Paradigm Diagnostics Salmonella Indicator Broth (PDX-SIB)
User Guide
Salmonella Test Kit

Intended Use

Paradigm Diagnostics Salmonella Indicator Broth is intended for use in screening environmental samples for the presence of viable *Salmonella* species. Positive samples will exhibit a color change from blue to yellow if *Salmonella* bacteria are growing in the liquid medium. The color change indicates a presumptive positive. Positive samples should be followed up with characterization by cultivation on a selective agar, immuno-diagnostic or genetic analysis such as PCR for confirmation.

Scientific Principal of the Test

PDX-SIB contains selective agents to prevent the growth of competitive microflora while providing nutrients for growth of the resistant *Salmonella*. *Salmonella* are further differentiated from any active background microflora by metabolism of a specific energy source metabolized primarily by *Salmonella*. As the population of *Salmonella* metabolizes the growth substrate, the compound is fermented to an acidic by-product, which turns the pH indicator in the broth from blue to yellow. A yellow color observable after incubation at 37 ± 1^{o}C for 24-48 hours is deemed presumptively positive. Any sample that is not presumptively positive at 24 hours must be incubated for a total of 48 hours to ensure the sample is a true negative.

Diagnostic Performance Parameters

PDX-SIB was subjected to a panel of more than 100 *Salmonella* and non-*Salmonella* organisms. The test exhibited 99% sensitivity. The tests were conducted with inocula at both low (<10 CFU per sample) as well as high (>100 CFU per sample).

Additional Notes

- Environmental samples are best collected with pre-wetted swabs or sponges such as those available from 3M Company, or Whirl-Pak™ Corporation.

Materials and Equipment Required

- An incubator capable of maintaining 32 - 40^{o}C such as an environmental cabinet, a water bath or a heating block.
- Sample collection devices such as sterile swabs, sponges or vials for liquid samples.
- Swabs and sponges should be pre-wetted with commonly employed *Salmonella* recovery media such lactose broth or DE broth.

Confirmation Step

Confirmation of presumptive positive samples can be carried out utilizing selective agars and biochemical tests such as those described in the U.S. FDA Bacteriological Analytical Manual[1] (BAM).

Disposal

Decontaminate the PDX-SIB by autoclave is preferred, bleach or other disinfectant can be used following a validated inactivation procedure in accordance with local, state and federal regulations.

Product Shelf Life

PDX-SIB currently has sixty day of shelf stability documented. The product should be stored at refrigerator temperatures (4^{o}C) to obtain maximum useful life.

Precautions

1. Most *Salmonella* species are human pathogens and enriched samples should be handled employing Good Microbiological Practices.
2. All materials used should be handled and disposed of as potentially infectious material. Autoclaving is the preferred method of disposal. If autoclaving is not available, disinfectant solutions should be used; the disinfection protocol should be validated to inactivate the microorganisms.

[1] www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManual BAM/UCM070149

3. Immuno-compromised individuals are particularly sensitive to infection by *Salmonella* and should not be allowed in the vicinity of the testing.
4. False positives have been observed with high-level inoculations of some *Citrobacter* species underscoring the need for confirmation on by FDA-BAM methods.
5. In two instances false negatives were observed with *S.* Gallinarum and one strain of *S.* Cubana.

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Instruction for PDX-SIB Use

1. Sampling: Environmental samples can be taken with a range of commercially available pre-wetted sterile collection devices, such as Whirl-pak™ bags (available through Fischer Scientific), and Tecra Enviroswabs™ (available from 3M Company). Swabs wetted with any of the acceptable wetting agents, DE, Lactose broth or BPW are sufficient. Samples should be held at room temperature for preferably six hours, to permit recovery of sub-lethally injured cells. Transfer the contents of the screw-cap vials (15 mL of SIB: blue solution) to the bag or Enviroswab plastic container. Place the sample back into the incubator and hold for 24 to 48 hours at 37 ± 1^{o}C.

2. Interpretation: At or before 48 hours of incubation presumptively positive samples will turn **yellow** due to the accumulation of acidic metabolic products. **Blue** samples must be held for 48 hours and remain blue to be deemed negative.

3. Positive samples can be confirmed by streaking onto a selective agar, such as the XLD agar. Additional selective differential media such as bismuth sulfite and Hektoen agars aid in confirmation of Salmonella species. Plates should be incubated at 37 ± 1°C a minimum of 24 hours. Positive colonies should be streaked onto Lysine Iron Agar and Triple Sugar Iron slants as well as additional biochemical panel analyses, such as are available from bioMérieux (API) or Microgen. Alternative confirmation methods are described in the most recent publication of the FDA-BAM.

4. The PDX-SIB method has been certified through the AOAC Research Institute *Performance Tested Methods*SM Program for detection of *Salmonella* on four environmental surfaces; stainless steel, plastic, sealed concrete and ceramic tile.

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