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MAST®STREP

RST 201

Intended Use
A rapid slide agglutination test for identification of streptococci of Lancefield groups A, B, C, D, F and G.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents
MAST®STREP contains the following components:
1. Latex Reagents. Ready to use. 6 x 2.5ml each for Lancefield groups A, B, C, D, F and G. Contain latex particles coated with specific rabbit antibody and less than 0.1% sodium azide as preservative.
2. Extraction Enzyme 2 x lyophilised reagent. Contains less than 0.01% Thimerosal as preservative.
3. Polyvalent Control. Ready to use. 1 x 2.5ml. Contains less than 0.1% sodium azide as preservative.
4. 50 disposable 6-place test cards.
5. 300 single use disposable Mixing Sticks.
6. Instruction Leaflet.

Each component may also be sold separately.

Stability and storage
Store unopened at 2 to 8°C until the expiry date shown on the pack label. Once opened, MAST®STREP should be stored at 2 to 8°C and may be used until the expiry date given on the label. **Do not freeze Latex Reagent.**
Once reconstituted the Extraction Enzyme will remain active for up to 3 months when stored at 2 to 8°C. Alternatively the Extraction Enzyme may be stored in 0.4ml aliquots at minus 20°C where it is active for up to 6 months or until the expiry date given on the bottle, whichever is the sooner. **Do not re-freeze aliquoted Extraction Enzyme.**

Warnings and precautions
For *in vitro* diagnostic use only. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Sodium azide preservative may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. Always dispose of by flushing to drain with plenty of water. Refer to Product Safety Data sheet.

Materials required but not provided
Standard microbiological supplies and equipment such as loops, water bath, small tubes and pipettes.

Procedure
1. Allow the MAST®STREP reagents to equilibrate to room temperature before use.
2. Reconstitute the Extraction Enzyme with 10.0ml of distilled or deionised water for use.
3. Only freshly grown overnight cultures of organisms from MAST® Blood Agar Base (DM100D) or similar media should be used for testing. Note colony characteristics, haemolysis and cell morphology before commencing the test and ensure the organism is Gram positive and catalase negative.
4. Using a sterile loop, pick 2 to 6 well separated colonies of suspected *Streptococcus* (avoiding other types of colony on the plate) and emulsify them into 0.4ml of reconstituted Extraction Enzyme. If a broth culture is to be used pipette 0.1ml of an overnight broth culture into 0.4ml of Extraction Enzyme in a clean test tube.
5. Incubate the mixture in a water bath at 37°C for 10 minutes, shaking the tube vigorously after 5 minutes. Longer periods of incubation may lead to false positive reactions.
6. Shake each of the latex reagents to suspend the particles. Then add one drop of each to the corresponding circle on the test card.
7. Using a Pasteur Pipette, add 1 drop of the suspension to each of the circles on the test card.
8. Mix and spread the fluid over the whole area of each circle, using a clean mixing stick. It is important to use a clean stick each time.
9. Rotate and rock the card gently for up to 1 minute. Note the result and dispose of the test card safely.

Interpretation of results
A positive result is indicated by visible aggregation of the latex particles. This will occur within a few seconds of mixing depending on the strength of the antigen extract.
A negative reaction is indicated by a milky appearance without any visible aggregation of the latex particles.
The first latex to show strong agglutination indicates positive identification of that specific group.
Only strong agglutination is significant. Occasionally strains of streptococci may give weak reactions with more than one group. Weak and granular reactions without clearing of the background should be ignored. If agglutination occurs in all groups, either too much enzyme has been used in the extraction procedure, in which case repeat the test, or a mixed culture has been tested, in which case check for purity of the culture and retest.

Limitations of use
False positive reactions (non-specific agglutination in all latex reagents) can occur with organisms of unrelated genera e.g. *Escherichia*, *Klebsiella* or *Pseudomonas*.
The group D antigen is common to organisms of groups Q, R and S. Only Group R is considered medically important.
False negative results can occur if an inadequate amount of organisms is used in the extraction process.

Quality control
It is recommended that quality control should be performed with the Polyvalent Control provided to verify that the latex reagents are working correctly. The Polyvalent Control requires no extraction or dilution before use and should be used as in steps 6-9 of the procedure above with 40µl of Positive Control and 1 drop of latex suspension. All latex reagents should show strong agglutination within 1 minute. Also periodically check that latex reagents agglutinate with known reference streptococci and that no autoagglutination is seen with normal saline solution. Check for signs of deterioration. Do not use reagents if they are contaminated or cloudy.

References
Bibliography available on request.

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