LGGS, INC. / LGGS FLORIDA, INC.
QUALITY MANUAL

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Approval:

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Quality Systems Management Representative

LGGS, INC. / LGGS FLORIDA, INC.

LGGS, INC. DISTRIBUTION LIST
Controlled copies of 13485:2003 Quality Manual

1) Word Processing
2) General Office
3) General Micro Lab

LGGS FLORIDA, INC. DISTRIBUTION LIST
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1) Word Processing
2) Conference Room
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Quality Manual Revision History

Revision no.	Description of Change	Author	Effective Date
0	Initial release	George Szorenyi	04/01/02
1	Change of format and changes made per TUV recommendation	George Szorenyi	06/07/02
2	Added ISO 13488 in preface section	George Szorenyi	9/10/04
3	Re-write according to ISO 13485:2003	George Szorenyi	9/21/05
4	Changes made per Intertek finding # MA-1 and MA-2	George Szorenyi	10/18/05
5	Add LGGS Florida Organizational Chart	George Szorenyi	02/21/07
6	Identify Site 2 (LGGS Florida) within scope of QMS; correct typographical error (page nos.); update distribution list	George Szorenyi	5/1/07
7	Change of Scope to include exclusions	George Szorenyi	10/19/07

Note: This Revision Record is a summary of change control only. All obsolete sections of the manual are maintained in the change control log book.

1.0 PREFACE

1.1 General:

This manual defines LGGS, Inc. / LGGS Florida, Inc.'s policies that reflect the requirements of ISO guidelines. Implementation of these policies ensures that we consistently meet the quality and performance requirements of customers in a timely and cost-effective manner.

I personally affirm my commitment to enhancing LGGS, Inc. / LGGS Florida, Inc.'s Quality System through the implementation of ISO 13485:2003. I fully support the provisions of this manual and solicit the active partnership of all LGGS, Inc. / LGGS Florida, Inc. personnel in its implementation throughout the laboratory.

1.2 Application:

Design and development (7.3) is excluded from this Quality Manual for the following reasons: LGGS, Inc. / LGGS Florida, Inc. follow industry and regulatory requirements and for this reason; LGGS Inc. / LGGS Florida Inc. does not design or develop testing methods. Regulatory requirements permit exclusions of design and development controls (see 7.3).

George Szorenyi
Director of Microbiological Programs

2.0 QUALITY POLICY

"LGGS, Inc. / LGGS Florida, Inc. is committed to providing the highest quality in microbiological testing services in conformance with applicable regulatory requirements while meeting each customers' service and business objectives"

3.0 KEY DEFINITIONS

Customer	Any organization or individual that enters into a formal agreement with LGGS, Inc. / LGGS Florida, Inc. for delivery of LGGS, Inc. / LGGS Florida, Inc.'s services.
Quality Policy	Overall intentions and directions of LGGS, Inc. / LGGS Florida, Inc. with regard to quality as formally expressed by executive management.
Quality Record	A subset of records that demonstrates conformance to requirements and the effective operation of the quality system.
Quality System	LGGS, Inc. / LGGS Florida, Inc.'s organizational structure, procedures, processes, and resources needed to implement quality management.
Service	Consulting, physical work, and/or intellectual work

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

LGGS, Inc. / LGGS Florida, Inc. has established, documented and maintained a Quality System as a means of ensuring that product conforms to specified requirements. The activities governed by the Quality System are identified and documented. LGGS, Inc. / LGGS Florida, Inc. has prepared and implemented a quality system in compliance with procedures and the stated quality policy.

4.2 Documentation Requirements

4.2.1. General

These documented procedures are controlled and effectively implemented to ensure that LGGS, Inc. / LGGS Florida, Inc. meet customer requirements. The Quality System is defined in the following controlled documents:

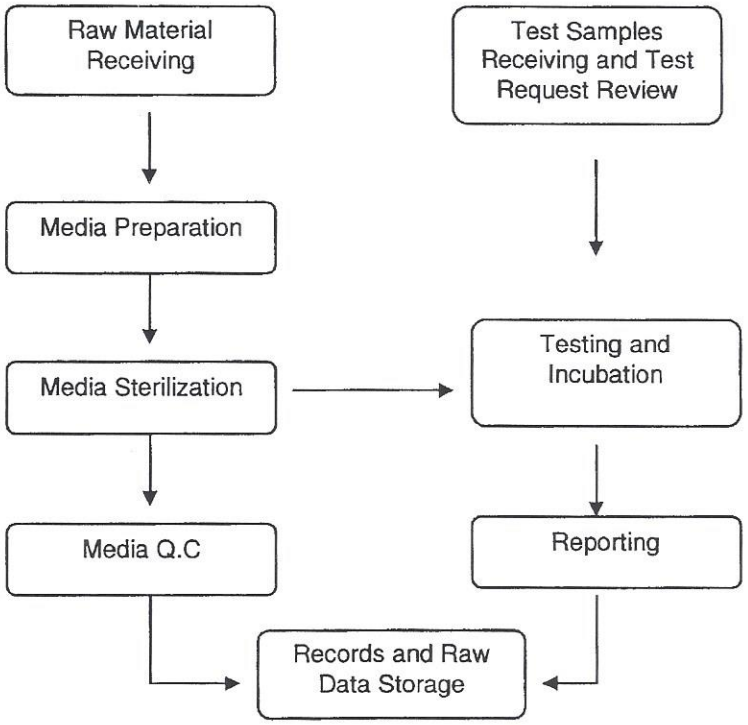
Quality System Document Levels
Quality Policy

Document	Purpose
Quality Manual	Quality Policies
QC-SOP- & SOP PROCEDURE BOOKS	Operating Procedures
Test Specifications	Working Instructions
Quality Records	Objective Evidence of Quality System Maintenance

Procedures that form part of the quality system depend on the complexity of the work, the methods used and the skills and training needed by personnel involved in carrying out the activity. The scope of documented operational procedures shall be sufficient to define how the requirements for quality are met.

4.2.2. Quality Manual

LGGS, Inc. / LGGS Florida, Inc. has established, documented and maintained a Quality System as a means of ensuring that product conforms to specified requirements. The activities governed by the Quality System are identified and documented. LGGS, Inc. / LGGS Florida, Inc. has prepared and implemented a quality system in compliance with procedures and the stated quality policy. For the interaction between the processes of the quality management system, see flowchart below:



4.2.3. Control of Documents

LGGS, Inc. / LGGS Florida, Inc. ensures that current Quality System documentation and Quality System data are readily available to all QA personnel via a document and data control system. This system ensures that all Quality System documentation and Quality System data are reviewed and approved prior to their initial release and any subsequent modifications. Obsolete or invalid Quality System documents and Quality System data are destroyed or, if retained, properly marked. It is the responsibility of laboratory management to identify needed documents to assure execution of stated quality policy objectives. Provisions for control of documents and data on electronic media are not applicable. The authority for review and approval of controlled documents is granted to the Director of Micro Programs or the VP/Quality Assurance Microbiology.

LGGS, Inc. / LGGS Florida, Inc. has written procedures to ensure that documents are reviewed and approved for adequacy by designated individuals prior to issue. These procedures include steps to ensure that needed documents are available at all points of use, that obsolete documents are removed from points of use in a timely manner and then retained in change control files. Changes to documents and data are reviewed and approved by the same functionaries that performed the original reviews/approvals. The signatories will have access to pertinent background information when needed upon which to base their review and approval. The nature of document changes is identified in the change control records. A master list documenting revision status of all operational procedures is available.

4.2.4. Control of Records

LGGS, Inc. / LGGS Florida, Inc. maintains all quality records to demonstrate conformance to procedures designed to prevent deterioration, loss and allow rapid retrieval. Reports are collected and filed on a daily basis by customer in order, using the lab number for identification and indexing. The archives facility is under climate control and is a restricted access area, with removal procedures specified within O-SOP-0080. Records are to be stored in designated areas or a qualified archival facility for a minimum of seven (7) years. At this time, sponsors of records under review for destruction shall be notified and given the opportunity to acquire and maintain the data at their facility.

The Quality Assurance Technologist has responsibility of maintaining all quality records. The Management Representative/ Quality Assurance Manager and Director of Micro Programs / Senior Technologist have authority to approve and review record storage procedures.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

The Quality Policy statement is defined by executive management that it is communicated to and understood by LGGS, Inc. / LGGS Florida, Inc. personnel. The Management Representative shall document and maintain the Quality Policy and ensure its implementation. The policy statement has been posted in laboratory areas and signed copies have been included as a permanent element in each employee's training records.

The quality policy has been included in QC-SOP and SOP books which are referenced daily by employees during normal business activities. GMP orientation is conducted for each new employee hired. Regulatory, service and business objectives of each customer are detailed, outlining each employee's personal contribution to quality commitment and meeting customer expectation.

5.2 Customer Focus

Management ensures that customer requirements are determined and met (see 7.2.1 and 8.2.10).

5.3 Quality Policy

The Quality Policy statement is defined by executive management that it is communicated to and understood by LGGS, Inc. / LGGS Florida, Inc. personnel. The Management Representative shall document and maintain the Quality Policy and ensure its implementation. The policy statement has been posted in laboratory areas and signed copies have been included as a permanent element in each employee's training records. The quality policy has been included in QC-SOP and SOP books which are referenced daily by employees during normal business activities. GMP orientation is conducted for each new employee hired. Regulatory, service and business objectives of each customer are detailed, outlining each employee's personal contribution to quality commitment and meeting customer expectation.

5.4 Planning

5.4.1.Quality Objectives

False positive rates will be maintained within 1% of the total cultures tested each month. Revised reports due to laboratory error will be maintained at less than 5% of total reports issued per month. Regulatory, service and business objectives of each customer are detailed, outlining each employee's personal contribution to quality commitment and meeting customer expectation.

5.4.2. Quality Management System Planning

Quality plans shall be consistent with all other requirements of the quality system and documented. Consideration shall be given to the following activities, as appropriate, in meeting the specified requirements for products, projects, or contracts:

- Preparation of quality plans,
- Identification and acquisition of any controls, processes, equipment, fixtures, resources and skills that may be needed to achieve the required quality,
- Ensuring the compatibility of the design, process, installation, inspection, test procedures and applicable documentation,
- Updating, as necessary, quality control, inspection, and testing techniques, including the development of new instrumentation,
- Identification, in sufficient time for the needed capability to be developed, of any measurement requirement involving capability that exceeds the known state of the art
- Identification of suitable verification of appropriate stages in the realization of project,
- Clarification of standards of acceptability for all features and requirements including those which contain a subjective element, and
  Identification and preparation of Quality Records,

5.5 Responsibility, Authority and Communication

5.5.1. Responsibility, Authority

Executive management has the authority to direct organizational structure. Each employee has the responsibility to execute assigned job and organizational responsibilities. The responsibility, authority and interrelation of personnel who manage, perform and verify work affecting quality shall be documented and defined within organization charts and job descriptions (Fig.1 The Director of Microbiological

Programs/Senior Technologist and Management Representative / Quality Assurance Manager are provided the organizational freedom and authority to initiate action to prevent non-conformities, identify and record quality problems, initiate or recommend solutions through designated channels and verify implementation of solutions and control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

Fig. 1
LGGS, INC.
ORGANIZATIONAL CHART

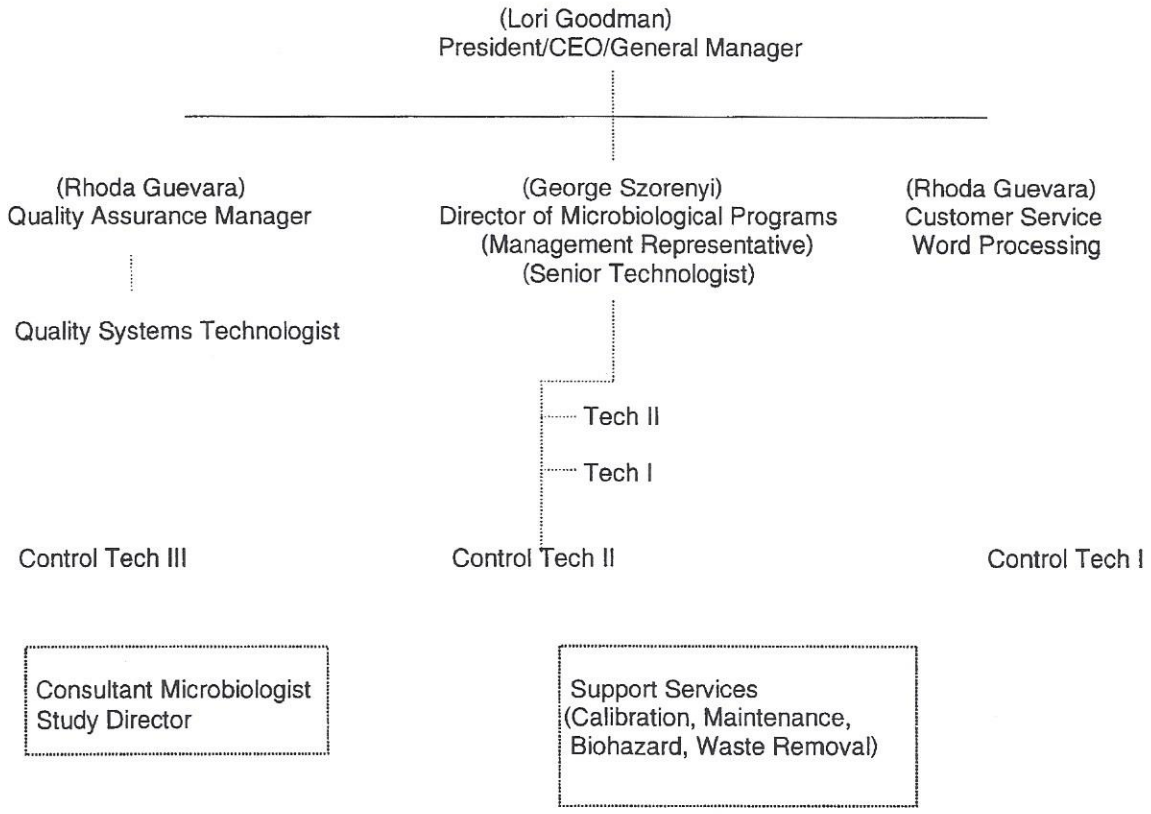
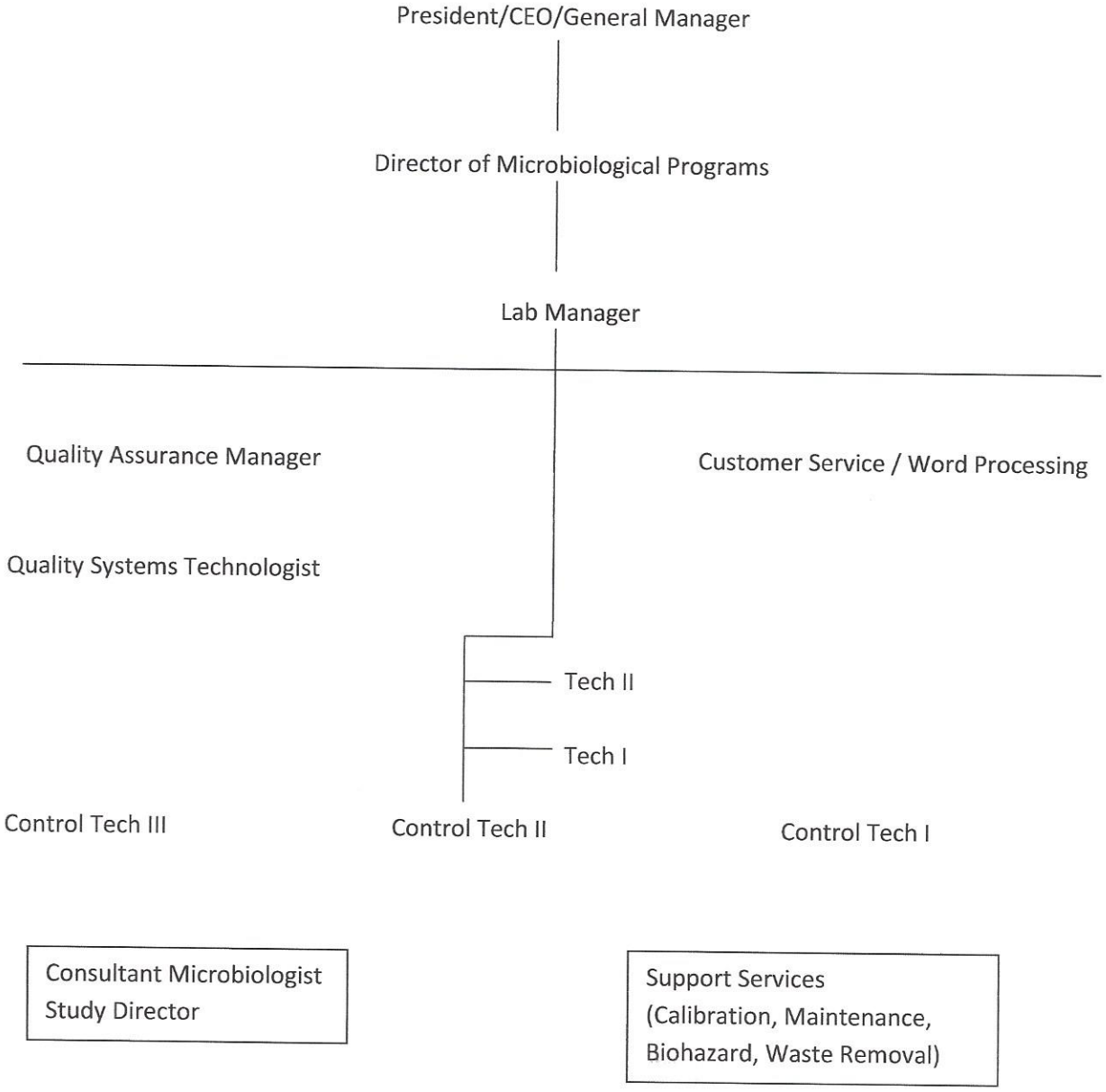


Fig. 2
LGGS FLORIDA, INC.
ORGANIZATIONAL CHART



5.5.2. Management Representative

Executive management has appointed the Director of Microbiological Programs as the management representative. The representative shall provide to executive management reports of quality system suitability and effectiveness.

The **Quality System Management Representative** shall:

- Document and maintain the LGGS, Inc. / LGGS Florida, Inc. Quality Policy.
- Ensure that the Quality System is established, implemented, and maintained in accordance with LGGS, Inc. / LGGS Florida, Inc.'s Quality Manual.
- Coordinate and chair the Quality Management Review meetings to determine if the performance of the Quality System is suitable, adequate and effective in meeting the goals and objectives of LGGS, Inc. / LGGS Florida, Inc.'s Quality Policy and the Quality System.

5.5.3. Internal Communication

Internal communication will be extended to all employees via meetings, emails, and internal memos.

5.6 Management Review

5.6.1 General

Quality Management Review meetings shall be held no less than once a year and shall include the following attendance of:

- President/CEO/General Manager
- Director of Microbiological Programs
- Quality Assurance Manager

5.6.2 Review Input

Quality Management Review meeting agendas shall include reports in the following areas:

- Open action items from previous Quality Management Review meetings
- Findings of quality audits conducted as per O-SOP-0105 and QC-SOP-0010
- Changes that could affect the quality system, including strategic, financial, partnerships and regulatory changes
- Results of audits, including internal, customer and registrar audits
- Customer satisfaction, including complaints
- Status of corrective and preventive action
- Review of organizational structure, the quality of actual service in relation to quality objectives, preventive action, corrective action, nonconformities, audit finding from the outside auditor and determine potentially necessary updates of the quality system due to new technology, quality concepts or other conditions.
- Discussion on the suitability, adequacy and effectiveness of the LGGS, Inc. / LGGS Florida, Inc. Quality Management System in meeting the Quality Policy and its objectives
- Opportunities for improvement

5.6.3 Review Output

Ensure minutes of the Quality Management Review meetings are prepared and distributed and that the status of assigned action items is tracked. A Quality Record containing Quality Management Review documents and minutes shall be generated and managed by the Management Representative. Quality Records will be kept in the archive room.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resource

LGGS, Inc. / LGGS Florida, Inc. has established an organizational structure and defined individual job descriptions to meet laboratory functional needs. Executive management maintains final authority over allocation of resources. The VP/Quality Assurance Manager and Quality Systems Technologist are responsible for verification and training documentation. The Quality Systems Technologist performs laboratory verifications and internal quality audits while having no direct responsibility for the conduct of the tests under verification review. Executive management reviews laboratory resource requirements during management reviews conducted once per year.

6.2 Human Resources

6.2.1 General

LGGS, Inc. / LGGS Florida, Inc. has established an organizational structure and defined individual job descriptions to meet laboratory functional needs.

6.2.2 Competence, Awareness and Training

LGGS, Inc. / LGGS Florida, Inc maintains a staff with sufficient background and training to meet stated quality policy objectives. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. An ongoing training program is in place which includes: GMP orientation - review and signing of the quality policy -- SOP reading assignments each quarter and documented "on the job" training. Appropriate records of training shall be maintained. Qualifications and records of consultants utilized are also part of the laboratory training records. Responsibility for personnel training is granted to designated trainers and supervisors in the laboratory. Executive management holds authority for providing sufficient personnel

6.3 Infrastructure

Procedures included as SOP's have been prepared and reviewed to assure conformance to applicable guidelines. Test specifications, which provide product specific instructions are prepared and jointly approved by laboratory management and the test sponsor. These process control procedures ensure that testing conforms to quality policy objectives. Processing deficiencies may become apparent only after the product is in use, the process shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that requirements are met. Where applicable, qualifications of operations, equipment and personnel are specified and records maintained. LGGS, Inc. / LGGS Florida, Inc. does not utilize computer software for process control.

6.4 Work Environment

LGGS, Inc. / LGGS Florida, Inc. minimizes the risk of damage to or deterioration of LGGS, Inc. / LGGS Florida, Inc. materials and products by handling, storing, packaging, preserving, and delivering materials and products in accordance with standard operating procedures unless special requirements are identified or specified.

Responsibilities for proper handling procedures are applicable to all personnel at appropriate functions.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

To ensure that quality requirements are met, LGGS, Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures for the following inspections and test activities in order to verify that the specified requirements for the product are met and have been identified, are performed and documented prior to dispatch of test results. To reduce risks to a minimum, to avoid them entirely, or reduce them to a minimum and limit potential expenditures arising from accidents or emergencies, risk management is established based on ISO 14971: 2000 guidelines, current revisions of USP and additional AAMI / ISO guidelines.

7.2 Customer-Related Process

7.2.1 Determination of requirements related to the product

LGGS, Inc. / LGGS Florida, Inc. develops and executes agreements with its customers. LGGS, Inc. / LGGS Florida, Inc. defines a customer as any organization or individual entering a formal agreement with LGGS, Inc. / LGGS Florida, Inc. for delivery of LGGS, Inc. / LGGS Florida, Inc.'s services. LGGS, Inc. / LGGS Florida, Inc. shall utilize test request forms completed by test sponsors as a contract for each study. The test request forms shall be reviewed at receipt to verify that test requirements are defined and any differences or problems are resolved and documented by amendment to the test request at this time, orders shall not be received by verbal means.

7.2.2 Review of requirements related to the product

Once requirements are verified and capability is present, the test will be processed by laboratory personnel using the test request as a guide of specification selection. Reviews of test requests (contract review) are documented by the initials of the technician performing the review. All appropriate personnel involved in test processing must review contracts (test requests) to verify conformance of testing to contract requirements.
The technician or designee shall incorporate all approved amendments, changes, and revisions to the original test request form. These changes will follow the same process for review, approval, dissemination, and filing as the original agreement. Changes on test request forms are made according to documented procedures.
All test requests become a part of the raw data and are retained for not less than seven (7) years in the designated archives.

7.2.3 Customer Communication

LGGS Inc. / LGGS Florida, Inc will communicate with customers in the most effective way about all inquiries.

7.3 Design and Development

Testing performed by LGGS, Inc. / LGGS Florida, Inc. follows industry and regulatory guidelines and as such, LGGS, Inc. / LGGS Florida, Inc. does not design testing methods.

7.4 Purchasing

7.4.1 Purchasing Process

The LGGS, Inc. / LGGS Florida, Inc. purchasing control procedure is designed to assess vendor capability and quality commitment. All supplies purchased by LGGS, Inc. / LGGS Florida, Inc. are finished products that are used following manufacturer's directives. LGGS, Inc. / LGGS Florida, Inc., however, has instituted the purchasing control procedures to assure continued quality can be maintained by the supplier and to establish needs for further quality documentation from vendors with notification in the event that changes to vendor products occur. Purchasing documents clearly describe ordered products including type, class, grade or other precise identification. When necessary specification requirements or other technical data shall be included with the purchase orders. LGGS, Inc. / LGGS Florida, Inc. has instituted incoming inspections to verify identity and condition of incoming supplies.
LGGS, Inc. / LGGS Florida, Inc. evaluates and selects subcontractors based on their ability to deliver products that meet specified requirements. Records of vendor evaluation / performance are maintained in the archive room.

7.4.2 Purchasing Information

LGGS, Inc. / LGGS Florida, Inc. controls the purchase of materials, products, and services incorporated into products delivered to LGGS, Inc. / LGGS Florida, Inc. customers. LGGS, Inc. / LGGS Florida, Inc. ensures that all purchasing documents describe the product or service to be delivered. LGGS, Inc. / LGGS Florida, Inc. reviews and approves purchasing documents for completeness of specified requirements prior to release. This ensures that purchased materials, products, and services are verified (inspected and accepted) against documented and specified requirements.

7.4.3 Verification of Purchased Product

Supplier Verification at Subcontractors Premises

When LGGS, Inc. / LGGS Florida, Inc. decides to inspect and/or accept a purchased product at the vendor's facility, the purchasing document will specify inspection and/or acceptance arrangements and the method delivery. LGGS, Inc. / LGGS Florida, Inc. does not do subcontractor verification of product, however, certain criteria's are evaluated bi-annually. If incoming material does not meet LGGS, Inc. / LGGS Florida, Inc.'s quality requirements, LGGS, Inc. / LGGS Florida, Inc. will refuse the shipment, to show the extent of control over subcontractors.

Customer Verification at Subcontractors Premises

When required by customer agreement and specified by LGGS, Inc. / LGGS Florida, Inc. contract, LGGS, Inc. / LGGS Florida, Inc. customers are allowed to verify the product at the vendor's facility. Such verification by the customer does not absolve LGGS, Inc. / LGGS Florida, Inc. of its responsibility to provide an acceptable product. Where subcontractors are employed, LGGS, Inc. / LGGS Florida, Inc. will verify conformance to specified requirements and arrange on-site customer verification of subcontractor capabilities as requested however this will not absolve LGGS, Inc. / LGGS Florida, Inc. of the responsibility to control purchases from and records of vendor certification. Quality records are maintained for vendors and subcontractors.

7.5 Production and Service Provision

7.5.1 General Requirements

LGGS, Inc. / LGGS Florida, Inc. provides testing which follows current USP, AAMI, HIMA, ISO, IES, FDA or other regulatory or industry guidelines. All testing is conducted in a suitable working environment following documented procedures utilizing equipment, reference standards and workmanship appropriate to ensure required process capability.

7.5.2 Validation of Processes and Service Provision

Qualification of equipment and personnel is specified when applicable. Maintenance monitoring and control of required test or equipment elements to ensure continuing process capability is specified and documented.

7.5.3 Identification and Traceability

It is the responsibility of all laboratory personnel involved in test processing to follow lab procedures and properly identify samples. All trained personnel have authority for proper identification of in-process samples during test activities.

Upon receipt, each sample group is assigned a unique lab number that is utilized as identification at all stages of testing. Labels containing the name of the test sponsor and the lab number are prepared for use in the lab. Where specified unique identification of individual media batches used during testing become a part of the test raw data.

7.5.4 Customer Property

LGGS, Inc. / LGGS Florida, Inc. does not receive customer supplied product for incorporation into supplies or for related activities. However, any product received for microbial testing, supplier (customer) shall be notified if product is lost, damaged, or is otherwise unsuitable for testing. This shall be recorded and reported to the customer. Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

7.5.5 Preservation of Product

LGGS, Inc. / LGGS Florida, Inc.'s standard operating procedures are designed in a manner which shall promote appropriate methods for preservation and segregation of product when the product is under LGGS, Inc. / LGGS Florida, Inc. control such as handling of lab supplies, test samples and test reports. These procedures are intended to prevent mix-ups, damage, deterioration or other adverse affects, and specify storage procedures, methods of control, and working requirements.
LGGS, Inc. / LGGS Florida, Inc. has documented procedures to ensure that storage of media, reagents, purified water, sterile laboratory supplies and laboratory hard goods are controlled to prevent mix-ups, damage, deterioration or other adverse affects.

Office storage shall be considered acceptable storage for electronic media, unless otherwise specified by standard documented procedures.

If storage areas other than LGGS, Inc. / LGGS Florida, Inc. warehouse areas, laboratories, and shop floors are to be used for storing material or product, the authorized personnel shall designate such areas and specify any applicable authorizations for receipt into and release from these storage areas.

If product or material is stored for a period of time such that deterioration could occur, the

authorized personnel shall decide the intervals and methods for assessing the condition of the product stored. The authorized personnel shall ensure the assessment is performed.

Standard warehouse environmental conditions shall be considered acceptable for preservation unless a special storage environment is required. Storage in an office environment shall be considered acceptable preservation for electronic media unless otherwise specified by standard documented procedures.

7.6 Control of Monitoring and Measuring Devices

The manufacturer calibrates all monitoring and measuring devices.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENTS

8.1.1 General

LGGS, Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring and test equipment. Each item that requires calibration is entered into the documented calibration program and identified with a calibration sticker. Inspection measuring and test equipment shall be used in a manner, which ensures that the measurement uncertainty is known and consistent with required measurement capability. LGGS, Inc. / LGGS Florida, Inc. and /or certified calibration company shall determine the measurements to be made and the accuracy required, and selects the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision.
At their work location, LGGS, Inc. / LGGS Florida, Inc. personnel have access to current and approved versions of Quality System documents, Quality System data, and external documentation pertinent to their work that affects the quality of LGGS, Inc. / LGGS Florida, Inc.'s services.

8.1.2 Control Procedure

Calibration records identify all equipment, ID numbers, locations, frequency of checks, check methods, acceptance criteria and actions to be taken when results are unsatisfactory.

Records of all calibrations are maintained and available when required by customers for verification. Once calibrated a calibration sticker is affixed to each instrument, and results are reviewed following SOP directive. If equipment is found to be out of calibration, validity of previous measurements is reviewed.

All calibrations are conducted by certified calibration companies using NIST traceable standards and suitable environmental conditions. Test facilities and equipment are handled by designated individuals in a manner, which ensures that accuracy and fitness for use are maintained.

Adjustment logs are utilized to ensure that no adjustments that would invalidate calibration settings are performed.

8.2 Monitoring and Measurement

8.2.1 Feedback

Customer feedback is established in the current revision of O-SOP-100 - Handling of Customer Complaints.

8.2.2 Internal Audit

LGGS, Inc. / LGGS Florida, Inc. conduct internal quality audits following O-SOP-0105 and QC-SOP-0040 to determine the status and effectiveness of the Quality System. LGGS, Inc. / LGGS Florida, Inc. ensure that timely corrective action is taken on non-conformances found during an internal audit. This includes verifying the implementation and effectiveness of corrective action and recording it as a Quality Record.

The Quality Manager shall develop an audit schedule and obtain approval from the Management Representative. The Quality Manager shall ensure that audits are performed in accordance with the schedule and documented procedures.

Quality audits covering testing are conducted and shall be scheduled bi-annually on the basis of the status and importance of the activity to be audited and shall be carried out by Management. LGGS, Inc. / LGGS Florida, Inc. shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing internal quality audits.

A quality audit covering quality system and quality procedures are conducted and scheduled no less than once per year, and are carried out by a Quality Manager. Results of these audits are reviewed with personnel having responsibility for the area audited and follow-up activities verify and record effectiveness of corrective action taken. The management representative prepares a report on findings of the quality audit results and presents it to executive management for review. These reviews and any follow up activities are completed in a timely manner and are documented.

8.2.3 Monitoring and Measurement of Processes

The internal audit is a measurement of the quality system processes.

8.2.4 Monitoring and Measurement of Product

8.2.4.1 Incoming Product

Materials received for laboratory use are finished devices that have passed FDA pre-marketing requirements for in-vitro diagnostic products. Therefore, incoming inspections focus on verifying identity and condition. Dehydrated media and stock culture organism are received with certificates of conformance or analysis, which are maintained in logbooks. Materials are not utilized until properly received and inspected.

8.2.4.2 Type of Receiving Inspection

That the requirements for receiving inspection procedures take into consideration any recorded testing, inspections, or other controls that exist at the vendor's or sub-contractor's premises that demonstrate conformance to requirements.

8.2.4.3 Urgent Releases

That the procedures specify that no incoming materials can be used or processed until the completion of the specified receiving inspection and testing. If the incoming material must be released for Urgent Use, the procedures shall call for it to be positively identified and the Quality Record of this action documented

8.2.4.4 In-Process Inspection and Testing

As applicable, in-process tests are performed and documented per procedural directive. Products are held until the required inspection and test have been completed or necessary reports have been verified except when product is released under positive recall procedures. Examples of in-process testing would include pH and growth promotion testing of media products, environmental monitoring of sterility testing environments and in-process culture inspections prior to release.

8.2.4.5 Final Inspection and Test

Each report is verified by quality assurance prior to release to verify conformance to specified requirements. The verification shall confirm that required inspections or tests have been completed. Test data is not dispatched until all the activities specified have been satisfactorily completed and associated data and documentation are available and certified.

8.2.4.6 Inspection and Test Records

Verification of required inspections/testing is documented on each raw data sheet and associated laboratory logbooks. These records shall clearly show whether the product (test) has passed or failed the inspection and /or tests according to defined acceptance criteria. If any inspections/tests have failed to meet required criteria, a nonconformance report will be prepared.

8.3 Control of nonconforming product

8.3.1 General

LGGS, Inc. / LGGS Florida, Inc. prevent the unintended use, installation, or delivery of nonconforming product to LGGS, Inc. / LGGS Florida, Inc. customers via documented procedures. These procedures provide for the identification, documentation, evaluation, segregation (when practical), disposition, and appropriate notification of the occurrence of non-conformances.

LGGS, Inc. / LGGS Florida, Inc. ensure that the authority and the responsibility for controlling nonconforming product are delegated to the appropriate management authority. The VP/Quality Assurance Microbiology or Director of Micro Programs must approve review and final disposition of nonconformance and corrective action reports. Records are stored in the Quality Records maintained for the laboratory.

8.3.2 Review and Disposition of Nonconforming Product

LGGS, Inc. / LGGS Florida, Inc. ensure that nonconforming product is reviewed in accordance with documented procedures to determine how the product should be used. If a nonconforming product disposition is "use as is" or "repair and use," the customer is informed per documented procedures. If the nonconforming product disposition is "repair" or "rework," the product is re-inspected in accordance with the appropriate documented procedures. Descriptions of nonconformance that have been accepted, and of repairs, are recorded to denote the actual condition and are maintained as Quality Records.

Note: Due to the nature of laboratory tests, reworking or scrapping of test results is not applicable. All results would be reported to the customer with a statement of nonconformity or deviation.

8.4 Analysis of data

LGGS, Inc. / LGGS Florida, Inc. has identified the need to utilize statistical techniques to develop a proactive corrective action response plan for environmental recoveries in the cleanroom areas, perform trend analysis of customer complaints and track sterility test false positive rates.

Responsibility to prepare statistical presentation is granted to the Quality Systems Technologist. Authority to request statistical techniques to be applied to operations is granted to the Director of Micro Programs and the VP/Quality Assurance Microbiology

8.5. Improvement

8.5.1 General

LGGS, Inc. / LGGS Florida, Inc. emphasize the use of problem prevention or problem correction to determine the potential cause or actual cause of non-conformances (including customer complaints, nonconforming products, and nonconforming processes) and prevent their occurrence or recurrence.

LGGS, Inc. / LGGS Florida, Inc. investigates the causes of non-conformances relating to the Quality System, including Quality System products and processes. The results of these investigations are maintained as Quality Records. Investigations resulting in changes to documented procedures are processed in accordance with the document and data control system or the configuration management control system.

Preventive and corrective action is taken to eliminate potential or existing nonconformance to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered to eliminate or minimize the impact on safety, performance, dependability, processing cost, quality-related cost, and customer satisfaction.

The responsibility for preparation of corrective and preventive action records is granted to all employees. Authority for review and approval of corrective and preventive actions is given to the Management Representative/Quality Assurance Manager and the Director of Microbiological Programs / Senior Technologist.

8.5.2 Corrective Action

Corrective action shall be initiated as a result of, but not limited to, the following:

- Nonconformances identified during audits and audits of suppliers' Quality Systems
- Action items from executive management reviews of Quality System effectiveness
- Customer complaints
- Process or product problems identified by employees
- Investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of investigation (see 4.2.4);
- Determination of the corrective action needed to eliminate the cause of non-conformities Application of controls to ensure that corrective action is taken and that it is effective.

8.5.3 Preventive Action

Preventive action shall be determined from the analysis of appropriate data to detect trends and identify causes that may result in future non-conformances. Data sources may include, but are not limited to, the following:

- the use of appropriate source of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of non-conformities;
- determination of the steps needed to deal with any problems requiring preventive action;
- initiation of preventive action and application of controls to ensure that it is effective;
- ensuring that relevant information on actions taken is submitted for management review (see 5.6.1 and 5.6.2).