PRO-LAB DIAGNOSTICS

Prolex™ *E. coli* O91 Latex Reagent

(for *in vitro* diagnostic use)

PRODUCT CODE PL.1078

Σ 50

INTENDED USE

The Prolex™ *E. coli* O91 Latex Reagent provides a rapid method to identify *Escherichia coli* O91 isolated from cultured specimens.

SUMMARY AND EXPLANATION

Although *E. coli* O157 is the most common cause of Shiga toxin producing *Escherichia coli* (STEC) illness it has now been recognized that non-O157 strains of *E. coli* cause severe human disease that is comparable with that caused by *E. coli* O157. Of these strains *E. coli* O91 has been reported as a cause of infectious diarrhoea among infants[1]. In the United States, the CDC has recommended that all clinical laboratories screen for STEC[2].

PRINCIPLE OF THE TEST

Polystyrene beads are sensitized with immunoglobulins against the serotype specific *E. coli* somatic antigen (*E. coli* O91). When the coated polystyrene particles are mixed with fresh organisms of the corresponding *E. coli* serotype the bacteria will bind to the antibody, causing the particles to visibly agglutinate (positive reaction). Bacteria which are not of serotype O91will not bind to the antibody and will not result in agglutination (negative reaction).

MATERIALS PROVIDED

The reagent is sufficient for 50 tests and is supplied ready for use.

- *E. coli* O91 Latex Reagent: One dropper bottle containing 2.5 ml of latex particles coated with purified rabbit IgG that react with *E. coli* somatic antigen O91. Polystyrene particles are suspended in a buffer containing 0.098% sodium azide as a preservative.
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Phosphate buffered saline (PBS)
- 12 x 75 mm test tubes
- Inoculating loop or needle
- Pasteur pipettes
- Timer
- Test cards
- Mixing sticks

The Prolex™ *E. coli* O91 Latex Reagent is designed to be used in conjunction with the Prolex™ *E. coli* Non-O157 Identification Kit (PL.1070). The kit contains the following components.

Reagent or Component	Catalogue Number
Prolex™ *E. coli* O26 Latex Reagent	PL.1071
Prolex™ *E. coli* O45 Latex Reagent	PL.1072
Prolex™ *E. coli* O103 Latex Reagent	PL.1073
Prolex™ *E. coli* O111 Latex Reagent	PL.1074
Prolex™ *E. coli* O121 Latex Reagent	PL.1075
Prolex™ *E. coli* O145 Latex Reagent	PL.1076
Prolex™ Negative Control Latex Reagent	PL.1077
Mixing Sticks	PL.091P
Test Cards	PL.092-48

Note: All components of this kit are available separately for purchase.

STABILITY AND STORAGE

The reagent should be stored at 2 to 8°C. **Do not freeze**. Reagent stored under these conditions will be stable until the expiration date shown on the product label.

PRECAUTIONS

1. This reagent is intended for *in vitro* diagnostic use only.
2. Do not use the reagent after the expiration date shown on the product label.
3. The reagent contains 0.098% sodium azide. Sodium azide can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagent is minimal, large quantities of water should be used if reagents are flushed down the sink.
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. Do not use the reagent if autoagglutination is visible. This would appear as agglutination of the test reagent or negative control in the absence of a test isolate.
6. The procedures, storage conditions, precautions, and limitations specified in these directions must be followed to obtain valid test results.
7. The reagent contains materials of animal origin and should be handled as a potential carrier and transmitter of disease.

PREPARATION OF CULTURES

Clinical specimens should be cultured on media that will facilitate optimal growth, such as MacConkey Agar, Sorbitol MacConkey Agar, Blood Agar, etc. Suspect colonies may be tested directly or from a sub-culture. Colonies from an overnight culture (18-24 hours) must be cleanly removed from the agar surface for testing using a sterile loop or needle. Young, fast-growing cultures typically give the best results.

TEST PROCEDURE

1. Allow the reagent to come to room temperature before use.
2. Using a pipette transfer 0.3 ml of phosphate buffered saline into a 12 x 75 mm culture tube or equivalent.
3. Select sufficient suitable colonies from the test culture with a loop or needle and prepare a suspension in the phosphate buffered saline corresponding to a 3-5 McFarland Standard.
4. Label the test card with the serotype and then add one drop of the latex reagent into the appropriate test circle.
5. Using a pipette transfer one drop (35 µl) of the test suspension onto the test circle.
6. Mix the test circle with a separate mixing stick.
7. Rock the card gently and examine for agglutination. A positive reaction (agglutination) will be visible within 30 seconds.
8. Isolates that give a positive test with the test reagent must be tested further by repeating the procedure using the Prolex™ Negative Control Latex Reagent.

QUALITY CONTROL PROCEDURE

The Prolex™ *E. coli* O91 Latex Reagent and the Prolex™ Negative Control Latex Reagent must be tested with phosphate buffered saline before running the test isolates. There must be no agglutination in either of the reagents within 30 seconds.

INTERPRETATION OF RESULTS

The following table shows how the results obtained with the Prolex™ *E. coli* Non-O157 Latex Reagents and the Prolex™ Negative Control Latex Reagent should be interpreted:

Organisms	Results with Latex Reagents							Results with Negative Control Latex Reagent
	***E. coli* O91**	***E.coli* O26**	***E. coli* O45**	***E. coli* O103**	***E. coli* O111**	***E. coli* O121**	***E. coli* O145**	
E. coli O91	+	-	-	-	-	-	-	-
E. coli O26	-	+	-	-	-	-	-	-
E. coli O45	-	-	+	-	-	-	-	-
E. coli O103	-	-	-	+	-	-	-	-
E. coli O111	-	-	-	-	+	-	-	-
E. coli O121	-	-	-	-	-	+	-	-
E. coli O145	-	-	-	-	-	-	+	-

Uninterpretable results: If the test isolate agglutinates with both the latex reagent and the Negative Control Latex Reagent, an auto-agglutinating or cross-reacting strain is present. Perform further testing to rule out non-O157 *E. coli*. If the test isolate reacts with more than one of the test reagents, the test is uninterpretable.

LIMITATIONS OF THE PROCEDURES

1. Positive test results should be confirmed using routine biochemical testing.
2. Although this test has been developed to reduce cross-reactivity, rare strains can cross-react. Do not observe for agglutination after 30 seconds.
3. If the test isolate fails to react with any one of the test reagents and you suspect that it is a pathogen please send it to your local reference centre for further study.
4. If the test isolate reacts with more than one of the test reagents please send it to your local reference centre for further study.

PERFORMANCE CHARACTERISTICS

The performance of the reagents was evaluated at a Reference Laboratory. Each of the reagents was tested against 177 different serotypes of *E. coli* including many other STEC serotypes.
The results from this evaluation showed 100% specificity and sensitivity for each of the reagents.

Cross Reactivity

Each of the reagents was tested against the following enteric bacteria including *Shigella* species for cross reactivity. No cross reactions were found.

Organism	Result
Aeromonas hydrophila	Negative
Bacillus cereus	Negative
Bacillus subtilis	Negative
Campylobacter coli	Negative
Campylobacter fetus	Negative

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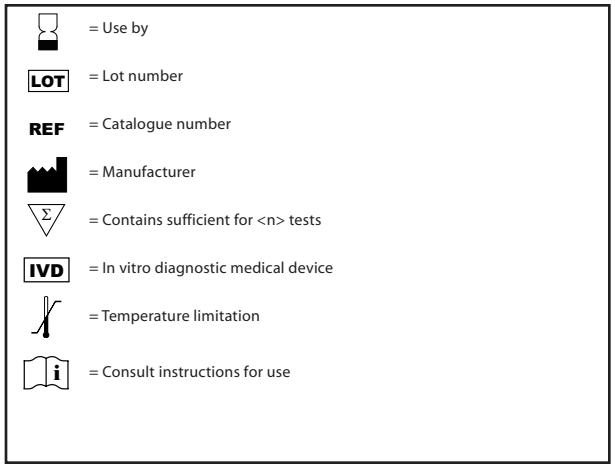
Campylobacter jejuni	Negative
Citrobacter braakii (freundii)	Negative
Enterobacter aerogenes	Negative
Enterobacter cloacae	Negative
Enterococcus faecalis	Negative
Escherichia hermanii	Negative
Klebsiella pneumoniae	Negative
Proteus vulgaris	Negative
Pseudomonas aeruginosa	Negative
Salmonella enteriditis	Negative
Salmonella typhimurium	Negative
Serratia marcescens	Negative
Serratia liquefaciens	Negative
Shigella flexneri	Negative
Shigella dysenteriae	Negative
Shigella sonnei	Negative
Staphylococcus aureus	Negative
Vibrio parahaemolyticus	Negative

REFERENCES

1. **Hughes M.H., Greaves J.L., Bettelheim K.A.** Infant diarrhoea due to *Escherichia coli* O91 K? H7. J. Clin. Path. 1968 21:387-389.
2. **CDC 2009**. Recommendations for diagnosis of Shiga toxin-producing *Escherichia coli* infections in clinical laboratories. MMWR Morb. Mortal. Wkly. Rep 58:1-14.



Revision: 2015 07