



One Step Rapid Test for Salmonella

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

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.¹

The American Bionostica Rapid Test for Salmonella allows for screening of samples following enrichment culture in appropriate media. This test system was designed to provide results quickly. The test is easy to use, and is economical to incorporate into pathogen screening programs.

PRINCIPLE

To perform the test, 100 uL of the enrichment culture medium is transferred to the sample pad of the test strip. 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 Test Line where another anti-Salmonella antibody is immobilized. The immune complex with gold conjugate is captured, aggregates on the Test Line, and displays a red-violet line. The reagents continue to migrate to the Control Line, where gold-conjugated control indicator is captured to display a red violet line. Regardless of the presence or absence of Salmonella, the Control Line will form in the control zone to indicate the test is working properly.

MATERIALS REQUIRED BUT NOT SUPPLIED:

1. Timer, sample container and gloves, pipette for delivering specimen to strip
2. Appropriate culture media in which the Salmonella test specimen is grown prior to testing
3. Salmonella positive and negative controls

REAGENTS

The test device contains anti-Salmonella gold conjugate in the reagent pad and Salmonella conjugate immobilized on the test membrane.

PRECAUTIONS

1. For professional diagnostic use only. Do not use after the expiration date.
2. The foil pouch containing the test strip must remain completely sealed before use. Do not use if the foil pouch seal is not intact.
3. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kits are handled.
4. All specimens should be considered potentially hazardous and handled as an infectious agent.
5. Wipe up all spills thoroughly with a suitable disinfectant.
6. Treat all materials in the test as if they were infectious.
7. Dispose of all specimens and used assay materials as if they contained infectious agents. Preferred methods are autoclaving for 60 minutes at 121° or incineration.
8. Avoid any contact of hands with eyes and nose during specimen collection and testing.
9. Avoid cross-contamination of specimens by using a new pipette or dropper for each specimen.

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 when stored under these conditions. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND HANDLING

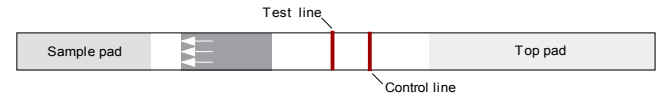
1. Use fresh specimens. Test specimens immediately after collection. Make sure test strips and TB Developer are at room temperature before using.
2. Handle and dispose of specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin.

ASSAY PROCEDURE

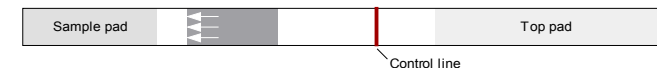
1. Allow the unopened pouch containing the test strip, the test specimen, and and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test strip from the sealed pouch and use it as soon as possible.
3. Transfer 100ul test specimen to the sample pad on the test strip.
4. Wait for the red line(s) to appear on the test membrane and read the result after approximately 10 minutes. Do not interpret the result after 20 minutes.

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 Salmonella concentration is at or above the detectable level of 10⁵ CFU/ml.



NEGATIVE: no line appears in the control region, and no line should be visible in the test region. This negative result indicates that the Salmonella concentration is below the detectable level of 10⁵ 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 Salmonella Test provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. It is a qualitative screening assay and can not determine either the concentration 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.

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