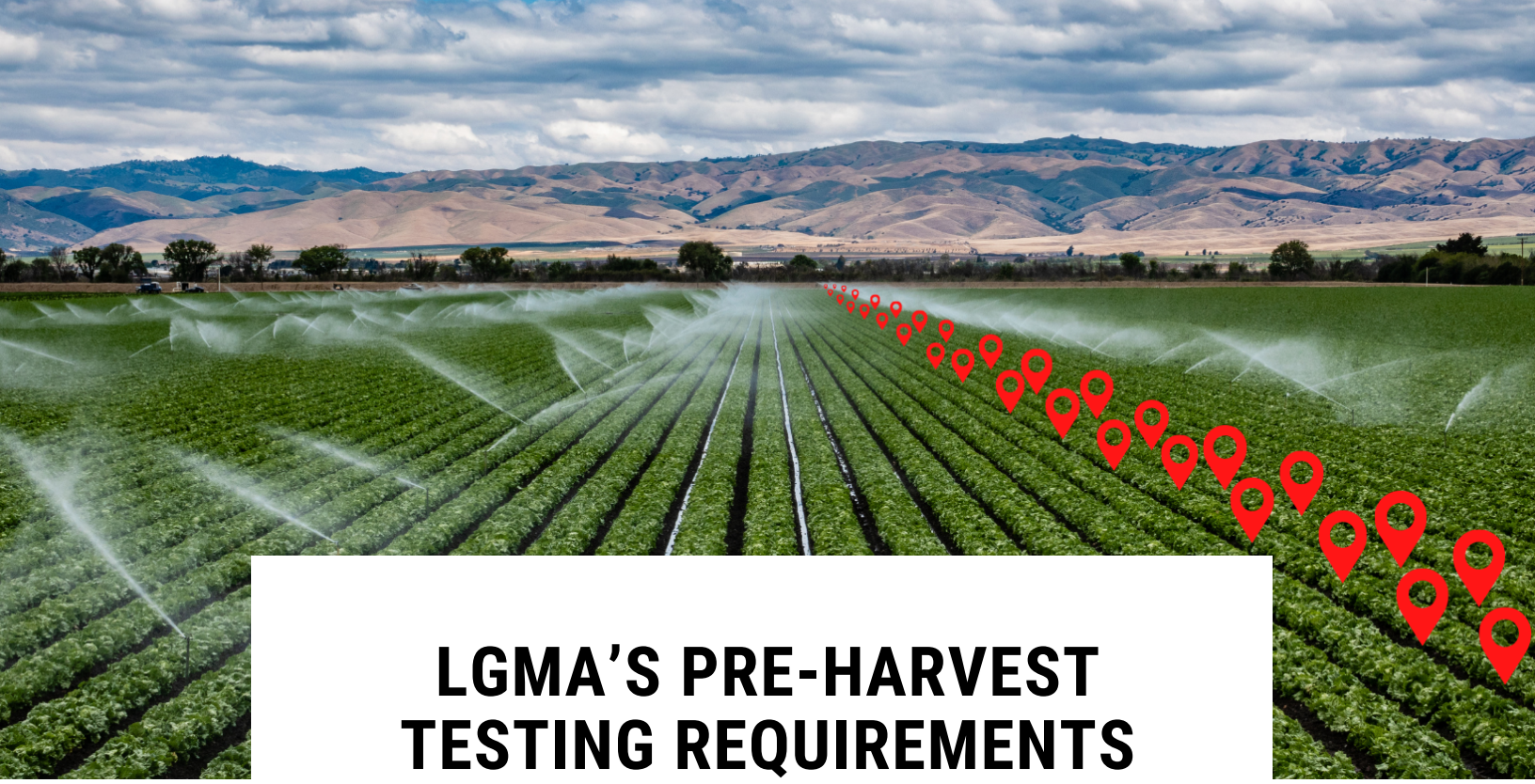
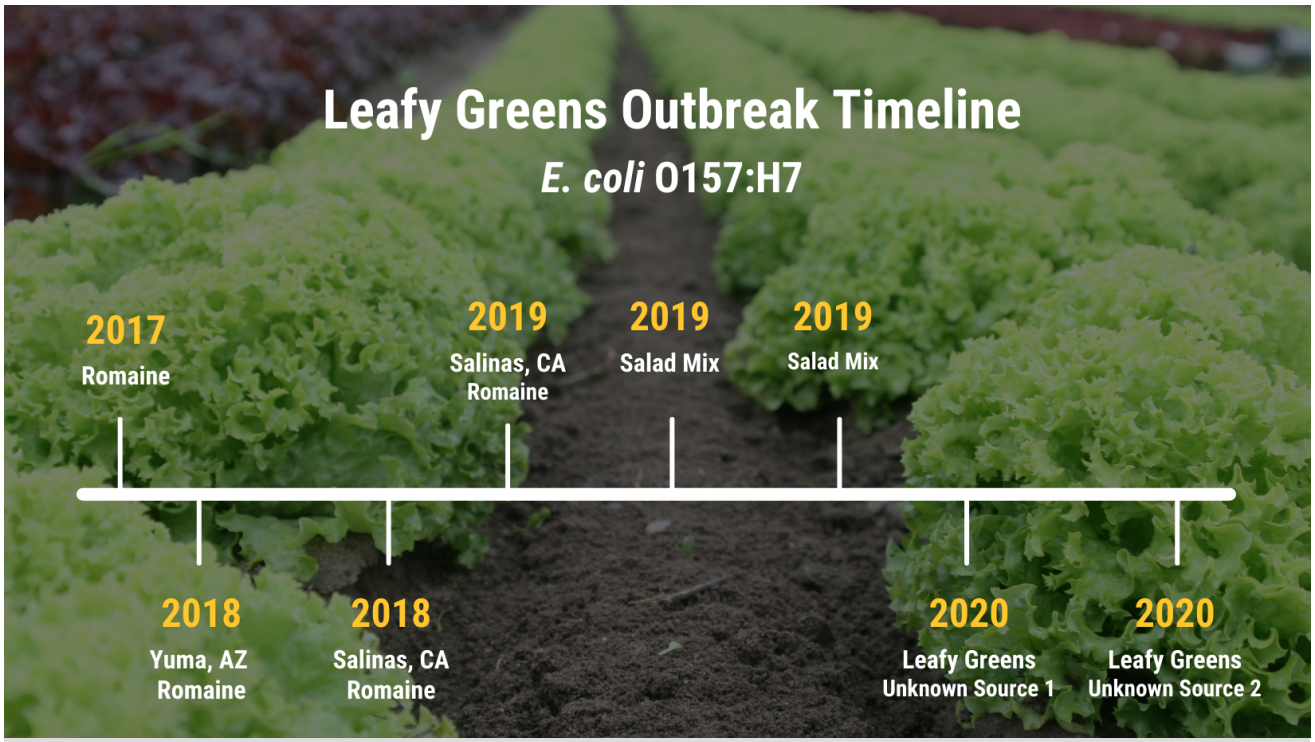


LGMA'S PRE-HARVEST TESTING REQUIREMENTS

UNDERSTANDING HOW THE CHANGES AFFECT YOUR CURRENT TESTING REGIMEN AND HOW PRIMUSLABS CAN HELP

In April 2021, the California Leafy Green Marketing Agreement (LGMA) board released new guidance surrounding pre-harvest testing. The guidance document focuses on outlining conditions that can contribute to an "elevated risk," and recommending pre-harvest testing if any of the factors are present. Following this endorsement by LGMA, the LGMA board and Western Growers released draft guidance documents for comment to the industry with prescribed pre-harvest sampling plans and testing requirements. In June 2021, Wal-Mart and Sam's Club released a letter to suppliers applauding LGMA's endorsement of the pre-harvest testing along with requirements for suppliers to comply with LGMA's testing guidance when "'Elevated Risk Factors' are observed or detected." The letter requests compliance with the outlined requirements by no later than July 31, 2021.

In early July, LGMA released updated guidance outlining the laboratory test criteria, sample sizes, sample plans, remedial actions, and more. There have been several updates to the guidance since; the most current version of the document "Appendix C: Pre-harvest Product Sampling and Testing Protocol" can be found **here**. (Note: final version is still pending and has not yet been released)



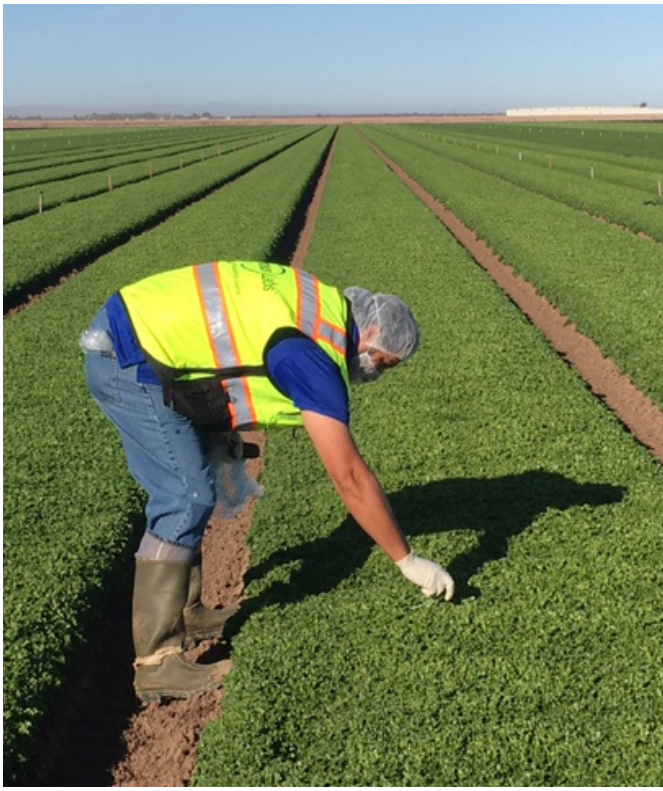
How can PrimusLabs Help? This document is intended to provide resources and information to assist with complying with the requirements outlined in Appendix C and covers information on utilizing PrimusLabs' team of sampling professionals, understanding the requirements for testing validations, how to view and access your results, and more.

From 375g to 1500g – "What size do I test?"

Historically, methods developed for testing for food were validated by sub-sampling 25g from a larger collection of sample. Over the last decade, sample sizes have evolved depending on need, sample type, and regulatory testing manuals, such as FDA-BAM* and USDA MLG*.

Most laboratory methodologies for leafy green products are currently validated to test up to 375g in a single enrichment. Appendix C requires approximately 1500g to be sampled, and for the entire sample collected to be tested. To comply with the method validations, this means that the entire 1500g sample will be broken down to sub-samples with sizes adhering to the method. For example, four (4) 375g samples could be tested to equal the 1500g, or five (5) 300g samples (LGMA has recently specified the maximum allowable subsample size to be 375g, even if the method validation allows for larger sample sizes). Regardless of the subsample size, the entire 1500g must be enriched and tested.

Understanding the Sample Collection



*Pictured above Mario Duarte, PrimusLabs Sampling Supervisor.

The LGMA pre-harvest testing plan outlines two distinct sampling events – routine sampling and risk-based sampling. While similarities between the two exist, differences are outlined in how each type of sample is approached in terms of lot size, time-frames for sampling to be completed, and how sample plans are designed (i.e. randomized or biased to account for elevated risk-factors). There are many sampling plans available and readily utilized in the industry. In Appendix C, LGMA has specified samples should be collected according to "stratified random and representative locations with a designated lot" focusing more on randomized locations than the pattern walked. LGMA notes that "no current single statistically valid or fixed sampling configuration" currently exists, so sampling plans will need to be customized to the lot being sampled. Significantly, they also mark a move away from the traditional Z-pattern, citing it's potential to miss in-field contaminants if they are not on the border or the edges being sampled. LGMA has provided Center for Produce Safety's **CPS Rapid Response (Yuma Valley)** as a reference that may help guide you in your decisions in picking a sampling plan that is right for you. If you have questions, PrimusLabs stands ready to serve as a resource for you. We are happy to discuss your operation, growing situation, and goals for the sampling to help you pick a plan that best suits your needs. When requesting sampling from the lab, you should communicate which approach you are requesting to ensure the correct sampling plans and information is collected.

There are numerous resources available for understanding how to sample product. Alternatively, PrimusLabs' team of dedicated samplers have experience collecting pre-harvest samples following industry standards and buyer-designed protocols. Each sample collected comes with GPS points corresponding to each sub-sample grab, providing peace of mind that every sample adheres to the agreed upon protocol. GPS points are available on every result COA, as well as available for review on the free PrimusLabs App. To schedule a sampler, contact our Dispatch Group at 805-922-0055 or email **dispatchgroup@primuslabs.com**.

Cost-Saving Solutions

The increase in number of samples to be collected, along with the changes in sample sizes to be tested can represent a significant increase in the amount of testing performed by the labs. PrimusLabs has validated the use of wet-compositing or "pooling" as a cost-saving option for our customers. The validation demonstrates that 4 to 6 samples (up to 375g each) can be enriched separately and then portions of each enrichment are "pooled" together. The combined "pool" is then tested via the molecular screening technology. If negative, the entire 4 to 6 samples are deemed negative.

If one or more of the individuals is positive, the "pool" will show as "positive". To learn more about pooling, follow this link to a **flowchart and validations**.

For compliance with the LGMA requirements, (4) 375g or (5) 300g samples would be enriched individually, pooled and tested to provide results encompassing the entire 1500g of product sampled. In the event of a positive pool, retesting the individual enrichments may be used for investigative purposes only and may not be used to clear portions of a lot.

Contact **salesgroup@primuslabs.com** for a quote and additional information on pooling capabilities.

Analyses and Methodologies

PrimusLabs blends traditional, tried-and-true technologies with cutting edge and emerging detection methods to provide the flexibility needed to meet industry needs across an assortment of complex matrices in as little as 12-15 hours. PrimusLabs only uses approved, validated, fit-for-purpose methods to ensure our testing is reliable and robust. We currently offer the **Hygiena BAX (PCR)** and **3M MDS (LAMP)** technologies for molecular detection of pathogens, which both boast regulatory recognition and routine use by FDA and USDA. Both platforms are validated for leafy green samples up to 375g and are included in our scope of **ISO 17025** accreditation, for both individual and pooled samples. In the event of a molecular (presumptive) positive, samples are culturally confirmed following **FDA BAM 8th ed. methodologies**. For STEC testing, rapid molecular confirmation options may be available.

For more information on these methods, please see below:

Hygiena BAX (PCR)

- Salmonella **AOAC 2013.02**
- STEC* **AOAC-RI 091301**

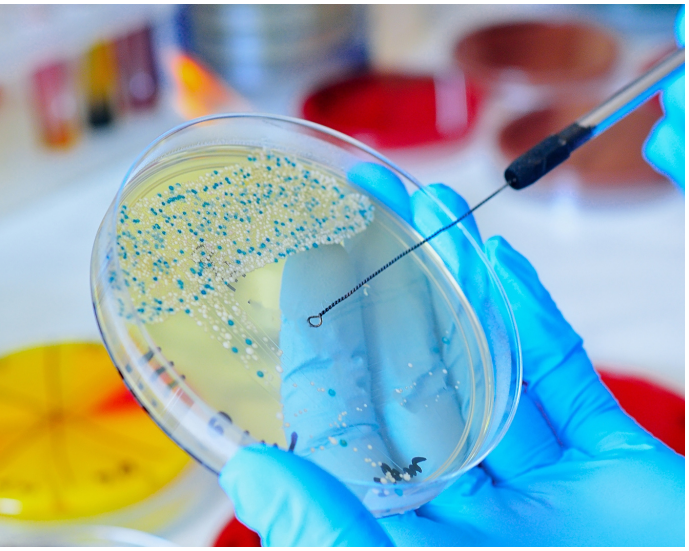
3M – MDS (LAMP)

- Salmonella **AOAC 2016.01**
- STEC* **AOAC-RI 071902**

*Includes clinically relevant STEC (O157, O26, O45, O103, O111, O121, O145) as required by LGMA Appendix C

Next Steps with Presumptive Positives

When a sample is positive on the Hygiena BAX or 3M MDS systems, it means that the DNA of the target organism has been detected. In the industry, this is referred to as a "presumptive positive" or "molecular positive". At this point, an organization can either act on the presumptive, or can choose to proceed with cultural confirmation of the sample. In STEC testing, PrimusLabs can offer a secondary molecular screen for clinically relevant STEC (O157, O26, O45, O103, O111, O121), which may clear a presumptive positive lot in as little as 3 to 6 hours. In cultural confirmation, the samples are plated across a series of selective agar plates and tubed media, in which colony morphology and biochemical reactions are used to isolate the organism of interest and "weed out" any non-target background flora. At the end of the cultural process, suspect isolates are run through a panel of biochemical tests to build a profile of the organism which allows scientists to positively identify the organism. At this point, isolates can be sent out for further characterization via methods like serology or Whole Genome Sequencing. While these tests can be useful in trending and identifying sources of contamination, they are not currently required by LGMA. Any lots associated with a confirmed positive must be destroyed, and cannot be put into commerce. The organization must perform a root cause analysis and corrective action to attempt to identify the source of the contamination and prevent a recurrence.



Our laboratories are open 24 hours a day, seven days a week, and 365 days a year to provide customers with perishable products answers when they need them.

CONTACT US TODAY to start your custom pre-harvest testing program!

805-922-0055 | www.primuslabs.com

Find a lab near you.

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Resources

Canadian Food Inspection Agency. (2021, June 4). Anticipated fall 2021 import requirements for romaine lettuce from California. Canadian Food Inspection Agency. https://www.primuslabs.com/wp-content/uploads/2021/07/CFIA-to-FFV-Industry-on-Romaine-Imports-for-Fall-2021.pdf

Walmart Global Governance . (2021, June 8). Leafy Greens Food Safety Risk Assessments and Pre-Harvest Testing. https://www.primuslabs.com/wp-content/uploads/2021/07/Walmart-Leafy-Greens-Supplier-Letter.pdf

Western Growers Science. (n.d.). Appendix C Pre-harvest Product Sampling and Testing Protocol. https://www.wga.com/sites/default/files/resource/files/2021-08-27_appendix-c.pdf

Home. PrimusLabs. (n.d.). http://www.primuslabs.com/.

Food Safety & Supply Chain Compliance Systems. Azzule Systems. (n.d.). https://azzule.com/.

Portfolio Management Association of Canada. PMAC. (2016, July 20). https://pmac.org/.

Firm, A. U. T. H. O. R. P. L. (2020, November 3). Romaine E. coli Outbreaks, a Timeline 2017 -2020. Pritzker Hageman, P.A.https://www.pritzkerlaw.com/personal-injury/2020/romaine-e-coli-outbreaks-a-timeline-2017-2020/.

Centers for Disease Control and Prevention. (2018, January 25). Multistate Outbreak of Shiga toxin-producing Escherichia coli O157:H7 Infections Linked to Leafy Greens (Final Update). Centers for Disease Control and Prevention. https://www.cdc.gov/ecoli/2017/o157h7-12-17/index.html.

when food safety counts