

Performance Summary

iQ-Check *Listeria* spp. Method



Introduction

The iQ-Check *Listeria* spp. 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 all *Listeria* spp. 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 *Listeria* spp. method has been rigorously tested and validated by internationally recognized validation agencies (Table 1).

Table 1. Validations for the iQ-Check *Listeria* spp. method.

Validation	Certificate Number
AOAC	PTM 090701
NF Validation	BRD 07/13-05/07
Health Canada	MFLP 39

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *Listeria* spp. while exclusivity studies test non-*Listeria* organisms to ensure there is no cross-reactivity. Exclusivity strains were enriched in Brain Heart Infusion Broth for 24 hr at $37 \pm 1^\circ\text{C}$ and were tested at high levels. A target of 10–100 colony forming units (CFU) of each *Listeria* spp. inclusivity strain (listed below) was cultured in LSB for 24 ± 2 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.

<i>Listeria monocytogenes</i>	<i>Listeria marthii</i>
<i>Listeria fleischmannii</i>	<i>Listeria rocourtiae</i>
<i>Listeria grayi</i>	<i>Listeria seeligeri</i>
<i>Listeria innocua</i>	<i>Listeria weihenstephanensis</i>
<i>Listeria ivanovii</i>	<i>Listeria welshimeri</i>

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results*
161 <i>Listeria</i> strains tested	161	100% inclusivity
86 non- <i>Listeria</i> strains tested	0	100% exclusivity

* Results generated from AOAC and NF Validations.

Limit of Detection

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

The average LOD_{50} of the iQ-Check *Listeria* spp. method was determined to be 0.6 (range: 0.5–0.8).

Table 3. LOD_{50} for the iQ-Check *Listeria* spp. method.

Matrix/Strain Pair	LOD_{50} , CFU/sample size (range)
Deli salad/ <i>Listeria ivanovii</i>	0.7 (0.4–1.2)
Rillettes/ <i>Listeria welshimeri</i>	0.2 (0.1–0.4)
Raw milk/ <i>Listeria monocytogenes</i>	0.7 (0.4–1.3)
Mixed vegetables/ <i>Listeria seeligeri</i>	0.8 (0.4–1.4)
Smoked salmon/ <i>Listeria monocytogenes</i>	0.7 (0.4–1.2)
Process water/ <i>Listeria innocua</i>	0.6 (0.3–1.1)

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 *Listeria* spp. 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 *Listeria* spp. method.

Category	Matrices
Environmental samples	Stainless steel, plastic, ceramic, sealed concrete, residue, process water, broths (HiCap, Letheen, D/E neutralizing), material (cellulose, polyurethane)
Composite foods RTE, RTRH, pastries and egg products	RTE: Salads (ham, cheese, grapefruit, rice, pasta, roasted chicken, tuna, cabbage), sandwiches (ham, cheese, butter, tuna), tabbouleh RTRH: Pizza, quiche lorraine, couscous, pasta, paella, moussaka, rice, veal, green lentils Pastries and egg products: Profiteroles, coconut cream pie (125 g), pastries, tarts, tortillas, red fruits, desserts
Meat products Raw and RTC, RTE and RTRH, deli	Raw and RTC: Beef, veal, pork, lamb, turkey, horse, duck, chicken, ground meats, liver, filet, leg, wing, breast, seasoned chicken, beef trims, frozen ground beef, fresh sausage, raw fermented sausage RTE and RTRH: Fermented sausage, ham, bacon, liver pâté, beef, pork, turkey, veal, sausage, lamb, duck, chicken, hot dogs Deli: Ham, turkey
Dairy products Raw milk and products, heat processed	Raw milk and products: Milk (goat, sheep, cow), cheeses (goat, sheep, cow), Roquefort, Comté, Abondance, Rocamadour, Munster, Camembert, Brie, Maroilles, Saint-Nectaire, Tomme Heat processed: Processed cheeses, natural cheese (125 g), milk powders, WPC, WPI, high protein dairy seasoning, high salt dairy seasoning
Fishery products Raw and RTC, RTE and RTRH	Raw and RTC: Salmon, shrimp, tilapia, crayfish tails, perch, pollock, sole, halibut, saithe, jumbo shrimp, prawns, herring, haddock, frozen seafood cocktail, fish tartare (salmon, tuna) RTE and RTRH: Smoked fish (salmon, tuna, haddock), marinated herrings, cooked shrimp, salmon, calamari, crab, jumbo shrimp terrine, cod fritters, scallops, crab, surimi, tarama, tuna and salmon rillettes
Produce Fresh, frozen, processed	Fresh: Raw vegetables (broccoli, cauliflower, mushrooms, cucumber, beetroot, spinach, celery, green beans, carrots, red and white cabbage, leeks, chickpeas, peas, potatoes), mixed vegetables Frozen: Vegetables (green beans, mushrooms, peppers, cauliflowers, spinach, Brussels sprouts, potatoes, French fries), mixed vegetables Processed: Mixed vegetables with and without dressing, grated carrots, prebaked and roasted potatoes, RTE salad, fresh fruits salad, hash browns, ratatouille, tapenade, celeriac, beetroot salad, tomato salad, eggplant caviar, guacamole, RTRH vegetables

RTC, ready to cook; RTE, ready to eat; RTRH, ready to reheat; WPC, whey protein concentrate; WPI, whey protein isolate.

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