INDOXYL ACETATE DISK

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.

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.

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.

REAGENTS
Reactive Ingredient: Indoxyl Acetate

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.

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.

SPECIMEN COLLECTION, STORAGE, TRANSPORT
Specimens should be collected and handled following recommended guidelines.4

MATERIALS REQUIRED BUT NOT SUPPLIED

PROCEDURE
1. The test isolate should be 18-72 hours old and in pure culture.
2. 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.
3. 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.

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

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
<table>
<thead>
<tr>
<th>Organism</th>
<th>Incubation</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter jejuni</td>
<td>Ambient, 20 min. @ 25°C</td>
<td>Positive</td>
</tr>
<tr>
<td>ATCC® 33291</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Campylobacter fetus subsp. fetus</td>
<td>Ambient, 20 min. @ 25°C</td>
<td>Negative</td>
</tr>
<tr>
<td>ATCC® 27374</td>
<td></td>
<td></td>
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</tbody>
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INOCULATION

RESULTS

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<td></td>
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</tr>
</tbody>
</table>
EXPECTED VALUES

- 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 succinogenes

PERFORMANCE CHARACTERISTICS

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

BIBLIOGRAPHY


PACKAGING

REF R21087, Indoxyl Acetate Disk .......25 Disks/Vial

Symbol Legend

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