PRO-LAB DIAGNOSTICS

E. coli O157 Antiserum

(for *in vitro* diagnostic use)

PRODUCT CODE PL.6250

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UK CA CE

INTENDED USE

Pro-Lab *E. coli* O157 Antiserum is for use in the slide agglutination test for the presumptive identification of *Escherichia coli* serotype O157 antigen on laboratory culture media.

SUMMARY AND EXPLANATION

Escherichia coli serotype O157:H7 is a verotoxin producing (VT-producing) pathogen.[1,2] This serotype has been reported as an etiological agent in sporadic and outbreak cases of haemorrhagic colitis.[3,4,5] It is also associated with haemolytic uraemic syndrome.[6] Certain *E. coli* serotypes other than O157:H7 also produce verotoxin.[7,8,9] However, the diarrhoea caused by these other serotypes is not usually bloody. Additionally, *E. coli* serotype O157:H7 does not ferment sorbitol whereas the majority of other serotypes do ferment sorbitol.[10,11] Therefore, if Sorbitol-MacConkey agar medium is used as a primary screen, the colonies of *E. coli* serotype O157:H7 appear colourless (non-sorbitol fermenting colonies - NSFC) while colonies of other serotypes appear characteristically pink (sorbitol fermenting colonies - SFC).[11]

The work of Kauffmann[12], Edward and Ewing[13], Ewing[14] and Orskov[15] contributed to the development of a system for serological typing of *E. coli* cultures and resulted in an antigenic classification scheme which can be used to identify the serotypes of *Escherichia coli* which are associated with bacteriuria or diarrheal disease.

The principle of the test involves mixing the suspected organisms with the antiserum containing *E. coli* O157 antibodies. The bacteria will agglutinate (clump) in the presence of homologous antiserum.

REAGENTS

Pro-Lab *E. coli* O157 Antiserum is prepared using delipidized, whole absorbed rabbit serum containing antibodies to *E. coli* serotype O157.

Pro-Lab *E. coli* O157 Antiserum is supplied in a dropper bottle containing 3.0 ml of ready-to-use diluted antiserum with 0.01% thimerosal as preservative.

PRECAUTIONS

1. Do not use antiserum after the expiry date shown on the product label.
2. The antiserum contains thimerosal, which is a highly toxic mercury based compound. Although the amount of thimerosal in the antiserum is minimal, safety precautions should be taken in handling, processing and discarding the reagent.
3. Avoid contamination of the reagent bottle.
4. Universal precautions should be taken in handling, processing and discarding all clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.
5. The reagent is intended for *in vitro* diagnostic use only.
6. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.
7. Product contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

MATERIAL REQUIRED BUT NOT PROVIDED

- Glass Slides
- Normal Saline (0.85% sodium chloride solution)
- Disposable or Wire Loops
- Mixing sticks

STABILITY AND STORAGE

Pro-Lab *E. coli* O157 Antiserum should be stored tightly capped at 2° - 8°C. Stored under these conditions the antiserum will be stable until expiry date shown on the product label.

SPECIMEN COLLECTION AND CULTURE PREPARATION

Clinical specimens should be cultured on Sorbitol-MacConkey medium. NSFC may be subcultured on non-selective agar medium. Colonies from overnight growth must be cleanly removed from agar surface for testing using a sterile loop. Young, fast growing cultures will yield typical results.

PROCEDURE

1. Place two separate drops of normal saline (0.85% sodium chloride) on a clean glass slide.
2. Take a suspect *Escherichia coli* colony from an overnight culture plate and mix thoroughly with both drops of normal saline on the slide to obtain a smooth suspension.
3. Add one drop of antisera to one of the bacterial suspension drops on the slide, to the other (control) add one drop of normal saline.
4. Mix the antiserum with the bacterial suspension using a mixing stick. Then mix the saline (control) with a fresh mixing stick.
5. Gently rock the slide back and forth for one minute and observe for agglutination under normal lighting conditions or using a low power objective.

INTERPRETATION OF RESULTS

A distinct agglutination (granular clumping) in the antiserum test, within 60 seconds, is regarded as a positive result. There must be no agglutination in the saline control or else the test is not valid (auto-agglutination).

LIMITATIONS OF THE PROCEDURE

1. A normal saline control should be included in every test to insure the specificity of the reaction.
2. Rough strains give auto-agglutination in slide tests. False positives usually agglutinate in control saline.
3. It is recommended to check the potency of *Escherichia coli* antisera with stock cultures of known antigenic structure.
4. The antiserum is a presumptive identification or confirmation of cultures which have been previously characterized biochemically.

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 = Use by

LOT = Lot number

REF = Catalogue number

 = Manufacturer

EC REP = Authorized Representative in the European Community

 = Contains sufficient for <n> tests

IVD = In vitro diagnostic medical device

 = Temperature limitation

 = Consult instructions for use