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# NordVal International Certificate

| | |
|---|---|
| Issued for: | **Easy Plate AC for the enumeration of aerobic plate count in a broad range of foods, pet food, animal feed and environmental samples** |
| NordVal No: | 059 |
| First approval date: | 01 September 2023 |
| Valid until: | 01 September 2025 |

## Easy Plate AC

**Manufactured by:**

Kikkoman Biochemifa Company
2-1-1, Nishi-shinbashi, Minato-ku,
Tokyo 105-0003, Japan

fulfils the requirements of the NordVal Validation Protocol 1. The reference method was EN ISO 4833-1:2013 Microbiology of the food chain -- Horizontal method for the enumeration of microorganisms - Part 1: Colony count at 30°C by the pour plate technique.

NordVal International has studied the enclosures to the application and evaluated the results obtained in the validations conducted by the expert laboratory Campden BRI. The validations have been carried out according to ISO 16140-2:2016. NordVal International concludes that it has been satisfactorily demonstrated that the results document no difference in the performances between the Easy Plate AC and the reference method.

The production of the Easy Plate AC is fulfilling the requirements given in ISO 9001.

Date: 01 September 2023

Yours sincerely,

Hilde Skår Norli
Chair of NordVal International

Eystein Oveland
NMKL Executive Director

## PRINCIPLE OF THE METHOD

Easy Plate AC is a prepared microbiological culture plate made up of a waterproof sheet, a dry medium on the sheet and a transparent cover over the medium. The Easy Plate AC method is intended to indicate the level of aerobic bacteria in food and beverage products. After incubation at 30°C ±1°C for 48h ±3h, the aerobic colonies are visible as red colonies on the Easy Plate AC growth medium.

## FIELD OF APPLICATION

The method is applicable for the enumeration of total aerobic bacteria in a broad range of foods, animal feed and primary production samples.

## METHOD COMPARISON STUDY

### Relative trueness study

The relative trueness study is a comparative study between the results obtained by the reference method and the results of the alternative method. This study was conducted using naturally or artificially contaminated samples. Different categories, types and items were tested.

A total of 7 categories were included, whereof 15 items for each category were tested by both the reference method and the alternative method. Each category was made up of 3 types, with at least 5 items representative for each type. The categories, the types and the number of samples analysed are presented in **Table 1**.

**Table 1. List of categories, types, number of samples analysed and results obtained from testing within the relative trueness study**

| Category | Types | Items (examples) | Number of samples analysed | Number of samples with interpretable results | ISO 6887 and Diluent used |
|---|---|---|---|---|---|
| Milk and dairy products (combined category raw and heat processed Milk and dairy products) | Raw milk and dairy products | Raw milk , raw milk cheese | 5 | 5 | 6887-5 sodium citrate solution |
| | Pasteurised milk and milk based products | Milk, ice-cream, milk based drinks | 5 | 5 | 6887-5 PSD* |
| | Dry milk products | Milk powder, dessert powder | 5 | 5 | 6887-5 PSD |
| | **Total** | | **15** | **15** | |
| Fishery products Combined category: raw, RTE, RTRH, RTC | Raw fish (unprocessed) | Raw salmon fillet, tuna | 5 | 5 | 6887-3 PSD |
| | RTE/RTC/RTRH fish and seafoods | Smoked salmon, frozen seafoods | 5 | 5 | 6887-3 PSD |
| | Crustaceans | Shrimp, crab | 5 | 5 | 6887-3 PSD |

| Category | Types | Items (examples) | Number of samples analysed | Number of samples with interpretable results | ISO 6887 and Diluent used |
|---|---|---|---|---|---|
| | **Total** | | **15** | **15** | |
| Produce and fruits (combined category fresh and processed) | Cut ready-to-eat vegetables/leafy greens and sprouts | Bagged pre-cut lettuce shredded carrot | 5 | 5 | 6887-4 PSD |
| | Fresh fruit/Cut RTE fruit and vegetable products | Cut fruits, freshly squeezed juice, smoothies | 5 | 5 | 6887-4 PSD |
| | Heat treated fruit and vegetables | Pasteurised smoothies/juice, blanched frozen vegetables | 5 | 5 | 6887-4 PSD |
| | **Total** | | **15** | **15** | |
| Multi-component foods or meal components | Composite foods with substantial raw ingredients | Chilled pasta salad, sandwiches | 5 | 5 | 6887-1 PSD |
| | RTRH/RTE foods (chilled, frozen) | Cooked chilled pasta, frozen fries, rice products, | 5 | 5 | 6887-1 PSD |
| | Mayonnaise based deli-salads | Vegetable salad | 5 | 5 | 6887-1 PSD |
| | **Total** | | **15** | **15** | |
| Raw and Ready to cook RTC Meat and poultry | Raw poultry and meat cuts | Raw chicken, beef, pork, turkey | 5 | 5 | 6887-2 PSD |
| | Raw processed meat | Frozen burger patties, pork meat balls, | 5 | 5 | 6887-2 PSD |
| | RTC processed poultry | seasoned chicken, turkey meat balls, | 5 | 5 | 6887-2 PSD |
| | **Total** | | **15** | **15** | |
| Pet food and animal feed | Dry Food | Pellets, kibbles, treats | 5 | 5 | 6887-4 PSD |
| | Wet food (raw and canned) | Pates, sausages | 5 | 5 | 6887-2 PSD |
| | Animal feeds (poultry and fish) | seasoned chicken, turkey meat balls, | 5 | 5 | 6887-4 PSD |
| | **Total** | | **15** | **15** | |
| Environmental samples (food or feed production) | Surfaces (wipes, swabs) | Equipment, floors, walls | 5 | 5 | 6887-1 ISO 18593:2018 PSD |
| | Process water | Wash water, cooling water | 5 | 5 | 6887-1 PSD |

| Category | Types | Items (examples) | Number of samples analysed | Number of samples with interpretable results | ISO 6887 and Diluent used |
|---|---|---|---|---|---|
| | Dusts | Bakery and food manufacturing environment | 5 | 5 | 6887-1<br>ISO 18593:2018<br>PSD |
| | **Total** | | **15** | **15** | |
| **Total number of samples** | | | **105** | **105** | |

*PSD = peptone salt diluent

In total, 105 samples were analysed leading to 105 explotiable results. The mean difference (bias) of the samples obtained by the the alternative method and the reference method, and the presision thereof, expressed as standard deviation, SD, was calculated and a summary is provided in **Table 2**.

**Table 2. Summary of the calculated values per category**

| Category | N | Bias | SD |
|---|---|---|---|
| Environmental samples (food or feed production) | 15 | -0.282 | 0.336 |
| Fishery products combined category: raw, RTE RTRH, RTC | 15 | 0.122 | 0.364 |
| Milk and dairy products (combined category raw and heat processed milk and dairy) | 15 | -0.167 | 0.272 |
| Multi-components foods or meal components | 15 | 0.000 | 0.341 |
| Pet food and animal feed | 15 | 0.110 | 0.200 |
| Produce and fruits (combined category fresh and processed) | 15 | -0.066 | 0.131 |
| Raw and ready to cook RTC meat and poultry | 15 | -0.126 | 0.254 |
| **All categories** | **105** | **-0.058** | **0.306** |

Bias: Average difference, SD: standard deviation of differences, N: number of samples

The results are presented in a Bland-Altman plot (**Figure 1**), including the ± 95% confidence level for the standard deviation of all categories.

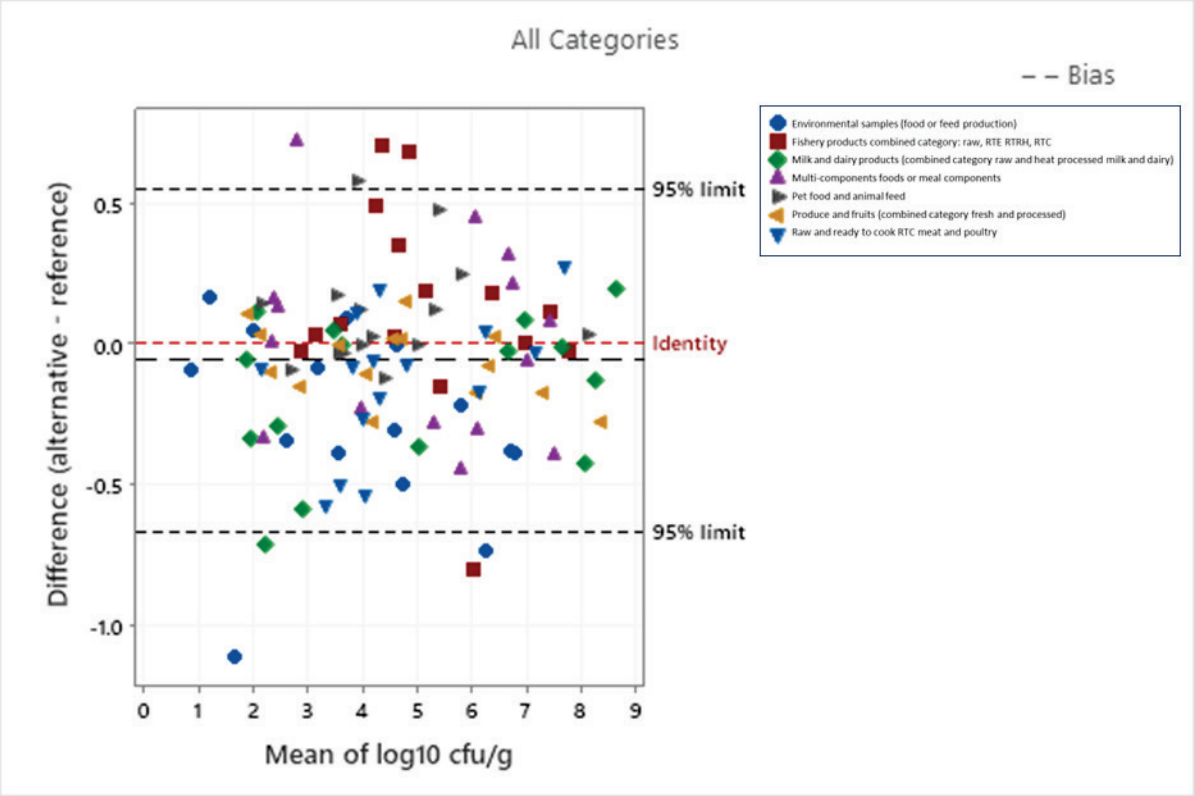



**Figure 1. The Bland-Altman plot for all the samples**

It is expected that not more than one in 20 data values will lie outside the confidence levels.

For this data set there are 8 in 105 data values which lie outside the levels. This is higher than the expectation, however, there are no trends to the outlying data which represented five of the seven categories.

The samples covered a diverse range of food items with different groups of naturally present organisms present and therefore these results show good agreement between the two methods for enumeration of total aerobic count.

### Accuracy profile study

The accuracy profile study is a comparative study between the results obtained by the reference and the results of the alternative method. This study is conducted using artificially contaminated samples. One type per category is tested.

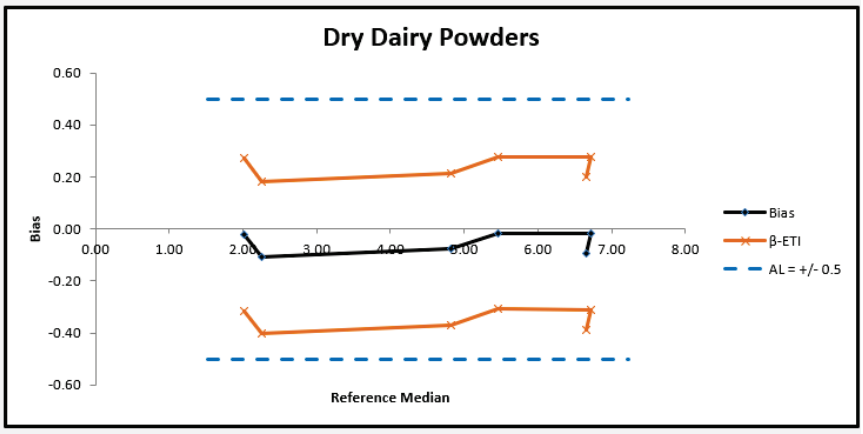
Two samples were contaminated at a low level, 2 at intermediate level, 2 at a high level. For each sample, 5 replicates (5 different test portions) were tested. A total of 30 samples were analysed per food type. The tested categories, types and items in the accuracy profile study are provided in **Table 3**.

All results are tabulated, calculated and interpreted according to ISO 16140-2. The statistical results are shown in Figures 2 to 8.

**Table 3. Categories, types, items, strains and inoculation levels for accuracy profile study**

| Category | Types | Strain | Item | Level | Test portions |
|---|---|---|---|---|---|
| Dairy products (combined category; raw milk and heat processed) | Dry dairy products | *Bacillus cereus* CRA 1724 from Dried milk | Milk powder | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Dessert powder | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Fishery products Combined category: raw, RTE, RTRH, RTC | RTC | *Pseudomonas fragi* CRA7222 from spoiled fish | Frozen white fish | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Chilled tuna steak | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Produce and fruits (combined category fresh and processed) | Cut ready to eat | *E.coli* CRA3379 from spinach | Lettuce | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Grated carrot | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Raw and RTC Meat and poultry (Combined category) | Fresh meats | *Citrobacter freundii* CRA403 from chicken | Raw stir fry beef strips | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Chicken breast fillets | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Multicomponent | Composite foods with raw /processed ingredients | *Hafnia alvei* CRA7417 from pate | Sandwich | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Pasta salad | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Pet food and animal feed | Wet food (cooked) | *Staph aureus* CRA 1246 from pork sausage | Dog pate | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Cat food with gravy | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| Environmental samples | Process water | *Pseudomonas fluorescens CRA 7774* from wash house | Wash water | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |
| | | | Cooling water | Low $10^2$ | 5 |
| | | | | Medium $10^4$ | 5 |
| | | | | High $10^6$ | 5 |

| (Food) Category | Dairy products |
|---|---|
| (Food) Type | Dry Dairy Powders |

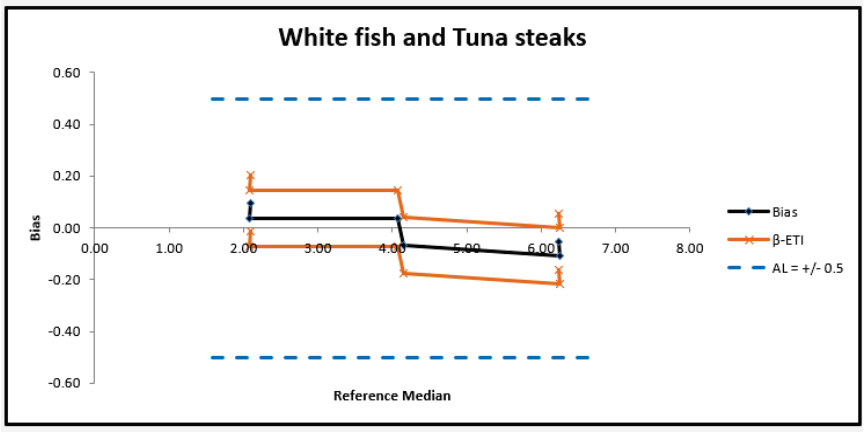



| Sample Name | Reference central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 1 | 2.02 | -0.021 | -0.314 | 0.272 | YES | YES |
| 4 | 2.26 | -0.109 | -0.402 | 0.184 | YES | YES |
| 2 | 4.83 | -0.078 | -0.371 | 0.215 | YES | YES |
| 5 | 5.46 | -0.015 | -0.308 | 0.278 | YES | YES |
| 3 | 6.72 | -0.017 | -0.310 | 0.276 | YES | YES |
| 6 | 6.66 | -0.095 | -0.388 | 0.198 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.374 | 0.203 | NO | +/- 0.500 |

**Figure 2. Accuracy profile of dairy products (dry dairy powders) for Easy Plate AC method**

| (Food) Category | Fishery products (Combined |
|---|---|
| (Food) Type | White fish and Tuna steaks |

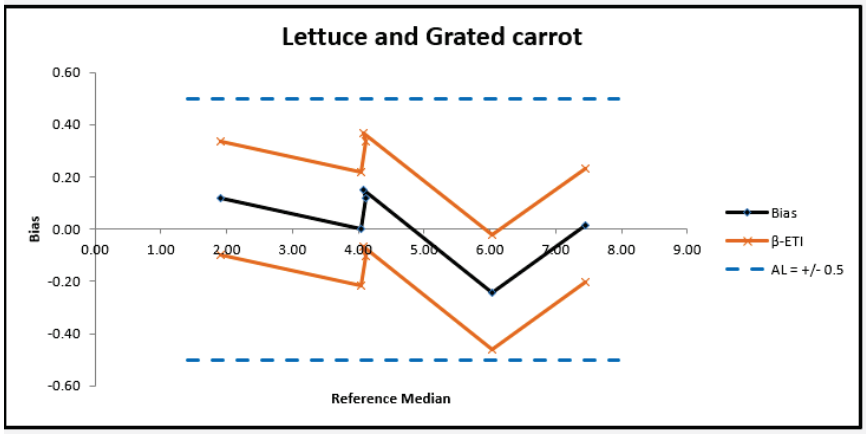



| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 7 | 2.10 | 0.093 | -0.015 | 0.202 | YES | YES |
| 10 | 2.08 | 0.035 | -0.074 | 0.143 | YES | YES |
| 8 | 4.08 | 0.035 | -0.074 | 0.143 | YES | YES |
| 11 | 4.15 | -0.067 | -0.175 | 0.041 | YES | YES |
| 9 | 6.26 | -0.109 | -0.217 | -0.001 | YES | YES |
| 12 | 6.23 | -0.054 | -0.163 | 0.054 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.079 | 0.075 | YES | +/- 0.500 |

**Figure 3. Accuracy profile of Fishery products for Easy Plate AC method**

| (Food) Category | Produce and fruits (combined |
|---|---|
| (Food) Type | Lettuce and Grated carrot |

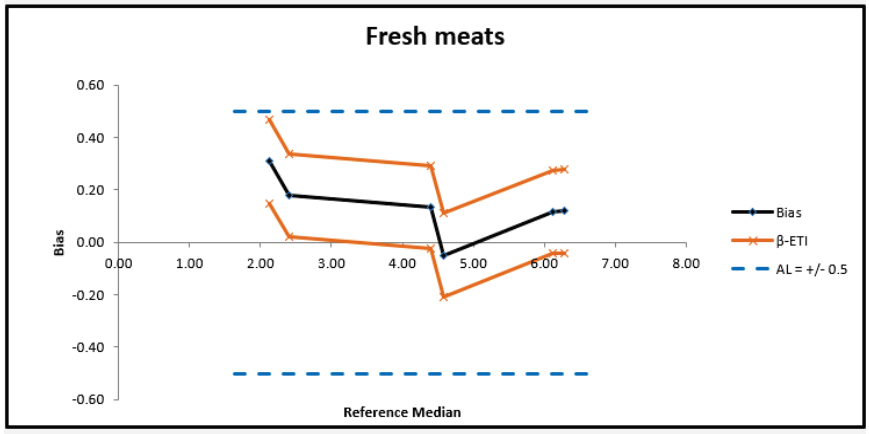



| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 13 | 1.90 | 0.118 | -0.100 | 0.336 | YES | YES |
| 16 | 4.04 | 0.000 | -0.218 | 0.218 | YES | YES |
| 14 | 4.11 | 0.117 | -0.101 | 0.334 | YES | YES |
| 17 | 4.08 | 0.151 | -0.067 | 0.369 | YES | YES |
| 15 | 6.04 | -0.242 | -0.460 | -0.024 | YES | YES |
| 18 | 7.45 | 0.015 | -0.203 | 0.233 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.118 | 0.151 | YES | +/- 0.500 |

**Figure 4. Accuracy profile for Produce and fruits for Easy Plate AC method**

| (Food) Category | Raw and RTC Meat and poultry |
|---|---|
| (Food) Type | Fresh meats |

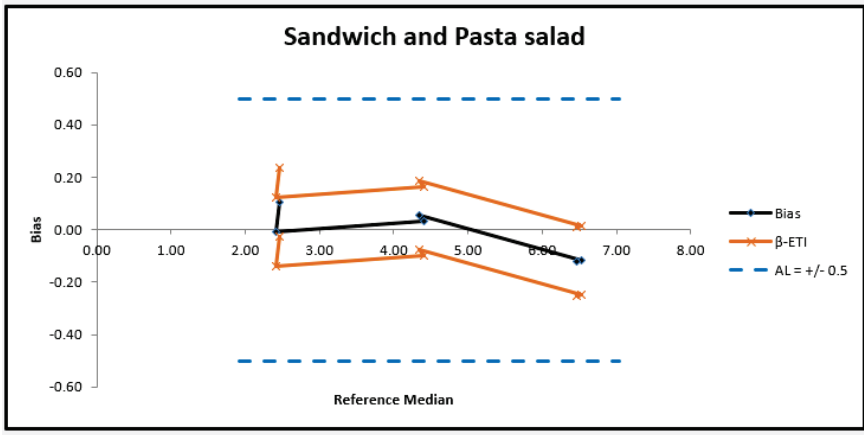



| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 19 | 2.13 | 0.309 | 0.150 | 0.468 | YES | YES |
| 22 | 2.41 | 0.179 | 0.020 | 0.338 | YES | YES |
| 20 | 4.40 | 0.134 | -0.025 | 0.292 | YES | YES |
| 23 | 4.58 | -0.048 | -0.207 | 0.110 | YES | YES |
| 21 | 6.11 | 0.117 | -0.042 | 0.275 | YES | YES |
| 24 | 6.28 | 0.119 | -0.040 | 0.278 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.103 | 0.110 | YES | +/- 0.500 |

**Figure 5. Accuracy profile for Meat and poultry for Easy Plate AC method**

| (Food) Category | Multicomponent |
|---|---|
| (Food) Type | Sandwich and Pasta salad |

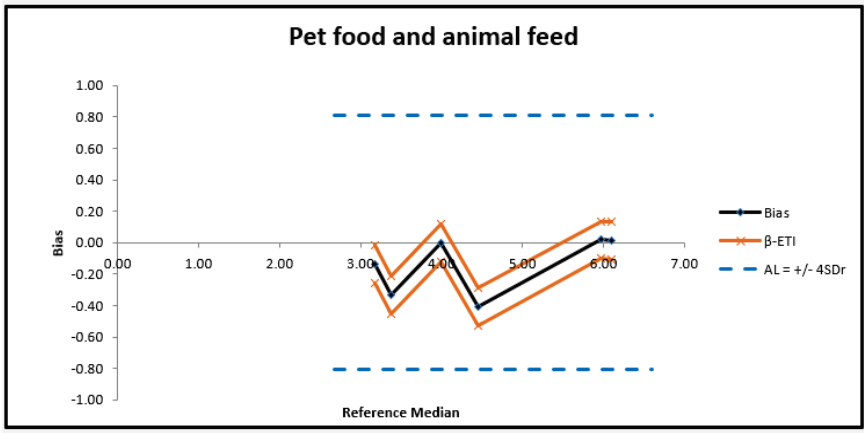



| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 25 | 2.46 | 0.106 | -0.026 | 0.237 | YES | YES |
| 28 | 2.41 | -0.008 | -0.140 | 0.123 | YES | YES |
| 26 | 4.41 | 0.032 | -0.099 | 0.164 | YES | YES |
| 29 | 4.34 | 0.056 | -0.076 | 0.187 | YES | YES |
| 27 | 6.53 | -0.117 | -0.248 | 0.015 | YES | YES |
| 30 | 6.46 | -0.120 | -0.251 | 0.011 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.125 | 0.091 | YES | +/- 0.500 |

**Figure 6. Accuracy profile for Multicomponent for Easy Plate AC method**

| (Food) Category | Pet food and animal feed |
|---|---|
| (Food) Type | Pet food and animal feed |

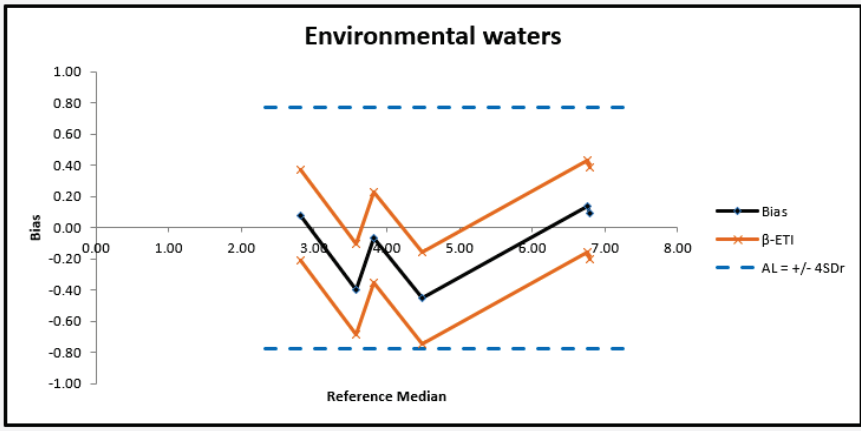



| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 31 | 3.18 | -0.135 | -0.255 | -0.015 | YES | YES |
| 34 | 3.37 | -0.332 | -0.451 | -0.212 | YES | YES |
| 32 | 4.00 | 0.000 | -0.120 | 0.120 | YES | YES |
| 35 | 4.45 | -0.406 | -0.526 | -0.286 | NO | YES |
| 33 | 5.98 | 0.018 | -0.102 | 0.138 | YES | YES |
| 36 | 6.10 | 0.014 | -0.106 | 0.133 | YES | |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.202 | 0.083 | NO | +/- 0.808 |

**Figure 7. Accuracy profile for Pet food and animal feed for Easy Plate AC method**

| (Food) Category | Environmental |
|---|---|
| (Food) Type | Environmental waters |




| Sample Name | Reference Central value | Bias | Lower β-ETI | Upper β-ETI | β-ETI compared to AL=±0.5 Acceptable | β-ETI compared to final AL Acceptable |
|---|---|---|---|---|---|---|
| 37 | 2.82 | 0.080 | -0.213 | 0.373 | YES | YES |
| 40 | 3.58 | -0.395 | -0.688 | -0.102 | NO | YES |
| 38 | 3.82 | -0.064 | -0.357 | 0.229 | YES | YES |
| 41 | 4.49 | -0.450 | -0.743 | -0.157 | NO | YES |
| 39 | 6.76 | 0.136 | -0.157 | 0.429 | YES | YES |
| 42 | 6.80 | 0.093 | -0.200 | 0.386 | YES | YES |

| | Reference method | Alternative method | SD repeatability of reference method <= 0.125 | Final AL |
|---|---|---|---|---|
| SD Repeatability | 0.193 | 0.203 | NO | +/- 0.772 |

**Figure 8. Accuracy profile for Environmental samples for Easy Plate AC method**

Five of the seven categories met the AL of 0.5 log (dairy, fresh produce, fish and seafood, multicomponent foods, meat). Two categories (petfood and environmental samples) required the new AL to be calculated. All data met the new AL values of 0.808 and 0.772.

The accuracy of the Alternative method (Easy Plate AC) is satisfied as all categories met the 0.5 log AL or the re-calculated AL.

## INTERLABORATORY STUDY

The interlaboratory study is a study performed by multiple collaborators testing identical samples at the same time, the results of which are used to estimate alternative method performance characteristics.

Samples were sent to 12 collaborators. The matrix and strain used in the study was smoked salmon inoculated with *Staphylococcus aureus* CRA 1208 (isolated from smoked fish).

Each collaborator received a set of samples containing 2 samples at a low level, two samples at a medium level, two samples at a high level and a single uninoculated blank sample. The samples were blind-coded so that the collaborators did not know the intended contamination level.

All laboratories delivered valid results. The results are given in **Table 4** and the results of the calculations given in **Table 5**. The results are illustrated in accuracy profiles in **Figure 9**.

**Table 4. Summary of the results of the interlaboratory study per analyte level**

| Collaborator | Level | Reference method (log cfu/g) | | Alternative method (log cfu/g) | |
|---|---|---|---|---|---|
| | | Duplicate 1 | Duplicate 2 | Duplicate 1 | Duplicate 2 |
| 1 | low | 2.43 | 2.53 | 2.30 | 2.58 |
| 2 | low | 4.04 | 2.20 | 3.86 | 2.36 |
| 3 | low | 3.90 | 2.64 | 3.53 | 2.63 |
| 4 | low | 3.00 | 3.54 | 2.94 | 3.04 |
| 5 | low | 2.53 | 2.59 | 2.48 | 2.51 |
| 6 | low | 3.11 | 3.18 | 3.08 | 3.18 |
| 7 | low | 3.85 | 2.87 | 3.66 | 2.83 |
| 8 | low | 3.11 | 4.41 | 2.74 | 3.17 |
| 9 | low | 3.57 | 2.52 | 3.57 | 2.26 |
| 10 | low | 4.15 | 4.00 | 3.93 | 3.89 |
| 11 | low | 2.45 | 2.64 | 2.34 | 2.72 |
| 12 | low | 2.43 | 2.53 | 2.30 | 2.58 |
| 1 | medium | 5.78 | 5.88 | 5.88 | 5.80 |
| 2 | medium | 5.67 | 5.94 | 5.86 | 5.99 |
| 3 | medium | 6.04 | 5.80 | 5.81 | 5.81 |
| 4 | medium | 5.73 | 5.81 | 5.92 | 5.83 |
| 5 | medium | 6.04 | 5.89 | 6.11 | 5.94 |
| 6 | medium | 5.89 | 5.88 | 5.86 | 5.92 |
| 7 | medium | 5.76 | 5.83 | 5.98 | 5.79 |
| 8 | medium | 5.85 | 5.86 | 5.90 | 5.88 |
| 9 | medium | 5.81 | 5.87 | 5.86 | 5.79 |
| 10 | medium | 6.00 | 6.04 | 6.08 | 6.00 |
| 11 | medium | 5.69 | 5.66 | 5.59 | 5.72 |
| 12 | medium | 5.78 | 5.88 | 5.88 | 5.80 |
| 1 | high | 6.87 | 6.93 | 6.98 | 6.87 |
| 2 | high | 6.73 | 6.73 | 6.87 | 6.81 |
| 3 | high | 7.11 | 7.08 | 7.08 | 7.15 |
| 4 | high | 6.90 | 6.71 | 6.99 | 6.76 |
| 5 | high | 7.20 | 7.00 | 7.18 | 7.08 |
| 6 | high | 6.93 | 6.98 | 6.92 | 6.92 |
| 7 | high | 6.92 | 6.68 | 6.89 | 6.77 |
| 8 | high | 6.84 | 6.92 | 7.00 | 6.00 |
| 9 | high | 9.11 | 6.67 | 9.08 | 6.85 |
| 10 | high | 7.00 | 6.99 | 7.04 | 6.99 |
| 11 | high | 6.65 | 6.74 | 6.77 | 6.86 |
| 12 | high | 6.87 | 6.93 | 6.98 | 6.87 |

**Table 5. Statistical analysis of the ILS data according to the ISO spreadsheet**

| | Alternative method | | | Reference method | | |
|---|---|---|---|---|---|---|
| **Levels** | **Low** | **Medium** | **High** | **Low** | **Medium** | **High** |
| **Target value** | **3.070** | **5.863** | **6.910** | | | |
| Number of participants (K) | 8 | 8 | 8 | 8 | 8 | 8 |
| Average for alternative method | 2.992 | 5.884 | 6.949 | 3.070 | 5.863 | 6.910 |
| Repeatability standard deviation (sr) | 0.499 | 0.085 | 0.059 | 0.611 | 0.103 | 0.085 |
| Between-labs standard deviation (sL) | 0.347 | 0.109 | 0.117 | 0.318 | 0.081 | 0.145 |
| Reproducibility standard deviation (sR) | 0.608 | 0.138 | 0.131 | 0.689 | 0.131 | 0.168 |
| Corrected number of dof | 12.985 | 10.131 | 8.580 | 13.904 | 12.497 | 9.032 |
| Coverage factor | 1.405 | 1.439 | 1.465 | | | |
| Interpolated Student t | 1.350 | 1.371 | 1.389 | | | |
| Tolerance interval standard deviation | 0.6323 | 0.1449 | 0.1381 | | | |
| Lower TI limit | 2.139 | 5.685 | 6.757 | | | |
| Upper TI limit | 3.846 | 6.083 | 7.140 | | | |
| **Bias** | **-0.077** | **0.021** | **0.039** | | | |
| **Relative Lower TI limit (beta = 80%)** | **-0.931** | **-0.178** | **-0.153** | | | |
| **Relative Upper TI limit (beta = 80%)** | **0.777** | **0.220** | **0.231** | | | |
| **Lower Acceptability Limit** | **-1.37** | **-1.37** | **-1.37** | | | |
| **Upper Acceptability Limit** | **1.37** | **1.37** | **1.37** | | | |
| **New acceptability limits may be based on reference method pooled variance** | | | | | | |
| Pooled repro standard dev of reference | 0.416 | | | | | |

TRUE
TRUE

Select ALL blue lines to draw the accuracy profile as illustrated in the worksheet "Graph Profile"

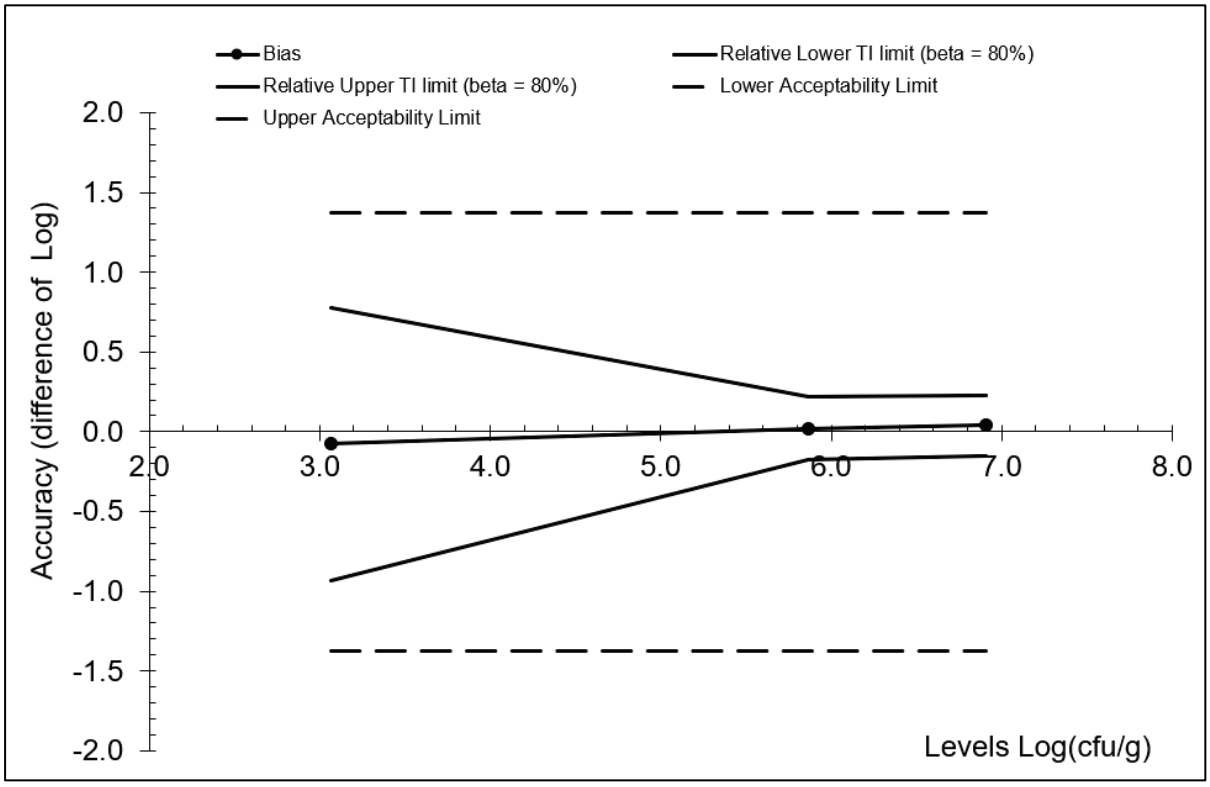



**Figure 9. Accuracy profile of Easy Plate AC from the ILS**

A review of the accuracy profile and statistical analysis revealed that there was a variability higher than expected in the aerobic plate values observed for the low level of contamination in the ILS samples. A root cause analysis was carried out to determine possible reasons for this. The log difference in the counts obtained in the reference method for the expert lab ranged from -0.22 to 0.12 and was -0.06 and 0.12 for the low level samples respectively. The same batches of media were used for all participants in the study and the time and temperature used for the incubation of the plates was correct.

It was noted that the reproducibility of the low-level samples was significantly higher than at the other levels being 0.611 for the reference method and 0.499 for the Easy Plate AC, compared to <0.1 recorded for both the medium and high count respectively.

Heat treated samples were used during the study due to the high level of background seen in the batch of smoked salmon used for the study. The higher variability in bacterial load could be explained by the difference in kill of the natural flora in the sample that would impact on the level of organisms able to grow at 30°C during the analysis.

In conclusion, the results in the interlaboratory study falls within the acceptability limits, and hence the alternative method show satisfactory performance.

## CONCLUSION

According to the comparison and the collaborative study no statistical differences were found between the Easy Plate AC and the reference method for the enumeration of total aerobic bacteria in in a broad range of foods, pet food, animal feed and environmental samples.