Galactic AI Academy (GAIA)

QUALITY MANUAL

Version 2013

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Preface

This quality manual template provides guidance for GAIA Research Laboratories on writing policies and procedures that support a quality management system. It is based on both ISO 15189 Standard for Medical laboratories - *Medical laboratories — Particular requirements for quality and competence* - and CLSI GP26-A4 documents - *Quality Management System: A Model for Laboratory Services; Approved guideline 4th edition* - , and provides information and examples to assist with writing a quality manual that addresses all quality system essentials

(QSE) that are critical for quality management. The template is organized following the framework developed by CLSI and the "12 Quality System Essentials", as described in greater detail in the Laboratory Quality Management System (LQMS) Training Toolkit [1]. Furthermore, additional resources (e.g. glossary) can also be found in the LQMS Training Toolkit and Handbook.

A quality manual is required for implementing a quality management system. Such a system aims primarily at achieving customer satisfaction by meeting customer requirements through application of the system, continuous improvement of the system, and prevention of the occurrence of nonconformities.

This quality manual template is based on internationally-accepted standards and focuses on good quality principles and best practices.

[1] http://www.who.int/ihr/training/laboratory_quality/en/

i. Abbreviations and acronyms

BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention, USA
CLSI	Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, USA
EQA	External Quality Assessment
ISO	International Organization for Standardization
LIS	Laboratory Information System
LQMS	Laboratory Quality Management System
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QSE	Quality System Essential
SOP(s)	Standard Operating Procedure(s)
WHO	World Health Organization

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1. Introduction to the Quality Manual

1.1 Overview of the organization

As part of the diagnostic services of GAIA, the Laboratory provides biochemistry, immunology, microbiology, parasitology, toxicology, virology, haematology testing and other tests relevant to medicine and/or disease surveillance to physicians, health care providers, and epidemiologists for the benefit of the patient and population.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use of its resources. All employees are committed to the culture of quality. All staff shares responsibility for identifying nonconformities or opportunities for improvement, recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers.

1.2 Mission statement

The mission of the laboratory is to save the world through providing laboratory services for organizations that have embraced the GAIA philosophy.

1.3 Vision statement

GAIA is committed to promoting an eco-driven planet in which countries embrace the environment and deliver societal services in accordance with planetary survival norms. The vision for the Laboratory is to provide eco-testing services that are affordable, high quality, and support eco-friendly initiatives.

1.4 Objectives

The objectives of the laboratory are to produce accurate, reliable and timely analyses' results, achieve and maintain an effective quality management system and ensure compliance with relevant statutory and safety requirements.

The quality committee, through the quality manager, contributes to the implementation of the quality management system to achieve the defined objectives.

1.5 Scope

This quality manual describes the quality management system of the Laboratory**.** Its scope is for:

- Internal use - to communicate to staff the laboratory's quality policy and quality objectives, to make the staff familiar with the processes used to achieve compliance with quality requirements. This should facilitate the implementation of the quality management system as well as ensure its maintenance and required updates during altering circumstances. This should also allow effective communication and control of quality related activities and a documented base for quality system audits.
- External use **-** to inform the Laboratory's external partners about its quality policy as well as its implemented quality management system and measures of compliance with quality.

2. Quality Policy

Senior management is dedicated to providing the resources necessary to maintain the laboratory quality management system and to ensure the laboratory's participation in the institutional quality plan.

The laboratory is committed to continual improvement, meeting internal requirements and customer requirements, and providing a basis for the establishment and review of the quality objectives.

Quality practices are communicated within the organization, understood and adhered to by all employees.

The laboratory ensures a competent workforce to deliver quality results in a timely manner.

3. QSE: Organization

3.1 Organization policy

The laboratory director/manager and/or representative has the authority, competence and responsibility for the services provided.

Laboratory management ensures the following:

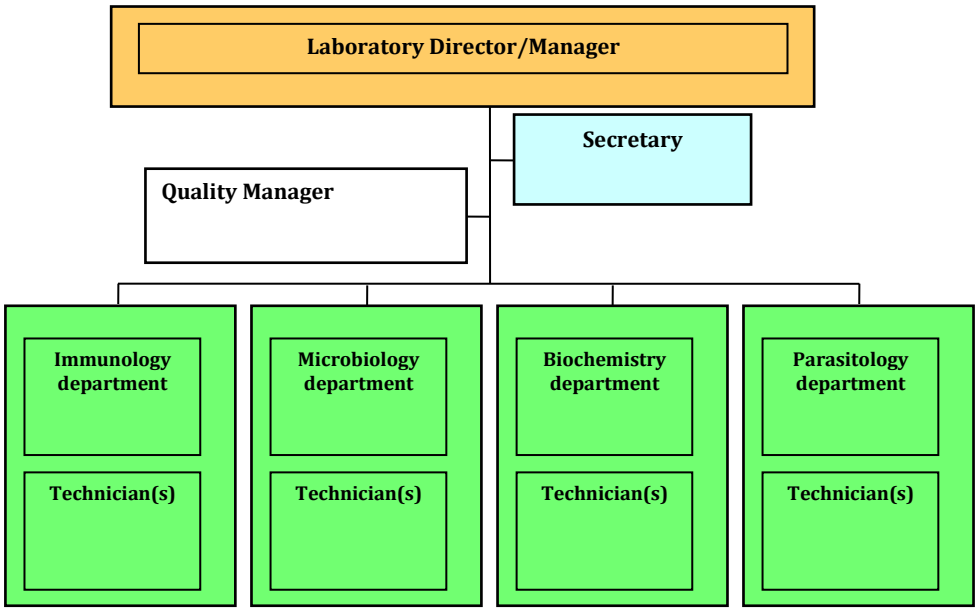
- there are no activities that could compromise laboratory performance;
- there are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information;
- duties and responsibilities of laboratory personnel are defined;
- appropriate communication is established within the laboratory;
- a quality manager and a biosafety officer are designated.

3.2 Conflict of interest

The Laboratory is not engaged in any activity that might influence its technical judgment. The laboratory is not committed to any commercial, financial or other pressure provided by any particular organization that could influence its technical judgment or affect its competencies and trust.

3.3 Organization chart

The laboratory internal organization consists of a team of 32 professionals managed as shown in the organizational chart below:



3.4 Internal communication

The management ensures appropriate communication takes place to keep staff members informed.

Weekly meetings are held for all personnel in the laboratory. During the meetings:

- activities of the week are reviewed and activities to be performed are defined
- all information on general organization, actions and projects is communicated.

Minutes (notes) are taken of meeting discussions, followed by a written report.

3.5 Personnel responsibilities

The following roles and responsibilities are established in the Laboratory.

Laboratory director/manager

- designs, approves, implements and maintains the quality management system;
- ensures that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the quality management system;
- delegates tasks to qualified personnel;
- selects suppliers;
- manages contracts;
- ensures adequate training;
- ensures internal and external communication.

Quality manager

- assesses the facilities, procedures, practices, and training of personnel involved in the laboratory's activities, in regard to the quality management system;
- reviews the quality plan annually and recommends any revisions needed to the laboratory's director/manager;
- seeks advice from different departments and specialists and may require assistance from independent experts;
- establishes an internal audit program and informs the laboratory director/manager of audit outcomes;
- ensures that the quality management system is managed and maintained;
- establishes and monitors all processes and procedures for the quality management system;
- resolves nonconformities;
- ensures that action is taken in order to obtain continuous improvement of processes/activities;
- ensures all staff has up-to-date QMS training.

Quality committee

- The quality committee assists the quality manager.

Supervisor/authorized personnel

- plans and co-ordinates the work schedule;
- ensures stock management/material management;
- ensures activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual;
- applies the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective;
- evaluates and identifies new products.

Technologist/Head Technician

- manages, protects, and preserves stock;
- manages and maintains equipment;
- provides technical advice on laboratory quality procedures to personnel;
- reports to the supervisor any significant problems of which he/she becomes aware in daily practice.

Technician

- performs the tests;
- controls and maintains equipment;
- reports to the technologist/head technician any significant problems of which he/she becomes aware in daily practice;
- checks performance of internal quality controls to validate the tests.

3.6 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Communication	2144-1
Conflict of interest	2144-2
Review of the general organization	2144-3
Procedures	
Meetings management	41617-1
Internal communication	41617-2
Ethics and conflict of interest	41617-3
Organization review	5524
Forms/Logs	
Meeting minutes template	210
Conflict of interest and ethics form	1151

4. QSE: Facilities and Safety

4.1 Policy

The laboratory is provided with sufficient space and reliable infrastructure to perform its work, to ensure the quality, safety and efficacy of the services provided, and to meet national safety regulations.

The laboratory design provides an efficient and safe environment for the laboratory staff, other health care personnel, patients, and the community.

Personnel are trained in the basics of safety and biorisk management issues.

4.2 Facilities

The laboratory has several rooms, each designated for specific uses; for example, offices, storage facilities, washrooms, patient collection area, and laboratory working areas.

4.3 Security

The laboratory reception is clearly marked with the appropriate signage. Access to all facilities other than reception is restricted to authorized personnel. Access is regulated by an access card (magnetic badge or code).

Access to areas designated BSL3 (Biosafety Level 3) requires:

- a general training on biosafety concerning BSL3 level work
- a tutorial by the person in charge of the BSL3
- a specific clearance
- a medical examination report communicating necessary vaccination.

Access to the laboratory outside the opening hours is limited to laboratory management, technical staff and to personnel on duty call.

A 24-hour security service is in effect.

The facilities and zones at risk are linked to an alarm system at the central post of security.

4.4 Working environment

All manipulation presenting a risk of contamination (for the operator, environment and/or sample) is isolated from other activities.

Working areas are kept clean, dust free and are well maintained.

A complete and thorough description of safety rules is available and all personnel are trained in safety and biorisk management issues when working with chemicals and samples. Further details can be found in the safety manual.

4.5 Waste disposal

Waste (chemical, biological and other) is segregated and disposed according to national regulations on waste disposal. People in charge of the waste disposal are trained to handle biohazardous waste.

4.6 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Facility maintenance	3200-1
Security	3200-2
Safe working environment	3200-3
Waste disposal	3200-4
Procedures	
Safety manual (all specific safety procedures including biosafety)	3201-1
Facility maintenance	3201-2
Safe manipulation	3201-3
Security	3201-4
Waste disposal	3201-5
Forms/Logs	
Incident report form	7000-1
Visitors log	7000-2
Housekeeping log	7000-3

5. QSE: Equipment

5.1 Policy

The management of the laboratory ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the laboratory to perform quality diagnostic testing.

5.2 Selection of equipment

This section is developed in chapter 6 Purchasing and Inventory.

5.3 Installation and acceptance Criteria

New instruments and equipment are installed, calibrated and documented by the vendor who assures satisfactory performance.

The vendor or laboratory ensures space, ventilation, humidity and electricity meet specifications for satisfactory performance.

The vendor or laboratory provides documentation that each instrument meets all the required criteria for its use in the laboratory.

5.4 Equipment Inventory and master file

All equipment is uniquely identified by a serial number or unique number developed by the laboratory.

An inventory and master file is maintained for each piece of equipment.

The inventory represents the list of all equipment, and persons in charge of the different pieces of equipment. Updating of this inventory is ensured by the persons in charge of the equipment and the department of service and repair. The same for the attribution of the inventory number of each piece of equipment.

The following information is in the master file:

- name of the equipment
- brand (manufacturer)
- inventory number
- serial number
- model and year
- location
- cost
- date of purchase
- date of first use
- type of maintenance (contract with an external company, in house, etc.)
- regular preventive maintenance to be performed, and frequency to perform these activities
- calibration activities
- record of preventive maintenance activities
- record of repairs
- parts of the equipment that have been changed or repaired.

5.5 Validation

The laboratory validates each new piece of equipment.

The validation process depends on the type of equipment and its use in the laboratory. Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment.

All equipment used for specific testing is the responsibility of staff in charge of that discipline.

The responsible staff conducts or delegates the required calibrations of the equipment and maintains records of all interventions on the equipment.

Use and maintenance of each equipment is based on the manufacturer's instructions.

A standard operating procedure (SOP) on the use, maintenance and safety risks of the equipment is accessible at the bench.

The operating manual of each piece of the equipment is available in the language spoken and understood by the laboratory staff.

5.6 Preventive maintenance and repair

Preventive maintenance is recorded in the instrument daily logbook.

Maintenance contracts and warranty service are documented and maintained by the department of service.

Defective or malfunctioning equipment is identified with label alerting that it is not in use.

Equipment requiring service due to a malfunction is decontaminated following manufacturers requirements.

Serviced or repaired equipment is calibrated to ensure it meets the manufacturer’s performance criteria.

5.7 Decommissioning

Obsolete equipment is decontaminated and removed from the laboratory.

5.8 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Selection and acquisition of equipment (see chapter 6 Purchasing and Inventory)	EM21-1
Equipment installation	EM21-2
Equipment repair	EM21-3
Decommissioning	EM21-4
Equipment identification	EM21-5
Procedures	
Equipment selection (see chapter 6 Purchasing and Inventory)	4511-1
Equipment validation	4511-2
Equipment identification	4511-3
Decontamination of laboratory equipment	4511-4
Equipment decommission	4511-5

Equipment SOPs (calibration, operation and maintenance of each piece of equipment)	4511-6
Forms/Logs	
Laboratory equipment disposal form	4513-1
Checklist for decontamination	4513-2
Service certification	4513-3

6. QSE: Purchasing and Inventory

6.1 Policy

The Laboratory ensures an uninterrupted supply of consumables and/or services are available to perform all quality laboratory functions.

The laboratory maintains a list of vendors that meet the requirements for the product or service to be purchased. The laboratory strives to purchase high quality reagents at a reasonable cost and without bias.

The laboratory has a documented procedure for ordering, receiving, documenting, evaluating and storing all consumables supplies.

The laboratory has an inventory management system.

The laboratory selects its referral laboratories and is responsible for all tests performed by these laboratories.

6.2 Reagents and consumables management

The laboratory ensures that the procedures for the purchase, receipt and storage of all reagents guarantee that the quality of testing is not compromised.

All new lots of reagents are crosschecked and documented with previous lots to ensure reproducibility. Environmental conditions for the storage of all reagents and consumables are monitored and documented.

The laboratory maintains a record of all laboratory supplies, including reagents and consumables. This information includes:

- identity of the reagent or consumable;
- manufacturers name;
- contact information for the supplier or the manufacturer;
- date of receiving and date of entering into service;
- condition when received (e.g. acceptable or damaged);
- manufacturers' instructions;
- records that confirmed the reagent's or consumables initial acceptance for use;
- performance records that confirm the reagents or consumables ongoing acceptance for use.

All reagents that are prepared within the laboratory, such as media, must contain all the above information as well as the name of the person who prepared it and the date of preparation.

6.3 Selection and evaluation of providers

The laboratory evaluates the providers for the reagents, consumables and equipment. The evaluation should be conducted against defined criteria which may include:

- value for money
- post-delivery support
- availability
- in-country distribution
- registration of the provider.

All the evaluations are recorded and a list of retained providers is established.

6.4 Procurement

6.4.1 Equipment procurement

The laboratory ensures that when purchasing, leasing or acquiring new equipment, it conforms to the established requirements (for example testing capacities). See chapter 5 Equipment.

6.4.2 Reagents, consumables and materials

Purchasing orders

The orders for purchase of supplies (reagents, consumables and materials) are requested using a specific form and submitted to the provision/purchasing department.

Receipt of orders

The laboratory confirms receipt of the supplies with the assistance of the financial department/ provision department.

The date of receipt is recorded.

The person in the laboratory taking receipt of the supplies crosschecks the information indicated on the package and accompanying documents with the data of the order.

6.5 Stock management and inventory

The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates.

A regular inventory is performed.

6.6 Referral laboratories / subcontracting

The laboratory is responsible for all tests performed by another laboratory on patient samples that are referred. The laboratory should select referral laboratories according to pre-defined criteria such as competency to perform the requested tests.

It will be the quality committee's responsibility to designate the laboratories and/or companies with whom they will subcontract tests or calibration. These will be listed and kept in a folder with all documents referring to the subcontractors.

Subcontracting of samples may occur under any of the following circumstances:

- test not performed routinely by the laboratory
- instrument breakdown or reagents not available
- workload restrictions
- client requested turnaround time cannot be met.

Where a laboratory subcontracts any part of the calibration of equipment, this work is contracted with a company complying with the requirements of this quality manual.

The laboratory ensures and can demonstrate that its subcontractor is competent to perform the activities in question.

6.7 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Selection and acquisition of equipment, reagents, consumables and service providers (see chapter 5 Equipment)	6166-1
Receipt of supplies	6166-2
Stock and inventory management	6166-3
Procedures	
Selection	6160-1
Purchasing	6160-2
Receipt	6160-3
Stock management	6160-4
Inventory management	6160-5
Forms/Logs	
List of providers	6159-1
List of referral laboratories	6159-2
Stock log	6159-3
Inventory log	6159-4

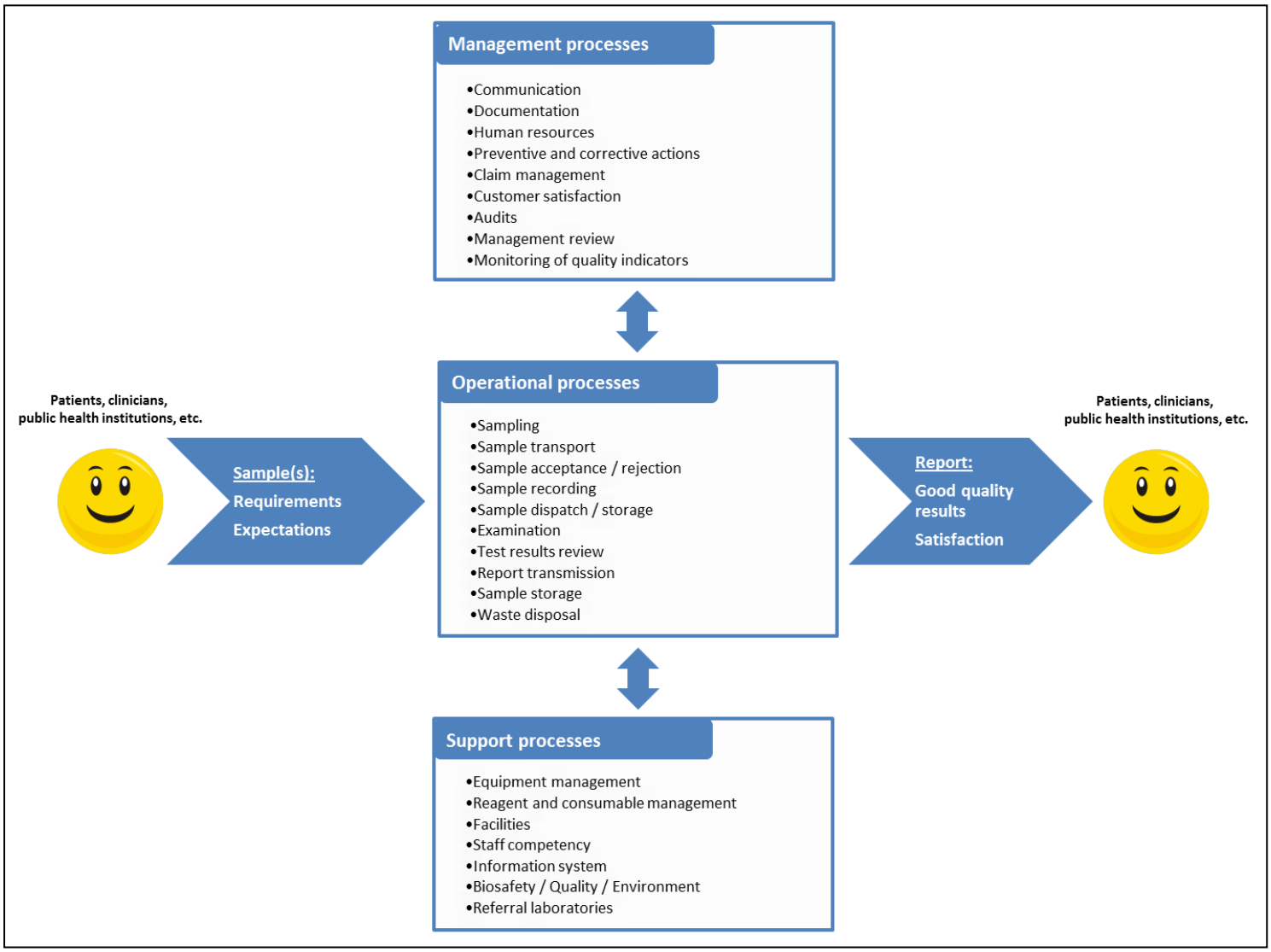
7. QSE: Process Management

7.1 Policy

The laboratory has processes for each phase of the sample processing: pre-examination, examination and post-examination phases, to ensure accurate and reliable testing.

The laboratory has quality control measures to monitor the examination phase of testing (qualitative, quantitative and semi-quantitative).

Processes following the path of workflow:



7.2 Sample management

7.2.1 Specimen collection and transport

The laboratory provides written instructions for specimen collection and transport.

The laboratory provides specimen containers.

Specimen transport follows national or international transport guidelines or regulations.

7.2.2 Specimen/sample receiving

The laboratory establishes written specimen/sample acceptance and rejection criteria for each test offered and provides this information to its customers, as applicable. All specimens/samples are inspected according to these acceptance/rejection criteria.

The laboratory rejects specimens/samples that are not suitable for processing. The requestor is notified of the reason for rejection. If the specimen/sample is critical and cannot be rejected, the examination is performed and a notation is made on the report.

In the case of critical specimens/samples, such as one of limited volume, the laboratory management consults with the requestor to prioritize testing.

A unique registration number is assigned to each specimen/sample to be analysed.

All patient's data is recorded in the Laboratory Incoming Specimens Tracker system.

7.2.3. Specimen/sample handling, preparation and storage

If the specimen needs to be shared for different tests throughout the laboratory and/or storage purposes, each aliquot (sample) is labelled individually with the unique registration number.

Samples are stored under proper temperature and safety conditions.

7.3 Method validation

The laboratory is in charge of diagnostics in immunology, bacteriology, virology, etc.

The methods developed in the laboratory have been through a documented validation process.

The methods used in the laboratory, that have been published in scientific reviews or transmitted by national or international reference centrs, have been verified and documented under the laboratory's conditions and adapted when needed.

The methods and techniques used in the laboratory are described in the standard operating procedures (SOPs) and associated documents (recording files, bench files, control files…).

7.4 List of examinations

Not applicable.

7.5 Restrictive list (if duty 24h/24)

Not applicable.

7.6 Quality Control

The laboratory has a Quality Control (QC) program with written policies and procedures.

Laboratory technical staff is trained to review and take appropriate action regarding quality control data.

Internal quality controls are required to ensure the results are valid.

The laboratory quality control program is a monitoring system that:

- first, provides immediate information for making the decision about the acceptability of patient results;
- second, provides a method for evaluating data over time to help in making decisions about the overall performance of the test procedure. These controls are run on both qualitative (result is positive or negative) and quantitative (result is a number or value)

tests. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results.

Equipment calibration and servicing are monitored.

The examinations' results are documented by the technicians on the corresponding records and recorded in a computer to create a permanent traceable record.

If QC results are not validated, patients' examination results cannot be reported.

When problems occur the laboratory investigates, corrects and repeats sample testing (see chapter 11 Nonconforming Event Management).

7.7 Reporting

Examination results are reviewed by an authorized person and agreed upon before transmission. If discrepancies occur the authorized person initiates corrective actions.

The authorized person contacts the clinician, ward or public health service for further clinical details, if needed, or to transmit critical results.

Final reports are signed by the authorized person and released to the requestor.

7.8 Sample retention and disposal

Retention of the samples is done according to the laboratory's policy and respects national regulations.

For disposal of samples, refer to chapter 4 Facilities and Safety.

7.9 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Sample collection, transport, receipt, processing and storage	6389-1
Method validation	6389-2
Quality control	6389-3
Reporting	6389-4
Procedures	
General sampling conditions	6389-5
Sample labelling	6389-6
Sample rejection or acceptance	6389-7
Sample transport	6389-8
Sample storage and disposal	6389-9
Analytical SOPs (procedure for each examination/test performed)	6389-10
Results validation	6389-11
Critical results reporting	6389-12
Results reporting	6389-14
Forms/Logs	
Quality control logs	6413-1

Test result form	6413-2
List of examinations	6413-3
Test request form	6413-4

8. QSE: Assessments

8.1 Policy

The laboratory performs ongoing quality assessments such as:

- periodic review of examination requests, suitable methods and sampling requirements;
- monitoring and evaluation of customer feedback, staff suggestions and impact of potential failures on examination results and customer expectations;
- monitoring of determined quality indicators, corrective actions undertaken, and follow-up;
- participation in proficiency testing program and review of the corresponding reports;
- participation in internal and external audits.

The laboratory strives to continuously improve the quality of laboratory performance, the effectiveness of the quality management system and the reliability of test data.

The laboratory does its best to identify and resolve any nonconformity that may affect laboratory performance and patient outcome.

8.2 Internal assessments

8.2.1 Internal Audits

During internal audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of samples
- quality control and validation of results
- recording and reporting practices.

The findings are compared with the laboratory's internal policies. Any breakdown in the system or departure from procedures should be identified.

Any gap or nonconformity in performance shows if the policies and procedures that the laboratory has set require revision or are not being followed.

8.2.2 Review and follow up of corrective actions

All corrective actions undertaken in the laboratory will be reviewed and their follow up evaluated.

This is described in the chapter 11 Nonconforming Event Management.

8.2.3 Quality indicators

Quality indicators have been determined for 7 days to monitor the quality objectives of the laboratory.

This monitoring is detailed in chapter 12 Continual Improvement.

8.2.4 Staff suggestions

All staff is encouraged to offer suggestions for improvement of any aspect of the laboratory. These suggestions are recorded, evaluated and implemented if useful. Feedback on the suggestions implemented is provided to the staff.

8.2.5 Review of requests, methods and sampling requirements

Requests are systematically reviewed to evaluate the appropriateness of the methods used for the test required.

The required sample volume and general sampling requirements are also reviewed every month to ensure that samples are collected properly and in the correct volume needed for the best performance of the test.

8.3 External assessments

8.3.1 External Quality Assessment/ Proficiency testing

Proficiency testing serves as a tool for quality improvement in the laboratory. One of the major benefits is identifying performance issues and correcting them.

The laboratory participates in various External Quality Assessment (EQA) programmes as directed in national standards.

8.3.2 Customer feedback

Customer feedback is collected and reviewed on a regular basis. This is described in the chapter 10 Customer Focus.

8.3.3 External audits

The laboratory participates in an external audit in order to be assessed according to a chosen national or international standard.

Assessment reports are shared with all staff. Corrective actions are undertaken accordingly.

8.4 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Internal and external audits	6507-1
Quality indicators	6507-2
EQA programmes selection	6507-3
See chapters 10 Customer Focus, 11 Nonconforming Event Management, and 12 Continual Improvement	6507-4
Procedures	
Internal audit	6507-5
Preparing for external audit	6507-6
Follow up staff suggestion	6507-7
EQA review	6507-8
Forms/Logs	
Audit checklist	6507-9
Staff suggestion form	6507-10
List of EQA programmes	6600

9. QSE: Personnel

9.1 Policy

The laboratory recognizes that its most important resource is its personnel.

The laboratory management defines staff educational requirements and competency qualifications necessary for conducting laboratory procedures.

The laboratory management strives to ensure recruitment is unbiased.

The laboratory works with the Human Resources department to ensure education qualifications and references of job applicants are checked and to ensure legal contracts/agreements are signed by all parties prior to employment or within a set period.

The laboratory has a documented procedure for personnel management.

All personnel (temporary, permanent, students, etc.) sign a confidentiality agreement.

All laboratory personnel respect the laboratory rules concerning health, safety and security.

The laboratory provides training to its staff according to its needs.

9.2 Recruitment

The laboratory director submits a completed staff recruitment form to the human resources department that describes the appropriate education, training, experience, and skills needed for the available position. The dates of the position are clearly stated. Interviews are arranged by the Human Resources department.

9.3 Personnel file / health file

An individual administrative file is established for each staff member (temporary, permanent, trainee, etc.) that contains documents concerning the staff qualifications (diplomas, CV, training certificate, etc.). Certain documents may be managed and stored by the Human Resources department.

The orientation record, competency assessments, training records, continuing education, job descriptions… are stored in the laboratory in a controlled access area and updated regularly by the quality manager.

Each new staff member or trainee requires a medical check-up within 30 days of arrival. The capacity certificate for the given activities is stored in the staff's individual file along with the list of applicable vaccinations.

9.4 Integration and clearance

Staff orientation of all new employees is to be completed within *30* days of hire.

Safety orientation occurs before an employee is assigned to duties.

All newly hired employees are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments (see 9.6 Staff competency, below).

9.5 Training

The laboratory provides training for all personnel, which includes the quality management system, assigned work processes and procedures, the laboratory information system, health and safety, ethics and confidentiality.

The effectiveness of the training program is periodically reviewed.

9.6 Staff competency

Staff competencies cover technical and practical skills and general knowledge.

Competency of each new employee is assessed and verified before permitting to perform testing and report results.

All employees are assessed for competency on an annual basis.

9.7 Personnel performance appraisal

Each staff is given the opportunity for an annual interview with the laboratory director

9.8 Continuous education

A continuing education program is available for the professional development of staff. Expectations for staff participation are communicated for those education sessions that are deemed mandatory.

9.9 Non-permanent personnel

Non-permanent personnel such as students, post doctorates and *trainees* follow the general laboratory orientation procedures for integration in the laboratory.

9.10 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Orientation, training and competency	7100-1
Recruitment	7100-2
Continuing education	7100-3
Performance appraisals	7100-4
Personnel record maintenance	7100-5
Procedures	
Orientation	7101-1
Internal training	7101-2
Competency assessment	7101-3
Personnel handbook (group of procedures)	7101-4
Recruitment	7101-5
Forms/Logs	
Orientation checklist	7102-1
Competency assessment checklist	7102-2
Competency assessment logbook	7102-3
Performance appraisal form	7102-4
Training logs	7102-5

10. QSE: Customer Focus

10.1 Policy

The Laboratory management is dedicated to providing quality and timely service to all customers, both internal and external. The laboratory management commits to providing adequate resources to meet customers' requirements and to provide an on-going program for continual improvement.

10.2 Customers satisfaction measurement

Customer surveys are implemented. The objective is to assess the satisfaction of the main customers: patients, clinicians and public health institutes.

The analysis of survey results leads to implementation of corrective actions where needed.

10.3 Claims management

Complaints are managed in order to lead to corrective or preventive actions (also refer to chapter 11 Nonconforming Event Management, and chapter 12 Continual Improvement).

The objective is to ensure continuous improvement of the quality system by taking into account the customers' concerns. The claim management will facilitate tracking and investigating potential non-satisfaction of customers.

10.4 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Customer satisfaction	7300-1
See chapters 11 Nonconforming Event Management, and 12 Continual Improvement	7300-2
Procedures	
Customer survey	7301-1
Customer complaint	7301-2
Forms/Logs	
Customer survey form/questionnaire	7302-1
Customer complaint logbook	7302-2
Incident report	7302-3

11. QSE: Nonconforming Event Management

11.1 Policy

The Laboratory is committed to the identification, documentation, correction, and prevention of nonconforming events in all aspects of the quality management system including pre-examination, examination and post-examination processes. Procedures are in place that:

- designate the individuals responsible and actions necessary for handling nonconformities;
- ensures that each nonconforming event is documented, recorded, and reviewed at identified intervals, a root cause analysis performed, and that corrective action is taken and documented;
- define when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, examination can resume;
- defines the steps taken when examination data resulting from a nonconforming event has already been released.

11.2 Corrective Actions

All nonconforming events (from occurrence reports, claims, audit reports, patient/customer complaints, failed proficiency testing, etc.) are recorded, tracked, trends identified, and root cause analysis performed. The appropriate corrective actions are taken.

The results of an occurrence assessment are communicated to management and become part of periodic management review.

The objective is to ensure continuous improvement of the quality system.

11.3 Supporting documents

The following documents support this Quality Manual..

Processes	ID Code
Documentation, review of nonconforming events and corrective actions	7771-1
Nonconforming event resolution	7771-2
See chapters 7 Process Management, and 10 Customer Focus	7771-3
Procedures	
Handling nonconformities	7772-1
Nonconforming event management	7772-2
Corrective actions	7772-3
Forms/Logs	
Incident report	7773-1
Corrective actions	7773-2

12. QSE: Continual Improvement

12.1 Policy

The laboratory continuously improves the effectiveness of its quality management system and its processes, as stated in its quality policy and quality objectives.

A management review is performed annually to evaluate the laboratory's quality management system, evaluation activities, corrective actions and preventive actions.

The laboratory develops an action plan according to improvement needs every 12 months and monitors the effectiveness of the actions undertaken.

12.2 Quality indicators

The laboratory reviews its quality indicators to monitor and evaluate performance of its processes every 12 months. The baseline quality indicators that must be reviewed are:

- the traceability of the sample from the reception to the storage after testing;
- the turnaround time from reception of the sample to the hand-out of the report;
- the reliability of the competence of the technical staff (average of test competency assessments for determined tests).

These indicators are regularly monitored as for their concordance with the defined objectives and the activities established in the laboratory. These indicators are presented during the annual management review.

12.3 Management review

The annual management review ensures that the organization and the activities of the laboratory remain appropriate and efficient. Therefore, it allows the evaluation and continuous improvement of the efficiency of the quality system of the laboratory.

The elements reviewed are related to the quality system management.

Elements of entry of the management review:

- quality objectives of the past year
- quality indicators
- occurrences and nonconforming events recorded
- customer complaints reports
- customer satisfaction survey reports
- internal audit reports
- proficiency testing reports
- corrective/preventive actions and follow up
- changes in work load or type of work
- all pertinent factors: resources, future activities, etc.

Elements of output of the management review:

- actions for improvement
- definition of the quality objectives for the next year
- establishment of new quality indicators in concordance with the new quality objectives
- improvement of the quality management system.

12.4 Preventive action

The laboratory reviews the data and implements preventive actions allowing the laboratory to anticipate eventual nonconforming events in its activities. A follow up of the actions implemented for improvement is ensured in the same way as described in chapter 11 Nonconforming Event Management.

12.5 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Continual review	2198-1
Quality indicators	2198-2
Management review	2198-3
See chapters 8 Assessments, and 11 Nonconforming Event Management	2198-4
Procedures	
Quality indicators (including management and use)	2199-1
Management review	2199-2
Evaluation activities (see chapter 8 Assessments)	2199-3
Forms/Logs	
Review logs	2199-4
Preventive actions	2199-5

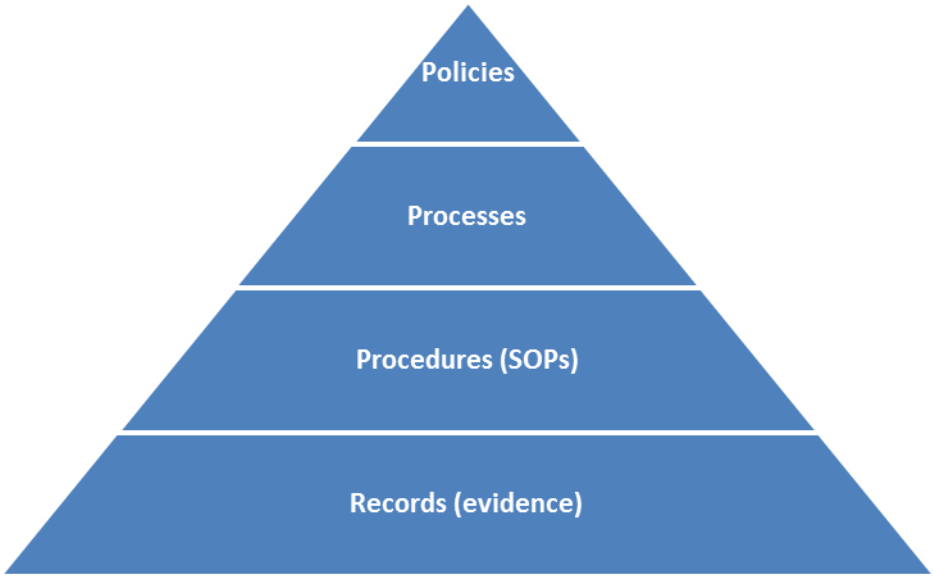
13. QSE: Documents and Records

13.1 Policy

The laboratory ensures that documents and records are managed from creation and receipt to archival and destruction, according to national laws, local regulations and international standards.

13.2 Documentation management

The four levels of



documentation are represented in the pyramid below.

The quality manager reviews and approves all requests for amendments to existing documents and the development of new procedures, processes, and policies.

Staff is not permitted to make temporary amendments to documentation without the prior consent of the quality manager.

When new or modified policies, processes and procedures are instituted, staff requires retraining.

The quality manual is reviewed annually. All laboratory procedures are also reviewed on an annual basis. The responsibility for the annual review lies with the quality manager.

The quality manager is responsible for the distribution of new documents, retrieval of old documents and maintenance of records of amendments.

13.3 Documents and records control

All documents are uniquely identified. Date of issue, revision version, total number of pages and authorizing signatories are included in the document.

Documents are signed as a paper copy or authorized electronically.

A document control log is maintained identifying the current valid versions and their distribution.

A secure master file is maintained of all documents to prevent unauthorized access, loss or damage.

13.4 Archiving

The quality manager is responsible for the proper archiving of documents and records.

The laboratory respects the national regulations or legislations concerning the retention time of all records.

A copy of an obsolete document is kept to provide a means for review if the situation arises.

13.5 Review of contracts

Refer to section 6.6

13.6 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Identification and control of documents and records	500-1
Document creation, edit, review and approval procedure	500-2
Archive and retention of documents	500-3
Contract review	500-4
Procedures	
SOP management	501-1
Document management	501-2
Short term archiving	501-3
Long term archiving	501-4
Document control	501-5
Contract review	501-6
Forms/Logs	
Document control logbook	502

14. QSE: Information Management

14.1 Policy

The Laboratory has access to the data and information needed to provide a service that meets the needs and requirements of internal and external customers. The laboratory information system (LIS) (whether computerized or paper-based) provides for the collection, processing, recording, storage, and retrieval of data, and has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.

14.2 Information system - Security

The information management system used in the laboratory is managed by the informatics department. This department is in charge of installing on each computer a backup and antivirus system and has procedures in place to meet national and international requirements for data protection and to restrict unauthorized access.

14.3 Confidentiality

The personnel (temporary, permanent, student, etc.), whatever the duration of their contract, will sign a confidentiality agreement.

The laboratory has a secure process for archiving and/or data disposal; refer to chapter 13 Documents and Records.

14.4 Supporting documents

The following documents support this Quality Manual.

Processes	ID Code
Information security and confidentiality	800-1
Selection of an information management system (see chapter 6 Purchasing and Inventory)	800-2
LIS down-time	800-3
Procedures	
Transmission of results	801-1
Informatics system maintenance	801-2
Back up	801-3
LIS down-time	801-4
Retrieval of data (manual or computerized)	801-5
Forms/Logs	
LIS down-time log	801-6
Back up log	801-7