Testing for Gluten and Allergens - Why do it, and how to do it well

Presented by:
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Hosted-PJLA , Tracy Szerszen, President

Tuesday, December 14, 2021
1:00-2:00 PM EDT

PJLA

Presentation Overview

Tracy Szerszen
President
Perry Johnson Laboratory Accreditation (PJLA)

- Why test for Allergens/Gluten (requirements, regulatory, customer specific)
- Challenges Associated with these Tests (sensitivity, preparations, PTs)
- Questions & Answers

PJLA

Webinar Housekeeping

- This webinar will be recorded
- All PJLA webinars are made available on our website & YouTube channel
  - https://www.pjlabs.com/training/pjla-webinars/past-webinars
- All attendees are muted
- Please utilize the question tool bar to submit questions
  - To be answered at the end of presentation

Our Presenters

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Lauren Stainback is the Global Product Manager for NSI Lab Solutions. Lauren has 18 years of experience in clinical and analytical laboratory science. Formerly a Forensic Lab Director now working with NSI for the past six years.

Emily Kaufman founded Emport LLC in 2011 with the motto More Safe Food, More Happy People. Although originally focused on developing the GlutenTox line of rapid tests, she has since expanded Emport's catalog to include both ELISAs as well as rapid tests for additional allergens and other food safety concerns. As someone with a restricted diet herself, she takes great pride in helping to ensure consumer safety.

Testing for Gluten and Allergens:

Why to do it, and how to do it well

Emport
LLC

Who am I … and why am I talking?

- Emily Kaufman, president of Emport LLC
- US launch of both GlutenTox Pro and AlerTox Sticks
- 10+ years of working with gluten-free and allergen-free food manufacturers
- 20+ years of eating gluten-free

Emport LLC: More Safe Food, More Happy People

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Today’s Topics

- Why care about gluten and allergens?
- How do allergen rules and definitions differ between Canada and the USA?
- Why do manufacturers do onsite testing?
- What do they need from their third party labs?
- Alphabet Soup: What testing tools are available?
  - What are their strengths and ideal uses?

Why do we care about allergens?

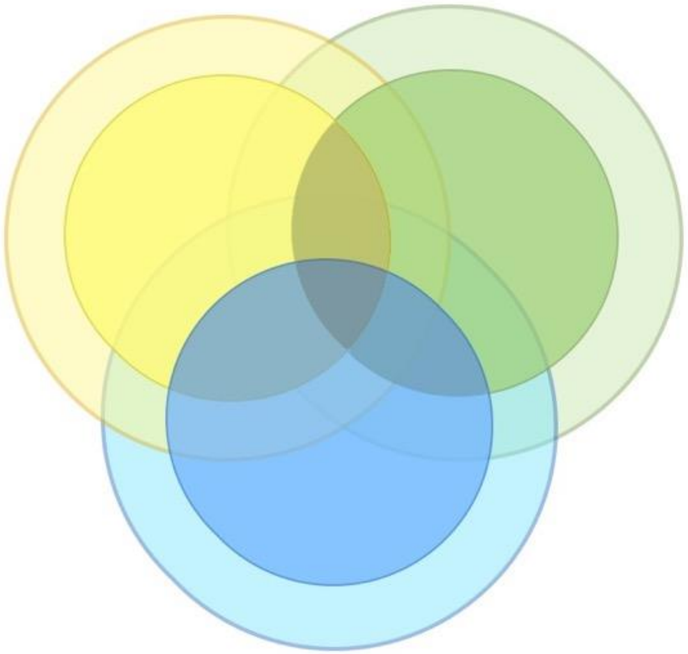
- More than 32 million Americans and 3 million Canadians have food allergies (roughly 10% of the population).
- In the US:
  - 1 in 13 children under the age of 18 have one or more food allergies
  - A food allergen reaction sends someone to the ER every 3 minutes
- In Canada 1 in 2 households are impacted by food allergies
- An additional 1% of the population is estimated to have celiac disease
- Celiac Disease and Food Allergies have no cure

The NA market for food allergen testing is estimated to reach $1B by 2028

Allergen Labeling Laws (FALCPA / FSMA / SFCR)

- Original regulations addressed intentionally-included ingredients
  - **Required** labeling for all packaged foods
  - While many foods are allergens, not all are covered under laws
- FSMA / SFCR were the logical evolution
  - Now facilities must also plan for unintentional allergen cross-contact
  - Allergens are considered a hazard; hazards require preventative controls
    - Facilities must look for ways that allergenic cross-contact *could* happen
    - Once they find those hazards they must prevent them
    - No stated permissible ppm/ppb thresholds
  - Greatly expanded need for documentation
    - If it isn’t documented, it isn’t done

Allergen Rules in Canada and the USA



- **Shared:** Sesame*, Egg, Fish, Milk, Peanut, Shellfish (Crustacean), Soy, Wheat
- Tree Nuts are **Complicated:**
  - In Canada, tree nuts covers 9 specific nuts (almond, Brazil nut, cashew, hazelnut, macadamia nut, pecan, pine nut, pistachio, and walnut)
  - In the US there are many more, most notably **coconut** and **chestnut**
- Only in Canada: Mustard, Shellfish (Mollusc)
- Gluten and Sulfites are **Complicated**

Allergens, Gluten, and Sulfites

- **Sulfites** must be labeled if ≥10ppm.
  - Not an allergen but can cause similar symptoms
  - A “priority allergen” in Canada
  - Not a “major allergen” in the US (but can still trigger a recall)
- **Gluten**
  - Mandatory in Canada at 20ppm (a priority allergen)
  - Voluntary in the US (not FALCPA)
  - Gluten is not (always) from wheat, wheat does not (always) contain gluten

US Gluten Labeling Laws (2014/2020)

- Entirely voluntary – only applies if product labeled “gluten-free”
- Product must have < 20ppm gluten
- Any detectable gluten present must be from unavoidable cross-contact (despite following cGMP) – not from intentional inclusion
- Distillation guidance
  - cGMPs make distillation safe, protein tests can confirm
- Fermentation/Hydrolyzation guidance
  - Items must be **demonstrably** GF pre-fermentation/hydrolyzation
  - Products/enzymes grown on gluten-containing media not exempt

Gluten and allergen testing: why?

Client need lab analysis for multiple reasons. They may:

- ✓ Simply prefer to outsource all testing
- ✓ Be working with complex matrices
- ✓ Want to confirm/quantify on-site results
- ✓ Need to validate their on-site methods

Clients need allergen testing to confirm their incoming ingredients, work surfaces, and finished products are free from unexpected allergens.

Matrix Considerations

Matrix limitations will vary allergen to allergen, test format to test format, and manufacturer to manufacturer.

Always read the manual carefully; contact your supplier with any questions. If testing a new-to-you matrix: validation!

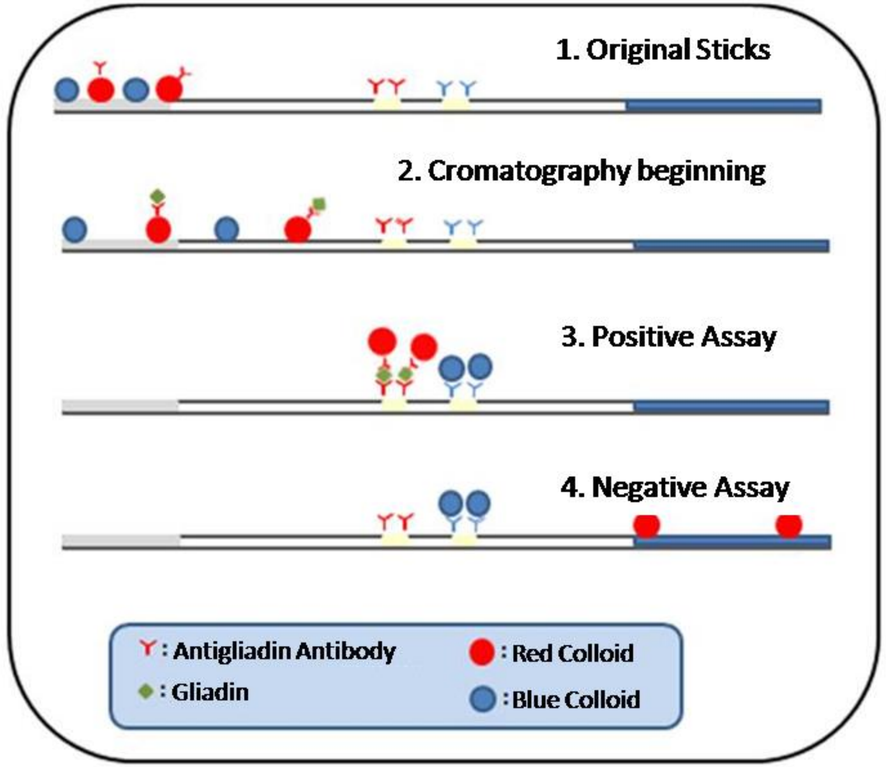
Some key indicators to watch out for:

- Heat
- Fat
- Tannins, antioxidants, polyphenols
- Fermentation, hydrolyzation
- Extreme pH
- High salt content
- Preserving via tinning or canning
- Cross-reactivities

The alphabet soup of allergen testing: LFDs

Lateral Flow Devices (LFDs) use antibodies and look for protein

- Generally quicker, cheaper and easier
- Can run a single test
- Qualitative yes/no answer
- Very popular for day-to-day use in facilities
- Each kit will have strengths and weaknesses



More alphabet soup: ELISAs

ELISAs also use antibodies to look for protein

- Enzyme-Linked ImmunoSorbent Assay
- Multiple formats and manufacturers — read carefully
- Complex matrices may require additional steps
- Lower LOD than most LFDs
- Quantification (within a range)
- Cost-effective only when running multiple samples
- Results in (usually) 90-120 minutes

Typical 'Needed not Supplied' List for Sandwich ELISA:

- *Multi-channel pipettes, tips*
- *Vials/Recipients*
- *ELISA Plate Reader*
- *Water Bath*
- *Centrifuge*
- *Vortexer*
- *Blender*

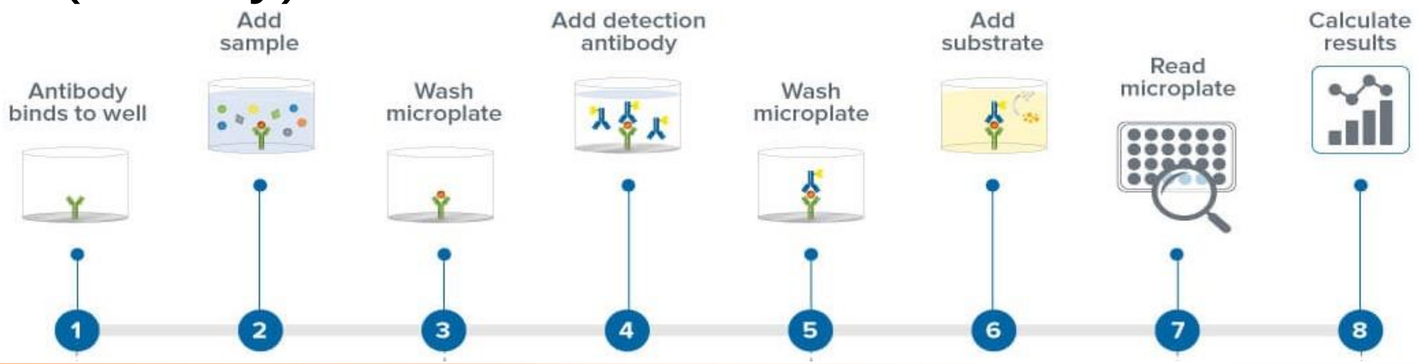


Illustration source: https://bit.ly/30IwsAg

More alphabet soup: PCR

PCR tests look for genetic material (DNA/RNA)

- Polymerase Chain Reaction
- If you're already running PCR, not hard to add on
- Quantification possible, with additional steps
- Helpful for samples with little/no protein
- High specificity
- Can help identify food at the species level
- Can be really helpful, or useless
    - Loose correlation between DNA and allergens
    - Egg looks like chicken, no DNA in milk

More alphabet soup: LC-MS

LC-MS

- Liquid Chromatography Mass Spectrometry
- Mostly used in research settings, but shows promise
- Has the potential to help with incurred / complex samples
- Stay tuned!

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Allergen
Proficiency Tests (PTs) & Certified Reference Materials (CRMs)

Tips and Tricks for Success:

Getting to Know Your Matrix
(Raw Unprocessed vs. Fermented or Roasted/Heated)

Sample Prep is Key!

Practice makes perfect
(Method Validation & PTs)

PTs + CRMs = build confidence into your lab results

Thanks for listening! Questions?

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