Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
02/18/22	02/18/22	02-18-22
Title: QC Laboratory Director	**Title: Analytical Development Manager**	**Title: VP of Quality & Regulatory Affairs**

1.0 Purpose

The objective of the Laboratory Operations process is to perform testing services meeting customer requirements, according to applicable test methods and in conformance with ISO 17025 requirements.

The purpose of this procedure is to describe the method by which laboratory operations activities are conducted under controlled conditions to ensure that tests are completed using validated test methods and to ensure that customer requirements are met. This procedure also addresses the treatment of lab nonconforming work discovered before, during and after laboratory operations are completed.

2.0 Scope

This procedure applies to all ISO 17025 accredited testing activities.

3.0 Responsibility and Applicability

3.1 This procedure applies to all QC laboratory personnel, which includes QC Laboratory Management, QC Laboratory Analysts, QC Laboratory Technicians, and others as designated who perform accredited testing activities.

3.2 QC laboratory personnel are responsible for, and authorized to, perform their assigned activities and to react appropriately to those results.

3.3 QC laboratory personnel are also responsible for and authorized to stop testing when problems are discovered and to control further testing while management is notified for resolution.

3.4 QC Laboratory Management is responsible for authorizing specific personnel to perform specific types of laboratory tasks, to perform accredited testing, and to operate types of equipment.

3.5 QC Laboratory Management is responsible for providing opinions and interpretations to persons external to the Lab.

3.6 QC Laboratory Management is responsible for and authorized to develop, validate, and approve lab developed test methods and changes to test methods if lab-developed or non-standard methods are used (refer to D-103 Analytical Method Validation and Verification).

3.7 Responsibilities regarding Lab nonconforming work (section 11.4 below) are as follows:

3.7.1.1 Evaluate significance: QC Laboratory Management

3.7.1.2 Disposition authority: QC Laboratory Management

3.7.1.3 Authorize resumption of work: QC Laboratory Management

3.8 QC Laboratory Management is responsible for establishing lab work priorities/schedules and for communicating priorities to QC laboratory personnel accordingly. QC Laboratory Management is responsible for identifying infrastructure/work environment resource needs.

3.9 QC Laboratory Management, and QC Laboratory Analysts or Technicians are responsible for monitoring supplies and equipment to the extent they affect testing activities and quality. (Resource needs are fulfilled according to SOPs E-601 Vendor Qualification, D-117 Laboratory Purchasing and Receiving, or hired according to SOP A-113 Training Procedure, A-117 Personnel Qualifications, and D-120 Laboratory Management Structure and Position Requirements).

3.10 QC Laboratory Management is responsible for ensuring that this procedure is accurate, understood and implemented effectively. This procedure may not be changed without the authorization of QC Laboratory Management.

4.0 References

4.1 D-103, SOP, Analytical Method Validation and Verification

4.2 E-601, SOP, Vendor Qualification

4.3 D-117, SOP, Laboratory Purchasing and Receiving

4.4 A-113, SOP, Training Procedure

4.5 A-117, SOP, Personnel Qualifications

4.6 D-120, SOP, Laboratory Management Structure and Position Requirements

4.7 G-208, SOP, Analytical Calibration and Equipment Control

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

4.9 D-118, SOP, Laboratory Quality Assurance Activities Plan (Proficiency Testing)

4.10 D-101, SOP, Laboratory Housekeeping

4.11 D-602, SOP, Labeling and Expiration Dating of Laboratory Chemicals

4.12 D-105, SOP, Out of Specification / Out of Trend Investigation

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

4.14 D-119, SOP, Sales – Laboratory Sample Submission

5.0 General

5.1 QC Laboratory personnel handle customers' samples, lab reference standards and reference materials, and equipment in such a manner as to ensure their own safety and the safety of others. QC laboratory personnel take care to handle and store customers' samples, lab reference standards and reference materials in such a manner as to maintain their identification and traceability and to preserve their conformity with no contamination, loss, or damage to the item during handling, transporting, storing/waiting, and preparation for testing.

5.2 Competent QC laboratory personnel conduct testing service activities according to test methods, written instructions, or according to good laboratory practices and procedures to which they have been trained. QC laboratory personnel have access to equipment (including, but not limited to, instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

5.3 All internal or external personnel working in the QC laboratory and/or affiliated with lab testing services, that can influence the QC laboratory's activities shall act impartially, be competent and work in accordance with LMS.

5.4 QC laboratory personnel are trained in the handling and use of calibrated equipment to ensure continued accuracy of measurements and continued fitness of the instruments. All equipment used for lab testing, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the testing results are calibrated before being put into service. This equipment is controlled according to the G-208 Analytical Calibration and Equipment Control.

5.5 Records of the relevant authorizations are maintained in job descriptions and this procedure. The competence, educational and professional qualifications, training, skills, and experience of the QC laboratory personnel, including contracted personnel, are maintained in the training records in accordance with SOP A-113 Training Procedure, A-117 Personnel Qualifications, and D-120 Laboratory Management Structure and Position Requirements. Roles and responsibilities are also identified in this procedure.

5.6 Any customer property that is in the facility and becomes lost or unintentionally damaged will be brought to the attention of Quality Management, or QC Laboratory Management who will ensure the incident is recorded on the Quality Events Log and reported to the customer. As appropriate, Quality Management or QC Laboratory Management will initiate a corrective action and inform the customer of the problem as well as any actions taken to avoid its recurrence in accordance with SOP QS-108 Corrective and Preventative Action (CAPA).

5.7 Reports are not released for distribution to the customer until all requirements are fulfilled (the test results have been reviewed and approved) unless otherwise approved by the customer.

5.8 Testing and/or reports which result in laboratory nonconforming work are recorded and dispositioned according to section 5.4 of this procedure.

5.9 Laboratory testing validity and accuracy are monitored by various means as described in the D-118 Laboratory Quality Assurance Activities Plan (Proficiency Testing).

6.0 Laboratory Accommodation and Environmental Conditions

6.1 Management ensures that energy sources, lighting and environmental conditions are adequate to facilitate correct performance of the testing services performed.

6.2 Laboratory personnel performing testing activities ensure that the environmental conditions at the time of the testing do not invalidate the results or adversely affect the quality of any measurement, reference material, reference standard or testing procedure. Lab testing is not performed at sites other than Ion Labs.

6.3 The technical requirements for accommodation and environmental conditions that can affect the results of the test are documented in test methods (see SOP D-103 Analytical Method Validation and Verification).

6.4 Due attention is paid to dust, electromagnetic disturbances, humidity, electrical supply, temperature, and vibration levels, as appropriate to the technical activities concerned. Tests are stopped when the environmental conditions jeopardize the results of the tests. (It should be noted that radiation and sound levels are not likely present or not likely to influence or jeopardize the results of the accredited testing).

6.5 Should there be a neighboring area in which there are incompatible activities, an effective separation will be implemented. Measures will be taken to prevent cross-contamination if necessary.

6.6 Top management has determined that the circumstances of the testing activities in the laboratory and use of areas affecting the quality of the test results do not require controlled access beyond the current access in place.

6.7 QC laboratory personnel practice good housekeeping and organization in the lab. Established policies such as SOP D-101 Laboratory Housekeeping and D-602 Labeling and Expiration Dating of Laboratory Chemicals identify requirements and evidence of QC laboratory personnel's awareness is in their training records in accordance with SOP A-113 Training Procedure and A-117 Personnel Qualifications.

6.8 The laboratory does not perform sampling, therefore Reports of Sampling" are not provided.

7.0 Metrological Traceability

7.1 Equipment used for accredited testing, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the testing result is controlled in accordance with SOP G-208 Analytical Calibration and Equipment Control.

7.2 Certified reference materials are purchased from accredited reference material producers. Measurements are calibrated at appropriate intervals to ensure they maintain validity (see SOP G-208 Analytical Calibration and Equipment Control). Reference materials are used prior to their expiration date.

7.2.1 External calibration services and external certified reference material providers are approved in accordance with SOP E-601 Vendor Qualification and D-117 Laboratory Purchasing and Receiving based on their accreditation to ISO 17025 or ISO 17034 as appropriate, which ensures they can demonstrate competence, measurement capability, and traceability.

7.2.2 The calibration certificates provided by external calibration service providers for each calibrated or verified measurement equipment and reference standard used during calibrations contain the measurement results, including the measurement uncertainty and a statement of conformity with an identified metrological specification, including the decision rule applied.

7.2.3 The certificates for reference materials provided by external reference material producers contain the standards used, measurement results, including the measurement uncertainty, and the decision rule applied.

7.3 Currently, there are no testing results that cannot be made or traceable to the International System of Units (SI). Direct or indirect comparison to national or international standards are confirmed.

8.0 Control of Data

8.1 Upon completion of any calculations or data transfers, QC laboratory personnel verify the calculations or transfers are accurate and consistent.

8.2 When mistakes occur in electronic records, measures are taken to avoid loss or change of original electronic data and may include saving files by other filenames or in locations that preclude data from being overwritten, thereby allowing original mistaken data to be retrieved, or by electronic versioning and dating.

8.3 Records are revised in accordance with SOP C-502 Record Storage, Retention and Destruction.

9.0 Equipment and Maintenance

9.1 Equipment maintenance requirements are planned and completed in accordance with SOP G-208 Analytical Calibration and Equipment Control.

10.0 Process Inputs

10.1 Inputs to the Laboratory Operations process include, but are not limited to:

10.1.1 Projects generated as the result of the Sales-Laboratory Sample Submissions process (refer to SOP D-119 Sales – Laboratory Sample Submission).

10.1.2 Existing work priorities established by the current schedule.

11.0 Process Activities

11.1 Laboratory Operations Planning

11.1.1 Required testing is planned when samples are received from a customer.

11.1.2 The laboratory's schedule is derived from pending orders. General planning for the laboratory is performed by Laboratory Management.

11.2 Laboratory Operations and Testing

11.2.1 According to the order assigned, QC laboratory personnel retrieve the sample from the sample area and begin to set up the equipment, retrieve the required standards and reagents, prepare blanks, etc. Identification and lot traceability, expiration dates, etc., are recorded as required in the test data.

11.2.2 Abnormalities or departures from normal or specified conditions, as described in the test method, are also recorded in the test data. All concerns regarding

the suitability of the sample are resolved with Laboratory Management and customer, as necessary.

11.2.3 QC laboratory personnel complete the final adjustments and setups in accordance with the designated test methods recording actions taken in their lab notebook or designated prep sheets.

11.2.4 All steps in the test method are completed in the order prescribed.

11.2.5 At the completion of the test, the following occurs:

11.2.5.1 Where applicable, the instrument data files are downloaded and stored electronically in the proper folder for the instrument. This is where the raw data and report are stored for that date.

11.2.5.2 The test area and equipment are cleaned up.

11.2.5.3 The samples are discarded, any sample vessels or pans are cleaned, and are placed in the designated storage area.

11.2.5.4 Any issues found during the cleanup are included in the report.

11.2.6 QC laboratory personnel review the resulting data and determine if the results indicate retesting is required (where feasible) in accordance with SOP D-105 Out of Specification / Out of Trend Investigation procedure.

11.2.6.1 If the data is acceptable, the report is written. The report is saved in the folder as the raw data.

11.3 Internal Certificate of Analysis

11.3.1 QC laboratory management has implemented lab notebooks, and data collection forms as well as equipment software data collection that ensure each test or series of tests carried out by laboratory personnel are reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test methods. These documentation methods facilitate the identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory's activities under conditions as close as possible to the original.

The documentation identifies the laboratory personnel for each lab activity in the test.

11.3.2 The results are reported in the lab notebooks, data collection forms and equipment software data collection which includes all information requested by the customer and necessary for the interpretation of the test results and all information required by the method used.

11.3.3 The format of the lab notebooks, data collection forms and equipment software data collection designed to accommodate the testing carried out ensuring that the possibility of misunderstanding or misuse is minimized.

11.3.4 The information from the lab notebooks, data collection forms and equipment software data collection are documented onto the appropriate Certificate of Analysis by laboratory personnel (see attachment 1 as an example format).

11.3.5 Quality reviews the records to release. The reviewer verifies the test results are provided accurately, clearly, unambiguously, and objectively, and include all the information agreed upon with the customer and necessary for the interpretation of the results and all information required by the method used.

11.3.5.1 If the results are acceptable, the certificate of analysis is released to the customer.

11.3.5.2 If the results are not acceptable, Laboratory Management will initiate the OOS process in accordance with SOP D-105 Out of Specification / Out of Trend Investigation.

11.3.6 Internal Certificates of analysis are provided only to customers. As such, less formal or simplified reports for test results are permitted. However, if any information is not reported to the customer, it will be readily available if necessary. All issued reports are retained as technical records.

11.3.7 Quality sends the approved Certificate of Analysis to the customer via hard copy or email.

11.3.8 If requested by customers, formal Certificate of Analysis include, but are not

limited to, the following information (but not necessarily in the order indicated) unless Laboratory Management has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse):

11.3.8.1 The title (Internal Certificate of Analysis),

11.3.8.2 Our address which is the location of the where the testing was carried out,

11.3.8.3 Unique Identification by Batch# and on each page, the Batch # is listed in order to ensure that the page is recognized as a part of the Certificate of Analysis, and a clear identification of the end of the Certificate of Analysis,

11.3.8.4 Identification of the methods used,

11.3.8.5 A description of the condition of, and the unambiguous identification of the samples by Batch #,

11.3.8.6 The date(s) of performance of the Lab activities,

11.3.8.7 The date of issue of the report (QC Reviewed By/Date)

11.3.8.8 The test results with, where appropriate, the units of measure,

11.3.8.9 The identification of the person(s) authorizing the test report (QC Reviewed By/Date),

11.3.8.10 Where relevant, a statement to the effect that the results relate only to the sample tested,

11.3.8.11 Where necessary, deviations from, additions to, or exclusions from the test method,

11.3.8.12 Information on specific test conditions, such as environmental conditions,

11.3.8.13 When customer required, the measurement uncertainty presented in the same unit as that of the measured or in a term relative to the measured (e.g., percent) when: it is relevant to the validity or

application of the test results, when a customer's instructions so require, or when the uncertainty affects conformity to a specification limit,

11.3.8.14 Where appropriate, opinions and interpretations.

11.3.9 The Laboratory is not responsible for the sampling activity:

11.3.10 When a statement of conformity to a specification or standard is requested and provided, the lab documents the decision rule employed, taking into account the level of risk (such as a false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the design rule.

11.3.10.1 The decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

11.3.10.2 If the decision rule is prescribed by the customer, regulations, or normative documents, a further consideration of the level of risk is not necessary.

11.3.11 The statement of conformity on the Certificate of Analysis clearly identifies:

11.3.11.1 To which results the statement of conformity applies,

11.3.11.2 Which specifications, standards or parts of standards are met or not met,

11.3.11.3 The decision rule applied (unless it is inherent in the requested specification or standard).

11.3.12 When opinions and interpretations are included, Laboratory Management, who are authorized to provide opinions and interpretations, will document the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such on the informal or formal Certificate of Analysis.

11.3.12.1 Opinions and interpretations included in a certificate of analysis

may comprise, but not be limited to the following:

11.3.12.2 An opinion on the statement of compliance/noncompliance of the results with requirements,

11.3.12.3 Fulfillment of contractual requirements,

11.3.12.4 Recommendations on how to use the results,

11.3.12.5 Guidance to be used for improvements.

11.3.12.6 When opinions and interpretations by direct dialogue with the customer occur, the dialogue is recorded.

11.3.12.7 Opinions and interpretations are distinguished from statements of conformity as described above.

11.3.13 Subcontractors are typically not used for any accredited testing; however, if subcontractors are procured to perform testing, Test Reports containing results of tests performed by subcontractors will clearly identify the subcontractor's test results. Laboratory Management ensures subcontractors' reports are provided in writing or electronically.

11.3.14 The Laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer is clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where the Laboratory has not been responsible for the sampling stage (the sample has been provided by the customer, the report states that the results apply to the sample as received.)

11.3.15 Issued reports that need to be changed, amended, or re-issued clearly identify any change of information and where appropriate, the reason for the change is included in the report.

11.3.16 Amendments to an issued Certificate of Analysis, are made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Certificate of Analysis, Batch #,…" or an equivalent form of

wording. Such amendments also meet the requirements of this procedure and ISO 17025.

11.3.17 If it is necessary to issue a complete, new Certificate of Analysis the document is uniquely identified and contains a reference to the original Certificate of Analysis that it replaces.

11.4 Laboratory Nonconforming Work

11.4.1 Nonconforming work is any laboratory activity or the results of lab work that do not conform to the Lab's own procedures or the agreed requirements of the customer (e.g., equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). Lab nonconforming work consist of, but is not limited to:

11.4.1.1 a Test Method was not followed properly

11.4.1.2 incorrect equipment setup

11.4.1.3 faulty equipment

11.4.1.4 the incorrect test method was used

11.4.1.5 measurement equipment with an expired calibration status was used

11.4.1.6 inaccurate or incomplete reports

11.4.1.7 report issued to wrong customer

11.4.1.8 wrong samples used

11.4.1.9 sample not stored or identified correctly

11.4.1.10 actual or potential partiality

11.4.2 Laboratory nonconforming work information and related disposition information is captured on the Quality Events Log or in accordance with D-105 Out of Specification / Out of Trend Investigation. Laboratory nonconforming work reporting is entered by either the Laboratory Management or the Laboratory Analysts and Technicians. The significance of

the nonconforming work is evaluated to determine if the effect of the incident infers the lab's activities are not in compliance with ISO 17025 or the validity of the test results are questionable or invalid.

11.4.3 Actions may include halting or repeating of work and withholding reports from the customer, as necessary.

11.4.4 If, upon further evaluation by Laboratory Management, it is determined that the testing and/or documentation is conforming after all and therefore the situation is not nonconforming, the entry on the Quality Events Log is noted as such and the testing and documentation is processed accordingly.

12.0 Process Outputs

12.1 Outputs from the Laboratory Operations process include, but are not limited to:

12.1.1 Completed testing meeting customer requirements,

12.1.2 The associated records including test reports sent to the customer,

12.1.3 Laboratory nonconforming work and the records of identification and disposition, which are recorded on the Quality Events Log.

13.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	11/05/21	New procedure.	N/A	J. Sassman

14.0 Attachments

14.1 Attachment 1 – Internal Certificate of Analysis Example

Attachment 1 – Internal Certificate of Analysis

Testing Location: 8031 114th Ave, Suite 4000, Largo, FL 33773
PHONE: 727.527.1072
FAX: 727.527.6758

Date Received:
Date Started:
Condition Received:

Product Name:
Customer:

Customer Lot Number:
Report Issued Date/ Revision:

INTERNAL CERTIFICATE OF ANALYSIS

IDENTITY

Test	Method	Release Specification	Date Performed	Results	Calculated Measurement of Uncertainty (if applicable)
Organoleptic – Appearance	D-722	Round tablet with SC&F embossed on one side			
Organoleptic – Color	D-722	Off-purple to off-grey with specks			
Organoleptic – Aroma	D-722	Berry			
Organoleptic - Taste	D-722	Sweet			

COMPOSITION

Test	Method	Release Specification	Date Performed	Results	Calculated Measurement of Uncertainty (if applicable)
Disintegration	D-703	NMT 60 Minutes			
FTIR	D-823	NLT 0.90 when compared to the standard			

Attachment 1 – Internal Certificate of Analysis (cont'd)

ION LABS

Testing Location: 8031 114th Ave, Suite 4000, Largo, FL 33773
PHONE: 727.527.1072
FAX: 727.527.6758

Date Received:
Date Started:
Condition Received:

Product Name:
Customer:

Customer Lot Number:
Report Issued Date/ Revision:

PURITY

Test	Method	Release Specification	Date Performed	Results	Calculated Measurement of Uncertainty (if applicable)
Total Aerobic Plate Count	D-715.0	NMT 1,000 CFU/g			
Total Yeast and Mold	D-715.0	NMT 100 CFU/g			
E. Coli	D-715.0	Absent			
Salmonella	D-715.0	Absent			
S.aureus	D-715.0	Absent			
P. aeruginosa	D-715.0	Absent			
Coliforms	D-715.0	Absent			

QC Reviewed By: _____ **Date:** _____

Note: Sample results apply as received.

END OF REPORT