



FoodChek™ - Listeria spp.

Prepack Media Kit Product Information

Intended Use:

The *FoodChek™ - Listeria spp.* is a lateral flow immunonanomagnetic screening assay for the rapid detection of *Listeria spp.* from environmental and food samples. The assay was validated according to the Performance Tested MethodsSM of the AOAC. The test detects with high efficiency *L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, and *L. welchimeri*. *L. grayi* is not detected.

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 *MICT FoodChek™ 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™ 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 *MICT FoodChek 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:

FoodChek™ - *Listeria* spp. Prepack Media Kit (cat. # FCLS-004) comprising of 20 assay cassettes, 20 pouches of *Actero™ Listeria Enrichment Media* (dehydrated), 20 sampling swabs, 20 tubes with Dey-Engley (D/E) neutralizing buffer. A prepack media kit is intended for 20 tests) – Available from FoodChek™ Systems Inc.

Additional Materials Required:

1. *FoodChek™ MICT v2 Reader* (cat. # FCR-004) – available from FoodChek™ Systems Inc.
2. Sterile stomacher bags with and without filter.
3. Stomacher.
4. Vortex.
5. Distilled/deionized water.
6. Incubator: at 29 ± 0.5 °C or 32 ± 0.5 °C.
7. Graduated cylinder with a capacity of 100 mL, 200 mL and 1L.
8. Polypropylene tube with cap. Any source.
9. Disposable transfer pipettes. Any source.
10. Micropipette able to dispense 150 µL.
11. Pipette tips fitting with the micropipette. Any source.
12. Water bath able to provide 100 °C to boil the enriched samples.
13. Regular laboratory equipment is also required.

Procedure:

Preparation of Samples for Testing with FoodChek™ *Listeria* spp. Cassettes

NOTE: The sample preparation depends on the type 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. Prepare the *Actero™ Listeria Enrichment Media* following the manufacturer instruction.



Environmental Sample Preparation

Food Contact Surface Samples (Stainless Steel, Plastic)

1. Use a non-bactericidal 8×4×0.3 cm sterile cellulose sampling sponge that has been pre-moistened with D/E buffer.
2. Swab the surface to be tested with one side of the swab(s) 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 swab 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™ Listeria Enrichment Media* at **29** or **32 °C**.
5. Add **90 mL** of the pre-warmed *Actero™ Listeria Enrichment Media* to each sponge sample in its sample bag.
6. Stomach the sample for **30 seconds at 265 rpm** in a Stomacher® 400 circulator. Hand mixing is an acceptable alternative for stomaching. To hand mix, massage each sponge that is in the sealed bag for approximately one minute.
7. For the enrichment phase, close the bags and incubate the samples in an incubator for **24h at 29 ± 0.5 °C** or for **28h at 32 ± 0.5 °C**. Adherence to temperature is important for accurate results.

Non-Food Contact Surface Samples (Ceramic, Sealed Concrete, Rubber)

1. Use a non-bactericidal 8×4×0.3 cm sterile cellulose sampling sponge that has been pre-moistened with D/E buffer.
2. Swab the surface to be tested with one side of the swab(s) 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 swab 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™ Listeria Enrichment Media* at **32 °C**.
5. Add **90 mL** of the pre-warmed *Actero™ Listeria Enrichment Media* to each sponge sample in its sample bag.



6. Stomach the sample for **30 seconds at 265 rpm** in a Stomacher® 400 circulator. Hand mixing is an acceptable alternative for stomaching. To hand mix, massage each sponge that is in the sealed bag for approximately one minute.
7. For the enrichment phase, close the bags and incubate the samples in an incubator for **28h at 32 ± 0.5 °C**. Adherence to temperature is important for accurate results.

Analysis of Samples Using FoodChek™ Listeria spp. Cassettes

1. Turn on the *FoodChek™ MICT Reader*. Initialization will take a few minutes. When the instrument is ready for use, the screen will show four pictograms. Select the pictogram representing a cassette by touching the screen.
2. Allow the required number of the *FoodChek™ - Listeria spp.* cassettes to equilibrate to room temperature prior to use (at least 30 minutes). One cassette per sample is required.
3. Following the enrichment, for each sample, label a 15 mL tube, place it in a tube rack, and remove the cap of the tube.
4. Mix the sample thoroughly, and transfer 5 ± 0.2 mL of the enriched culture sample from the bag to the tube. Cap the tube.
5. Keep the sample bag for cultural confirmation of any positive result obtained with *FoodChek™ Listeria spp.* assay.
6. Using a boiling water bath (100 °C), heat-treat the tube of 5 mL of enriched sample for 15 minutes. Allow the sample to cool down to room temperature.
7. Ensure that each heat-treated **sample is cooled down** to room temperature before proceeding to the test.
8. When the samples are cooled down, **mix** each of them thoroughly using a vortex and a micropipette.
9. When processing a large number of samples, proceed per batches of 10 cassettes.
10. Using a micropipette, transfer **150 µL** of the heat-treated sample (cooled) directly into the sample port of the *FoodChek™ - Listeria spp.* cassette. Change pipette tips between each sample. When testing heavily coagulated heat-treated samples, use wide bore micropipette tips to facilitate the pipetting.
11. Allow the assay to **develop for 30 minutes** at room temperature before reading in the *FoodChek™ MICT Reader*. Note that interpreting results before 25 minutes or after 35 minutes may lead to inaccurate results.



12. Open the front door of the reader, and insert the cassette. Ensure that the barcode is on the up side. Close the door of the reader. Closing the reader door will initiate the reading process.
13. The reader will generate an output on the LCD screen as well as a printed result on paper tape.

Interpretation of Test Results and 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 either *L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, or *L. welshimeri*.
3. **Positive Result.** A positive result should be interpreted as the sample being **possibly** contaminated with either *L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, or *L. welshimeri*.

Confirmation of Positive Results. Since, *FoodChek™ - Listeria spp.* assay is a screening test for *Listeria spp.*, **all positive samples should be culturally confirmed** according to the USDA-FSIS Microbiology Laboratory Guidebook Chapter 8.09 (2013).

Product Storage and Shelf Life:

The *FoodChek™ Listeria spp.* assay should be stored at the temperature 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 and enrichment broths. All enrichment broths may contain various pathogens whether they contain *Listeria 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:

FCLS-004: FoodChek[™] - *Listeria* spp. Prepack Media Kit

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FoodChek™

Food safety, **simplified.**

