
remel

BETA LACTAM DISK

REF R261605..... 25 Disks/Vial

1. INTENDED USE

Remel Beta Lactam™ Disk is a reagent-impregnated disk recommended for use in qualitative procedures as a rapid, acidimetric method to detect β-lactamase production by certain strains of *Haemophilus spp.*, *Neisseria gonorrhoeae*, and *Staphylococcus spp.*

2. SUMMARY AND EXPLANATION

β-lactamase is an enzyme produced by certain gram-positive and gram-negative bacteria. The enzyme inactivates penicillin and confers resistance to all antibiotics in the β-lactam group, including cephalosporins. Several acidimetric methods using phenol red as an indicator and benzylpenicillin as a substrate have been published.^{1,2} In 1977, Slack et al. developed a rapid acidimetric method to detect β-lactamase in certain strains of *Staphylococcus aureus* using benzylpenicillin as the substrate and cresol red as the indicator.³ In further testing, Wheldon and Slack detected β-lactamase production by ampicillin-resistant strains of *H. influenzae* using a rapid method with benzylpenicillin as the substrate and bromocresol purple as the indicator.⁴ In 1976, β-lactamase-producing strains of *N. gonorrhoeae* were identified by Percival et al. using a rapid acidimetric method.⁵ According to Clinical and Laboratory Standards Institute, a rapid β-lactamase test can be used to detect clinically relevant strains of *Haemophilus spp.* and *N. gonorrhoeae* more quickly than the disk diffusion test.^{6,7}

3. PRINCIPLE

Beta Lactam Disk is impregnated with benzylpenicillin which contains a β-lactam ring. When the β-lactamase enzyme is produced by an organism, the β-lactam ring of benzylpenicillin is hydrolyzed to form penicilloic acid. This cleavage of the β-lactam ring inactivates the antibiotic. The resulting fall in pH is indicated by the brom cresol purple indicator changing from purple to yellow.

4. REAGENTS

Reactive Ingredient: Benzylpenicillin

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 color has changed from purple, (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.⁸

9. MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swab, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Forceps, (7) Clean microscope slide or petri dish, (8) Water or saline (pH 6.5-7.2).

10. PROCEDURE

1. Place a small drop (approximately 10 μl) of sterile water or saline (pH 6.5-7.2) on a microscope slide or in a petri dish. Caution: Avoid over-saturating the disk as this may dilute the substrate and cause a slow or weak reaction.
2. Using forceps remove a Beta Lactam Disk from the vial and place it on the drop of sterile water or saline. Immediately, return the vial to 2-8°C.
3. Allow a few seconds for the disk to rehydrate.
4. Using an inoculating loop, remove several isolated colonies of the test isolate from an 18-24 hour culture.
5. Streak the organism across the surface of the disk.
6. Observe for a color change from purple to yellow. Do not hold longer than 30 minutes. The usual reaction time for a β-lactamase-producing organism is 1-10 minutes.

11. INTERPRETATION

- Positive Test - Color change from blue to yellow, indicates β-lactamase produced
- Negative Test - No color change, indicates β-lactamase not produced

12. QUALITY CONTROL

All lot numbers of Beta Lactam 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
<i>N. gonorrhoeae</i> ATCC® 49981	Ambient, up to 30 min. @ 25°C	Positive
<i>H. influenzae</i> ATCC® 10211	Ambient, up to 30 min. @ 25°C	Negative

13. LIMITATIONS

- β-lactamase-negative, ampicillin-resistant (BLNAR) strains of *H. influenzae* have been reported.^{6,7}
- Organisms should be tested for antimicrobial susceptibility by an acceptable, standardized method.⁶⁻⁸
- Certain strains of *S. aureus* produce β-lactamase in quantities insufficient to be detected unless induced by growth in the presence of sub-inhibitory concentrations of penicillin or semi-synthetic penicillins, such as methicillin or oxacillin. Reactions may be enhanced by testing colonies from zone margins of a 10 µg methicillin disk.⁸









14. BIBLIOGRAPHY

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15. PACKAGING

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16. SYMBOL LEGEND

 REF	Catalogue Number
 IVD	<i>In Vitro</i> Diagnostic Medical Device
 i	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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