1.0 Purpose

This procedure gives guidelines for recording all GMP samples delivered to the QC laboratory for analysis and defines how the samples are controlled once received. This procedure also gives guidelines for recording all samples requesting ISO 17025:2017 accredited tests.

2.0 Scope

This procedure applies to all samples delivered to the QC Laboratory for GMP testing and/or storage, including raw material, finished product, stability, special request, retain or customer complaint samples. This procedure only covers samples physically delivered to the laboratory. This procedure covers sample received from both internal and external sources.

The QC Laboratory Sample Log Book does not take the place of the batch record log, stability profile log, or customer complaint log.

3.0 Responsibility

3.1 QC laboratory personnel are responsible for the maintenance of the log and physical verification of the receipt of samples listed.

3.2 QC laboratory personnel are responsible for maintaining control of all laboratory samples and following instructions as defined in this procedure.

3.3 All individuals delivering samples for analysis to the QC laboratory are responsible for adhering to this procedure.

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

3.5 It is the responsibility of QC Laboratory Management to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **QC** – Quality Control

4.2 **GMP** – Good Manufacturing Practices

4.3 **PQV** – Process Quality Verification

5.0 References

5.1 D-201-F1, Form, QC Laboratory Sample Log – Internal Submission

5.2 D-201-F2, Form, QC Laboratory Sample Log – ISO 17025 Accredited Testing

5.3 D-201-F3, Form, QC Laboratory Sample Log – External Submission

5.4 D-201-F4, Form, Ion Nutritional Labs Sample Custody Form

5.5 D-821, SOP, DicksonOne Data Loggers

5.6 A-106, SOP, Documentation Guidelines for cGMP Records

5.7 C-502, SOP, Document Storage, Retention, and Destruction

6.0 Procedure

6.1 Sample Delivery and Receipt for internal samples

6.1.1 The delivery person will deliver the sample to the QC laboratory bin or area designated for incoming samples.

6.1.2 The delivery person will log into Form D-201-F1 QC Laboratory Sample Log or D-201-F2 QC Laboratory Sample Log – ISO 17025 Accredited Testing the following information:

6.1.2.1 Date delivered

6.1.2.2 Time delivered

6.1.2.3 Delivered by

6.1.2.4 Product Name or Raw Material Name

6.1.2.5 Batch Number or Lot/R Number

6.1.2.6 Sample Type and Quantity

6.1.2.7 ISO 17025 accredited testing required and any additional customer requirements (Form D-201-F2 QC Laboratory Sample Log – ISO 17025 Accredited Testing only)

6.1.3 QC laboratory personnel will review the information entered by the delivery person and have the delivery person make any corrections to the log before confirming the delivery of the sample. Confirmation will be indicated by entering the following information:

6.1.3.1 Received By and Date

6.1.4 Samples can be analyzed only after the logbook entry is properly recorded.

6.2 Sample Delivery and Receipt for external samples

6.2.1 All samples received for testing from an external source shall be accompanied by Form D-201-F4, Ion Nutritional Labs Sample Custody Form. This form will minimally contain the following information:

6.2.1.1 Company and Contact information

6.2.1.2 Sample Name/ Description

6.2.1.3 Sample lot/ batch number/ unique identifier

6.2.1.4 Testing requested

6.2.1.5 Acceptance Criteria for testing requested

6.2.1.6 Turnaround time (TAT) requested

6.2.1.7 Direction on Data Reporting and Sample Disposition

6.2.2 External samples should be shipped with attention to QC Lab Sample Receipt.

6.2.3 Any special sample storage conditions shall be notated on Form D-201-F4 Ion Nutritional Labs Sample Custody Form.

6.2.4 External samples are received by warehouse and delivered to the QC Laboratory.

6.2.5 External samples are log into Form D-201-F3 QC Laboratory Sample Log External Submission. Additionally, Form D-201-F4, Ion Nutritional Labs Sample Custody Form should be copied and placed into the External Sample Submission logbook.

6.2.6 Once external samples are received into the laboratory they will be stored in the required condition and tracked through the internal laboratory process.

6.3 Laboratory Sample Control

6.3.1 The QC Laboratory is secured by badge access only doors. Only appropriate personnel are allowed access to the QC Laboratory.

6.3.2 For samples to be maintained at room temperature, once samples are brought into the laboratory, they should be placed into the laboratory sample cabinet into the appropriate coded sample bin(s).

6.3.2.1 Sample bins located in the QC laboratory sample cabinet are coded by test type or method number.

6.3.2.2 The QC laboratory sample cabinet is monitored for temperature and humidity conditions. Temperature/Humidity is maintained at 15-30°C and 20-75%RH and monitored by the Dickson Data Logger system as outlined in SOP D-821 DicksonOne Data Loggers.

6.3.3 For samples that require refrigeration (2-8°C), once samples are brought into the laboratory, they should be placed into one of the laboratory refrigerators.

6.3.3.1 Internally generated samples that require refrigeration are designated with an "R" in our internal inventory system and present on paperwork that accompanies delivery to the laboratory.

6.3.3.2 Laboratory refrigerators are maintained at 2-8°C and are monitored by the Dickson Data Logger System as outlined in SOP D-821 DicksonOne Data Loggers.

6.3.4 At the conclusion of each work day, laboratory personnel should return all samples to their appropriate storage locations.

6.3.5 When all testing is completed, laboratory samples should be stored in disposition bins located at the bottom of the sample cabinet.

6.4 Documentation Requirements

6.4.1 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

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

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/03/10	New procedure.	-	-
1	02/05/13	Updated SOP to new format.	13-059	B. Johns
2	01/20/15	Updated SOP to new format. Expanded scope. Expanded responsibilities. Removed test completion entries. Biennial Review.	15-0016	B. Johns
3	03/24/17	Added time delivered to log sheet. Created separate log sheet for pharmaceuticals.	17-0321	B. Johns
4	07/20/20	Update formatting. Remove second log book for pharmaceuticals since pharmaceuticals are not being recorded in a separate log book anymore. Remove separate log book for special projects. Update responsibilities.	CC-20-0498	S. Sassman
5	10/19/21	Added ISO 17025:2017 requirements.	CC-21-0411	J. Sassman
6	03/29/23	Added laboratory sample control to scope. Changed SOP title. Updated logo and format.	CC-23-0165	J. Sassman
7	06/23/23	Added samples received from an external source to scope of SOP. Added documentation review and maintenance requirements. Added forms D-201-F3 and D-201-F4. Changed logo.	CC-23-0321	J. Sassman
8	08/14/23	Corrected typos.	CC-23-0408	J. Sassman

Logbook Number: ____________________

Date	Time	Submitted By	Material Name	Lot Information	Sample Type & Quantity	Received By/Date
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	
	□ am □ pm				□ RM ____ □ Lab Test ____ □ Micro____ □ Reserve ____ □ Stability ____	

ION Nutritional Labs	QC Laboratory Sample Log – ISO 17025 Accredited Testing		
	Form: D-201-F2	CCR No. CC-23-0321	Revision: 1

Logbook Number: _____

Date	Time	Submitted By	Material Name	Lot Information	ISO 17025 Testing Requirements	Received By/Date
	□ am □ pm					
	□ am □ pm					
	□ am □ pm					
	□ am □ pm					
	□ am □ pm					

ION Nutritional Labs	QC Laboratory Sample Log – External Submissions		
	Form: D-201-F3	CCR No. CC-23-0321	Revision: 0

Logbook Number: ____________________

Date Received	Customer	Material Name	Lot Information	Sample Type & Quantity	Received By/Date
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
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				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	
				☐ RM ____ ☐ Finished Product ____ ☐ Micro____	

Please send samples to:
Ion Nutritional Labs
8031 114th Ave Suite 4000
Attention: QC Lab Sample Receipt
Largo, Fl 33773
727-527-1072
qclab@ionnl.com
www.ionnl.com

Sample Submission Form
Form D-201-F4 R0

Company Name:

Report Results To:

Phone #
Email Results To:

10 Day TAT

Rush **

Standard turn-around-time (TAT): Micro = 7 calendar days, Chemistry = 10 business days.

Sample Information -

#	Description	Lot #	Analysis Required	Specifications	Sample Storage Requirements	10 Day TAT	Rush **
1-					Fridge ☐ Freezer ☐ RT ☐	☐	1 day ☐ 3 day ☐ 5 day ☐
2-					Fridge ☐ Freezer ☐ RT ☐	☐	1 day ☐ 3 day ☐ 5 day ☐
3-					Fridge ☐ Freezer ☐ RT ☐	☐	1 day ☐ 3 day ☐ 5 day ☐
4-					Fridge ☐ Freezer ☐ RT ☐	☐	1 day ☐ 3 day ☐ 5 day ☐
5-					Fridge ☐ Freezer ☐ RT ☐	☐	1 day ☐ 3 day ☐ 5 day ☐

Sample Disoposition: All samples will be disposed after 30 days unless otherwise requested.

Special Instructions per Sample number?

Add More Samples?

Click Here To Add More

***Unless otherwise noted, standard turn-around-time (TAT) for micro is 7 calendar days, and standard TAT for chemistry is 10 business days. Please contact with questions regarding rush availability.*

Submited By: [Printed Name, Date]	**Received By:** [Printed Name, Date]		**Sample/s Condition:**
Signature:	**Signature:**		