Food testing

Performance Equivalency and Stability Analysis of Handling Improvements of the Thermo Scientific SureTect PCR Workflow

Salman Zeitouni¹, Nicole Prentice¹, Daniele Sohier¹, Jessica Williams¹, Marian Teye². (1) Thermo Fisher Scientific, Basingstoke, United Kingdom, (2) Thermo Fisher Scientific, Vantaa, Finland.

Introduction

Real-time PCR detection of foodborne pathogens from food and environmental surfaces is a widely used principle in the food safety industry. The Thermo Scientific[™] SureTect[™] PCR Assay workflow is a real-time PCR detection method for a number of foodborne pathogens with over 13 assays currently available in the portfolio.

The importance of efficiency in process is a critical factor in food pathogen testing, therefore several handling improvements were identified and analysed for equivalency and stability (detailed below).

Blue dye relocation

• Blue dye currently located in Lysis reagent 1 (pre-filled into SureTect Lysis Tubes, was moved to the Proteinase K reagent to visually aid pipetting. New format shown in figure 2.

Pierceable Lysis Tube seal

• Used to seal the Lysis Tubes to enable transfer of Lysate to the SureTect PCR tubes without the need to uncap to streamline handling.

Improved plastics

- Rigid snappable PCR Assay tube frame to improve handling.
- Added color-coding of PCR Assay rube frame and orientation markers as visual aids.

New handling tools

- Cutting Tool compatible with new rigid PCR Assay tube plastic frame, allowing flexibility for number of tubes used.
- New and improved Lysis and PCR tube opening and closing tools.
- Handling tools were not analysed due to no impact to performance. (Shown below in figure 1).

Figure 1. New PCR handling tools







Strip Cutting Tool

- Uncapping Tool
- Capping Tool

Method and Results



Blue dye relocation	
Method	 Reagent stability testing 37° C and 5° C, 0 weeks to 24 months Two new batches analyzed with 3 assay-matrix combinations Lysis enzymatic activity analysis
Results	Equivalent performance in PCR and enzyme activity across all time points

Learn more at thermofisher.com/suretect

Figure 2. SureTect PCR Assay workflow Improvement Equivalence and Stability Methods and Results





Pierceable lysis seal

- Equivalency testing with 1 assay-matrix combination
- Contamination risk testing all 96 wells with
- Method
- 100 CFU/lysis • 1,000 CFU/lysis
- Alternating columns of 0 CFU and 10,000 CFU/lysis
- Results
- performance No additional contamination risk.

Equivalent

Improved plastics

- Lysis equivalency-11 assay-matrix combinations
- PCR equivalency-11 assays using 100, 1,000 and 10,000 gDNA.
- PCR stability testing 37°C and 5°C, 0 weeks to 24 months

Results: Equivalent performance for lysis and PCR, across all time points

Methods continued

Studies were designed in accordance with the manufacturing site quality system (ISO 13485:2016 certified) with added enhancements where required (detailed in figure 2). All studies included the following

- System
- PCR System

Acceptance criteria was based on the current variation between SureTect Assays (Ct value ± 1.5 and dRn at $\pm 50\%$).

Conclusion

The data show the SureTect PCR Assay workflow improvements offer increased efficiency and a reduced handling steps with no impact to performance or stability. SureTect PCR Assay workflow improvements have been certified by the following



References

regulatory purposes

Trademarks/licensing

© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. Performance Tested Methods is a service mark of AOAC INTERNATIONAL, Rockville, MD, USA. Official Methods of Analysis is a service marks of AOAC INTERNATIONAL, Gaithersburg, MD, USA. This information is not intended to encourage use of these products in any manner that might infringe the intellectual property rights of others.

Method

Thermo Fisher SCIENTIFIC

• Applied Biosystems[™] 7500 FAST Real-Time Food Safety PCR

• Applied Biosystems[™] SimpliAmp[™] Thermal Cycler • Applied Biosystems[™] QuantStudio[™] 5 Food Safety Real-Time

AOAC Performance Tested Methods^{s™}

AOAC Official Method of AnalysisSM

ISO 16140-2:2016 by AFNOR Certification

ISO 16140-2:2016 by MicroVal certification

1. ISO 13485:2016 Medical devices — Quality management systems — Requirements for

thermo scientific