Key Code TSMX7810B

www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 2360 190

CA 1 855 805 8539 ROW +31 20 794 7071

# Meningococcus Agglutinating Sera

EN

REF

| | |
|---|---|
| R30166601 | 2ml |
| R30166701 | 2ml |
| R30166801 | 2ml |
| R30166901 | 2ml |
| R30167001 | 2ml |
| R30167101 | 2ml |
| R30167201 | 2ml |
| R30167301 | 2ml |
| R30167401 | 2ml |

## 1. 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 are intended for screening purposes and should augment, not replace, culture procedures.

## 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.

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 immunoelectroophoresis is also described in literature [2, 3, 4, 5].

## 3. PRINCIPLE OF THE PROCEDURE

Serological 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.

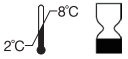
## 4. REAGENTS

KIT CONTENTS

| Meningococcus Agglutinating Sera | 1 dropper bottle (2 ml) |
|---|---|
| Group A | (ZM37/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 | (ZM33/R30166601) |
| Polyvalent Groups X-Z, W135 | (ZM34/R30166701) |

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions**




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.

On storage some sera become slightly turbid. This does not necessarily indicate deterioration and normally it will not interfere with the results, but the sera may be clarified by centrifugation or membrane filtration (0.45 µm) before use. Gross turbidity indicates contamination and such sera should be discarded.

## 5. 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. *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.

ANALYTICAL PRECAUTIONS

1. Do not use antisera beyond the stated expiry date. Microbiological contamination of the antisera must be avoided as this may cause erroneous results and reduce product life.
2. Do not modify the test procedure, incubation time or temperatures. Do not dilute.
3. After use return sera to recommended storage temperature.
4. Do not use a microbiological loop to dispense the antiserum. Use dropper provided.

## 6. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

The use of fresh cultures is recommended.

For details on specimen collection and preparation a standard text book should be consulted.

## 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 background using indirect lighting. Discard the used slide for safe disinfection and disposal. |

## 8. RESULTS

Agglutination should be strong and clearly visible within one minute. There should be no visible agglutination in the control suspension; if agglutination is seen in the control, the suspension is not suitable for testing by this method. A culture of an unknown strain may first be tested using the polyvalent sera. If positive agglutination is observed the group may be determined using single factor sera.

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.

## 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[2,3,4] 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

1. **Fallon, R.J. and McIllmurray, M.B.** (1976). *Escherichia coli* K1. *Lancet,* **i,** 201.
2. **Grados, O. and Ewing, W.H.** (1970). Antigenic relationship between *Escherichia coli* and *Neisseria meningitidis*. *J. Infect. Dis.,* **122,** 100.
3. **Myerowitz, R.L., Gordon, R.E.** *et al.* (1973). Polysaccharides of the genus Bacillus cross-reactive with the capsular polysaccharides of *Diplococcus pneumoniae* type III, *Haemophilus influenzae* type b, and *Neisseria meningitidis* group A. *Infect. Immun.,* **8,** 896.
4. **Robbins, J.B., Myerowitz, R.L.** *et al.* (1972). Enteric bacteria cross-reactive with *Neisseria meningitidis* groups A and C and *Diplococcus pneumoniae* types I and III. *Infect. Immun.,* **6,** 651.
5. **Tobin, B.M. and Jones, D.M.** (1972). Immunoelectroosmophoresis in the diagnosis of meningococcal infections. *J. Clin. Path.,* **15,** 583.

## 12. PACKAGING

REF

| | |
|---|---|
| ZM33/R30166601 | 2 ml |
| ZM34/R30166701 | 2 ml |
| ZM37/R30166801 | 2 ml |
| ZM39/R30166901 | 2 ml |
| ZM40/R30167001 | 2 ml |
| ZM41/R30167101 | 2 ml |
| ZM42/R30167201 | 2 ml |
| ZM43/R30167301 | 2 ml |
| ZM44/R30167401 | 2 ml |

**Symbol legend**

| | |
|---|---|
| REF | Catalogue Number |
| IVD | In Vitro Diagnostic Medical Device |
|  | Consult Instructions for Use (IFU) |
|  | Temperature Limitations (Storage temp.) |
|  | Contains sufficient for <N> tests |
|  | Contains or prescence of natural rubber latex |
| LOT | Batch Code (Lot Number) |
|  | Use By (Expiration Date) |
|  | Manufactured by |

CE

IFU X7810B revised December 2015 Printed in the UK

Remel Europe Ltd.
Clipper Boulevard West, Crossways
Dartford, Kent, DA2 6PT
UK

For technical assistance please contact your local distributor.