

Salmonella

25 DET

Ref. I0007

INTENDED USE

The Salmonella Test is an immunochromatographic assay for the qualitative detection of Salmonella pathogen in food or human feces and environmental samples from a 24-hour enrichment broth. The test kit detects as low as one Salmonella organism per 25 grams of sample. Use standard enrichment media and method for sample enrichment process.

PRINCIPLES OF THE PROCEDURE

The Salmonella Test is a rapid, non-culture diagnostic assay that can detect the presence of this organism directly from a fecal sample. This test is comprised of colloidal gold particle-labeled anti Salmonella antibodies dried in a binding zone and immobilized antibodies in a capture zone. In this one step procedure, several drops of stool specimen is added to a cassette test. Within minutes, the test result is read. A positive result is indicated by a colored band at the test zone.

MATERIALS PROVIDED

1. Salmonella test.
2. Disposable sample Dropper.
3. Instructions for use.

STORAGE OF KIT COMPONENTS

All kit components should be stored in a cool, dry place at room temperature of 2 to 30°C.

SPECIMEN COLLECTION AND HANDLING

Specimens should be stool samples. Samples that will not be tested within 48 hours should be refrigerated at 2 to 8°C.

SPECIMEN PREPARATION

Liquid Specimens: Specimen should sit undisturbed to allow large particles to settle before transferring an aliquot of specimen to begin assay procedure.

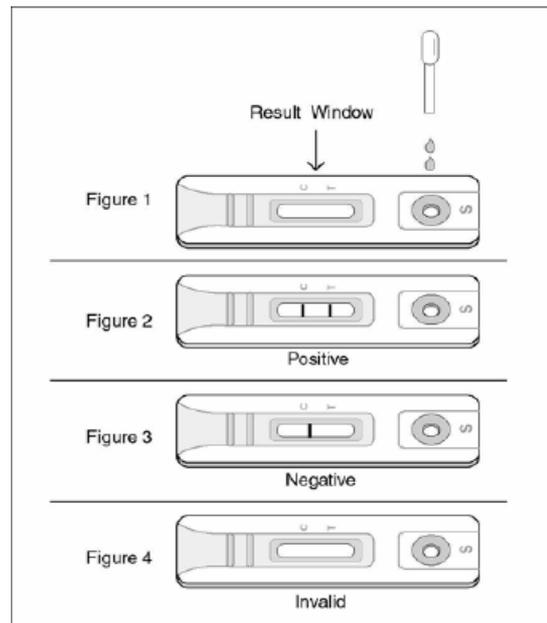
Semi-soft or Formed Specimens: Add five drops of Enrichment Buffer Solution to a clean labeled tube. Using an applicator stick, transfer a small bead-sized amount of sample to the tube containing the buffer and mix vigorously. Allow large particles to settle before beginning the assay procedure. A sufficient volume of extracted sample should be present to proceed with the assay procedure.

TEST PROCEDURE

1. Remove the test cassette from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test cassette, squeeze 2 to 3 drops of specimen into the sample well (Figure 1).
3. As the test begins to work, you will see purple color move across the Result Window in the center of the test.
4. Interpret test results at 5 to 20 minutes. Do not interpret after 30 minutes.

INTERPRETATION OF TEST

1. As the test kit begins to work, a color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Line.
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Line.



POSITIVE RESULT: TWO COLOR BANDS

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

NEGATIVE RESULT: ONE COLOR BAND

The presence of only one purple color band within the result window indicates a negative result (Figure 3).

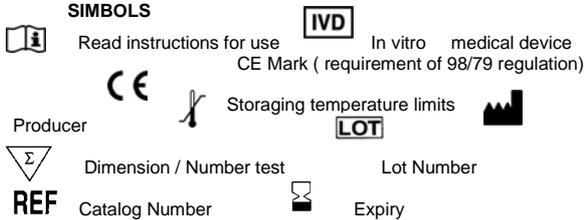
INVALID RESULT:

After performing the test and no purple color band is visible within the result window, this result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit (Figure 4).

LIMITATIONS OF THE PROCEDURE

1. This test is designed as an aid in the presumptive diagnosis of diarrhea caused by Salmonella and should be used as an adjunct to culture.
2. Specimens containing large amounts of mucous may migrate slowly up the test cassette. Follow the instructions recommended in the TEST PROCEDURE for transferring these specimens to a test tube containing buffer and allow a maximum of 30 minutes for migration to occur.
3. False positive results may be observed with certain E. Coli shares a common antigenic epitope with Salmonella.
4. On occasion, specimens containing very high concentrations of Salmonella may produce a strong positive "Test" line and a weak or faint "Control" line on the test cassette. This is due to large amounts of conjugate being deposited on the "Test" line depleting the amount of conjugate available for binding at the "Control" line. If a strong positive specimen is suspected, the specimen may be serially diluted in buffer to view the "Control" line and ensure proper performance of the test procedure.
5. Administration of antibiotics prior to collection of the fecal specimen may produce discrepant results between stool culture results and the results of the Salmonella Test.

SIMBOLS



REFERENCES

1. Gray, L.D. Escherichia, Salmonella, Shigella and Yersina. p. 450 -452. In Manual of Clinical Microbiology. 6th ed . Patrick R. Murray, ed. 1995. American Society for Microbiology, Washington, D.C.

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