AOAC-RI PTM and NF Validation of the Thermo Scientific Listeria Species PCR Assay using the QuantStudio 5 Food Safety PCR Instrument

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INTRODUCTION

Studies were performed to extend the current AOAC-RI Performance method modification (PTM) and NF VALIDATION™ by AFNOR Certification for the Thermo Scientific™ SureTect™ Listeria species PCR Assay (candidate method) to include the use of the Applied Biosystems™ QuantStudio™ 5 Real-Time Food Safety PCR Instrument with associated Applied Biosystems™ RapidFinder™ Analysis software.

Figure 1. Thermo Scientific™ SureTect™ Real-Time PCR System

RESULTS

AFNOR Validation

The NF VALIDATION by AFNOR Certification extension studies were conducted in comparison to ISO 11290-1:1996 in accordance with ISO 11290-1:2016².

Table 1: Sensitivity, relative trueness and false positive ratio of the candidate methods

<table>
<thead>
<tr>
<th>Matrix type</th>
<th>Spike level</th>
<th>No. tested</th>
<th>Reference method positives</th>
<th>Candidate method positives</th>
<th>dPOD[^]</th>
<th>95% CI[^]</th>
</tr>
</thead>
<tbody>
<tr>
<td>All food matrices[^]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>-0.16, 0.16</td>
</tr>
<tr>
<td>High</td>
<td></td>
<td>80</td>
<td>46</td>
<td>38</td>
<td>-0.10</td>
<td>-0.25, 0.05</td>
</tr>
<tr>
<td></td>
<td>n/a</td>
<td>15</td>
<td>16</td>
<td>15</td>
<td>0.05</td>
<td>-0.40, 0.21</td>
</tr>
<tr>
<td>All surface matrices[^]</td>
<td></td>
<td>40</td>
<td>10</td>
<td>10</td>
<td>0.00</td>
<td>-0.19, 0.19</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>10</td>
<td>8</td>
<td>8</td>
<td>0.00</td>
<td>-0.24, 0.34</td>
</tr>
</tbody>
</table>

[^]*Reference in POD between the candidate and reference methods.

[^]*If the 95% confidence interval does not contain zero the results are statistically significant at the 5% level.

The Probability of Detection (POD) analysis (table 2) demonstrated no statistically significant differences between the candidate methods and the reference method.

Inclusivity and exclusivity testing demonstrated that the candidate methods successfully detected all target Listeria spp. isolates and excluded all non-target isolates.

REFERENCES

3. AOAC Appendix J

TRADEMARKS/ LICENSING

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