

Summary of AOAC-RI Performance Tested Methods Validation for InSite™ Salmonella Media

Hygiena InSite Salmonella utilizes the Paradigm Diagnostics *Salmonella* Indicator Broth (PDX-SIB). This reagent has undergone AOAC-RI *Performance Tested Methods*SM Validation.¹

PDX-SIB is a single step selective enrichment indicator broth to be used as a simple screening test for the presence of *Salmonella spp.* in environmental samples. The test is designed to identify presumptively positive or negative samples for *Salmonella spp.* Presumptive positive samples turn PDX-SIB media from purple to yellow through the fermentation of substrates specific to *Salmonella spp.* The AOAC-RI study includes method comparison between PDX-SIB and the FDA-BAM method.

The findings are summarized here as follows:

- Duration of the tests:
 - FDA-BAM: several incubation and enrichment steps over 3 – 5 days
 - PDX-SIB: one step over 24 – 48 hours
- Inclusivity studies:
 - Inoculated at 10-100 CFU/sample
 - PDX-SIB is sensitive to 99 of 101 different *Salmonella* serotypes
- Exclusivity studies:
 - Exclusion of 33 of 35 non-*Salmonella* Gram-negative species
 - Improved sensitivity for *C. freundii* and *C. koseri* (3 orders of magnitude)
- Surface studies:
 - Four *Salmonella* serovars: *S. Anatum*, *S. Abaetetuba*, *S. Typhimurium* and *S. Newport*
 - Four different surface materials: plastic, stainless steel, sealed concrete and ceramic tile
 - No statistically significant difference between the PDX-SIB method and the FDA-BAM method. PDX-SIB was found to be at least as sensitive as the reference method in all the surfaces studied. In fact, PDX-SIB was slightly more sensitive than the reference method in one of the method comparison studies: five positives for PDX-SIB, versus three for the FDA-BAM method in the stainless steel study.

Substantial equivalence between the PDX-SIB method and FDA-BAM method.

¹ License # 071102