Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Listeria monocytogenes Common Findings – Establishment Testing

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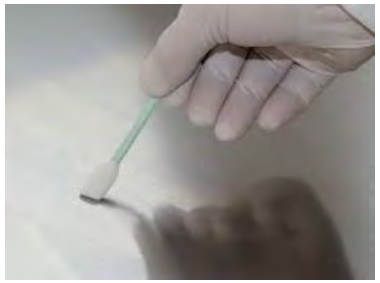
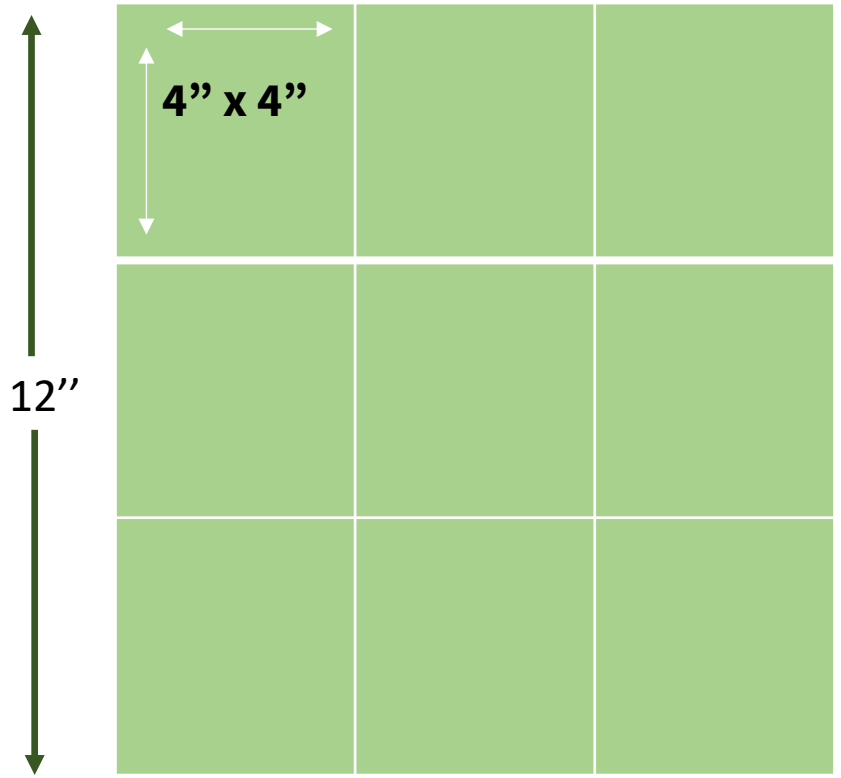
Inappropriate Sized Sampling Devices

- A 12”x12” area should be sampled, when possible, for FCS and NFCS. If the entire surface area is smaller than 12”x12”, then the entire surface should be sampled.
- Smaller sampling devices are not recommended for sampling large areas because they may become saturated.

12 square inches



Smaller devices may be used for small spaces.



Not using a neutralizing broth.

Establishments should utilize a neutralizing broth in FCS and NFCS sampling devices. If not, this could result in false negative results.

USDA FSIS utilizes Dey Engley (DE) Broth because;

- It neutralizes a broad spectrum of antimicrobials, disinfectants, and sanitizers
- DE broth had the greatest efficacy at the time it was adopted.

Other neutralizing broths:

- Letheen Broth
- Neutralizing Buffer
- HiCap Neutralizing Buffer (newest)

Improper storage, shipment, or analyses of samples.

FSIS Guidance;
Samples should be stored and shipped under refrigeration.

- No freezing or excessive heat.
- Refrigeration temps are typically about 2 – 8 C, or 33 – 45 F.

More FSIS Guidance;

- For external labs, limit to 2-3 days from collection to start of analyses.
- For in house lab, initiate testing immediately after collection.
- If not, must support alternative timeframe won't compromise sensitivity.

Sampled Portion vs. Test Portion

- The entire swab or sampling device should be included in the enrichment step.

- Microbiological contamination is non-homogonous.
  - NFCS are typically the original source of contamination of FCS and product.
  - A negative FCS swab only indicates that the specific portion of the FCS that was swabbed was negative at the time it was sampled.
  - A single negative product sample is not proof the entire lot is negative.

Sample Compositing

One sampling device should be utilized per surface location.
If not;

- Potential cross contamination across various surface locations.
- Potential saturation of sampling device.

FSIS recommends that no more than 5 samples be composited;

- Supported by the Lm compliance guide.
- Best if composited by laboratory staff.
- Will lose location specific results.
- Must take corrective actions as if all locations are positive.

Analytical Methods

See Foodborne Pathogen Test Kits Validated by Independent Organizations (usda.gov).

Establishments and laboratories should choose test kits that are:

1. Validated for testing relevant foods by a:
    a) Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal),
    b) U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or
    c) International Organization for Standardization (ISO) process.

Analytical Methods

2) In addition, the validated method should be:
   a) Fit for the intended purpose and application, and
   b) Performed per the conditions of the validated protocol

by a laboratory that assures the quality of the analytical results.

Is the lab performing the method as it was validated?

- Look for the matrices that were used in the validation
- Also, look at sample size, enrichment broth(s), times, temperatures, etc.

Submit questions or concerns to askFSIS.

Selection of a Laboratory

Is the lab accredited to ISO 17025 or following FSIS guidance?

Our Selection of a Lab C.G. contains sections on;

- Qualifications of personnel.
- Sample receipt and handling.
- Quality Assurance Management System.
- Method Selection and Implementation.
- Reporting Results.
- Laboratory Assessment Checklist in the Appendix.

Establishment Implementation Issues

- Not listing or testing all FCS sites.
  - Sampling program should include both random and discretionary samples.
  - Should sample the riskiest locations the most often.

- Not testing at the frequency stated.

- Not applying an antimicrobial agent or process AMAP appropriately.

- Not supporting Lm or Sal is not a hazard RLTO for RTE ingredients introduced post-lethality, i.e., spices, sauces, etc.

Implementation Issues

Testing for Lm, but their program states they will test for L. species.

- A product that passes over an FCS which tests positive for Lm is considered adulterated.
- A finding of *Listeria* spp. on an FCS indicates conditions where *Lm* may be present, but the product is not considered adulterated.

Establishments must take corrective actions for all *Listeria* spp. or Lm positives so that product does not become adulterated.

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Part 2- Common Issues with EIAO RLm or IVT Sampling

EIAO Sampling, Shipping, or Packaging Issues.

- Not check sampling supplies upon receipt, only to realize they're short of supplies when they arrive at the establishment.

- Improper use of gel packs. Frozen gel packs should be removed from the freezer and placed into shipping containers on the day of shipment.

- Breaking establishment procedures due to not reviewing the establishment's operational SSOPs, GMPs, etc., before sampling.

EIAO Sampling, Shipping, or Packaging Issues.

- Allowing an establishment to drastically shorten its RTE lot size to the degree it is no longer representative of routine processing.
- Collecting samples only on the day of packaging, when there was processing, handling, etc., the day before.
- Not understanding the difference between the **sampled lot** vs. a possible **implicated lot** (see page 4 of Directive 10,240.3).

EIAO Sampling, Shipping, or Packaging Issues.

- Examples of issues with aseptic technique;
  - Finger going below the thumb stop on the sponge stick.
  - Sponge contact with the lip of the bag when removing or replacing sponge.

- Collection related mistakes;
  - Not squeezing the broth out of the sponge before removing it from the Whirl-Pak bag.
  - Not squeezing air out of the Whirl-Pak bag before folding down the top.
  - Thinking NFCS samples must be collected near the line.
  - Thinking samples must be collected at pre-op.

EIAO Sampling, Shipping, or Packaging Issues.

Including samples from more than one line or lot within one unit of samples.

- Each unit should be associated with only one line, one production lot, and one 430 Alternative.
- If not, leads to confusion when positives are found.
- Which production lots are implicated by the positive?

Issues with Forms, Seals, Bar-Coded Labels.

- There must be a corresponding form for all samples within each shipping container.
- Each form must be signed.
- Each shipping container should be sealed to ensure sample integrity, as illustrated in Directive 7355.1, revision 3.

DE Broth and Pre-hydrated Sponges

- DE broth can be held at room temperatures for long periods of time, e.g., during sampling.
- Should be refrigerated for long term storage.
- Printed shelf life is dependent on refrigeration.
- Must not be temperature abused.
- The higher the temperature, the faster DE broth degrades.

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Questions??

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