



October 23, 2018

To: Gervaise Wilhelm

From: Alan Olstein

Re: Preliminary report on LIB 2.0 field trials results.

Rationale and objective

We have had several reports concerning the performance characteristics of product, PDX-LIB, an environmental screening test for identifying presumptive positive swabs with *Listeria* contamination. Reports suggested that LIB results in unacceptable levels of false positive *Listeria* results. Therefore we have undertaken to modify the LIB formulations to render it more restrictive to *Listeria* sp. without sacrificing the products' sensitivity. Laboratory studies allowed us to identify the best candidate to replace LIB with. We have designated this product, LIB 2.0. We commissioned Professor Joellen Feirtag of the University of Minnesota to conduct a series of field trials in which identical samples were enriched using the original LIB formulation and LIB 2.0. The presumptive positive samples were identified and confirmed as *Listeria* sp. by plating onto modified MOX medium and PCR, following procedures described in the FDA Bacteriological Manual¹.

Results

Table 1 summarizes the results of the filed trials to date.

Medium	Total Samples	Presumptive Positives	Negatives	TP	TN	FP
LIB	91	13	78	3	88	10
LIB 2.0	91	3	88	3	88	0

TP=true positive, TN=true negative, FP=false positive

Data is attached as appendix A.

¹ Available at:

<https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm279532.htm>.

Discussion and conclusion

The field trial data while on-going support the conclusion that the changes to the LIB formulation appear to address the issue of higher than desirable false positive results, by reducing the false positives between LIB and LIB2.0, 100%, without sacrificing the sensitivity of the method. Further the data collection cites (see Appendix A) reflect a broad range of potential food processing environments and products. We are still gathering field data and will update this information as the data become available.

Appendix A

Ready to Eat Food Facility			
Location	OLD - LIB	NEW - LIB	MOX
Cooler 1: Aisle A: Pepper Pallet	NEG	NEG	
Squeege in Cooler 2	NEG	NEG	
Curtain between coolers 1 & 2; aisle A	NEG	NEG	
Curtain between coolers 2 & 3; aisle A	NEG	NEG	
Wood under Plate Cooler 2	NEG	NEG	
Dampness behind Wood on floor	POS	NEG	NEG
Blue CHEP pallet Cooler 3 (damp)	NEG	NEG	
Cooler 3 darin	NEG	NEG	
Wood Pallet (damp) Cooler 3	NEG	NEG	
Floor Under Rack (105) wet - cooler 3	NEG	NEG	
ICE from case of Brussel Sprouts Rack 105 Cooler 3	NEG	NEG	
Underneath Table 26; School Cooler	NEG	NEG	
Inside of Floor Scrubber lid	POS	NEG	NEG
Blue Filter of Floor Scrubber reservoir	NEG	NEG	
Inside of Floor Scrubber hose	POS	NEG	NEG
Floor Scrubber Brush	NEG	NEG	
Dishwasher Floor Drain (Bin cleaning area)	POS	NEG	NEG

Meat Processing - Fermentation/Drying			
Location	OLD - LIB	NEW - LIB	MOX
Drain in packaging room	NEG	NEG	
Vacuum Machine	NEG	NEG	
Under Packaging Room table	NEG	NEG	
Dishwater room drain	POS	NEG	NEG

Underneath foot stool	NEG	NEG	
Handsink drain	NEG	NEG	
Squeegee	NEG	NEG	
RTE room drain by ECA device	NEG	NEG	
Drain in cooked cooler	NEG	NEG	
Coving in cooked cooler	NEG	NEG	
Smoke cart wheels	POS	NEG	NEG
Black cart wheels	NEG	NEG	
Dishsink drain right	NEG	NEG	
Dishsink drain middle	NEG	NEG	
Dishsink drain left	POS	NEG	NEG
RTE floor drain outside aging cooler	NEG	NEG	
Raw Door Floor	POS	NEG	NEG

RTE Food Facility/Sandwiches/Salads	OLD - LIB	NEW - LIB	MOX
Cooling Unit # 1	NEG	NEG	
Cooling Unit #2	NEG	NEG	
Cooling Unit #3	NEG	NEG	
Cooling Unit #5	NEG	NEG	
Cooling Unit #6	NEG	NEG	
Drain #14	NEG	NEG	
Drain #15	POS	POS	LM
Line #3 Bag hole	NEG	NEG	
Threshold Swing Door #3	NEG	NEG	
Threshold Swing Door #2	NEG	NEG	
Threshold Swing Door #1	NEG	NEG	
Above ceiling in Wash Room	NEG	NEG	
Threshold H&C cooler door fr. St	NEG	NEG	
Drain #27	NEG	NEG	
Threshold M&C cooler door fr. Rec	NEG	NEG	
Receiving Threshold	NEG	NEG	
Drain # 9	NEG	NEG	
Threshold shipping cooler Door #2	NEG	NEG	
Mat in Hallway QA office	NEG	NEG	

Retail Store Food Areas			
Deli - Back Room	OLD - LIB	NEW - LIB	MOX
Drain in front of raw chicken sink, inside	POS	POS	LM
Drain in front of 3-compartment sink, inside	NEG	NEG	
Drain in back wall underneath racks	NEG	NEG	
Inside condenser pipe in-between racks by drain #7	POS	NEG	NEG

Drain underneath food prep sink	NEG	NEG	
Mop sink	NEG	NEG	
Drain behind ice machine	NEG	NEG	
Top of dishwasher	NEG	NEG	
Drain under dishwasher (no cover)	NEG	NEG	
Drain in front of Deli cooler	NEG	NEG	
Produce Cooler	OLD - LIB	NEW - LIB	MOX
Inside access port - drain plug - Produce cooler	POS	NEG	NEG
Wall in Produce cooler	NEG	NEG	
Cooling unit guard inside Produce cooler	NEG	NEG	
Frame of shelf in Produce cooler (left side)	NEG	NEG	
PRE - by drain in produce cooler - water present	NEG	NEG	
PRE - water on floor of produce cooler below box	NEG	NEG	
Outside box of produce that was dripping bottomshelf	POS	POS	LM
hole in wall right side middle	NEG	NEG	
shelf leg by floor right side	NEG	NEG	
shelf leg by door	NEG	NEG	
bottom shelf where iced produce sits	NEG	NEG	
middle shelf where iced produce sits	NEG	NEG	
shelf where organic produce sits	NEG	NEG	
coving on left side by iced produce	NEG	NEG	
hole in wall left side by iced produce	NEG	NEG	
water on floor where cut fruit sits	NEG	NEG	
Deli (Front Room)	OLD - LIB	NEW - LIB	MOX
Food prep sink drain + underneath cover	NEG	NEG	
Drain underneath Combi Oven (cover)	NEG	NEG	
Drain under Food Prep Sink	NEG	NEG	
Café	OLD - LIB	NEW - LIB	MOX
Drain under soda fountain	POS	NEG	NEG
Drain in front of dishwasher	NEG	NEG	
Drain under 3-compartment sink	NEG	NEG	
Drain under prep sink	NEG	NEG	
Drain by mop sink	NEG	NEG	
mop sink	NEG	NEG	
Coffee Shop	OLD - LIB	NEW - LIB	MOX
Drain under sink	NEG	NEG	
Foam drain for coffee maker machine	NEG	NEG	
Drain under milk/coffee bar	NEG	NEG	