QUALITY POLICY

GLOBAL QUALITY REQUIREMENTS

IGENOMIX is a conglomerate of clinical laboratories, belonging to the Vitrolife Group, specialised in reproductive genetics and genomic diagnosis that offers its services in more than 20 countries. The tests and services offered are in the area of preconception genetics, preimplantation genetics, prenatal diagnosis and precision genomic diagnosis.

Igenomix Laboratories worldwide are accredited/registered to either CLIA (Clinical Laboratory Improvement Amendments), CAP (College of American Pathologists), ISO 15189, ISO 13485 or other relevant quality standards in the market that the laboratory operates.

OUR COMMITMENT TO QUALITY

Igenomix Management commits to:

- Implement and maintain a Quality Management System (QMS), in the IGENOMIX laboratories, in accordance with the requirements established by one or more relevant Quality Standards for clinical laboratories.
- Offer services and products in accordance with good professional practice and ensuring that the offered products/services comply with their intended use as described in the technical documentation, taking into consideration patient safety.
- Continuously improve the products and services offered and managing any related risks.
- Comply with applicable regulations and established quality principles, by using this policy as a foundation when establishing quality objectives.
- Safeguarding impartiality of all laboratory and business activities, including personnel relationships.
- Maintaining the confidentiality of patient information, personnel data, sensitive business and laboratory activities.
- Ensuring that patient's well-being, safety and rights are protected and are free from discrimination.

MAIN ASPECTS OF THE IGENOMIX QUALITY MANAGEMENT SYSTEM

- Ensure, for each laboratory, the compliance with applicable regulations and standards.
- Establish a QMS based on a risk-based approach, ensuring that risks are assessed and addressed.
- Monitor, on a continuous basis, the overall customer experience ensuring, compliance with customer safety, needs and expectations.
- Establish impartial selection and monitoring requirements for suppliers and subcontractors.
- Establish mechanisms to ensure full traceability of all products and services offered.
- Ensure the effectiveness of the QMS processes.
- Establish specific, measurable, achievable, relevant and timely indicators.
- Implement systematic auditing procedures to control the processes identified, manage risks in the QMS, as well as the products and services offered.
- Provide sufficient and conveniently located space for the various activities performed.
- Ensure the acquisition and adequate maintenance of equipment and other resources necessary for the provision of the service.
- Ensure the introduction, recruitment and training of staff, to provide a comprehensive and effective service to our users.
- Ensure that all staff are familiar with the Quality Policy, understand the objectives, participate in quality improvement activities and are familiar with the contents of the Quality Manual and all procedures relevant to their work.
- Ensure adequate access to QMS documentation and ensure that all obsolete documentation is removed from circulation and complies with expected record retention times.
- Implement a corrective and preventive action methodology to address incidents, non-conformities, complaints, manage risks and ensure patient safety.
- Report test results in a timely, confidential, accurate and clinically useful manner.
- Ensure that instructions for use include all necessary user information and are always accessible.
- Establish procedures for market monitoring and surveillance, as well as for notification of competent authorities.
- Ensure the health, safety and welfare of all employees, visitors and customers in accordance with our Good Laboratory and Safety Practices Manual.

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