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MAST® ASSURE ANTISERUM YERSINIA PSEUDOTUBERCULOSIS O GROUPING

Intended Use
Liquid stable antisera for the determination of O serogroups of *Yersinia pseudotuberculosis.*

FOR IN VITRO DIAGNOSTIC USE ONLY

PLEASE NOTE
This product does not bear the CE mark indicating compliance with European in vitro diagnostic medical device regulations.
Both in Europe and the rest of the world this product is only for veterinary or research purposes only.

All users must sign a declaration that they will not use this product for diagnostic purposes on samples of human origin.

Contents: See pack label.

Formulation
MAST® ASSURE ANTISERA are prepared from rabbits hyperimmunised with standard strains of killed organisms possessing known serotypes or group specific antigens and contain 0.085% sodium azide as preservative.

Stability and storage
Store unopened at 2 to 8°C until the expiry date shown on the pack label. Once opened, MAST® ASSURE ANTISERA should be stored at 2 to 8°C and may be used until the expiry date given on the label.
Do not freeze reagents.

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, applicator sticks, clean glass microscope slides or glass test tubes swabs, MAST® culture media, incinerators and incubators, etc., as well as reagents and additives such as sterile 0.85% saline solution.

Procedure
Slide agglutination of live organisms
1. Dispense two 5 to 10 µl volumes of sterile 0.85% saline solution (saline) onto a carefully cleaned microscope slide. The slide may be partitioned using a chinagraph pencil. With a platinum wire or disposable inoculation loop take one 1 to 2mm colony of live organisms from a fresh culture on MAST® Columbia Agar DM115 with added 5 to 7% horse blood or similar at 25°C for 24 to 48 hours and emulsify into each drop of saline to produce a distinct and uniform turbidity.
2. Place a drop (30 to 40 µl) of antiserum onto one of the emulsified isolates and on to the other a drop (30 to 40µl) of saline as a control.
   Note: Do not allow the organism to contaminate the antiserum dropper bottle.
3. Mix the reagents by tilting the slide back and forth for 60 seconds while viewing it under indirect light against a dark background.
4. Distinct clumping or agglutination within this period, without clumping in the saline control (auto-agglutination), should be regarded as a positive result. Weak agglutination should be recorded as negative.

Interpretation of results
Isolates producing a distinct positive reaction with a specific monovalent antiserum are assumed to be *Yersinia pseudotuberculosis* from the Group represented by the antiserum. If no reaction is observed with one monovalent antiserum further testing should be conducted as described in steps 1 to 3, with the other monovalent antisera.

Limitations of use
Only cultures of organisms identified as *Yersinia pseudotuberculosis* by morphological and biochemical features should be serotyped with this product.
The monovalent antisera are intended for use in rapid slide agglutination tests.

Quality control
It is recommended that quality control should be performed with at least one organism to demonstrate a positive reaction and at least one organism to demonstrate a negative reaction. Do not use the product if the reactions with the control organisms are incorrect. Check for signs of deterioration. Do not use reagents if they are contaminated or cloudy.

References
Bibliography available on request.