AOAC-PTM Level 2 Modification for Hygiena™ BAX® System SalQuant™ Utilizing BAX® System Real-Time PCR Assay for *Salmonella* for Matrix Extensions

Process control and final product decisions based only prevalence have shown limitations reducing consumer risk, therefore, adoption of validated quantification methodologies with low error and wide enumerable ranges should be utilized to make data-driven food safety decisions.

This certification provides the poultry, beef, and pork industries with an accurate, reliable, and validated quantification tool to reduce product hold-times, verify corrective actions, monitor process control, and promote faster data-driven diversion decisions which ultimately reduces consumer risk in animal protein products.

Validation Methods

- The evaluation consisted of 7 matrix studies to extend the methods' claims.
- Three distinct levels with a range of 1.0 Log CFU/mL(g) are established by the AOAC committee based upon enumeration capabilities of the candidate method.
- Each level has 5 unpaired individual samples that are tested for each level with the mean and error of each level utilized for comparison to the reference method.
- The candidate method must be within +/- 0.5 Log CFU/mL(g) of the MLG MPN 2.05 reference method for each level and be within the 90% confidence interval.

Matrix	Sample Size	Incubation Conditions	Enumerable Range
Poultry Rinsate	30 mL	42°C for 6 h	1 – 10,000 CFU/mL
Ground Beef	375 g	42°C for 6 h	1 – 10,000 CFU/g
Ground Pork	375 g	42°C for 6 h	1 – 10,000 CFU/g
Beef Trim	375 g	42°C for 6 h	1 – 10,000 CFU/g
Pork Trim	375 g	42°C for 6 h	1 – 10,000 CFU/g
MicroTally™ - Beef Trim	1 Swab	42°C for 6 h	1 – 10,000 CFU/mL
MicroTally™ - Pork Trim	1 Swab	42°C for 6 h	1 – 10,000 CFU/mL

Validation Results

- The Level 2 modification to the **BAX® System Real-Time PCR Assay for *Salmonella*, BAX® System SalQuant™** (Certification No. 081201) was evaluated and approved by the AOAC Research Institute *Performance Tested Methods*SM Program on January 12, 2022**.**
- Results of the validation study showed the SalQuant™ demonstrated comparable performance to that of the USDA-FSIS MPN reference methods for estimating *Salmonella* spp.

Application Highlights

- **One enrichment, one sample prep, one assay**; no additional equipment, consumables, or steps.
- **Widest enumerable range** across all matrices to facilitate contamination levels observed in sample types taken from farm to final product.
- **Lowest level of enumeration** (1 CFU/g(mL) in order to truly quantify consumer risk.
- **Largest data generation (>100,000 tests)** to develop, verify, and validate on real industry samples across matrices, locations, facilities, instruments, and users for robustness and integrity of results.

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