Intended Use

Wellcolox Colour Salmonella provides a simple, rapid qualitative latex test for the screening, detection and presumptive serogroup identification of Salmonella from Selenite F broth and colonies from solid agar. Wellcolox Colour Salmonella has been categorised as highly complex under CLIA.

Summary and Explanation of the Test

The genus Salmonella is responsible for a wide spectrum of human disease ranging from mild forms of gastroenteritis to severe, life-threatening septicemia, fever and in addition, asymptomatic carriage can occur. Early, reliable identification is important to the provision of appropriate therapy and to control outbreaks. Minimal identification of the organisms involves both biochemical and serological procedures. Definitive serological testing requires a large number of antisera to both cell-associated "O" antigens and flagellar "H" antigens, and ideally this process is performed in a reference laboratory to identify the isolate to the "O" serogroup level prior to submitting it to a reference laboratory for specific identity.

Principle of the Procedure

To perform Wellcolox Colour Salmonella, a sample from a Selenite F broth culture (18 to 24 hours incubation) or a suspension of colonies cultured on nutrient agar is reacted with two test reagents, consisting of a mixture of suspensions of red, blue and green latex particles, each of which is coated with antibody specific for different Salmonella serogroups. In the presence of homologous antigen, one of the latex particles agglutinates to form a particle, which is visible to the naked eye, but with no antigen present, the particles remain in smooth grey-brown clumps. The agglutinates are readily differentiated from a positive or negative reaction and may give unsatisfactory results and should not be used.

Reagents

<table>
<thead>
<tr>
<th>REF</th>
<th>R30858301</th>
<th>R30858302</th>
<th>Colour</th>
<th>Latex Reagents</th>
<th>Cards</th>
<th>Sample Dispensers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex reagent 1</td>
<td>1 dropper bottle (white cap)</td>
<td>1 dropper bottle (white cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Latex reagent 2</td>
<td>1 dropper bottle (red cap)</td>
<td>1 dropper bottle (red cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Red Positive Control</td>
<td>1 dropper bottle (red cap)</td>
<td>1 dropper bottle (red cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Blue Positive Control</td>
<td>1 dropper bottle (blue cap)</td>
<td>1 dropper bottle (blue cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Green Positive Control</td>
<td>1 dropper bottle (green cap)</td>
<td>1 dropper bottle (green cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Blue Positive Control</td>
<td>1 dropper bottle (blue cap)</td>
<td>1 dropper bottle (blue cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Blue Positive Control</td>
<td>1 dropper bottle (blue cap)</td>
<td>1 dropper bottle (blue cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
<tr>
<td>Blue Positive Control</td>
<td>1 dropper bottle (blue cap)</td>
<td>1 dropper bottle (blue cap)</td>
<td>Cards</td>
<td>1 pack</td>
<td>2 packs</td>
<td></td>
</tr>
</tbody>
</table>

Safety Precautions

- Use personal protective equipment before use.
- Obtain special instructions from the manufacturer before use as this product contains formaldehyde. It may also be used for testing with Wellcolex Colour Shigella (ZC51/R30858401).

Procedure

- Place 0.5 ml sample as a flat bed of bacteria from solid agar is reacted with two test reagents, reference laboratory and 100 tests (ZC51/R30858101), see also

Practice

- For laboratory use only.
- Each laboratory should have its own quality control procedures for Wellcolox Colour Salmonella. A full set of the quality control procedures for Wellcolox Colour Salmonella is provided in the Wellcolox Quality Control Manual (ZC50/R30858303).

Warrnings and Precautions

- In order to perform the test correctly, the test reagents should be handled with care. For optimum results, the reagents are to be stored in a dry place, away from direct sunlight and out of reach of children.

Additional Precautions

- The test should be performed on a flat bed rotator with an orbital diameter of 15 ± 5 cm (25 cm maximum) and at 150 ± 5 rpm for 2 minutes.

This result should be used as a basis for comparison.

Reading of Results

- The colour of the agglutinated reagents is read against a cleared background (Figure 9). It is possible that some agglutinates may be observed with a mixed Salmonella culture, two colour agglutinates as shown in Figure 10. If there is any doubt about the reaction it should be re-tested after allowing the sample to stand for 15 minutes.

Control Procedures

- Quality control samples should be run with each shipment and new lot number received. Each laboratory should follow their state or federal guidelines for control.

Negative

- The card should be discarded for safe disposal and the sample re-tested after allowing the sample to stand for 15 minutes.

Osborneactive components may be observed with a mixed Salmonella culture, two colour agglutinates as shown in Figure 10. If there is any doubt about the reaction it should be re-tested after allowing the sample to stand for 15 minutes.

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The prevalence of Salmonella in the samples studied was 44.8%. The predictive value of a positive result was 99.3% (432/435) in this study. Wellcolex Colour Salmonella is designed as a screening procedure for salmonellae from faecal samples. A negative result indicates that the sample under test does not contain antigens belonging to the Salmonella serogroup. If a non-specific reaction is obtained the result is not interpretable. Mixed growths of non-lactose fermenters are frequently present in stool cultures, and if a negative result is obtained when testing colonies it may be necessary to repeat the test on other selected colonies before discarding the culture as negative.

### Table 1

<table>
<thead>
<tr>
<th>Routine Result</th>
<th>Colour</th>
<th>Numerators</th>
<th>Denominators</th>
<th>Positive Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salmonella</strong></td>
<td><strong>115</strong></td>
<td>7</td>
<td>114</td>
<td>99.1%</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Routine Result</th>
<th>Numerators</th>
<th>Denominators</th>
<th>Positive Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSITIVE</strong></td>
<td><strong>115</strong></td>
<td><strong>114</strong></td>
<td><strong>99.1%</strong></td>
</tr>
<tr>
<td><strong>NEGATIVE</strong></td>
<td><strong>115</strong></td>
<td><strong>1</strong></td>
<td><strong>99.9%</strong></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>121</strong></td>
<td><strong>312</strong></td>
<td><strong>99.4%</strong></td>
</tr>
</tbody>
</table>

### 12. LIMITATIONS OF THE PROCEDURE

Once enrichment broth cultures have been transferred to the sorbitol MacConkey (SMC) and XLD plates, a red precipitate will be found on bacteria other than Salmonella; these may be differentiated using the colour of the agglutinated latex particles only. In such a case identification is made using the colour of the agglutinated latex particles only. In such a case identification is made using the colour of the agglutinated latex particles only.

### 13. EXPECTED RESULTS

<table>
<thead>
<tr>
<th>Serum to be Used</th>
<th>Numerators</th>
<th>Denominators</th>
<th>Positive Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSITIVE</strong></td>
<td><strong>112</strong></td>
<td><strong>1</strong></td>
<td><strong>99.1%</strong></td>
</tr>
<tr>
<td><strong>NEGATIVE</strong></td>
<td><strong>112</strong></td>
<td><strong>1</strong></td>
<td><strong>99.9%</strong></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>126</strong></td>
<td><strong>313</strong></td>
<td><strong>99.4%</strong></td>
</tr>
</tbody>
</table>

### 14. BIBLIOGRAPHY