

Salmonella Zephyr Assay

CANARY® Biosensor

The CANARY®- Zephyr System allows for unparalleled detection of low levels of *Salmonella* in less than 5 minutes.

CANARY® technology was developed by MIT-Lincoln Laboratory under a DARPA contract, and commercialized by PathSensors, Inc. The technology utilizes biosensors created from B lymphocytes (white blood cells) modified to express surface-bound, target-specific antibodies and a bioluminescent protein. When the biosensor binds to its target pathogen, the antibodies trigger the intracellular release of calcium. This calcium causes the bioluminescent protein to emit light. Sophisticated algorithms analyze this light output, resulting in definitive “positive” or “negative” test results.

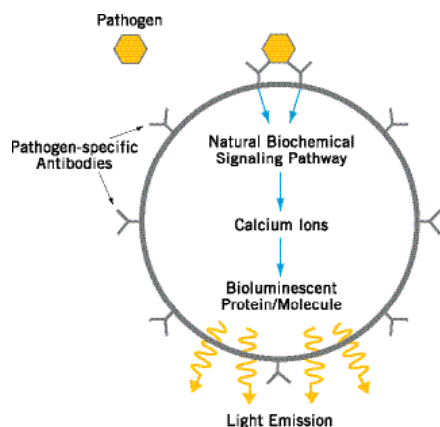
Advantages of this system are its extreme speed and sensitivity. The speed of detection is a result of rapid intracellular signaling. The sensitivity is achieved through signal amplification within the cell. This leading edge technology identifies targets in 3 minutes with analytical sensitivities down to 10's of CFU of target per sample.

Assay Specifications

Analytical Sensitivity (LoD) *Salmonella enterica subsp. enterica serovar:*
 Typhimurium = 10-1000 cfu/mL
 Enteritidis = 100-1000 cfu/mL
 Gallinarum = 40-100 cfu/mL
 Heidelberg = 100-1000 cfu/mL

Cross-Reactivity None Known

Time to Results 5 minutes



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MADE IN THE USA

Testing Protocol:

Start Zephyr Program.



Enter Cartridge I.D.



Place a vial containing 1 mL of the test sample (enrichment media or rinsate) into the Zephyr Centrifuge. Spin for 2 minutes.



Remove Sample Supernatant.



Add 250uL of Assay Buffer to the Test Sample and place the vial into the Zephyr System centrifuge. Spin for 2 minutes.



Enter Sample I.D.



Add 20uL of *Salmonella* Biosensor Reagent into the test tube cap and place into the Zephyr System centrifuge.



Transfer Test Sample to the Luminometer.



Light output of Biosensors will be read for 1 minute.



RETRIEVE POSITIVE OR NEGATIVE RESULT

Salmonella Inclusivity/Exclusivity

Inclusivity

All Positive

56 Salmonella strains –

17 strains of *S. typhimurim*

21 strains of *S. enteritis*

4 strains of *S. Newport*

3 strains of *S. Heidelberg*

5 strains of *S. Kentucky*

>20 direct food isolates

Exclusivity

All Negative

Citrobacter fruendi (3)

Citrobacter diversus (2)

Enterobacter cloacae

E. coli (5)

Listeria innocua

Listeria monocytogenes

Listeria ivanovii

Listeria seeligeri

Listeria welshimeri

Listeria grayi

Salmonella Testing in Various Matrices

Positive (PPV) & Negative (NPV) Predited Values

Test Outcome:		Positive by culture	Negative by culture	
Salmonella testing of lettuce cultured in tetrathionate (TT) broth.	Positive by Zephyr	45	2	PPV = 0.96
	Negative by Zephyr	0	17	NPV = 1.00
<i>Field testing performed at the FDA.</i>				
Salmonella testing of lettuce cultured in Rappaport-Vassiliadis (RV) medium.	Positive by Zephyr	44	1	PPV = 0.98
	Negative by Zephyr	0	19	NPV = 1.00
<i>Field testing performed at the FDA.</i>				
Salmonella testing of spices (mustard and cinnimon) from pre-enrichment samples in tryptic soy borth (TSB).	Positive by Zephyr	29	0	PPV = 0.97
	Negative by Zephyr	1	5	NPV = 1.00
<i>Field trials conducted at PathSensors with blind test samples supplied by a client.</i>				
Salmonella testing of turkey neck skin rinsattes with no enrichment.	Positive by Zephyr	20	0	PPV = 1.00
	Negative by Zephyr	0	20	NPV = 1.00
<i>Field trials conducted at PathSensors with test samples supplied by a client.</i>				



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