Performance Summary

RAPID'*Campylobacter* Method

Introduction

RAPID'*Campylobacter* Agar is a chromogenic medium for the detection and enumeration of the main species of thermophilic *Campylobacter* (*C. jejuni, C. coli,* and *C. lari*). The RAPID'*Campylobacter* method allows the presumptive identification of *Campylobacter*, using a proprietary mixture of a chromogenic substrate, selective mix, and nutritive mix. *Campylobacter* form brick-red colonies, while other bacterial species, yeasts, and molds are inhibited by the selective agents. The RAPID'*Campylobacter* method has been rigorously tested and validated by an internationally recognized validation agency (Table 1).

Table 1. Validation for the RAPID'*Campylobacter* method.

Validation	Certificate Number
NF Validation	BRD 07/25–01/14

Inclusivity/Exclusivity Testing

Inclusivity testing is performed to verify that the method can detect the targeted *Campylobacter* spp., while exclusivity studies test non-*Campylobacter* strains to ensure there is no cross-reactivity. Inclusivity strains were cultured in Brucella Broth for 48 ± 2 hr at 41.5°C in microaerophilic conditions. Exclusivity strains were cultured under conditions appropriate for the organism being tested. Decimal dilutions were made and cultured onto RAPID'*Campylobacter* Agar and incubated at 41.5 ± 1°C for 40–48 hr. All colonies were confirmed regardless of morphology. Results are shown in Table 2.

Table 2. Results of inclusivity/exclusivity testing.

Strains Tested	Positives Detected	Results
54 *Campylobacter* strains tested	48/54*	89% inclusivity
31 non-*Campylobacter* strains tested	0/31	100% exclusivity

* Three strains of *Campylobacter upsaliensis* did not grow on RAPID'*Campylobacter* Agar, but also did not grow on the standard media (ISO 10272-2).

Method Comparison: Relative Trueness

Relative trueness is the degree of agreement between the results obtained by the reference method and the results obtained by the RAPID'*Campylobacter* method on identical food samples. The following matrices have been tested (Table 3) and statistically analyzed (Table 4). The statistical analysis of the relative trueness study did not show any difference between enumeration performed with the RAPID'*Campylobacter* method and with the reference method.

Table 3. Matrices tested with the RAPID'*Campylobacter* method.

Category	Matrices Tested
Meat and poultry products Raw and RTC, RTE and RTRH, deli	**Raw and RTC**: Ground beef, ground veal, raw carpaccio beef, beef trim, lamb meat, pork meat, chicken meat, chicken gizzard, chicken leg, chicken wing, cockerel meat, quail meat, duck meat, guinea fowl skin, duck filet, duck thigh, turkey neck skin, chicken neck skin, beef carcass, pork carcass, chicken carcass, guinea fowl carcass **RTE and RTRH**: Sausage, pork sausage with spices, pork sausage with herbs, pork sausage with onion, processed pork, marinated pork, processed beef, marinated beef trim, salted chicken meat, cooked chicken, cooked turkey, processed turkey, processed duck, processed chicken, processed veal **Deli**: Duck liver pâté, poultry pâté
Environmental samples	Process water, siphon water, dust, food production environmental surfaces, turkey waste, guinea fowl waste, pig waste, cow waste, poultry waste

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

Table 4. Statistical analysis of relative trueness.

Protocol	Category	Samples Tested	$\bar{D}$	Standard Deviation	95% Lower Limit	95% Upper Limit
40–48 hr incubation	Meat products	26	0.02	0.25	–0.50	0.54
	Poultry products	23	0.05	0.30	–0.59	0.69
	Production environmental samples	19	0.04	0.35	–0.73	0.81
40–48 hr incubation plus 72 hr plate storage	Meat products	26	0.02	0.25	–0.50	0.54
	Poultry products	23	0.01	0.33	–0.69	0.72
	Production environmental samples	19	0.05	0.35	–0.72	0.82

$\bar{D}$, average difference, in log value, between colony forming unit (CFU) enumeration on RAPID'*Campylobacter* Agar and on the reference method.

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Method Comparison: Accuracy Profile

The accuracy profile study is a comparative study between the results obtained by the reference method and the results of the RAPID'*Campylobacter* method. This study is conducted using artificially contaminated samples in three levels (low, medium, and high) in each food category. Examples of accuracy profiles are shown in Figure 1. All accuracy profiles were generated within acceptability limits for both spread and pour-plate RAPID'*Campylobacter* methods and all matrices tested.

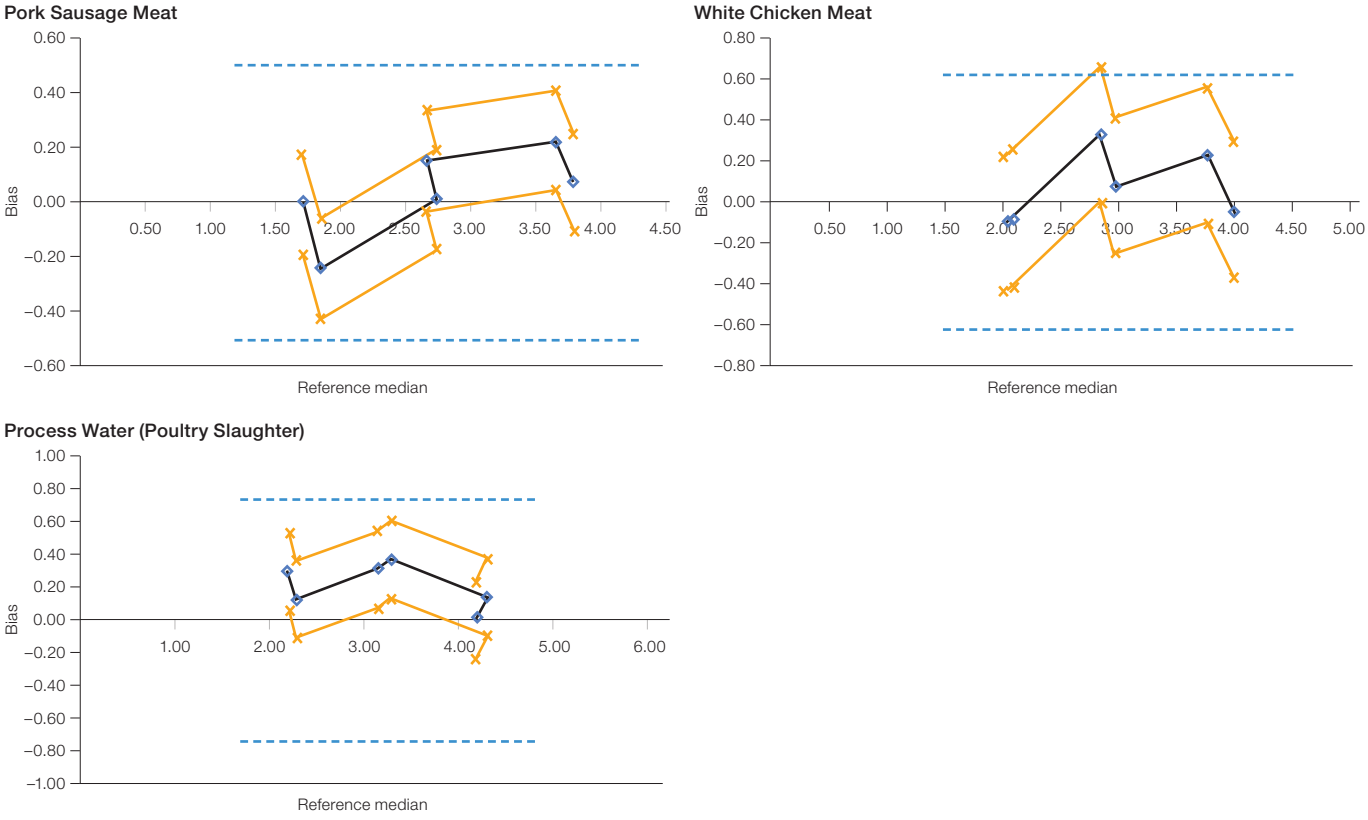

Fig. 1. Example of accuracy profiles for RAPID'C*ampylobacter* method on selected matrices. Bias ( ); β-ETI, expectation tolerance interval ( ); AL, acceptability limit ( ). AL was set at ±0.5 standard deviation repeatability (SDr) for pork sausage meat and ±4 SDr for white chicken meat and process water.

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