

# Thermo Scientific SureTect Salmonella species PCR Assay Method ISO 16140-2:2016 Matrix Extensions

Evangelos J. Vandoros<sup>1</sup>, Annette Hughes<sup>1</sup>, Jessica Williams<sup>1</sup>, David Crabtree<sup>1</sup>, Kateland Koch<sup>2</sup>, Wesley Thompson<sup>2</sup>, Erin Crowley<sup>2</sup>, Salman Zeitouni<sup>1</sup>, Nicole Prentice<sup>1</sup>, Daniele Sohier<sup>1</sup> (1)Thermo Fisher Scientific, Wade Road, Basingstoke, RG24 8PW, United Kingdom, (2) Q Laboratories, 1930 Radcliff Drive, Cincinnati, OH

## Introduction

*Salmonella* is a major global foodborne pathogen with a severe impact on public health<sup>1</sup>. The Thermo Scientific™ SureTect™ Salmonella species PCR Assay workflow provides an accurate and reliable method for the detection of *Salmonella* from a broad range of foods and environmental surfaces (validated in accordance with ISO 16140-2:2016<sup>2</sup>).

The objective of the extension was to increase the scope and capability of the method by adding pet food and animal feed matrices and enhancing protocols for meat, vegetable and powdered infant formula (PIF) categories (Figure 1).

Figure 1. Benefits of new protocols

- NEW!** Pet food and animal feed
- SureTect Salmonella and SureTect STEC<sup>a</sup> enrichments **paired** for meat and vegetables
- SureTect Salmonella and SureTect Cronobacter<sup>b</sup> enrichments **paired** for PIF

<sup>a</sup>Thermo Scientific™ SureTect™ Escherichia coli O157:H7 and STEC Screening PCR Assay and SureTect™ Escherichia coli STEC Identification PCR Assay method  
<sup>b</sup>Thermo Scientific™ SureTect™ Cronobacter species PCR Assay method

## Methods

In accordance with ISO 16140-2:2016, a sensitivity study and relative level of detection (RLOD) study were conducted for each category on a test portion size of up to 375 g: meat, vegetables, pet food, animal feed, and powdered infant formula (PIF). Pet food was tested with both a paired and unpaired study design with the ISO 6579-1:2017<sup>3</sup> reference method. All other categories followed an unpaired design with ISO 6579 reference method. The enrichment conditions for each category can be seen in Table 1.

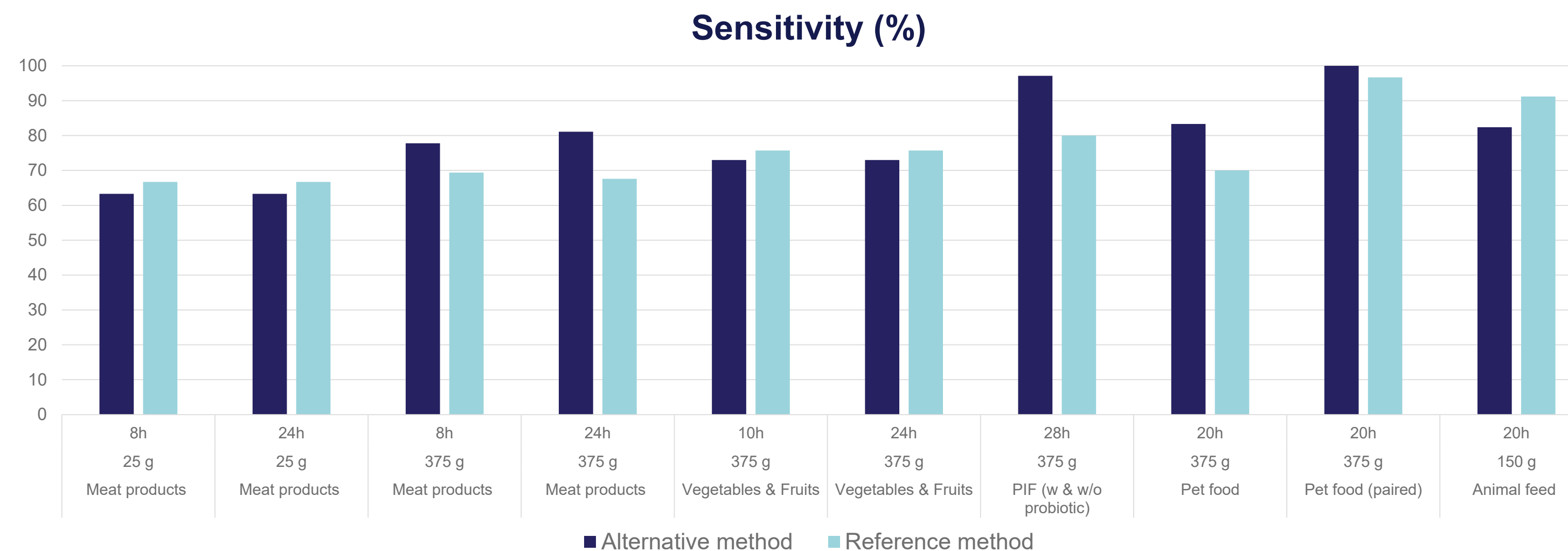
Table 1. SureTect Salmonella PCR Assay method validation extension enrichment conditions

Category	Meat products		Vegetables & fruit	PIF (with & without probiotic)	Pet food		Animal feed
	25 g	Up to 375 g	Up to 375 g	Up to 375 g	Up to 375 g	Up to 375 g	Up to 150 g
Enrichment broth and dilution	1-in-10 dilution with pre-warmed (41.5±1°C) BPW ISO	1-in-5 dilution with pre-warmed (41.5±1°C) BPW ISO	1-in-10 dilution with pre-warmed (41.5±1°C) BPW ISO	1-in-6 dilution with pre-warmed (37±1°C) BPW ISO (supplement with 6 mg/L novobiocin for probiotic)	1-in-6 dilution with pre-warmed (37±1°C) BPW ISO	1-in-10 dilution with pre-warmed (37±1°C) BPW ISO	1-in-10 dilution with BPW ISO with 12 mg/L novobiocin
Incubation	41.5±1°C for 8-24 hours		41.5±1°C for 10-24 hours	34-38°C for 18-26 hours	34-38°C for 20-28 hours		34-38°C for 20-28 hours

## Results

The results of each category for the sensitivity (Figure 2) and RLOD studies met the ISO 16140-2:2016 standard requirements meaning that the performance of the SureTect Salmonella species PCR Assay method was statistically equivalent to or better than the performance of the reference method. The matrix extensions in Table 1 complement the already approved claims for a broad range of foods.

Figure 2. Summary of sensitivity results using the Applied Biosystems™ QuantStudio™ 5 Food Safety PCR instrument



The alternative method was comparable to the reference method for all the categories tested. For meat and vegetables, the results were comparable at the two time points tested. All results met the specified criteria.

## Conclusions

The SureTect Salmonella species PCR Assay method was proven to be an accurate and reliable method for the detection of *Salmonella* from the additional matrices, and the harmonized protocols for meat, vegetable and PIF categories.

- Accuracy & Reliability
- Harmonization
- Simple workflow

## References

- Centers for Disease Control and Prevention, Salmonella <https://www.cdc.gov/salmonella/index.html>. (Accessed March 2023)
- ISO 16140-2:2016: Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method
- ISO 6579-1:2017: Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of Salmonella — Part 1: Detection of Salmonella spp.

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