IGENOMIX QUALITY POLICY

GLOBAL QUALITY REQUIREMENTS

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

OUR COMMITMENT TO QUALITY

Igenomix Management committs to:

- Implement 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, such as: 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.
- Offer services and products in accordance with good professional practice, ensuring that the offered products/services comply with their intended use as described in the technical documentation.
- Continuously improve the products and services offered.
- Providing resources to implement and maintain a suitable QMS.
- Comply with the applicable regulations and the established quality objectives, using this policy as a foundation when establishing these objectives.

MAIN ASPECTS OF THE IGENOMIX QUALITY MANAGEMENT SYSTEM

- Monitor, on a continuous basis, the overall customer experience ensuring, compliance with customer needs and expectations.
- Establish 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 Quality Management System processes.
- Ensure, for each laboratory, the compliance with applicable regulations and standards.
- Establish specific, measurable, achievable, relevant and timely indicators.
- Implement systematic auditing processes to control the processes identified in the Quality Management System, 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 and complaints.
- 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.
- Establish a Quality Management System based on a risk-based approach, ensuring that risks are assessed and addressed.

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