

QUALITY POLICY MANUAL

- This document together with the procedures specified in this manual, represent the quality management system of Laboratory Services & Consultations Ltd.
- It has been compiled to meet the requirement of the ISO 15189:2003 Standard.
- All procedures specified herein are mandatory within Laboratory Services & Consultations Ltd.

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LOCATION OF COPIES	<ol style="list-style-type: none">1. Office of the Director2. The Quality Manager3. Laboratory

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0 GENERAL INFORMATION

0.1 Scope of services

Laboratory Services & Consultations Ltd. consists of eight locations strategically located throughout St.Lucia. The main diagnostic testing facility is at the Tapion Hospital where inpatient and outpatient services are provided. Comprehensive diagnostic testing includes Microbiology, Biochemistry including Hormonal assays, Immunochemistry, Serology, Immunoheamatology, Histopathology, Cytology, Blood Banking and referral services for every available diagnostic test including DNA paternity testing.

Laboratory Services & Consultations Ltd provides services to the population of St Lucia. The resident population is approximately 160,000. Services are provided for hospitals, clinics, doctors, patients and institutions.

0.2 Legal Identity

Laboratory Services & Consultations Ltd was established in July 1993. It was registered as a Company under the Business Names Act , Certificate # 77, on 28th May 1993.

0.3 Contact Information

Laboratory Services & Consultations Ltd
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Castries
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0.4 MISSION

“To deliver the highest quality, comprehensive, preventative and diagnostic services to our clients, to allow optimal patient care. Our team of qualified laboratory specialists uses modern technology in an environment of integrity and confidentiality.”

0.5 VISION

“To be the leading provider of the highest quality, comprehensive, preventative, diagnostic and diversified laboratory services within the Caribbean Common Market (CARICOM). We will accomplish this by building a broad network of national and regional outlets and laboratory professionals who are committed to providing these services in keeping with the ethical values of our discipline.”

0.6 GOAL

“To achieve accreditation by year 2010.”

1 QUALITY POLICY STATEMENT

We at Laboratory Services & Consultations Ltd are committed to providing a service of highest quality and remain aware and take into consideration the needs and requirements of our users.

We at Laboratory Services & Consultations Ltd are going to meet the needs and requirements of our users by fulfilling the following objectives:

- Operating a quality management system to integrate the organization, procedures, processes and resources
- Setting quality objectives and plans in order to implement this quality policy
- Ensuring that all personnel are familiar with the quality policy, the quality manual and all procedures relevant to their work so as to ensure user satisfaction
- Commitment to the health, safety and welfare of all our staff
- Ensuring that visitors to the laboratory are treated with respect and due consideration given to their safety while on site
- Upholding professional values and being committed to good professional practice and conduct.

We will comply with the ISO 15189:2003 standard, taking into consideration local and regional standards and guidelines, and are committed to:

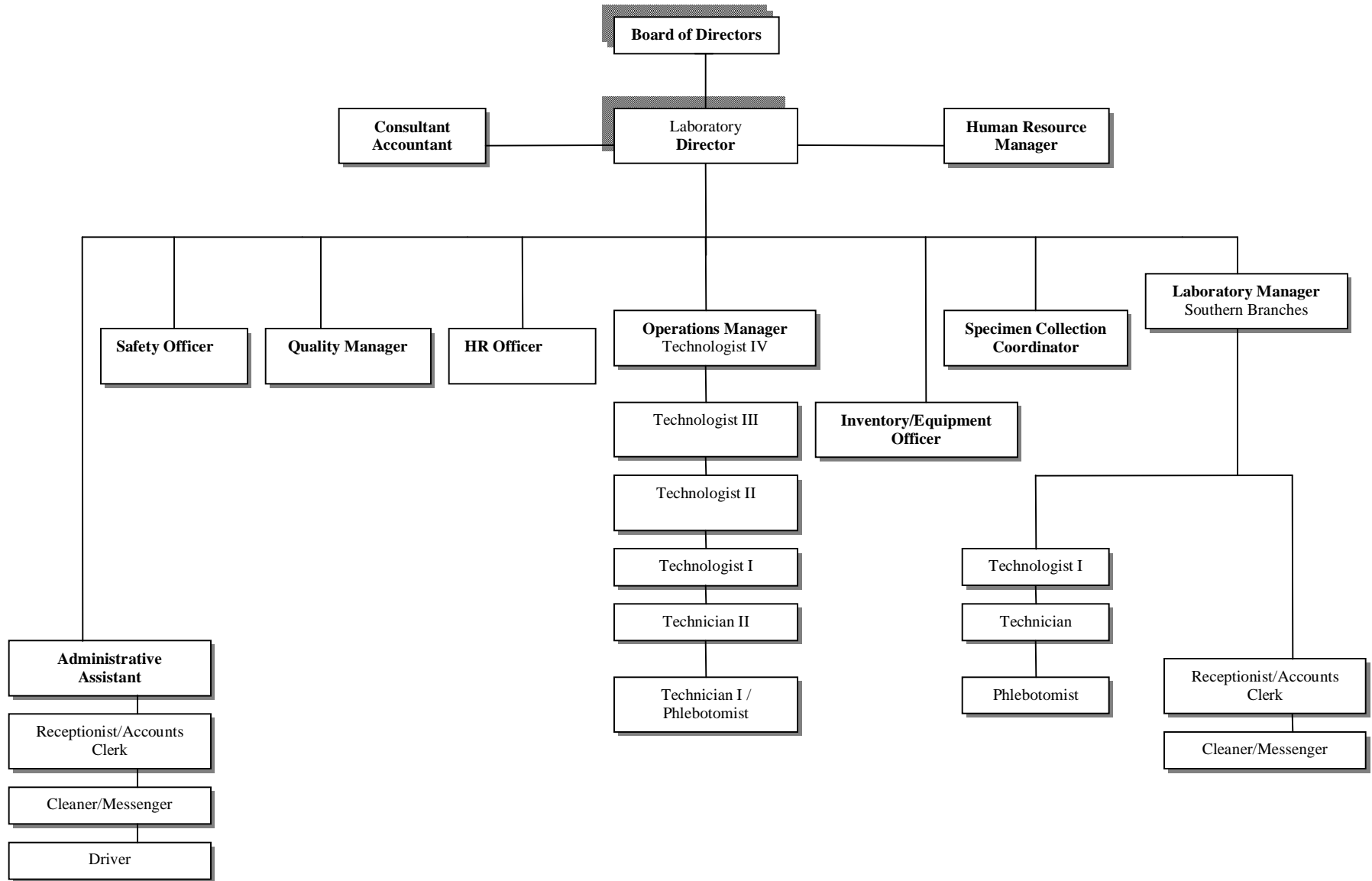
- Staff recruitment, training, development and retention and to provide a full and effective service to our users
- The proper procurement and maintenance of the equipment and other resources needed for the provision of service
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- The use of examination procedures that will ensure the highest achievable quality of all tests performed
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

Laboratory Services & Consultations Ltd. scope of services is defined by our eight locations strategically located throughout St.Lucia where services are provided in the areas of Microbiology, Biochemistry including Hormonal assays, Immunochemistry, Serology, Immunoheamatology, Histopathology, Cytology, Blood Banking and referral services for every available diagnostic test including DNA paternity testing.

2 DEFINITIONS

Term	Definition
Accuracy of measurement	Closeness of the agreement between the result of a measurement and a true value of the material being measured.
Audit	An internal quality audit is a structured and independent examination to determine whether activities and their related results comply with planned arrangements, and whether these arrangements are implemented effectively.
Auditee	An auditee is the person who is being audited. He must supply information to the auditor. In many audits there is more than one auditee.
Auditor	An auditor is a person who is qualified to carry out the task of auditing the laboratory's quality management system. He will survey and sample the quality management system by questioning, listening, observing, challenging and noting facts, which allow him to compare the activity with the planned arrangements in an impartial manner. Where ever possible, the auditor will be independent of the process/activity being audited.
Author	Person designated to create or revised a document or quality system data.
Biological reference interval	Central 95% interval of the distribution of reference values.
Calibrate	Correlate the readings of (an instrument) with a standard.
Continual improvement	Recurring activity to increase the ability to fulfill requirements.
Client	An organization or individual that enters into a formal agreement with our laboratory for the delivery of products and services.
Client complaint	Client statement that our product or services do not meet requirements and/or expectations.
Client satisfaction	Client's perception of the degree to which the client's requirements have been fulfilled.
Delivery	The method of transferring product from our laboratory to a client.
Document	Quality system procedure, work instructions, process plan or associated form which is used to control the processes that affect the quality of the final product.
Examination	Set of operations having the object of determining the value or characteristics of a property.
Handling	Actions taken to move or handle product while preventing damage or deterioration.
Laboratory capability	Physical environment and information resources, personnel, skills and expertise available for examination in question.
Laboratory director	Competent person with responsibility for, and authority over, a laboratory.

Laboratory management	Person(s) who manage the activities of a laboratory headed by the laboratory director.
Management representative (Quality Manager)	A member of the management team, who irrespective of other duties, has the authority to ensure the quality system is established, maintained and implemented and report on the performance of the quality system as a basis for improvement.
Measurement	Set of operations having the object of determining a value of a quantity.
Objective evidence	Information that can be proven true based on facts obtained through observation, measurement, test or other means.
Post-examination procedures	Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of results, and storage of samples of the examinations.
Pre-examination procedures	Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory, and ending when the analytical examination procedure begins.
Preservation	Measures taken to ensure that product does not deteriorate.
Primary sample	Set of one or more parts initially taken from a system.
Plan	Document that establishes the overall baseline for implementation.
Quality policy	Overall intentions and directions of our laboratory with regards to quality as formally expressed by management.
Quality record	Records required to validate compliance as specifically defined in the lower-level procedures.
Quality system	Organizational structure, procedures, processes, and resources needed to implement quality management.
Referral laboratory	External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report.
Sample	One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production.
Storage	Keeping product free from damage or deterioration until ready to deliver to client
Trueness of measurement	Closeness of agreement between the average value obtained from a large series of results of measurements and a true value.
Uncertainty of measurement	Parameter, associated with the result of a measurement, which characterizes the dispersion of the values that could reasonably be attributed to the measurand.
Reference	ISO 15189:2003



4 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENT

Our Laboratory has established a quality management system that is described in this Quality Manual and continues to improve its effectiveness by the conduct of an annual management review and by evaluations and quality improvement activities described in section 8 of this manual. Throughout this quality manual the processes required to ensure the effective working of the laboratory are identified and their sequence and interactions defined.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 General

Our Laboratory's documentation includes a Quality Manual together with documented statements of policy, objectives and plans. Our laboratory documents and controls all procedures and instructions required to ensure effective planning and control of its examination processes. It maintains and controls process and quality records and clinical material with appropriate procedures.

4.2.2 Quality Manual

Our Laboratory has established a Quality Manual which is reviewed on an annual basis by the Quality Manager on the behalf of the Laboratory Management and issued under the authority of the Laboratory Director.

Personnel are familiar with and work to the current version of the Quality Manual and all referenced documentation.

4.2.3 Document Control

Our Laboratory has established a procedure to control all documents. We have ensured that approval, distribution, removal, retrieval, revision and retention of all documents are clearly defined.

Only current versions of documents are available at appropriate locations.

4.2.4 Control of Process and Quality Records

Our Laboratory has established procedures for storage and disposal of our process and quality records. Length of storage is clearly defined in accordance with current legislation, regulations and guidelines. Our quality and process records are readily available, in order to reconstruct the process of any examination.

4.2.5 Control of Clinical Material

Our Laboratory has established procedures for the control of clinical material which includes identification and indexing, security, retention, storage and retrieval and disposal.

Retention times are determined with regard to current legislation, regulations and guidelines.

Retained clinical material is stored in a manner that ensures validity of a repeat examination.

4.2.6 Documentation structure

The general structure of the documentation used by Laboratory Services & Consultations Ltd consists of **policies** (Quality Manual), **procedures** (managerial and technical), **laboratory instructions and forms**.

<p><u>Supporting Documents</u></p>	<p><u>The following processes and documents support this policy</u></p>
	<ul style="list-style-type: none"> • Certificate of registration • Document control process • Process for control of clinical records • Process for storage and disposal of Quality Records • Process for the control of clinical Records • Record of review of Quality Management System • Record of review of Quality Policy Manual • Record of signoff by staff for the review of Quality Policy Manual

5 ORGANIZATION AND MANAGEMENT RESPONSIBILITY

5.1 GENERAL MANAGEMENT

- 5.1.1 The structure within our laboratory is illustrated in the overview of the organization section of this manual (section 3).
- 5.1.2 Our Laboratory Director is ultimately responsible for the overall functioning of the laboratory.
- 5.1.3 Our Operations Manager is responsible for the overall day-to-day management and operations of the laboratory and reports to the Laboratory Director.
- 5.1.4 Our laboratory conducts Management and staff meetings where strategic and operational matters pertaining to the laboratory are discussed and addressed. Records are kept of meetings and agreed action points noted.
- 5.1.5 Management meetings are conducted on a monthly basis and are attended by the Lab Director, Quality Manager, Southern Branch Manager Operations Manager, Human Resource Officer, Safety Officer, Specimen Collection Coordinator, Procurement Officer, and Administrative Assistant.
- 5.1.6 Quality Management meetings are conducted bi-weekly and are attended by the Laboratory Director and the Quality Assurance Team, and/or other staff as required based on the agenda of the meeting.
- 5.1.7 Staff meetings are conducted bi-weekly and are attended by the Quality Manager, Technical and Administrative staff. The Quality Manager is provided with reports from each department supervisor.

5.2 ORGANIZATION

- 5.2.1 Our Laboratory has arrangements to ensure the avoidance of involvement in any activities that would diminish confidence in its impartiality, judgment and operational integrity.
- 5.2.2 Our laboratory ensures compliance with the professional code of conduct and encourages membership of a professional body.
- 5.2.3 Our laboratory has arrangements that protect the user's confidential information. Internal action to achieving this end includes an item in the induction program; control access to the laboratory; and a secure system for access to laboratory records and computers.
- 5.2.4 Our laboratory meets the requirements of the standards to satisfy the needs of the users and regulatory or accreditation bodies.

5.3 MANAGEMENT RESPONSIBILITY

5.3.1 Our laboratory management has responsibility for the design, implementation, maintenance and improvement of the quality management system. This includes, but is not limited to the following:

- a) Management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;
- b) Technical management with the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory procedures;
- c) Appointment of a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system;
- d) Appointment of deputies (where necessary) for key functions;
- e) Adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures.

<u>Supporting Documents</u>	The following processes and documents support this policy <ul style="list-style-type: none">• Records of management meeting• Records of staff meetings• Professional code of conduct• Organizational plans• Record of review of the Quality Management System
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6 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

6.1.1 Our Laboratory is responsible for the provision of all resources necessary for the effective functioning of the laboratory so as to fulfill the quality policy specified in this quality manual and to ultimately meet the needs and requirements of our users. These resources include:

- Personnel
- Equipment
- Materials
- Reagents and supplies
- Other resources

6.2 PERSONNEL

6.2.1 The management of our laboratory supports all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties and other functions of the quality management system.

6.2.2 Our management has organizational plans, personnel policies and job descriptions that define qualifications and duties for laboratory personnel.

6.2.3 Our management maintains records of the relevant educational and professional qualifications, training and experience, and competence of personnel. This information is readily available to relevant personnel.

6.2.4 Our Laboratory is directed by a person having the competence and overall responsibility for the services provided.

6.2.5 The responsibility of the Laboratory Director includes professional, scientific, consultative, administrative and educational matters. These are relevant to the services offered by our laboratory.

6.2.6 Our Operations Manager apart from having other duties has the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory procedures.

6.2.7 Our laboratory has assigned the function of a Quality Manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system and who report directly to Laboratory Management.

- 6.2.8 Our laboratory has personnel with training specific to quality assurance and quality management for services offered.
- 6.2.9 Our Laboratory management has authorized personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment including the use of computers.
- 6.2.10 Our laboratory provides continuing education programs which are available to staff at all levels.
- 6.2.11 Our personnel have the applicable theoretical and practical background as well as recent experience when making professional judgments with reference to examinations.
- 6.2.12 Competencies of each person who perform tasks are assessed following training. Retraining and reassessment occur annually and when necessary.
- 6.2.13 The management of personnel is conducted according to documented procedures.

Supporting Documents

The following processes and documents support this policy

- Process for management of personnel
- Job descriptions
- Record of education and professional qualification, training, experience and competence.
- Record of orientation
- Record of continuing education programe
- Record of competency assessment for personnel

6.3 PREMISES AND WORK ENVIRONMENT

6.3.1 Our Laboratory has arrangements to ensure:

- Adequate space for workload undertaken and environmentally controlled in a manner that does not compromise the quality of work or the services to users.
- Effective separation of incompatible activities
- Controlled access to areas where examinations are conducted and samples and confidential records are kept
- Appropriate communications
- Health and safety of laboratory staff
- The protection of patients and visitors from known hazards
- The privacy and comfort of patients
- Appropriate storage for quality and processed records, clinical material and materials used in the course of examinations.

6.3.2 Our Laboratory facilities have sufficient space to allow for the correct performance of examinations.

6.3.3 The laboratory monitors, controls and records environmental conditions, as required by relevant specifications or where they may influence the quality of the results.

6.4 HEALTH AND SAFETY

6.4.1 Our laboratory management is committed to providing a safe work environment for all laboratory personnel, those who work in, or carry out activities in the laboratory.

6.4.2 Our laboratory management has assigned the function of Safety Officer to competent laboratory personnel to coordinate, give advice and report on all safety activities carried out in the laboratory.

6.4.3 A safety manual was produced and implemented in our laboratory. This safety manual describes the various safety programs to be executed in the laboratory.

6.4.4 The manual is the reference/standard document for all safety activities in our laboratory and is revised annually and only the current version is available.

Supporting Documents

The following processes and documents support this policy

- Laboratory layout-floor plan
- MedLabs Safety Plan St Lucia 2006(revised 2009)
- Process for incident/accident reporting
- Record of incident/accident
- Immunization records

6.5 EQUIPMENT, EXTERNAL SERVICES AND SUPPLIES

- 6.5.1 Our laboratory has documented policies and procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of services. There are procedures and criteria for the inspection, acceptance/rejection, and storage of consumable materials.
- 6.5.2 Purchased equipment and consumable supplies that affect the quality of service are subjected to a process of verification prior to use for the procedures concerned. This is accomplished by examining quality control samples and verifying that the results are acceptable.
- 6.5.3 An inventory control system for supplies exists within the laboratory. Appropriate quality records of external services, supplies and purchased products are established and maintained.
- 6.5.4 Our laboratory evaluates suppliers of critical reagents, supplies and services that affects the quality of examinations and maintain records of these evaluations and list those approved.
- 6.5.5 A procedure is employed for the procurement and management of equipment and consumable supplies.
- 6.5.6 The laboratory is furnished with items of equipment required for the provision of services which include primary sample collection; sample preparation and processing; examination and storage.
- 6.5.7 Programs that regularly monitor calibration and function of instruments, reagents and analytical systems are established and maintained. There is also a documented and recorded program for preventive maintenance (PM) for all laboratory equipment that affects quality. Manufacturer recommendations along with other information are use to fulfill requirements of the PM program.
- 6.5.8 Each item of equipment is uniquely labeled, or marked for identification purposes.
- 6.5.9 Records are maintained for each piece of equipment contributing to the performance of examinations.
- 6.5.10 Only personnel trained and authorized are allowed to operate equipment. Up-to-date instructions on the use and maintenance of equipment are readily available to laboratory personnel at the work stations.

- 6.5.11 Equipments are maintained in safe work conditions. Manufacturer's specifications and instructions together with the information provided in the safety manual are appropriate for use to meet this requirement
- 6.5.12 Whenever equipment is found to be defective, it is taken out of service, clearly labeled and/or appropriately stored until it has been repaired and shown by means of verification or testing to meet specified acceptance criteria before being reinstated for the purpose of performing examination procedures. Our laboratory examines the effect of this defect on previous examinations and instates procedure.
- 6.5.13 Whenever a piece of equipment is to undergo repair, servicing or decommissioning our laboratory takes reasonable measures to decontaminate the equipment.
- 6.5.14 For computers and automated examination equipment used for the collection, processing, recording, reporting, storage or retrieval of examination data, our laboratory ensures that:
- Computer software, including those that built into equipment, is documented and suitably validated as adequate for use in the facility,
 - Procedures are established and implemented for protecting the integrity of data at all times,
 - Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and
 - Computer programs and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons.
- 6.5.15 Where calibrations give rise to a set of correction factors, our laboratory have procedures for ensuring that copies of prior correction factors are correctly updated.
- 6.5.16 Procedures are employed for the procurement and management of equipment and supplies.

Supporting Documents

The following processes and documents support this policy

- Process for equipment procurement and management
- Process for consumable supplies procurement and management
- Process for decommissioning of equipment
- Records of Preventative maintenance for equipment
- Records of Inventory control
- Record of evaluation of suppliers
- Record of calibration of equipment
- Process for data management

7 EXAMINATION PROCESSES

7.1 PRE-EXAMINATION PROCESSES

- 7.1.1 Our laboratory has request forms in circulation for the users of our services.
- 7.1.2 The request forms contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical details and other relevant information and examinations requested.
- 7.1.3 Specific instructions for the proper collection and handling of primary samples are documented and implemented and are available to those responsible for primary sample collection.
- 7.1.4 Primary samples are traceable, normally by request form, to an identified individual. Where the primary sample lacks proper identification the specimen acceptance/rejection policy is evoked.
- 7.1.5 Where there is uncertainty in the identification of the primary sample or instability of the analyze in the primary sample (cerebrospinal fluid, biopsy, etc) and the primary sample is irreplaceable or critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection takes responsibility for identifying and accepting the sample, or for providing proper information, or all of these. The signature of that person taking responsibility for the primary sample identification should be recorded on, or traceable to, the request form. If this requirement is not met for any reason, the person responsible shall be identified in the report if the examination is carried out.
- 7.1.6 Our Laboratory monitors the transportation of samples to the laboratory such that they are transported
- a) Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned,
 - b) Within the appropriate temperature interval and with designated preservatives to ensure the integrity of the samples, and
 - c) In a manner that ensures safety of the carrier, general public and receiving laboratory.
- 7.1.7 All primary samples are recorded in a computer and accession books. The date and time of receipt of samples, as well as the identity of the receiving officer is recorded.

- 7.1.8 Criteria are set for the acceptance and rejection of primary samples. When compromised primary samples are accepted, the final report indicates the nature of the problem, and when applicable, that caution is required when interpreting the results.
- 7.1.9 A procedure for the receipt, labeling processing and reporting of primary samples that are marked urgent/STAT is defined and implemented. The turn around time for STAT samples are clearly defined.
- 7.1.10 The laboratory allows for verbal requests of examinations by requesting physicians. The verbal requests should be followed by a written request. If the request is made via the telephone then the conversation must be recorded in the telephone log.

<u>Supporting Documents</u>	The following processes and documents support this policy <ul style="list-style-type: none">• User manual (Guide to Laboratory services)• Process for Specimen collection and receipt• Specimen collection telephone log
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7.2 EXAMINATION PROCESSES

- 7.2.1 Our Laboratory uses examination procedures, including those for selection/taking sample portions, which meet the needs of the users of the laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, or in international, national or regional guidelines.
- 7.2.2 When in house procedures are used, they are appropriately validated for they intended use and fully documented
- 7.2.3 Our laboratory use only validated procedures for confirming that examination procedures are suitable for intended use. The validation is as extensive as necessary to meet the needs in the given application or field of application. Our laboratory records the results obtained and the procedure used for the validation.
- 7.2.4 The methods and procedures selected for use are evaluated and must give satisfactory results before being used for medical examinations. A review of procedures by management is undertaken initially and then annually. These reviews are documented.
- 7.2.5 All procedures are documented and made available at the workstations for relevant staff. Documented procedures and necessary instructions are available in a language commonly understood by the staff in the laboratory.
- 7.2.6 The procedures are based in whole or in part on the instructions for use written by the manufacturer, provided that they describe the procedure as it is performed in the laboratory. Any deviation is reviewed and documented. Each new version of examination kit with major changes in reagents or procedure is checked for performance and suitable for intended use. Any procedural changes are dated and authorized as for other procedures.
- 7.2.7 In addition to document control identifiers, documentation includes when applicable the following:
- Purpose of examination;
 - Principle of the procedure used for examinations;
 - Performance specifications (e.g. linearity, precision, accuracy expressed as uncertainty of measurement, detection limits, measuring interval, trueness of measurement, sensitivity and specificity);
 - Primary sample system (e.g. plasma, serum, urine);
 - Type of container and additive;
 - Required equipment and reagents;
 - Calibration procedure;
 - Procedural steps;
 - Quality control procedures;

- Interferences (e.g. lipemia, hemolysis, bilirubinemia) and cross reactions;
- Calculation of results;
- Biological reference intervals;
- Reportable intervals of patient examination results;
- Alert/critical values, where appropriate;
- Laboratory interpretation;
- Safety precautions;
- Potential sources of variability;
- References.

7.2.8 Our laboratory management is responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

7.2.9 Performance specifications for each procedure used in an examination relates to the intended use of that procedure.

7.2.10 Biological reference intervals are periodically reviewed. If the lab has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation is undertaken then followed, if necessary, by corrective action. A review of biological reference intervals also takes place when the laboratory changes an examination procedure or pre-examination procedure, if appropriate.

7.2.11 Our Laboratory makes a list of current examination procedures, including primary sample requirements, and relevant performance specifications and requirements, available to users of laboratory services.

7.2.12 When our Laboratory changes an examination procedure such that results or their interpretations could be significantly different, the implications are explained to the users of the laboratory services in writing, prior to the introduction of the change.

7.3 REFERRAL TO OTHER LABORATORIES

7.3.1 Our Laboratory has established a procedure for evaluating and selecting referral laboratories. Our laboratory management is responsible for selecting and monitoring the quality of referral laboratories and where necessary, consultants who provide second opinion for histology, cytology and related disciplines, ensures that the referral laboratory or referral consultant is competent to perform the requested examinations.

7.3.2 Arrangements with referral laboratories are reviewed annually to ensure that

- a) The referral laboratory is able to meet the requirements and that there is no conflict of interest,
- b) Requirements, including pre-examination and post-examination procedures, are adequately defined, documented and understood,

- c) Selection of examination procedures is appropriate for intended use, and
- d) Respective responsibility for interpretation of examination results is clearly defined.

Records of such reviews are maintained.

- 7.3.3 Our laboratory maintains a register of all referral laboratories that we use. A register is kept of all samples that have been referred to another laboratory. The name and address of the laboratory responsible for the examination is provided to the user of the laboratory services if required.
- 7.3.4 Our Laboratory and not the referral laboratory is responsible for ensuring that the referral laboratory examination results and findings are provided to the person making the request. When we prepare the report, it includes all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation. Procedures are employed for evaluating and selecting referral laboratories.

7.4 ASSURING THE QUALITY OF EXAMINATIONS

- 7.4.1 Our laboratory has designed internal quality control systems that verify the attainment of the intended quality of results. The quality control system provides staff members with clear and easily understood information on which to base technical and medical/clinical decisions.
- 7.4.2 Our laboratory determines the uncertainty of results where relevant and takes action to ensure the reliability of tests results.
- 7.4.3 A program for calibration and running of controls was designed and implemented so as to ensure reliable results.
- 7.4.4 The laboratory participates in inter-laboratory comparisons such as those organized by external quality assessment schemes. Our Laboratory management monitors the results of external quality assessment and ensures the implementation of corrective actions when results criteria are not fulfilled.
- 7.4.5 Our participation in External quality assessment programs provides, as far as possible, clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.
- 7.4.6 Our Laboratory documents, record and, as appropriate, expeditiously act upon results from its internal quality control program or external quality assessment schemes. Problems or deficiencies identified are acted upon and records of actions retained.
- 7.4.7 Whenever a formal interlaboratory comparison program is not available, our laboratory develops a mechanism for determining the acceptability of procedures not otherwise

evaluated. Whenever possible, this mechanism utilizes externally derived challenge materials such as exchange of samples with other laboratories. Our Laboratory monitors the results of this mechanism of interlaboratory comparison and participates in the implementation and recording of corrective actions.

- 7.4.8 Our Laboratory has procedures for the management of participation in external quality assessment schemes is conducted.

7.5 POST EXAMINATION PROCESSES

- 7.5.1 The department senior or medical technologist responsible for the department, systematically review the results of examinations, evaluate them in conformity with clinical information available regarding the patient before the results are authorized and released.

- 7.5.2 Storage of primary samples and other laboratory samples is in accordance with laboratory Procedure.

- 7.5.3 Safe disposal of samples no longer required for examination are carried out in accordance with local regulations or recommendations for waste management.

7.6 REPORTING OF RESULTS

- 7.6.1 The format of the laboratory report is specific for each department/discipline and is a function of the test results to be reported, the instrument/equipment used and computer software used to generate results.

- 7.6.2 Results generated and issued by the laboratory are legible, without mistakes in transcription and reported to persons authorized to receive and use medical information. The reports include but are not limited to the following:

- a) Clear, unambiguous identification of the examination including, where appropriate, the testing procedure;
- b) The identification of the laboratory;
- c) Identification of the patient and destination of the report;
- d) The identification and location of the requester;
- e) Date and time of collection of primary sample, when available and relevant to patient care, and time of receipt in the laboratory;
- f) Date, and in some instances time, of release of report;
- g) Results of examination reported in SI units where applicable;
- h) Biological reference interval, where applicable;
- i) Other comments (e.g. quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);

- j) Signature of the person authorized to release the report.
- 7.6.3 Records of results/reports issued are stored in log books and computers. These results are readily retrievable.
- 7.6.4 Our Laboratory has developed and implemented procedure for the immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals. This includes results received on samples sent to referral laboratories for examination.
- 7.6.5 Records of actions taken in response to results in the critical intervals are maintained. These include date, time, responsible laboratory staff member, person notified and examination results.
- 7.6.6 For results issued as interim report, the final report is always forwarded to the requester.
- 7.6.7 When an examination procedure is delayed, in relation to established turn around time, for any reason and this delay could compromise patient care then our laboratory informs the clinical personnel of such a delay.
- 7.6.8 Our Laboratory has a procedure with details instructions for the release of examination results, including details of who may release results and to whom. The procedure also includes guidelines for the release of results directly to patients.
- 7.6.9 Telephone results are only issued to authorized clinical personnel responsible for patient care. Results issued verbally are followed by properly recorded report. Conversations of telephone reports are recorded in the telephone log.
- 7.6.10 Under no circumstances are telephone reports issued to patients.
- 7.6.11 Laboratory personnel responsible for and authorized to issue results/reports can make alterations to reports. When altered, the report shows the time, date and name of the person responsible for the change.
- 7.6.12 Original electronic records are retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.
- 7.6.13 Results that have been available for clinical decision making and revised are retained in subsequent cumulative reports and be clearly identified as having been revised.

Supporting Documents

The following processes and documents support this policy

- Examination processes
- Examination procedures
- Validation for procedures process
- Procedure Modification Process
- Telephoned report process
- Altered report preparation and delivery process
- Provision of Clinical Advice Process
- Report issuing and delivery process
- Critical value reporting process
- Referral Services Process
- Review of Biological Reference interval process
- Record of review of Biological Reference interval
- Record of review of procedures
- Record of evaluation of referral services
- Log for telephoned results

8 EVALUATION AND QUALITY IMPROVEMENT

8.1 GENERAL

8.1.1 The overall aim of evaluation and quality improvement of our Laboratory is to continue to meet the needs and requirements of users. Our laboratory continues to plan and implement activities that enable us to demonstrate the conformities of the results of examination procedures, the proper functioning of the Quality Management System and provision evidence of continual improvement.

8.2 INTERNAL AUDIT

8.2.1 In order to verify that operations in our laboratory continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical are conducted on a regular basis. The internal audit addresses these elements and emphasizes areas critically important to patient care.

8.2.2 Audits are formally planned and organized by the Quality Manager. The audits are carried out by the Quality Manager and/or designated qualified personnel.

8.2.3 When deficiencies or opportunities for improvement are noted, our laboratory undertakes corrective or preventive actions, which are executed in the form of action plans.

8.2.4 Internal audits are conducted according to procedure which contains instructions for the types of audit, frequencies, methodologies and required documentation.

8.2.5 The results of the internal audit are submitted to laboratory management for review.

8.3 EXTERNAL ASSESSMENT

8.3.1 Our Laboratory participates in external quality assessments schemes. Refer to section (7.4). The management of participation in external quality assessment schemes is conducted according to documented procedures.

8.3.2 Sections of the laboratory is audited / assessed from time-to-time by external organizations/agencies such as the Caribbean Epidemiology Centre. Results of these external assessments / audits are acted upon by taking corrective action and the development and execution of action plans.

8.3.3 When our laboratory is enrolled in an accreditation scheme we will participate in all assessments/inspections that are carried out by the accreditation body.

8.4 ASSESSMENT OF USER SATISFACTION AND COMPLAINTS

- 8.4.1 All complaints and feedback received from clinicians, patients or other parties are resolved by the laboratory in a timely and efficient manner. The complaints are investigated and all necessary corrective actions taken.
- 8.4.2 At Laboratory Services & Consultations Ltd all complaints, verbal or written, are recorded on the user complaint form. They are dealt with within the first instance by the department senior, or depending on the seriousness of the issue, by the Laboratory Manager or the Laboratory Director.
- 8.4.3 Complaints made by members of the laboratory staff against users are registered as complaints on the form.
- 8.4.4 Documented Procedures are used for dealing with complaints received by the laboratory.
- 8.4.5 The laboratory carries out systematic customer surveys so as to get both positive and negative feedback from users of the services. The results of these surveys are acted upon so as to contribute to the overall quality improvement of the laboratory.

8.5 NONCONFORMITY

- 8.5.1 Procedures are implemented when the laboratory detects that any aspect of the examinations does not conform to established procedures or agreed upon requirements of the quality management system or the requesting clinician. This procedure ensure that
- a) Personnel responsible for problem resolution are designated,
 - b) The actions to be taken are defined,
 - c) The medical significance of the nonconforming examinations is considered and where appropriate, the requesting physician informed,
 - d) Examinations are halted and reports withheld as necessary,
 - e) Corrective action taken immediately,
 - f) The results of nonconforming examinations already released are recalled or appropriately identified,
 - g) The responsibility for authorization of the resumption of examinations is defined, and
 - h) Each episode of nonconformity is documented and recorded, with these records being reviewed at regular intervals by the laboratory management to detect trends and initiate preventive action.
- 8.5.2 If it is determined that nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in this manual, procedures to identify, document and eliminate the root cause(s) shall be promptly implemented.

8.6 CORRECTIVE ACTION

- 8.6.1 Whenever our laboratory initiates or undertakes any form of corrective action, the procedures include an investigative process to determine the underlying cause or causes of the problem. Corrective actions are appropriate to the magnitude of the problem and commensurate with the risks encountered.
- 8.6.2 Our Laboratory management documents and implements any changes required to its operational procedures resulting from corrective action investigations.
- 8.6.3 When any corrective action is taken our laboratory monitors the results of such action, in order to ensure that they have been effective in overcoming the identified problems.
- 8.6.4 When the identification of nonconformance or the corrective action investigation casts doubt on compliance with policies and procedures or the Quality Management System, laboratory management ensures that the appropriate areas of activity are audited. The results of corrective action are submitted for laboratory management review.

8.7 PREVENTIVE ACTION

- 8.7.1 Our laboratory strives for continual improvement of our organization and its services. Possibilities for quality improvement, either technical or concerning the Quality Management System, are gathered, reviewed and, when possible, implemented.
- 8.7.2 Our laboratory authorizes personnel directly in charge of a particular process to take any preventive action to eliminate the causes of potential non-conformities to the degree appropriate to the magnitude of problems and commensurate with the risks encountered.
- 8.7.3 In general the procedures for preventive action include:
- The use of appropriate sources of information such as processes and work operations which affect quality, audit results, quality records, service reports, external quality assurance 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
 - Development and implementation of action plans
 - Initiation of preventive action and application of controls to ensure that it is effective.

8.8 CONTINUAL IMPROVEMENT

- 8.8.1 All operational procedures are systematically reviewed by senior laboratory personnel at least annually in order to identify any potential sources of non conformance or other opportunities for improvement in the quality management system or technical practices. Action plans for improvement are developed, documented and implemented as appropriate.
- 8.8.2 After action has been taken resulting from the review, laboratory management evaluates the effectiveness of the action through a focused review or audit of the area concerned.
- 8.8.3 The results of action following the review are submitted to the laboratory management for review and implementation of any needed changes to the Quality Management System.
- 8.8.4 Our Laboratory management implements quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. When this programme identifies opportunities for improvement, our Laboratory management addresses them regardless of where they occur. Our Laboratory management ensures that Laboratory Services & Consultations Ltd participates in quality improvement activities that deal with relevant areas and outcomes of patient care.
- 8.8.5 Our Laboratory management provides access to suitable educational and training opportunities for all laboratory personnel and relevant users of our laboratory services.

8.9 MANAGEMENT REVIEW

- 8.9.1 Our Laboratory Management reviews the quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements.
- 8.9.3 Findings and actions that arise from the management reviews are recorded, and the laboratory staff informed of these findings and the decisions made as a result of the review. Laboratory management ensures that arising actions are discharged within an appropriate and agreed-upon time.

Supporting Documents

The following processes and documents support this policy

- Continuous Improvement Process
- Examination procedures
- Validation for procedures process
- Procedure Modification Process
- Telephoned report process
- Altered report preparation and delivery process
- Provision of Clinical Advice Process
- Report issuing and delivery process
- Critical value reporting process
- Referral Services Process
- Preventative Action Process
- Corrective Action Process
- Continual Improvement Process
- Record of validation of procedures
- Review of Biological Reference interval process
- Record of review of Biological Reference interval
- Record of review of procedures
- Record of evaluation of referral services
- Log for telephoned results

9 PROFESSIONAL CODE OF CONDUCT

Laboratory Services & Consultations Ltd has adopted and is guided by the following code of conduct.

1. Medical laboratory staff shall protect the confidentiality of all patient information at all times.
2. Medical laboratory staff shall always be properly dressed accompanied by relevant personal protective clothing.
3. Medical laboratory staff shall work with other health care professionals to provide effective patient care.
4. Medical laboratory staff shall endeavor to develop and improve their skills and knowledge and keep current with scientific advances, sharing their knowledge and promoting continuing education with colleagues and other health care professionals.
5. Medical laboratory staff shall behave in a courteous manner towards co-workers, customers and other health care providers. They shall beware of their mannerism of communication and exercise self-control and tact in difficult situations.
6. Medical laboratory staff shall be dedicated to serving the health care needs of the public. The welfare of the patient and respect for the dignity of the individual shall be paramount at all times.
7. Medical laboratory staff shall maintain high standards in their professional practice and through membership and support of their professional associations.
8. Medical laboratory staff shall be committed to the profession and practice in accordance with standard operating procedures within the scope of their professional competence.
9. Medical laboratory staff shall be responsible and accountable for their professional acts.
10. Medical laboratory staff shall adhere to the laws and regulations governing laboratory technology as per national recognized standards.
11. Medical laboratory staff shall practice safe procedures at all times to ensure the safety of patient and co-workers and the protection of the environment.
12. Medical laboratory staff shall endeavor to be customer-focused and demonstrate effectiveness and consistency in their profession.

Note: Copies of this professional code of conduct can be found elsewhere in the laboratory as well as in other laboratories on the island. It is the national code of conduct that was collectively developed by laboratories island-wide.

10 LIST OF REFERENCES

1. ISO 15189:2003- International Standard- First edition.
2. Strengthening of Medical Laboratory Services in the Caribbean- A Guidance Document for the Application of ISO 15189:2003 to Medical Laboratories.
3. David Burnett- A Practical Guide To Accreditation In Laboratory Medicine- 2002.
4. CPA- Standards for the Medical Laboratory-2000.

11 REVISION HISTORY

<i>Revision #</i>	<i>Revised by</i>		<i>Nature of revision</i>
00	T. Joseph		Original version
01	T. Joseph	20-1-2004	
02	T. Joseph	15-1-2005	Rewrite as per ISO criteria
03	M. McKenzie	12-1-2009	<ul style="list-style-type: none"> ✓ Total rewrite with a new table of content ✓ A cover page added ✓ Document control elements modified and a file name given ✓ Some sections were modified, deleted, updated, or new material added ✓ The supporting procedures were added to the manual and were given filenames ✓ The organizational chart was reconstructed in the form of a flow chart.
04	D. Joseph	26-2-2009	<ul style="list-style-type: none"> ✓ Rewording of contents to reflect actual policies that govern our Quality Management System. ✓ Supporting documents added in the form of a table at the end of every section
05	Dr S King	02/10/2009	Restructuring of the Organization chart to reflect changes in organization.