To Be Positive…Find Positives.

Why a Better Pathogen Test Matters

Kenna Huff, RM (NRCM)
Field Applications Specialist

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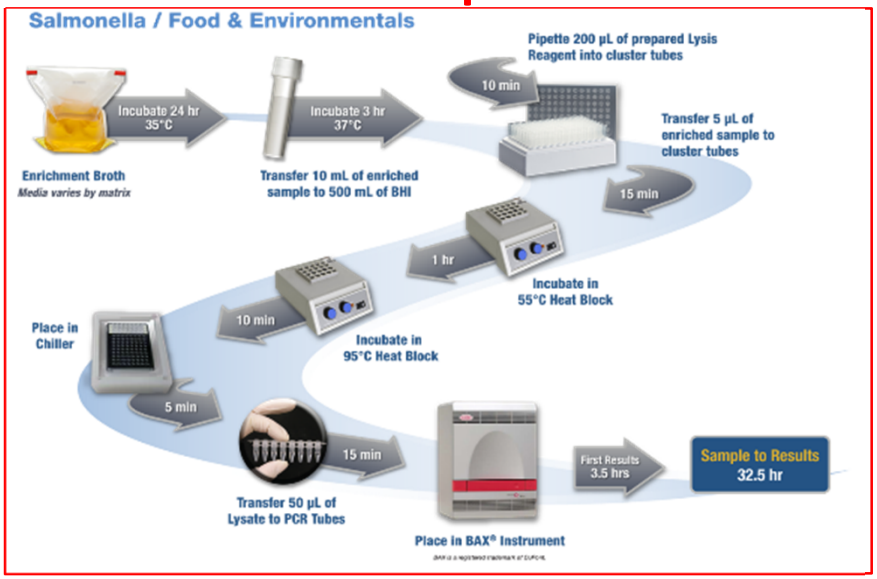
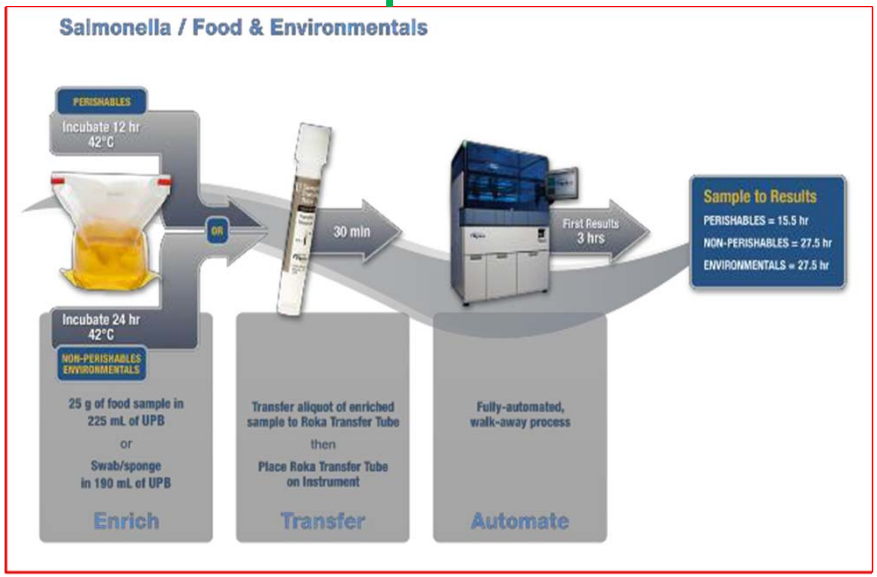
The Atlas Advantage

Single Step Sample Processing

10+ Steps on PCR



1 Step on Atlas



Confidence:

Fewer Touchpoints = Fewer Operator Errors

Improved Workflow and Higher Quality Results from your Laboratory

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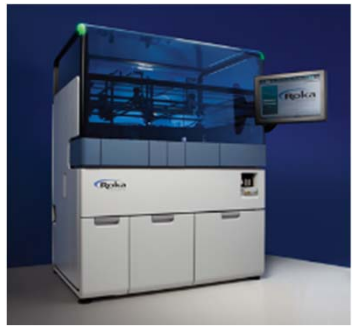
Atlas® System
Walkaway Automation Post Enrichment

Continuous Access	• Flexibility and time to results improved with no need for sample batching • Minimizes sample prep resource allocation
Integrated Process Controls	• Removes operator to operator and lab to lab variation • Ensures accurate, actionable results
Complete Electronic Audit trail	• No manual transcription required • LIMS compatible
Greater Laboratory Efficiency	• Minimized hands-on time • >300 Samples in 8 h throughput with a single user • Automation pays for itself in 6-9 months



Accurate, consistent, and actionable picture of your Risk Management program

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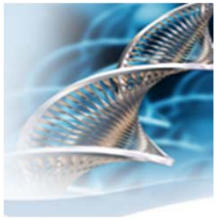

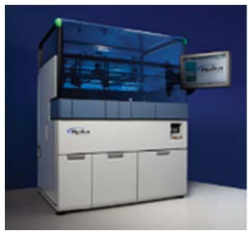

RNA	Isolate with Target Capture	Amplify Via TMA	Detect through HPA	Automate on the Atlas System
More copies per cell enables lower limit of detection & faster time to result	Removes interferences to minimize false negatives and indeterminate	Isothermal process allows for automation and faster results	Single base pair specificity to reduce false positives from cross reactors	Minimize operator error and provides complete electronic traceability

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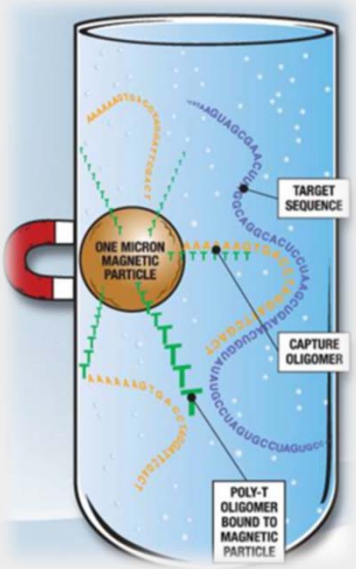
How Can Roka's Technology Help?

Target Capture



Remove Matrix Inhibition
- Lipids, polyphenols, pH, salts
- Other unknown inhibitory compounds

Removes Competing Microbial Flora
- Increases sensitivity
- Removes cross reactors

Flexible Sample Volume
- Purifies and concentrates target sequences for amplification

Improves Accuracy
- Reduced false positives
- Reduced false negatives

Be Certain. Lower risk with accurate Atlas results.

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Recalls in 2016

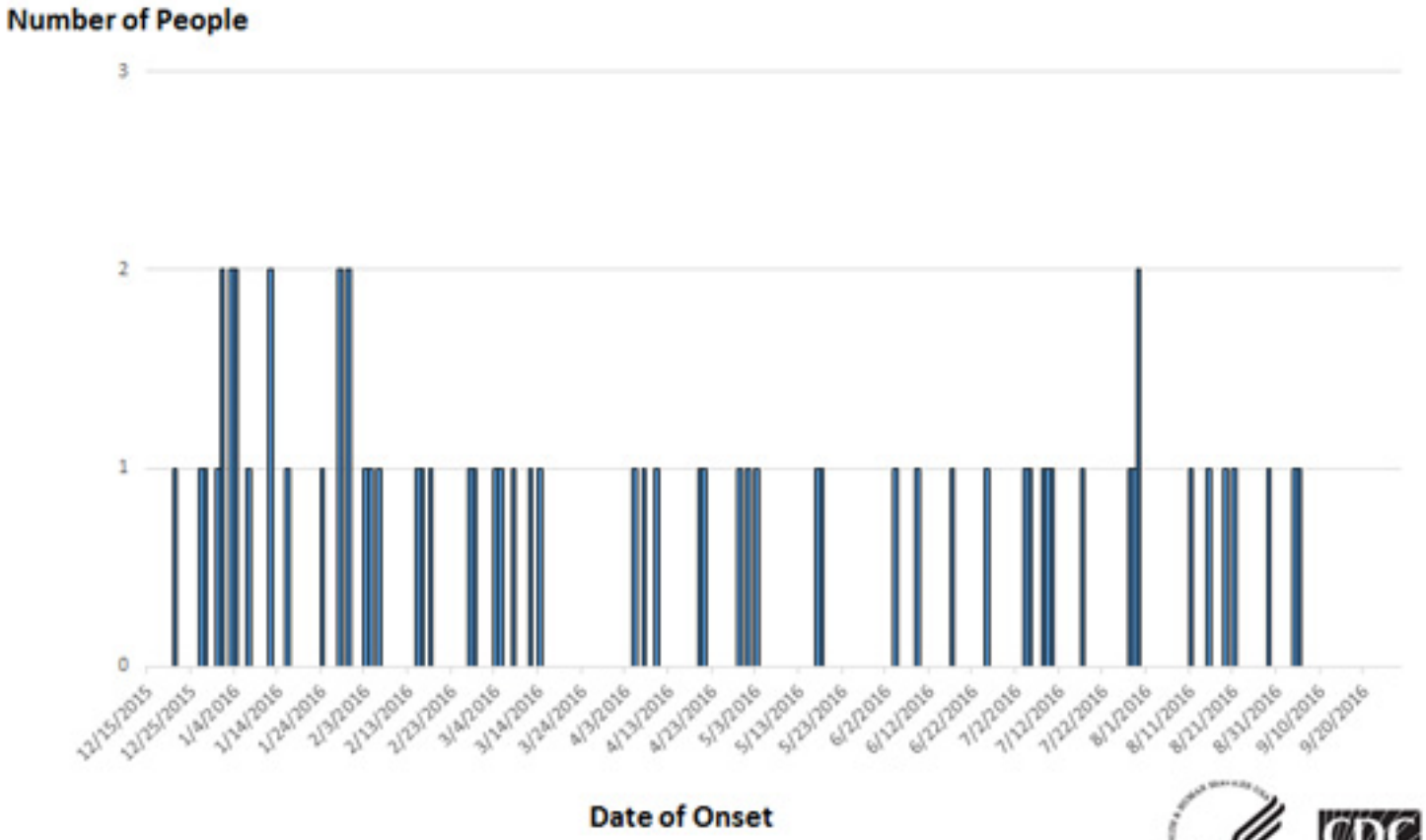
>125 Recalls

"[One] scenario that is all too familiar is waiting for positive data to drive changes in design. That is attacking* Listeria *after it has crossed enemy lines…way too close for comfort. Don't wait for positive data to start making changes. Don't wait for the enemy to get that close"
- Christine Hurckes, OSI Group, from National Provisioner

Multistate Outbreak of Shiga toxin-producing *Escherichia coli* Infections Linked to Flour

- 63 people infected with the outbreak strains of STEC O121 or O26 were reported from 24 states.
- 17 ill people were hospitalized. One person developed hemolytic uremic syndrome, a type of kidney failure. No deaths were reported.
- Epidemiologic, laboratory, and traceback evidence indicated that flour produced at a General Mills facility in Kansas City, Missouri was the likely source of this outbreak.
- Multiple recalls occurred as a result of this investigation.

Multistate Outbreak of Shiga toxin-producing *Escherichia coli* Infections Linked to Flour



CDC

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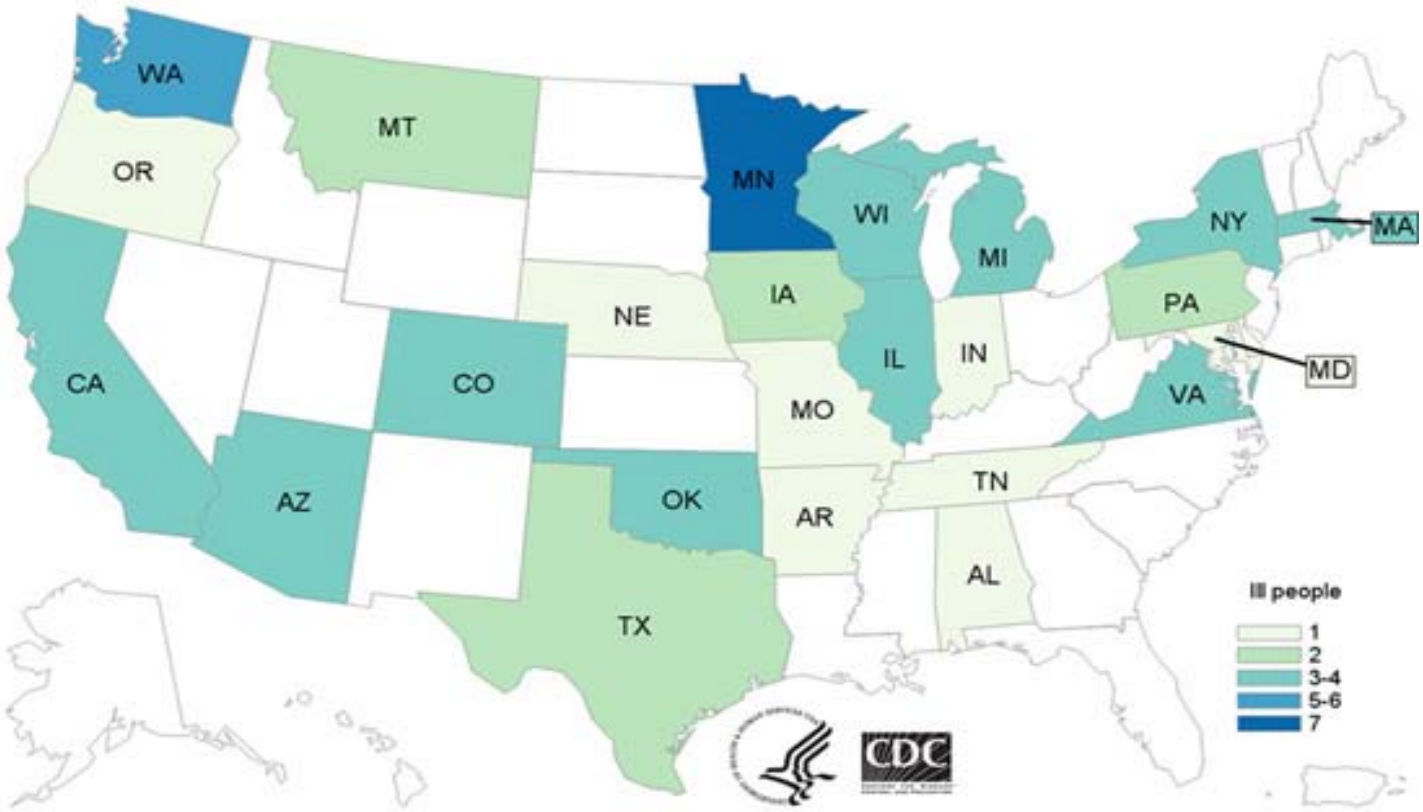
Multistate Outbreak of Shiga toxin-producing *Escherichia coli* Infections Linked to Flour



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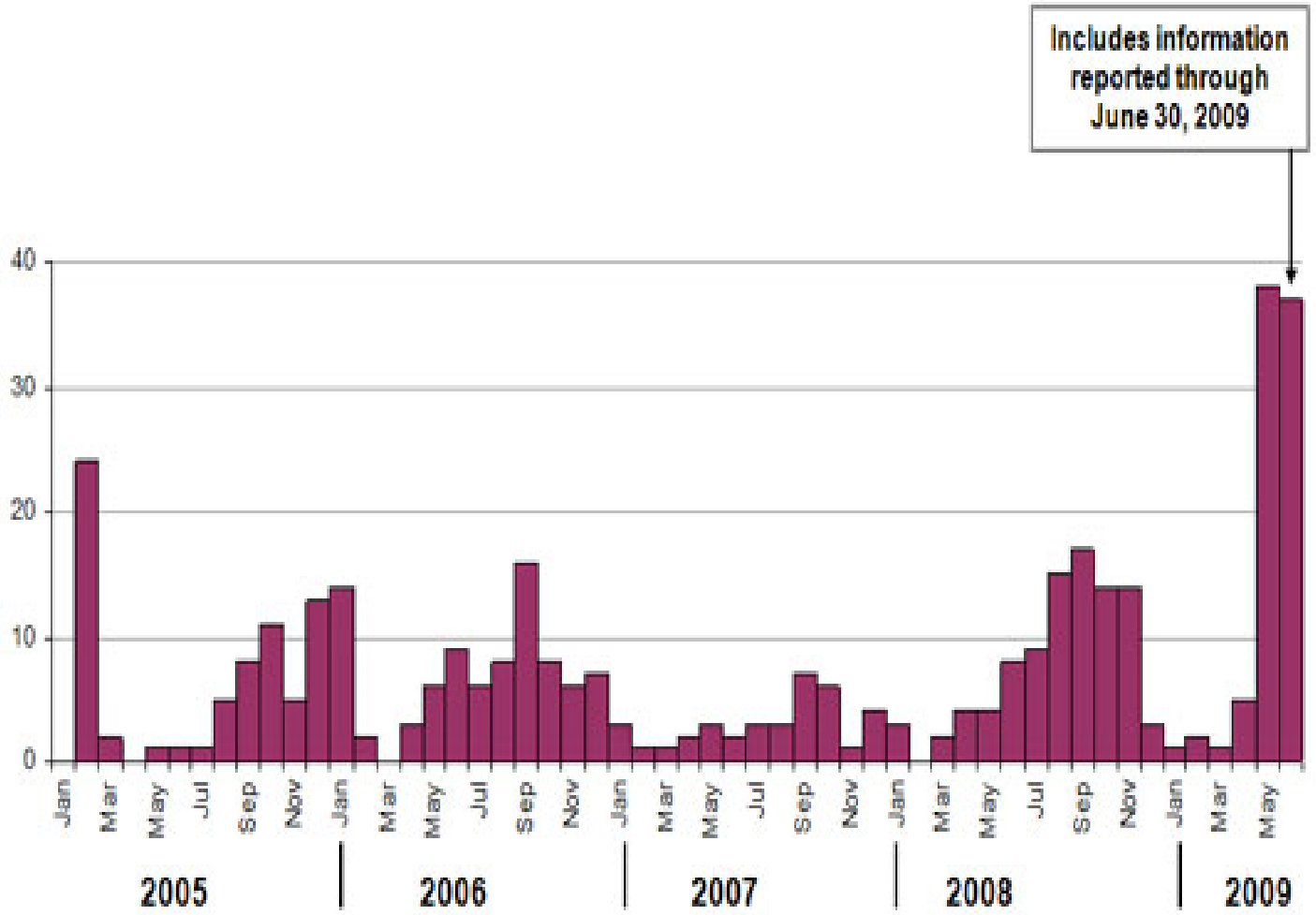
Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Eating Raw Refrigerated, Prepackaged Cookie Dough (FINAL UPDATE)

- 72 persons infected with a strain of *E. coli* O157:H7 with a particular DNA fingerprint have been reported from 30 states.
- Of these, 51 have been confirmed by PFGE and MLVA as having the outbreak strain.
- A culture of a sample of prepackaged Nestle Toll House refrigerated cookie dough yielded *E. coli* O157:H7. The contaminated sample was collected at the firm on June 25, 2009.
- The isolate had a different PFGE than the outbreak strain.

Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Eating Raw Refrigerated, Prepackaged Cookie Dough (FINAL UPDATE)



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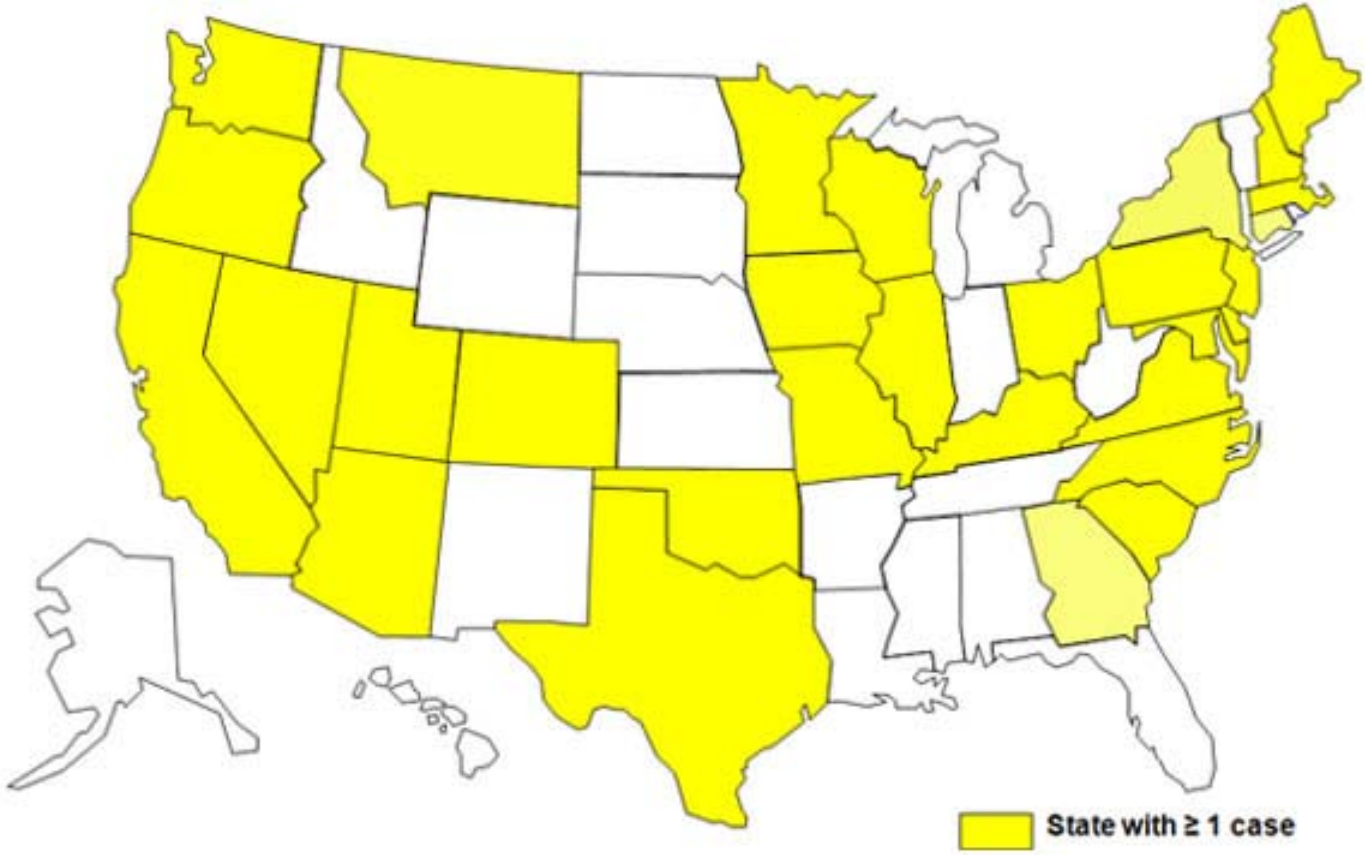

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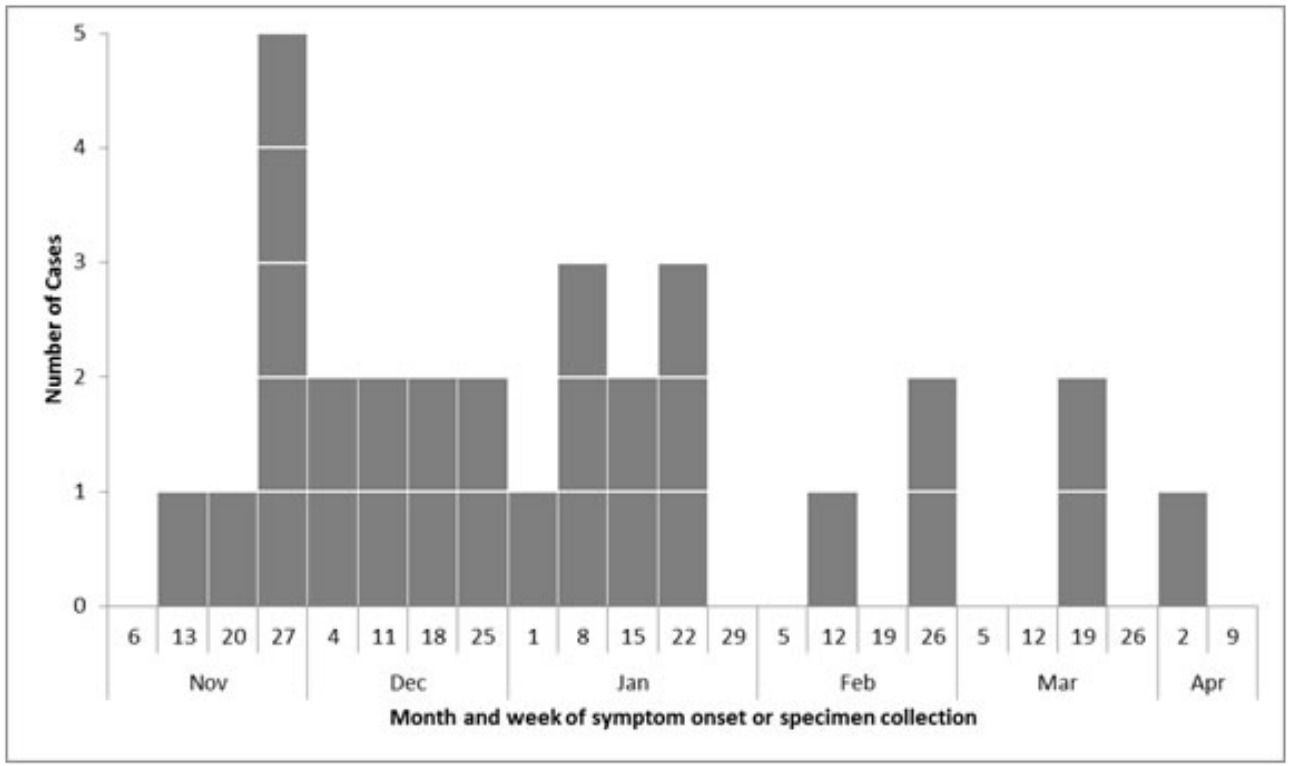
Continuing Trend in 2017

Figure 1: Number of people infected with E. coli 0121



- 28 people in Canada were infected with *E. coli* O121 from Ardent Mills Flour in 2017

Wheat Market Prevalence Data

	N	# Positive	% Positve
Salmonella	3,891	48	1.23%
EHEC	3,891	17	0.44%
Listeria spp	1,285	1	0.08%
Listeria mono	1,285	0	0
E. coli O157	3,891	0	0

- Control of your environment and ingredients are crucial to prevent cross contamination in your environment
- Powders such as flour can migrate through your facility

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Environmental Testing:
Ghosts of Sampling Past:

- Testing for the negatives
- Cursory pathogen control plans
- “Check the box” mentality

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Program Goal

Environmental Sampling Program

Can be designed two ways:

Find it		Don't Find It
Find the positive: Proactively search for pathogen harborage	or	"Prove" the negative: Monitoring that shows the absence of pathogens

Seek → Discover → Destroy

Finding the positives will transform your operation from:

Reactive Crisis Modes

Proactively managing minor variation

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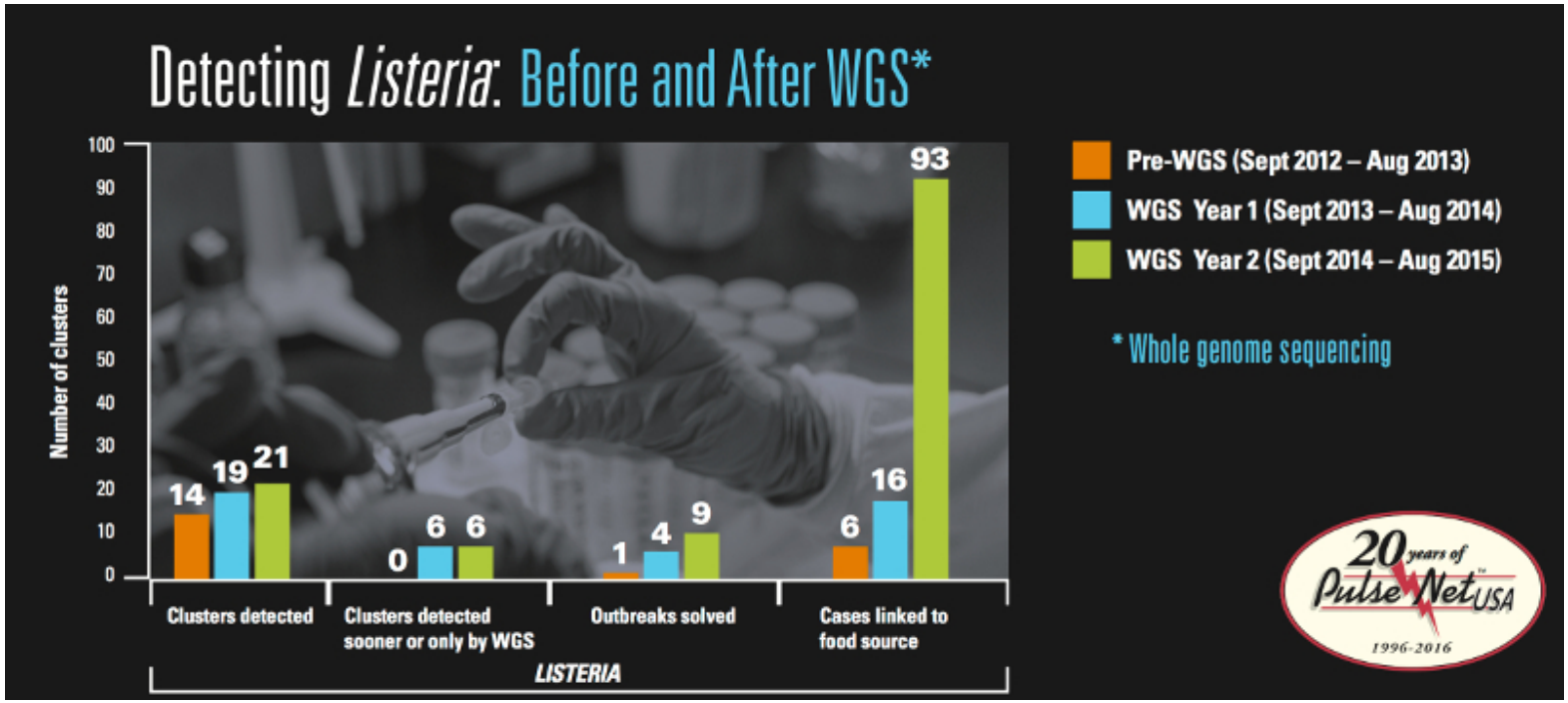
Why it is more important than ever to know <u>your environment</u>



* Food Safety News, Monday April 5, 2016

93 Cases linked to Food in Year 2 of WGS

Technology is being rolled out to the state level over the next two years

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Most Environmental Sample Processing

Collection

Magical Sample Fairy (Courier, FedEx etc.) delivers samples to a lab for testing

Results reported 2-4 days later

If this sounds familiar, you are missing the whole story

And that story could be adding higher risk to your program

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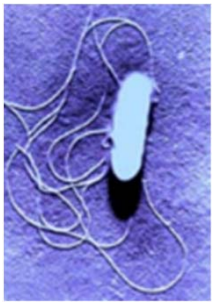
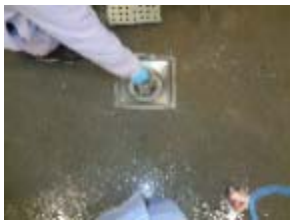
Anatomy of Environmental Sample Testing

Listeria spp., Salmonella spp., STEC



Sanitation & Collection



Sampling Device & Buffer/Broth

Enrichment Media & Incubation Time

Detection Method

Culture Method

Each step can impact both the ability to detect *Listeria* spp. in your environment and subsequently culture confirm

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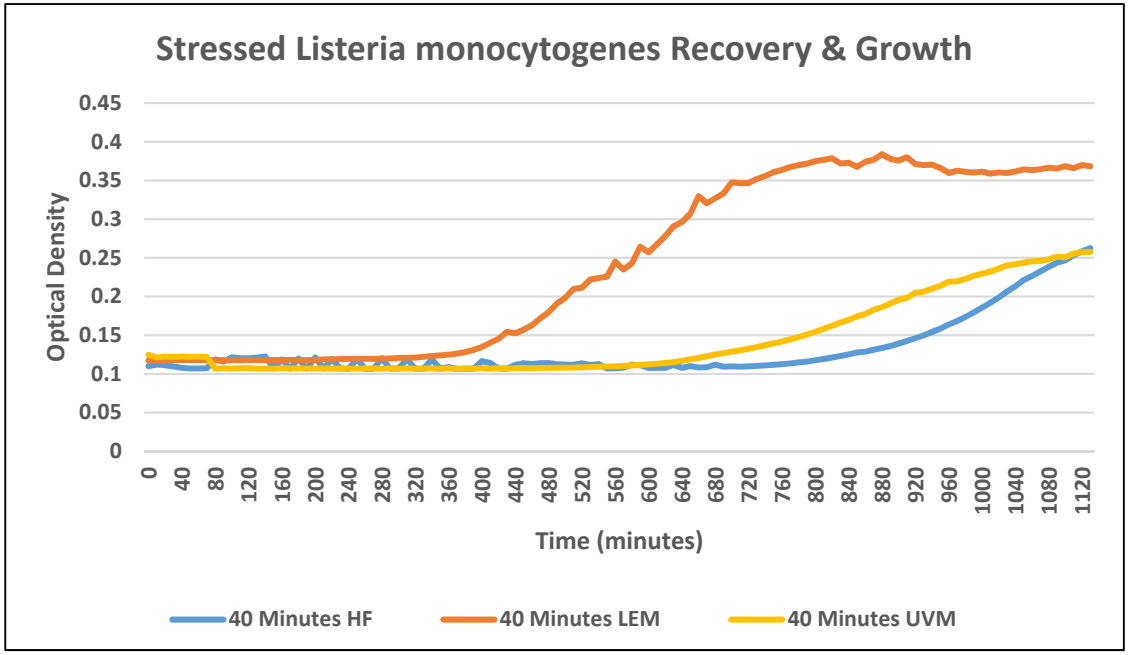
Anatomy of an Environmental Sample Enrichment Media: *It's more than speed*

Enrichment Media can dramatically improve the lag phase length and log growth of stressed bacterial pathogens



When paired with a sensitive detection method, faster time to results can be achieved **without** compromising quality or increasing risk.

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Where Does the Pathogen Test Fit?

Significant Investment Focused on……

Your Pathogen Test Matters:

Serving as the lens that monitors the effectiveness of your investment & preventative control plan

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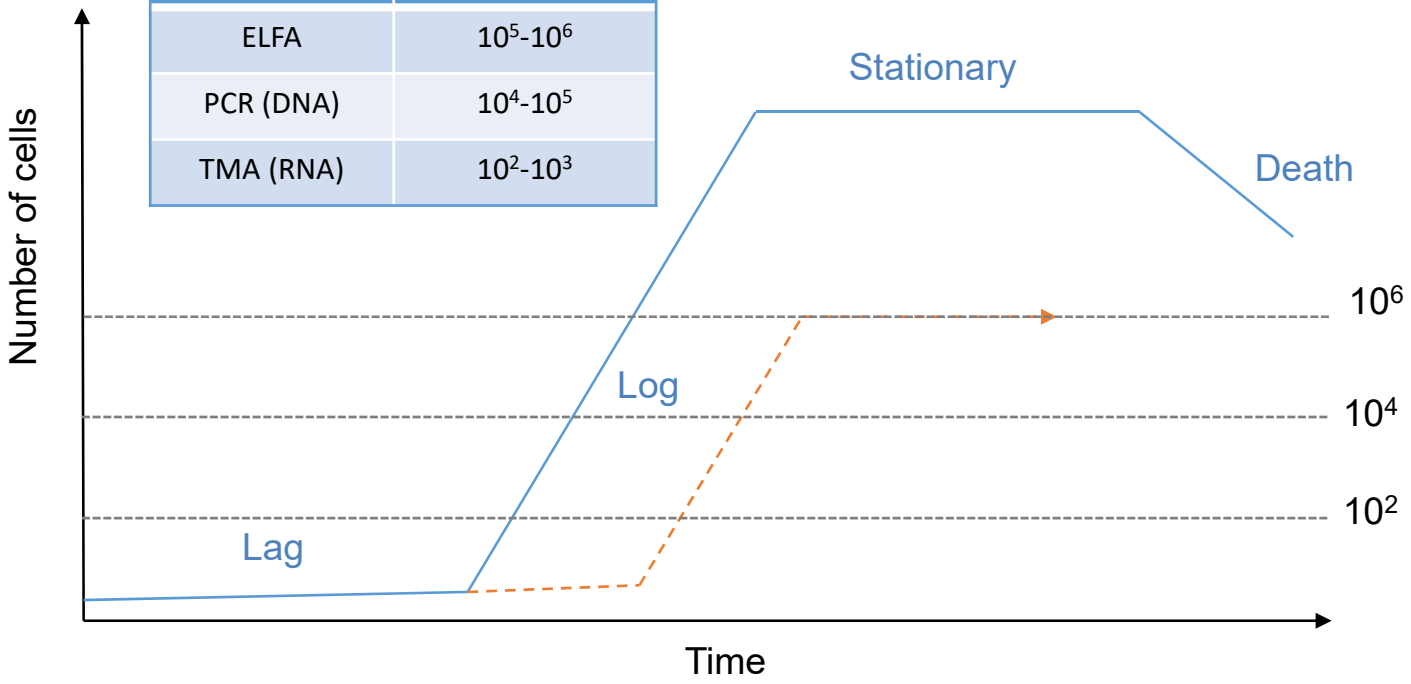
Detection Methods

If you want to culture confirm, the collection, enrichment, and confirmation need to be maximally nutritive

BUT

If you truly want to find it: You need to be using a sensitive detection method

Technology	LOD (CFU/mL)
ELFA	10^5-10^6
PCR (DNA)	10^4-10^5
TMA (RNA)	10^2-10^3



A detection method with a low LOD can overcome performance challenges created by less than optimal conditions in other steps of the environmental testing process

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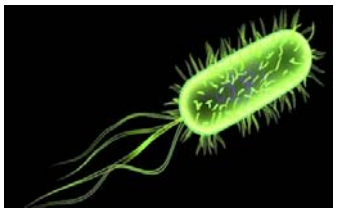
Historical Challenges: Environmental Samples &Testing

Swab sites can be dirty with significant amounts of both particulate & background flora

Sanitizers & cleaners can inhibit both ELFA & molecular reactions



Low level prevalence can prevail in small niches of manufacturing environment

Negative results are rarely, if ever confirmed to ensure method performance

Competition in growth media (false -) and potential cross reactors (false +)

Inhibition of method or generation of low level positivity (Invalids or false -)

Lack of detection of biofilm formation can cause pervasive issues in same area

No true picture of environment, preventing effective mitigation until growth is significant

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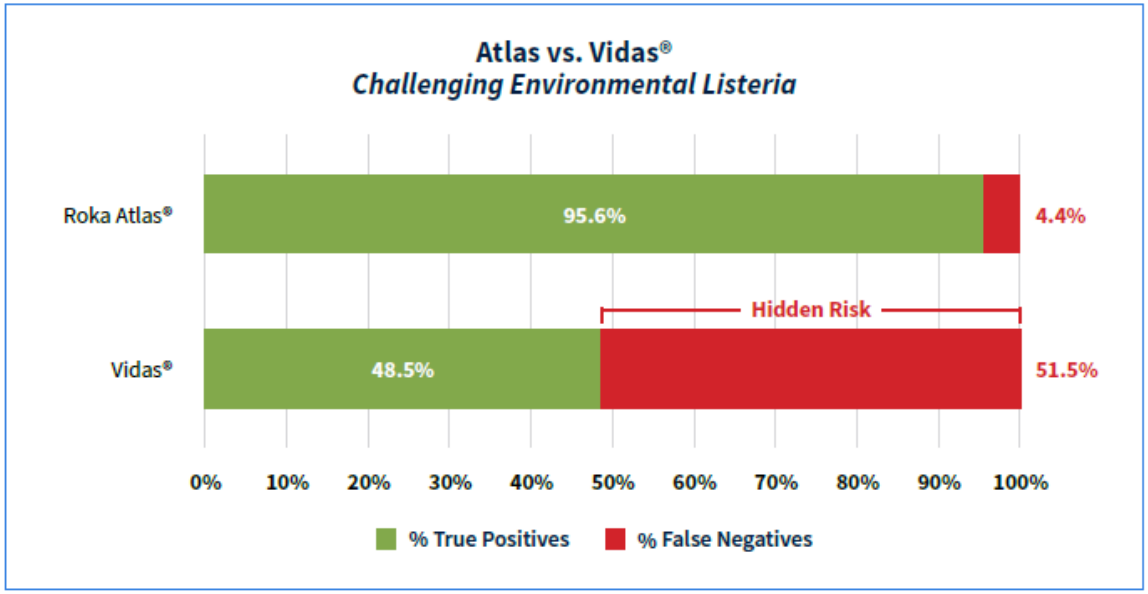
Is there risk currently hiding in your results?

“It ain't what you don't know that gets you into trouble. It's what you know for sure that just ain't so.”- Mark Twain(?)



Your detection method plays a critical role in the understanding of your pathogen control program and applied interventions.

Using a method that does not provide a clear lens could be masking risk in your environment.

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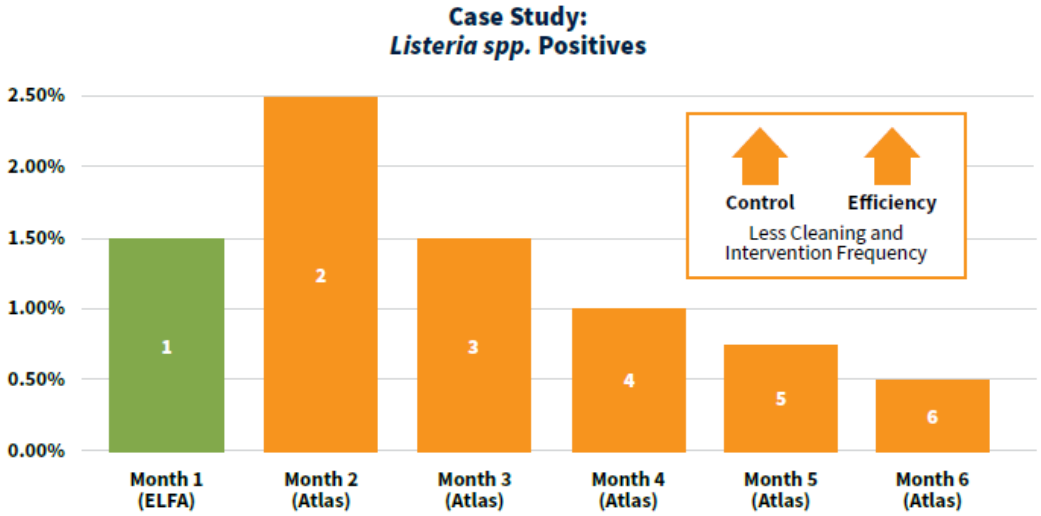
Detection Method: The Payoff of a Proactive Food Safety Culture

❶ Years using dated detection technology created a baseline of around 1.5% which did not improve

❷ Switch to Atlas initially increased positivity slightly- Now Finding the positives and risk that was lurking in the environment.

❸ Interventions and Mitigations "Seek and Destroyed" new identified risk in manufacturing.

❹ Further mitigations and identification has enabled the company to reduce risk below initial levels in less than 3 months.



Payoff:

- Dramatically reduced hidden risk in their environment
- Improved intervention effectiveness, efficiency & process control
- Within 3 months reduced downtime and sanitization costs

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Key Takeaways

- **The new regulatory environment and incorporation of WGS has enabled a more effective, efficient source trace back to outbreaks and recalls**
- **The consequences of recalls & outbreaks has been elevated**
- **New technology and detection method can provide higher resolution, lowering your risk, and enabling more effective preventative control programs.**
- **Your Detection Method Matters**

Be Proactive | **Be Inquisitive** | **Be Positive**

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So what can you do today?

Build the Right Food Safety Culture

- Finding a positive is a positive
- Do you have a Environmental positive metric (<3% acceptable)
- When you find a positive what do you do? Clean and go? Vector? Stop Sampling there?

Bypass the Sample Fairy and Ask Questions

- What method are you using to test samples?
- Have you validated it for my sanitizers, etc. ?
- Am I missing positives- test your negatives
- DO NOT Shop for the Negative!

Play FDA for a Day

- Do a high resolution, deep dive self audit to understand your risk

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Thank you

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