

Title	CODE SPA_L_P_002_EN	VERSION 2.1
QUALITY POLICY	Author (Name): Belén Arnau	Date of issue: 14/July/2020
	Authorized by (Name): Carlos Simón, David Jiménez	Date of next review: 14/July/2021

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QUALITY POLICY

Igenomix Spain is a multinational private company, medical testing laboratory (Company No.10800) specialising in reproductive genetic services. Igenomix S.L.U. currently offers a huge variety of tests within the preimplantation genetic area, prenatal diagnosis and other genetic analysis whose goal is to increase the probability of pregnancies through FIV treatments. Igenomix S.L.U. maintains a data protection infrastructure in line with REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ('GDPR').

In order to maintain quality and ensure continued quality improvement, Igenomix S.L.U. 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 organisation, 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.
- Maintaining a high standard of customer support service to all users.
- 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.



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Igenomix S.L.U. will comply with the standards set by CLIA and ISO15189 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.
- 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.
- Continuing compliance with CLIA and ISO15189 program standards.

Name: Carlos Simón, M.D., Ph. D. (Laboratory Director) Signature:

Signature:

Name: David Jiménez, CEO

Date: 14/July/2020

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