STREPTOCOCCAL GROUPING LATEX TEST KIT

**INTENDED USE**
This kit is for the identification of streptococci of Lancefield’s groups A, B, C, D, F and G by agglutination of specific antibody - coated latex particles in the presence of enzymically extracted antigen.

**WARNINGS AND PRECAUTIONS**
For in vitro diagnostic use only
For professional use only

Health and Safety warnings:
All patient samples and isolates derived from patient samples and reagents should be treated as potentially infectious and the user should wear protective gloves, eye protection and laboratory coats when performing the test.
Non disposable apparatus must be sterilised after use by an appropriate method.
Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

Spillages of potentially infectious material should be absorbed with disinfectant or 70% alcohol.

**COMPOSITION**
1. 6x50 Test Kit
   - 6x50 Test Kit
   - 6x0 ml Extractions Enzyme. 2 vials. (Green label). Reconstitute each
   - Polyvalent positive control 2ml. (Red label)
   - Disposable test cards x 50.
   - Mixing sticks 300 and kit insert.

**STORAGE AND SHELF LIFE**
Store latex reagents and controls upright at 2-8°C.
DO NOT FREEZE LATEX REAGENTS.
Do not use reagents after the stated expiry date.
Once opened latex reagents may be used until the expiry date provided they have been stored correctly and have not been contaminated.

The freeze dried Extraction Enzyme should be stored at 2-8°C. Once reconstituted with 10ml of sterile distilled water, it will retain its activity for at least 3 months or until the date shown on the bottle label, whichever is sooner. Alternatively the enzyme may be stored in aliquots of 0.4ml frozen at -20°C, when it will remain active for at least 6 months or until the date shown on the original bottle, whichever is the sooner.

Do not freeze and thaw more than once!

**MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED**
Water bath @ 377°C.
Test tubes.
Pasteur and graduated pipettes.

**SPECIMEN AND SAMPLE PREPARATION**
Cultures
Note colonial characteristics, haemolysis, and cell morphology before starting the test.
Ensure that the organisms to be tested are Gram-positive and catalase-negative. Any blood agar plate culture yielding 2-6 well-separated colonies may be used, they should have been inoculated from a pure culture of the organism.

**PROCEDURE**
Principle
Streptococci carry group specific carbohydrate antigens in their cell walls. After extraction by a specially developed enzyme preparation these antigens will agglutinate latex particles coated with the corresponding antibody. The latex remains in smooth suspension in the absence of group specific antigen.

**PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE METHOD**

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<th>Reference method</th>
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<tr>
<td>+</td>
<td>607</td>
<td>55</td>
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<td>-</td>
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Sensitivity 607/662 = 92% Specificity 24/24 = 100%

**INTERNAL QUALITY CONTROL**
A positive control is provided and should be used to verify that the latex reagents are working satisfactorily under test conditions. Periodically check the following:
1. The test reagents agglutinate with a known reference Streptococcus strain
2. The test reagents do not auto agglutinate in normal saline solution.

**REFERENCES**

PSTE.V3 4/4/03