Meningococcus Agglutinating Sera

INTENDED USE

Meningococcus Agglutinating Sera are intended for use in the qualitative serological identification of Neisseria meningitidis Groups A, C, D, X, Y, Z and W135 for epidemiological and diagnostic purposes.

SEROLOGICAL TESTS

Sero logical tests are intended for screening purposes and should not replace culture procedures.

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

The sera should be stored at 2 to 8°C under which condition they will retain their potency at least until the date shown on the bottle label.

AGGLUTINATING SERUM

Meningococcus Agglutinating Sera

Produced in rabbits and are preserved with 0.5% phenol. Each bottle, fitted with teat and dropper, contains 2 ml liquid and is supplied ready for use.

NOTE: The polyvalent sera are for slide use only. The monovalent meningococcus agglutinating sera are suitable for use in slide agglutination tests. An alternative method of typing, counter immunoelectrophoresis is also described in literature 1, 3, 4, 5, 6.

1. INTENDED USE

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2. SUMMARY AND EXPLANATION OF THE TEST

Group specificity is based on the identity of capsular polysaccharides and strains possessing these materials are specifically agglutinated by the homologous antiserum.

It is important in cases of bacterial meningitis to obtain a presumptive identification of the infecting agent as early as possible, so that adequate antimicrobial therapy can be initiated.

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3. PRINCIPLE OF THE PROCEDURE

Sero logical tests are based on the fact that antibodies in serum, produced in response to exposure to bacterial antigens, will agglutinate with bacteria carrying homologous antigens.

4. REAGENTS

KIT CONTENTS

Meningococcus Agglutinating Sera 1 dropper bottle (2 ml)

Group A  (ZM3/R30166801)
Group C  (ZM39/R30166901)
Group D  (ZM40/R30167001)
Group X  (ZM41/R30167101)
Group Y  (ZM42/R30167201)
Group Z  (ZM43/R30167301)
Group W135 (ZM44/R30167401)
Polyvalent Groups A-D  (ZM13/R30166601)
Polyvalent Groups X-Z, W135 (ZM34/R30167601)

5. WARNINGS AND PRECAUTIONS

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. N. meningitidis is classified as a pathogen and should be handled according to appropriate local and statutory guidelines.

2. Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is to autoclave for at least 15 minutes at 121°C. Disposables should be autoclaved or incinerated.

3. Spillage of potentially infectious material should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a standard bacterial disinfectant or 70% alcohol. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

4. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

5. These reagents contain phenol. Although the concentration is low, phenol is known to be toxic by ingestion and skin contact. Avoid ingestion of the reagents. If any come in contact with skin or eyes wash the area extensively by immediately rinsing with plenty of water.

6. In accordance with the principles of Good Laboratory Practice it is strongly recommended that samples and reagents should be treated as potentially infectious and handled with all necessary precautions.

7. PROCEDURE

MATERIALS PROVIDED

See Kit Contents.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 0.85% saline.
2. Glass slides.
3. Microbiological loop and bunsen burner.
4. Light source over dark background.
5. Timer.
6. Pasteur pipette.

TEST PROCEDURE

Step 1 Put two separate drops (40 µl) each of saline on a glass slide. Emulsify portions of the culture under test with a loop in each drop of saline to give a smooth, fairly dense suspension.

Step 2 To one suspension as a control add one drop (40 µl) of saline and mix. To the other suspension add one drop (40 µl) of undiluted antiserum and mix.

Step 3 Rock slide for one minute and observe for agglutination,

which can be easily seen by viewing against a dark ground background using indirect lighting. Discard the used slide for safe disinfection and disposal.

9. LIMITATIONS OF THE PROCEDURE

Meningococcus agglutinating sera have been absorbed as necessary to render them group specific within the species Neisseria meningitidis, with the exception of group D (ZM40/R30167001), since this organism is rough in culture. Cross-reactions have been reported to occur with organisms of other species 7-13 and it is therefore important to confirm the species of the organism under test by the established morphological, cultural and biochemical techniques. This cautionary note applies to all serological test methods.

Antisera provide serological identification only; full identification of an organism must only be made in conjunction with biochemical testing.

10. EXPECTED RESULTS/PERFORMANCE CHARACTERISTICS

Visible agglutination in the presence of homologous antigens (refer to bottle label for specificity of the antisera). See limitations of the procedure.

11. BIBLIOGRAPHY


12. PACKAGING

REF ZM3/R30166601 .......................... 2 ml
ZM39/R30166801 .......................... 2 ml
ZM40/R30167001 .......................... 2 ml
ZM41/R30167101 .......................... 2 ml
ZM42/R30167201 .......................... 2 ml
ZM43/R30167301 .......................... 2 ml
ZM44/R30167401 .......................... 2 ml

QUALITY CONTROL

It is recommended to test the product, throughout its use, with known positive and negative cultures. In practice, a run may be defined as a testing period of up to 24 hours.

Homologous cultures should be used for positive control organisms. For a negative control culture use Neisseria lactamica. Strains with the appropriate serotypes may be obtained from a recognised culture collection such as NCTC or ATCC.

INTERPRETATION OF RESULTS

Slide agglutination reactions which are weak or which take longer than one minute to appear are not significant. If agglutination is seen in the control suspension, the culture is not suitable for testing.

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Symbol legend

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For technical assistance please contact your local distributor.