remel
NOVOBIOCIN DISK

REF R21134..... 25 Disks/Vial

1. INTENDED USE

Remel Novobiocin Disk is a reagent-impregnated disk recommended for use in qualitative procedures to differentiate *Staphylococcus saprophyticus* from other coagulase-negative *staphylococci*.

2. SUMMARY AND EXPLANATION

An increase in awareness that *S. saprophyticus* is a common cause of urinary tract infections in female patients has lead to an integration of several methods to identify this pathogen in clinical laboratories.[1] In 1975, Kloos and Schleifer reported a simplified scheme for differentiating coagulase-negative Staphylococcus spp. which included a novobiocin disk test.[2] In further testing, separate studies were conducted in 1977 to investigate the novobiocin disk test for presumptive identification of *S. saprophyticus* isolated from clinical specimens.[3,4] In 1984, Harrington and Gaydos compared the results obtained with an overnight novobiocin disk diffusion technique to those obtained with a broth disk procedure read after 5 hours.[5]

3. PRINCIPLE

The mechanisms of novobiocin-resistance include inhibition of cell wall synthesis as well as inhibition of protein and nucleic acid synthesis. Novobiocin resistance is intrinsic in *S. saprophyticus*. The Novobiocin Disk can be used to differentiate *S. saprophyticus* from other coagulase-negative *staphylococci* by the overnight disk test method or the 5 hour broth disk procedure.

4. REAGENTS

Reactive Ingredient: Novobiocin (5 µg)

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 (20-25°C) before use.

7. PRODUCT DETERIORATION

This product should not be used if (1) the disk color has changed from white, (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.[1]

9. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Forceps, (7) Sterile petri dish, (8) Caliper or ruler, (9) McFarland 0.5 Turbidity Standard (REF R20410) or equivalent.

10. PROCEDURE

Plate Method:

1. The test isolate should be 18-72 hours and in pure culture. Prepare a suspension of the test isolate in tryptic soy broth equal to a McFarland 0.5 standard or equivalent.
2. Immerse a sterile swab into the suspension and rotate it against the side of the tube above the fluid level to remove excess inoculum.
3. Using the expressed swab, inoculate a blood agar or Mueller Hinton agar plate by streaking the swab over the entire agar surface and repeat in 2 planes.
4. Allow the agar surface to dry no more than 15 minutes before applying a Novobiocin Disk. Using sterile forceps apply disk to the agar surface and tap to ensure contact.
5. Incubate in ambient air for 16-18 hours at 35-37°C.
6. Measure the diameter of the zone of inhibition using sliding calipers or a metric ruler.

Tube Method:

1. The test isolate should be 18-24 hours old and from a pure culture. Using well-isolated colonies, lightly inoculate two tubes of tryptic soy broth (3 ml). Lightly inoculated broth should have no visible turbidity.
2. Using sterile forceps, add a Novobiocin Disk to one test isolate tube. Shake the tube for 10 seconds. The second test isolate tube serves as a control tube. Do not add a Novobiocin Disk to the control tube.
3. Incubate both tubes for up to 5 hours at 35-37°C or until the control tube (without novobiocin) reaches the turbidity of a McFarland 0.5 standard or equivalent.
4. Observe the tube containing the Novobiocin Disk for turbidity.

11. INTERPRETATION

Plate Test:

Sensitive - Zone of inhibition equal to or greater than 16 mm

Resistant - Zone of inhibition less than 16 mm

Tube Method:

Sensitive - Turbidity less than control tube

Resistant - Turbidity equal to or greater than the control tube

12. QUALITY CONTROL

All lot numbers of Novobiocin 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
Staphylococcus epidermidis ATCC® 12228	Ambient, 16-18 h @ 35-37°C	Sensitive
Staphylococcus saprophyticus ATCC® 15305	Ambient, 16-18 h @ 35-37°C	Resistant

13. BIBLIOGRAPHY

1. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry, and M.A. Pfaller. 2007. Manual of Clinical Microbiology. 9th ed. ASM Press, Washington, D.C.
2. Schleifer, K.H. and W.E. Kloos 1975. Int. J. Syst. Bacteriol. 25:50-61.
3. Hovelius, B. and P. Mardh. 1977. Acta. Path. Microbiol. Scand. B. 85:427-434.
4. Pead, L., J. Crump, and R. Maskell. 1977. J. Clin. Path. 30:427-431.
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14. PACKAGING

REF R21134, Novobiocin Disk ..... 25 Disks/Vial

15. SYMBOL LEGEND

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

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