



remel

## Catarrhalis Test Disk

(English)

### INTENDED USE

Remel Catarrhalis Test Disk is a reagent-impregnated disk recommended for use in qualitative procedures for the presumptive identification of *Moraxella catarrhalis* isolated from clinical specimens.

### SUMMARY AND EXPLANATION

*Moraxella catarrhalis* is recognized as a significant pathogen. Literature has reported that the isolation of this organism from routine sputum cultures is associated with clinical infection.<sup>1</sup> The rapid identification of this organism is important, since most strains produce beta-lactamase and are resistant to penicillin and ampicillin. Conventional methods of identification may take up to 48 hours to perform.<sup>2,3</sup> In 1962, Berger described the detection of an enzyme, butyrate esterase, as a rapid means of identifying *Moraxella catarrhalis*.<sup>4</sup>

### PRINCIPLE

The enzyme, butyrate esterase, releases indoxyl from indoxyl butyrate and spontaneously forms indigo in the presence of oxygen.<sup>5</sup>

### REAGENTS

Catarrhalis Test Disk (25 disks/vial)  
Reactive Ingredient: Indoxyl butyrate

### 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.

### 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 come to room temperature before use. Do not incubate prior to use.

### 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.

### SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.<sup>6,7</sup>

### 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) Forceps, (8) Petri dish or microscope slide, (9) Wooden applicator sticks.

### PROCEDURE

1. Gram stain isolate prior to performing test. Test only oxidase-positive, gram-negative diplococci.
2. Using forceps, place the disk in an empty petri dish or on a clean glass slide. **DO NOT REHYDRATE THE DISK.**
3. Rub several colonies (a visible inoculum) across the disk using a wooden applicator stick.
4. Observe for a blue-green color development within 2 minutes.

### INTERPRETATION OF THE TEST

Positive Test - Blue-green color development within 2 minutes  
Negative Test - No color development within 2 minutes

### QUALITY CONTROL

All lot numbers of Catarrhalis Test 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® 25238	Aerobic, 2 min. @ 25°C	Positive
<i>Neisseria lactamica</i> ATCC® 23970	Aerobic, 2 min. @ 25°C	Negative

### PERFORMANCE CHARACTERISTICS

In a collaborative study of 154 clinical isolates of *Moraxella catarrhalis*, all were found to produce butyrate esterase on Catarrhalis Test Disk.<sup>8</sup>

### LIMITATIONS

This product is only part of the overall scheme for identification. Procedures for biochemical and serological tests for identification may be found in appropriate references.<sup>6,7</sup>

### BIBLIOGRAPHY

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### PACKAGING

REF R21121, Catarrhalis Test Disk..... 25 Disks/Vial

### Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
EC REP	European Authorized Representative



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