HBI Ion Labs	Standard Operating Procedure **Raw Material Sampling Procedure**	**SOP Number** **E-703**	**Revision** **12**
		Effective Date 10/01/25	**Page 1 of ~~6~~ 7** ①
Written by/ Date 10/01/25	**Reviewed by/ Date** AJS 10/01/25	**Approved by/ Date** 10/01/25	
Title: QC Microbiologist II	**Title: QC Lab Manager**	**Title: QA/QC Director**	

1. Purpose

The purpose of this procedure is to define the process for the sampling of raw materials.

2. Scope

This procedure applies to all raw materials used at Ion Labs, Inc.

3. Responsibility

3.1. It is the responsibility of QC Laboratory Management to implement and maintain this procedure.

3.2. It is the responsibility of Warehouse personnel to strictly follow the procedure.

4. Definitions

4.1. **R #** – Receiving number assigned to raw material upon receipt

4.2. **RMID –** Unique number assigned to a raw material for identification purposes

4.3. **IPA** – 70% Isopropyl Alcohol

4.4. **Alconox** – A powdered precision concentrated cleaning anionic detergent

4.5. **Simple Green** – All-purpose cleaner

4.6. **QC** – Quality Control

5. References

5.1. B-103, SOP, Cleaning Product Preparation and Small Parts Cleaning

5.2. D-111, SOP, Allergen Testing for Production Equipment

5.3. D-201, SOP, QC Laboratory Sample Logbook Recording

5.4. A-106, SOP, Documentation Guidelines for cGMP Records

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5.5. C-502, SOP, Record Storage, Retention, and Destruction

5.6. E-703-F1, Form, Raw Material Sampling Log

5.7. E-703-F2, Form, Sampling Room Cleaning Log

5.8. D-201-F1, Form, QC Laboratory Sample Log Book

5.9. World Health Organization Technical Report Series, No.929, 2005

6. Sampling Procedure

6.1. All sampling is to be performed in the sampling room. Prior to bringing the material into the sampling room, the room and any equipment in that room must be cleaned. Reference Form E-703-F2 Sampling Room Cleaning Log to ensure that the sampling room has been cleaned prior to use.

6.1.1. If necessary, clean the outside of the containers before transporting into the sampling room to avoid contamination of the sample.

6.1.2. Wear gloves, lab coat, hair nets, safety glasses, sleeves, and face masks to prevent contamination of self and/or material when sampling. Observe any safety warnings associated with the material being sampled. Reference B-103 Cleaning Product Preparation and Small Parts Cleaning for cleaning sampling utensils.

6.1.3. Only one R# is to be brought to the sampling room and sampled in the room at any time.

6.1.4. Choose a suitable, clean spatula/scoop/sampling spear and 20cc scintillation vial or equivalent container to collect and store the material. Any sampling equipment should be cleaned.

6.1.5. Any disposable sampling utensils used must be discarded between each use and a new sampling utensil retrieved for next samples taken.

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6.1.6. The number of samples for each raw material R# is determined

6.1.6.1. For materials that have a history of compliance and product quality that have been received from currently approved, one (1) representative container will be sampled for each R#.

6.1.6.2. For materials which the previous receival from the specific supplier/manufacturer that did not meet acceptance criteria and was rejected, the Expanded Sampling Plan ad detailed in the table in 6.1.6.4 will be utilized.

6.1.6.3. For materials that are new to the facility or from a new manufacturer for the material, the Expanded Sampling Plan is detailed in the table in 6.1.6.4.

6.1.6.4. Expanded Sampling Plan

Quantity of Containers Received (*N*)	Quantity of Containers to sample (*n*)
1	1
2 - 3	2
4 - 6	3
7 - 13	4
14 - 20	5
21 - 30	6
31 - 42	7
43 - 56	8
57 - 72	9
73 -90	10
91-110	11
111-132	12
133-156	13
157-182	14
183-210	15

This table is based on the calculation using the formula for all shipments with more than one container. Any amount of containers received not captured in the table above will need to be hand calculated for √N+1 sampling.

n= √N+1

where:
N = the number of individual containers for the R#
n= the number of containers to be sampled for the R#

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6.1.6.5. For materials that have a history of compliance and product quality that have been received from currently approved, one representative container will be sampled for each R#.

6.2. Sampling Allergens

6.2.1. When specific allergens are to be sampled (Dairy, Egg, Soy, etc.), identified sampling utensils will be used to sample their specific raw material (unless using disposable utensils). At completion of sampling, clean the utensils and place them in a specific cabinet. The sampling booth will be cleaned by a Major Clean (see section 7.5) upon completion of sampling after each allergen material and before non-allergen materials will be sampled.

6.3. Collect samples per the *sampling requirements* defined on the raw material specification sheet defined on Batch Master.

6.3.1. Samples collected for laboratory testing should be a composite sample that is representative of each container sampled.

6.3.2. Unless otherwise specified, 150g of sample should be collected for the lab divided into six (6) bags divided as follows:

Sample Label	Amount (g)
Lab (3)	30 (Each)
Micro	20
Reserve	10
Outsource	30

6.4. Identify the samples with the following information

6.4.1. Raw material Name

6.4.2. Manufacturer/Vendor's Name

6.4.3. R #/ RMID

6.4.4. Manufacturer's lot #

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6.4.5. No. of containers collected – e.g., 1 of 2, 2 of 2.

6.4.6. Sampled by/Date sampled

6.5. Close and reseal each container then place into another plastic bag (secondary confinement) after sampling to protect content integrity. If a bag has been punctured to take a sample, then the sampling hole should be appropriately closed with food grade tape.

6.6. Sampled containers should be identified with a "Sampled" sticker.

6.7. After each sampling, the Form E-703-F1 Sampling Log is completed as follows:

6.7.1. Date of sampling, R#/RMID sampled, number of containers received, samples taken, performed by, etc.

6.8. The samples will be delivered to the QC laboratory for analysis. Log the samples on form D-201-F1 QC laboratory Sample Log Book. Refer to SOP D-201 QC Laboratory Sample Logbook Recording for logging instructions.

6.9. Reserve Samples

6.9.1. Reserve samples will be pulled and delivered to the QC Laboratory in the same manner as defined in section 6.3.

6.9.2. Reserve samples are logged and maintained by the QC Laboratory.

7. Cleaning Procedure

7.1. Monthly cleaning for the sampling room

7.1.1. Vacuum ceiling.

7.1.2. Wipe the wall and vinyl strips with warm water. Disinfect with IPA.

7.2. Weekly cleaning for the sampling room

7.2.1. Mop the floor with warm water containing damp mop floor cleaner. Allow to dry.

7.3. Daily cleaning for the sampling room

7.3.1. Empty waste container.

7.3.2. Sweep the floor with a dust headed broom, a sweeper, or vacuum, to diminish the possibility of powder or dust to the air.

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7.3.3. Wipe shelves and equipment with IPA and allow to air dry.

7.3.4. After use and reuse, wash any non-disposable sampling tools with Simple Green or Alconox cleaning solution, rinse with warm water, spray with IPA, and allow to dry.

7.4. After each cleaning, document the cleaning on Form E-703-F2 Sampling Room Cleaning Log.

7.5. Cleaning following Allergen Sampling

7.5.1. The sampling booth will be cleaned by a Major Clean upon completion of sampling each allergen material and before non-allergen materials will be sampled.

7.5.1.1. Prepare cleaning solution as described in SOP B-103 Cleaning Product Preparation and Small Parts Cleaning for cleaning curtains, cabinets, and shelves.

7.5.1.2. Vacuum the ceiling.

7.5.1.3. Wipe curtains, cabinets, and shelves with Alconox.

7.5.1.4. Clean the floor with damp mop floor cleaner.

7.5.2. After cleaning, document the cleaning as a major cleaning in the daily cleaning section of Form E-703-F2 Sampling Room Cleaning Log.

7.5.3. Once the Major clean is completed after allergen sampling, the sampling booth will be swabbed for allergens as defined in SOP D-111 Allergen Testing for Production Equipment. Results will be documented on Form E-703-F2 Sampling Room Cleaning Log.

8. Documentation Requirements

8.1. A PQV (process quality verification) check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

8.2. Documents will be maintained following SOP C-502 Record Storage, Retention, and Destruction.

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8.0 Revision History

Revision	Date	Description of Changes	CCN	By
0	05/06/10	New procedure	-	-
1	09/21/11	Changed sections 5.3.4, 5.3.5.,5.3.6, removed section 5.5.	-	-
2	12/13/12	Changed the SOP title and format, revised SOP for clarity.	-	-
3	04/02/13	Changed the SOP logo and number.	-	-
4	02/05/14	Changed the SOP title and format, revised entire procedure.	14-0122	V. Iltcheva
5	03/14/14	Changed section 6.8 add secondary confinement .	14-0182	L. Titolo
6	04/16/14	Added section for allergen sampling and cleaning.	14-0337	M. Wienke
7	09/06/16	Biennial review; added reference to SQF, rearranged cleaning steps.	16-0793	E. Hasanbasic
8	02/03/20	Triennial review; updated to current process, minor corrections.	CC-20-0075	J. Sassman
9	09/24/21	Added allergen swabbing to cleaning procedure.	CC-21-0365	J. Sassman
10	12/06/21	Updated to correct $\sqrt{N+1}$ table and correct cleaning solutions.	CC-21-0453	J. Sassman
11	01/06/23	Added use of disposable sampling utensils. Updated format and wording throughout. Added checkboxes for each sampling booth to both forms. Added documentation requirements and SOP references.	CC-22-0480	J. Murphy
12	08/15/25	Add the amount in grams of raw materials for the warehouse operators to pull for lab testing to the SOP.Updated company logo in SOP and forms F1 & F2	CC-25-0197	M. Autrey

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HBI Ion Labs	Raw Material Sampling Log		
	Form: E-703-F1	CCR No. CC-25-0197	Revision: 6

Location (check one): **Sampling Booth 1** ☐ **Sampling Booth 2** ☐

Date	R #	RMID	Quantity of containers received	Sampling Plan		Quantity of containers Sampled	√ if Allergen	Performed By/ Date
				# Containers to Sample	Assigned By/Date			

PQV: _____

HBI Ion Labs	Sampling Room Cleaning Log		
	Form: E-703-F2	CCR No. CC-25-0197	Revision: 4

Month: _____ **Year:** _____ **Location (check one):** **Sampling Booth 1** ☐ **Sampling Booth 2** ☐

Day	Empty Waste Container	Floor (Dust, Mop)	Shelves/Eqp. (IPA)	Sampling Tools (Alconox, IPA)	Floor (Wet Mop, Cleaner)	Strip Curtain Walls (IPA)	√ if cleaning after allergen	Allergen Swab Locations (Number)	Allergen Swab Results	Initials
	Perform Daily				Perform Weekly	Perform Monthly				

PQV: _____

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