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Scope: Analytical procedures: Genetic and Immunology Laboratory People in Charge: General Manager Laboratory Directors Quality Department		

IGLS
QUALITY POLICY

Elaborado:	Revisado:	Aprobado:
María van der Hofstadt Rovira	María Enciso y Jonás Sarasa	Javier Flors
Dpto. Calidad	Dirección Lab	CEO

Change Log

Review	Date	Reason	Affected points:
01	30-07-2018	New document	----------
02	01-12-2021	Full review to harmonise with the ISO 15189 standard. Adaptation of Quality Management System documents to the structure and format set forth in the PGC-01.	The document as a whole.
03	24-03-2022	Full review to correct deviations detected by the internal audit.	The document as a whole.
04	15-11-2023	Full review to add improvements detected by the internal audit.	The document as a whole

1. PURPOSE AND SCOPE OF APPLICATION

1.1. About the company

The IGLS laboratory, health center with registration number 40125 located at Calle Britania, 7 for clinical analysis and the IGLS Genetic Laboratory, health center with registration number 21595 located at Avda. Ansaldo, 12, for genetics, immunology, microbiology and parasitology, owned by: Integrated Genetic Lab Services SLU, performs a wide range of diagnostic tests that offer effective solutions to a wide variety of fertility problems.

IGLS specializes in reproductive genetics and immunology and works to develop new techniques from the research side that can be transferred to the clinical setting in the form of robust diagnostic tests.

The team of specialists in molecular genetics, biotechnology and immunology work closely with medical professionals using state-of-the-art technologies and equipment to provide accurate answers to assisted reproduction centers, hospitals and other healthcare institutions around the world.

1.2. Purpose

The IGLS Quality Policy is focused on the quality assurance and control of the diagnostic services provided by the laboratory. With the objective of satisfying the requirements and expectations of our clients and users, our contractual obligations, legal and regulatory requirements, as well as to allow the continuous improvement of our own general quality system and the processes that compose it.

2. SCOPE

The quality policy shall be applied to all the organisation's activities, levels and personnel involved in performing genetic diagnosis services.

3. TERMS AND DEFINITIONS

- Quality assurance: The series of planned, systematic tasks that provide the desired confidence level that a product or service will satisfy the established quality requirements.
- Quality control: Set of systematic actions that are necessary to detect and follow the established quality requirements
- Quality management system: The structure that defines the responsibilities, procedures, processes, critical points and related or interacting resources through which the quality goals required to monitor the organisation from the quality perspective are set and carried out.
- Quality Policy: Management's statement of intent and commitment with the quality goals.
- Quality Goals: The goals derived from the Quality Policy set for all the relevant levels of the organisation.
- Laboratory Director: Person or people who manage and administer the activity of a laboratory.
- Clinical analysis laboratory: A laboratory devoted to the biological, microbiological, immunological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, genetic and

other kinds of analysis of materials derived from the human body with the aim of providing information for the diagnosis, management, prevention and treatment of diseases or assessment of the health of human beings. Such a laboratory can also provide an advisory or consultancy service that covers all aspects of laboratory testing including interpretation of the results and recommendations for the most appropriate additional tests.

4. REFERENCE DOCUMENTS

The IGLS Management follows at all times the fulfilment of all regulatory requirements, and defines its Quality Objectives, according to the UNE-EN ISO 9001 Standard and the UNE-EN ISO 15189 Standard, specific to clinical laboratories, being deeply convinced of its benefits, assuming the commitment to comply and enforce compliance with such regulations, in its current version. As well as any other document that may be related to the implementation of the same and the services provided by IGLS that have been included in the scope of accreditation (guides, recommendations and technical notes of ENAC, specific legislation related to the sector, regulations defined by the competent authority (AEMPS/EMA) as well as related scientific literature and good practice guides of international societies that may be of interest.

5. RESPONSIBILITIES

Director of the Laboratory, Lab Technicians, Quality Department: Responsible in each case for compliance with this Quality Policy, for ensuring that it is appropriate for the organisation, is implemented, disseminated, enforced and is known and understood by all the Company's employees. They shall also foster a culture of quality among the organisation's personnel on the understanding that the goal can only be reached by working together in a coordinated manner.

All employees: All employees at all levels and functions have an individual and collective responsibility to comply with this Quality Policy. They must be familiar with the documentation and put its contents into practice while understanding the importance of the details to be taken into account during processes where joint responsibility for its implementation and maintenance is an essential requirement for fulfilment of the Company's goals.

6. DEVELOPMENT

Laboratory Managers are responsible for defining, implementing and maintaining this Quality Policy, for which reason they shall foster the creation of the Quality Manual to support the Quality Management System in accordance with the requirements defined by the following provisions:

- UNE-EN ISO 15189
- UNE-EN ISO 9001
- European Directive 98/79/EC

- Transposition of the Directive into Spanish law by RD 1662/2000
- The requirements of the Spanish health authority AEMPS
- ENAC's guidelines and technical notes (comparing and contrasting, flexible scope, calibration, etc.)

The IGLS Quality Management System includes all its requirements in general terms in the Quality Manual, and is made up of the procedures, records and instructions establishing the lines of action described in this Quality Policy, the purpose of which is to guarantee the traceability and quality of the results obtained, and specifically the following principles and commitments:

- IGLS is committed to good professional practice, the quality of its diagnostic services and research projects, as well as compliance with its overall quality system.

- The Laboratory Management is committed to compliance with quality standards, good laboratory practices and to the strict monitoring and implementation of regulatory requirements while maintaining professional ethics and morals to ensure excellence in the quality of performance of the declared analytical services.

- The general quality system is implemented with the aim of achieving excellence in the services provided, with the general objective of offering a service of excellence for diagnosis, based on rigour and commitment, and to achieve this through the continuous improvement of processes and the periodic review of quality objectives, in order to respond to the needs of patients, doctors and collaborators.

The following are specific goals:

- Compliance with the specific quality and competence-related requirements for clinical laboratories set forth in the UNE-EN ISO 15189 standard.

- Commitment to excellence and continuous improvement of all processes and services, constant innovation in technical and operational processes that enable effective, safe responses. We aim to understand and meet the needs and requirements of our customers in order to provide the best service and attention possible to patients and the medical community in general. To foster customer confidence in the suitability of our analyses for their intended use, the reproducibility of our tests, the reliability of results and reports, security in data protection, technical capacity and diligence in the provision of services and in the development of our projects.

- To ensure, by means of approved procedures, that the entire process of obtaining, assessing, processing, conserving, storing and distributing or transporting human cells and tissues complies with the highest quality and safety standards.

- To implement continuous review of the quality management system by the Laboratory Directors by the Internal Audit Plan and reviews by management.

- To employ qualified experts with sufficient technical competence, ensuring that they are committed to the Company's quality policies and training and motivating them to ensure that they are conversant with the processes and procedures that comprise the Quality Management System.

- To conserve, grow and consolidate innovation and learning to ensure mastery of management and operational processes in a culture of continuous improvement.
- To create a working environment in which the priorities are respect for people and the environment and the safety of our employees.

The efficacy of IGLS's Quality Management System depends on the unconditional support of all our employees. Management provides the following guidelines:

- All laboratory personnel involved in analysis activities must be conversant with the General Quality System documentation and must implement the applicable procedures as efficiently as possible at all times by following the instructions provided and assuming the goals and objectives as their own. All laboratory workers must understand the importance of the task they perform in order to contribute to achievement of quality objectives from their workstation.

- All personnel must apply the established ethical values with the highest professional standards, integrity, honesty, social responsibility, service mindset, impartiality and confidentiality.

- All personnel shall apply the appropriate guidelines to prevent errors and must take the initiative in analysing, rectifying and eradicating the causes of any incidents, poor professional practice or inefficiencies they may detect that could cause quality problems. The entire organisation must take responsibility for detecting the deficiencies that may arise with a preventive purpose within the framework of continuous improvement.

- Selection of subcontracted laboratories suitable for IGLS quality requirements.

- IGLS ensures proper processing of personal data in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council (the GDPR) to safeguard the confidentiality of the information and responsible use of the same.

General Management has established the measures required to ensure dissemination of the Quality Policy in all areas of the organisation and ensuring that it will be understood, applied, reviewed and updated.

General Management defines the Company's specific objectives and the key procedures to comply with the provisions of the Quality policy, endowing each department with the required authority and responsibility and placing the human, technical and economic resources at their disposal to enable them to achieve the goals.

INTEGRATED GENETIC LAB SERVICES S.L.
Avda. Ansaldo, 12 - 03540 Alicante
CIF: B91968958

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Elaborado:	Revisado:	Aprobado:
María van der Hofstadt Rovira	María Enciso y Jonás Sarasa	Javier Flors
Dpto. Calidad	Dirección Lab	CEO