ION LABS	Standard Operating Procedure **Allergen Testing for Production Equipment**	**SOP Number** **D-111**	**Revision** **7**
		Effective Date 05/13/22	**Page** **Page 1 of 7**

Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
04/18/22	04/18/22	04/26/22
Title: Quality Systems Manager	**Title: Analytical Development Manager**	**Title: QC Laboratory Director**

1.0 Purpose

The purpose of this procedure is to define the use of the surface protein allergen test using 3M™ Clean-Trace Surface Protein (Allergen) and Neogen Accuclean Advanced Rapid Protein Residue Test to demonstrate production equipment is allergen free.

2.0 Scope

This procedure describes the use of allergen test methods in the validation and refinement of cleaning instructions to ensure each piece of production equipment is allergen free. These allergen test methods are not valid for the testing of cleaning fluids used in removing allergen from production surfaces. This procedure is specific to the testing of dry production equipment surfaces. A general protein test is the primary screen for non-selective testing of protein allergens on production equipment surfaces.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Management and/or designee to implement and maintain this procedure and to ensure that the procedure is being followed.

3.2 It is the responsibility of Quality Unit to execute monitoring activities.

3.3 It is the responsibility of Production Personnel to clean production equipment as per SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment and other applicable cleaning procedures.

3.4 It is the responsibility of Quality Management to review and approve all validation and test documentation and to notify production management when revalidation is required.

4.0 Definitions

4.1 **DC** – Document Control

4.2 **QC** – Quality Control

4.3 **AD** – Analytical Development

5.0 References

5.1 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

5.2 C-502, SOP, Record Storage, Retention, and Destruction

5.3 D-111-F1, Form, Allergen Test Ticket

5.4 RPT-20-0007, Report, Validation of Allergen Swabs: AccuClean Advanced Rapid Protein Residue Test

5.5 RPT-20-0008, Report, Justification of Detection Limits for using General Protein Swabs for Detection of Allergen Residues after Cleaning

6.0 Equipment/Materials

6.1 Surface Protein Allergen Test Kit

6.1.1 Product

6.1.1.1 3M™ Clean-Trace™ Surface Protein (Allergen), Cat #ALLTEC60

6.1.1.2 Neogen Accuclean Advanced Rapid Protein Residue Test or equivalent

6.1.2 Equipment

6.1.2.1 Biotrace International Digital Heating Block, model DHB120 or 1100.

6.1.2.2 Clean-Trace™ Surface Protein (Allergen) Test Method

6.1.3 Specifications (3M)

6.1.3.1 Sensitivity: Screens swabs at 3µg/100cm^2 surface protein

6.1.3.2 Test Time: 15 minutes

6.1.3.3 Storage: Refrigerated (2°C – 8°C)

6.1.4 Specifications (Neogen)

6.1.4.1 Sensitivity: Screens swabs at 5µg/100cm^2 surface protein

6.1.4.2 Test Time: 10 seconds

6.1.4.3 Storage: Room Temperature

7.0 Procedure

Note: All employees performing allergen tests must be properly garbed (hair net, gloves, lab coat or frock, shoe covers, etc.)

7.1 All production equipment in blending, tableting, encapsulation, coating, compression, gummy, or packaging areas that has product contact with an allergen should be cleaned, swabbed, and approved before continued use.

7.1.1 After equipment is cleaned, operation personnel will notify quality that the cleaned equipment is ready to be swabbed.

7.1.2 Quality will swab NLT 5 areas from each defined equipment grouping (see attachment 1) for the presence of allergens as defined in section 7.2. Some equipment grouping may not contain 5 different areas for swabbing. In these cases, swabbing of each product contact area should be performed.

7.1.3 Quality will prioritize hard to clean areas or any area in which accumulation of product may occur during the swabbing procedure.

7.1.4 Once the equipment is cleared to be allergen free, quality will notify operations that the equipment is approved for continued use.

7.2 Procedure – Surface Protein (Allergen). The instructions below are generalized for the 3M Clean Trace and Neogen Rapid Residue test. Manufacturer's instructions should be followed for equivalent swab technologies and more specific instructions.

7.2.1 Label a fresh Clean-Trace Surface Protein/Accuclean Advanced test tube with the location of the area swabbed.

7.2.2 Remove the swab from the tube without puncturing the membrane that separates the liquid at the tip of the tube from the swab.

7.2.3 Swab the area of approximately 10cm x 10cm (if the equipment allows) for Allergens.

7.2.4 The surface should be swabbed firmly (slight flex in the handle is acceptable) with a gentle rolling motion of the swab. If applicable, Swab in one direction from side to side and then from top to bottom. If the surface is dry, it may be necessary to wet the swab with the moisturizer supplied in the kit before swabbing.

7.2.5 Return the swab to the tube then press down from the top until the swab head penetrates the membrane and is submerged in the solution.

7.2.6 Vortex or shake the tube from side to side for 10 seconds.

7.2.7 If using 3M test swabs, place the tube into the digital heating block pre-equilibrated to 55°C and incubate for 15 minutes.

7.2.8 If using the Neogen test swabs, proceed to 7.2.10

7.2.9 Remove the tube vertically from the digital heating block.

7.2.10 Immediately note the color of the solution at the bottom of the tube.

7.2.11 Document testing information and report the result on the applicable Redzone data sheet or on form D-111-F1 Allergen Test Ticket.

7.2.12 Report testing results to the correct personnel.

7.2.13 Due to the nature of both allergen testing swabs, any protein present will be detected as a positive reading. If multiple positive results are observed, specific allergen tests for the potential allergen(s) of concern in the batch ran directly before the clean may be performed to rule out that allergen's presence.

8.0 Records

8.1 Redzone is the preferred method for documentation of ATP swab results. Use form D-111-F1 Allergen Test Ticket if not using Redzone. Fill in information as follows:

8.1.1 Room#- Location of equipment at the time of testing

8.1.2 Test Date – The date the test was performed

8.1.3 Description of equipment swabbed

8.1.4 Equipment Group – The cleaning instruction that will be impacted if the cleaning validation passes or fails on any one or combination of machine tests (See Attachment 1).

8.1.5 Initial Test / Retest- Identify the iteration of test for release of equipment.

8.1.6 Test Type – indicate the specific allergen or surface protein to distinguish type of allergen test being performed.

8.1.7 Major Clean Performed – Identify if a major clean was performed just prior to allergen testing

8.1.8 Allergen Exposure – The presence or potential presence of allergens in the finished product processed immediately before the major clean

8.1.9 Results: The test passes if the result is negative for allergens. The result fails id an allergen is detected.

8.1.10 Total Result – The combined result of all swab tests. If all tests are negative, the survey passes. If one or more tests fail, the survey fails

8.1.11 Survey Failure – Operational Management must be notified immediately of the failure. The equipment must be re-cleaned and retested.

8.1.12 Repeat steps 7.2.1-7.2.12.

8.2 Allergen Test Records are maintained by the Quality Group following SOP C-502 Record Storage, Retention, and Destruction.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/21/14	New	14-0178	B. Johns
1	04/21/14	Changed from Romer EIA kits to Neogen EIA kits. Added identification of protein source.	14-0357	B. Johns
2	10/06/14	Changed from Soy 3-D Reveal EIA kit to Alert EIA kit. Added new equipment. Changed log form.	14-0779	B. Johns
3	11/27/15	Adjusted equipment locations. Aligned SOP to present allergen test practices. Updated forms to improve clarity and traceability. Enhanced criteria for validating a cleaning process.	15-1142	B. Johns
4	10/18/17	Added 6.1.1.4 and note for gluten in section 6.0.	17-1064	S. Millar
5	08/19/19	Updated SOP and changed title to reflect current practices and procedures. Removed Allergen validation from SOP as the current practice is to swab after every batch containing an allergen	19-0676	I. Garrett
6	03/04/20	Updated to allow the use of alternate swabs	CC-20-0172	J. Maignan
7	04/18/22	Revised section 8.1 to include reference to Redzone data entry preference. Updated logo.	CC-22-0194	K. Burris

10.0 Attachments

10.1 Attachment 1 – Major Equipment Grouping

Attachment 1 – Major Equipment Grouping

Production Equipment Grouping List	
Blending	**Tableting**
Compression	**Encapsulation**
Packaging	**Coating**
Gummy	**Liquid**

ION LABS	Allergen Test Ticket		
	Form: D-111-F1	CCR No. CC-22-0194	Revision: 4

Room#: _____ **Test Date:** _____

Equipment Group: _____ □ **Initial Test** □ **Retest (1 2 3 __)**

Type Test (circle one): ***Surface Protein*** ***Other:*** _____

Previous Batch #: _____ **Formula#:** _____

Major Clean Performed (Y/N): _____ **Allergen Exposure (Y/N):** _____

Swab 01
Equipment Description: Result (circle one): Pass Fail

Swab 02
Equipment Description: Result (circle one): Pass Fail

Swab 03 □ **N/A**
Equipment Description: Result (circle one): Pass Fail

Swab 04 □ **N/A**
Equipment Description: Result (circle one): Pass Fail

Swab 05 □ **N/A**
Equipment Description: Result (circle one): Pass Fail

Final Result (Circle One): **Pass** **Fail**

Test Performed By/Date: _____ Reviewed By/Date: _____

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ION LABS	Cleaning Validation Log		
	Form: D-111-F2	CCR No. CC-22-0194	Revision: 5

Ion #: ______________________________

Equipment Description: ______________________________

Date	Test Type	Pass / Fail	Test / Retest	Validation Status	Due	Signature/Date
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
	□ Milk (Cow)	□ Pass □ Fail	□ Retest	□ Validated	□ ________	
	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	
	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
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	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
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	□ General	□ Pass □ Fail	□ Initial Test	□ Under Validation		
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	□ Egg (Chicken)	□ Pass □ Fail		□ Revalidated	□ Next Allergen	
	□ Soy	□ Pass □ Fail		□ Failed Validation	Major	

Second Reviewer: ______________________________

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