



## American Bionostica, Inc.

### One Step Rapid Test Cassette Salmonella Item no. 401C

#### A rapid, one step test for the qualitative detection of Salmonella following enrichment culture

*For professional diagnostic use only*

#### INTENDED USE

The ABI One Step Salmonella Test is a rapid immunochromatographic assay for the detection of Salmonella following enrichment culture in an appropriate medium.

#### SUMMARY

It is estimated that from 2 to 4 million cases of salmonellosis occur in the U.S. annually. Salmonella is a Gram-negative rod-shaped, motile bacterium. Non-motile exceptions are *S. gallinarum* and *S. pullorum*. It is found in animals, especially in poultry and swine. Environmental sources of the organism include water, soil, insects, factory surfaces, kitchen surfaces, animal feces, raw meats, raw poultry, and raw seafoods. It is believed that enterotoxins produced by Salmonella cause acute symptoms such as nausea, vomiting, abdominal cramps, diarrhea, fever, and headache. Arthritic symptoms may follow 3-4 weeks after onset of acute symptoms.<sup>1</sup>

The American Bionostica test for Salmonella allows for screening of samples following enrichment culture. 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, 110 ul of the enrichment culture (specimen) is transferred to the sample port of the Salmonella test cassette. The sample migrates through a reagent zone which contains anti-Salmonella 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 migrates through the nitrocellulose membrane to the results area where a band of anti-Salmonella antibody has been applied. The immune complex with gold conjugate is captured and displays a visible line.

The remainder of the sample continues to migrate to the control line region where residual colloidal gold-antibody conjugate is captured to form another visible red band. Regardless of the presence or absence of Salmonella, the control line will form in the control zone, indicating the test is working properly.

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

#### 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:

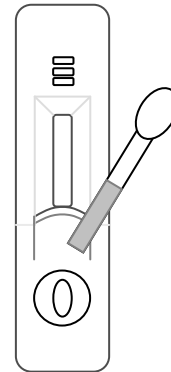
- Test cassette in foil pouch
- Package insert

Materials Required But Not Provided:

- Specimen collection container
- Enrichment culture medium
- Transfer pipette
- 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 110 ul test specimen to specimen port of cassette.
4. The result should be read at 20 minutes.

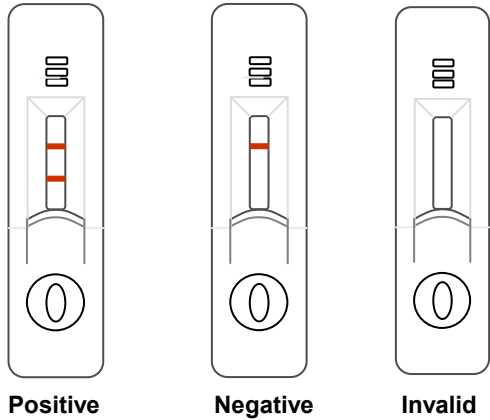


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## INTERPRETATION OF RESULTS

Read results after five to ten minutes. When reading the test results, keep the test cassette immersed in the sample or read results immediately upon taking test cassette out of test tube.



**POSITIVE:** Two red-purple lines appear. One line should be in the control region, and another line should be in the test region. This positive result indicates that the *Salmonella* 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 *Salmonella* 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.

## LIMITATIONS

The Rapid *Salmonella* Test provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. The One Step *Salmonella* 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. Under no circumstances will American Bionostica, Inc. be liable for any indirect or consequential damages.

## TECHNICAL ASSISTANCE

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

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