

Title	CODE US_M_P_001_EN	VERSION 2.0
QUALITY POLICY	Author (Name): Ania Pinares	Date of issue: August/28/2019
	Authorized by (Name): Brynn Levy, Victor Llinares	Date of next review: August/28/2021

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## **QUALITY POLICY**

In order to maintain quality and ensure continued quality improvement, Igenomix USA undertakes to:

- Establishing the following policy that will act as a framework for establishing and reviewing the quality objectives. This policy will be periodically reviewed to ensure its continued suitability.
- Operating a Quality Management System to integrate the organization, procedures, processes and resources.
- Setting and reviewing quality objectives and plans in order to implement this Quality Policy.
- Ensuring that all personnel are familiar with the Quality Policy and understand the objectives and participate in quality improvement activities and are familiar with the contents of the Quality Manual and all procedures relevant to their work.
- Fostering an open 'no blame' culture to encourage personnel to discuss nonconformity issues in order to improve the service provided.
- Seeking continuous improvement in the lines of communication both internally within our affiliates and with users of the services and other interested parties.
- Committing to the health, safety and welfare of all staff. Visitors to the department will be treated with respect and due consideration will be given to their safety.
- Ensuring that all laboratory documentation is available at the point of use and that all obsolete documentation is removed from circulation.
- Giving primary consideration to the well-being of patients and confidentiality of patient information and ensuring that improper internal or external commercial, financial or other pressure does not affect the work performed by the laboratory.
- Upholding the very highest professional values and committing to good professional practice and conduct.

## Igenomix USA will comply with the standards set by CLIA and CAP and is committed to:

- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- Providing sufficient conveniently located space for the various activities of the laboratory.
- The collection, transport and handling of all specimens in such a way as to preserve
  the quality and integrity of the specimen and to ensure the correct performance
  of laboratory examinations.
- Examination procedures that are fit for intended use and ensure the highest achievable quality of all tests performed.



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- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful.
- The systematic audit and assessment of all aspects of its operations in order to determine its compliance with stated quality objectives and to utilize the information thereby gathered to produce continual quality improvement that will be mainly focused on improving laboratory services.
- Compliance with environmental legislation, both local and national.
- Compliance with statutory and regulatory requirements.
- Continuous compliance with CAP program standards.

All personnel may communicate with the 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.

Name: Brynn Levy (Laboratory Director)

Signature:

Date: August 28, 2019

Name: Victor Llinares (Managing Director US and Canada)

Signature:

Date: August 28, 2019