Key Code TSMX4147C

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E. coli O157 Latex Test

REF DR0620M.....100 Tests **EN**

1. E. coli O157 LATEX TEST

A latex agglutination test for the identification of E. coli serogroup O157.

Certain strains of *Escherichia coli* have been implicated in cases of haemorrhagic colitis (HC) and haemolytic ureamic syndrome (HUS).

It has been shown that these strains produce a vero-cytotoxin (VT). The *E coli* serotype most frequently isolated from HC and HUScases is O157:H7. Isolation of this serotype from a diarrhoeal stool particularly with the presence of blood is indicative of a vero-cytotoxin producing strain[1, 2, 3, 4, 5, 6, 7 ,8].

The Oxoid E coli O157 latex test will demonstrate by slide agglutination *E. coli* strains possessing the O157 serogroup antigen. The test is best used in conjunction with Sorbitol MacConkey Agar (Oxoid CM0813). E. coli O157:H7 strains do not ferment Sorbitol and therefore give colourless colonies on this medium. The majority of *E coli* isolates do ferment Sorbitol and give characteristic pink colonies.

Sorbitol MacConkey Agar should be used as the primary screen. Non-sorbitol fermenting colonies can then be tested with the latex reagents, to determine whether the isolate belongs to the O157 serogroup and therefore a potential VT- producing strain.

2. COMPONENTS OF THE KIT

DR 621M Test Latex

Consists of blue latex particles sensitised with specific rabbit antibody reactive with the O157 somatic antigen. Each kit contains sufficient reagent for 100 tests.

DR 622M Control Latex

Consists of blue latex particles sensitised with pre-immune rabbit globulin. Each kit contains sufficient reagent for 100 tests.

DR 623M Positive Control Suspension

A suspension of inactivated *E coli* O157 cells in buffer. Sufficient for 25 tests.

DR 624M Negative Control Suspension

A suspension of *E coli* O116 cells in buffer. Sufficient for 25 tests.

DR 500G Reaction Cards

There are 35 disposable reaction cards provided in the kit.

Instruction leaflet.

3. MATERIALS REQUIRED

The following materials are required but not provided in this kit

Microbiological loop and bunsen burner.

0.85% saline.

Suitable disinfectant e.g. sodium hypochlorite solution >1.3% w/w.

4. PRECAUTIONS

This product is for *in vitro* diagnostic use only.

Do not freeze.

Reagents with different lot numbers should not be interchanged.

Reagents contain 0.1% sodium azide as a preservative.

Sodium azide may react with lead or copper plumbing to produce metal azides which are explosive by contact detonation. To prevent azide accumulation in plumbing, flush with copious amounts of water immediately after waste disposal.

Specimen materials may contain pathogenic organisms handle with appropriate precautions.

5. STORAGE

This kit must be stored at 2 to 8°C. Under these conditions the reagents will retain their reactivity until the expiry date shown on the kit box.

6. CONTROL PROCEDURES

The control suspensions provided should be used to check the correct working of the latex reagents each day before routine tests are performed.

The positive control suspension must cause visible agglutination with the latex reagent within one minute.

The negative control suspension should cause no agglutination within one minute.

Do not use the test if reactions with the control suspensions are incorrect.

7. IMPORTANT PROCEDURE NOTES

Do not allow the reagents to become contaminated by letting the dropper tip touch the specimen on the reaction card.

Ensure that the caps are securely fitted after each use to prevent contamination and drying out of the reagent.

After use return the kit to the refrigerator ensuring that the bottle is stored in an upright position.

8. CULTURE MATERIAL

Non-sorbitol fermenting (NSF) colonies may be taken from Sorbitol MacConkey Agar (Oxoid CM0813) or alternatively NSF isolates may be inoculated onto non- selective media such as Nutrient Agar for testing. It is necessary to test up to 10 separate NSF colonies to ensure a high probability of detecting any O157 strains which may be in a mixed culture with NSF *E. Coli* of other serotypes. The use of the control latex will ensure that the isolate is not an autoagglutinating strain.

9. TEST METHOD

1. Bring the latex reagents to room temperature. Make sure the latex suspensions are mixed by vigorous shaking. Expel any latex from the dropper pipette for complete mixing.
2. Dispense 1 drop of the test latex onto a circle on the reaction card. Place it close to the edge of the circle.
3. Add some loopfuls or a pasteur pipette drop of saline to the circle. Ensure that the latex and saline do not mix at this stage.
4. Using a loop pick off a portion of the colony to be tested and carefully emulsify in the saline drop. Ensure that the resulting suspension is smooth.
5. Mix the test latex and suspension together and spread to cover the reaction area using the loop. Flame the loop.
6. Rock the card in a circular motion observing for agglutination. Do not rock the card for more than 1 minute and do not use a magnifying glass.
7. If no agglutination occurs then proceed to test other NSF colonies if these are present.
8. If agglutination with the test reagent does occur, then it is necessary to test a further portion of the colony with the control latex reagent to ensure that the isolate is not an auto-agglutinating strain.
9. When finished dispose of the reaction card into disinfectant.

10. INTERPRETATION OF TEST RESULTS

Agglutination of the test latex within one minute is a positive result. This indicates the presence of *E coli* Serogroup O157.

No agglutination occurring within one minute is a negative result. This indicates the absence of *E coli* Serogroup O157.

Results cannot be interpreted if there is agglutination of both the test and control latex.

Some strains of *E coli* are difficult to emulsify in saline and may give a stringy type reaction with both the test and the control reagents. This does not look like true agglutination and should be ignored. If this stringiness is found to be too severe for a correct judgement to be made then the colony should be suspended in 0.3 ml of saline. Allow the lumps to settle and retest this smooth supernatant.

11. LIMITATIONS OF THE TEST

If a positive result is obtained on a colony of unknown species, then biochemical tests should be performed to confirm that the organism is an *E. coli* strain.

Neither the Sorbitol MacConkey Agar nor the E. coli O157 latex test will directly confirm the isolate a toxin-producing strain.

Other serotypes have been found which produce the vero-cytotoxin.

Some strains of *Escherichia hermanii* may cross react with E. coli O157 sera and the latex test due to a shared antigen (borczyk et al)[1]. *E. hermanii* may be differentiated from *E coli* as they ferment cellobiose, grow in the presence of KCN and produce a yellow pigment, which may be delayed[10].

12. PERFORMANCE CHARACTERISTICS

In clinical comparisons of the performance of the Oxoid *E coli* O157 latex test and commercially antisera, results demonstrated 99.3% (151/152) agreement between the two methods[9]. The sensitivity of the Oxoid tests was 100% (49/49), and the specificity was 99.0% (101/103). The discrepant sample was further tested and found to be positive for *E coli* O157. This was in agreement with the Oxoid test result.

The Oxoid reagents did not show crossreactivity with other *E coli* strains or nonsorbitol fermenting organisms. The Oxoid test was performed directly from a variety of culture media. None of these media were found to cause interference with the latex test.

WARNING: This product contains sodium azide. Harmful if swallowed.

13. REFERENCES

1. Borczyk A. Lior H. Crebin B (1987) Int. J. Food. Microbiol. 4, 347-349.
2. Konowalchuk, J., Speirs, J. and Stavric S. (1977) Infect. Immun. 18, 775-779.
3. Scotland S., Day N. and Rowe B. (1980) FEMS. Microbiol. Lett,7, 15-17.
4. Centres for Disease Control (1982) Morbid Mortal Wkly 31 580-585.
5. Karmali M, Still, B., Petrick M., and Lim C. (1983),Lancet i,619-620.
6. Johnson,W., Liroh, H. and Bezanson. (1983) Lancet i, 76.
7. March S., and Ratnam (1986) J.Clin. Microbiol.23. - 869-872.
8. Krishnan, C., Fitzgerald V., Dakin S., and Behme R. (1987) J. Clin. Microbial. 25, 1043-1047.
9. P.A.Chapman (1989) Evaluation of Commercial latex slide test for identifying Escherichia coli O157.42:1109-1110.
10. Bremer et al (1982) Journal of Clinical Microbiology Vol. 15 No.4 p.703

Symbol Legend

REF	Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use
	Temperature Limitation
LOT	Batch Code
	Use By
	Manufacturer

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