Key Code TSMX7804A

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Meningococcus Group B Monoclonal Antibody

REF R30167501 .....2ml **EN**

1. INTENDED USE

The meningococcal B monoclonal antibody is intended for use in the qualitative slide agglutination test to serologically identify *Neisseria meningitidis* group B for epidemiological and diagnostic purposes.

2. SUMMARY AND EXPLANATION OF THE TEST

Strains of *Neisseria meningitidis* possessing group B polysaccharide can be detected by agglutination with specific group B monoclonal antibody.

3. PRINCIPLE OF THE PROCEDURE

Slide agglutination tests are used to determine the serological identity of cultures of *Neisseria meningitidis* by means of the group specificity of capsular polysaccharide antigens. Strains possessing group B are specifically agglutinated by the group B monoclonal antibody. An alternative method of typing, counter immunoelectrophoresis, is also described in literature. [1, 2, 3, 4, 5]

4. REAGENTS

KIT CONTENTS

Meningococcus Group B Monoclonal Antibody	2 ml
ZM51/R30167501	1 dropper bottle

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions**

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

AGGLUTINATING SERUM

Meningococcus group B Monoclonal Antibody

Murine monoclonal antibody to *Neisseria meningitidis* group B diluted in 1% bovine serum albumin preserved with 0.05% Bronidox®. Each bottle, fitted with teat and dropper, contains 2 ml liquid and is supplied ready to use.

On storage slight turbidity may develop but does not necessarily indicate deterioration, the sera may be clarified before use by centrifugation or membrane filtration (0.45 µm). Gross turbidity indicates contamination in which case the reagent should be discarded.

5. WARNINGS AND PRECAUTIONS

IVD

For *in vitro* diagnostic use only.

For professional use only.

Please refer to the safety data sheet and the product labelling for information on potentially hazardous components.

Body fluid specimens may contain pathogenic organisms and must be handled with appropriate precautions.

HEALTH AND SAFETY INFORMATION

1. *N. meningitidis* is 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. This reagent contains Bronidox® and bovine serum albumin. Although the concentration is low, Bronidox® 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 the antisera beyond the stated expiry date. Microbiological contamination of the antibody 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 the agglutinating sera.
3. After use return to recommended storage temperature.
4. Do not dispense antibody using a microbiological loop. Use dropper provided.

6. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

For details on culture 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 PROCEDURES

Slide Agglutination Test

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

Step 3 Rock the slide for one minute and observe for agglutination, which can be more easily seen by viewing against a dark background using indirect lighting. Discard the test after one minute for safe disinfection and disposal.

8. RESULTS

Slide Agglutination

Homologous reactions are strong and appear rapidly. Discard the test after one minute. There should be no visible agglutination in the control suspension; if agglutination is seen in the control suspension, the suspension is not suitable for testing by this method.

QUALITY CONTROL

It is recommended to test the product, throughout its use, with known positive and negative cultures.

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.

A positive reaction is a presumptive identification of *N. meningitidis* group B.

9. LIMITATIONS OF THE PROCEDURE

Because the reagent is a monoclonal antibody, no reactions should occur with heterologous organisms. However, it is recognised that capsular antigen K1 of *Escherichia coli* is, as far as can be determined, identical with *N. meningitidis* group B antigen[7,8,9], and the monoclonal antibody reacts strongly with *E. coli* K1 strains. It is therefore important to confirm the species of the organism under test by the established morphological and cultural techniques.

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

10. EXPECTED RESULTS

Visible agglutination in the presence of homologous antigens.

11. SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity

In four studies, a total of 223 cultures of *N. meningitidis* group B were tested for slide agglutination. These included fresh clinical isolates, carrier strains and laboratory stock cultures. All reacted with the monoclonal antibody. Seven of the stored carrier strains reacted more strongly with a polyclonal serum than with the monoclonal antibody, but these were shown by other procedures to have reduced capsule production.

12. BIBLIOGRAPHY

1. **Coonrod, J.D. and Rytel, M.W.** (1972). Determination of Aetiology of bacterial meningitis by counter-immunoelectrophoresis. *Lancet,* **i,** 1154.
2. **Estela, L.A. and Heinrichs, T.F.** (1978). *Amer. J. Clin. Pathol.,* **70,** 239.
3. **Greenwood, B.M., Whittle, H.C.** *et al.* (1971). Counter-current immunoelectro-phoresis in the diagnosis of meningococcal infections. *Lancet,* **ii,** 519.
4. **Myhre, E.B.** (1974). Rapid diagnosis of bacterial meningitis. *Scand. J. Infect. Dis.,* **6,** 237.
5. **Tobin, B.M. and Jones, D.M.** (1972). Immunoelectroosmophoresis in the diagnosis of meningococcal infections. *J. Clin. Path.,* **15,** 583.
6. **Culliford, B.J.** (1964). Precipitin reactions in forensic problems. *Nature,* **201,** 1092.
7. **Bhattacharjee, A.K., Jennings, H.J.** *et al.* (1975). *J. Biol. Chem.,* **250,** 1926.
8. **Fallon, R.J. and McIlmurray, M.B.** (1976). *Escherichia coli* K1. *Lancet,* **i,** 201.
9. **Kasper, D.L., Winkelhake, J.L.** *et al.* (1973). *J. Immunol.,* **110,** 262.

13. PACKAGING

REF ZM51/R30167501.....2 ml

Symbol legend

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

Bronidox® is the registered trade name of Cognis UK Ltd.

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