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Bordetella pertussis/ parapertussis Agglutinating Sera

REF R30165501.....2ml
REF R30165601.....2ml

EN

1. INTENDED USE

Bordetella antisera are suitable for use in slide agglutination tests to serologically identify *Bordetella pertussis* and *Bordetella parapertussis* for epidemiological and diagnostic purposes.

The sera have been absorbed to render them specific within the genus described; full identification of an organism must only be made in conjunction with biochemical testing.

2. SUMMARY AND EXPLANATION OF THE TEST

Bordetella pertussis and *B. parapertussis* are antigenically related but can be distinguished in a simple slide agglutination test using absorbed antisera.

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

Bordetella Pertussis/ Parapertussis Agglutinating Sera	1 dropper bottle	(2 ml)
Bordetella pertussis	ZM10/R30165501	
Bordetella parapertussis	ZM11/R30165601	

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

Bordetella Agglutinating Sera

Produced in rabbits and are preserved with 0.5% phenol. Each bottle, fitted with teat and dropper, should contain sufficient sera for 40 to 50 tests and are ready to 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 safety data sheet and the product labelling for information on potentially hazardous components.

It may be difficult to prepare a uniform suspension for the slide agglutination test, as these species do not emulsify readily in saline. A good suspension can be made by transferring bacteria to a small amount of saline in a bijou bottle and forcing this repeatedly through the nozzle of a Pasteur pipette as the teat is squeezed and released[1]. To minimise the danger of aerosol-contamination of the laboratory, care should be taken to ensure that no air bubbles enter the pipette.

HEALTH AND SAFETY INFORMATION

5.1.1 Handle all bacteria according to appropriate local and statutory guidelines.

5.1.2 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.

5.1.3 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.

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

5.1.5 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.

5.1.6 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.
3. Poor agglutination may be obtained with cultures grown on Lacey's medium.

4. After use return sera to recommended storage temperature.

6. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

The use of fresh cultures, grown on charcoal non-selective media, 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.

TEST PROCEDURE

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 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 more 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.

QUALITY CONTROL

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

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

9. LIMITATIONS OF THE PROCEDURE

Serological tests used alone provide no more than presumptive identification and confirmatory biochemical identification tests must be performed.

To eliminate potential interference from other bacterial antigens only organisms with a gram stain and appearance consistent with a *Bordetella sp.* should be tested.

10. EXPECTED RESULTS

Visible agglutination in the presence of homologous cultures.

INTERPRETATION OF RESULTS

Strong agglutination in the test suspension with ZM10 (R30165501) antisera and no agglutination in the control suspension indicates a *Bordetella pertussis* culture, strong agglutination in the test suspension with ZM11 (R30165601) antisera and no agglutination in the control suspension indicates a *Bordetella parapertussis* culture. Biochemical testing must be performed to confirm this presumptive identification.

11. SPECIFIC PERFORMANCE CHARACTERISTICS

The ZM10 (R30165501) and ZM11 (R30165601) antisera should show visible agglutination in the slide test with *Bordetella pertussis* and *Bordetella parapertussis* cultures respectively.

12. BIBLIOGRAPHY

1. **Preston, N.W.** (1970). Technical problems in the laboratory diagnosis and prevention of whooping-cough. *Lab. Practice,* **19,** 482.

Symbol legend

	Catalogue Number
	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
	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

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For technical assistance please contact your local distributor.