

# CERTIFICATION

## **AOAC<sup>®</sup>** *Performance Tested*<sup>SM</sup>

Certificate No. **111802** 

The AOAC Research Institute hereby certifies the test kit known as:

### **Clear Safety**

manufactured by

Clear Labs, Inc. 3565 Haven Ave, Suite 2 Menlo Park, CA 94025 USA

This method has been evaluated in the AOAC<sup>®</sup> *Performance Tested Methods*<sup>SM</sup> Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC<sup>®</sup> Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*<sup>SM</sup> certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (December 02, 2019 – December 31, 2020). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director Signature for AOAC Research Institute December 2, 2019

Date

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|--|--|
| KIT NAME(S)<br>Clear Safety  | CATALOG NUMBERS<br>CL-00100 (Reagent kit I); CL-00200 (Reagent kit II)   |
| INDEPENDENT LABORATORY<br>Q Laboratories, Inc.<br>1930 Radcliff Dr.<br>Cincinnati, OH 45204  | AOAC EXPERTS AND PEER REVIEWERS<br>Yi Chen <sup>1</sup> , Yvonne Salfinger <sup>2</sup> , Maria Cristina Fernandez <sup>3</sup><br><sup>1</sup> FDA CFSAN, College Park, MD, USA<br><sup>2</sup> Independent Consultant, Tallahassee, FL, USA<br><sup>3</sup> Universidad Maimonides, Buenos Aries, Argentina  |
| <ul> <li>APPLICABILITY OF METHOD</li> <li>Analyte – Salmonella enterica</li> <li>Matrices – MLG 4.09: Raw ground chicken (375 g), ready-to-eat deli turkey breast (375 g), chicken carcass rinse (30 mL)</li> <li>BAM Ch 5: dry pet food (375 g), stainless steel (sponge)</li> <li>Performance claims - The Clear Safety method (both manual and automated) performed as well or better than the US Food and Drug Administration (FDA) Bacterial Analytical Manual (BAM) Chapter 5</li> <li>Salmonella (2) and the US Department of Agriculture Food Safety and Inspection Service (FSIS) Microbiology Laboratory Guidebook (MLG) Chapter 4.09 Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg, and Siluriformes (Fish) Products and Carcass and Environmental Sponges (3) for all claimed food matrices and stainless steel surface. Additionally, the Clear Safety method accurately detected all 106 inclusivity organisms and accurately excluded all 34 exclusivity organisms.</li> </ul> | REFERENCE METHODS<br>Food and Drug Administration Bacteriological Analytical Manual Chapter 5:<br>Salmonella. Revised: August 2016. (Accessed September 2018)<br>https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm070149.htm<br>(2)<br>United States Department of Agriculture Microbiological Laboratory Guidelines 4.09:<br>Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg, and<br>Siluriformes (Fish) Products and Carcass and Environmental Sponges. Updated:<br>January 2017. (Accessed September 2018). (3) |
| ORIGINAL CERTIFICATION DATE<br>November 20, 2018   | CERTIFICATION RENEWAL RECORD<br>Renewed annually through December 2020   |
| METHOD MODIFICATION RECORD   |  |

| NONE  | NONE  |
|---|---|
|   |   |
| Under this AOAC <sup>®</sup> Performance Tested <sup>SM</sup> License Number, 111802 this | Under this AOAC <sup>®</sup> Performance Tested <sup>SM</sup> License Number, 111802 this |
| method is distributed by:   | method is distributed as:   |
| NONE  | NONE  |

#### **PRINCIPLE OF THE METHOD (1)**

The Clear Safety method is a next-generation sequencing (NGS) method that combines nucleic acid amplification and sequencing on an automated platform. Clear Safety is designed to be used for the detection of *Salmonella enterica* in select foods and environmental surfaces. The Clear Safety method utilizes polymerase chain reaction (PCR) amplification and targeted NGS sequencing technology to selectively detect *Salmonella enterica*. Advanced NGS technology enables deep molecular characterization of pathogens that is not possible with other methods. NGS is the most modern, high throughput DNA sequencing technology on the market, enabling the generation of millions of sequences simultaneously (4).

#### **DISCUSSION OF THE VALIDATION STUDY (1)**

The Clear Safety Method provides qualitative detection of *Salmonella enterica* following a 14 hour enrichment for stainless steel environmental sponges, after 16 hours of enrichment for chicken carcass rinse, raw ground chicken and RTE deli turkey, and after 20 hours of enrichment for dry pet food. The matrix studies showed the Clear Safety method was equivalent to the USDA FSIS MLG 4.09 and FDA BAM Chapter 5 reference methods for the target food matrixes and surface. The Clear Safety Method demonstrated no statistically significant differences between candidate and reference method results (dPOD<sub>c</sub>), or between presumptive and confirmed results (dPOD<sub>c</sub>) for all target pathogens.

The inclusivity and exclusivity evaluations tested the sensitivity and specificity of the Clear Safety method. All 106 inclusivity organisms were correctly included and all 34 exclusivity organisms were correctly excluded.

| Table | 4. Clear Safety Inclusivity      | Results for Sa | lmonella enteric           | a (1)                           |            |    |                                      |  |                 |                   |            |
|-------|----------------------------------|----------------|----------------------------|---------------------------------|------------|----|--------------------------------------|--|-----------------|-------------------|------------|
| No    | Species and<br>subspecies        | Serovar        | Source                     | Origin                          | Resu<br>It | No | Species<br>and<br>subspeci<br>es     | Serovar                                | Sourc<br>e      | Origin            | Resu<br>It |
| 1     | S. enterica subsp.<br>arizonae   |                | ATCC <sup>1</sup> 13314    | Not Available                   | +          | 21 | S.<br>enterica<br>subsp.<br>enterica | Anatum                                 | ATCC<br>9270    | Pork liver        | +          |
| 2     | S. enterica subsp.<br>arizonae   |                | ATCC BAA-<br>1577          | Not Available                   | +          | 22 | S.<br>enterica<br>subsp.<br>enterica | Arkansas                               | UPenn<br>STs 11 | Not<br>Available  | +          |
| 3     | S. enterica subsp.<br>arizonae   |                | QL <sup>2</sup> 11007-4    | Veterinary Isolate              | +          | 23 | S.<br>enterica<br>subsp.<br>enterica | Bareilly                               | FDA<br>1206H    | Not<br>Available  | +          |
| 4     | S. enterica subsp.<br>diarizonae |                | ATCC BAA-<br>1579          | Not Available                   | +          | 24 | S.<br>enterica<br>subsp.<br>enterica | Berta                                  | UPenn<br>STs 13 | Not<br>Available  | +          |
| 5     | S. enterica subsp.<br>diarizonae |                | ATCC BAA-<br>216           | Human blood                     | +          | 25 | S.<br>enterica<br>subsp.<br>enterica | Binza                                  | UPenn<br>STs 14 | Not<br>Available  | +          |
| 6     | S. enterica subsp.<br>diarizonae |                | ATCC BAA-<br>639           | Human feces                     | +          | 26 | S.<br>enterica<br>subsp.<br>enterica | Bovis-<br>Morbifica<br>ns              | UPenn<br>STs 16 | Not<br>Available  | +          |
| 7     | S. enterica subsp.<br>houtenae   | Halmstad       | QL024.1                    | Clinical isolate                | +          | 27 | S.<br>enterica<br>subsp.<br>enterica | Brandenb<br>urg                        | UPenn<br>STs 18 | Not<br>Available  | +          |
| 8     | S. enterica subsp.<br>houtenae   | Harmelen       | ATCC 15783                 | Boa constrictor                 | +          | 28 | S.<br>enterica<br>subsp.<br>enterica | Bredeney                               | NCTC<br>5731    | Not<br>Available  | +          |
| 9     | S. enterica subsp.<br>houtenae   | Ochsenzo<br>II | ATCC 29932                 | Not Available                   | +          | 29 | S.<br>enterica<br>subsp.<br>enterica | California                             | NCTC<br>6018    | Not<br>Available  | +          |
| 10    | S. enterica subsp.<br>indica     | Ferlac         | ATCC 43976                 | Not Available                   | +          | 30 | S.<br>enterica<br>subsp.<br>enterica | Cerro                                  | UPenn<br>STs 22 | Not<br>Available  | +          |
| 11    | S. enterica subsp.<br>indica     | Ferlac         | NCTC <sup>3</sup><br>10458 | Ceylonese dessicated<br>coconut | +          | 31 | S.<br>enterica<br>subsp.<br>enterica | Choleraes<br>uis                       | ATCC<br>10708   | Equine<br>isolate | +          |
| 12    | S. enterica subsp.<br>indica     |                | ATCC BAA-<br>1578          | India                           | +          | 32 | S.<br>enterica<br>subsp.<br>enterica | Choleraes<br>uis var<br>Kunzendo<br>rf | ATCC<br>12011   | Not<br>Available  | +          |
| 13    | S. enterica subsp.<br>salamae    | Artis          | ATCC<br>700149             | Not Available                   | +          | 33 | S.<br>enterica<br>subsp.<br>enterica | Cubana                                 | UPenn<br>STs 24 | Not<br>Available  | +          |
| 14    | S. enterica subsp.<br>salamae    | Basel          | ATCC<br>700151             | Not Available                   | +          | 34 | S.<br>enterica<br>subsp.<br>enterica | Derby                                  | NCTC<br>5721    | Not<br>Available  | +          |
| 15    | S. enterica subsp.<br>salamae    |                | QL02415                    | Pet food                        | +          | 35 | S.<br>enterica<br>subsp.<br>enterica | Drypool                                | UPenn<br>STs 26 | Not<br>Available  | +          |
| 16    | S. enterica subsp.<br>enterica   | Abaetetu<br>ba | ATCC 35640                 | Creek water                     | +          | 36 | S.<br>enterica<br>subsp.<br>enterica | Dublin                                 | UPenn<br>STs 27 | Not<br>Available  | +          |
| 17    | S. enterica subsp.               | Abortuse       | FDA <sup>4</sup> 9842      | Not Available                   | +          | 37 | S.                                   | Eastbourn                              | FDA             | Not               | +          |

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|    | enterica                       | qui             |                 |               |   |    | enterica<br>subsp.<br>enterica       | е           | 4017H           | Available                 |   |
|----|--------------------------------|-----------------|-----------------|---------------|---|----|--------------------------------------|-------------|-----------------|---------------------------|---|
| 18 | S. enterica subsp.<br>enterica | Abortuso<br>vis | NCTC 10241      | Not Available | + | 38 | S.<br>enterica<br>subsp.<br>enterica | Enteritidis | ATCC<br>13076   | Not<br>Available          | + |
| 19 | S. enterica subsp.<br>enterica | Abony           | NCTC 6017       | Not Available | + | 39 | S.<br>enterica<br>subsp.<br>enterica | Galiema     | QL024<br>.2     | Environme<br>ntal isolate | + |
| 20 | S. enterica subsp.<br>enterica | Adelaide        | UPenn⁵ STs<br>2 | Not Available | + | 40 | S.<br>enterica<br>subsp.<br>enterica | Give        | UPenn<br>STs 42 | Not<br>Available          | + |

1. ATCC – American Type Culture Collection, 2. QL – Q Laboratories Culture Collection, 3. NCTC – National Culture Type Collection 4. FDA – US Food and Drug Administration Culture Collection, 5. UPENN – University of Pennsylvania Culture Collection

### Table 4. Clear Safety Inclusivity Results for Salmonella enterica (continued) (1)

| No<br>· | Species and subspecies         | Serovar     | Source          | Origin                   | Resul N<br>t . |    | Species<br>and<br>subspeci<br>es     | Serovar        | Source               | Origin                        | Resul<br>t |
|---------|--------------------------------|-------------|-----------------|--------------------------|----------------|----|--------------------------------------|----------------|----------------------|-------------------------------|------------|
| 41      | S. enterica subsp.<br>enterica | Dublin      | UPenn<br>STs 27 | Not Available            | +              | 61 | S.<br>enterica<br>subsp.<br>enterica | Livingstone    | UPenn<br>STs 63      | Not<br>Available              | +          |
| 42      | S. enterica subsp.<br>enterica | Eastbourne  | FDA<br>4017H    | Not Available            | +              | 62 | S.<br>enterica<br>subsp.<br>enterica | London         | UPenn<br>STs 64      | Not<br>Available              | +          |
| 43      | S. enterica subsp.<br>enterica | Enteritidis | ATCC<br>13076   | Not Available            | +              | 63 | S.<br>enterica<br>subsp.<br>enterica | Manhattan      | UPenn<br>STs 65      | Not<br>Available              | +          |
| 44      | S. enterica subsp.<br>enterica | Galiema     | QL024.2         | Environmental<br>isolate | +              | 64 | S.<br>enterica<br>subsp.<br>enterica | Mbankaka       | FDA<br>37N           | Low<br>moisture<br>ingredient | +          |
| 45      | S. enterica subsp.<br>enterica | Give        | UPenn<br>STs 42 | Not Available            | +              | 65 | S.<br>enterica<br>subsp.<br>enterica | Menden         | ATCC<br>15992        | Feces                         | +          |
| 46      | S. enterica subsp.<br>enterica | Haardt      | UPenn<br>STs 44 | Not Available            | +              | 66 | S.<br>enterica<br>subsp.<br>enterica | Meleagridis    | QL1207<br>4-1        | Environment<br>al isolate     | +          |
| 47      | S. enterica subsp.<br>enterica | Hadar       | ATCC<br>51956   | Not Available            | +              | 67 | S.<br>enterica<br>subsp.<br>enterica | Menhaden       | QL024.2<br>0         | Pet food                      | +          |
| 48      | S. enterica subsp.<br>enterica | Havana      | UPenn<br>STs 47 | Not Available            | +              | 68 | S.<br>enterica<br>subsp.<br>enterica | Minnesota      | UPenn<br>STs 70      | Not<br>Available              | +          |
| 49      | S. enterica subsp.<br>enterica | Heidelberg  | ATCC<br>8326    | Not Available            | +              | 69 | S.<br>enterica<br>subsp.<br>enterica | Montevide<br>o | ATCC<br>8387         | Not<br>Available              | +          |
| 50      | S. enterica subsp.<br>enterica | Illinois    | ATCC<br>11646   | Not Available            | +              | 70 | S.<br>enterica<br>subsp.<br>enterica | Muenchen       | ATCC<br>BAA-<br>1594 | Human stool                   | +          |
| 51      | S. enterica subsp.<br>enterica | Indiana     | NCTC<br>11304   | Turkey                   | +              | 71 | S.<br>enterica<br>subsp.<br>enterica | Neasden        | QL024.4              | Raw material                  | +          |
| 52      | S. enterica subsp.             | Infantis    | ATCC            | Pasta                    | +              | 72 | S.                                   | Newington      | QL024.8              | Fish oil                      | +          |

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|    | enterica                       |                  | 51741           |               |   |    | enterica<br>subsp.                   |                 |                 |                     |   |
|----|--------------------------------|------------------|-----------------|---------------|---|----|--------------------------------------|-----------------|-----------------|---------------------|---|
| 53 | S. enterica subsp.<br>enterica | Javiana          | ATCC<br>10721   | Not Available | + | 73 | S.<br>enterica<br>subsp.<br>enterica | Newport         | ATCC<br>6962    | Food<br>poisoning   | + |
| 54 | S. enterica subsp.<br>enterica | Jerusalem        | QL024.1<br>2    | Pet food      | + | 74 | S.<br>enterica<br>subsp.<br>enterica | Ohio            | UPenn<br>STs 81 | Not<br>Available    | + |
| 55 | S. enterica subsp.<br>enterica | Johannesbu<br>rg | UPenn<br>STs 56 | Not Available | + | 75 | S.<br>enterica<br>subsp.<br>enterica | Oranienbur<br>g | ATCC<br>9239    | Not<br>Available    | + |
| 56 | S. enterica subsp.<br>enterica | Kahla            | ATCC<br>17980   | Not Available | + | 76 | S.<br>enterica<br>subsp.<br>enterica | Orthmarsh<br>en | QL024.1<br>3    | Pet kibble          | + |
| 57 | S. enterica subsp.<br>enterica | Kaitaan          | QL024.7         | Pet food      | + | 77 | S.<br>enterica<br>subsp.<br>enterica | Paratyphi A     | ATCC<br>9150    | Not<br>Available    | + |
| 58 | S. enterica subsp.<br>enterica | Kentucky         | ATCC<br>9263    | Not Available | + | 78 | S.<br>enterica<br>subsp.<br>enterica | Paratyphi B     | ATCC<br>10719   | Not<br>Available    | + |
| 59 | S. enterica subsp.<br>enterica | Krefeld          | UPenn<br>STs 58 | Not Available | + | 79 | S.<br>enterica<br>subsp.<br>enterica | Paratyphi C     | ATCC<br>13428   | Not<br>Available    | + |
| 60 | S. enterica subsp.<br>enterica | Lille            | UPenn<br>STs 59 | Not Available | + | 80 | S.<br>enterica<br>subsp.<br>enterica | Pomona          | ATCC<br>10729   | Clinical<br>isolate | + |

1. ATCC – American Type Culture Collection, 2. QL – Q Laboratories Culture Collection, 3. NCTC – National Culture Type Collection 4. FDA – US Food and Drug Administration Culture Collection, 5. UPENN – University of Pennsylvania Culture Collection

| Table 4 | 4. Clear Safety Inclusivity Re | sults for Salmonel | la enterica (con | ntinued) (1)            |            |         |                                      |             |                  |                      |            |
|---------|--------------------------------|--------------------|------------------|-------------------------|------------|---------|--------------------------------------|-------------|------------------|----------------------|------------|
| No      | Species and subspecies         | Serovar            | Source           | Origin                  | Resul<br>t | No      | Species<br>and<br>subspecie<br>s     | Serovar     | Source           | Origin               | Resul<br>t |
| 81      | S. enterica subsp.<br>enterica | Poona              | NCTC 4840        | Infant<br>enteritis     | +          | 94      | S.<br>enterica<br>subsp.<br>enterica | Tennessee   | QL024.6          | Clinical<br>isolate  | +          |
| 82      | S. enterica subsp.<br>enterica | Potsdam            | QL15091-<br>1A   | Pet food                | +          | 95      | S.<br>enterica<br>subsp.<br>enterica | Thompson    | FDA<br>2051H     | Not<br>Availabl<br>e | +          |
| 83      | S. enterica subsp.<br>enterica | Preston            | QL024.16         | Low moisture<br>product | +          | 96      | S.<br>enterica<br>subsp.<br>enterica | Tranoroa    | NCTC<br>10252    | Not<br>Availabl<br>e | +          |
| 84      | S. enterica subsp.<br>enterica | Pullorum           | ATCC<br>13036    | Egg                     | +          | 97      | S.<br>enterica<br>subsp.<br>enterica | Typhi       | ATCC<br>6539     | Not<br>Availabl<br>e | +          |
| 85      | S. enterica subsp.<br>enterica | Rubislaw           | UPenn STs<br>92  | Not Available           | +          | 98      | S.<br>enterica<br>subsp.<br>enterica | Typhimurium | ATCC<br>14028    | Animal<br>tissue     | +          |
| 86      | S. enterica subsp.<br>enterica | Saintpaul          | ATCC 9712        | Cystitis                | +          | 99      | S.<br>enterica<br>subsp.<br>enterica | Utrect      | NCTC<br>10077    | Not<br>Availabl<br>e | +          |
| 87      | S. enterica subsp.<br>enterica | San-Diego          | UPenn STs<br>94  | Not Available           | +          | 10<br>0 | S.<br>enterica<br>subsp.             | Urbana      | UPenn<br>STs 110 | Not<br>Availabl<br>e | +          |

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|    |                                |                    |                 |               |   |         | enterica                             |                 |                  |                      |   |
|----|--------------------------------|--------------------|-----------------|---------------|---|---------|--------------------------------------|-----------------|------------------|----------------------|---|
| 88 | S. enterica subsp.<br>enterica | Schalkwijk         | QL024.10        | Cat food      | + | 10<br>1 | S.<br>enterica<br>subsp.<br>enterica | Vellore         | ATCC<br>15611    | Rectal<br>swab       | + |
| 89 | S. enterica subsp.<br>enterica | Schwarzengrun<br>d | UPenn STs<br>95 | Not Available | + | 10<br>2 | S.<br>enterica<br>subsp.<br>enterica | Virchow         | ATCC<br>51955    | Not<br>Availabl<br>e | + |
| 90 | S. enterica subsp.<br>enterica | Senftenberg        | ATCC<br>43845   | Not Available | + | 10<br>4 | S.<br>enterica<br>subsp.<br>enterica | Volta           | QL024.9          | Raw<br>material      | + |
| 91 | S. enterica subsp.<br>enterica | Stanley            | ATCC 7308       | Not Available | + | 10<br>5 | S.<br>enterica<br>subsp.<br>enterica | Westhampto<br>n | QL024.1<br>4     | Dog<br>kibble        | + |
| 92 | S. enterica subsp.<br>enterica | Sylvania           | QL091313.<br>4  | Raw dog food  | + | 10<br>6 | S.<br>enterica<br>subsp.<br>enterica | Worthington     | UPenn<br>STs 114 | Not<br>Availabl<br>e | + |
| 93 | S. enterica subsp.<br>enterica | Tallahassee        | ATCC<br>12002   | Not Available | + |         |                                      |                 |                  |                      |   |

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 enterica
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 1. ATCC – American Type Culture Collection, 2. QL – Q Laboratories Culture Collection, 3. NCTC – National Culture Type Collection 4. FDA – US Food and Drug

 Administration Culture Collection, 5. UPENN – University of Pennsylvania Culture Collection \

| Tab | le 5. Clear Safety Exclusivity Result | s (1)      |                  |        |    |   |            |                     |        |
|-----|---------------------------------------|------------|------------------|--------|----|---|------------|---------------------|--------|
| No  | Organism                              | Source     | Origin           | Result | No | Organism                                  | Source     | Origin              | Result |
| 1   | Acinetobacter baumanii                | ATCC 19606 | Urine            | -      | 18 | Klebsiella oxytoca                        | ATCC 43165 | Clinical isolate    | -      |
| 2   | Alcaligenes faecalis subsp. faecalis  | ATCC 8750  | Not Available    | -      | 19 | Klebsiella pneumoniae<br>subsp. pneumonia | ATCC 4352  | Cow's milk          | -      |
| 3   | Aeromonoas hydrophila                 | ATCC 49140 | Clinical isolate | -      | 20 | Morganella morganii                       | ATCC 25829 | Human               | -      |
| 4   | Citrobacter braakii                   | ATCC 43162 | Clinical isolate | -      | 21 | Mycobacterium<br>smegmatis                | ATCC 19420 | Not Available       | -      |
| 5   | Citrobacter farmeri                   | ATCC 51633 | Human feces      | -      | 22 | Pantoea agglomerans                       | ATCC 19552 | Sewage              | -      |
| 6   | Citrobacter freundii                  | QL11007-10 | Clinical isolate | -      | 23 | Proteus mirabilis                         | ATCC 7002  | Urine               | -      |
| 7   | Cronobacter sakazakii                 | ATCC 29544 | Infant formula   | -      | 24 | Providencia rettgeri                      | ATCC 14505 | Not Available       | -      |
| 8   | Edwardsiella tarda                    | ATCC 15947 | Human feces      | -      | 25 | Pseudomonas<br>aeruginosa                 | ATCC 9027  | Outer ear infection | -      |
| 9   | Enterobacter aerogenes                | ATCC 35029 | Not Available    | -      | 26 | Rahnella aquatilis                        | ATCC 55046 | Soil                | -      |
| 10  | Enterobacter cloacae                  | ATCC 13047 | Spinal fluid     | -      | 27 | Salmonella bongori                        | ATCC 43975 | Not Available       | -      |
| 11  | Escherichia coli                      | ATCC 8739  | Feces            | -      | 28 | Serratia marcescens                       | ATCC 13880 | Human               | -      |
| 12  | Escherichia coli O157                 | ATCC 43895 | Raw hamburger    | -      | 29 | Shigella boydii                           | ATCC 9207  | Feces               | -      |
| 13  | Escherichia fergusonii                | ATCC 35469 | Human feces      | -      | 30 | Shimwellia blattae                        | ATCC 29907 | Clinical isolate    | -      |
| 14  | Escherichia hermanii                  | ATCC 33650 | Mouse brain      | -      | 31 | Vibrio vunificus                          | QL02111-1A | Shellfish           | -      |
| 15  | Escherichia vulneris                  | ATCC 29943 | Human wound      | -      | 32 | Salmonella bongori                        | NCTC 10946 | Amphibian; Frog     | -      |
| 16  | Hafnia alvei                          | ATCC 51815 | Milk             | -      | 33 | Salmonella bongori                        | ATCC 43975 | Not Available       | -      |
| 17  | Haemophilus influenzae                | ATCC 19418 | Not Available    | -      | 34 | Salmonella bongori                        | NCTC 12419 | Not Available       | -      |

1. ATCC – American Type Culture Collection, 2. QL – Q Laboratories Culture Collection, 3. MSU – Michigan State University Culture Collection, 4. NCTC – National Culture Type Collection (1)

| Table 6. Clear Safety   | detection presumptive result vs. co | onfirmed result – P | OD analysis (1)        |                |         |            |               |            |         |       |               |            |                     |             |
|-------------------------|-------------------------------------|---------------------|------------------------|----------------|---------|------------|---------------|------------|---------|-------|---------------|------------|---------------------|-------------|
|                         |                                     |                     |                        |                |         | Clear Safe | ty presumptiv | e          |         | Clear | Safety confir | med        |                     |             |
| Matrix per test portion | Strain                              | Method              | MPN per test partian " | n <sup>b</sup> | Time, h | xc         | PODer         | 95% CI     | Time, h | x     | PODccf        | 95% CI     | dPOD <sub>2</sub> s | 95% CI      |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0.00                | -0.47, 0.47 |
| 375 g RTE deli turkey   | Salmonella Mnenchen (ATCC BAA-1594) | Manual              | 0_34 (0_14-0.88)       | 20             | 16      | 12         | 0_60          | 0_39, 0.78 | 24      | 12    | 0.60          | 0.39, 0.78 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 3.21 (1.37-8.95)       | 5              | 16      | 5          | 1_00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00                | -0_47, 0_47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0_00          | 0.00, 0.43 | 0.00                | -0.47, 0.47 |
| 375 g RTE deli turkey   | Salmonella Muenchen (ATCC BAA-1594) | Manual              | 0_34 (0_14-0.88)       | 20             | 24      | 12         | 0_60          | 0_39, 0_78 | 24      | 12    | 0.60          | 0_39, 0_78 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 3.21 (1.37-8.95)       | 5              | 24      | 5          | 1.00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00                | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0.00                | -0_47, 0_47 |
| 375 g RTE deli turkey   | Salmonella Muenchen (ATCC BAA-1594) | Automated           | 0_34 (0_14-0_88)       | 20             | 16      | 12         | 0_60          | 0_39, 0_78 | 24      | 12    | 0.60          | 0_39, 0_78 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 3.21 (1.37-8.95)       | 5              | 16      | 5          | 1.00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00                | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0_00          | 0.00, 0.43 | 0.00                | -0.47, 0.47 |
| 375 g RTE deli turkey   | Salmonella Muenchen (ATCC BAA-1594) | Automated           | 0_34 (0_14-0_88)       | 20             | 24      | 12         | 0.60          | 0_39, 0.78 | 24      | 12    | 0.60          | 0_39, 0_78 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 3.21 (1.37-8.95)       | 5              | 24      | 5          | 1.00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00                | -0_47, 0_47 |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0.00                | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual              | 68 CFU                 | 20             | 16      | 6          | 0_30          | 0.15, 0.52 | 24      | 6     | 0_30          | 0.15, 0.52 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 190 CFU                | 5              | 16      | 5          | 1.00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00                | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0_00          | 0.00, 0.43 | 24      | 0     | 0_00          | 0.00, 0.43 | 0_00                | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual              | 68 CFU                 | 20             | 24      | 6          | 0_30          | 0.15, 0.52 | 24      | 6     | 0_30          | 0.15, 0.52 | 0.00                | -0.13, 0.13 |
|                         |                                     |                     | 190 CFU                | 5              | 24      | 5          | 1.00          | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0_00                | -0.47, 0.47 |

<sup>o</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>*d*</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup>CI = Confidence interval.

<sup>f</sup> POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>1</sup>Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

| Table 6. Clear Safety   | y detection presumptive vs. confirr | ned result – POD an | alysis (continued) (1) |                |         |            |                |            |         |       |                    |            |                    |             |
|-------------------------|-------------------------------------|---------------------|------------------------|----------------|---------|------------|----------------|------------|---------|-------|--------------------|------------|--------------------|-------------|
|                         |                                     |                     |                        |                |         | Clear Safe | ty presumptive | •          |         | Clear | Safety confin      | ned        |                    |             |
| Matrix per test portion | Strain                              | Method              | MPN per test partian " | n <sup>b</sup> | Time, h | xc         | POD            | 95% CI     | Time, h | x     | PODcc <sup>f</sup> | 95% CI     | dPOD. <sup>g</sup> | 95% Cl      |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0.00           | 0.00, 0.43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Autom ated          | 68 CFU                 | 20             | 16      | 6          | 0_30           | 0.15, 0.52 | 24      | 6     | 0_30               | 0.15, 0.52 | 0.00               | -0.13, 0.13 |
|                         |                                     |                     | 190 CFU                | 5              | 16      | 5          | 1.00           | 0.57, 1.00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0_47, 0_47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0.00           | 0.00, 0.43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0_00               | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Autom ated          | 68 CFU                 | 20             | 24      | 6          | 0_30           | 0.15, 0.52 | 24      | 6     | 0_30               | 0.15, 0.52 | 0_00               | -0.13, 0.13 |
|                         |                                     |                     | 190 CFU                | 5              | 24      | 5          | 100            | 0.57, 1.00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0.00           | 0_00, 0_43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0_00               | -0_47, 0_47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual              | 74 CFU                 | 20             | 16      | 11         | 0.55           | 0_34, 0_74 | 24      | 11    | 0.55               | 0_34, 0_74 | 0.00               | -0.13, 0.13 |
|                         |                                     |                     | 222 CFU                | 5              | 16      | 5          | 1.00           | 0.57, 1.00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0.00           | 0.00, 0.43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual              | 74 CFU                 | 20             | 24      | 11         | 0.55           | 0_34, 0_74 | 24      | 11    | 0.55               | 0_34, 0_74 | 0.00               | -0_13, 0_13 |
|                         |                                     |                     | 222 CFU                | 5              | 24      | 5          | 100            | 0_57, 1_00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                         |                                     |                     | -                      | 5              | 16      | 0          | 0.00           | 0.00, 0.43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Autom ated          | 74 CFU                 | 20             | 16      | 11         | 0.55           | 0_34, 0_74 | 24      | 11    | 0_55               | 0_34, 0_74 | 0.00               | -0.13, 0.13 |
|                         |                                     |                     | 222 CFU                | 5              | 16      | 5          | 1.00           | 0.57, 1.00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0_47, 0_47 |
|                         |                                     |                     | -                      | 5              | 24      | 0          | 0.00           | 0.00, 0.43 | 24      | 0     | 0.00               | 0.00, 0.43 | 0.00               | -0_47, 0_47 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Autom ated          | 74 CFU                 | 20             | 24      | 11         | 0.55           | 0_34, 0_74 | 24      | 11    | 0.55               | 0_34, 0_74 | 0.00               | -0.13, 0.13 |
|                         |                                     |                     | 222 CFU                | 5              | 24      | 5          | 1.00           | 0.57, 1.00 | 24      | 5     | 1.00               | 0.57, 1.00 | 0.00               | -0.47, 0.47 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup> x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>*h*</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>*i*</sup> Matrix study was performed by Independent Lab

#### Table 6. Clear Safety detection presumptive vs. confirmed result – POD analysis (continued) (1)

|                                       |                                    |            |                        |                | Clear Safety presumptive |    |       | e          |         | Clear | Safety confir | med        |        |             |
|---------------------------------------|------------------------------------|------------|------------------------|----------------|--------------------------|----|-------|------------|---------|-------|---------------|------------|--------|-------------|
| Matrix per test portion               | Strain                             | Method     | MPN per test portion " | n <sup>b</sup> | Time, h                  | xc | PODpd | 95% CI     | Time, h | x     | PODccf        | 95% CI     | dPOD." | 95% CI      |
| Stainless steel with a                | Salmonella Derby (NCIC 5721)       |            |                        | 5              | 14                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0_00   | -0.47, 0.47 |
| compatitor <sup>1</sup>               | &                                  | Manual     | 52 & 800 CFU           | 20             | 14                       | 9  | 0.45  | 0.26, 0.66 | 24      | 9     | 0.45          | 0.26, 0.66 | 0.00   | -0.13, 0.13 |
| compensa                              | Citrobacter freundii (QL 11007.10) |            | 380 & 5600 CFU         | 5              | 14                       | 5  | 1.00  | 0_57, 1_00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0_00   | -0.47, 0.47 |
| Stainless steel with a                | Salmonella Derby (NCTC 5721)       |            | -                      | 5              | 24                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0_00   | -0.47, 0.47 |
|                                       | &.                                 | Manual     | 52 & 800 CFU           | 20             | 24                       | 9  | 0.45  | 0.26, 0.66 | 24      | 9     | 0.45          | 0.26, 0.66 | 0.00   | -0.13, 0.13 |
| competition                           | Citrobacter freundii (QL 11007.10) |            | 380 & 5600 CFU         | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00   | -0.47, 0.47 |
| Stainless steel with a                | Salmonella Derby (NCTC 5721)       |            | -                      | 5              | 14                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0_00   | -0.47, 0.47 |
|                                       | &                                  | Autom ated | 52 & 800 CFU           | 20             | 14                       | 9  | 0.45  | 0.26, 0.66 | 24      | 9     | 0.45          | 0.26, 0.66 | 0.00   | -0.13, 0.13 |
| competitie                            | Citrobacter freundii (QL 11007.10) |            | 380 & 5600 CFU         | 5              | 14                       | 5  | 1.00  | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00   | -0_47, 0_47 |
| Stainlers steel with a                | Salmonella Derby (NCTC 5721)       |            | -                      | 5              | 24                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0.00   | -0.47, 0.47 |
|                                       | &.                                 | Autom ated | 52 & 800 CFU           | 20             | 24                       | 9  | 0.45  | 0.26, 0.66 | 24      | 9     | 0.45          | 0.26, 0.66 | 0.00   | -0.13, 0.13 |
| campenum                              | Citrobacter freundii (QL 11007.10) |            | 380 & 5600 CFU         | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00   | -0.47, 0.47 |
| Stainless steel without a             |                                    |            | -                      | 5              | 14                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0_00          | 0.00, 0.43 | 0_00   | -0.47, 0.47 |
| i i i i i i i i i i i i i i i i i i i | Salmonella Derby (NCTC 5721)       | Manual     | 66 CFU                 | 20             | 14                       | 10 | 0_50  | 0_30, 0.70 | 24      | 10    | 0_50          | 0.30, 0.70 | 0.00   | -0.13, 0.13 |
| competitie                            |                                    |            | 460 CFU                | 5              | 14                       | 5  | 1.00  | 0.57, 1.00 | 24      | 5     | 1.00          | 0.57, 1.00 | 0.00   | -0_47, 0_47 |
| Stainless steel without a             |                                    |            | -                      | 5              | 24                       | 0  | 0.00  | 0.00, 0.43 | 24      | 0     | 0.00          | 0.00, 0.43 | 0.00   | -0.47, 0.47 |
| summers seed without a                | Salmonella Derby (NCTC 5721)       | Manual     | 66 CFU                 | 20             | 24                       | 10 | 0_50  | 0_30, 0.70 | 24      | 10    | 0_50          | 0.30, 0.70 | 0.00   | -0.13, 0.13 |
| competitiv                            |                                    |            | 460 CEU                | 5              | 24                       | 5  | 1.00  | 0.57.1.00  | 24      | 5     | 1.00          | 0.57 1.00  | 0.00   | -047047     |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup> x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

#### Table 6. Clear Safety detection presumptive result vs. confirmed result – POD analysis (continued) (1) Clear Safety presumptive Clear Safety confirmed Matrix per test portion Strain Method Time, b Time, h 95% CI dPOD<sup>,g</sup> 95% C MPN per test partian ' POD<sub>P</sub> 95% CI x PODc 14 0.00, 0.43 24 0.00, 0.43 -0.47, 0.47 5 0 0.00 n 0.00 0.00 Stainless steel without a Salmonella Derby (NCTC 5721) Autom ated 66 CFU 20 14 10 0.50 0.30, 0.70 24 10 0\_50 0.30, 0.70 -0.13, 0.13 0.00 competitor 460 CFU 0.57, 1.00 -0.47, 0.47 5 14 1.00 0.57, 1.00 24 5 1.00 0.00 -5 24 24 5 0 0.00 0 00 0 43 0 0.00 000 043 0.00 -0.47, 0.47 Stainless steel without a Salmonella Derby (NCTC 5721) Autom ated 66 CFU 20 24 24 10 0.50 0.30, 0.70 10 0.50 0.30, 0.70 0.00 -0.13, 0.13 competitor ' 460 CFU 5 24 1000.57, 1.00 24 1.00 0.57, 1.00 0.00 -0.47, 0.47 5 5 Salmonella Derby (FSL R8-2528) 24 -0.47, 0.47 5 14 n 0.00 0.00.0.43 n 0.00 0.00, 0.43 0.00 Stainless steel with a Manual 65 & 950 CFU 20 14 11 0.55 0.34.0.74 24 11 0.55 0.34. 0.74 0.00 -0.13.0.13 æ competitor 450 & 6000 CFU Citrobacter freundii (ATCC 43864) 5 14 1.00 0.57, 1.00 24 5 1.00 0.57, 1.00 0.00 -0.47.0.47 5 Salmonella Derby (FSL R8-2528) 24 0.00, 0.43 24 0.00, 0.43 -0.47, 0.47 5 0 0.00 0 0.00 0.00 Stainless steel with a Manual 65 & 950 CFU æ 20 24 11 0.55 0.34, 0.74 24 11 0.55 0.34, 0.74 0.00 -0.13, 0.13 competitor Citrobacter freundii (ATCC 43864) 450 & 6000 CFU 24 1.00 24 1.00 0.57, 1.00 0.00 -0.47, 0.47 5 0.57, 1.00 -5 - 5 Salmonella Derby (FSL R8-2528) 5 14 0 0.00 0.00, 0.43 24 0 0.00 0.00, 0.43 0.00 -0.47, 0.47 Stainless steel with a Autom ated 65 & 950 CFU 20 14 11 0.55 0.34, 0.74 24 11 0.55 0.34, 0.74 0.00 -0.13, 0.13 competitor 450 & 6000 CFU 0.57, 1.00 0.57, 1.00 -0.47, 0.47 Citrobacter freundii (ATCC 43864) -5 14 5 1.00 24 5 1.00 0.00 Salmonella Derby (FSL R8-2528) 24 24 -0.47, 0.47 5 0 0.00 0.00, 0.43 0 0.00 0.00.0.43 0.00 Stainless steel with a Autom ated 65 & 950 CFU 20 24 11 0.55 0.34, 0.74 24 11 0.55 0.34, 0.74 0.00 -0.13, 0.13 æ competitor Citrobacter freundii (ATCC 43864) 450 & 6000 CFU 24 0.57, 1.00 24 0.57, 1.00 1.00 1.00 0.00 -0.47, 0.47

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>1</sup> Matrix study was performed by Independent Lab

#### Table 6. Clear Safety detection presumptive result vs. confirmed result – POD analysis (continued) (1)

|                           |                                |           |                        |                | Clear Safety presumptive |    |       | e          | Clear Safety confirmed |    |       |            |                    |             |
|---------------------------|--------------------------------|-----------|------------------------|----------------|--------------------------|----|-------|------------|------------------------|----|-------|------------|--------------------|-------------|
| Matrix per test portion   | Strain                         | Method    | MPN per test partian " | n <sup>b</sup> | Time, h                  | xc | PODer | 95% CI     | Time, h                | x  | PODcc | 95% CI     | dPOQ. <sup>g</sup> | 95% CI      |
| Stainlorg stud without a  |                                |           | -                      | 5              | 14                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0.00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| stamess siet winten a     | Salmonella Derby (FSL R8-2528) | Manual    | 57 CFU                 | 20             | 14                       | 12 | 0_60  | 0_39, 0.78 | 24                     | 12 | 0.60  | 0.39, 0.78 | 0.00               | -0.13, 0.13 |
| compensa                  |                                |           | 570 CFU                | 5              | 14                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1_00  | 0.57, 1.00 | 0_00               | -0.47, 0.47 |
| Stainless steel without a |                                |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0_00  | 0.00, 0.43 | 0_00               | -0_47, 0_47 |
| compatibu                 | Salmonella Derby (FSL R8-2528) | Manual    | 57 CFU                 | 20             | 24                       | 12 | 0_60  | 0_39, 0.78 | 24                     | 12 | 0.60  | 0.39, 0.78 | 0_00               | -0.13, 0.13 |
| compensa                  |                                |           | 570 CFU                | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
| Stainless steel without a |                                |           | -                      | 5              | 14                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| convetitor                | Salmonella Derby (FSL R8-2528) | Automated | 57 CFU                 | 20             | 14                       | 12 | 0_60  | 0_39, 0_78 | 24                     | 12 | 0_60  | 0_39, 0_78 | 0_00               | -0.13, 0.13 |
| campen na                 |                                |           | 570 CFU                | 5              | 14                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0_00               | -0.47, 0.47 |
| Stainless steel without a |                                |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0.00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| compatitor                | Salmonella Derby (FSL R8-2528) | Automated | 57 CFU                 | 20             | 24                       | 12 | 0.60  | 0_39, 0_78 | 24                     | 12 | 0.60  | 0_39, 0_78 | 0.00               | -0.13, 0.13 |
| campenna                  |                                |           | 570 CFU                | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1_00  | 0.57, 1.00 | 0_00               | -0.47, 0.47 |
|                           |                                |           | -                      | 5              | 20                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375g Dry pet food         | Salmonella Anatum (ATCC 9270)  | Manual    | 0.55 (0.28-0.88)       | 20             | 20                       | 14 | 0.70  | 0.48, 0.85 | 24                     | 14 | 0.70  | 0.48, 0.85 | 0.00               | -0.13, 0.13 |
|                           |                                |           | 4.13 (1.15-5.78)       | 5              | 20                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0_47, 0_47 |
|                           |                                |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375g Dry pet food         | Salmonella Anatum (ATCC 9270)  | Manual    | 0.55 (0.28-0.88)       | 20             | 24                       | 14 | 0.70  | 0.48, 0.85 | 24                     | 14 | 0.70  | 0.48, 0.85 | 0.00               | -0.13, 0.13 |
|                           |                                |           | 4.13 (1.15-5.78)       | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 100  | 0.00               | -0.47, 0.47 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>*d*</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>*h*</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

#### Table 6. Clear Safety detection presumptive result vs. confirmed result – POD analysis (continued) (1)

|                          |                                 |           |                        |                | Clear Safety presumptive |    |       |            | Clear Safety confirmed |    |       |            |                    |             |
|--------------------------|---------------------------------|-----------|------------------------|----------------|--------------------------|----|-------|------------|------------------------|----|-------|------------|--------------------|-------------|
| Matrix per test portion  | Strain                          | Method    | MPN per test partian " | n <sup>b</sup> | Time, h                  | xc | PODep | 95% CI     | Time, h                | x  | PODcc | 95% CI     | dPOD; <sup>g</sup> | 95% Cl      |
|                          |                                 |           | -                      | 5              | 20                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0.00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375g Dry pet food        | Salmonella Anatum (ATCC 9270)   | Automated | 0.55 (0.28-0.88)       | 20             | 20                       | 14 | 0_70  | 0.48, 0.85 | 24                     | 14 | 0_70  | 0.48, 0.85 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 4.13 (1.15-5.78)       | 5              | 20                       | 5  | 1_00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                          |                                 |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 0  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375g Dry pet food        | Salmonella Anatum (ATCC 9270)   | Automated | 0.55 (0.28-0.88)       | 20             | 24                       | 14 | 0.70  | 0.48, 0.85 | 24                     | 14 | 0.70  | 0.48, 0.85 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 4.13 (1.15-5.78)       | 5              | 24                       | 5  | 1_00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0_47, 0_47 |
|                          |                                 |           | -                      | 5              | 16                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 5  | 0.00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263) | Manual    | 0_45 (0.25-0.85)       | 20             | 16                       | 5  | 0.25  | 0.11, 0.47 | 24                     | 20 | 0.25  | 0.11, 0.47 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 1.69 (0.85-3.72)       | 5              | 16                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                          |                                 |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 5  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263) | Manual    | 0_45 (0.25-0.85)       | 20             | 24                       | 5  | 0.25  | 0.11, 0.47 | 24                     | 20 | 0.25  | 0.11, 0.47 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 1.69 (0.85-3.72)       | 5              | 24                       | 5  | 1_00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                          |                                 |           | -                      | 5              | 16                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 5  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263) | Automated | 0.45 (0.25-0.85)       | 20             | 16                       | 5  | 0.25  | 0.11, 0.47 | 24                     | 20 | 0.25  | 0.11, 0.47 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 1.69 (0.85-3.72)       | 5              | 16                       | 5  | 1_00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |
|                          |                                 |           | -                      | 5              | 24                       | 0  | 0_00  | 0.00, 0.43 | 24                     | 5  | 0_00  | 0.00, 0.43 | 0.00               | -0.47, 0.47 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263) | Automated | 0.45 (0.25-0.85)       | 20             | 24                       | 5  | 0.25  | 0.11, 0.47 | 24                     | 20 | 0.25  | 0.11, 0.47 | 0.00               | -0.13, 0.13 |
|                          |                                 |           | 1.69 (0.85-3.72)       | 5              | 24                       | 5  | 1.00  | 0.57, 1.00 | 24                     | 5  | 1.00  | 0.57, 1.00 | 0.00               | -0.47, 0.47 |

<sup>o</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup> x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>*i*</sup> Matrix study was performed by Independent Lab

| Table 7. Clear Safety   | vs. reference – POD analysis (1)    |           |                        |                |         |     |           |            |         |    |                  |            |        |             |
|-------------------------|-------------------------------------|-----------|------------------------|----------------|---------|-----|-----------|------------|---------|----|------------------|------------|--------|-------------|
|                         |                                     |           |                        |                |         | (le | ar Safety |            | _       |    | Reference        |            |        |             |
| Matrix per test portion | Strain                              | Method    | MPN per test partian " | n <sup>b</sup> | Time, h | xc  | POD_P     | 95% CI     | Time, h | x  | POD <sub>4</sub> | 95% CI     | dPOD;" | 95% CI      |
|                         |                                     |           | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0_00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| 375 g RTE deli turkey   | Salmonella Muenchen (ATCC BAA-1594) | Manual    | 0_34 (0_14-0.88)       | 20             | 16      | 12  | 0_60      | 0_39, 0.78 | 24      | 10 | 0_50             | 0_30, 0_70 | 0_10   | -0.19-0.37  |
|                         |                                     |           | 3.21 (1.37-8.95)       | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00             | 0.57, 1.00 | 0      | -0.43, 0.43 |
|                         |                                     |           | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0_00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| 375 g RTE deli turkey   | Salmonella Mnenchen (ATCC BAA-1594) | Manual    | 0_34 (0_14-0_88)       | 20             | 24      | 12  | 0_60      | 0_39, 0.78 | 24      | 10 | 0_50             | 0_30, 0_70 | 0_10   | -0.19-0.37  |
|                         |                                     |           | 3.21 (1.37-8.95)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00             | 0.57, 1.00 | 0      | -0.43, 0.43 |
|                         |                                     |           | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0.00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| 375 g RTE deli turkey   | Salmonella Mnenchen (ATCC BAA-1594) | Automated | 0_34 (0_14-0_88)       | 20             | 16      | 12  | 0.60      | 0_39, 0_78 | 24      | 10 | 0_50             | 0_30, 0_70 | 0_10   | -0.19-0.37  |
|                         |                                     |           | 3.21 (1.37-8.95)       | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00             | 0.57, 1.00 | 0      | -0.43, 0.43 |
|                         |                                     |           | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0_00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| 375 g RTE deli turkey   | Salmonella Muenchen (ATCC BAA-1594) | Automated | 0_34 (0_14-0_88)       | 20             | 24      | 12  | 0.60      | 0_39, 0_78 | 24      | 10 | 0_50             | 0_30, 0_70 | 0_10   | -0.19-0.37  |
|                         |                                     |           | 3.21 (1.37-8.95)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00             | 0.57, 1.00 | 0      | -0.43, 0.43 |
|                         |                                     |           | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0_00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual    | 68 CFU                 | 20             | 16      | 6   | 0_30      | 0.15, 0.52 | 24      | 5  | 0.25             | 0.11, 0.47 | 0.05   | -0_22, 0_31 |
|                         |                                     |           | 190 CFU                | 5              | 16      | 5   | 1_00      | 0.57, 1.00 | 24      | 5  | 1.00             | 0.57, 1.00 | 0      | -0_43, 0_43 |
|                         |                                     |           | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0.00             | 0.00, 0.43 | 0      | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028) | Manual    | 68 CFU                 | 20             | 24      | 6   | 0_30      | 0.15, 0.52 | 24      | 5  | 0.25             | 0.11, 0.47 | 0.05   | -0.22, 0.31 |
|                         |                                     |           | 190 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1_00             | 0.57, 1.00 | 0      | -0.43, 0.43 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>*d*</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>*h*</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

| Table 7. Clear Safety   | y vs. reference – POD analysis (cont | inued) (1) |                        |                |         |     |           |            |         |    |           |            |                    |             |
|-------------------------|--------------------------------------|------------|------------------------|----------------|---------|-----|-----------|------------|---------|----|-----------|------------|--------------------|-------------|
|                         |                                      |            |                        |                |         | Cle | ar Safety |            |         |    | Reference |            |                    |             |
| Matrix per test portion | Strain                               | Method     | MPN per test portion " | n <sup>b</sup> | Time, h | xc  | PODepd    | 95% CI     | Time, h | x  | POD       | 95% CI     | dPOD₂ <sup>g</sup> | 95% Cl      |
|                         |                                      |            | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0.00      | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Automated  | 68 CFU                 | 20             | 16      | 6   | 0_30      | 0.15, 0.52 | 24      | 5  | 0.25      | 0.11, 0.47 | 0.05               | -0.22, 0.31 |
|                         |                                      |            | 190 CFU                | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00      | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                         |                                      |            | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0_00      | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Automated  | 68 CFU                 | 20             | 24      | 6   | 0_30      | 0.15, 0.52 | 24      | 5  | 0.25      | 0.11, 0.47 | 0.05               | -0.22, 0.31 |
|                         |                                      |            | 190 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1.00      | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                         |                                      |            | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Manual     | 74 CFU                 | 20             | 16      | 11  | 0.55      | 0_34, 0_74 | 24      | 14 | 0.7       | 0.48-0.85  | -0.15              | -0.41, 0.14 |
|                         |                                      |            | 222 CFU                | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                         |                                      |            | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Manual     | 74 CFU                 | 20             | 24      | 11  | 0.55      | 0_34, 0_74 | 24      | 14 | 0_7       | 0.48-0.85  | -0.15              | -0.41, 0.14 |
|                         |                                      |            | 222 CFU                | 5              | 24      | 5   | 1_00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                         |                                      |            | -                      | 5              | 16      | 0   | 0.00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Automated  | 74 CFU                 | 20             | 16      | 11  | 0_55      | 0_34, 0_74 | 24      | 14 | 0_7       | 0.48-0.85  | -0.15              | -0.41, 0.14 |
|                         |                                      |            | 222 CFU                | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                         |                                      |            | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| Chicken carcass rinse   | Salmonella Typhimurium (ATCC 14028)  | Automated  | 74 CFU                 | 20             | 24      | 11  | 0_55      | 0_34, 0_74 | 24      | 14 | 0_7       | 0.48-0.85  | -0.15              | -0.41, 0.14 |
|                         |                                      |            | 222 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup> x = Number of positive test portions.

<sup>*d*</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>1</sup> Matrix study was performed by Independent Lab

| Table 7. Clear Safety     | vs. reference – POD analysis (cor  | ntinued) (1) |                        |                |         |     |           |            |         |   |                    |            |        |             |
|---------------------------|------------------------------------|--------------|------------------------|----------------|---------|-----|-----------|------------|---------|---|--------------------|------------|--------|-------------|
|                           |                                    |              |                        |                |         | (De | ar Safety |            |         |   | Reference          |            |        |             |
| Matrix per test portion   | Strain                             | Method       | MPN per test partian " | n <sup>b</sup> | Time, h | xc  | PODep     | 95% CI     | Time, h | x | POD <sub>4</sub> f | 95% CI     | dPOD;# | 95% CI      |
| Stainless steel with a    | Salmonella Derby (NCTC 5721)       |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
|                           | &                                  | Manual       | 52 & 800 CFU           | 20             | 14      | 9   | 0_45      | 0.26, 0.66 | 24      | 8 | 0_4                | 0.22, 0.61 | 0.05   | -0.24-0.33  |
| compentor                 | Citrobacter freundii (QL 11007.10) |              | 380 & 5600 CFU         | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |
| Stainless steel with a    | Salmonella Derby (NCTC 5721)       |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
|                           | &                                  | Manual       | 52 & 800 CFU           | 20             | 24      | 9   | 0.45      | 0.26, 0.66 | 24      | 8 | 0_4                | 0.22, 0.61 | 0.05   | -0.24-0.33  |
| competitor                | Citrobacter freundii (QL 11007.10) |              | 380 & 5600 CFU         | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |
| Stainless steel with a    | Salmonella Derby (NCTC 5721)       |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
| sameditar <sup>i</sup>    | &                                  | Automated    | 52 & 800 CFU           | 20             | 14      | 9   | 0_45      | 0.26, 0.66 | 24      | 8 | 0_4                | 0.22, 0.61 | 0.05   | -0.24-0.33  |
| cangenta                  | Citrobacter freundii (QL 11007.10) |              | 380 & 5600 CFU         | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |
| Stainlass steal with a    | Salmonella Derby (NCTC 5721)       |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
|                           | &                                  | Automated    | 52 & 800 CFU           | 20             | 24      | 9   | 0_45      | 0.26, 0.66 | 24      | 8 | 0_4                | 0.22, 0.61 | 0.05   | 0.24 0.33   |
| competitor                | Citrobacter freundii (QL 11007.10) |              | 380 & 5600 CFU         | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |
| Stainless steel without a |                                    |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
| i                         | Salmonella Derby (NCTC 5721)       | Manual       | 66 CFU                 | 20             | 14      | 10  | 0_50      | 0_30, 0_70 | 24      | 7 | 0_35               | 0.18, 0.57 | 0.15   | -0.15, 0.41 |
| competitor                |                                    |              | 460 CFU                | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |
| Stainless chel without a  |                                    |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0 | 0                  | 0.00, 0.43 | 0      | -0.43, 0.43 |
| Stainless steel without a | Salmanella Derby (NCTC 5721)       | Manual       | 66 CFU                 | 20             | 24      | 10  | 0_50      | 0_30, 0_70 | 24      | 7 | 0_35               | 0.18, 0.57 | 0.15   | -0.15, 0.41 |
| competitor                |                                    |              | 460 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5 | 1                  | 0.57, 1.00 | 0      | -0.43, 0.43 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

1

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

| Table 7. Clear Safety v   | /s. reference – POD analysis (cor  | ntinued) (1) |                        |                |         |     |           |            |         |    |           |            |                    |             |
|---------------------------|------------------------------------|--------------|------------------------|----------------|---------|-----|-----------|------------|---------|----|-----------|------------|--------------------|-------------|
|                           |                                    |              |                        |                |         | (De | ar Safety |            | _       |    | Reference | -          |                    |             |
| Matrix per test portion   | Strain                             | Method       | MPN per test partian " | n <sup>b</sup> | Time, h | xc  | PODer     | 95% CI     | Time, h | x  | POD       | 95% CI     | dPOD. <sup>g</sup> | 95% CI      |
| Stainless steel without a |                                    |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| competitor i              | Salmonella Derby (NCTC 5721)       | Automated    | 66 CFU                 | 20             | 14      | 10  | 0_50      | 0_30, 0.70 | 24      | 7  | 0_35      | 0.18, 0.57 | 0.15               | -0.15, 0.41 |
| campenta                  |                                    |              | 460 CFU                | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel without a |                                    |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| computitor i              | Salmonella Derby (NCTC 5721)       | Automated    | 66 CFU                 | 20             | 24      | 10  | 0_50      | 0_30, 0_70 | 24      | 7  | 0_35      | 0.18, 0.57 | 0.15               | -0.15, 0.41 |
| campenta                  |                                    |              | 460 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel with a    | Salmonella Derby (FSL R8-2528)     |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
|                           | æ                                  | Manual       | 65 & 950 CFU           | 20             | 14      | 11  | 0.55      | 0_34, 0_74 | 24      | 10 | 0.5       | 0_34, 0_74 | 0.05               | -0.24, 0.33 |
| campen na                 | Citrobacter freundii (ATCC 43864)  |              | 450 & 6000 CFU         | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel with a    | Salmonella Derby (FSL R8-2528)     |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| compatitor                | æ                                  | Manual       | 65 & 950 CFU           | 20             | 24      | 11  | 0.55      | 0_34, 0_74 | 24      | 10 | 0.5       | 0_34, 0_74 | 0.05               | -0.24, 0.33 |
| campenna                  | Citrobac ter freundii (ATCC 43864) |              | 450 & 6000 CFU         | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainlers steel with a    | Salmanella Derby (FSL R8-2528)     |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| compatitor                | æ                                  | Automated    | 65 & 950 CFU           | 20             | 14      | 11  | 0.55      | 0_34, 0.74 | 24      | 10 | 0_5       | 0_34, 0_74 | 0.05               | -0.24, 0.33 |
| campenta                  | Citrobac ter freundii (ATCC 43864) |              | 450 & 6000 CFU         | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Strinkov staal with a     | Salmonella Derby (FSL R8-2528)     |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0         | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| competitor                | æ.                                 | Automated    | 65 & 950 CFU           | 20             | 24      | 11  | 0.55      | 0_34, 0_74 | 24      | 10 | 0.5       | 0_34, 0.74 | 0.05               | -0.24, 0.33 |
| CAMIFEITT                 | Citrobac ter freundii (ATCC 43864) |              | 450 & 6000 CFU         | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1         | 0.57, 1.00 | 0                  | -0.43, 0.43 |

<sup>o</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

| Table 7. Clear Safety   | vs. reference – POD analysis (cor | ntinued) (1) |                        |                |         |     |           |            |         |    |                    |            |                    |             |
|---|-----------------------------------|--------------|------------------------|----------------|---------|-----|-----------|------------|---------|----|--------------------|------------|--------------------|-------------|
|   |                                   |              |                        |                |         | (]e | ar Safety |            |         |    | Reference          |            |                    |             |
| Matrix per test portion   | Strain                            | Method       | MPN per test partian " | n <sup>b</sup> | Time, h | xc  | PODend    | 95% CI     | Time, h | x  | POD <sub>k</sub> f | 95% CI     | dPOQ. <sup>g</sup> | 95% CI      |
| Stainlage and without a   |                                   |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| stantess sizer winton a   | Salmonella Derby (FSL R8-2528)    | Manual       | 57 CFU                 | 20             | 14      | 12  | 0_60      | 0_39, 0.78 | 24      | 9  | 0.45               | 0.26, 0.66 | 0.15               | -0.15, 0.41 |
| competition   |                                   |              | 570 CFU                | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel without a   |                                   |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| compatibut  | Salmonella Derby (FSL R8-2528)    | Manual       | 57 OFU                 | 20             | 24      | 12  | 0_60      | 0_39, 0.78 | 24      | 9  | 0.45               | 0.26, 0.66 | 0.15               | -0.15, 0.41 |
| compensa.   |                                   |              | 570 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel without a   |                                   |              | -                      | 5              | 14      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| competitor  | Salmonella Derby (FSL R8-2528)    | Automated    | 57 CFU                 | 20             | 14      | 12  | 0_60      | 0_39, 0_78 | 24      | 9  | 0.45               | 0_26, 0_66 | 0.15               | -0.15, 0.41 |
| campen ma   |                                   |              | 570 CFU                | 5              | 14      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |
| Stainless steel without a   |                                   |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| compatitor  | Salmonella Derby (FSL R8-2528)    | Automated    | 57 CFU                 | 20             | 24      | 12  | 0.60      | 0_39, 0_78 | 24      | 9  | 0_45               | 0.26, 0.66 | 0.15               | -0.15, 0.41 |
| competition and a second se |                                   |              | 570 CFU                | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|   |                                   |              | -                      | 5              | 20      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375g Dry pet food   | Salmonella Anatum (ATCC 9270)     | Manual       | 0.55 (0.28-0.88)       | 20             | 20      | 14  | 0.70      | 0.48, 0.85 | 24      | 10 | 0_5                | 0_30, 0.70 | 0_20               | -0.1, 0.45  |
|   |                                   |              | 4_13 (1_15-5_78)       | 5              | 20      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|   |                                   |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                  | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375g Dry pet food   | Salmonella Anatum (ATCC 9270)     | Manual       | 0.55 (0.28-0.88)       | 20             | 24      | 14  | 0_70      | 0.48, 0.85 | 24      | 10 | 0.5                | 0_30, 0_70 | 0_20               | -0.1, 0.45  |
|   |                                   |              | 4.13 (1.15-5.78)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                  | 0.57, 1.00 | 0                  | -0.43, 0.43 |

<sup>a</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

<sup>c</sup>x = Number of positive test portions.

<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

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<sup>f</sup>POD<sub>cc</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

NOTE: Carcass rinses and stainless steel values are based on plate counts of the inoculum.

| Table 7. Clear Safety v  | s. reference – POD analysis (cor | ntinued) (1) |                        |                |         |     |           |            |         |    |                  |            |                    |             |
|--------------------------|----------------------------------|--------------|------------------------|----------------|---------|-----|-----------|------------|---------|----|------------------|------------|--------------------|-------------|
|                          |                                  |              |                        |                |         | (De | ar Safety |            |         |    | Reference        |            |                    |             |
| Matrix per test portion  | Strain                           | Method       | MPN per test partian " | n <sup>b</sup> | Time, h | xc  | PODer     | 95% CI     | Time, h | x  | POD <sub>4</sub> | 95% CI     | dPOQ₂ <sup>g</sup> | 95% CI      |
|                          |                                  |              | -                      | 5              | 20      | 0   | 0.00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375g Dry pet food        | Salmonella Anatum (ATCC 9270)    | Automated    | 0.55 (0.28-0.88)       | 20             | 20      | 14  | 0.70      | 0.48, 0.85 | 24      | 10 | 0_5              | 0.30, 0.70 | 0_20               | -0.1, 0.45  |
|                          |                                  |              | 4_13 (1_15-5_78)       | 5              | 20      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                          |                                  |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375g Dry pet food        | Salmonell a Anatum (ATCC 9270)   | Automated    | 0.55 (0.28-0.88)       | 20             | 24      | 14  | 0.70      | 0.48, 0.85 | 24      | 10 | 0_5              | 0_30, 0.70 | 0_20               | -0.1, 0.45  |
|                          |                                  |              | 4.13 (1.15-5.78)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                          |                                  |              | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263)  | Manual       | 0.45 (0.25-0.85)       | 20             | 16      | 5   | 0.25      | 0.11, 0.47 | 24      | 6  | 0_3              | -0_27-0_27 | -0.05              | -0.31, 0.22 |
|                          |                                  |              | 1.69 (0.85-3.72)       | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                          |                                  |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263)  | Manual       | 0.45 (0.25-0.85)       | 20             | 24      | 5   | 0.25      | 0_11, 0.47 | 24      | 6  | 0_3              | -0.27-0.27 | -0.05              | -0.31, 0.22 |
|                          |                                  |              | 1_69 (0.85-3_72)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                          |                                  |              | -                      | 5              | 16      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263)  | Automated    | 0.45 (0.25-0.85)       | 20             | 16      | 5   | 0.25      | 0.11, 0.47 | 24      | 6  | 0_3              | -0.27-0.27 | -0.05              | -0_31, 0_22 |
|                          |                                  |              | 1_69 (0.85-3_72)       | 5              | 16      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |
|                          |                                  |              | -                      | 5              | 24      | 0   | 0_00      | 0.00, 0.43 | 24      | 0  | 0                | 0.00, 0.43 | 0                  | -0.43, 0.43 |
| 375 g Raw ground chicken | Salmonella Kentucky (ATCC 9263)  | Automated    | 0.45 (0.25-0.85)       | 20             | 24      | 5   | 0.25      | 0.11, 0.47 | 24      | 6  | 0_3              | -0.27-0.27 | -0.05              | -0_31, 0_22 |
|                          |                                  |              | 1.69 (0.85-3.72)       | 5              | 24      | 5   | 1.00      | 0.57, 1.00 | 24      | 5  | 1                | 0.57, 1.00 | 0                  | -0.43, 0.43 |

<sup>o</sup> MPN is calculated using the LCF MPN calculator version 1.6 provided by AOAC Research Institute, with 95% confidence intervals indicated in parentheses.

<sup>b</sup> n = Number of test portions.

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<sup>d</sup> POD<sub>CP</sub> = Candidate method presumptive outcomes divided by total number of trials.

<sup>e</sup> CI = Confidence interval.

<sup>f</sup>POD<sub>CC</sub> = Candidate method confirmed positive outcomes divided by the total number of trials

<sup>g</sup> dPOD<sub>c</sub> = Difference between the confirmed candidate method result and the reference method confirmed result POD values.

<sup>h</sup> If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

<sup>i</sup> Matrix study was performed by Independent Lab

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