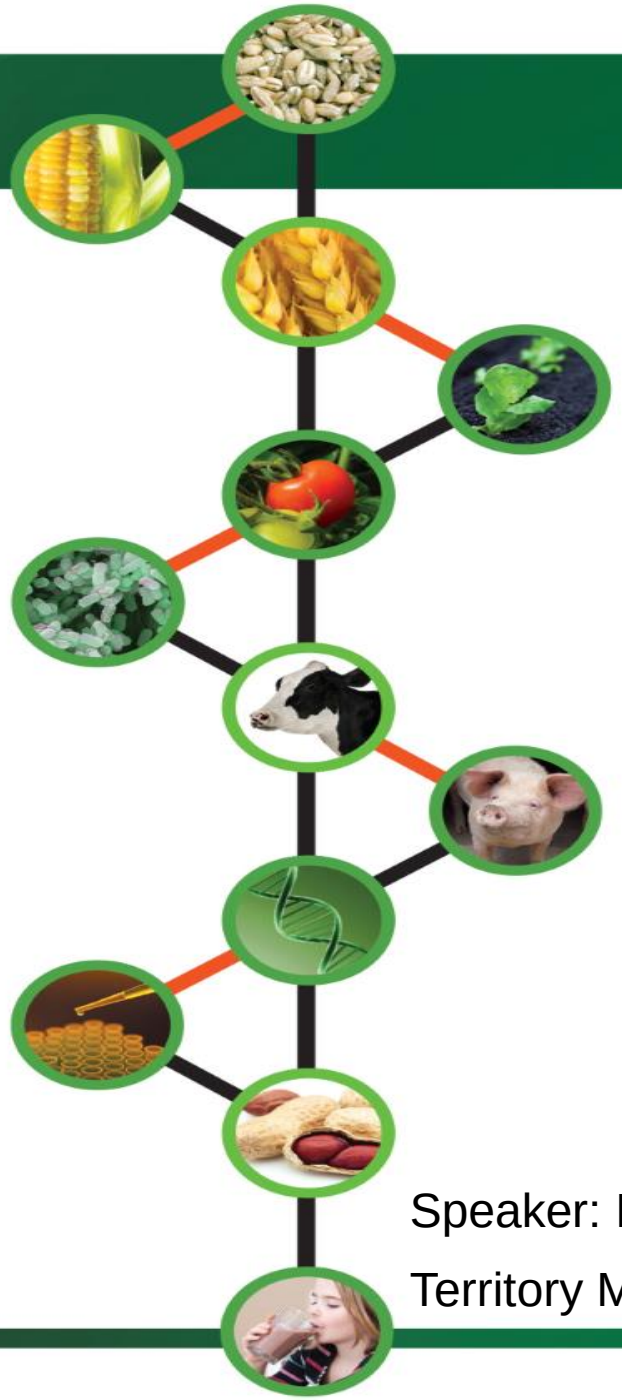


Food Allergen Management in the Ice Cream Industry

IDFA Ice Cream Technology Conference

Speaker: Danielle Wellington

Territory Manager for Dairy Food Safety Solutions

NEOGEN®

Agenda

- Neogen Corporation
- Allergen Concerns
- Components of an Allergen Control Plan (ACP)
- Validation and Verification of Allergens
- Role of Rapid Testing with Future of Food Allergens

Global Presence

Representation in >100 countries

Connections

Reference

AOAC
AFNOR
GFSI
FARRP
ISO
Pet Food Institute

Regulatory

USDA
FDA
GIPSA
NCIMS
CFIA
CDC
Health Canada

Industry

IFT
IAFP
IDFA
AMI/NMA
FMI
APHA
ISBT
United Fresh

Plus many more…

Neogen/FARRP Collaborative

- FARRP is the expert in the industry
- Neogen joined FARRP in 1997

food allergy research & resource program
farrp

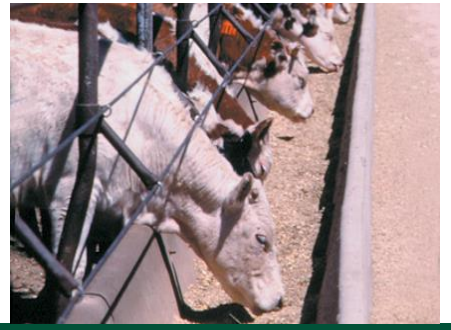
- Collaborated on development of rapid test kits for peanut, milk, egg, almond, hazelnut, gliadin, mustard, lupine and soy

NEOGEN®

A Leader in Food and Animal Safety

Food Safety Solutions

- Diagnostic test kits
- Instrument systems
- Consumables
- Culture media
- Services



Animal Safety Solutions

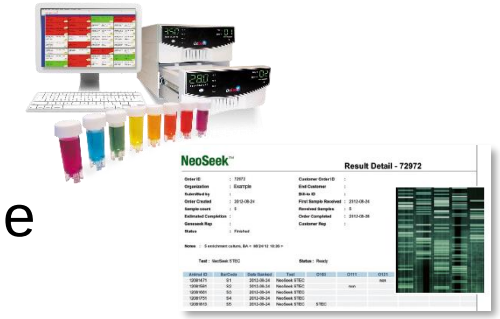
- Veterinary supplies
- Instruments
- Nutritional supplements
- Disinfectants
- Rodenticides

Genomic Solutions

Neogen in the Food Chain

A Broad Portfolio of Products

Routine and genomic bacteria/spoilage organism tests



Mycotoxin screen and quantify

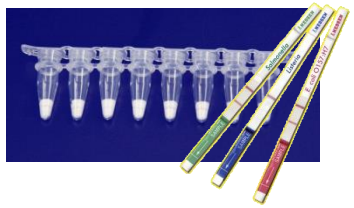
Antibiotic screening for milk

Water test for coliforms and E. coli

Allergen screen and quantify

Dehydrated culture media and ampoule media

RNA, DNA and ELISA pathogen screening tests



Sanitation monitoring & alkaline phosphatase testing

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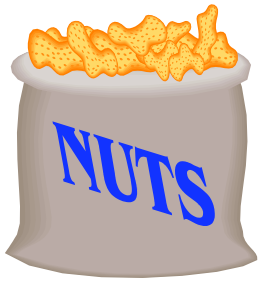
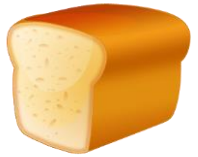
What Are Food Allergens?

- Naturally occurring proteins
- Heat and processing resistant
- Resistant to extremes in pH
- Usually major proteins in food
- Foods can have 1 or many allergens
- No known cure…strict avoidance





Allergens of Concern

Europe & Canada

- Peanut
- Soy
- Milk
- Eggs
- Seafood (fish, crustaceans, shellfish
- Mustard
- Tree Nuts
- Wheat
- Sesame Seeds
- Sulfites

U.S. i.e., Big 8

- Peanuts
- Soy
- Milk
- Eggs
- Fish
- Shellfish
- Tree Nuts
- Wheat

Know What You ARE Detecting

Neogen Test Kit	Detection
Peanut	Total peanut proteins
Egg	Raw and cooked egg white proteins
Milk	Casein and whey proteins
Almond	Almond protein
Hazelnut	Hazelnut protein
Gliadin	Prolamins (gliadin, secalin, hordein)
Processed Soy	*Most* soy ingredients
Mustard	Mustard proteins
Sesame	Sesame proteins
Crustacea	Crustacea protein

And NOT detecting….

- Oils
- Enzymes
- Gums
- Flavors/Extracts
- Lecithin
- Lactose
- Starch
- Gelatin
- Processing Aids
- Colorings

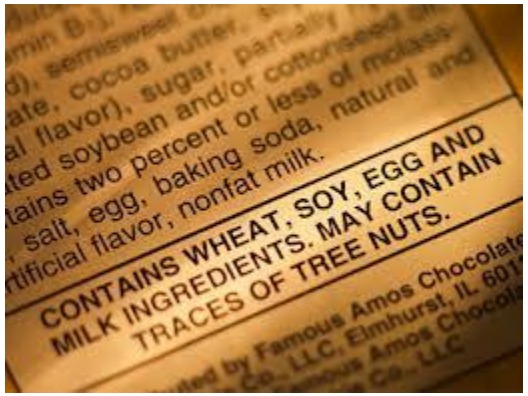
“Hidden Risks”

- Recycled CIP and COP rinses
- Oils re-contaminated after refining
- Rework
- Labeling terms i.e. *non-dairy creamer*
- *Many others…*

Importance of an Allergen Control Plan (ACP)

- **Main objective is to protect the food-allergic consumer by:**
  - Preventing **<u>cross-contamination</u>**
  - Insuring the label is accurate
  - Insuring documentation is adequate & appropriate

- **Secondary objective is to avoid regulatory issues and recalls**



Who are the key leaders in your organization?

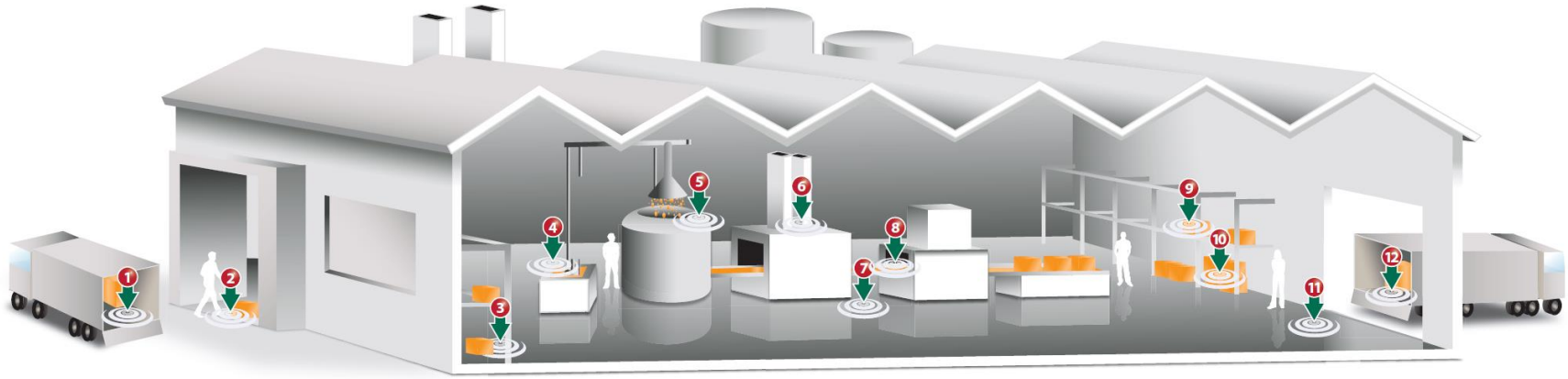
Form an allergen control team

- Manufacturing
- Quality
- Labeling/Regulatory Compliance
- Research and Development
- Engineering
- Sanitation
- Food Safety

Provide general training on allergen awareness and control for all employees at all levels of the company.

Fundamentals for your ACP

- Conduct a Risk Assessment
- Develop an Allergen Process Flow Diagram — “Allergen Map”
- Develop an Allergen Control Plan specific to each processing facility.
- Review the Allergen Control Plan regularly and update when necessary.



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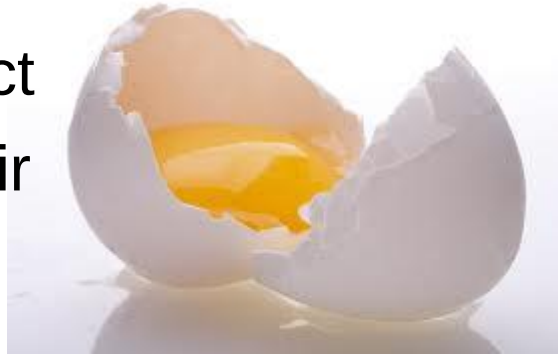
Product Design

- Limit adding allergenic foods to new product
- Question suppliers of allergens used in their formulation
- Understand the existing allergens
- Review allergens in new products with the manufacturing facility
- Avoid using allergenic ingredients in low amounts



Segregation of Allergenic Foods/Ingredients

Where are allergens present in your facility?

- Receiving
- Storage
- Handling
- Process

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Supplier Control Programs for Ingredients and Labels

- Require from suppliers:
  - To have a documented ACP and updated COA's.
  - Written guarantee the ingredients do not contain undeclared allergens.
  - Immediately notify any changes to the allergen status of the ingredients they supply prior to any changes.
  - To have sanitation cleaning procedures in place.

- Audit your suppliers on a regular basis to assess the effectiveness of their Allergen Control Plan.

Prevention of Cross-Contact During Processing

Scheduling of processing runs

- Schedule long runs of products containing allergenic ingredients
- Segregate production areas for allergenic and non-allergenic products
- Schedule sanitation immediately after production of allergenic foods
- When product design permits, add allergenic ingredients as late in the process as possible.

During manufacturing of allergenic ingredients…

- Limit the traffic patterns of raw materials, packaging supplies, and employees
- Dedicate processing equipment and lines
- Run similar allergens on the same equipment
- Prevent cross-contamination
- Add physical barriers
- Dedicate clearly marked equipment
- Ensure allergens are identified throughout process

Validation Definition 21 CFR 117.3

- "Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."

Are you doing the right thing to control the hazard?

- Required for process preventive controls
- Performed or overseen by a preventive controls qualified individual

Verification Definition 21 CFR 117.3

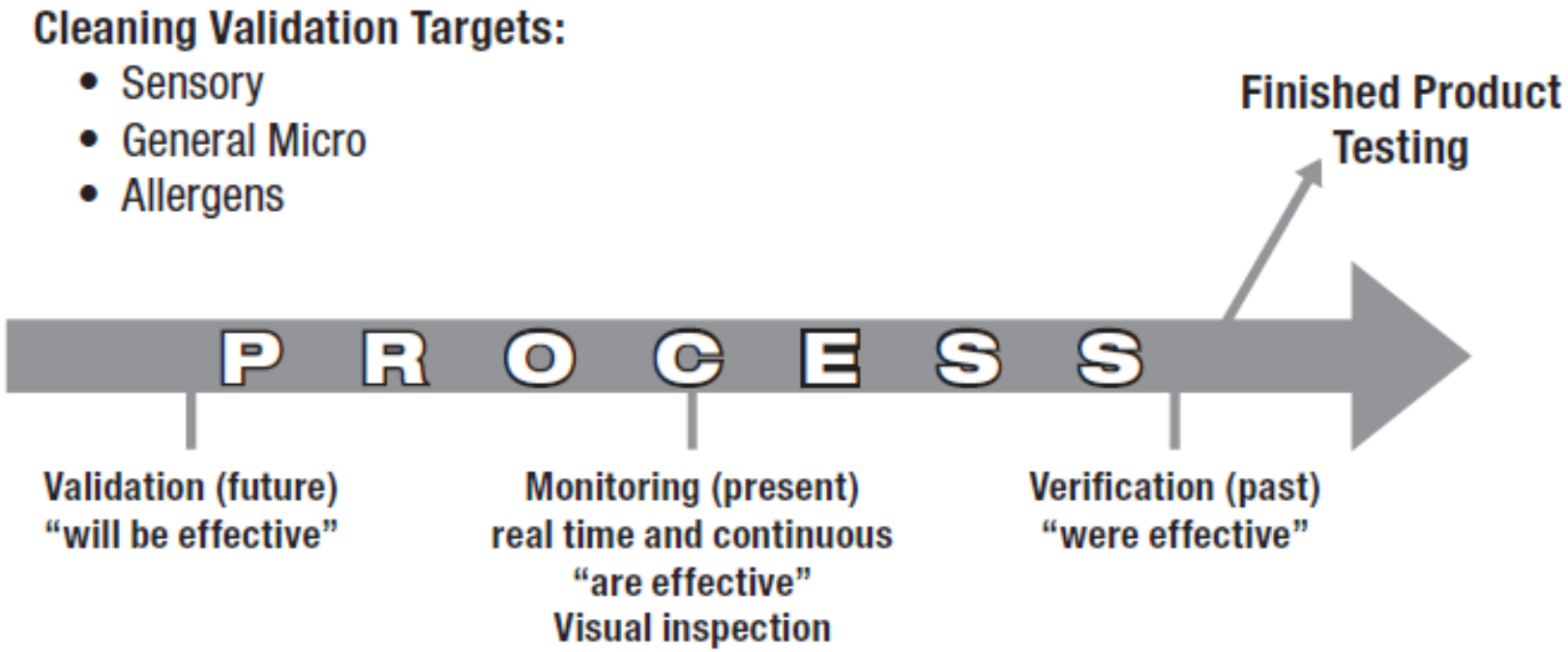
- “The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.”

Are you doing what you say you are doing in your food safety plan?

- Demonstrates that the Food Safety Plan is consistently being implemented as written
- Targeted testing: Product and Environmental Monitoring
- Records review:
  - Monitoring records
  - Corrective action
  - Verification records

Validation and Verification Process

Validation and verification processes are considered to be an ongoing component of the food safety system and there is always a scope for continuous improvement.



Allergen specific vs ATP/general protein

Allergen Specific (ELISA) When:

- Performing allergen validation
- Most allergen verification/monitoring activities
- Testing products
- Making label claims i.e allergen-free

General Protein/Sensitive ATP When:

- Verification of cleaning & sanitation
- Allergen verification if have built data to support correlation.

NEOGEN® CORPORATION

NEOGEN®

Environmental Monitoring

AccuPoint Advanced

RFID Sanitation Checkpoint

- The ONLY system in the world with an AOAC approval
- Measures ATP to instantly verify sanitation system effectiveness
- Uniquely designed samplers provide consistent results
- Easy-to-implement RFID system

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE
LICENSE NUMBER 091601


AOAC RESEARCH INSTITUTE
CERTIFICATION
AOAC® Performance Tested℠
Certificate No.
091601
AccuPoint® Advanced ATP Hygiene Monitoring System

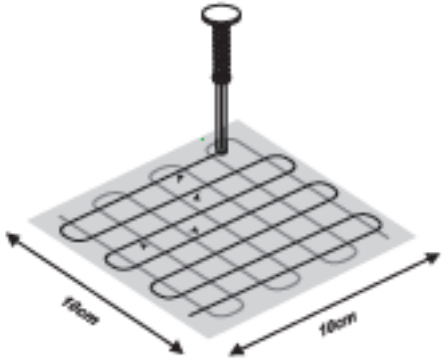
AccuClean Advanced
Rapid Protein Residue Test

- Fast with results in 10 seconds
- Sensitive as low as 10 µg protein per sample
- Simple, no equipment required

NEOGEN®

AccuClean Simple Directions

1. Sample – crisscross a 4”x4” portion of the surface



2. Activate – return plunger to cartridge and activate by pressing it fully into the cartridge. Gently swirl while keeping cartridge upright for ten seconds.

3. Interpret – read by examining the color of the remaining solution using below color comparison.

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Food Allergen Control Plans

Factors effecting monitoring of controls include: sampling plan, sample frequency, sample type, method 'fit for purpose', range of applicability, method approvals, method validation, calibration, sensitivity, specificity, precision, accuracy, matrix effects, units of measurement, proficiency, training, records, facilities, laboratory accreditation, cost, time

SCREENING ***QUANTITATIVE***

Reveal/Reveal 3-D *Alert* *Veratox* *BioKits*

CAUTION: 'One size fits all' claims ….




Allergen Specific Tests

Almond
Crustacea
Egg
Gliadin
Gluten
Hazelnut
Mustard
Peanut
Sesame
Soy
Total Milk

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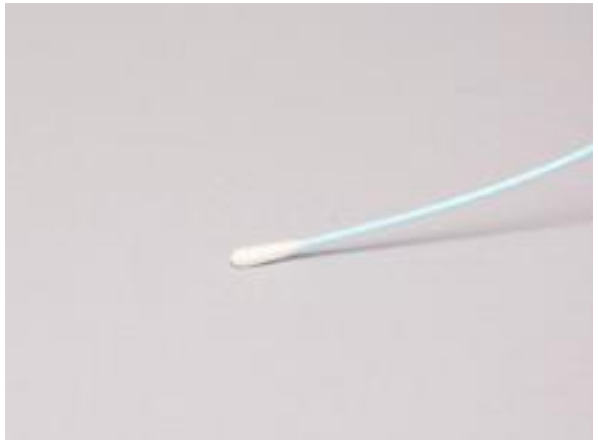
Reveal 3-D™ Components

Components provided:

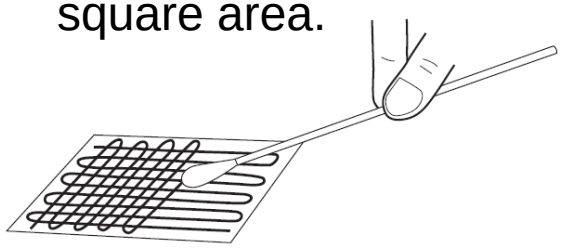
- **Extraction buffer sachet**
- **Sample tube & cap**
- **Reveal 3-D test device**
- **Swab**

Reveal 3-D Procedure with Swabs

1. <u>All other Reveal 3-D kits</u>: cut off the top of the appropriate buffer sachet and add the entire contents to the sample tube.



2. Remove a sterile swab from it's packaging and wet the end by dipping into the buffer or swab wetting solution. Collect the sample by swabbing a 4 x 4 inch square area.



3. Return the swab to the extraction buffer in the sample tube and carefully break off at the pre-scored area. Secure the cap of the sample tube.

4. Shake vigorously for one minute

Reveal 3-D Procedure with Swabs

5. Remove the lid and fill with the liquid from the tube

6. Dip the head of the Reveal 3-D Device in the liquid in the lid. Leave the device in the liquid until you see the saturation in the test window.

7. Place the device on a flat surface and allow the device to develop for 5 minutes then interpret results.

Reveal 3-D Procedure with CIP/Rinsates

CIP/RINSATES:

1. Add supplied buffer solution(s) to tube per kit insert, add cap
2. Add appropriate volume of CIP or rinsate to a clean sample tube
3. Shake tube for 1 minute
4. Remove cap and fill with solution
5. Dip head of device into cap until you see liquid wick up device (approx 5 seconds)
6. Wait 5 minutes, read results

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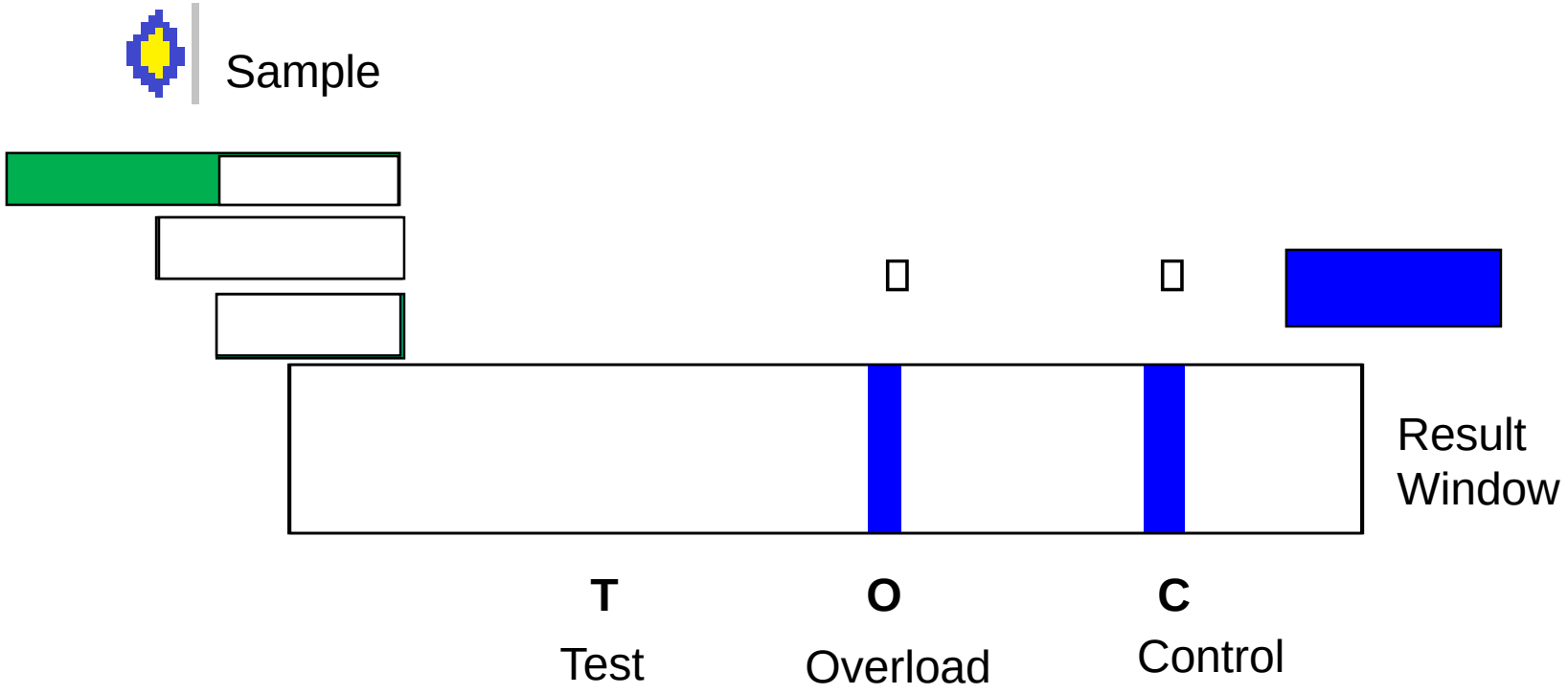
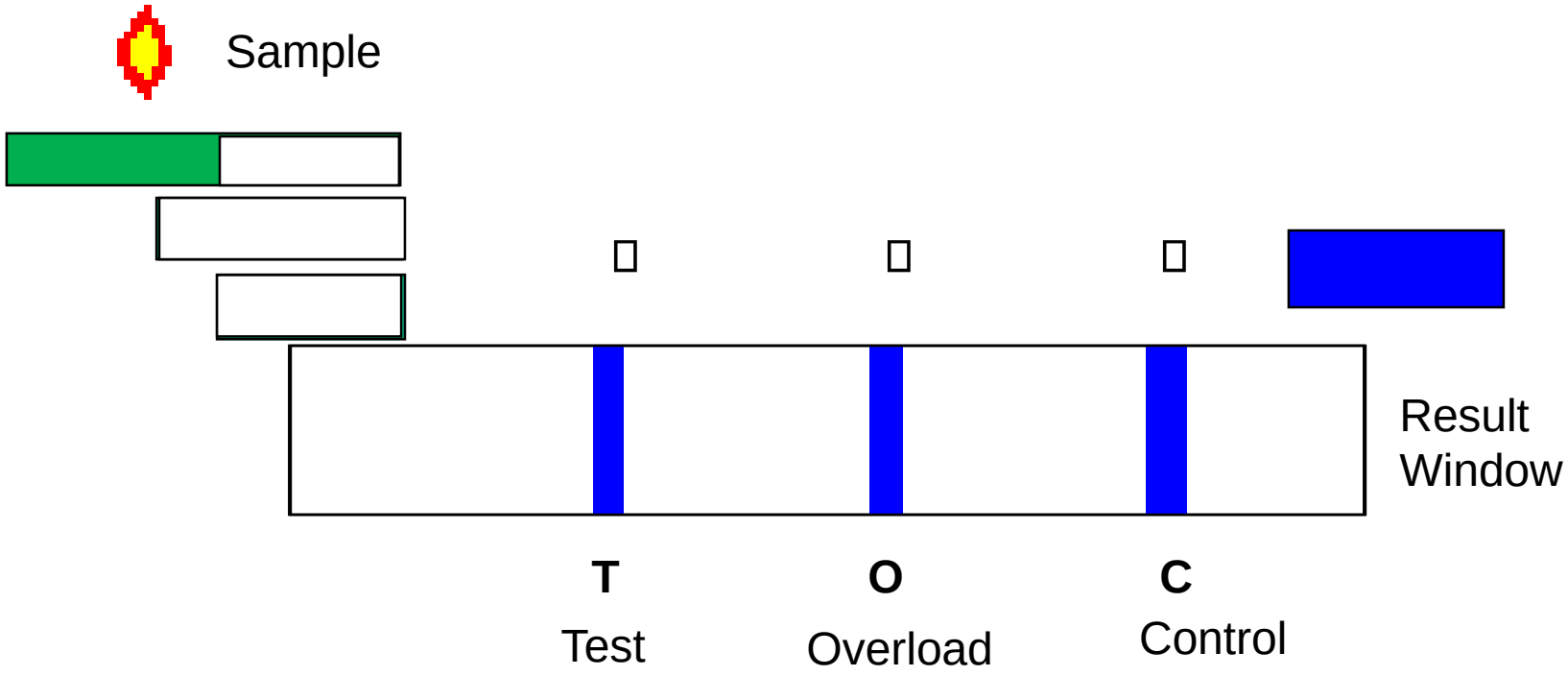
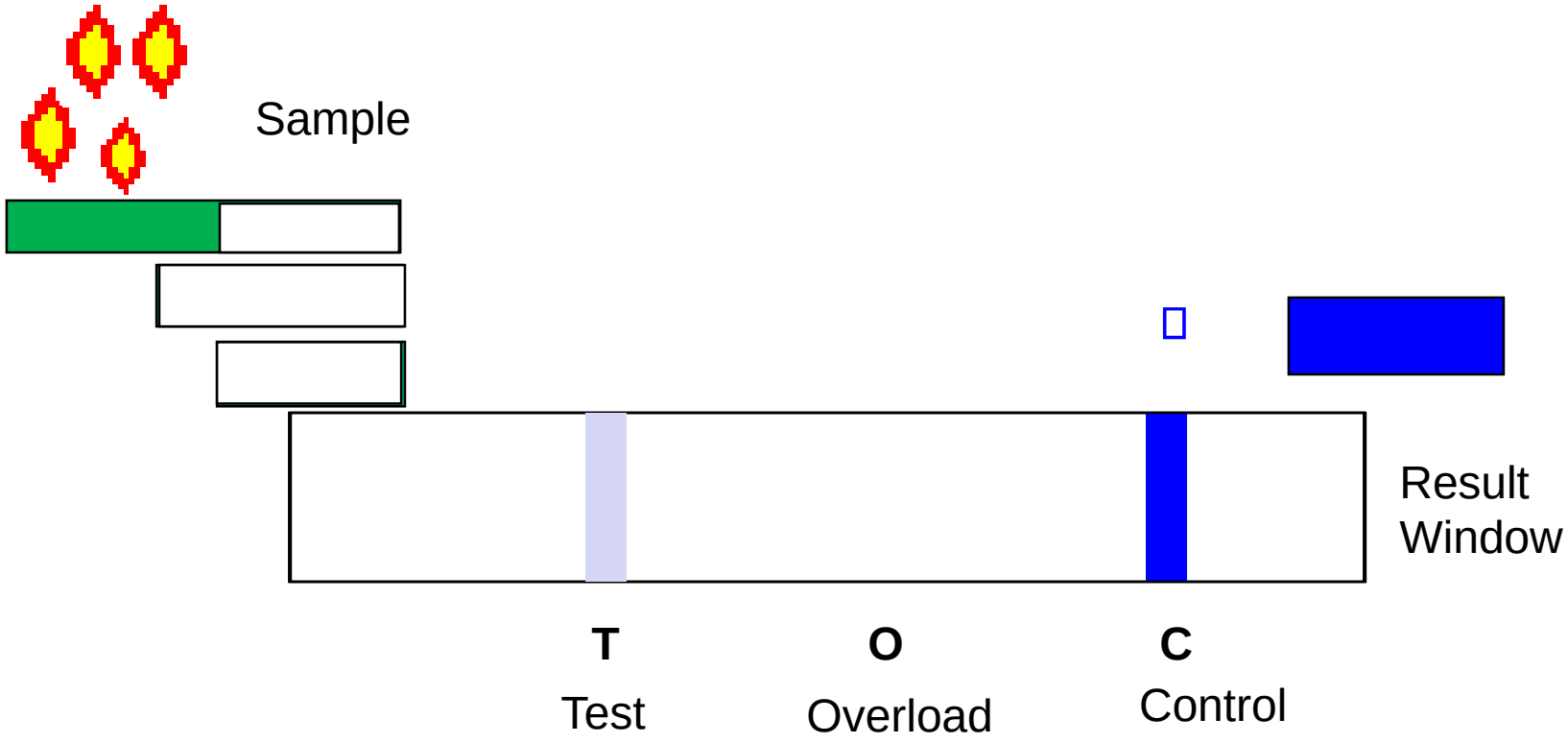
Reveal 3-D™ Test – Negative Result



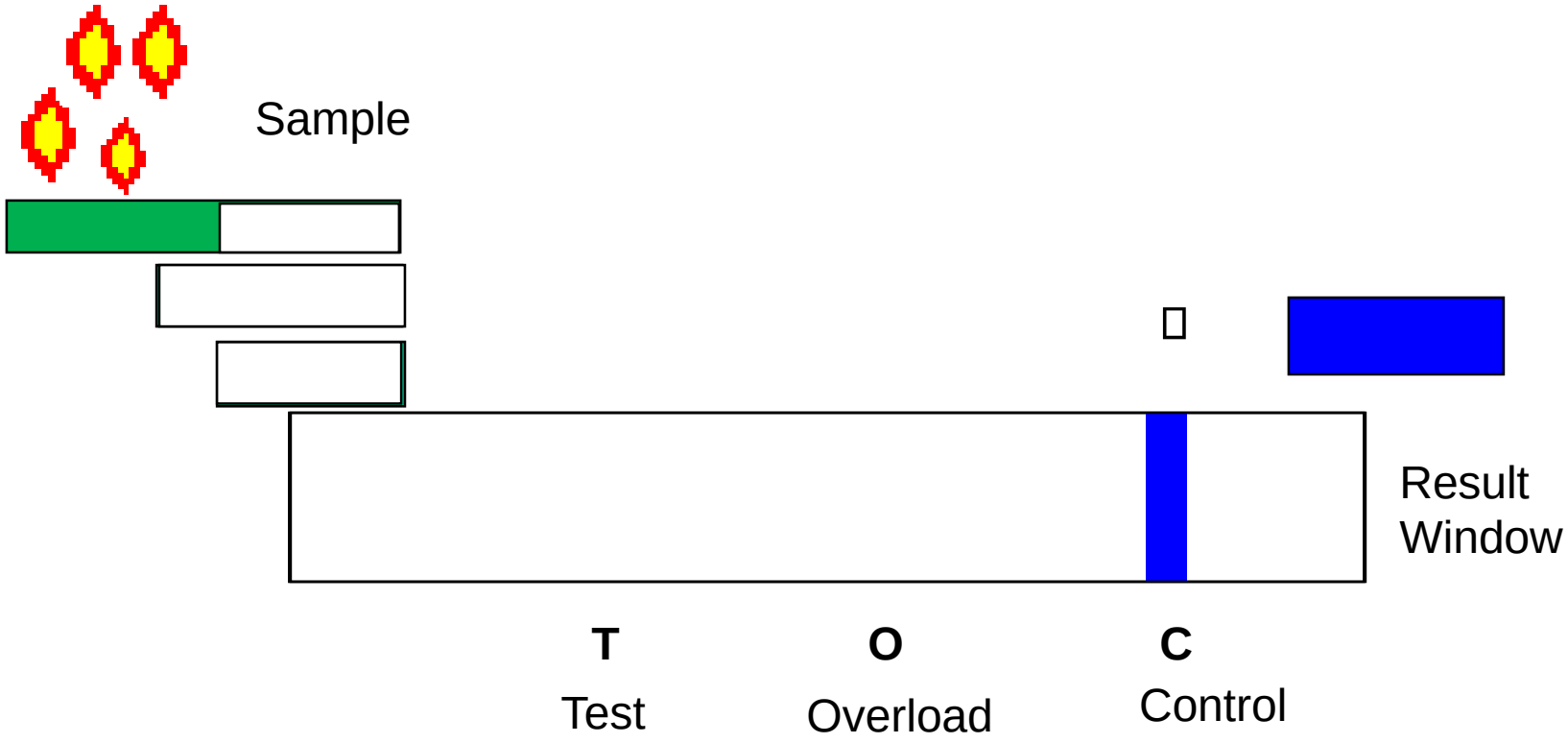
Reveal 3-D™ Test - Positive



Reveal 3-D™ Test – Overload Result



Reveal 3-D™ Test – Overload Result



Reveal for Multi-Treenut

Lateral Flow Device detecting any one or combination of six tree nuts:

Almond	**Hazelnut**
Pecan	**Walnut**
Cashew	**Pistachio**

Test time: 10 min

Tests/kit: 10 samples/swabs

Results: 2 line test

1 line negative
2 lines positive

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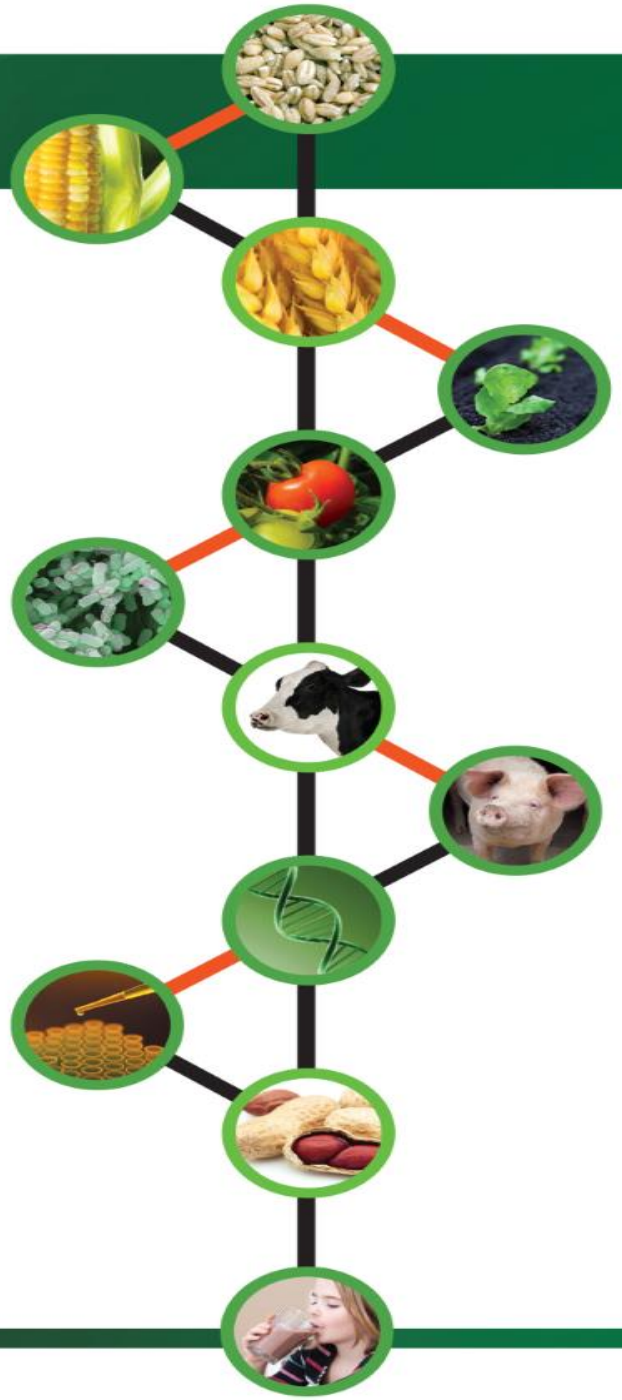
Results Interpretation



Please visit my table top for more information and to introduce yourself…

www.neogen.com

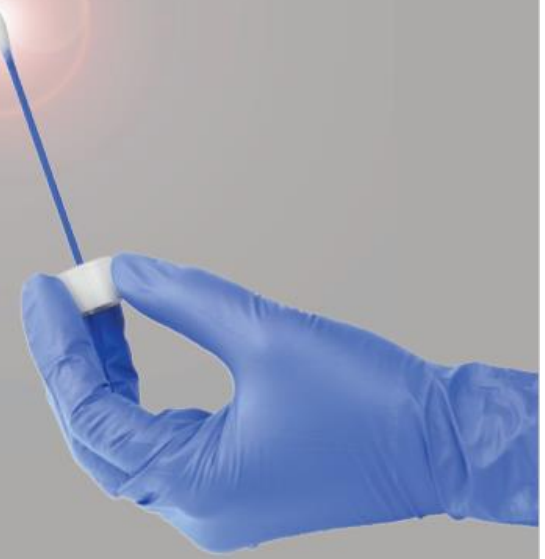
1-800-234-5333

foodsafety@neogen.com

Listeria Right Now

- Rapid *listeria spp.* test for Environmental Monitoring

- **Results in 1 hour**
- **No enrichment**



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Drug Residue Testing

- Recent FDA/NCIMS 2400 approval for Beta lactam and Tetracycline antibiotics
- Quickest and easiest test on the market!
- Just add milk operation