



FoodChek™ - Salmonella

Assay Cassettes Product Information

Intended Use:

FoodChek™ - Salmonella is a lateral flow immunomagnetic screening assay for the rapid detection with high efficiency of *Salmonella* species belonging to group B to E. The method has been validated according to the Performance Tested MethodsSM of the AOAC-RI in eggs and derivatives samples (whole liquid eggs, liquid egg white (liquid egg albumen), shell eggs, dried whole eggs and dried egg yolks) and environmental surfaces (stainless steel, plastic, rubber, ceramic tiles and sealed concrete).

The FoodChek™ - Salmonella test was validated with *Salmonella enterica* serovars of somatic groups B-E. This includes the most common serovars from both food and non-food sources. Any positive result can be confirmed through the confirmation procedures found in either the BAM or the MLG. If a presumptive-positive result cannot be confirmed using somatic groups B-E antisera, then the use of other somatic group antisera should be considered.

The assay cassette, a lateral flow separation device, that has the testing sample loaded into the sample port of the cassette that is then allowed to laterally flow in the device followed by analysis in the FoodChek™ MICT Reader. The cassette has a printed label attached that contains written and bar-coded identity information, the expiry date, and the required values for automated analysis by the FoodChek™ MICT Reader. Cat # FCR-004.

Principle of Operation:

The cassette is composed of a conjugate pad that contains nano-sized magnetic particles conjugated to a specific antibody that will bind the complimentary antigen. The test comprises a second antibody in a narrow strip called the capture zone. Capillary flow moves the loaded sample through the sample pad onto the conjugate pad, where the target bacteria will bind to the antibody-coated particles. This antigen-antibody immune complex now flows onto the test strip to the capture zone. The result is an accumulation of specific magnetic particles in the capture zone. If the target pathogen is absent, immune complexes do not form and particles do not accumulate at the capture line, and the test result is negative. Further downstream, a “Control Line” that has been placed in a strip format, but with different reagents, acts to verify that the test has performed correctly. The cassette is read in an instrument, the “FoodChek™ MICT Reader” that is capable of detecting very low concentrations of magnetic particles. The instrument compares the detection signal with a



positive threshold value encoded in a barcode on the individual cassette, and then reports a positive or negative result. The results are displayed on the instrument's liquid crystal display (LCD) screen and printed. In addition to all analysis parameters, the barcode also encodes the test name, lot number and expiry date that are printed along with the test result.

Contents:

A box of 20 assay cassettes (cat. # FCSM-004) intended for 20 independent analytical procedures.

Additional Materials Required:

All samples

1. Actero™ Salmonella Enrichment Media (Actero™ Salmonella) – The medium will be selling in bottle of 500 g of dehydrated medium accompanied of ready-to-used supplements (cat. # FCM-009) or in 1 L polycarbonate bottle of prepared medium (cat. # FCM-017) or in FoodChek MediaBox™ that provides fully prepared, fresh, sterile media in an easy to handle, stackable storage box with an internal bladder. Available in 5 L (cat. # FCM-047) and 10 L (cat. # FCM-048)
2. FoodChek™ MICT v2 Reader (cat. # FCR-004) – available from FoodChek™ Systems Inc.
3. Distilled/deionized, sterile water. Any source.
4. Graduated cylinders with a capacity range between 90 mL to 3L.
5. Sterile stomacher bags.
6. Polypropylene tube with cap. Any source.
7. Disposable transfer pipettes. Any source.
8. Micropipette able to dispense 150 µL.
9. Pipette tips fitting with the micropipette. Any source.
10. Stomacher (optional). Available from multiple sources such as Seward, Fisher Scientific.
11. Regular laboratory equipment is also required.

Environmental Surfaces

1. Non-bactericidal, non-bacteriostatic 8×4×0.3 cm sterile cellulose sampling sponges pre-moistened with neutralizing Dey-Engley buffer. (D/E). (FoodChek Cat # FCSM-003)

Procedure:

General Preparation



Preparations of Samples for Testing with FoodChek™ - Salmonella cassettes

NOTE: The sample preparation depends on the type and size of the sample. Thus, the protocol to prepare the sample should be chosen in function of those conditions. However, all the other steps are the same.

Enrichment Media Preparation

1. Prepared the Actero™ Salmonella Enrichment Media following the manufacturer instruction.
2. Warm media to $39 \pm 0.5^\circ\text{C}$. Note: for optimum assay performance it is important that the media is at $39 \pm 0.5^\circ\text{C}$ before use.

Food Sample Preparation

Liquid Whole Eggs, Liquid Egg White, Dried Whole Eggs, Dried Egg Yolks

1. Weigh **100 g** of food in a stomacher bag.
2. Add 7 volumes (**$700 \pm 15 \text{ mL}$**) of pre-warmed Actero™ Salmonella Enrichment Media to each sample in a stomacher bag.
3. Stomach sample 30 seconds at 80 rpm in a Stomacher® 3500. Hand mixing is an acceptable alternative for stomaching. To hand mix, massage each sealed stomacher bag until homogeneity.
4. Adjust pH of **liquid egg white** to **7.0 ± 0.4** prior to incubation
5. Close bag and incubate the samples for **$18 \pm 0.5 \text{ h}$** at **$39 \pm 0.5^\circ\text{C}$** in an incubator for enrichment. Adherence to temperature is important for accurate results.
6. Place one labeled tube (with the cap removed) for each sample into a rack.
7. After the 18 h enrichment period:
 - a. For liquid egg white, dried whole eggs and dried egg yolks: mix sample thoroughly and transfer **$5.0 \pm 0.1 \text{ mL}$** of the enriched sample to a tube containing 5 mL of fresh Actero™ Salmonella Enrichment Media. Mix well and incubate for **4 h** at **$39 \pm 0.5^\circ\text{C}$** . At the end of this enrichment, cap the tube.
 - b. For whole liquid eggs: mix sample thoroughly and transfer **$10.0 \pm 0.1 \text{ mL}$** of the enriched sample to a tube. Cap the tube.
8. Keep the tube for cultural confirmation of any positive result obtained with FoodChek™ - Salmonella assay.

Shell Eggs



Preparation of Shell Egg Samples

1. Remove any adherent material from the shell surface.
2. Disinfect eggs with 3:1 solution consisting of 3 parts of 70% alcohol (ethyl or isopropyl) to 1 part iodine/potassium iodide solution. Prepare 70% alcohol solution either by diluting 700 mL 100% alcohol with sterile distilled water for a final volume of 1000 mL or by diluting 700 mL 95% alcohol with sterile distilled water for a final volume of 950 mL. Prepare iodine/potassium iodide solution by dissolving 100 g potassium iodide in 200-300 mL sterile distilled water. Add 50 g iodine and heat gently with constant mixing until the iodine is dissolved. Dilute the iodine/potassium iodide solution to 1000 mL with sterile distilled water. Store iodine/potassium iodide solution in amber glass-stoppered bottle in the dark. Prepare the disinfection solution by adding 250 mL iodine/potassium iodide solution to 750 mL 70% alcohol solution and mix well. Submerge eggs in disinfection solution for at least 10 seconds. Remove eggs and allow to air dry.
3. Eggs with chipped, cracked, or broken shells are not included in the sample.
4. Each sample shall consist of twenty (20) eggs cracked aseptically into a Whirl-Pak bag.
5. Eggs are cracked aseptically by gloved hands, with a change of gloves between samples. Mix samples thoroughly by gloved hands, with a change of gloves between samples. Mix samples thoroughly by hand until yolks are completely mixed with the albumen.

Short Protocol Methodology

1. Add **3 volumes (3 ± 0.05 L)** of pre-warmed Actero™ Salmonella Enrichment Media to the sample in the stomacher bag.
2. Massage by hand each sealed stomacher bag until homogeneity.
3. Close bag and incubate the samples for **18±1 h** at **39±0.5°C** in an incubator for enrichment. Adherence to temperature is important for accurate results.
4. Place one labeled tube (with the cap removed) for each sample into a rack.
5. At the end of the enrichment period, mix sample thoroughly and transfer 10.0 ± 0.1 mL of the enriched sample to a tube. Cap the tube.
6. Keep the tube for cultural confirmation of any positive result obtained with FoodChek™ - Salmonella assay.

Regular Protocol Methodology

1. Store the 20 egg sample at room temperature for 96 h.



2. After the 96 h, hands mix the sample thoroughly.
3. Transfer **25 mL** of the sample in a sterile stomacher bag.
4. Add **7 volumes (175 ± 3 mL)** of pre-warmed Actero™ Salmonella Enrichment Media to the sample.
9. Stomach the sample for **30 seconds at 265 rpm** in a Stomacher® 400. Hand mixing, is an acceptable alternative for stomaching. To hand mix, massage each sealed stomacher bag until homogeneity.
5. Close bag and incubate the samples for **18 ± 0.5 h** at **39 ± 0.5°C** in an incubator for enrichment. Adherence to temperature is important for accurate results.
6. Place one labeled tube (with the cap removed) for each sample into a rack.
7. At the end of the enrichment period, mix sample thoroughly and transfer **10.0 ± 0.1 mL** of the enriched sample to a tube. Cap the tube.
8. Keep the tube for cultural confirmation of any positive result obtained with FoodChek™ - Salmonella assay.

Environmental Sample Preparation

Environmental Surface Samples (Stainless Steel, Plastic, Rubber, Ceramic Tile and Sealed Concrete)

1. Use a non-bactericidal, non-bacteriostatic 8×4×0.3 cm sterile cellulose sampling sponge that has been pre-moistened with D/E buffer.
2. Wipe the surface to be tested with one side of the sponge (with excess liquid gently squeezed out) in a horizontal direction (approximately 10 cm), and with the other side in a vertical direction (approximately 10 cm) back and forth (one stroke back and one stroke forward) to cover the entire area of 100 cm².
3. Place each surface sampled sponge in a sterile sample bag, and keep at 4 ± 2 °C until it is ready for testing. The sample should be tested within 8 h.
4. When ready to test, pre-warm the prepared Actero™ Salmonella Enrichment Media at **39 °C**.
5. Add **90 ± 5 mL** of the pre-warmed Actero™ Salmonella Enrichment Media to each sponge sample in its sample bag.
6. Stomach the sample for **30 seconds at 265 rpm** in a Stomacher® 400. Hand mixing, is an acceptable alternative for stomaching. To hand mix, massage each sponge that is in the sealed stomacher bag for approximately one minute.



7. For the enrichment phase, close the bags and incubate the samples in an incubator for **18 ± 0.5 h** at **39 ± 0.5 °C**. Adherence to temperature is important for accurate results.
8. At the end of the enrichment period, mix sample thoroughly and transfer **10.0 ± 0.1 mL** of the enriched sample to a tube. Cap the tube.
9. Keep the tube for cultural confirmation of any positive result obtained with FoodChek™ - Salmonella assay.

Analysis of Samples Using FoodChek™ - Salmonella cassettes

1. Bring the required number of cassettes to room temperature at least 30 min prior to use.
2. Turn on the FoodChek™ reader. Initialization takes a few minutes. When the instrument is ready for use, display will show four pictograms. Touch the pictogram that represents a cassette.

Note: For better accuracy, warm the reader for 1 h. It is recommended that the MICT® reader can be left on at all times.

3. **Mix slightly** the sample and, using a micropipette, transfer 150 µL directly to the sample port of a FoodChek™ - Salmonella cassette. Change pipette tips between samples.
4. Allow the assays to develop for 30 min at room temperature before reading in the FoodChek™ reader. Note: interpreting results before 25 min or after 35 min may yield inaccurate results.

Note: if the sample doesn't seem to migrate in the cassette, touch the sample pad with a pipette tip.

5. Open the door on the front of the FoodChek MICT v2 Reader and insert the cassette.
6. Closing the reader door initiates the reading process and generates an output on the LCD screen and a printed result on paper tape.

Interpretation and Test Result Report

1. **Results Output.** The results are indicated on both the instrument LCD display and the instrument printout. These results are reported as being either “Positive” or “Negative”. If an Invalid or Indeterminate result is obtained, see FoodChek Instrument User Manual for further instructions/troubleshooting.
2. **Negative Result.** A negative result should be interpreted as the sample **NOT** being contaminated with *Salmonella* belonging to group B to E.
3. **Positive Result.** A positive result should be interpreted as the sample being **possibly** contaminated with *Salmonella*.



4. **Confirmation of Positive Results.** Since, FoodChek™ Salmonella is a screening test for *Salmonella* spp. (from group B to E confirmed), all positive samples should be culturally confirmed by an approved USDA/FSIS (<http://www.fsis.usda.gov/wps/wcm/connect/700c05fe-06a2-492a-a6e1-3357f7701f52/MLG-4.pdf?MOD=AJPERES>) or FDA confirmatory method <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm>

Product Storage and Shelf Life:

The FoodChek™ - Salmonella assay should be stored at a temperature ranging between 2–8°C. The expiry date is indicated on the box.

Disposal:

Dispose all materials used and the enrichment media by autoclaving or according to an approved practice. Ensure that all bio hazardous waste is disposed of according to local, municipal, provincial, state and/or federal regulations.

Precautions:

Biosafety level 2 procedures should be exercised (BMBL, <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>). Extreme care should be taken in handling test samples, enrichment broths and cassettes. All enrichment broths may contain various pathogens whether they contain *Salmonella* spp. or not.

Terms and Conditions:

FoodChek Systems Inc. makes no representations and warranties concerning its products other than those stated herein. All Product(s) delivered hereunder by FoodChek Systems Inc., its affiliates or any other person on its behalf shall, at the time of delivery, be manufactured to meet FoodChek Systems Inc.'s specifications and all applicable laws. All other terms, conditions and warranties, including any warranty of merchantability, quality, fitness or suitability for a particular or intended purpose, implied by common law or statute, (implied warranties) are expressly excluded.

FoodChek Systems Inc. warrants its new equipment to the original Customer only for a period of one (1) year after date of delivery against defects in material and workmanship and defects arising from failure to conform to FoodChek Systems Inc.'s specifications applicable on the date of delivery. FoodChek Systems Inc.'s sole obligation under this warranty shall be to replace or repair the defective product or part, for any defect found to have occurred



under normal use during the one (1) year period. This warranty does not cover replacement of products damaged due to misuse, abuse, alteration, self-repair, loss or theft.

Catalogue Number:

FCSM-004: FoodChek™ - Salmonella Assay Cassettes

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Food safety, **simplified.**

