Some strains of Staphylococcus spp., particularly S. saprophyticus, may cause non-specific aggregation of latex particles. Therefore a Control Latex is provided to assist with the identification of non-specific reactions.

**REAGENTS**

**KIT CONTENTS**

- Staphaurex Plus* 2L33/R30950102 2L34/R30950201 450 Tests
- 1. Test Latex (Yellow cap) 1 dropper bottle 3 dropper bottles
- 2. Control Latex (Grey cap) 1 dropper bottle 3 dropper bottles
- 3. Disposable Reaction Cards (RT64/R30369001) 2 packs 6 packs
- 4. Disposable Mixing Sticks 3 bundles 9 bundles
- 5. Instructions for Use 1

**DESCRIPTION OF REAGENTS, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS**

See also Warnings and Precautions.

**TEST LATEX**

A buffered suspension of yellow polystyrene latex particles coated with human fibrinogen and rabbit IgG. Contains 0.05% Bromidox® preservative. Materials of human origin have been tested for the presence of hepatitis B surface antigen, anti-HCV and anti-HIV-1/2 and found to be negative.

**CONTROL LATEX**

A buffered suspension of yellow polystyrene latex particles coated with a bovine serum protein unreactive with S. aureus. Contains 0.05% Bromidox® preservative.

Reaction Cards and Mixing Sticks should be stored at room temperature (15 to 30°C). Staphaurex Plus* (ZL33/R30950102 and ZL34/R30950201) was developed using RT64/R30369001 Disposable Reaction Cards. Do not substitute another disposable slide for the RT64/R30369001 Disposable Reaction Cards when samples are tested using Staphaurex Plus*.

**WARNINGS AND PRECAUTIONS**

**IVD**

For in vitro diagnostic use only.

For professional use only.

Please refer to the manufacturer’s safety data sheet and the product labelling for information on potentially hazardous components.

**HEALTH AND SAFETY INFORMATION**

1. CAUTION: This kit contains human sourced components. No known test can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human sourced material should be considered potentially infectious. It is recommended that these reagents and test specimens be handled using established good laboratory working practices.

2. Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is autoclave for 15 minutes at 121°C. Disposables should be autoclaved or incinerated. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a standard bacterial disinfectant. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

3. Wear laboratory coat, disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

4. When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions in these Instructions for Use, the reagents supplied are not considered to present a hazard to health.

**ANALYTICAL PRECAUTIONS**

1. Do not use the reagents beyond the stated expiry date.

2. Latex reagents should be brought to room temperature (15 to 30°C) before use. Latex reagents which show signs of aggregation or ‘lumpiness’ before use may have frozen and should not be used.

3. It is important when using dropper bottles that they are held vertically and that the drop forms at the tip of the nozzle. If the nozzle is not vertical an incorrect volume will form around the end of the stick. As a guide, an amount of growth roughly equivalent to six average-sized colonies should be used.

4. Emulsify the sample of culture in the drop of Test Latex by rubbing with the flat end of the stick. Rub thoroughly, but not too vigorously or the surface of the card may be damaged. Some strains, particularly of species other than S. aureus remain difficult to emulsify and this should be noted, since lumps of unmixed culture can make the latex appear ‘rough’ or ‘stringy’ when read. Spread the latex over approximately half the area of the circle. Discard the mixing stick for safe disposal.

5. Using a separate stick, emulsify a similar culture sample in the Control Latex, as stated in Step 4. Discard the mixing stick for safe disposal.

6. Rock the card slowly for up to 30 seconds while observing for agglutination. The card should be held at normal reading distance (25 to 35 cm) from the eyes. Do not use a magnifying lens.

7. Discard the used Reaction Card for safe disposal.

**RESULTS**

Positive Result

Agglutination of the Test Latex accompanied by a lack of agglutination of the Control Latex indicates the presence of either coagulase, protein A or antigens commonly found on S. aureus in the culture under test. Most positive reactions will be almost instantaneous. False positive results can occur if the test is read after more than 30 seconds.

**STAPHYLOCOCCUS AUREUS**

SUMMARY AND EXPLANATION OF THE TEST

*S. aureus* possess a number of properties which are used to confirm identification. These include free coagulase, clumping factor, or fibrinogen and immunoglobulin G (IgG), to detect both clumping factor and *S. aureus* particles which have been coated with fibrinogen and rabbit IgG. To detect both staphylococci which possess clumping factor, protein A and/or surface antigens characteristic of *Staphylococcus aureus*.

**INTENDED USE**

Staphaurex Plus* is a rapid latex agglutination test for the identification of staphylococci which possess clumping factor, protein A and/or surface antigens characteristic of *Staphylococcus aureus*.

**SPERM COLLECTED AND STORAGE**

For details of sperm collection and treatment a standard test book should be consulted. Cultures may be tested from any of the following media:

<table>
<thead>
<tr>
<th>Blood agar</th>
<th>Columbia CNA agar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrient agar</td>
<td>Muller Hinton agar with 5% blood</td>
</tr>
<tr>
<td>Tryptone soya agar</td>
<td>Baird-Parker agar</td>
</tr>
<tr>
<td>Tryptone soya agar with 5% blood</td>
<td>Mannitol-salt agar*</td>
</tr>
</tbody>
</table>

**Note:** specimens grown on media containing antibiotics or a high-salt-supplemented medium such as Mannitol-salt agar may give an agglutination containing stringy aggregates. **THE USE OF FRESH CULTURES GROWN OVERNIGHT IS RECOMMENDED.**

**PROCEDURE**

**MATERIALS PROVIDED**

Sufficient materials are provided for 150 (ZL33/R30950102) or 450 (ZL34/R30950201) tests, see Kit Contents.

**TEST PROCEDURE**

Please read Analytical Precautions carefully before performing the test.

**Step 1**

Shake vigorously and examine the latex reagents for aggregation before use. Refer to Quality Control Section and Visual Inspection for additional instructions.

**Step 2**

For each test sample place one drop of Test Latex in one circle on a Reaction Card (RT64/R30369001) and one drop of Control Latex in a separate circle. Ensure that the dropper bottles are held vertically to disperse an accurate drop.

**Step 3**

Using a mixing stick, remove sufficient growth from a pure culture or well-isolated colonies to cover the blunt end of the stick. As a guide, an amount of growth roughly equivalent to six average-sized colonies should be used.

**Step 4**

Emulsify the sample of culture in the drop of Test Latex by rubbing with the flat end of the stick. Rub thoroughly, but not too vigorously or the surface of the card may be damaged. Some strains, particularly of species other than S. aureus remain difficult to emulsify and this should be noted, since lumps of unmixed culture can make the latex appear ‘rough’ or ‘stringy’ when read. Spread the latex over approximately half the area of the circle. Discard the mixing stick for safe disposal.

**Step 5**

Using a separate stick, emulsify a similar culture sample in the Control Latex, as stated in Step 4. Discard the mixing stick for safe disposal.

**Step 6**

Rock the card slowly for up to 30 seconds while observing for agglutination. The card should be held at normal reading distance (25 to 35 cm) from the eyes. Do not use a magnifying lens.

**Step 7**

Discard the used Reaction Card for safe disposal.
Suitable reference strains are shown below.

**EXPECTED RESULTS**

Strong agglutination with S. aureus cultures, no agglutination with staphylococci which possess neither clumping factor, protein A or surface antigens characteristic of S. aureus.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The performance of Staphaurex Plus® has been evaluated in four North American and two European microbiological reference laboratories on a total of 646 routine (presumed staphylococcal) clinical isolates and 671 stored cultures. The cultures were tested in parallel with the tube coagulase procedure, Gram stain and at least one alternative rapid test for the identification of S. aureus. The results are summarised Tables 1 and 2.

**CLINICAL ISOLATES**

**Methicillin Resistant S. aureus (MRSA)**

A total of 151 fresh S. aureus cultures shown to be resistant to one or more antibiotics were tested. Staphaurex Plus® correctly identified 281 of these isolates. The discrepant culture was positive with a tube coagulase test and negative with an alternative rapid latex test.

The sensitivity of Staphaurex Plus® on this group of MRSA cultures is estimated to be 99.65% (281/282).

**Methicillin Sensitive S. aureus (MSSA)**

Staphaurex Plus® correctly identified 242 of 248 confirmed S. aureus cultures from the microbiological reference laboratories. The discrepant cultures included four which also gave a negative result with the alternative rapid latex test.

The sensitivity of Staphaurex Plus® on this group of MSSA cultures is estimated to be 97.6% (242/248).

**Other staphylococci**

A total of 139 stored non-S. aureus staphylococcal cultures were also tested. Staphaurex Plus® gave a negative result with 132 of these isolates which included S. saprophyticus, S. epidermidis and S. haemolyticus. The remaining seven cultures which gave a positive result with Staphaurex Plus® included two which were also positive with an alternative rapid latex test.

The specificity of Staphaurex Plus® on this group of non-S. aureus staphylococcal cultures is estimated to be 95.0% (132/139).

**Overall Performance of Staphaurex Plus® in Comparison with Tube Coagulase on stored s. aureus cultures**

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>EXPECTED RESULT</th>
<th>TEST LATEX</th>
<th>CONTROL LATEX</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus (ATCC® 25923™)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>S. epidermidis (ATCC® 12288™)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

**INTERPRETATION OF RESULTS**

A positive reaction indicates the presence of one or more of clumping factor, protein A or cell surface antigens in the culture under test and a negative result indicates their absence.

**LIMITATIONS OF THE PROCEDURE**

1. Specimens grown on media containing antibiotics or a high-limitation of the Procedure

2. Some species of staphylococci in addition to S. aureus notably S. hyicus, S. intermedius, S. lugdunensis and S. schleifei, may give positive results in one test and may also react in rapid latex procedures. If necessary these species may be identified by biochemical test procedures. S. hyicus and S. intermedius are encountered rarely in the clinical laboratory.

3. Some other coagulase negative staphylococcal species, such as S. capitis possess plasminogen protein binding factors, which do not react in the Staphaurex Plus® test. However, a few strains identified biochemically as S. saprophyticus have given weak positive reactions and further identification of urinary isolates may be required.

4. Some streptococci and possibly other organisms possess immunoglobulin or other plasma protein binding factors which react in the latex test and there are several bacteria such as E. coli, which are able to non-specifically agglutinate latex particles. To eliminate potential interference from these organisms a Gram stain and catalase test should be performed so that only organisms with staphylococcal morphology are tested.

**STORRED CULTURES**

**Methicillin Resistant S. aureus (MRSA)**

A total of 282 stored S. aureus cultures shown to be resistant to one or more antibiotics were tested. Staphaurex Plus® correctly identified 281 of these isolates. The discrepant culture was positive with a tube coagulase test and negative with an alternative rapid latex test.

The sensitivity of Staphaurex Plus® on this group of MRSA cultures is estimated to be 99.65% (281/282).

**Methicillin Sensitive S. aureus (MSSA)**

Staphaurex Plus® correctly identified 242 of 248 confirmed S. aureus cultures from the microbiological reference laboratories. The discrepant cultures included four which also gave a negative result with the alternative rapid latex test.

The sensitivity of Staphaurex Plus® on this group of MSSA cultures is estimated to be 97.6% (242/248).

**OTHER STAPHYLOCOCCI**

A total of 139 stored non-S. aureus staphylococcal cultures were also tested. Staphaurex Plus® gave a negative result with 132 of these isolates which included S. saprophyticus, S. epidermidis and S. haemolyticus. The remaining seven cultures which gave a positive result with Staphaurex Plus® included two which were also positive with an alternative rapid latex test.

The specificity of Staphaurex Plus® on this group of non-S. aureus staphylococcal cultures is estimated to be 95.0% (132/139).

**Overall Performance of Staphaurex Plus® in Comparison with Tube Coagulase on stored s. aureus cultures**

<table>
<thead>
<tr>
<th>Reactivity of Staphaurex Plus® on Presumed Staphylococcal Clinical Isolates</th>
<th>Staphaurex Plus® result</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methicillin Resistant S. aureus (MRSA)</td>
<td>150</td>
<td>1</td>
<td>151</td>
<td></td>
</tr>
<tr>
<td>Methicillin Sensitive S. aureus (MSSA)</td>
<td>335</td>
<td>2</td>
<td>337</td>
<td></td>
</tr>
</tbody>
</table>

Non-S. aureus isolates:

A Staphaurex Plus® gave a non-interpretable result with 1 sample. This has been excluded from the table.

B includes S. saprophyticus, S. epidermidis and S. haemolyticus.

**Table 2**

<table>
<thead>
<tr>
<th>Reactivity of Staphaurex Plus® on Stored Staphylococcal Cultures</th>
<th>Staphaurex Plus® result</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Methicillin Resistant S. aureus (MRSA)</td>
<td>281</td>
<td>1</td>
<td>282</td>
<td></td>
</tr>
<tr>
<td>Methicillin Sensitive S. aureus (MSSA)</td>
<td>242</td>
<td>6</td>
<td>248</td>
<td></td>
</tr>
<tr>
<td>Non-S. aureus isolates</td>
<td>7</td>
<td>150</td>
<td>157</td>
<td></td>
</tr>
</tbody>
</table>

A Staphaurex Plus® gave a non-interpretable result with 2 samples. These have been excluded from the table.

B includes S. saprophyticus, S. epidermidis and S. haemolyticus.

**BIBLIOGRAPHY**

11. Henkel Klaas. Manufacturers Information and Safety Data Sheet for Bronidox® L. 

**PACKAGING**

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<td>Use by (Expiration Date)</td>
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<td></td>
<td>Caution, consult accompanying documents</td>
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<td></td>
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