

remel

M. Cat. Butyrate DISK

REF R901424..... 25 Disks/Vial

1. INTENDED USE

Remel *M. Cat.* Butyrate Disk is a reagent-impregnated disk recommended for use in qualitative procedures for the detection of the enzyme butyrate esterase to aid in the identification of *Moraxella catarrhalis* isolated from clinical specimens.

2. SUMMARY AND EXPLANATION

In 1962, Berger reported that tributyrin hydrolysis could be used to differentiate *M. catarrhalis* from *Neisseria* species.¹ Other authors have reported the value of butyrate esterase detection in differentiating these organisms, utilizing various substrates.²⁻⁵ The *M. Cat.* Butyrate Disk is intended for use along with the oxidase test, Gram stain, and colony morphology for presumptive identification of *M. catarrhalis* and for confirmation of presumptive carbohydrate or enzyme substrate test results.⁶

3. PRINCIPLE

The enzyme, butyrate esterase, hydrolyzes the ester linked butyrate group from the substrate 5-bromo-4-chloro-3-indolyl butyrate. Loss of the butyryl moiety releases indolyl which reacts with another indolyl molecule in the presence of oxygen to produce indigo, an insoluble blue pigment.

4. REAGENTS

Reactive Ingredient:

5-Bromo-4-chloro-3-indolyl butyrate

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 stored in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Protect from light and moisture.

7. PRODUCT DETERIORATION

This product should not be used if (1) the 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.^{6,7}

9. MATERIALS SUPPLIED

(1) *M. Cat.* Butyrate Disks, (2) Wooden applicator sticks.

10. 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) Gram stain reagents, (7) Oxidase reagent (R21540), (8) Forceps, (9) Microscope slide.

11. PROCEDURE

1. Gram stain the test isolate prior to performing test. Only oxidase positive, gram-negative diplococci should be tested.
2. Place the disk on a microscope slide and moisten with a drop of demineralized water (do not oversaturate).
3. Remove a visible "paste" of the test isolate from an 18-72 hour pure culture using a wooden applicator stick or loop.
4. Rub inoculum across the disk.
5. Incubate at room temperature for up to 5 minutes.
6. Observe disk for the appearance of a blue color.

12. INTERPRETATION

Positive Test - Blue color development

Negative Test - No color change

13. QUALITY CONTROL

All lot numbers of *M. Cat.* Butyrate 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>Moraxella catarrhalis</i> ATCC® 25240	Ambient, 5 min. @ 25°C	Positive
<i>Moraxella catarrhalis</i> ATCC® 25238	Ambient, 5 min. @ 25°C	Positive
<i>Neisseria gonorrhoeae</i> ATCC® 43069	Ambient, 5 min. @ 25°C	Negative
<i>Neisseria meningitidis</i> ATCC® 13090	Ambient, 5 min. @ 25°C	Negative

14. PERFORMANCE CHARACTERISTICS⁸

In independent studies conducted at two laboratories, the following results were obtained:

Organism	No. Tested	No. Positive	% Positive
<i>Moraxella catarrhalis</i>	173	173	100
<i>Neisseria flavescens</i>	22	0	0
<i>Neisseria gonorrhoeae</i>	3	0	0
<i>Neisseria lactamica</i>	1	0	0
<i>Neisseria meningitidis</i>	2	0	0
<i>Neisseria mucosa</i>	5	0	0
<i>Neisseria sicca</i>	13	1	7.7
<i>Neisseria subflava</i>	66	0	0

15. LIMITATIONS

1. This product is part of the overall scheme for the identification of oxidase-positive, gram-negative diplococci. Further biochemical and serological testing may be required for definitive identification. Consult appropriate references.^{6,7}
2. Some bacillary strains of *Moraxella* spp. may give a positive- or weak-positive reaction.⁵
3. Unrelated organisms such as staphylococci and pseudomonads may also give a positive reaction.²
4. False-negative results may occur if insufficient inoculum is used.









16. BIBLIOGRAPHY

1. Berger, U. 1962. Arch. Hyg. Bakteriol. 146:388-391.
2. Dealler, S.F., M. Abbott, M.J. Croughan, and P.M. Hawkey. 1989. J. Clin. Microbiol. 27:1390-1391.
3. Janda, W.M. and P. Ruther. 1989. J. Clin. Microbiol. 27:1130-1131.
4. Riou, J.Y., J. Buissiere, M. Guibourdenche, G. Brault, and J.P. Carlier. 1981. Ann. Microbiol. (Inst. Pasteur). 132:159-169.
5. Vanechoutte, M., G. Verschraegen, G. Claeys, and P. Flamen. 1988. J. Clin. Microbiol. 26:1227-1228.
6. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry, and D.W. Warnock. 2011. Manual of Clinical Microbiology. 10th ed. ASM Press, Washington, D.C.
7. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2007. Bailey and Scott's Diagnostic Microbiology. 12th ed. Mosby Elsevier, St. Louis, MO.
8. Data on file. 1990. Remel Inc., Norcross, GA.

17. PACKAGING


REF R901424, *M. Cat.* Butyrate Disk..... 25 Disks/Vial

18. SYMBOL LEGEND

	Catalogue Number
	<i>In Vitro</i> Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
	For Laboratory Use Only
	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

ATCC[®] is a registered trademark of American Type Culture Collection.

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