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Escherichia coli Agglutinating Sera

EN

REF ZA01/R30954901..... 2 ml
REF ZA02/R30955001..... 2 ml
REF ZA03/R30955101..... 2 ml

1. INTENDED USE

Escherichia coli Agglutinating Sera are intended for use in agglutination tests for the presumptive identification of *E. coli* serotypes traditionally associated with infantile gastroenteritis.

However, since antigenic components are shared widely throughout the Enterobacteriaceae it is important to confirm by biochemical tests that an organism is of the species *E. coli* when attempting serological identification.

IVD For *in vitro* diagnostic use only.

For professional use only.

2. SUMMARY AND EXPLANATION OF THE TEST

Most pathogenic *Escherichia coli* strains from infantile gastroenteritis have the classical biochemical reactions of the faecal type as shown in Table 1[1,2]. (Some strains of *E. coli* may be encountered which are non-lactose fermenting, anaerogenic or indole negative, and these should not be excluded from serological analysis.)

Table 1

Glucose	Lactose	Mannitol	Inositol	Inulin	Adonitol	Cellobiose
+	+	+	–	–	–	–

Indole	H_2S	Urease	Simmons Citrate	Methyl Red	Voges-Proskauer
+	–	–	–	+	–

Differentiation within the species is made on serological grounds and strains recognised as causing disease fall into a restricted number of serotypes. They are distinguished on the basis of two classes of antigens, O (somatic) and K (surface).

The K antigens possessed by most enteropathogenic strains of *E. coli* belong to the B subgroup. They are found on the sheaths or capsules and are inactivated by heating at 100°C for one hour. This treatment leaves the heat stable O antigens intact. *Escherichia coli* Agglutinating Sera contain agglutinins for both O and K antigens. They have been absorbed to remove cross reactions with other commonly occurring serotypes of *E. coli*.

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.

Test cultures with polyvalent sera, which are intended for use by the slide agglutination technique only. Both the confluent growth and selected colonies from the primary plate should be examined. A positive slide reaction with a live culture may be due to the presence of K antigen on the surface of the organisms.

4. REAGENTS

KIT CONTENTS

E. coli Agglutinating Sera	1 dropper bottle (2 ml)
ZA01/R30954901 *E. coli* Polyvalent 2 O26:K60 (B6), O55:K59 (B5), O111:K58 (B4), O119:K69 (B14), O126:K71 (B16)	
ZA02/R30955001 *E. coli* Polyvalent 3 O86:K61 (B7), O114:K90 (B), O125:K70 (B15), O127:K63 (B8), O128:K67 (B12)	
ZA03/R30955101 *E. coli* Polyvalent 4 O44:K74 (L), O112:K66 (B11), O124:K72 (B17), O142:K86 (B)	

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

E. coli Agglutinating Sera

Produced in rabbits and preserved with 0.5% phenol. Sera are supplied in bottles fitted with teat and dropper. Each bottle 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

Please refer to the Safety Data Sheet and the product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

1. Handle all bacteria 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, it 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.
3. After use, return sera to recommended storage temperature (2 to 8°C).
4. The polyvalent antisera are only suitable for testing using the slide agglutination test.

6. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

For details of specimen collection and preparation a standard text book should be consulted. The use of fresh cultures on non-selective media is recommended (e.g., nutrient agar).

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. Pippettes.

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 add one drop (40 µl) of saline as a control and mix. To the other suspension add one drop (40 µl) of undiluted antiserum 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 used slide for safe disinfection.

8. RESULTS

Slide Agglutination

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

Each laboratory should follow their state and local requirements for quality control testing.

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 *Hafnia alvei*. Cultures may be obtained from recognised culture collections such as the NCTC or ATCC.

INTERPRETATION OF RESULTS

Slide Agglutination

Non-specific agglutination, differing in appearance from the specific agglutination, may occur with the slide technique particularly when carried out on bacteria taken from selective media. This agglutination is usually fine and is slow to appear.

9. LIMITATIONS OF THE PROCEDURE

The sera are specific for other commonly occurring serotypes of *E. coli*. However, as antigenic components are widely shared throughout the Enterobacteriaceae it is important to confirm any isolate biochemically as well as serologically.

10. EXPECTED RESULTS

Visible agglutination in the presence of homologous cultures.

11. SPECIFIC PERFORMANCE CHARACTERISTICS

See **Interpretation of Results**

12. BIBLIOGRAPHY

1. International Enterobacteriaceae Subcommittee Reports (1958), *Int. Bull. bact. Nomencl. Taxon.*, **8**, 25.
2. **Edwards, P.R. and Ewing, W.H.** (1972). Identification of Enterobacteriaceae, 3rd Ed. Minneapolis, Burgess Publishing Co.

13. PACKAGING

REF ZA01/R30954901..... 2 ml
REF ZA02/R30955001..... 2 ml
REF ZA03/R30955101..... 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

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