remel INDOXYL ACETATE DISK

REF R21087......25 Disks/Vial

1. INTENDED USE

Remel Indoxyl Acetate Disk is a reagent-impregnated disk recommended for use in qualitative procedures to aid in the identification of *Campylobacter*, *Helicobacter*, and *Wolinella* based on the ability to hydrolyze indoxyl acetate.

2. SUMMARY AND EXPLANATION

In 1987, Mills et al. evaluated 112 strains of *Campylobacter* for the ability to hydrolyze indoxyl acetate. They found the indoxyl acetate test was a rapid and accurate method for identification of *Campylobacter spp.*, producing results that were not affected by the type of medium used for growth of the organism. Hodge et al. confirmed these findings in 1990, reporting the Indoxyl Acetate Disk was reliable for differentiation of *Campylobacter spp.* especially strains exhibiting aberrant phenotypic characteristics. In 1990, Popovic-Uroic et al. further investigated the Indoxyl Acetate Disk for identification of related genera, *Helicobacter* and *Wolinella*, as well as *Campylobacter*. They reported the method to be more reliable than nalidixic acid susceptibility for differentiation of *Campylobacter spp.* and useful in differentiating *Wolinella* and *Helicobacter*.

3. PRINCIPLE

Bacterial esterase releases indoxyl from indoxyl acetate which reacts spontaneously to produce indigo in the presence of oxygen. A positive result is indicated by the development of a blue color.

4. REAGENTS

Reactive Ingredient: Indoxyl Acetate

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.

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 and protect from light.

7. PRODUCT DETERIORATION

This product should not be used if (1) the disk 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.⁴

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) Forceps, (7) Microscope slide, (8) Demineralized water, (9) Applicator sticks.

10. PROCEDURE

- The test isolate should be 18-72 hours old and in pure culture.
- Using forceps, place an Indoxyl Acetate Disk on a clean glass microscope slide. Rehydrate the disk with one drop (20-40 µl) of demineralized water; do not oversaturate. Alternatively, the disk can be placed directly on the agar plate where it will absorb moisture from the medium.
- Using an applicator stick, inoculate the disk with several colonies of the test isolate.
- 4. Incubate the disk at room temperature for 20 minutes.
- 5. Examine for a blue or blue-green color development.

11. INTERPRETATION

Positive Test - Blue or blue-green color development Negative Test - No color development

12. QUALITY CONTROL

All lot numbers of Indoxyl Acetate 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
Campylobacter jejuni ATCC® 33291	Ambient, 20 minutes @ 25°C	Positive
Campylobacter fetus subsp. fetus ATCC® 27374	Ambient, 20 minutes @ 25°C	Negative

13. EXPECTED VALUES^{3,4}

Campylobacter jejuni+
Campylobacter jejuni subsp. doylei+
Campylobacter coli+
Campylobacter upsaliensis+
Campylobacter fetus subsp. fetus
Campylobacter fetus subsp. venerealis
Campylobacter lari
Campylobacter concisus
Campylobacter hyointestinalis
Helicobacter cinaedi
Helicobacter fennelliae+
Helicobacter pylori
Wolinella succinogens

14. PERFORMANCE CHARACTERISTICS

An evaluation of 22 strains of *Campylobacter* and related genera showed 100% agreement with expected values.⁵ In 1990, 981 strains of *Campylobacter*, *Wolinella*, and *Helicobacter* were evaluated in separate studies, published by Hodge et al. and Popovic-Uroic et al.^{2,3} They reported 100% agreement with earlier findings.¹

15. BIBLIOGRAPHY

- Mills, C.K. and R.L. Gherna. 1987. J. Clin. Microbiol. 25:1560-1561.
- Hodge, D.S., A. Borczyk, and L. Wat. 1990. J. Clin. Microbiol. 28:1482-1483.
- Popovic-Uroic, T., C.M. Patton, M.A. Nicholson, and J.A. Kiehlbauch. 1990. J. Clin. Microbiol. 28:2335-2339.
- 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. Data on file. 1992. Remel Inc., Lenexa, KS.

16. PACKAGING

REF R21087, Indoxyl Acetate Disk25 Disks/Vial

17. SYMBOL LEGEND

REF	Catalogue Number
IVD	In Vitro 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

 $\ensuremath{\mathsf{ATCC}}^{\circledast}$ is a registered trademark of American Type Culture Collection.

IFU IFU21087, Revised November, 2020 Printed in UK

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