

INTENDED USE

Pro-Lab *E. coli* H7 Latex reagent is an agglutination test reagent for use in identification of the H7 flagellar antigen.

SUMMARY AND EXPLANATION

Escherichia coli 0157:H7 is a verotoxin producing pathogen^{1,2} reported to be an etiological agent of hemorrhagic colitis and hemolytic uremic syndrome.^{3,4,5,6} Following presumptive identification of *E. coli* 0157 using Pro-Lab *E. coli* 0157 Latex Test Reagent Kit (PL.070 or PL.071), confirmation of *E. coli* 0157:H7 requires identification of the H7 flagellar antigen using *E. coli* H7 Latex reagent (PL.079).

PRINCIPLE OF THE PROCEDURE

Latex particles are sensitized with purified rabbit polyclonal antibodies specific for H7 flagellar antigen. These Latex particles are mixed with *E. coli* strains which have undergone multiple passages. The *E. coli* strains that have the H7 antigen will bind to the antiserum causing the Latex particles to visibly agglutinate. Thus, any *E. coli* strains that do not contain the H7 antigen will not bind to the antiserum and will not result in an agglutination reaction.

REAGENTS

E. coli H7 Latex particles coated with purified rabbit IgG to *E. coli* H7 antigen.

PRECAUTIONS

1. Do not use reagent after expiry date shown on product label.
2. Reagent contains sodium azide NaN_3 which can react explosively with copper or lead if allowed to accumulate. Although the amount of sodium azide in the reagent is minimal, large quantities of water should be used when flushing reagent down the sink.
3. Safety precautions appropriate to microbiological hazards must be taken in handling, processing and discarding all specimens.
4. The reagent is intended for *in vitro* diagnostic use only.
5. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.

STABILITY AND STORAGE

Reagent should be stored at 2°-8°C. Do not freeze. Reagents stored under these conditions will be stable until the expiry date shown on product label.

SPECIMEN COLLECTION & PREPARATION OF CULTURES

Specimens from which sorbitol-negative colonies have been isolated and that agglutinate with *E. coli* 0157 Latex reagent should be tested for the H7 antigen. The strains that have H7 antigen require multiple passages on Blood agar before the flagellar antigen is detected. For specific procedures regarding specimen

collection and preparation of cultures refer to a microbiological textbook.

MATERIAL SUPPLIED

A dropper vial containing 1.0 ml of Latex suspension reagent. This reagent is sufficient for 25 tests.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Normal saline
2. Glass tubes
3. Disposable cards with circles (Pro-Lab PL.090).
4. Disposable mixing sticks (Pro-Lab PL.091).
5. Pro-Lab Negative Control Latex Reagent (PL.076 or PL.077).
6. The following ATCC strain is recommended to check the performance of the reagent: ATCC # 23514.

TEST PROTOCOL

1. Streak colonies which are sorbitol-negative and give a positive agglutination reaction with *E. coli* 0157 Latex reagent on Blood agar overnight at 37°C.
2. Subculture colonies on Blood agar for 18 - 24 hours at 37°C to enhance flagellar antigen.
3. Allow reagent to warm to room temperature (22-28°C) prior to use.
4. Select colonies from the agar medium surface. Resuspend in 0.2 ml normal saline in a glass tube (12 x 75 mm or equivalent) to a turbidity corresponding to a McFarland 3-5.
5. Resuspend the Latex reagent by shaking prior to use.
6. Place one drop of *E. coli* H7 Latex Reagent onto a test circle on a test card. Using a pasteur pipette add one drop of the test specimen (colony suspension) to the test circle.
8. Mix and spread with the Latex Reagent using a mixing stick to cover the complete area of the circle.
9. Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
10. At 60 seconds, under normal Lighting conditions, observe for agglutination.

INTERPRETATION OF RESULTS

Positive result: a significant agglutination within 60 seconds is considered a positive result.

Negative Result: A milky appearance without visible agglutination of the Latex particles.

LIMITATIONS OF THE PROCEDURE

1. False results can occur if inadequate amounts of culture or reagent are used.
2. Any positive strains have to be tested for autoagglutination using Pro-Lab Negative Control Latex (PL.076 or PL.077). The results with this Latex must show no agglutination within 1 minute. If agglutination occurs with Negative Control Latex the results are considered uninterpretable.

3. Tests must be interpreted by an individual experienced in microbiology and examination of Latex agglutination.
4. Some strains of *E. coli* 0157 that have other H types or are non-motile can produce the shiga-like toxin.^{7,8,10} These strains will give negative results with this reagent. However, any *E. coli* 0157 should be reported to Local Health Departments.

REFERENCES

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= Use by

LOT

= Lot number



= Attention, see instructions for use

REF

= Catalogue number



= Manufacturer

EC REP

= Authorized Representative in the European Community.

IVD

= in vitro diagnostic medical device.



= Contains sufficient for <n> tests



= Temperature limitation



= Consult instructions for use.