

Performance Summary

iQ-Check *Listeria monocytogenes* II Method



Introduction

The iQ-Check *Listeria monocytogenes* II PCR Detection Kit is a test based on gene amplification and detection by real-time PCR after food and environmental samples are enriched in *Listeria* Special Broth (LSB). Ready-to-use PCR reagents contain oligonucleotides (primers and probes) highly specific for *L. monocytogenes*. A synthetic DNA internal control is included in the reaction mix. An internal control is critical in any reaction to monitor for inhibitors and allows for the validation of any negative result. The iQ-Check *L. monocytogenes* II method has been rigorously tested and validated by internationally recognized validation agencies (Table 1).

Table 1. Validations for the iQ-Check *L. monocytogenes* II method.

Validation	Certificate Number
AOAC	PTM 010802
NF Validation	BRD 07/10-04/05
Health Canada	MFLP-54
NordVal	37

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *L. monocytogenes* while exclusivity studies test non-*L. monocytogenes* organisms, including other species of *Listeria*, to ensure there is no cross-reactivity. Exclusivity strains were enriched in nutrient broth for 24 ± 2 hr at $30 \pm 1^\circ\text{C}$ and were tested at high levels. A target of 10–100 colony forming units (CFU) of each *L. monocytogenes* inclusivity strain was cultured in LSB for 18 hr at $30 \pm 1^\circ\text{C}$ and diluted to a low level ($\sim 10^3$) before testing. Results are shown in Table 2.

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results
55 <i>L. monocytogenes</i> strains	55	100% inclusivity
61 non- <i>L. monocytogenes</i> strains	0	100% exclusivity

Limit of Detection

Limit of detection (LOD_{50}) is an estimation of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices and environmental samples with *L. monocytogenes* and carrying out the validated enrichment, extraction, and detection protocols (Table 3).

The average LOD_{50} of the iQ-Check *L. monocytogenes* II method was determined to be 0.674 (range: 0.539–0.841).

Table 3. LOD_{50} for the iQ-Check *L. monocytogenes* II method.

Matrix/Strain Pair	LOD_{50} , CFU/sample size (range)
Ground beef/ <i>L. monocytogenes</i> 1/2a	0.573 (0.341–0.963)
Raw milk/ <i>L. monocytogenes</i> 1/2b	0.728 (0.419–1.264)
Cod fillet/ <i>L. monocytogenes</i> 1/2a	0.575 (0.328–1.006)
Green salad/ <i>L. monocytogenes</i> 1/2c	0.798 (0.462–1.375)
Pasta salad/ <i>L. monocytogenes</i> 3a	0.452 (0.263–0.778)
Processed water/ <i>L. monocytogenes</i> 4b	0.902 (0.517–1.574)

Method Comparison/Matrix Studies

Matrix testing is critical to demonstrating the performance of a method compared to the reference method with real-world food samples. The iQ-Check *L. monocytogenes* II method has been verified with external and internal testing on a wide variety of foods. No significant difference was found between the reference method and alternative method for all matrices tested (Table 4).

Table 4. Matrices tested with the iQ-Check *L. monocytogenes* II method.

Category	Matrices
Composite foods RTE, RTRH, pastries and egg products	RTE: Shrimp taboulé, shrimp and tuna bread, cauliflower cake, roasted potatoes, mixed salad RTRH: Fish, couscous, cooked rice in milk, sandwiches (ham, salmon, cheese, vegetables), pizza, quiche Pastries and egg products: Pastries, fruit tarts, coconut cream pie, cocoa powder, coffee cake, pudding
Meat products Raw and RTC, RTE and RTRH, deli	Raw and RTC: Fresh ground beef, frozen ground beef, pork, veal filet, duck, ground horse, rib eye steak, liver, chicken legs, chicken wings RTE and RTRH: Hot dogs, cooked ham, roast chicken, roast turkey, smoked chicken, smoked turkey, summer sausage, pepperoni, pepperette, beef tartare, chicken curry, white boudin sausage, merguez sausage, smoked sausage, liver pâté, bacon Deli: Turkey, roast beef, pastrami, prosciutto, salami
Dairy products Raw milk and products, heat processed, frozen	Raw milk and products: Milk (goat, sheep, cow), butter, cheeses (goat, sheep, cow), Munster, Livarot, Brie, Pont-l'Évêque, Maroilles, Epoisses, Reblochon Heat processed: Pasteurized milk cheeses (goat, sheep, cow), cottage cheese, yogurt, Greek yogurt, kefir, sour cream, nonfat dry milk Frozen: Ice cream, frozen yogurt
Fishery products Raw and RTC, RTE and RTRH	Raw and RTC: Frozen cod, frozen tilapia, frozen sole, frozen shrimp, raw salmon, raw tilapia, raw shrimp, raw squid, raw cod filet RTE and RTRH: Smoked salmon, cooked shrimp, cooked fish, cooked lobster, cooked crab
Produce Fresh, frozen, processed	Fresh: Raw vegetables and nuts (cashews, almonds, peanuts, walnuts, spinach, carrots, zucchini, red cabbage, cucumber, peas, peppers, cauliflower), mixed vegetables, mixed green salad Frozen: Vegetables (green beans, vegetables for soup) Processed: Apple cider, grape juice, orange juice, vegetable juice, sunflower seeds, precooked potatoes, vegetable puree, grated carrots
Environmental samples	Stainless steel, ground surfaces (slaughterhouse, fishery), residue, waste water, process water, broths (HiCap, Lethen, D/E Neutralizing), sponge/swab material (cellulose, polyurethane)

RTC, ready to cook; RTE, ready to eat; RTRH, ready to reheat.

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