

Rapid agglutination test for direct identification of *Escherichia coli* O157.

DESCRIPTION

E.COLI O157 LATEX KIT is a rapid agglutination test on card for direct identification of *Escherichia coli* O157. The test can be used both for the identification of bacterial cultures on plate/broth and for the confirmation of *E.coli* O157 directly from the relevant well in various Liofilchem identification panels.

PACKAGING

- 1 E.COLI O157 Latex Reagent (2.5 mL): dropper bottle containing latex particles coated with rabbit antibodies raised against *Escherichia coli* O157.
- 1 E.COLI O157 Latex Control (2.5 mL): dropper bottle containing negative control composed of latex particles coated with non-specific rabbit antibodies.
- 10 disposable cards each with 6 wells.
- 2 racks each with 25 disposable mixing sticks.

NECESSARY ITEMS NOT CONTAINED IN THE PACKAGE

Disposable pipettes and loops, Physiological solution, Timer.

METHOD PRINCIPLE

Latex particles in Latex Reagent are individually coated with antibodies against *Escherichia coli* O157 antigens. Mixed with a suspension of *Escherichia coli* O157, latex particles aggregate to give visible agglutination.

TEST PROCEDURE

- Bring Latex Reagent and Control to room temperature.
- From colonies on agar plate: dispense one drop of physiological solution onto two wells of an agglutination card. Using a disposable loop, add to each drop of saline well-isolated colonies from an agar plate. Emulsify each drop of physiological solution so to obtain a heavy and homogeneous suspension. Suspensions must only be made from colonies with morphologies resembling *Escherichia coli* O157.
- From enrichment broth: using a disposable pipette, take two drops of the culture broth and dispense them onto two wells of an agglutination card.
- From Liofilchem Systems: using a disposable pipette take two drops of the culture from a relevant well and dispense them onto two wells of an agglutination card.
- Dispense one drop of Latex Reagent into one well of the agglutination card containing the microbial suspension.
- Dispense one drop of Latex Control onto the second well containing the bacterial suspension to be examined.
- Mix the bacterial suspensions with Latex Reagent and Latex Control using the sticks and rock the card gently two or three times. Excessive rocking of the card is not necessary. Examine for agglutination within a maximum of 2 minutes. If there is agglutination it will be clearly visible to the naked eye.

INTERPRETATION OF RESULTS

Interpret the agglutination of Latex Reagent and Latex Control with the sample as indicated below:

Latex Reagent	Latex Control	Interpretation
+	-	Presence of <i>E.Coli</i> O157
-	-	Absence of <i>E.Coli</i> O157
+	+	Non-specific agglutination
-	+	Non-specific agglutination

(+) Agglutination, (-) No agglutination.

LIMITATION OF USE

- Results should be interpreted in the context of all available clinical and laboratory information.
- Positive samples should be confirmed by biochemical tests and serotyping of pure cultures.

PRECAUTION

E.COLI O157 LATEX KIT is designed for in vitro diagnostic use and must be used only by properly trained operators, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store E.COLI O157 LATEX KIT at 2-8 °C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions E.COLI O157 LATEX KIT will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After the use E.COLI O157 LATEX KIT, and the material that comes into contact with the sample must be decontaminated and disposed according to the techniques used in the laboratory for decontamination and disposal of potentially infectious materials. The reagent contains sodium azide must be handled with care. Sodium azide may react with copper and lead plumbing giving rise to explosive azides. Dispose of rinse with plenty of water to prevent azide build-up.

PRESENTATION

Product	REF	Σ
E.COLI O157 LATEX KIT	96150	50 tests

TABLE OF SYMBOLS

IVD In Vitro Diagnostic Medical Device	 Do not reuse	 Manufacturer	 Contains sufficient for <n> tests	 Temperature limitation
REF Catalogue number	 Fragile, handel with care	 Use by	 Caution, consult accompanying documents	LOT Batch code



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