1.0 Purpose

The purpose of this procedure is to set guidelines for the microbiological Environmental Monitoring Program (EMP) of Ion Labs two buildings (Operations/Administration and Warehouse). This program is used to verify the effectiveness of the facility's cleaning, maintenance and GMP programs at Ion Labs Inc. The EMP will focus on environmental air and non-product contact surfaces within the plant processing areas during normal production periods.

2.0 Scope

This procedure applies to all production areas and used to determine the effectiveness of the plant sanitation program. This SOP outlines the sampling plan to execute microbiological testing of air and non-product contact surfaces for an entire year. Sample points are defined by site location and testing type, with corresponding alert/action limits established. All defined locations are tested at least once each quarter and test results are documented on the forms provided. A summary report is generated each quarter to summarize observed trends, excursions events and corrective action(s) taken during that period.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Analysts to follow this procedure.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.

3.3 It is the responsibility of QC Laboratory Management to keep this procedure aligned with current practices and to oversee validations and recovery studies.

4.0 Definitions

4.1 **Zone 1: Product Contact Surface (PCS)** – surfaces that come into direct contact with ingredients and/or product

4.2 **Non-product Contact Surface (Non-PCS)** – surfaces that do not come into direct contact with the product and/or components

4.3 **Zone 2** – non-PCS adjacent to or within close proximity to the PCS; areas that, if contaminated, could reasonably lead to PCS contamination; examples include (but are not limited to):

4.3.1 Exterior of equipment that is in contact with the product

4.3.2 Conveyor belts, legs/framework in the filling process, and any areas of the filling equipment that is near floor drains

4.3.3 Platforms and handrails in Blending

4.3.4 Equipment housing (panel buttons, operator control buttons)

4.3.5 Floor drains below conveyors

4.3.6 Work surfaces adjacent to unsealed product (i.e., tables)

4.3.7 Ventilation and air handling equipment

4.4 **Zone 3** – the area that immediately that surrounds Zone 2; areas that, if contaminated, could lead to PCS contamination with human intervention (i.e., employee using compressed air to clean floors or a piece of equipment); examples include (but are not limited to):

4.4.1 Permanently mounted air and water hoses

4.4.2 Floors and floor drains

4.4.3 Damaged floors, i.e., cracks, crevices, missing piece of concrete

4.4.4 Corridors

4.4.5 Walls

4.5 **Zone 4** – the area immediately surrounding Zone 3, generally considered a remote area; area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery; examples include (but are not limited to):

4.5.1 Employee locker rooms

4.5.2 Warehouse

4.5.3 Breakrooms

4.5.4 Hallways

4.5.5 Labs

4.6 **EMP** – Environmental Monitoring Program

4.7 **EM** – Environmental Monitoring

4.8 **TSA** – Tryptic Soy Agar

4.9 **SDA** – Sabouraud Dextrose Agar

4.10 **NMT** – No More Than

4.11 **CFU** – Colony Forming Units

4.12 **QC** – Quality Control

4.13 **Alert Limit** – indication that microbial count is increasing in area

4.14 **Action Limit** – signals an apparent deviation from normal process conditions. Requires immediate action

4.15 **Confirmed Positive** – positive result determined using identification

4.16 **IQ** – Installation Qualification

4.17 **OQ** – Operation Qualification

4.18 **PQ** – Performance Qualification

4.19 **CAPA** – Corrective and Preventative Action

4.20 **GMP** – Good Manufacturing Practices

5.0 References

5.1 C-201, SOP, Deviation and Investigation Procedure

5.2 D-101, SOP, Laboratory Housekeeping

5.3 C-403, SOP, Change Control Procedure

5.4 A-106, Documentation Guidelines for cGMP Records

5.5 C-501, SOP, Document Control

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

5.7 QS-108, SOP, Corrective and Preventative Action (CAPA)

5.8 C-105, SOP, Protocol and Report Documentation Requirements

5.9 PRTCL-21-0037, Protocol, Environmental Monitoring of Air and Surfaces

5.10 The FDA's 2021 draft guidance is a key resource for understanding how to control microbiological quality in non-sterile drug manufacturing.

5.11 U.S. Pharmacopoeia, USP42-NF37 2S (2020). < 1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments

5.12 Parenteral Drug Association Technical Report No. 13. (2014). Fundamentals of an Environmental Monitoring Program (Revised Edition)

5.13 D-115-F2, Form, Alert/Action and Positive Result Resample Log

5.14 D-115-F1, Form, Air and Surface Sampling Log

5.15 D-115-F3, Form, Preliminary Pathogen Screening Log.

6.0 Required Supplies, Media, and Equipment

6.1 Sterile Swabs and/or Sponges

6.2 Tryptic Soy Agar (TSA) plates and contact plates

6.3 Sabouraud Dextrose Agar (SDA) plates and contact plates

6.4 20 °C to 25°C and 30 °C to 40°C Incubators (adjustable)

6.5 Biological Safety Cabinet

7.0 Procedure

7.1 Sample Labeling and Preparation

7.1.1 Obtain media and confirm it is not expired as of date of use.

7.1.2 Label swabs, contact plates and air plates with corresponding site location. (See Attachment 1 and 2)

7.2 Sampling Environmental Surfaces - Swab Sampling for TAPC and Yeast & Mold on Drains.

7.2.1 Allow swab to acclimate to ambient temperature (21-25 °C) before use. Use thumb to break snap-valve by bending bulb, releasing liquid into tube and wetting swab.

7.2.2 Drain swabbing should consist of those surfaces that can harbor bacteria and then be contact transferred to other areas of the business.

7.2.3 Surface Drains

7.2.3.1 Before sampling, ensure that no probiotics are being actively handled on the site location. Do not sample processing rooms running probiotics. Surface drain monitoring testing will be conducted after a major cleaning procedure is completed.

7.2.3.2 Pull swab out of tube and swab an area (4x4 inches) for flat surface and a representative area size for irregular surfaces.

7.2.3.3 Replace swab in tube and deliver to lab for inoculation.

7.2.4 Trench Drains (Gummy Lines)

7.2.4.1 Trench drains typically are comprised of multiple sections and individual covers.

7.2.4.2 Pull swab out of tube and swab an area (4x4 inches) for flat surface and a representative area size for irregular surfaces.

7.2.5 Sanitize the interior of the biological safety cabinet as per SOP D-101 Laboratory Housekeeping before plating.

7.2.6 Shake device 10 seconds to mix and pour content in 99ml buffered peptone water for 1:100 dilution. Vortex and place 500 µL in two Petri dishes.

7.2.7 Pour Tryptic Soy Agar and Saboraud Dextrose Agar onto one of each plate and swirl gently to mix.

7.2.8 Incubate TSA plates at 33°C ± 2°C for 48-72 hours. Incubate SDA plates at 23°C ± 2°C for 5-7 days.

7.2.9 All data collected for swabbing testing of the drains will be documented on Form D-115-F1 Air and Surface Sampling Log.

7.3 Sampling Environmental Surfaces - Contact Plates Sampling for TAPC and Yeast & Mold

7.3.1 Allow contact plates (TSA and SDA) to acclimate to ambient temperature (21-25 °C) before use.

7.3.2 Before sampling, ensure that no probiotics are being actively handled on the site location. Do not sample processing rooms running probiotics. Surface monitoring testing will be conducted after a major cleaning procedure is completed.

7.3.3 Remove cover, place contact plate directly on surface, and press slightly. Remove from surface and cover.

7.3.4 Incubate TSA plates at 33°C ± 2°C for 48-72 hours. Incubate SDA plates at 23°C ± 2°C for 5-7 days.

7.3.5 All data collected for contact plate testing will be documented on Form D-115-F1 Air and Surface Sampling Log.

7.4 Environmental Air – Settling Plate Sampling for TAPC and Yeast & Mold

7.4.1 Allow plates (TSA and SDA) to acclimate to ambient temperature (21-25 °C) before use.

7.4.2 Before sampling, ensure that no probiotics are being actively handled on the site location. Do not sample processing rooms running probiotics. Air monitoring testing will be conducted after a major cleaning procedure is completed.

7.4.3 Place one prepared SDA Plate and one TSA plate in the sample site location with covers removed.

7.4.4 Leave the plate exposed for a minimum of 15 minutes in each location.

7.4.5 Incubate TSA plates at 33°C ± 2°C for 48-72 hours.

7.4.6 Incubate SDA plates at 23°C ± 2°C for 5-7 days.

7.4.7 All data collected for air testing will be documented on Form D-115-F1 Air and Surface Sampling Log.

7.5 Reporting Results

7.5.1 Count colonies and record as CFU/plate.

7.5.2 If no colonies appear on the plate, the result should be reported as "ND".

7.5.3 If TNTC results are obtained on sites where probiotics were processed, these results should be invalided and a new sample must be collected. The location site should be sanitized prior to re-sampling.

7.5.4 If growth is observed on TSA or SDA, further isolate colonies with distinctive morphologies, if applicable. Non-selective media such as TSA or Blood Agar should be used for bacteria, and SDA for yeast isolation. Mold screening is not required and isolation from TNTC plates is not performed.

7.5.5 Each isolated growth will be labeled as sample location (See Attachment 1 – Sample Site Key) + colony isolated (A, B, C…).

7.5.5.1 For instance, B5-9A plate will refer to Blending Room 5 – Table, and the letter A is assigned to the first isolated colony from B5-9 environmental plate. If multiple colonies are isolated from same plate, next isolation plate will be B5-9B, B5-9C…

7.5.6 Incubate TSA or Blood Agar at 33°C ± 2°C for 24-48 hours.

7.5.7 Incubate SDA plates at 23°C ± 2°C for 5-7 days.

7.5.8 Inoculate the isolated growth onto pathogen specific media to determine the presence of pathogens. Refer SOP D-715.0 Microbial Limit Testing using Agar Plates. Commercially prepared chromogenic media may be used as supporting media for presumptive identification. Follow vendor instructions for incubation time and temperatures.

7.5.8.1 Alternatively, identification can be performed directly from growth isolated on TSA, Blood Agar or SDA, to confirm presence or absence of specific pathogens. Reference SOP D-1016 Microbial Identification via Biolog Microstation for identification instructions.

7.5.9 If typical growth is observed on the pathogen specific media, then this growth requires a confirmatory identification. Reference SOP D-1016 Microbial Identification via Biolog Microstation for identification instructions.

7.5.10 If no growth or atypical growth is observed report as "ND" for specific pathogen screening and no more testing is required. Document results on Form D-115-F3 Preliminary Pathogen Screening Log.

8.0 Specifications

8.1 Environmental Monitoring of Air and Surfaces for Alert/Action Limits specifications:

Test	Alert Limit	Action Limit
Air	88	126
Surface (Contact)	181	253
Surface (Drains)	2022	2869

8.2 Positive results are obtained with the confirmed identification of one of the following organisms:

Test	Specification
S. aureus	Negative
E. coli	Negative
L. monocytogenes	Negative
Salmonella spp.	Negative
P. aeruginosa	Negative
C. albicans	Negative

8.3 Any presumptive positive or typical growth observed, should be identified to the species level to confirm absence or presence of the organisms listed above. Reference SOP D-1016 Microbial Identification via Biolog Microstation for identification instructions.

9.0 Corrective Action

9.1 Exceeded Alert Limit

9.1.1 When results exceed the specified alert limit, a member of operational management must be notified, and the affected area resampled. The location site should be sanitized prior to re-sampling. Document on form D-115-F2 Alert/Action and Positive Result Resample Log.

9.2 Exceeded Action Limit or Confirmed Positive

9.2.1 Corrective actions must be taken when results exceed Action limits, or a confirmed positive is found in any zone. Verified presence of a pathogen listed in this SOP is an action limit failure.

9.2.2 Operational and Quality management must be immediately notified and the event exceeding action limits documented in a deviation.

9.2.3 QC personnel initiate a deviation after confirmation of the initial action limit failure result is obtained. Corrective actions will be documented on forms C-201-F1. Refer to SOP C-201 Deviation and Investigation Procedure. Deviations for an event exceeding action limits may include risk assessment and/or CAPA. Alternatively, initiation of a CAPA following SOP QS-108 Corrective and Preventative Action

(CAPA) may be performed. DEV or CAPA number assigned (if applicable), will be documented on Form D-115-F2 Alert/Action and Positive Result Resample Log.

9.2.4 Any product produced in the impacted area should be identified and documented on Deviation or CAPA initiated, along with the disposition decision based on the associated risk assessment.

9.2.5 Frequency of sampling of the impacted area and the areas directly surrounding the impacted area will be increased from once per quarter to once per business day until at least three consecutive results are below the action limits. Areas should be sanitized prior re-sampling gets started. All resamples taken will be documented on Form D-115-F2 Alert/Action and Positive Result Resample Log.

9.2.6 Increased sampling rates described above do not need to occur on days where there is no activity other than corrective actions intended to resolve the observed result(s). Whether the area is used for actual production activity depends on associated risk assessment.

9.2.7 After achieving three consecutive results below the action limits, resume the regular sampling frequency.

9.2.8 If re-sampling and/ or the areas directly surrounding the impacted area still show concerning or positive results then alternative corrective action(s) should be explored to correct any GMP deficiencies based on the findings. These may include:

9.2.8.1 Review of microbiological sampling methods and techniques

9.2.8.2 Reinforce or retrain hygienic practices with appropriate employees

9.2.8.3 Revision of the sanitization program, including selection of antimicrobial agents, application methods, and frequencies

9.2.8.4 Eliminate water if present

9.2.8.5 Repair damaged floors/walls and other structural damage

9.2.8.6 Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (employee and equipment) through the area, restrict forklift truck movement, redirect high-risk traffic patterns from adjacent areas, etc.

9.2.8.7 To verify the effectiveness of corrective actions taken, sampling frequency of these sites will be increased as previously described in sections 9.2.5 to 9.2.7. Document on Form D-115-F2 Alert/Action and Positive Result Resample Log. Then resume the regular sampling frequency.

9.2.8.8 If any of the re-samples do not meet specification, follow procedure again from the beginning of this section.

9.3 Consecutive Alert/ Action Level or Positive Results

9.3.1 Consecutive Alert/Action Level or positive results may indicate the primary source is a harborage site (where the organism may have been established and multiplying).

9.3.2 Map the contamination sites on a layout of the facility to aid in locating the source of contamination.

9.3.3 Reinforce GMP training and hygienic practices and provide additional attention to sanitation practices.

9.3.4 Visually inspect areas for potential niches. Intensify cleaning activities around these areas.

9.3.5 Observe handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.

9.3.6 Review equipment cleaning and preventative maintenance protocols and revise if necessary.

9.4 Construction or New Equipment

9.4.1 Construction or new equipment installation in the processing areas may affect the PCS. Assess plant traffic controls, sanitation activities, etc. during construction activities. Assess environmental monitoring requirements within protocols initiated at time of construction or new equipment installation (i.e. IQ/OQ/PQ for those processes).

10.0 Issuing, Reporting, and Filing

10.1 Attachment 1 through 2 will be utilized for each sampling plan to execute the Environmental Monitoring of Air and Surfaces for an entire year.

10.2 Document all routine samples taken and results obtained on forms D-115-F1 Air and Surface Sampling Log.

10.3 All resamples taken, CAPAs, or DEV numbers assigned (if applicable), and results obtained will be documented on form D-115-F2 Alert/Action and Positive Result Resample Log.

10.4 A summary report will be generated of each quarter with testing and trending to Document Control with an issued Report number. Refer to SOP C-105 Protocol and Report Documentation Requirements. This quarterly review should be documented within sixty calendar days of the end of each subject quarter.

10.5 Quarterly reports will summarize the monitoring data for the quarter and will contain trend reports for a rolling year. The reports will include:

10.5.1 Summation of the data collected

10.5.2 Evaluation of the adequacy of the current sampling plans

10.5.3 Evaluation of the adequacy of established alert and action limits

10.5.4 All reports will be approved by a minimum of four (4) signatures to include:

10.5.4.1 Author

10.5.4.2 QC Laboratory Management

10.5.4.3 Head of Quality or Quality designee outside the QC Laboratory

10.5.4.4 Head of Operations or designee

11.0 Revisions

11.1 Review specifications for alert/action limits annually or as needed.

11.1.1 A risk-based impact assessment should be conducted to understand each process and identify where microbial contamination could occur. The level of control should be on product-specific characteristics (e.g., dosage form, water activity, antimicrobial properties) and manufacturing process elements that are more likely to introduce bioburden or objectionable microorganisms.

11.1.2 The level of potential contamination should be adjusted, with consideration to the processing conditions within each area. These conditions include, but are not limited to, product's exposure, personnel traffic, material flow, and the effectiveness of cleaning and sanitization procedures. Example shown below.

Area	**Risk Factor**	**Processing Conditions**
Blending Room	High	Open product, high personnel traffic
Packaging Line	Medium	Product enclosed, moderate traffic
Warehouse	Low	No product exposure

11.1.3 Once each area has been assessed, alert and action limits will be calculated based on trend analysis of data collected over the previous calendar year. The microbial baseline level will be defined using updated historical data to ensure continued representation of the processes normal operating range and to reflect any improvements.

11.1.4 The calculation is performed using the average and the standard deviation of the analyzed data as follows:

Alert Limit = Average + 2 Standard Deviations

Action Limit = Average + 3 Standard Deviations

11.2 Adjust sampling plans throughout the year as necessary to accommodate added locations and new equipment installations.

11.3 Follow SOP C-403 Change Control Procedure to process all revisions made to sampling plans.

12.0 Documentation Requirements

12.1 All documentation will be distributed and maintained as outlined in SOP C-501 Document Control and SOP C-502 Record Storage, Retention, and Destruction.

12.2 All documentation will be completed as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

13.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/04/19	New procedure.	N/A	L. McWade
1	07/02/21	Added plans for each room including drains. Added flow chart for gram stain and additional testing to identify positive samples.	CC-21-0235	G. Shaw
2	11/08/21	Updated numbering of keys. Adjusted gummy room to quarterly testing scheme.	CC-21-0420	G. Shaw
3	03/21/22	Added stick pack rooms to schedule. Clarified testing and maps. Split R&D.	CC-22-0086	G. Shaw

4	04/28/22	Annual recalculation of alert and action limits.	CC-22-0208	G. Shaw
5	09/30/22	Kept drains on for temporary alert and action limits. Added layout and sites for the new warehouse building, including sampling booths.	CC-22-0390	G. Shaw
6	03/20/23	Added new testing for gummy lines and associated liquid and packaging rooms. Deleted unnecessary content. New form D-115-F3 Gummy Line Air and Surface Sampling Log created specifically for gummy line.	CC-23-0145	G. Shaw
7	07/12/23	Added mop sinks and log for all sinks. Adjusted plan to be just one that is followed quarterly. Added reference to drain sampling log. Added documentation requirements. Updated format.	CC-23-0340	G. Shaw
8	01/22/24	Revised to clarify current practices. Removed pathogen testing for gummy rooms. Clarified corrective actions. Added alert and action limits for drains. Added Drain Map.	CC-24-0035	J. Sassman
9	04/15/24	Revised to reflect current practices. Updated sample plan testing. Removed reference to obsolete forms. Added new forms D-115-F1 and D-115-F3.	CC-24-0158	A. Perez
10	09/09/24	Revised to reflect current practices. Updated sample plan testing. Clarified preliminary procedure for selective pathogen screening. Minor changes on forms D-115-F1 and D-115-F2. Added new form D-115-F3 Preliminary Pathogen Screening Log.	CC-24-0494	A. Perez
11	09/12/25	Revised to reflect current practices. Updated sample plan testing. Annual recalculation of alert and action limits.	CC-25-0359	A. Perez

14.0 Attachments

14.1 Attachment 1 – Sample Site Key

14.2 Attachment 2 – Quarterly Sampling Plan

14.3 Attachment 3 – Site Map

14.4 Attachment 4 – Layout for Kitting and Sampling Booths

14.5 Attachment 5 – Drain Maps

ATTACHMENT 1 – SAMPLE SITE KEY

Week Number

1-12

Rooms

B = Blending (Zone 2)
C = Encapsulation (Zone 2)
T = Tableting (Zone 2)
WB = Weigh Blend (Zone 2)
SB = Sampling Booth (Zone 4)
L = Liquids (Zone 2)
CT = Coating (Zone 2)
P = Packaging (Zone 2)
FP = Final Pack (Zone 3)
SA = Sanitation (Zone 3)
WC = Walk-in Cooler (Zone 4)
CR = Cold Room (Zone 4)
LR = Locker Room (Zone 4)
K = Kitting (Zone 4)
R&D = Research and Development Lab (Zone 4)

Air Sample Sites

1 = Closest end of room
2 = Center of room
3 = Far end of room
F = Front
B = Back
R - Right
L - Left

Surface Sample Sites

6 = Misc or Mix 3 Kettle (Zone 2)
7 = Main Equipment or Mogul Dispenser (Zone 2)
8 = Conveyor or Cooling Tunnel (Zone 2)
9 = Table or Premix Table (Zone 2)
10 = Drain (Zone 2 or Zone 3)

Gummy Lines

GL2 = Gummy Line 2
GL3 = Gummy Line 3
GL4 = Gummy Line 4/Gummy Line Packaging
GLSA = Gummy Line Sanitation
GLDR1 = Gummy Line Drying Room 1
GLDR2 = Gummy Line Drying Room 2
GLDR3 = Gummy Line Drying Room 3

ATTACHMENT 2 – QUARTERLY SAMPLING PLAN

Week	Air/Surface	Drain Swabs
W1	CT1-1/6,7,9	L1 F,B
W1	CT2-1/6,7,9	B1
W1	CT3-1/6,7,9	SA1-1
W1	CT4-1/6,7,9	SA1-2

Week	Air/Surface	Drain Swabs
W2	L1F,B-1/6,7,9(a)	L2 F,B
W2	L2F,B-1/6,7,9(a)	SA1-3
W2	L3F,B-1/6,7,9(a)	SA1-4
W2	L4F,B-1/6,7,9(a)	GL2
W2	L5F,B-1/6,7,9(a)	
W2	GLDR1-1	
W2	GLDR2-1	

(a) Liquid Rooms back only get air sampling

Week	Air/Surface	Drain Swabs
W3	FP1-1/6,7,9	SA1-5
W3	FP2-1/6,7,9	B2
W3	P1-1,2,3/6,7,8	L3 F,B
W3	P2-1,2,3/6,7,8	
W3	P3-1,2,3/6,7,8	
W3	GLSA-1/6	

Week	Air/Surface	Drain Swabs
W4	B1-1/6,7,9	SA1-6
W4	B2-1/6,7,9	SA1-7
W4	B3-1/6,7,9	SA1-8
W4	B4-1/6,7,9	SA1-9
W4	B5-1/6,7,9	
W4	B6-1/6,7	

ATTACHMENT 2 – QUARTERLY SAMPLING PLAN (CONTINUED)

Week	Air/Surface	Drain Swabs
W5	C1-1/6,7,9	SA1-10
W5	C2-1/6,7,9	B3
W5	C3-1/6,7,9	CT3
W5	C4-1/6,7,9	L4 F, B
W5	GL2 – 1, 2, 3/8	

Week	Air/Surface	Drain Swabs
W6	P4-1,2,3/6,7,8	SA2-1
W6	P5-1,2,3/6,7,8	B4
W6	P8-1,2,3/6,7,8	CT4
W6	CR-1/6	L5 F,B
W6	GLDR3 - 1	

Week	Air/Surface	Drain Swabs
W7	GL4 – 1,2,3/8	SA2-2
W7	T2-1/6,7,9	B5
W7	T3-1/6,7,9	GL4
W7	T4-1/6,7,9	
W7	T5-1/6,7,9	
W7	T6-1/6,7,9	
W7	T7-1/6,7,9	
W7	T8-1/6,7,9	

Week	Air/Surface	Drain Swabs
W8	B1 – 1/6,7,9	SA2-3
W8	B2 – 1/6,7,9	B6
W8	B3 – 1/6,7,9	
W8	B4 – 1/6,7,9	
W8	B5 – 1/6,7,9	
W8	B6 – 1/6,7	

ATTACHMENT 2 – QUARTERLY SAMPLING PLAN (CONTINUED)

Week	Air/Surface	Drain Swabs
W9	C5-1/6,7,9	SA2-4
W9	C6-1/6,7,9	SA2-5
W9	C7-1/6,7,9	GL3
W9	C8-1/6,7,9	
W9	GL3 – 1,2,3/8	

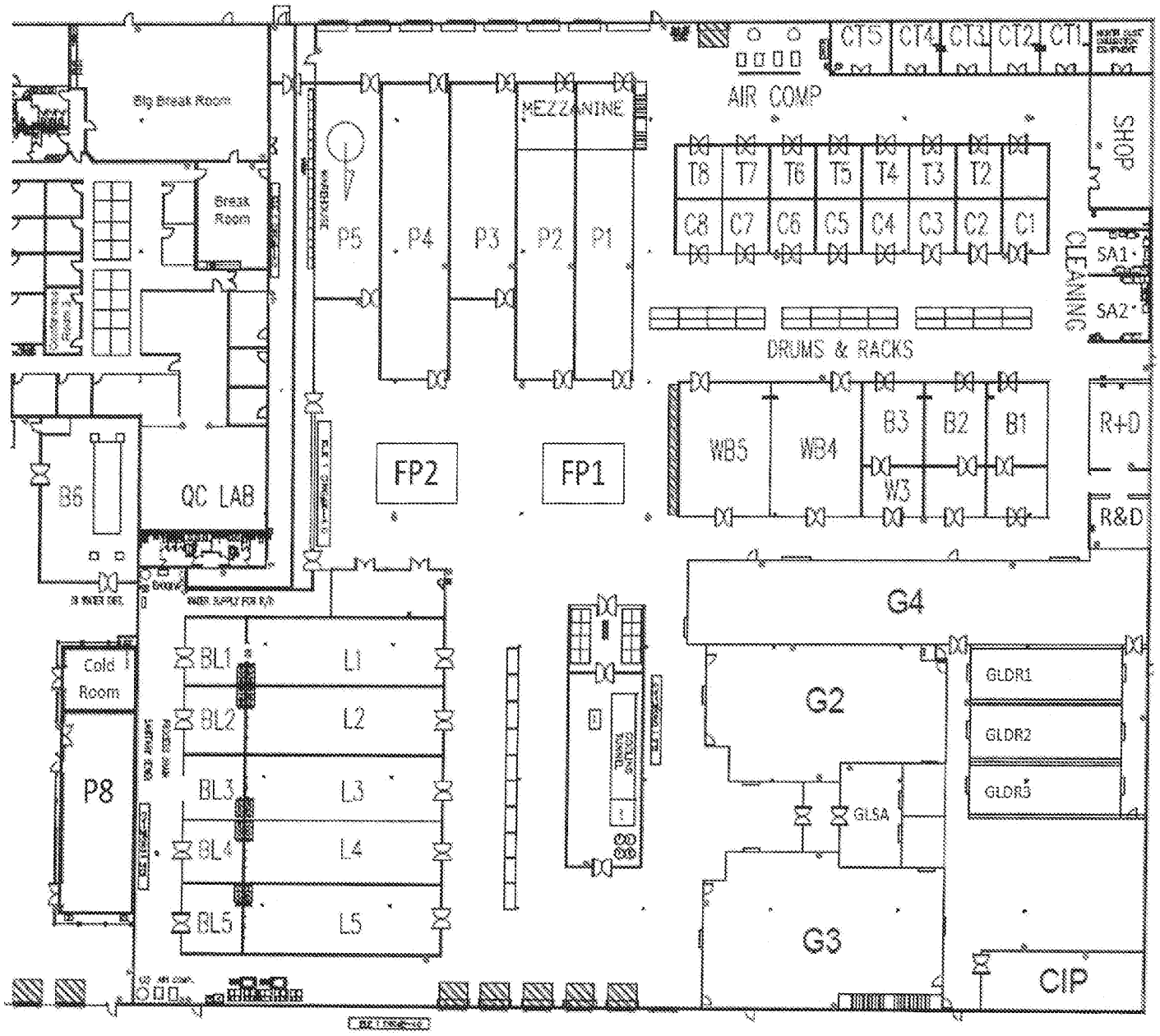
Week	Air/Surface	Drain Swabs
W10	R&D-R-1/6,7,9	SA2-6
W10	R&D-L-1/6,7,9	GLSA
W10	LR-1/6	
W10	SA1-1/6	
W10	SA2-1/6	
W10	GLSA-1/6	

Week	Air/Surface	Drain Swabs
W11	K1-1/6 (b)	Belcher Mop Sink (b)
W11	K2-1/6 (b)	
W11	K3-1/6 (b)	
W11	K4-1/6 (b)	
W11	SB-R-1 (b)	
W11	WC-1/6 (b)	

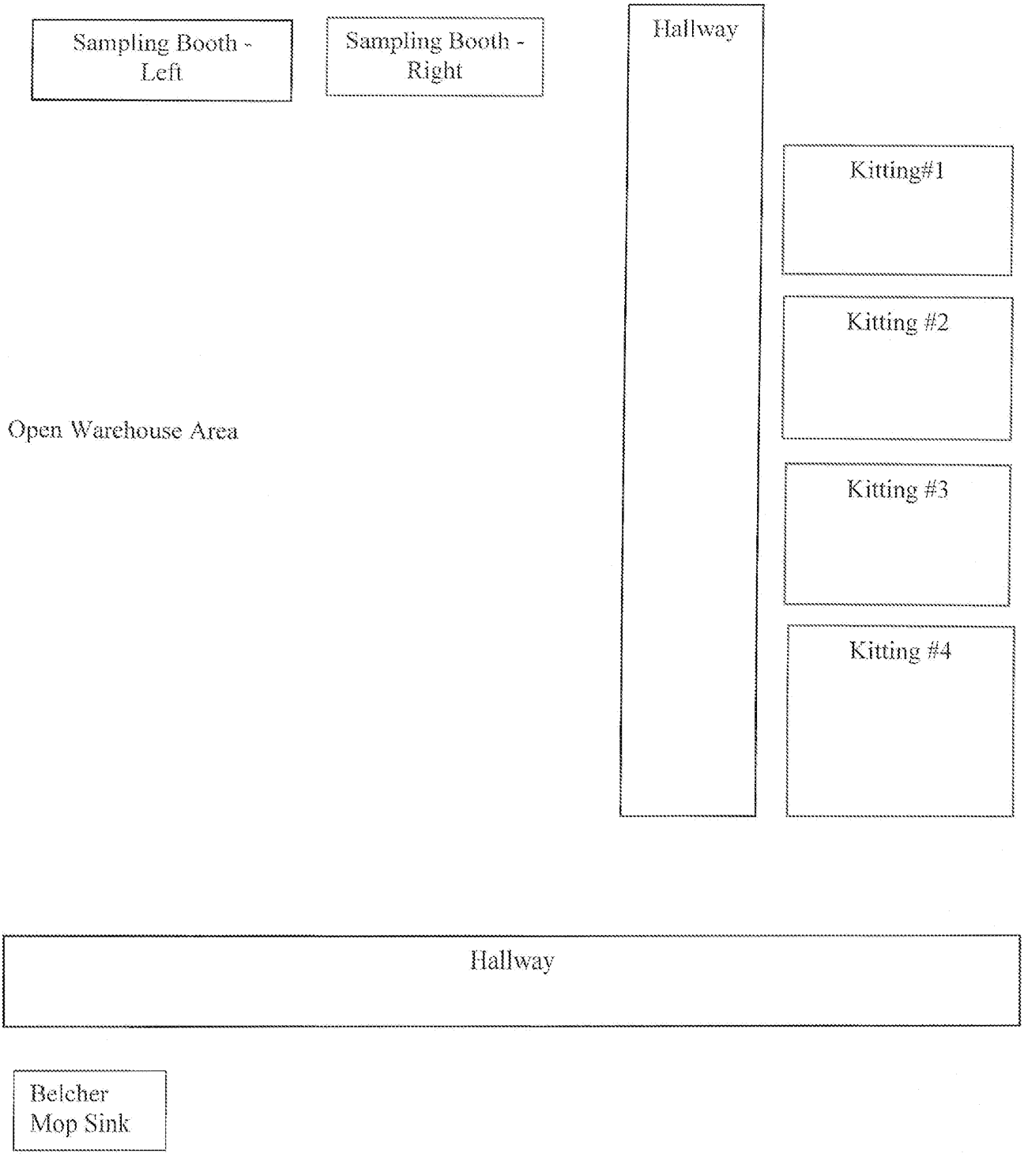
(b) Sampling done at Belcher

Week	Air/Surface	Drain Swabs
W12	B1 – 1/6,7,9	SA Mop Sink
W12	B2 – 1/6,7,9	L Mop Sink
W12	B3 – 1/6,7,9	
W12	B4 – 1/6,7,9	
W12	B5 – 1/6,7,9	
W12	B6 – 1/6,7	
W12	WB3 – 1/7	

ATTACHMENT 3 – SITE MAP

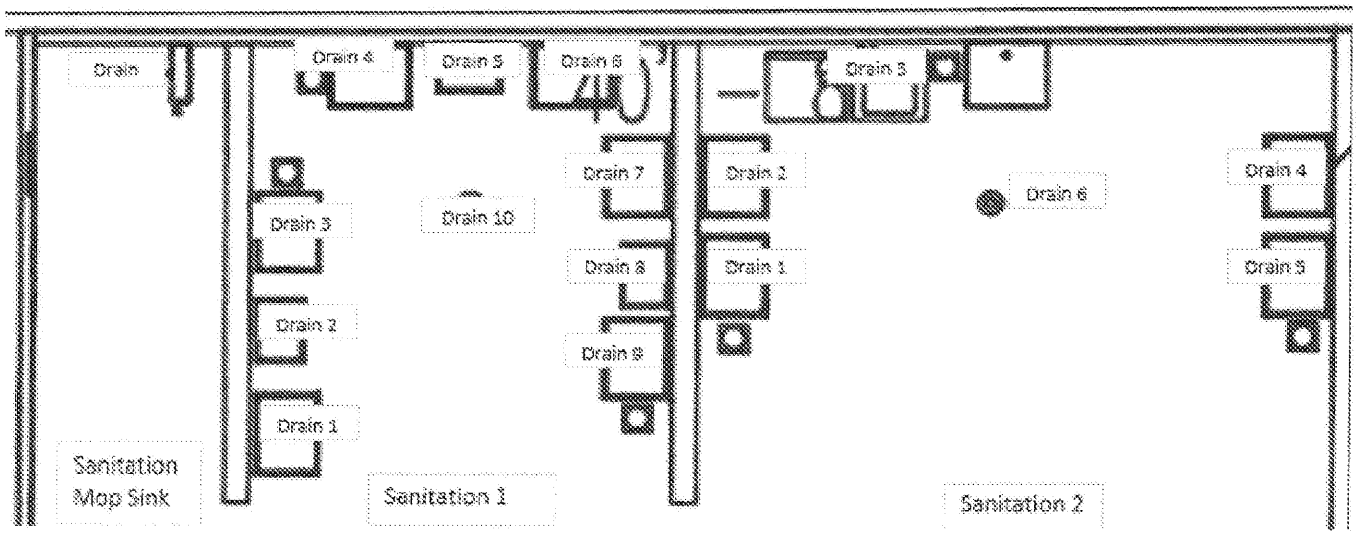


ATTACHMENT 4 - LAYOUT FOR KITTING AND SAMPLING BOOTHS

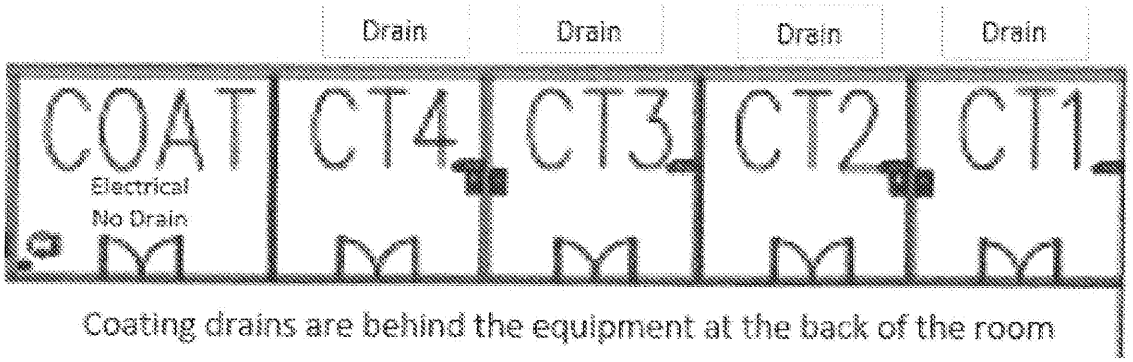


ATTACHMENT 5 – DRAIN MAPS

Sanitization Area

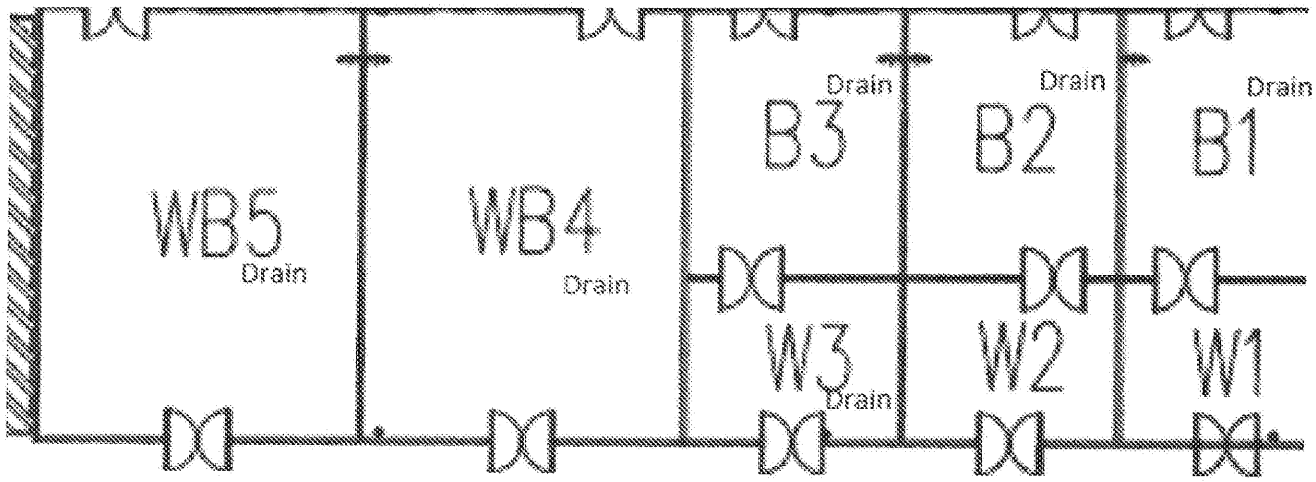


Coating



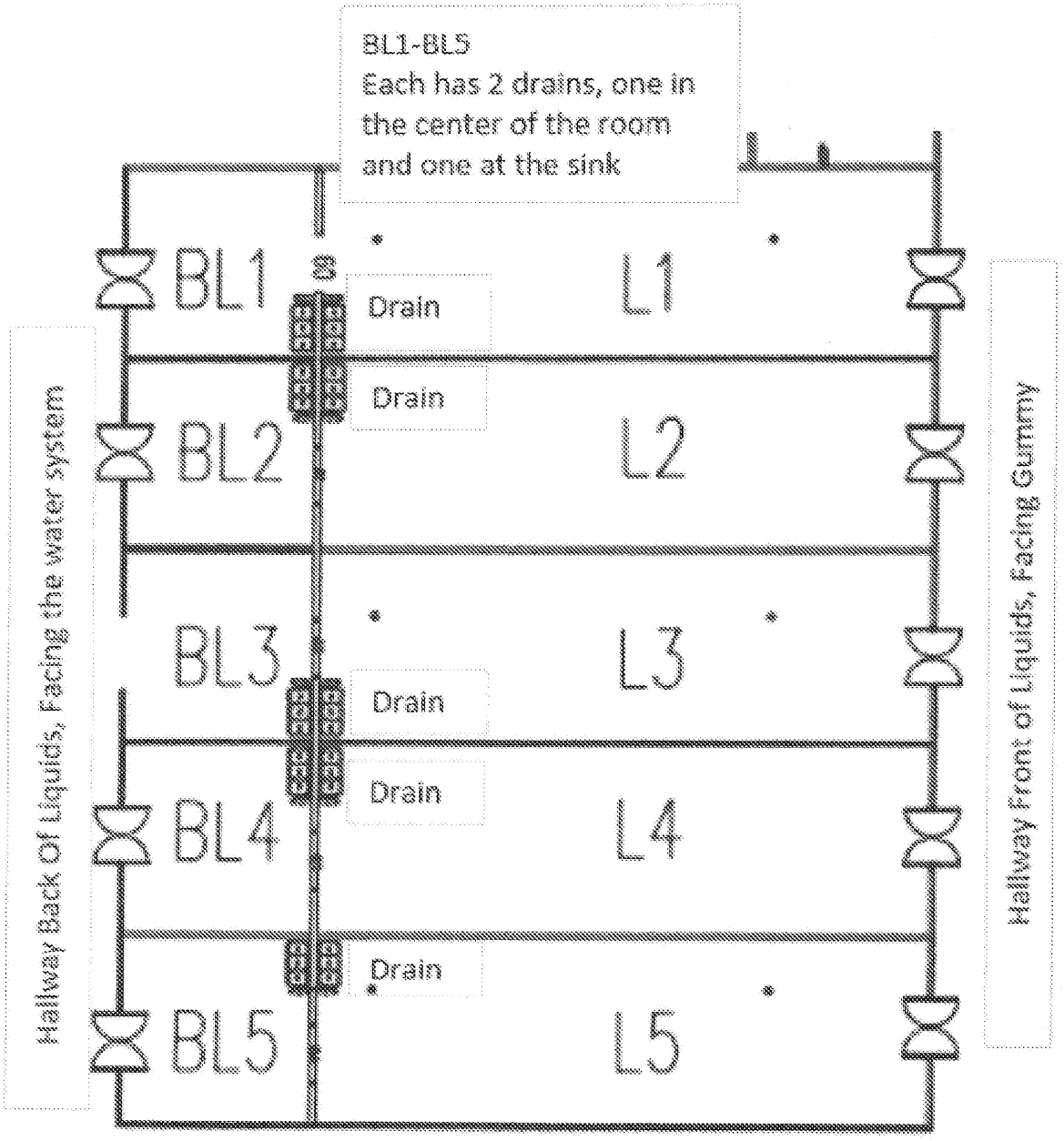
ATTACHMENT 5 – DRAIN MAPS

Blending

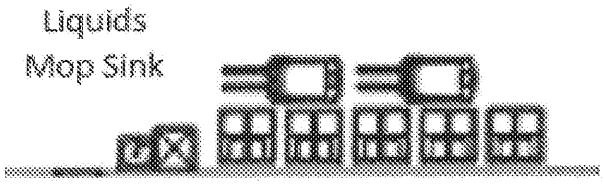


ATTACHMENT 5 – DRAIN MAPS

Liquid Blending



ATTACHMENT5 – DRAIN MAPS



Gummy Lines