Designing an EMP that gets you results

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Main Takeaways

- Focus the EMP on the packinghouse
- Clearly identify what you are testing for (*Salmonella, Listeria* spp., something else) and why
- Expect to find (*Listeria*) positives!
  - Success is judged by your corrective actions
  - 'Seek and destroy' ≠ "I sanitized the drain and got 3 negatives afterwards"
- Zone 1 sampling for *Listeria* species can be a useful, and manageable tool within an aggressive environmental monitoring program

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Primary Objectives of EMPs

- Preventing transient *pathogens* from becoming entrenched, forming biofilms
- Verifying existing control measures are effective
- Detecting *pathogens or their indicators* that have become entrenched in the produce handling environment before they can spread to the point of contaminating product, causing illness
- Determining & taking appropriate corrective action

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Transient vs. Resident: what's the difference?

- **Transient isolate:** a one-time isolate whose repeated presence via swabbing is not detected (minimum 3 consecutive negative results)

- **Resident isolate:** an isolate that is repeatedly found, indicating a potential lapse in GMPs or existence of an undiscovered niche which has allowed for a harborage site to be established

Produce Challenge = no kill step!

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What does an EMP consist of?

- A written, documented program, specifically detailing
  - Type of samples being taken
  - Sampling locations and Zones
  - Number of swabs being collected
  - Sampling frequency and timing
  - Testing method
  - Personnel training
  - ‘Special event’ contingency plan
  - Corrective Action and Root Cause Analysis strategy

- It’s not just sanitation and sampling
  - Hazard analysis of your facility, traffic flow, equipment design, condition of drains/floors

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Where to start?

- Have a clear purpose in mind

- Ask yourself – what would a positive (or negative) finding in ‘X’ location tell me? How would I react?

- Focus wherever you are most likely to find a positive
  - Cracks, crevices, damaged floors/equipment, etc..
  - Certain areas provide more useful information at certain times in production
    - Ex: Drains, Food contact surfaces

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Types of Samples: *Listeria, Salmonella,* or other

- *Listeria* –cool, damp/wet environments
  - Spp. – an indicator
  - *Monocytogenes* – the pathogen
- *Salmonella* – in a packing operation, not as likely to be an issue
  - pathogens
- Other (total/ aerobic plate count, coliforms, *Enterobacteriaceae,* generic *E. coli)*
  - Not pathogens
  - Could be indicators of general hygiene/ sanitation

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Types of Samples: *L. monocytogenes* vs. *Listeria* spp.

- To eliminate harborage sites, you need to find them
- *Listeria* spp. more commonly found in environment; if they can grow, so can *L. mono*
- Within reason, treat each *Listeria* spp. positive as if it were *Lm*

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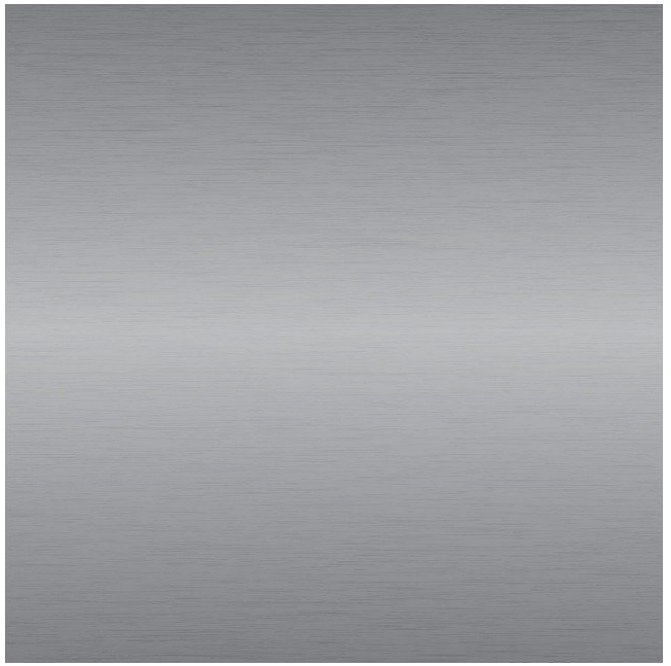
How many swabs?

- A few here:
- Niches:
  - Hollow rollers, table legs, etc.; floor wall junctures; floor cracks; difficult to clean areas; seals on doors, etc.
  - Sampling of niches more likely to identify source
- Transfer points:
  - Hands, door handles, floor, pallet jacks, trash cans
  - Sampling of transfer points requires follow up to identify source

- Could be better than a lot here:



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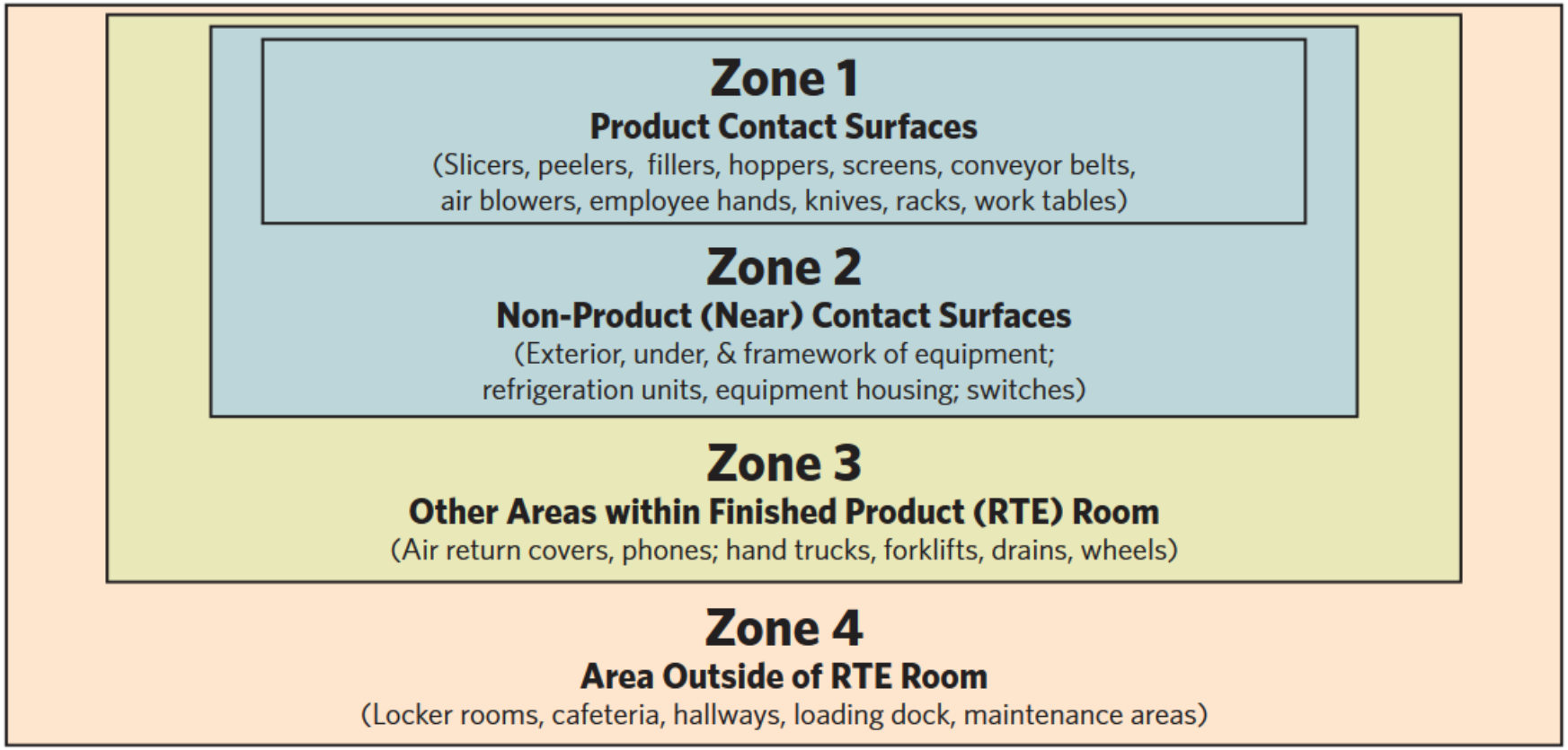
Zoning



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Why would I focus my sampling in:

- Zone 4
  - verifying your sampling program
    - Most likely to find +s
  - detecting ingress points

- Zone 3
  - Identifying **niches** and **harborage** points that can accumulate moisture and nutrients from the environment that can be transferred to Z2 and Z1

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Why would I focus my sampling in:

- Zone 2
  - Areas most likely to harbor bacteria
  - Areas most likely to transfer to Zone 1, *especially* after equipment has been running

- Zone 1
  - *Listeria* specific verification of sanitation processes (vs. ATP swabbing)
  - Recommended as a part of an aggressive EMP

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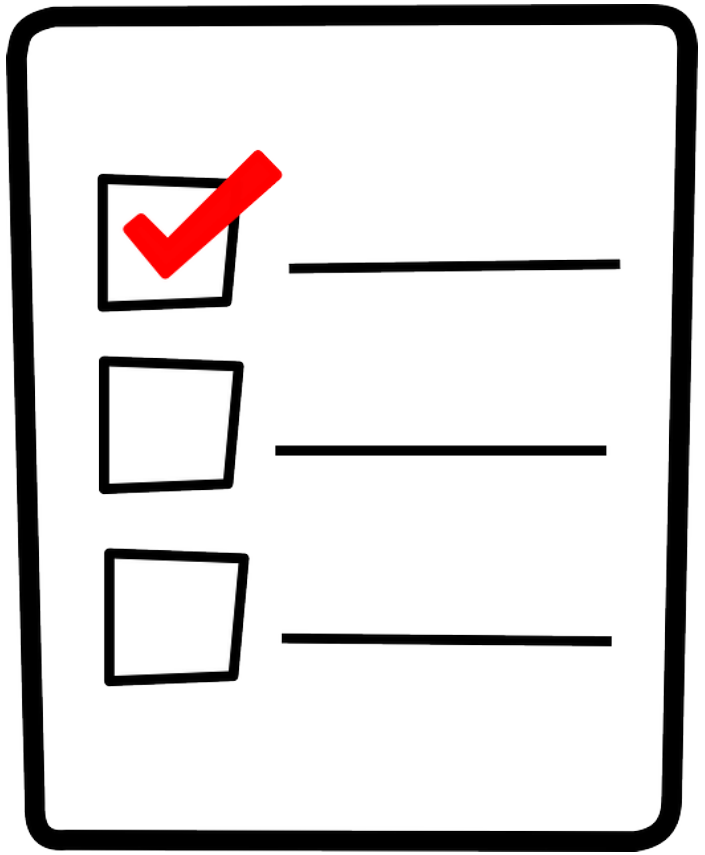
Select sites



- Pre-identify specific sites in each zone
- Rotate through
  - Document for follow up!
- Give the sampler flexibility to choose additional sites
  - FIND IT!

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Zone 1: Must (Should) I hold Product?

- *Listeria* spp.- no
- *Listeria monocytogenes*- yes
- *Salmonella*- yes
- Non-pathogen (other) organisms- no

- *Assuming there was no sanitizing after swabbing, before running product*

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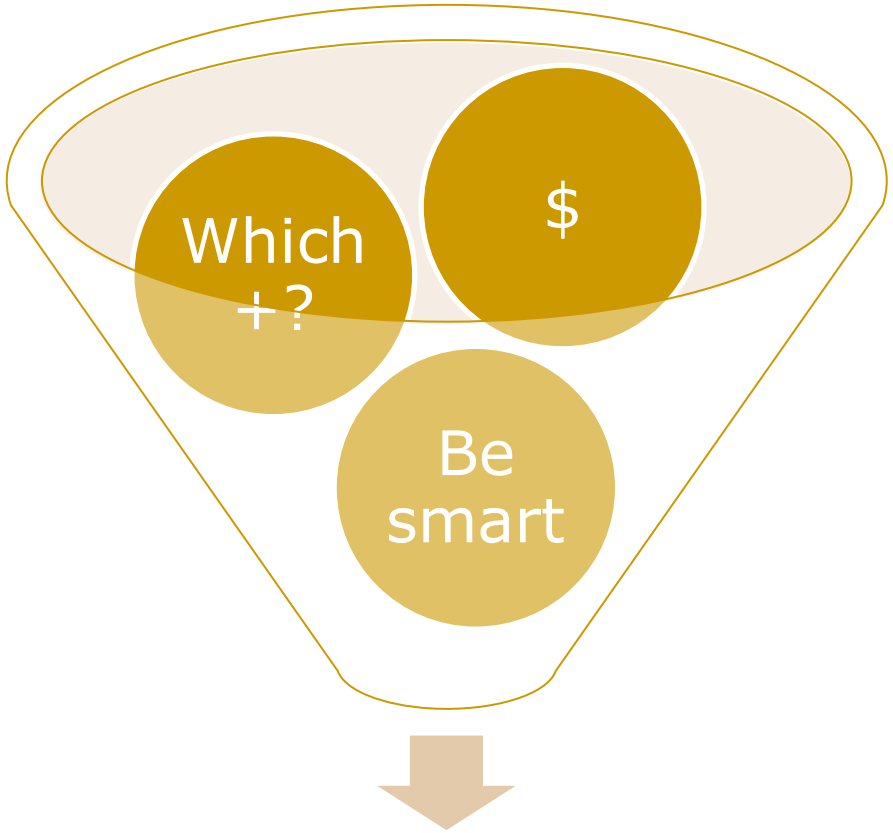

Should you composite?

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Swab Collection Timing and Interpretation

- Pre-Operational (post sanitizing/disinfection)
  - What does this tell you?
- During Production (3-4 hours into production)
  - ?
- After Pre-Rinse (pre-cleaning step)
  - ?

- Days of the week
  - Deep clean?
  - Lab capacity?

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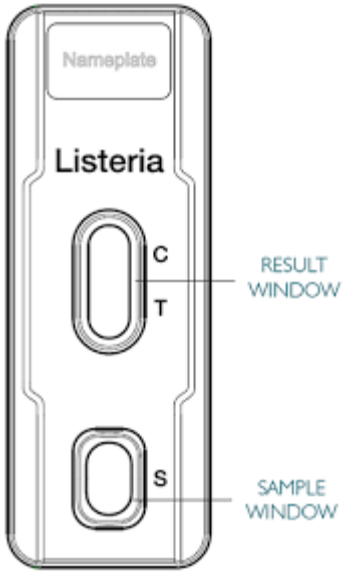
Best test method

- The one that gives accurate results

- How important is time to result?



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So, what if I get a positive?

- Move to a Root Cause Analysis after positive #1
  - Don't assume all positives are transients
  - Had line been running, or should area have been "clean"?

Try to find it again!

- Ask questions – investigate as a team
  - Re-swab for zones 2, 3 and 4, THEN clean/sanitize
  - Conduct vector swabs
  - Re-evaluate SSOPs, employee practices, traffic flow, **equipment/ facility condition**, etc

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So what if I get a positive AGAIN

- It depends
  - Where was the positive?
    - Product contact surface, or non-food contact surface?
  - Does the product support pathogen growth?
- Use FDA's Table 6 of the *Listeria* draft guidance as a guide
- Document your investigation!
- Seek outside help if necessary

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Table 6

FDA Draft Guidance: Control of Lm in RTE Foods

	Non-FCS Food supports growth	Non-FCS Food does not support growth	FCS Food supports growth	FCS Food does not support growth*
Routine sampling positive #1	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation
Follow up sampling positive #2	• Intensified cleaning and sanitizing (possibly including disassembly of equipment) • Intensified sampling and testing	• Intensified cleaning and sanitizing • Intensified sampling and testing	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Hold and test product • Reprocess, divert or destroy product on hold if there is positive product • Comprehensive investigation	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Consider hold and test • Comprehensive investigation
Follow up sampling positive #3	Root Cause Analysis	Root Cause Analysis	• Stop production and consult experts for comprehensive investigation • Intensified cleaning and sanitizing (escalated, e.g., steam equipment) • Intensified sampling and testing	• Intensified cleaning and sanitizing (including disassembly of equipment • Intensified sampling and testing • Hold and test product • Expand comprehensive investigation

EMP Disclaimers

- **Don't** embark on a *Listeria* environmental monitoring program if you know your facility is not clean
- **Don't** use ATP or total aerobic plate counts or coliform/generic *E. coli* testing as a replacement for a *Listeria* environmental monitoring program
- **Don't** conduct finished product testing to demonstrate *Listeria* is controlled in your facility instead of investing in a robust environmental monitoring program
- **Don't** think you need to change everything all at once
- **Don't** fool yourself and waste resources, as per the next slide…

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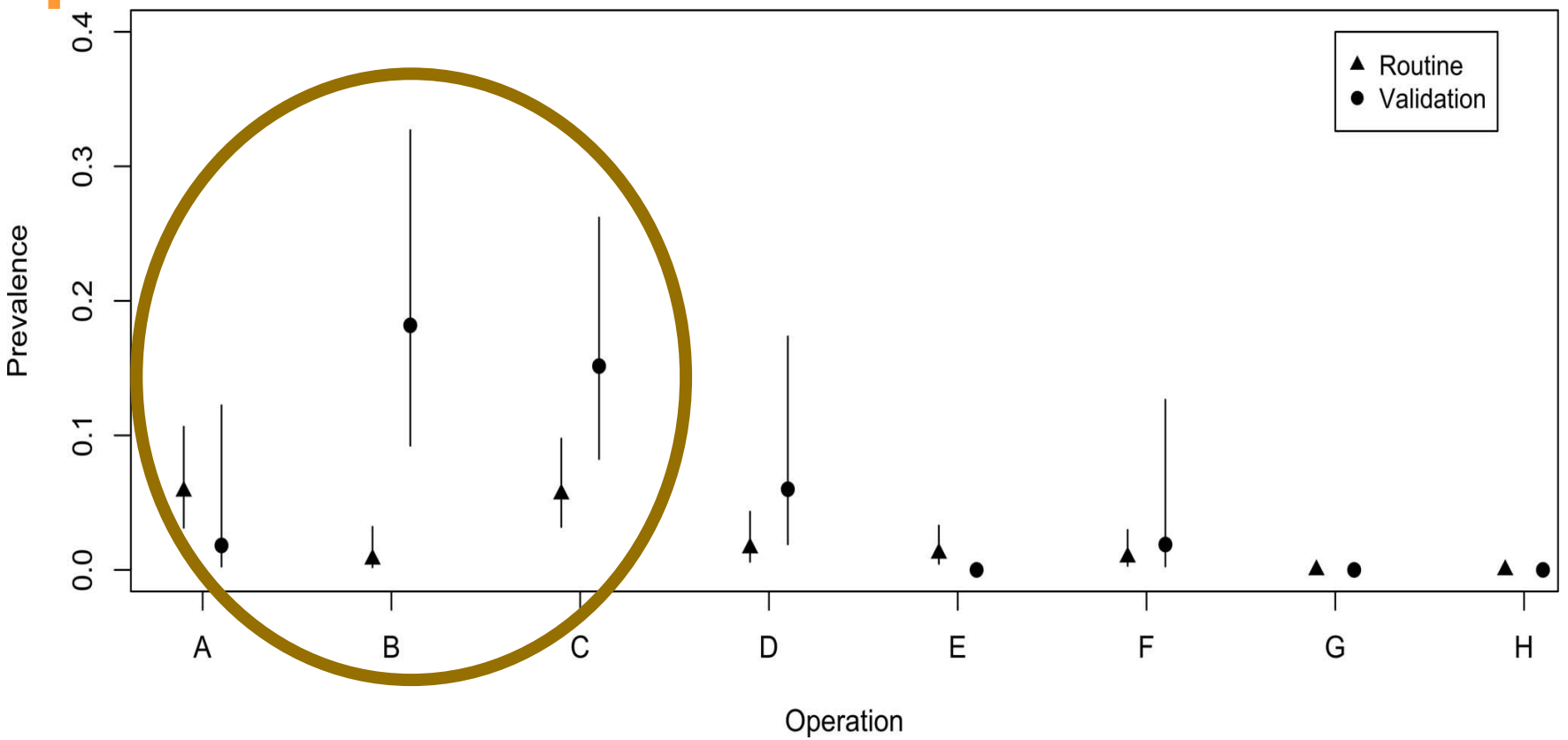

FIGURE 1. Routine and validation prevalence of *L. monocytogenes*, with 95% confidence intervals derived from the nested generalized linear model for eight produce operations: three packinghouses (A, B, and C) and five fresh-cut facilities (D, E, F, G, and H). Prevalence is the probability of a sample testing positive for *L. monocytogenes*.

Listeria monocytogenes can be somewhere in the packinghouse

These frequently tested positive for *Listeria* in this study:

-forklifts
-around bin dumpers
-in drains
-on floors

Sullivan & Wiedmann 2020, JFP
https://doi.org/10.4315/JFP-20-094

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Don’t penalize the positive!

- “Less than 5% positives”
- “Need fewer positives this year than last year”

- Use positives to improve your program- be data driven!
  - Justify replacing equipment or fixing infrastructure
  - Scale down frequency or number of swabs
    - Or focus them where they give more information
  - Focus sanitation efforts
    - Areas needing “special attention”
    - Defend master sanitation schedule

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