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**remel**

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**10% POLYSORBATE 80**

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**INTENDED USE**

Remel 10% Polysorbate 80 is a reagent recommended for use in the semiquantitative catalase test to aid in the differentiation and identification of *Mycobacterium* spp.

**SUMMARY AND EXPLANATION**

Most strains of mycobacteria produce catalase.<sup>1</sup> The semiquantitative catalase test was developed to aid in differentiation of organisms included in *Mycobacterium tuberculosis* complex from other *Mycobacterium* spp.<sup>2</sup> The semiquantitative catalase test was found to help distinguish drug-resistant strains of *M. tuberculosis* complex from non-drug-resistant strains.<sup>3,4</sup>

**PRINCIPLE**

Polysorbate 80 helps disperse the hydrophobic tightly-clumped mycobacterial cells from large aggregates to individual bacilli, maximizing the detection of catalase. By lowering the surface tension in a medium, 10% Polysorbate 80 permits more rapid entry of compounds, such as 30% hydrogen peroxide, into the mycobacterial cell.

**REAGENTS (CLASSICAL FORMULA)\***

Polysorbate 80 (CAS 9005-65-6)..... 0.2 g  
DeminerIALIZED Water (CAS 7732-18-5) ..... 1000.0 ml

\*Adjusted as required to meet performance standards

**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 equilibrate to room temperature before use. Do not incubate prior to use. Protect product from light.

**PRODUCT DETERIORATION**

This product should not be used if (1) the color has changed, (2) the expiration date has passed, or (3) there are other signs of deterioration.

**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) 30% hydrogen peroxide, (7) Test tubes, (8) Lowenstein-Jensen (LJ) Butt (REF R09512), (9) Mycobacteriological safety equipment, (10) Disinfectant, (11) Millimeter ruler.

**SPECIMEN COLLECTION, STORAGE, TRANSPORT**

Specimens should be collected and handled following recommended guidelines.<sup>1,4,5</sup>

**PROCEDURE**

Follow established laboratory safety procedures when working with acid-fast cultures and specimens. Consult appropriate references when necessary for detailed procedural information on specimen processing, media inoculation, and identification of test isolates.<sup>1,4,5</sup>

1. Inoculate an LJ Butt with 0.1 ml of a 7 day liquid culture of the test isolate or a loopful of growth from an actively-growing culture. Include a catalase-producing *Mycobacterium* spp. (e.g., *M. tuberculosis*, ATCC® 25177) as a positive control. An uninoculated LJ Butt tube may be used as a negative control.
2. Incubate the tubes in 5-10% CO<sub>2</sub> at 35-37°C for 2 weeks; caps must be loose during the entire incubation period.
3. After incubation, add 0.5 ml of catalase reagent (1:1 mixture of 10% Polysorbate 80 and 30% hydrogen peroxide) to the culture.
4. Place the tubes upright in a rack which is standing on paper towels or other absorbent material soaked with disinfectant. The column of bubbles may overflow the tube if the cap is not replaced and tightened quickly enough.
5. Allow tubes to stand at room temperature for 5 minutes before measuring. Measure the height of the column of bubbles in millimeters above the surface of the agar.

**INTERPRETATION**

Strong Positive Test - A column of bubbles >45 mm  
Weak Positive Test - A column of bubbles <45 mm  
Negative Test - No bubbles

**QUALITY CONTROL**

All lot numbers of 10% Polysorbate 80 have been tested using the following quality control organism and 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**

*Mycobacterium tuberculosis* ATCC® 25177          CO<sub>2</sub>, 2 weeks @ 35-37°C          Bubbles

LJ Butt, uninoculated          CO<sub>2</sub>, 2 weeks @ 35-37°C          No bubbles




**BIBLIOGRAPHY**

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5. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry, and M.A. Pfaller. 2007. Manual of Clinical Microbiology. 9<sup>th</sup> ed. ASM Press, Washington, D.C.

**PACKAGING**

REF R21275, 10% Polysorbate 80..... 10 ml/Btl

**Symbol Legend**

<b>REF</b>	Catalog Number
<b>IVD</b>	In Vitro Diagnostic Medical Device
<b>LAB</b>	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
<b>LOT</b>	Batch Code (Lot Number)
	Use By (Expiration Date)

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IFU 21275, Revised September 30, 2010

Printed in U.S.A.