

Performance Summary

iQ-Check *Salmonella* II Method



Introduction

The iQ-Check *Salmonella* 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 buffered peptone water (BPW).^{*} Ready-to-use PCR reagents contain oligonucleotides (primers and probes) highly specific for *Salmonella*. A synthetic DNA internal control is included in the reaction mix. An internal control is critical in any reaction to monitor for inhibitors and allow for the validation of any negative result. The iQ-Check *Salmonella* II method has been rigorously tested and validated by internationally recognized validation agencies (Table 1).

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

Validation	Certificate Number
AOAC	OMA 2017.06, PTM 010803
NF Validation	BRD 07/06-07/04
Health Canada	MFLP-38
NordVal	38

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect *Salmonella* spp., while exclusivity studies test non-*Salmonella* strains to ensure that there is no cross-reactivity. Exclusivity strains were enriched in nonselective broth for 24 hr at 37 ± 1°C and were tested at high levels. A target of 10–100 colony forming units (CFU) of each *Salmonella* inclusivity strain was cultured in BPW (or alternative enrichment) for 8–20 hr at 37 ± 1°C and 41.5 ± 1°C and diluted to a low level (~10³) before testing. Results are shown in Table 2.

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results
175 <i>Salmonella</i>	175/175	100% inclusivity
50 non- <i>Salmonella</i>	0/50	100% exclusivity

^{*} Refer to the iQ-Check *Salmonella* spp. II Kit User Guide (10000131519) for a complete list of media other than BPW required for protocols optimized for certain matrices.

Limit of Detection

Limit of detection (LOD₅₀) is an estimate of the contamination level required to achieve positive detection in 50% of cases. This is measured by inoculating food matrices with *Salmonella* strains and carrying out the validated enrichment, extraction, and detection protocols (Table 3).

The average LOD₅₀ of the iQ-Check *Salmonella* II method was determined to be 0.8 (range: 0.4–1.4).

Table 3. LOD₅₀ for the iQ-Check *Salmonella* II method.

Matrix/Strain Pair	LOD ₅₀ , CFU/sample size (range)
Deli salad/S. Typhimurium	1.2 (0.7–2.0)
Ground beef (25 g)/S. Infantis	0.9 (0.5–1.8)
Ground beef (375 g)/S. Newport	1.0 (0.5–1.9)
Raw milk (25 g)/S. Mbandaka	1.6 (0.9–3.0)
Raw milk (50 g)/S. Mbandaka	0.3 (0.2–0.6)
Liquid egg/S. Enteritidis	0.7 (0.4–1.5)
Perch fillet/S. Saintpaul	0.9 (0.5–1.7)
Dog food/S. Agona	0.4 (0.2–0.7)
Process water/S. Derby	0.6 (0.3–1.3)
Dry dog kibble/S. Derby	0.4 (0.2–0.8)
Boot socks/S. Kentucky	0.9 (0.5–1.5)
Veal meat/S. Enteritidis	0.6 (0.4–1.1)
Infant formula with probiotics (375 g)/S. Cerro	0.3 (0.1–0.5)
Raw spinach (375 g)/S. Kentucky	0.6 (0.4–1.1)
White chocolate (375 g)/S. Abony	0.5 (0.3–1.0)
Chocolate liquor (375 g)/S. Montevideo	0.7 (0.4–1.3)
Cannabis flower (10 g)/S. Typhimurium	0.7 (0.4–1.4)

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 *Salmonella* 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 *Salmonella* II method.

Category	Matrices Tested
Composite foods RTE, RTRH, pastries and egg products	RTE: Mixed salad, deli salad, coleslaw RTRH: Meat, poultry, pasta, fish, scallops, quiche, leek pie, pizza, chicory, ham, potatoes, moussaka, pâté Pastries and egg products: Sweet tarts, fruit tarts, sweet creams, flan, crème brûlée, tiramisu, éclair (vanilla, chocolate, and coffee), chocolate cake, mille-feuille, chantilly, flan tart, fraiser cake
Meat products Raw and RTC, RTE and RTRH, deli	Raw and RTC: Chicken, turkey, veal, ground veal, beef, ground beef, pork, lamb, beef carcass rinse, carcass sponge RTE and RTRH: Herb sausage, veal sausage, dry sausage, low moisture sausage, chicken nuggets, bacon Deli: Turkey, ham, low moisture ham, coppa
Dairy products Raw milk and products, heat processed, frozen	Raw milk and products: Raw cow milk, raw goat milk, raw sheep milk, raw cow milk cheese, raw goat milk cheese, raw sheep milk cheese, raw milk butter, raw milk yogurt, raw milk cream Heat processed: Cream, cow milk cheese, milk powder, fermented milk, cheese powder, whey powder, nonfat dry milk Frozen: Vanilla ice cream, chocolate ice cream, pistachio ice cream
Egg products Unprocessed, processed, dry	Unprocessed: Liquid egg product, liquid whole egg, whole eggs Processed: Mayonnaise, custard, flan, egg cream, egg powder Dry: Dehydrated egg for dessert preparation
Fishery products Raw and RTC, RTE and RTRH	Raw and RTC: Shrimp, clams, sea almond leaves, cod, pollock, mussels, tuna, mackerel, salmon, gurnard, whiting, shellfish RTE and RTRH: Smoked salmon, halibut, herring, haddock, trout, anchovies, mackerel, tuna, breaded pollock, seafood cocktail
Produce Fresh, frozen, processed	Fresh: Cantaloupe, spinach, red cabbage, green cabbage, celery, eggplant, chopped red peppers, carrots, mixed vegetables, turnips, potato, broccoli, artichoke, zucchini, mushroom, asparagus, sprouts, radish, leek, onion, pineapple, pear, apple Frozen: Peas, green pepper, red pepper, green beans, mixed vegetables, spinach, carrots, tomatoes, turnips, broccoli, sweet potatoes, mukimame, onions, mixed mushrooms Processed: Saffron rice, dried apple, raisins, puree (peach, blackberry, apple, and pear), mango coulis, fruit salad, cut banana, cut kiwi, cut tangerine, compote (raspberry, pear, rhubarb, apricot, and apple), applesauce
Canned products	Canned beets, canned tomatoes
Plant-based food products	Plant-based meat
Dried cereals, fruits, nuts, seeds, and vegetables	Peanut butter, flour, peanuts (includes dry roasted peanuts), almonds (includes honey roasted almonds), dried white beans, dried black beans, spirulina powder (green), dried apple, raisins, rosemary, sesame seeds, red pepper powder, coconut, chili powder, paprika, basil, marjoram, cumin, red pepper, cinnamon, garlic flakes, garlic, oregano, sage, thyme, white pepper, black pepper, parsley, coffee
Infant formula and cereals	Infant formula with and without probiotics, infant cereal with and without probiotics, infant formula ingredients (maltodextrin, whey powders, caseinate, starch, nonfat dry milk, and whey protein isolate)
Chocolate, bakery products, confectionary	Milk chocolate, white chocolate, chocolate liquor, chocolate chips, cocoa powder, cocoa products with cocoa mass, cocoa powder, cocoa butter, crumb
Pet food and animal feed	Raw pet food, wet pet food, dry pet food, cat food, bird food, bird seed, dog food, kitten food, canary food, sausage for dogs, croquettes for dogs, cattle feed, dehydrated poultry protein, flour raw material
Environmental samples	Ceramic, concrete, plastic, stainless steel, process water, footbath water, residue water, siphon water, dust, broths (HiCap, Lethen, and D/E Neutralizing), sponge/swab material (cellulose and polyurethane)
Primary production samples	Boot socks, floor wipe, pig feces, poultry feces, pig slurry, poultry manure, drinking water, dust
Cannabis plants and flowers Cannabis products, hemp	Cannabis products: Cannabis flower, cannabis concentrates, cannabis-infused edibles Hemp: Hemp flower

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

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