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Vibrio cholerae Agglutinating Sera

REF R30165001 Vibrio Cholerea O1 Polyvalent Agglutinating Serum..... 2 ml

1. INTENDED USE

Vibrio cholerae agglutinating serum (R30165001) is intended for the serological identification of *V. cholerae* O1 for epidemiological and diagnostic purposes. This polyvalent serum is intended for use in slide agglutination screening tests.

IVD For *in vitro* diagnostic use only.

For professional use only.

2. SUMMARY AND EXPLANATION OF THE TEST

The O-serogrouping is based on antibodies that recognise structural differences in the heat stable O-antigen (lipopolysaccharide) of the bacteria. Historically, V.cholerae serogroup O1 is associated with most epidemic outbreaks of cholera. V.cholerae O1 and V.cholerae non-O1 isolates can be distinguished on the basis of simple agglutination tests.

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 visibly agglutinate with bacteria carrying homologous antigens.

4. KIT CONTENTS

Vibrio cholerae	
Agglutinating Sera	2 ml
R30165001 (ZM05)	1 dropper bottle (blue cap)

5. 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. Test tubes and rack.
6. Adjustable waterbath with thermometer.
7. Timer.
8. 0.5% formalin or phenol saline.

6. 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

***Vibrio cholerae* 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.

7. WARNINGS AND PRECAUTIONS

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

7.1. HEALTH AND SAFETY INFORMATION

7.1.1 *V. cholerae* are classified as category 2 organisms; handle according to appropriate local and statutory guidelines.

7.1.2 Non-disposable apparatus should be sterilised by an 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.

7.1.3 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.

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

7.1.5 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 into contact with skin or eyes wash the area extensively by immediately rinsing with plenty of water.

7.1.6 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.

7.2. ANALYTICAL PRECAUTIONS

7.2.1 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.

7.2.2 Do not modify the test procedure, incubation time or temperatures.

7.2.3 After use return sera to recommended storage temperature.

7.2.4 It has been suggested that boiling suspensions for two and a half hours prior to testing by slide agglutination will eliminate a number of false positive and false negative reactions[1].

8. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

The use of fresh cultures on non-selective media is recommended eg nutrient agar. Do not use TCBS or any selective media. For details on specimen collection and preparation a standard textbook should be consulted.

9. 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 more easily seen by viewing against a dark background using indirect lighting. Discard the used slide for safe disinfection and disposal.

10. QUALITY CONTROL

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

11. EXPECTED RESULTS

Visible agglutination in the presence of homologous cultures.

12. INTERPRETATION OF 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.

13. LIMITATIONS OF THE PROCEDURE

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

If inconclusive results are achieved with slide agglutination, cultures may be steamed to reduce non-specific reactions.

Serological tests are intended for screening purposes and should augment, not replace culture and biochemical procedures.

14. SPECIFIC PERFORMANCE CHARACTERISTICS

The *Vibrio Cholerea* O1 Polyvalent Serum (R30165001 (ZM05)) should show visible agglutination in the slide test with *V. cholerae* O1 subtypes. Differentiation of El Tor Vibrios from *V. cholerae* should be carried out biochemically.

15. BIBLIOGRAPHY

1. **Isaacson, M.** (1975). Practical aspects of a cholera surveillance programme. *S.A. Med. J.,* **49,** 1699.

16. 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

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