

# PATHOGEN ENVIRONMENTAL MONITORING PROGRAM STANDARD OPERATING PROCEDURES (SOP)

## 1. PURPOSE

The purpose of this document is to set forth standard guidelines for implementing an effective Environmental Monitoring Program to control for *Listeria* in the dairy processing environment.

## 2. TEST ORGANISM(S)

*Listeria* spp.

## 3. ENVIRONMENTAL SAMPLING

Swabbing material: Hydrated sponges should be used. Do not use q-tip-like swabs.

We recommend pre-hydrated ready-to-use sponge kits with Dey Engley (D/E) neutralization buffer ([see example](#)).

### 3.1. Environmental Sampling schedule:

#### 3.1.1. Number of samples:

A minimum of 5 samples should be collected *each month*. It is always encouraged (and in some cases may be necessary) to sample more sites more frequently.

#### 3.1.2. Sampling times:

Samples should *not* be collected on the same day every month. Instead, sampling should be performed on a date that has been selected randomly (i.e., using a random number generator).

Random number generator link: [https://www.mathgoodies.com/calculators/random\\_no\\_custom](https://www.mathgoodies.com/calculators/random_no_custom)

Our generator will provide a random number between the two numbers of your choice. Just enter a lower limit number and an upper limit number and click ENTER. Your random number will be generated and appear in the box.

Enter a lower limit:	<input type="text" value="1"/>
Enter an upper limit:	<input type="text" value="31"/>
<input type="button" value="ENTER"/> <input type="button" value="CLEAR"/>	
Random Number:	<input type="text" value="26"/>

#### Notes:

- Routine environmental sampling that will be conducted by you going forward should be performed at least 4 hours after processing starts (“mid-operation”), in accordance with recommendations outlined in FDA’s Draft Guidance for Industry for *Listeria* environmental monitoring: <https://www.fda.gov/media/102633/download>

### 3.1.3. Sites:

Sites swabbed in each monthly sampling should be selected randomly from the full site list (i.e., using a random number generator).

Random number generator link: [https://www.mathgoodies.com/calculators/random\\_no\\_custom](https://www.mathgoodies.com/calculators/random_no_custom)

It is always encouraged (and in some cases may be necessary) to add additional sites to the site list.

Notes:

- *\*If any sample sites test positive for Listeria, corrective actions will need to be followed. See section 4. INTERPRETATION OF RESULTS AND CORRECTIVE ACTIONS for more information.*

## 4. INTERPRETATION OF RESULTS AND CORRECTIVE ACTIONS:

*\*see figure 1 flow diagram for handling positive and negative swabbing results*

*\*see figure 2 fishbone diagram for guidance with conducting root cause analysis*

A. Negative Results: Continue routine operations and testing.

B. Positive Results: Corrective Actions & Follow-Up Testing should be implemented as follows:

- **B.1.** Re-swab the positive site and collect “vector” swabs when appropriate. Vector swab sites should be selected to represent nearby sites that could be the source of initial positive findings (e.g., floor-wall junctures, drains, overhead drip-pans, or traffic path sites that intersect with the initial positive site). Generally, 3-5 vector sites are swabbed for each positive finding.
  - Ensure swabs are properly labeled before sending them to the lab. Site list should be updated to include a site description and picture of each vector site.
- **B.2.** After re-swabbing the positive site and performing vector swabbing, immediately clean and sanitize the location and surrounding area following your facility’s Sanitation SOP (SSOP).
  - Disassemble equipment where appropriate to ensure the positive site is cleaned and sanitized properly.
- **B.3.** Perform a root cause analysis to address the root cause of the contamination. Then implement appropriate corrective actions targeted at removing the contamination from the positive site.

### Results after re-swabbing the positive site, and all its vector sites if vector swabbing was performed:

**Case 1:** The positive site and all its vector sites are negative for *Listeria*

- Resume the normal sampling frequency and include the initial positive site in the next 2 cycles of sampling

**Case 2:** The positive site is still positive for *Listeria*, but the vector sites are all negative for *Listeria*

- Follow directions in section **B.1., B.2., and B.3.** for re-swabbing the positive site, but choose *new* vector sites that represent potential sources of the positive site.

**Case 3:** The positive site does not come back as positive for *Listeria*, but one or more of its vector sites do come back as positive for *Listeria*

- Follow directions in sections **B.1., B.2., and B.3.** for each vector site that came back as positive for *Listeria*. Include the vector positive sites in the next 2 cycles of sampling.

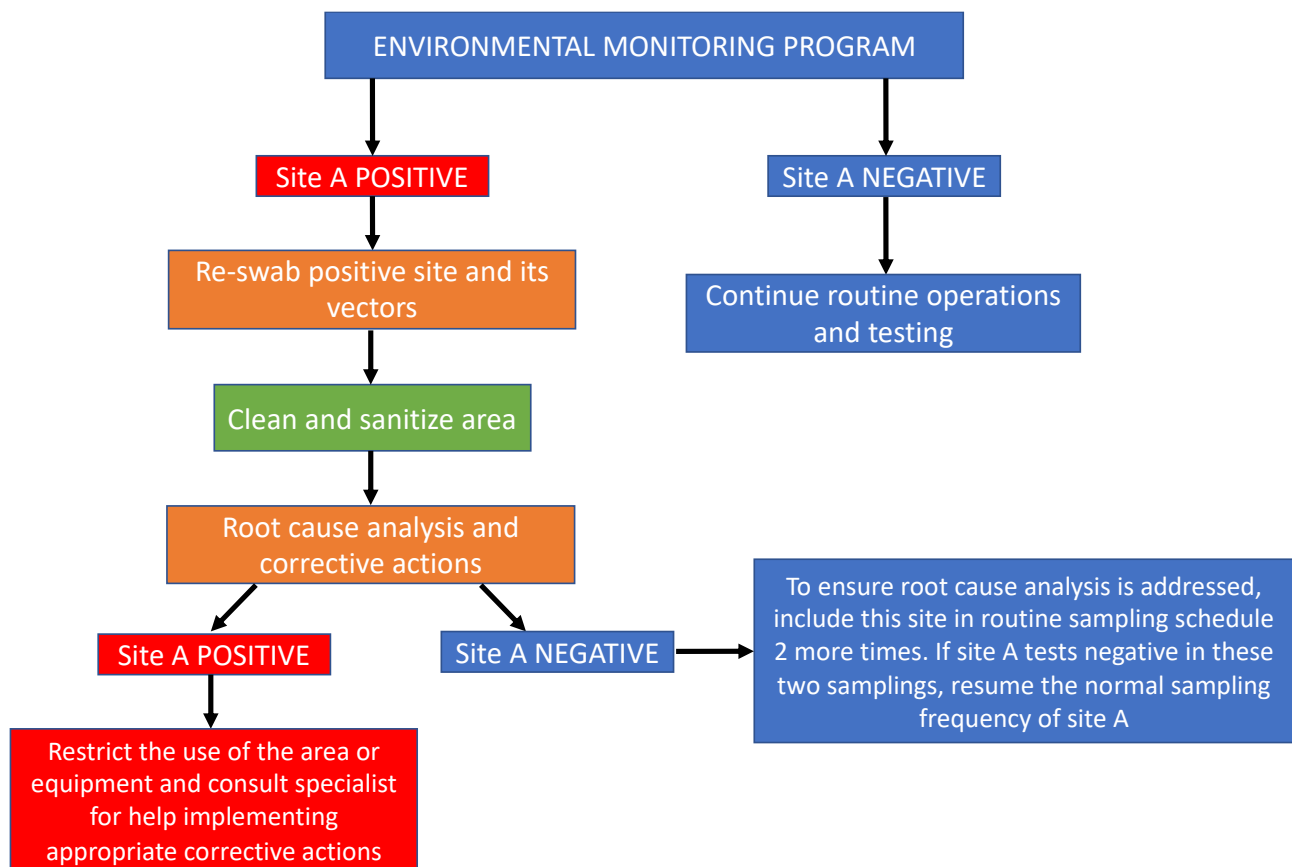
**Case 4:** The positive site and one or more of its vector sites are positive for *Listeria*

- Follow directions in sections **B.1., B.2., B.3.** for the positive site and each of the vector sites that came back as positive.

**In the event that the same site is positive in 2 or more routine sampling events:**

Please restrict the use of the area or equipment and consult with your chemical supplier and Cornell Extension Team. Contact Cornell Extension Team for help with determining the appropriate corrective actions to implement to address positive results.

**Figure 1.** Flow diagram for handling positive and negative swabbing results for example site A.



**Figure 2.** Fishbone diagram (A) and five whys template (B) for conducting root cause analysis.

