STREP B CARD

Qualitative Determination of Antigen
of Streptococcus β-hemolytic
Group B from Vaginal Swab

20 tests **REF 4012**

PRINCIPLE

Group B streptococci are most notable for their role in causing neonatal sepsis and meningitis. Two forms of neonatal infection have been recognised on clinical and epidemiological grounds:

1. early onset disease which usually occurs within the first 10 days after delivery.
2. late onset disease which thought not always occurs 10 days after the birth.

Late onset disease may be due to nosocomial acquisition of the organism and is rarely associated with material or obstetrical complications. Early onset disease is thought to be due to acquisition perhaps by aspiration of the organism from the female genital tract at the time of delivery. The incidence of Group B Streptococci range from 1 to 5% live births with mortality rates from 22 to 80%. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent.

The Strep-B card test is a rapid qualitative one-step assay for the detection of Streptococcus Group B antigen from vaginal swab specimens.

The method employs a unique combination of monoclonal-dye conjugate and polyclonal solid phase antibodies to selectively identify streptococcus-B with a high degree of sensitivity.

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

REAGENTS

Kit components:	**REF 4012**
Card	**20**
***Extraction solution 1**	**1 x 6,5 ml**
***Extraction solution 2**	**1 x 6,5 ml**
Swabs	**20**

WARNING: extraction reagent 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 cards and reagents are stable up to stated expire date when stored at 4-30°C. **Do not freeze the kit.**

SAMPLE

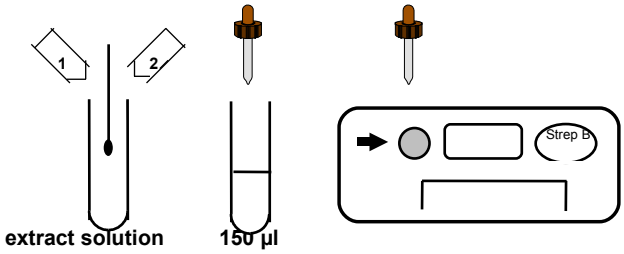
Vaginal swab

To obtain the best result specimens should be collected using standard swabs 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 gelatine.

STABILITY: patient 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.

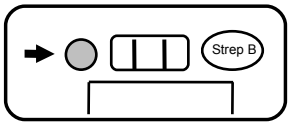
ASSAY PROCEDURE

1. Remove the card from the pouch.

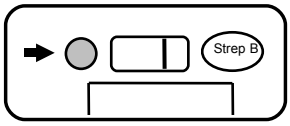


2. Label each card with the patient's name.
3. Place the specimen swab in a plastic tube. Add 9 drops of extraction reagent 1 (300 µl) and 9 drops of extraction solution 2 (300 µl). Twirl swab to mix the extraction reagents thoroughly. Incubate at room temperature for 2 min minimum and 5 min maximum
4. At the end of incubation, 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 4 drops (150 µl) of the extract solution into the sample well on the card (➡).Read results of the test between 5 to 10 min after addition of sample on the card.

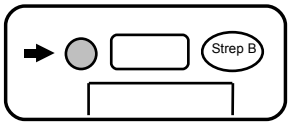
WARNING: a procedure performed non correctly or a damaged can give an inconclusive result. Verify if the result it caused by an expired card or a not correctly stored card.
Repeat the test with a fresh card.



POSITIVE: 2 bands



NEGATIVE: 1 band



INCONCLUSIVE: no band

PERFORMANCE CHARACTERISTICS

Sensitivity: The performance of STREP B CARD was evaluated on dilutions of a bacterial suspension 0.9 NaCl solution pH 7.4. The **sensitivity** of the STREP B CARD is 10^3 – 10^4 bacterial cells of Streptococcus group B per 0.1 sample; thus between 286 and 2857 bacteria per test.

Specificity: Different strains of bacteria were selected, grown on agar plates and tested for strain identity by molecular an biochemical accredited methods. These strains were assayed using STRP B CARD to evaluate cross-reaction. Results are summarized in the following table:

GROUP	STRAIN	RESULT
Streptococcus agalactiae	SK 19 ATCCC 13813	Positive
Streptococcus agalactiae	SK 43	Positive
Streptococcus agalactiae	BK 416 AN6643	Positive
Staphylococcus aureos	ATCC-29213	Negative

There was non cross-reaction with the above tested panel of organisms using STREP B CARD:

NOTE

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

REFERENCES

Hall R.T., Barnes W., Am. J. Obstet. Gynecol. 24, 630 (1976)
Jones D.E., Kanarek K.S. et al., J. Clin. Microbiol. 18,526 (1983)

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