**10% FERRIC CHLORIDE**
*(Phenylalanine Deaminase)*

**INTENDED USE**
Remel 10% Ferric Chloride reagent is recommended for use in qualitative procedures to detect phenylalanine deamination.

**SUMMARY AND EXPLANATION**
Henriksen and Closs reported *Proteus* could be differentiated from other enteric gram-negative bacilli based on the ability to deaminate phenylalanine into phenylpyruvic acid.\(^1,2\) This reaction, while primarily associated with *Proteus*, is also characteristic of *Providencia* and *Morganella* spp.\(^4,5\) A 10% Ferric Chloride solution is used to detect phenylpyruvic acid, formed in the deamination of phenylalanine.\(^6\)

**PRINCIPLE**
Phenylalanine is the substrate which undergoes oxidative deamination to yield phenylpyruvic acid, a keto acid. When 10% Ferric Chloride is added, it chelates with phenylpyruvic acid to form a green color.

**REAGENTS (CLASSICAL FORMULA)***
- Ferric Chloride (CAS 10025-77-1) ............... 120.0 g
- Hydrochloric Acid (Conc.) (CAS 7647-01-0) ... 25.0 ml
- Demineralized Water (CAS 7732-18-5) ......... 975.0 ml

*Adjusted as required to meet performance standards.

**PRECAUTIONS**
**DANGER! CORROSIVE**, may cause burns or irritation to skin, eyes or respiratory tract. Avoid breathing vapor and eye/skin contact.

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. Refer to Material Safety Data Sheet for additional information for reagent chemicals.

**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. 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.

**SPECIMEN COLLECTION, STORAGE, TRANSPORT**
Specimens should be collected and handled following recommended guidelines.\(^3\)

**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) Phenylalanine Agar (REF R062180).

**PROCEDURE**
1. Using a heavy inoculum from a pure, 18-24 hour culture, inoculate a Phenylalanine Agar slant.
2. Incubate the tube aerobically with cap loosened for 18-24 hours at 33-37°C. (If the medium is heavily inoculated, 4 hours incubation should be sufficient.)\(^4\)
3. Add 4-5 drops of 10% Ferric Chloride to the slant and gently rotate the tube.
4. Observe for development of a green color within 5 minutes.\(^5\)

**INTERPRETATION**
<table>
<thead>
<tr>
<th>Positive Test</th>
<th>Negative Test</th>
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</thead>
<tbody>
<tr>
<td>Green color developing within 5 minutes</td>
<td>No color development within 5 minutes</td>
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</table>

**QUALITY CONTROL**
All lot numbers of 10% Ferric Chloride have been tested using the following quality control organisms 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.

<table>
<thead>
<tr>
<th>CONTROL</th>
<th>INCUBATION</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Proteus vulgaris</em> ATCC® 6380</td>
<td>Aerobic, 18-24 h @ 33-37°C</td>
<td>Positive</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC® 25922</td>
<td>Aerobic, 18-24 h @ 33-37°C</td>
<td>Negative</td>
</tr>
</tbody>
</table>
LIMITATIONS
1. Because the green color of a positive test fades quickly, the test must be interpreted within the first 5 minutes after adding 10% Ferric Chloride.
2. A color change in the 10% Ferric Chloride reagent or the formation of a precipitate will not reduce the effectiveness of the reagent.

BIBLIOGRAPHY

PACKAGING
REF R21218, 10% Ferric Chloride .........25 ml/Btl

Symbol Legend
<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog Number</th>
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<tbody>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
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<tr>
<td>LAB</td>
<td>For Laboratory Use</td>
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<td>i</td>
<td>Consult Instructions for Use (IFU)</td>
</tr>
<tr>
<td>Temperature Limitation (Storage Temp.)</td>
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<tr>
<td>LOT</td>
<td>Batch Code (Lot Number)</td>
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<td>Use By (Expiration Date)</td>
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CAS (Chemical Abstracts Service Registry No.)