

GLOBAL QUALITY REQUIREMENTS

Igenomix is a clinic laboratory specialized in reproductive genetics and genomic diagnostic that offers its services in more than 20 countries. The tests and services offered, are mainly in the area of genetic preconception, genetic preimplantation, prenatal diagnosis and precision genomic diagnosis.

OUR COMMITMENT TO QUALITY

Igenomix Management is committed to:

- Implement a Quality Management System (QMS) in accordance with the standards established by CLIA (Clinical Laboratory Improvement Amendments), UNE-EN-ISO 15189 Clinical Laboratories, UNE-EN-ISO 13485 Medical devices.
- Offer services and products in accordance with the good professional practices, ensure that 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 an adequate QMS
- Comply with the applicable regulations and the quality objectives that are established taking this policy as a framework for their definition.

This commitment is materialized through the Quality Management System implemented in Igenomix.

MAIN LANDMARKS 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 Management System processes.
- Ensure compliance with applicable regulations and standards.
- Establish specific, measurable, achievable, relevant and temporary 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.

CERTIFICATIONS AND LICENSES

Certification in international standards gives our customers confidence in the Igenomix quality system and in the overall design and manufacturing processes.

IGENOMIX is registered in the autonomous registry of centers, services and health facilities of the Valencian Community (Spain) for the performance of activities related to clinical, genetic, microbiological and parasitological analysis (License 10800).

Our certificates are available through our website; <https://www.igenomix.eu/quality/>

Get more information on our quality website: <https://www.igenomix.eu/quality/>

Carlos Simón, M.D., Ph. D. (CSO Cientific Director)

Signature:



Date: xx/xx/2021

David Jiménez, (CEO General Manager)

Signature:



Date: xx/xx/2021