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Salmonella Polyvalent Agglutinating Sera EN

1. INTENDED USE

Salmonella Polyvalent Agglutinating Sera are prepared for use in slide agglutination screening procedures to serologically identify cultures for epidemiological and diagnostic purposes.

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

2. SUMMARY AND EXPLANATION OF THE TEST

Salmonella are distinguished by their antigenic characteristics. Polyvalent antisera allow the presumptive identification of Salmonella and can be the first step in full identification. In screening procedures colonies or isolates which show no agglutination in both polyvalent O and polyvalent H sera can be eliminated from further study, but colonies or isolates which agglutinate in either or both sera should be subjected to further identification.

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

Each kit contains one bottle of antisera (2ml) and Instructions For Use. The specificity of the antisera is given on the bottle label.

KIT CONTENTS

Salmonella Polyvalent Agglutinating Sera	1 dropper bottle (2 ml)
Salmonella Polyvalent O A-G	ZC01/R30858101
Salmonella Polyvalent O A-S	ZC02/R30858201
Salmonella Polyvalent H phase 1 and 2	ZD01/R30858501

5. 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

Salmonella Polyvalent Agglutinating Sera are are preserved with 0.1% Sodium Azide. The sera are produced in rabbits.

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.

6. 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.

6.1. HEALTH AND SAFETY INFORMATION

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

6.1.2 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.

6.1.3 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.

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

6.1.5 These reagents contain phenol or sodium azide. Although the concentration is low, both are 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.

6.1.6 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.

6.2. ANALYTICAL PRECAUTIONS

6.2.1 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.

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

6.2.3 After use return the sera to recommended storage temperature (2 to 8°C).

6.2.4 The sera are absorbed, but because other serotypes within the genus as well as some heterologous species possess common antigens and because of some naturally acquired antibodies to heterologous species in rabbit serum, reactions may be obtained with species outside the genus Salmonella or with Salmonella serotypes outside the range given on the bottle label.

6.2.5 Material for examination should be taken from a subculture of the suspected organism on non-selective media. Growth taken from primary, selective media may give unreliable serological results, and although tests may be performed for preliminary screening purposes, reactions must be interpreted with extreme caution[1].

7. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

SPECIMEN COLLECTION

Ideally cultures grown on non-selective media should be used.

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

SPECIMEN TRANSPORT AND STORAGE

Freshly isolated cultures (18 to 24 hrs) should be used.

8. 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. Disinfectant.

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 salineand 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.

9. 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.

10. QUALITY CONTROL

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

Positive Control organism: *Salmonella typhimurium* 4,5,12:i:1, 2 NCTC 3048.

Negative Control organism: *Hafnia alvei* NCTC 8535.

11. INTERPRETATION OF RESULTS

No definite conclusion may be drawn about the serological identity of a strain until biochemical testing confirms that it reacts as a Salmonella, but agglutination in polyvalent O as well as polyvalent H sera gives strong presumptive evidence that it is a Salmonella. Further serological tests should then be performed to determine the serotype. The possibility of serological cross reactions due to common antigens has already been mentioned; of particular relevance are relationships between different O groups, some of which are expressed in the Kauffmann-White scheme[2].

Agglutination in polyvalent O serum but not polyvalent H serum, if the biochemical reactions are consistent with Salmonella species, suggests that flagella are not well developed. The strain should be retested after passage on motility-enhancing medium, such as 0.5% nutrient agar. (*S. pullorum* and *S. gallinarum* are non-motile). Agglutination in polyvalent H serum but not polyvalent O serum, and biochemical reactions consistent with Salmonella species, suggests that the culture is outside the groups covered by the polyvalent O serum or the O antigens are masked by Vi antigen. The latter may be checked using Vi antiserum, and if the presence of Vi antigen is confirmed, identification of the O antigens should be possible using a suspension which has been boiled for one hour, washed and resuspended in saline.

If no agglutination is visible with either serum, the organism is unlikely to be a Salmonella.

12. LIMITATIONS OF THE PROCEDURE

Reactions may be obtained with species outside the genus Salmonella or with Salmonella serotypes outside the range given on the bottle label. Serological tests used alone provide no more than presumptive identification and biochemical examination must be performed in addition to serological analysis[1,3].

13. 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.

14. BIBLIOGRAPHY

1 **Cruickshank, R., Duguid, J.P.** *et al.* (1975). The practice of medical microbiology. *Medical Microbiology,* 12th Edition, Volume 2, page 415. Churchill Livingstone, London.

2 **Edwards, P.R. and Ewing, W.H.** (1986). *Identification of Enterobacteriaceae,* 4th Edition, Elsevier Science Publishing Co. Inc., New York.

3 **Martin, W.J. and Washington, J.A.** (1980). Enterobacteriaceae. *Manual of Clinical Microbiology,* 3rd Edition, pages 195-219. American Society for Microbiology, Washington, D.C.

PACKAGING

REF R30858101/ZC01 Salmonella Polyvalent-O A-G.....2ml
R30858201/ZC02 Salmonella Polyvalent-O A-S.....2ml
R30858501/ZD01 Salmonella Polyvalent-H Phase 1-2.....2ml

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

CE

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