

## Development and Verification of Hygiena™ BAX® System VibrioQuant™ for Oysters for Quantification of *Vibrio parahaemolyticus*, *V. cholerae*, and *V. vulnificus*

Though the Food and Drug Administration (FDA) monitors oyster beds for *Vibrio* spp. regularly, the methods have limitations when reducing risk to consumers. Moreover, adoption of verified quantification methodologies with reliable results and wide enumerable ranges should be utilized to make data-driven food safety decisions. *Vibrio* can become a resident or transient organism that causes positives results in oyster bays in spring and summer months; however, understanding the amount of organism present can greatly increase the ability for corrective actions and controlling consumer risk.

This verification provides food industries with an accurate, reliable, quantification tool to reduce time to results for oysters when testing for *Vibrio* spp.

### Verification Methods

- The evaluation consisted of 48 individual 25 g oyster samples inoculated with *Vibrio parahaemolyticus* (n=16), *V. cholerae* (n=16), and *V. vulnificus* (n=16) to be tested using the BAX® System Real-Time PCR Assays for *Vibrio*.
- Five distinct inoculation levels ranging from -0.57 to 3.49 Log CFU/g were used to inoculate 25 g of oysters and determine the BAX System recovery of inoculation levels at various time points.
- 25 g of raw, shucked oysters with 250 mL of pre-warmed Alkaline Peptone Water (APW) media incubated at 35° C for 8 h was used to determine recovery results.
- Estimations and comparisons were determined using the BAX System VibrioQuant assay and plate counts.

### Verification Results

- Results of the verification study showed VibrioQuant demonstrated comparable performance to that of the known inoculation levels determined by plate counts for estimating *Vibrio parahaemolyticus*, *V. cholerae*, and *V. vulnificus* in raw, shucked oyster samples.

### Application Highlights

- **One enrichment, one sample prep**, no additional protocols, equipment, or consumables needed to perform both quantification and prevalence testing.
- **Wide enumerable range** to facilitate contamination levels observed in oyster sample types taken from FDA sampled oyster bays.
- **Find positives faster**, utilize the range of quantification to receive faster results for positive samples, resulting in faster decision making and corrective actions.

