



FoodChek™ - *Listeria* spp.

Assay Cassettes Product Information

Intended Use:

The FoodChek™ - *Listeria* spp. is a lateral flow immunonanomagnetic screening assay for the rapid detection of *Listeria* spp. on environmental surfaces of stainless steel and plastic food contact surfaces. The assay was validated according to the Performance Tested MethodsSM of the AOAC-RI. The test detect with high efficiency *L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, and *L. welchimeri*. *L. grayi* was 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.

Specifications

Target	<i>Listeria</i> species (<i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. ivanovii</i> , <i>L. seeligeri</i> , and <i>L. welchimeri</i>) except <i>L. grayi</i> .
Matrices	Environmental samples (stainless steel and plastic)



Enrichment medium	Actero™ Listeria Enrichment Media
Enrichment time	~24 hours
Detection level	10 ⁵ cfu/mL after enrichment

Contents:

A box of 20 assay cassettes (cat. # FCLS-003) intended for 20 independent analytical procedures.

Additional Materials Required:

1. Actero™ Listeria Enrichment Media is available in two formats: a bottle of 500 g (cat. # FCM-011) and a box of 20 individual packs of 4.9 g of powder each one (cat. # FCM-007).
2. FoodChek™ MICT v2 Reader (cat. # FCR-004) – available from FoodChek™ Systems Inc.
3. Distilled/deionized, sterile water. Any source.
4. Non-bactericidal 8×4×0.3 cm sterile cellulose sampling sponges pre-moistened with neutralizing Dey-Engley broth (D/E). Cat# FCLS-002 or equivalent.
5. Graduated cylinder with a capacity of 100 mL.
6. Sterile stomacher bags.
7. Polypropylene tube with cap. Any source.
8. Disposable transfer pipettes. Any source.
9. Micropipette able to dispense 150 µL.
10. Pipette tips fitting with the micropipette. Any source.
11. Water bath able to provide 100°C to boil the enriched samples.
12. Regular laboratory equipment is also required.



Procedure:

General Preparation

Instruction to prepare FoodChek™ Listeria spp. cassettes (cat. # FCLS-003)

1. Bring the required number of cassettes to room temperature at least 10 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: Pre-warm the instrument at least 1-2 h, for optimum performance.

Food Contact Surface Sample Preparation

1. Open a non-bactericidal 8×4×0.3 cm sterile cellulose sampling sponge pre-moistened with D/E and swab a food contact surface.

***** Important surface swab technique: 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 cover the entire area of 100 cm².

2. Place each sponge in a sterile sample bag and keep at 4±2°C until testing. The sample should be tested within 8 h.

Analysis

1. Prepared the Actero™ Listeria Enrichment Media following the manufacturer instruction.
2. Warm media to 29±0.5°C. Note: for optimum assay performance it is important that the media is at 29±0.5°C before use.
3. Add 90 mL of pre-warmed Actero™ Listeria Enrichment Media to each sponge sample in a stomacher bag.
4. Stomach sample for 30 sec 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 stomacher bag for approximately 1 min.
5. Close bag and incubate the samples for 24±2 h at 29±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 5.0 ± 0.2 mL of the enriched samples to the tubes. Cap the tubes.
8. Keep the sample bag for cultural confirmation of any positive result obtained with FoodChek™ *Listeria* spp. assay.
9. Heat the sample tubes in boiling water for 15 min.
10. After heating, let the samples cool to room temperature.
11. Mix each sample thoroughly.
12. Using a micropipette, transfer 150 μ L of heat-treated sample (cooled) directly to the sample port of a FoodChek™ *Listeria* spp. cassette. Change pipette tips between samples.
13. 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.
14. Open the door on the front of the FoodChek MICT v2 Reader and insert the cassette.
15. 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

Results are reported on both the instrument LCD display and the instrument printout. Results are indicated as either “Positive” or “Negative” (see NOTE). Since, FoodChek™ *Listeria* spp. is a screening test for *Listeria* spp. (*L. monocytogenes*, *L. innocua*, *L. ivanovii*, *L. seeligeri*, and *L. welchimeri*), all positive samples should be culturally confirmed by an approved USDA/FSIS (http://www.fsis.usda.gov/PDF/MLG_8_07.pdf) or Health Canada confirmatory method <http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume2/mfhp30-eng.php>.

NOTE: If an Invalid or Indeterminate result is obtained, see FoodChek Instrument User Manual for further instructions/troubleshooting.

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. Moreover, pregnant women and potentially immunocompromised individuals should be prohibited from laboratory rooms or areas where *L. monocytogenes* isolation or identification procedures are in progress.

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-003: FoodChek[™] *Listeria spp.* Assay Cassettes

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Food safety, **simplified.**

