA - ITALY

Phone +39 045 6700870 - Fax +39 045 7157763

website: <http://www.farddiag.com>

e-mail: [farddiag@farddiag.com](mailto:farddiag@farddiag.com)