



American Bionostica, Inc.

One Step Rapid Test Cassette E. coli 0157:H7 Catalog no. 402C

**A rapid, one step test for the qualitative detection of E. coli 0157:H7 following enrichment culture
For professional diagnostic use only**

INTENDED USE

The ABI One Step E. coli 0157:H7 Test is a rapid immunochromatographic assay for the detection of E. coli 0157:H7 following enrichment culture in an appropriate medium.

SUMMARY

E. coli 0157:H7 is a deadly microorganism found in undercooked meat, especially hamburger, and in milk.¹ The American Bionostica test for E. coli 0157:H7 allows for screening of samples following as little as 8 hours of sample enrichment. Conventional media allows for screening with at least a 20 hour enrichment period.

This test system was designed to provide results quickly. The test is easy to use, and requires only a minor investment in equipment and training. It is cost effective to incorporate into pathogen screening programs.

PRINCIPLE

To perform the test, (100 uL) of the enrichment culture (specimen) is transferred to the sample port of the test cassette. The sample immigrates through a reagent zone which contains (anti-E. coli 0157:H7) antibodies conjugated to colloidal gold particles. If antigens are present in the sample, they will bind to the gold-conjugated antibodies. This antigen-antibody complex then leaves the reagent zone and migrates through the nitrocellulose membrane, which contains a zone of anti-E. coli 0157:H7 antibody. The immune complex with gold conjugate is captured, aggregates in this zone, and displays a visible line. The remainder of the sample continues to migrate to the end of the membrane where it is eventually deposited into a waste reservoir.

The reagent zone also contains gold conjugate of a proprietary antigen, which is eluted by the sample solution regardless of the presence of E. coli 0157:H7 antigen. The gold-conjugated control indicator migrates through the membrane to the negative control capture zone, containing antibody to the E. coli 0157:H7 antigen, where it is captured and aggregates to form a visible line. Regardless of the presence or absence of the E. coli 0157:H7 antigen, the control line will form in the control zone, indicating the test is working properly.

REAGENTS

The test device contains anti-E. coli 0157:H7 particles and E. coli 0157:H7 conjugate coated on the membrane.

PRECAUTIONS

1. For professional diagnostic use only. Do not use after the expiration date.
2. Do not use if the pouch the seal is broken, pouch is torn or punctured, or missing desiccant pack.
3. The test device should remain in the sealed pouch until use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION:

PROCEDURE

Materials Provided:

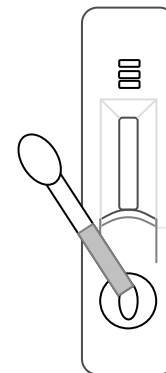
Test cassettes in foil pouch with desiccant
Package insert

Materials Required But Not Provided:

Specimen collection container
Enrichment culture medium
75 x 10 mm vial
Timer

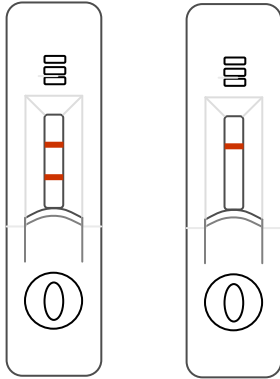
DIRECTIONS FOR USE

1. Allow the unopened pouch containing the test cassette, the test specimen, and and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test cassette from the sealed pouch and use it as soon as possible.
3. Transfer 100 ul of enrichment cultural to the sample port of the cassette and start the timer.
4. Wait for the red line(s) to appear. The result should be read after 5 minutes. Do not interpret the result after 10 minutes.



¹ U.S. Food & Drug Administration, Center for Food Safety & Applied Nutrition: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook

INTERPRETATION OF RESULTS



POSITIVE: Two lines appear. One red line should be in the control region, and another red or pink line should be in the test region. This positive result indicates that the *E. coli* 0157:H7 concentration is at or above the detectable level 10^5 CFU/ml.

NEGATIVE: One line appears in the control region, and *no* other line should be visible in the test region. This negative result indicates that the *E. coli* 0157:H7 concentration is below the detectable level of 10^5 CFU/ml.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

* **NOTE:** The shade of red in the test line region may vary, but it should be considered positive whenever there is even a faint pink line.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory testing practice to confirm the test procedure and to verify proper test performance.

TECHNICAL ASSISTANCE

If you require technical assistance please contact us at 856-467-7070

LIMITATIONS

The One Step *E. coli* 0157:H7 Test provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. The One Step *E. coli* 0157:H7 Test is a qualitative screening assay and can not determine either the concentration or identity of the microorganisms. It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

Any express or implied warranty offered by American Bionostica, Inc. is contingent upon observance of its published directions with respect to the use of American Bionostica's diagnostic products. Under no circumstances will American Bionostica, Inc. be liable for any indirect or consequential damages.