1. INTENDED USE
Wellcolex® Colour Salmonella provides a simple, rapid qualitative latex test procedure for the screening, detection and presumptive serogroup identification of Salmonella from faecal broth and on solid media. The Wellcolex® Colour Salmonella test has been categorised as highly complex under CIQ.

2. SUMMARY AND EXPLANATION OF THE TEST
Life-threatening enteric infections can be caused by a wide range of bacteria from the Enterobacteriaceae family. The genus Salmonella is responsible for a wide spectrum of human disease ranging from mild forms of gastroenteritis to severe, life-threatening enteric fever and, in addition, asymptomatic disease. Salmonella infections are caused by organisms with Salmonella group A or B antigens containing 0.05% B and Vi antigens or 0.05% F5 antigens or 0.5% formalin as preservative.

3. PRINCIPLE OF THE PROCEDURE
For professional use only.

4. MATERIALS PROVIDED

5. DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

6. WARNINGS AND PRECAUTIONS

7. SPECIMEN COLLECTION AND PREPARATION OF CULTURES

8. RESULTS

9. QUALITY CONTROL

10. CONTROL PROCEDURES

Control procedures should be run with each shipment and lot number received. Each laboratory should follow their state and local requirements.


**SPECIFIC PERFORMANCE CHARACTERISTICS**

**External Evaluation**

Two studies have been performed to evaluate Wellcolex® Colour Salmonella:

(a) A multicentre study involving five Public Health Laboratories in the UK and three hospital laboratories in the USA on routine cultures for Salmonella. Each laboratory performed tests on one or more of the following samples from each faecal specimen:

1. Salmonella enrichment broths (Salten® F).
2. Lactose negative colonies direct from enrichment broth subcultures on selective differential agar plates.
3. Lactose negative colonies direct from primary selective-differential agar plates (MacConkey, XLD, IDCA, 55 and 55b).
4. Pure subcultures of lactose negative colonies on nutrient agar.

An rotor was used throughout.

The results are shown in Tables 1 and 2. The performance of Wellcolex® Colour Salmonella was determined by comparison with results of traditional bacteriological methods on the samples.

In this study the sensitivity and specificity of Wellcolex® Colour Salmonella (see Tables 1 and 2) were:

- **Sensitivity**: 99.7% (242/243) from broth subculture.
- **Specificity**: 99.5% (192/193) from pure cultures.

The predictive value of a positive result was 99.3% (432/435) with 100% (393/393) for pure cultures and 98.0% (100/102) with 100% (90/90) for broth subculture.

(b) An independent study on fresh isolates and reference cultures.

The predictive value of a positive result was 99.3% (432/435) with 100% (393/393) for pure cultures and 98.0% (100/102) with 100% (90/90) for broth subculture.

Non-Salmonella cultures were encountered which carried Vi antigen: none of these reacted with group-specific components in the test.

The predictive value of a positive result was 99.7% (242/243) and 97.8% (205/208) respectively.

The prevalence of Salmonella in the samples studied was 44.8% (554/1237).

The occurrence of non-interpretable reactions with Wellcolex® Colour Salmonella was 4.9% (5/102) for primary plate cultures, 6.1% (1/105) for enrichment broth subcultures, 3.0% (1/35) for pure cultures and 2.1% (6/306) from Salmonella broth subcultures. These samples have been excluded from Tables 1 and 2.


### Table 2

<table>
<thead>
<tr>
<th>Wellcolex® Colour Salmonella</th>
<th>Routine Culture Method</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td><strong>Specificity</strong></td>
<td><strong>POSITIVE</strong></td>
</tr>
<tr>
<td>Primary plate cultures</td>
<td>Positivity</td>
<td>100%</td>
</tr>
<tr>
<td>Enrichment cultures</td>
<td>False negativity</td>
<td>97%</td>
</tr>
<tr>
<td>Subcultures</td>
<td>Positive</td>
<td>100%</td>
</tr>
<tr>
<td>Subculture from broth cultures</td>
<td>False negativity</td>
<td>100%</td>
</tr>
<tr>
<td>Pure cultures</td>
<td>Positive</td>
<td>99.0%</td>
</tr>
</tbody>
</table>

Note: When using Selenite F broth the background colour is usually reddish-brown. In this study less than 1% of Selenite F broth cultures were insufficient to give a positive result.

**12. LIMITATIONS OF THE PROCEDURE**

Wellcolex® Colour Salmonella is designed as a screening procedure for salmonellae from Salmonella F broths and from solid media as a culture identification test. The test will identify Salmonella isolates to serogroup level, which is satisfactory for most purposes when full identification can be performed by a reference laboratory.

Definitive identification requires conventional biochemical and serological procedures (18), selection of appropriate antimicrobes may be guided by the results of Wellcolex® Colour Salmonella.

### Table 1

<table>
<thead>
<tr>
<th>Wellcolex® Colour Salmonella</th>
<th>Routine Culture Method</th>
<th>Test Result</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary plate cultures</td>
<td>Positivity</td>
<td>100%</td>
<td>0.2%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Enrichment cultures</td>
<td>False negativity</td>
<td>97%</td>
<td>0.1%</td>
<td>97.1%</td>
<td></td>
</tr>
<tr>
<td>Subcultures</td>
<td>Positive</td>
<td>100%</td>
<td>0.2%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Subculture from broth cultures</td>
<td>False negativity</td>
<td>100%</td>
<td>0.2%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Pure cultures</td>
<td>Positive</td>
<td>99.0%</td>
<td>0.9%</td>
<td>99.9%</td>
<td></td>
</tr>
</tbody>
</table>

Note: When using Selenite F broth the background colour is usually reddish-brown. In this study less than 1% of Selenite F broth cultures were insufficient to give a positive result.

**12. LIMITATIONS OF THE PROCEDURE**

Wellcolex® Colour Salmonella is designed as a screening procedure for salmonellae from Salmonella F broths and from solid media as a culture identification test. The test will identify Salmonella isolates to serogroup level, which is satisfactory for most purposes when full identification can be performed by a reference laboratory.

Definitive identification requires conventional biochemical and serological procedures (18), selection of appropriate antimicrobes may be guided by the results of Wellcolex® Colour Salmonella.

Occasional false-positive reactions might be encountered due to the presence of shared antigens in heterologous species or to the presence of Vi antigen, which may be detected by this method.

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Other limitations of this method include:

- Some sub-optimal preparations of Salmonella F broth contain a brick-red precipitate and caution should be exercised in interpreting results obtained in this medium.
- The presence of Vi antigen may give a red, blue or green agglutination with the corresponding component of Latex Reagent 1 or 2.

### Table 1: Identification of Salmonella from Plate Cultures

<table>
<thead>
<tr>
<th>Wellcolex® Colour Salmonella</th>
<th>Routine Culture Method</th>
<th>Test Result</th>
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<th>Negative</th>
<th>Total</th>
</tr>
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<tr>
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<td>100%</td>
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<td></td>
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<td>Enrichment cultures</td>
<td>False negativity</td>
<td>97%</td>
<td>0.1%</td>
<td>97.1%</td>
<td></td>
</tr>
<tr>
<td>Subcultures</td>
<td>Positive</td>
<td>100%</td>
<td>0.2%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Subculture from broth cultures</td>
<td>False negativity</td>
<td>100%</td>
<td>0.2%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Pure cultures</td>
<td>Positive</td>
<td>99.0%</td>
<td>0.9%</td>
<td>99.9%</td>
<td></td>
</tr>
</tbody>
</table>

Note: When using Selenite F broth the background colour is usually reddish-brown. In this study less than 1% of Selenite F broth cultures were insufficient to give a positive result.

**12. LIMITATIONS OF THE PROCEDURE**

Wellcolex® Colour Salmonella is designed as a screening procedure for salmonellae from Salmonella F broths and from solid media as a culture identification test. The test will identify Salmonella isolates to serogroup level, which is satisfactory for most purposes when full identification can be performed by a reference laboratory.

Definitive identification requires conventional biochemical and serological procedures (18), selection of appropriate antimicrobes may be guided by the results of Wellcolex® Colour Salmonella.

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Other limitations of this method include:

- Some sub-optimal preparations of Salmonella F broth contain a brick-red precipitate and caution should be exercised in interpreting results obtained in this medium.
- The presence of Vi antigen may give a red, blue or green agglutination with the corresponding component of Latex Reagent 1 or 2.