remel BETA LYSIN DISK

REF R21120......25 Disks/Vial

1. INTENDED USE

Remel Beta Lysin™ Disk is a reagent-impregnated disk recommended for use in qualitative procedures to detect the production of CAMP factor by group B streptococci.

2. SUMMARY AND EXPLANATION

Christie, Atkins, and Munch-Peterson observed a lytic phenomenon when hemolytic and nonhemolytic group B streptococci were grown in a zone of staphylococcal beta lysin activity.¹ This phenomenon was used to develop a test for presumptive identification of group B streptococci which became known as the CAMP test.² Group B streptococci produce a protein-like compound, CAMP factor, which acts synergistically with beta lysin to produce a potent hemolysis in sheep blood agar. A filter paper disk impregnated with beta lysin may be used as a substitute for the beta lysin-producing Staphylococcus aureus culture.

3. PRINCIPLE

Beta Lysin Disk supplies beta lysin which acts synergistically with CAMP factor to produce an arrowhead-shaped zone of complete hemolysis on sheep blood agar. Beta lysin reacts with sphingomyelin in the sheep erythrocyte membrane to produce ceramide. CAMP factor reacts with ceramide causing disorganization of the erythrocyte lipid bilayer resulting in an area of complete hemolysis shaped like an arrowhead or crescent.

4. REAGENTS

Reactive Ingredient:

Beta Lysin obtained from Staphylococcus aureus

5. PRECAUTIONS

This product is for In Vitro diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

6. STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

7. PRODUCT DETERIORATION

This product should not be used if (1) the disk color has changed from light beige, (2) the expiration date has passed, (3) the desiccant has changed from blue to pink, or (4) there are other signs of deterioration.

Protect disks from moisture by removing from the vial only

those disks necessary for testing. Promptly replace the cap and return the vial to 2-8°C.

8. SPECIMEN COLLECTION, STORAGE, TRANSPORT

Specimens should be collected and handled following recommended guidelines.^{3,4}

9. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) TSA w/ 5% Sheep Blood (REF R01200), (5) Quality control organisms, (6) Forceps.

10. PROCEDURE

Test only catalase-negative, gram-positive cocci which are morphologically characteristic of streptococci on Gram stain and on sheep blood agar.

- Allow blood agar plate to equilibrate to room temperature.
- Using forceps, place a Beta Lysin Disk on the uninoculated agar surface.
- 3. Follow with a streak of the test isolate perpendicular to the disk and leave a 2-3 mm space in between.
- Incubate aerobically or in 5-10% CO2 for 18-24 hours at 35-37°C.
- Observe for a crescent-shaped zone of hemolysis at the intersect point of the disk and the test isolate indicating a positive test.

11. INTERPRETATION

Positive Test - Crescent-shaped zone of hemolysis

Negative Test - No hemolytic zone or a small helmetshaped hemolytic zone

12. QUALITY CONTROL

All lot numbers of Beta Lysin Disk have been tested using the following quality control organisms and have been found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
Streptococcus agalactiae ATCC® 12386	Aerobic, 18-24 h @ 35-37°C	Positive
Streptococcus pyogenes ATCC® 12344	Aerobic, 18-24 h @ 35-37°C	Negative

13. LIMITATIONS

- Sheep blood agar plates containing unwashed sheep erythrocytes that have not been pretested for anticamp factor may result in a false negative CAMP test.
- Some group A streptococci may demonstrate a helmetshaped zone of hemolysis, especially if incubated in CO2.

- 3. An agar depth of 1.5 mm will result in the most distinct zone of hemolysis.
- Beta Lysin Disk is only part of the overall scheme for identification of group B streptococci. Further testing may be required for definitive identification. Consult appropriate references for further instructions.3,4

14. BIBLIOGRAPHY

- Christie, R., N.E. Atkins, and E. Munch-Petersen. 1944. Aust. J. Exp. Biol. Med. Sci. 23:193-195.
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15. PACKAGING

REF R21120, Beta Lysin Disk25 Disks/Vial

16. SYMBOL LEGEND

REF	Catalogue Number	
IVD	In Vitro Diagnostic Medical Device	
[]i	Consult Instructions for Use (IFU)	
1	Temperature Limitations (Storage temp.)	
LAB	For Laboratory Use Only	
LOT	Batch Code (Lot Number)	
	Use By (Expiration Date)	
•••	Manufactured by	

 $\ensuremath{\mathsf{ATCC}}^{\circledast}$ is a registered trademark of American Type Culture Collection.

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