remel
LAP DISK

REF R21129 ..... 25 Disks/Vial

1. INTENDED USE

Remel LAP Disk is a reagent-impregnated disk recommended for use in qualitative procedures for rapid detection of leucine aminopeptidase activity in streptococci and related genera.

2. SUMMARY AND EXPLANATION

Colman and Ball investigated the use of leucine aminopeptidase (LAP) to aid in the identification of Gram-positive cocci.[1] In 1987, Fertally and Facklam investigated using LAP for identification of *Streptococcus* spp.[2] They found *Aerococcus* to be consistently negative for LAP, while strains of *Enterococcus* and *Streptococcus* are positive. LAP is an important parameter in the identification of *Leuconostoc*, *Pediococcus*, *Aerococcus*, and related genera.[3]

3. PRINCIPLE

L-leucine-β-naphthylamide is the substrate in LAP Disk which is hydrolyzed by leucine aminopeptidase, releasing β-naphthylamine. A positive test is indicated when the disk color changes from white to a pink to red color after addition of the reagent, ρ-dimethyl-aminocinnamaldehyde (PYR Reagent).

4. REAGENTS

Reactive Ingredient: L-Leucine-β-Naphthylamide

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 micro-biological 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, or (3) 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.[4,5]

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) Microscope slide, (7) Forceps, (8) Demineralized water, (9) Applicator sticks, (10) PYR Reagent (REF R21258).

10. PROCEDURE

1. Place an LAP Disk on the agar surface or in a sterile petri dish.
2. Rehydrate the disk with a drop (10-20 µl) of sterile demineralized water. Do not oversaturate the disk.
3. The test isolate should be 18-72 hours old and in pure culture. Using an inoculating loop or applicator stick, inoculate the disk with a heavy visible inoculum.
4. Incubate the disk at room temperature for 5 minutes.
5. Add one drop of PYR Reagent to the disk.
6. Allow up to one minute for a pink to red color to develop.

11. INTERPRETATION

Positive Test - Pink to red color development
Negative Test - No color change

12. QUALITY CONTROL

All lot numbers of LAP 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
Enterococcus faecalis ATCC® 29212	Ambient, 5 minutes @ 20°C	Positive
Aerococcus viridans ATCC® 11563	Ambient, 5 minutes @ 20°C	Negative

13. EXPECTED VALUES[4]

Aerococcus urinae .....(+)
Aerococcus viridans.....(-)
Enterococcus.....(+)
Gemella haemolysans ....(-)
Gemella morbillorum.....(+)
Globicatella .....(-)
Helococcus.....(-)
Leuconostoc .....(-)
Pediococcus .....(+)
Streptococcus .....(+)

14. LIMITATIONS

1. Color development noted after one minute should be disregarded.
2. False-negative reactions may result if inadequate inoculum is used.
3. This test is only part of the overall scheme for identification of Gram-positive cocci. Additional biochemical and/or serological testing may be required for definitive identification. Consult appropriate references for further instructions.[4,5]

15. PERFORMANCE CHARACTERISTICS[6]

An evaluation of 114 strains of streptococci and related genera resulted in 97% correlation with expected values.

Genus	Total Tested	Total Positive	% Positive
Aerococcus	17	0	0
Enterococcus	26	22	85
Gemella	13	9	69
Lactococcus	13	13	100
Leuconostoc	14	0	0
Pediococcus	11	11	100
Streptococcus	20	20	100

Note: *All E. faecalis and E. faecium, which comprise >95% of the enterococci isolated from clinical specimens, were LAP-positive in this evaluation (R.Facklam, unpublished data).*

16. BIBLIOGRAPHY

1. Colman, G. and L.C. Ball. 1984. J. Appl. Microbiol. 57:1-14.
2. Fertally, S. and R. Facklam. 1987. J. Clin. Microbiol. 25:1845-1850.
3. Ruoff, K.L., D.R. Kuritzkes, J.S. Wolfson, and M.J. Ferraro. 1988. J. Clin. Microbiol. 26:2064-2068.
4. 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.
5. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2007. Bailey and Scott's Diagnostic Microbiology. 12th ed. Mosby Elsevier, St. Louis, MO.
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17. PACKAGING

REF R21129, LAP Disk ..... 25 Disks/Vial

18. 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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Remel Inc., 12076 Santa Fe Trail Drive, Lenexa, KS 66215, USA

www.thermofisher.com/microbiology
Tel: (800) 255-6730 • International: (913) 888-0939

www.oxoid.com/IFU
Europe +800 135 79 135 • US 1 855 2360 190
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