E.coli O157:H7 Rapid Test (Card)

Cat. No.:DTS518
Pkg.Size:

Intended use

The E.coli O157:H7 Rapid Test is a one step coloured chromatographic immunoassay for the qualitative detection of Escherichia coli O157 in stool samples.

General Description

Infection with Escherichia coli O157:H7 (Enterohemorrhagic Escherichia coli) presents with a wide spectrum of clinical manifestations, including asymptomatic carriage, nonbloody diarrhea, hemorrhagic colitis, the hemolytic-uremic syndrome, and thrombotic thrombocytopenic purpura. Not only is E. coli O157:H7 an important agent for hemorrhagic colitis, it is also one of the leading causes of bacterial diarrhea. Transmission of E. coli O157:H7 is primarily food-borne. Undercooked meat is the most common culprit, dairy products and secondary person-to-person spread are also important. The organism produces at least two Shiga-like toxins. These toxins are thought to have direct pathogenic significance in E. coli O157:H7 infection. This infection is usually diagnosed from a positive stool culture, from the presence of Shiga toxins, or both. Timely collection (within 7 days of illness onset) of a stool sample for culture is imperative for a high recovery rate.
E. coli O157:H7 Rapid Test test provides a rapid detection of E. coli O157:H7 directly from the stool samples.

Principle Of The Test

The E. coli O157:H7 Rapid Test is a qualitative immunochromatographic assay for the determination of E. coli O157:H7 in stool samples. The membrane is pre-coated with mouse polyclonal antibodies, on the test band region, to recognize this serotype (polyclonal antibodies against O157:H7 antigens).
During testing, the sample is allowed to react with the coloured conjugate (anti-E. coli O157:H7 antibodies-red microspheres) which was pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate (result region). The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

Reagents And Materials Provided

1. E.coli O157:H7 Rapid Tests
2. Sample diluent
3. Instructions for use
4. Stool collection tubes

Materials Required But Not Supplied

1. Specimen collection container
2. Disposable gloves
3. Timer

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Storage

Store as packaged in the sealed pouch at 2-30ºC. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Specimen Collection And Preparation

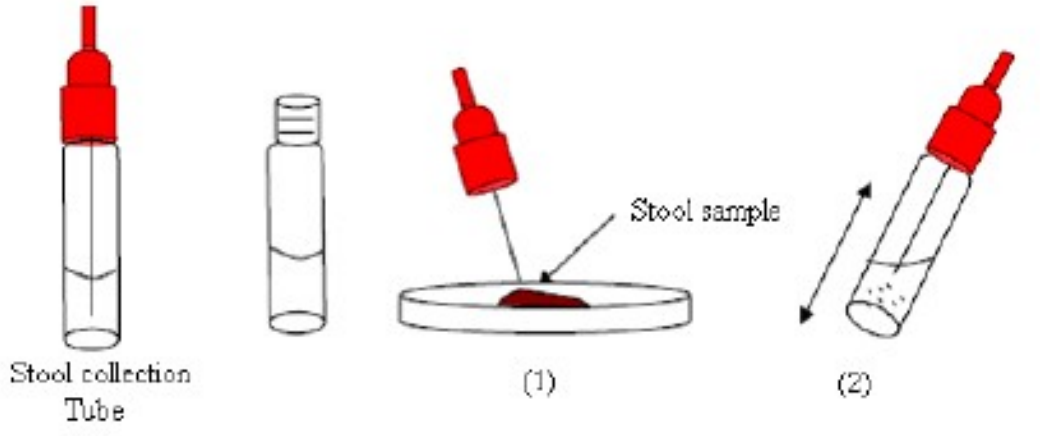
Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4 ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing.

To process the collected stool samples:

Use a separate vial for each sample.

Unscrew the tap and use the stick to pick up a little sample, if the stool sample was liquid take approx. 100 µL using a pipette, and add the sample into the stool collection tube.

Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.



Assay Procedure

Allow the tests, stool or enrichment samples and controls to reach to room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top.
2. Remove the E. coli O157:H7 Rapid Test device from its sealed bag just before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow.
4. Read the result at 10 minutes (the coloured bands appear).

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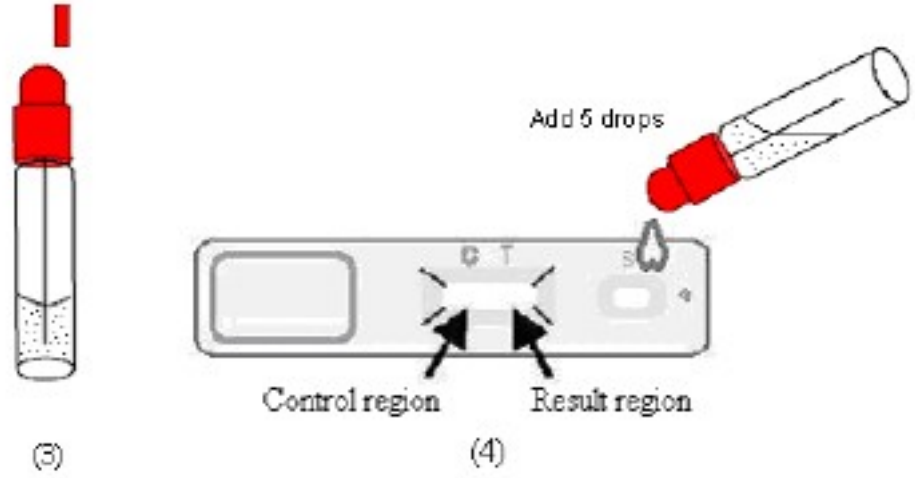

Quality Control

A green line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Interpretation of Results

NEGATIVE: Only one GREEN band appears across the central window in the site marked with the letter C (control line).
POSITIVE: In addition to the GREEN control band, a distinguishable RED band also appears in the site marked with the letter T (result line).
INVALID: A total absence of the control coloured band (GREEN) regardless of the appearance or not of the result line (RED). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the tests with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.
NOTES: The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigen present in the specimen. However, neither the quantitative value, nor the rate of increase in antigen can be determined by this qualitative test.

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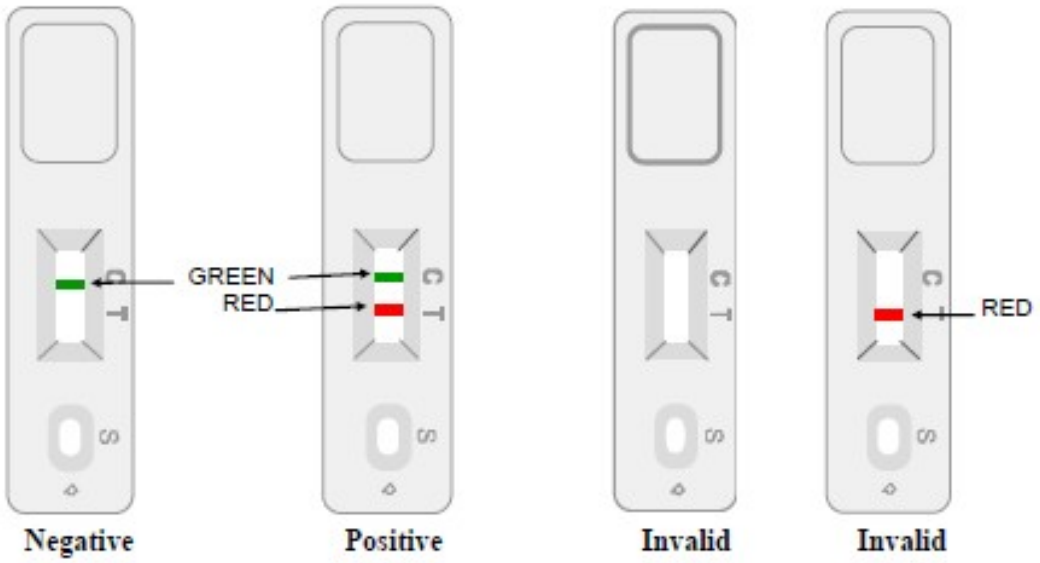

Sensitivity

The detection of E. coli O157:H7 showed a 100% of concordance in sensitivity.

Specificity

The detection of E. coli O157:H7 showed a 85% of concordance in specificity. PPV showed a 70% and NPV showed a 100%.

Precautions

1. Do not use after expiration date.
2. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
3. The tests should be discarded in a proper biohazard container after testing.

Limitations

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control green line.
4. A negative result is not meaningful because it is possible the E.coli content in the stool sample to be too small. An E. coli determination should be carried out on a sample from a enrichment culture.
5. This test provides a presumptive diagnosis of E. coli infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.

REFERENCES

1. THOMPSON, J., HODGE, D. and BORCZYK, A.; “Rapid Biochemical Test to Identify Verocytotoxin-Positive Strains of Escherichia coli Serotype O157”; Journal of Clinical Microbiology, Oct. 1990, Vol. 28, No. 10, pp 2165-2168
2. VALLANCE B.A. and FINLAY B.B., “Exploitation of host cells by enteropathogenic Escherichia coli”, PNAS, August 2000, Vol. 97, No. 16, pp. 8799-8806

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