

Thermo Scientific SureTect Cronobacter Species PCR Assay: NF VALIDATION using the Applied Biosystems QuantStudio 5 Food Safety PCR Instrument

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INTRODUCTION

The aim of this study was to extend the NF VALIDATION claims of the Thermo Scientific™ SureTect™ Cronobacter species PCR Assay (SureTect Cronobacter method) for the detection of *Cronobacter* species from powdered infant formula (PIF) and production environment samples to include use with the Applied Biosystems™ QuantStudio™ 5 Food Safety System (Figure 1).

Figure 1. Thermo Scientific™ SureTect™ Food Safety System

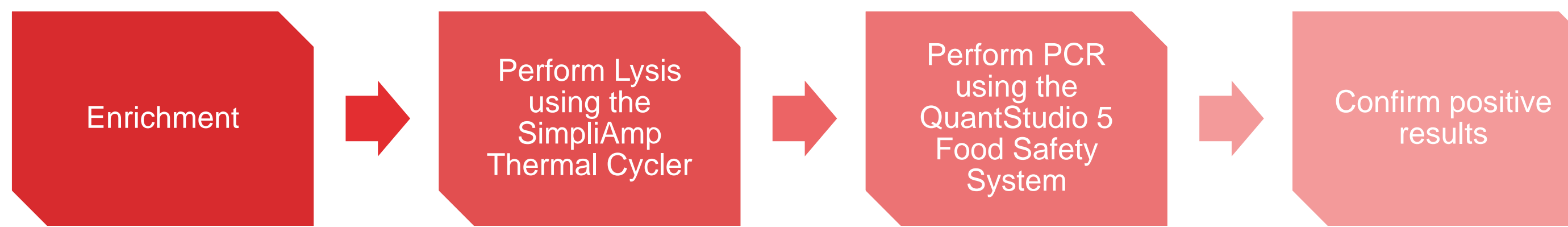


Left to right:
Applied Biosystems™ SimpliAmp™ Thermal Cycler
Applied Biosystems™ QuantStudio™ 5 Food Safety Real-Time PCR Instrument
Laptop with Applied Biosystems™ RapidFinder™ Analysis Software
Thermo Scientific SureTect PCR Assays

MATERIALS AND METHODS

The SureTect Cronobacter method (Figure 2) was compared to ISO 22964:2017¹, in accordance with ISO 16140-2:2016², and the previously validated workflow including the Applied Biosystems™ 7500 Fast Food Safety PCR Instrument with Applied Biosystems™ RapidFinder™ Express Software.

Figure 2: Workflow for the SureTect Cronobacter PCR Assay



RESULTS

During the sensitivity study, a total of eight negative deviation results occurred (six negative deviations and two positive presumptive negative deviations), these are likely due to the low spike levels and the natural variation of an unpaired study design.

A total of 14 positive deviations occurred, showing that the SureTect Cronobacter method has a superior performance for detection in comparison to the reference method. The SureTect Cronobacter method showed considerable improvement from the reference method when testing 300 g PIF samples, which gave nine out of the 14 positive deviations.

The sensitivity study results (Table 1) show that the SureTect Cronobacter method achieved a superior combined sensitivity (91.7%) compared to the reference method (85.4%).

Table 1. Sensitivity study result summary

Category	Sensitivity of the SureTect Cronobacter method (%)	Sensitivity of the Reference method (%)	Relative trueness (%)	False positive ratio (%)
PIF 10 g	100.0	96.7	98.4	5.9
PIF 300 g	86.5	75.7	81.8	10.5
Production environment samples	89.7	86.2	89.6	2.6
Combined result	91.7	85.4	89.4	6.3

The relative level of detection (RLOD) study was performed by analyzing PIF 300 g using the QuantStudio 5 Food Safety PCR System. The RLOD result met the acceptability limit (Table 2).

Table 2. RLOD study result summary

Category	RLOD	Acceptability limit
PIF 300 g	1.482	≤2.5

CONCLUSION

- The SureTect Cronobacter species PCR Assay workflow using the Applied Biosystems QuantStudio 5 Food Safety System has equivalent or improved performance compared to ISO 22964:2017.
- A total of 14 positive deviations show the SureTect Cronobacter method detected more positives than the reference method, particularly for 300 g PIF.
- The SureTect Cronobacter species PCR Assay is an accurate and sensitive method for the detection of *Cronobacter* species from powdered infant formula (10 g and 300 g) and production environment samples.

REFERENCES

- ISO 22964:2017 Microbiology of the food chain -- Horizontal method for the detection of *Cronobacter* spp.
- 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

TRADEMARKS/ LICENSING

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LT2473A
July 2019

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