Atlas Medical

***E. coli* Strip**

A rapid test for the qualitative detection of Escherichia coli (E. coli) antigens in human feces.

IVD *For In-Vitro diagnostic use only*

2 30°C Store at 2-30 °C

CE

INTENDED USE

Atlas *E. coli* Strip is a rapid chromatographic immunoassay for the qualitative detection of *E. coli* antigens in human feces specimens to aid in the diagnosis of *E. coli* infection.

SYNTHESIS

E. Coli is a gram-negative bacteria that are rod-shaped have the ability to survive in aerobic and anaerobic environments termed as a facultative anaerobe, bacteria normally live in the intestines of healthy people and animals. But a few particularly nasty strains, such as *E. coli* O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although most strains are harmless, this strain produces a powerful toxin by adhering to tissues and by forming aggregates or clumps of bacteria that can cause severe abdominal cramps, bloody diarrhea and vomiting. *E. coli* O157:H7 has been found in the intestines of healthy cattle, deer, goats, and sheep.

E. coli O157:H7 was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea; the outbreak was traced to contaminated hamburgers. Since then, more infections in all over the world have been caused by eating under-cooked ground beef than by any other food.

E. coli strains are one of the most frequent causes of several common bacterial infections, including cholecystitis, bacteremia, cholangitis, urinary tract infection (UTI), and other clinical infections such as neonatal meningitis, pneumonia, abdominal abscesses, and haemolytic uremic syndrome (HUS).

PRINCIPLE

The *E. coli* Strip is a qualitative lateral flow immunoassay for the detection of *Escherichia coli* antigen in human feces samples. The membrane is pre-coated with monoclonal antibodies against *E. coli* O157 antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*E. coli* O157 antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a colored line. A green colored line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed pack.

STORAGE AND STABILITY

- Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF).
- The test is stable through the expiration date printed on the sealed pack.
- The test must remain in the sealed pack until use.
- Do not freeze.

MATERIALS

Materials Provided

- Test strip
- Sample diluent in extraction tube
- Package insert

Materials Required But Not Provided

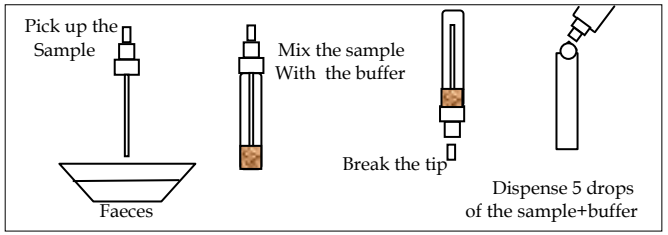
- Disposable gloves
- Timer
- Testing tubes or vials

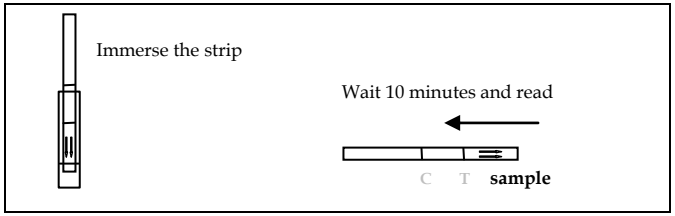
SPECIMEN COLLECTION AND PREPARATION

- Collect sufficient quantity of feces (1-2 g or ml for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8℃) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at -20℃.
In this case, the sample will be totally thawed, and brought to room temperature before testing.
- For the enrichment culture test, stool sample is inoculated into a SMAC medium and incubated overnight on a shaker at 37℃.

PROCEDURES

1. Allow the test strips, stool samples and buffer to reach room temperature (15-30ºC) prior to testing. Do not open the pack until ready to perform the assay.
2. Using the applicator stick of the provided sample diluent extraction tube, to pick up a little sample (125 mg) of stool specimen into the sample diluent.
3. Shake gently in order to unstuck and facilitate the sample dispersion. Break off the tip of the vial.
4. Dispense 5 drops of the sample+buffer in the extraction tube into a test tube.
5. Immerse the test strip in the liquid prepared in step 5, taking care of not surpassing the limit of immersion indicated with the arrows. Leave it for 1-3 minutes and place in a flat surface. Start the timer. **See the illustrations below**.
6. Read the result 10 minutes after the immersion of the strip.





INTERPREATATION OF RESULTS

POSITIVE: Two lines appear across the result zone, a red test line marked in the illustration 3 with the letter T and a green control line marked in the illustration 3 with the letter C.

NEGATIVE: Only one green line appears across the control line region marked in the illustration 3 with the letter C (control line).

INVALID: Total absence of the green control colored line regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor. **Refer to the illustration below.**

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red colored test line (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test:
A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. *E. coli* Strip will only indicate the presence of *Escherichia coli* antigens in the specimen (qualitative detection) and should be used for the detection of *E. coli* O157 antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *E. coli* antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *E. coli* infection.
5. This test provides a presumptive diagnosis of *E. coli* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Escherichia coli O157:H7 is a leading cause of foodborne illness. Based on a 1999 estimate, 73,000 cases of infection and 61 deaths occur in the United States each year.

PERFORMANCE CHARACTERISTICE

Sensitivity and Specificity

It was performed an evaluation using *E. coli* Strip. It was studied some stool samples and the results were confirmed by culture *E. coli* Strip showed >99% of sensitivity and 85% of specificity.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of *E. coli* Strip. There is not cross reactivity with common gastrointestinal pathogens occasionally present in feces.

- *Campylobacter*
- *Citobacter freundii*
- *Clostridium difficile*
- *E. coli O22:H8*
- *E. coli O91:H-*
- *E. coli O103:H2*
- *E. coli O111:H21*
- *E. coli O145:H-*
- *E. coli O171:H2*
- *E. coli O174:H8*
- *Klebriella pneumoniae*
- *Helicobacter pylori*
- *Listeria monocytogenes*
- *Morganelle morganii*
- *Proteus mirabilis*
- *Salmonella*
- *Shigella*
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Rangel, J. M., Sparling, P. H., Crowe, C., Griffin, P. M. & Swerdlow, D. L. 2005 Epidemiology of *Escherichia coli* O157:H7 outbreaks, United States, 1982–2002. Emerg. Infect. Dis. 11, 603–609.
- Griffin, P.M. "The Epidemiology of infections caused by *Escherichia coli* O157:H7, other enterohemorrhagic *E. coli*, and the associated haemolytic uremic syndrome". Epidemiol. Rev, 1991, 13:60-98.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry