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Salmonella Cassette Test

REF

Catalog No. R11-543

IVD

For Professional Use Only

INTENDED USE

Immunospec test kit detects as low as one Salmonella organism per 25 grams of sample (after growth in enrichment media). Use standard enrichment media and method for sample enrichment process. For professional use.

PRINCIPLES OF THE PROCEDURE

The Immunospec's Salmonella Cassette 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 procedure, several drops of stool specimen is added to a cassette test. Within minutes, the test result is read. A positive re-sult is indicated by a colored band at the test zone.

MATERIALS PROVIDED

1. Instructions.
2. Disposable Dropper.
3. Test device.

MATERIAL NEEDED BUT NOT PROVIDED

1) Incubator
2) Salmonella Growth Media: TT (Tetrathionate) Broth Base, Hajna (Becton Dickinson)

STORAGE OF KIT COMPONENTS

All kit components should be stored in a cool, dry place at room temperature of 4 to 25 degrees C.

SPECIMEN HANDLING

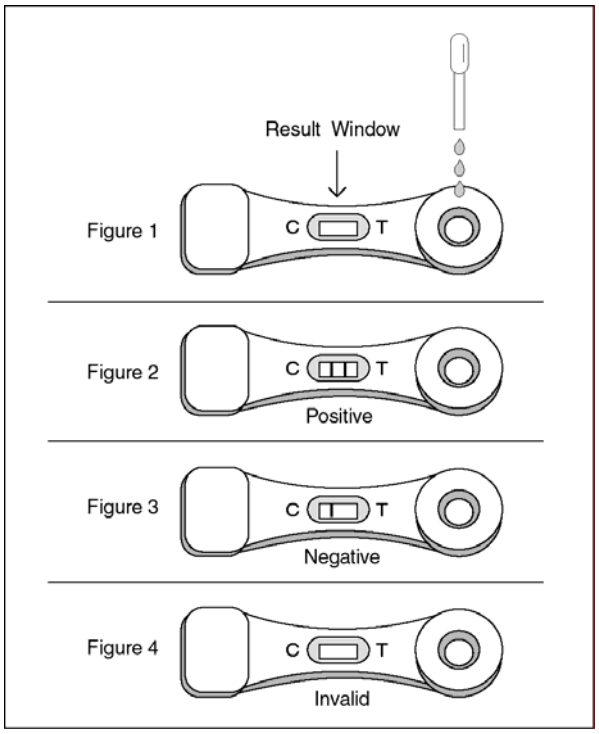
Specimens should be food/stool samples. Samples that will not be tested within 48 hours should be refrigerated at 2 to 8 degrees C.

SPECIMEN COLLECTION AND PREPARATION

1) Prepare media solution by following the instructions from the manufacturer of the selected salmonella growth media.
2) Use a small amount of the media solution to crush the collected sample within a sterilized tube and vigorous stirring/shake the tube.
3) Add an additional 10mls of the media solution to the tube, cap the tube and incubate for at least 19 to 24 hours at 42 C.
4) After completion of incubation, Specimen should sit undisturbed to allow large particles to settle before transferring an aliquot of specimen to begin assay procedure.

TEST PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, 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 disk.
4. Interpret test results at 10 to 15 minutes. Do not interpret after 15 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 2).

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 2).

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 Rapid Salmonella Test.

REFERENCES

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PIR11-543
Revision#:1
Revision Date: 03-10-2005