IGENOMIX QUALITY POLICY

GLOBAL QUALITY REQUIREMENTS

Igenomix is a conglomerate of clinical laboratories that belong to the Vitrolife Group and specializes in reproductive genetics and genomic diagnosis. The services offered by Igenomix are available in over 20 countries and mainly concentrate on preconception genetics, preimplantation genetics, prenatal diagnosis, and precision genomsic diagnosis.

COMMITMENT TO QUALITY

Igenomix management commits to:

- Implement a Quality Management System (QMS) in the Igenomix USA laboratories in accordance with the requirements established by regulatory organizations for clinical laboratories, such as: CLIA (Clinical Laboratory Improvement Amendments), CAP (College of American Pathologists), or other relevant quality standards in the market in which the laboratory operates, including the states that require out-of-state certifications, such as California, New Jersey, Maryland, New York, Pennsylvania, and Rhode Island.
- Provide services and products that adhere to good professional practice and ensure that the products and services offered comply with their intended use as described in the technical documentation.
- Continuously improve products and services offered.
- Providing resources to implement and maintain a suitable QMS.
- Comply with the applicable regulations and the established quality objectives, with this policy as a foundation.

KEY ASPECTS OF THE IGENOMIX QMS

To maintain quality and ensure continued quality improvement, Igenomix USA commits to:

- Continuously monitor the customer experience for compliance with customer needs and expectations.
- Establish requirements for the selection and monitoring of suppliers and subcontractors.
- Establish mechanisms to ensure traceability of all products and services offered.
- Ensure the effectiveness of the QMS.
- Ensure compliance with applicable regulations and standards for each laboratory.
- Establish specific, measurable, achievable, relevant, and timely indicators.
- Implement systematic auditing processes to control the policies identified in the QMS.
- Provide sufficient and convenient space for activities performed within Igenomix.
- Ensure that the necessary equipment and resources are acquired and maintained adequately to provide service.
- Introduce, recruit, and train staff to provide comprehensive and effective service to our users.
- Ensure that all staff members 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.
- Provide adequate access to QMS documentation (iPassport) and ensure that all obsolete documentation is removed from circulation while complying with expected record retention times.
- Implement a corrective and preventive action methodology to address incidents, nonconformities, and complaints.
- Ensure that results are reported 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 and visitors in accordance with our Good Laboratory Practices procedure.
- Establish a QMS based on a risk-based approach, ensuring that risks are assessed and addressed.

All personnel in CAP-accredited locations (Los Angeles) may communicate with CAP directly if they have a concern not addressed by the laboratory management (confidential CAP telephone lines for quality or safety concerns are 847-832-7533) without punitive actions against the employees.

Signed,
Brynn Levy (Laboratory Director)
Signature: 

Ania Pinares (Quality Manager)
Signature: 

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