Igenomix UK Ltd, Surrey Technology Centre, 40 Occam Road, Guildford, GU2 7YG. Email: info.uk@igenomix.com. Tel: +44(0)2080688176. www.igenomix.co.uk

Quality Policy

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QUALITY POLICY

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Igenomix UK Ltd is a private medical testing laboratory (Company No.10675550) specialising in reproductive genetic services and is part of a multinational company with headquarters (Igenomix SL) in Valencia, Spain. Igenomix is now part of the Vitrolife Group AB. The laboratory currently performs five tests in-house: Preimplantation Genetic Testing for Monogenic Disorders (PGT-M), Preimplantation Genetic Testing for Aneuploidy (PGT-A), Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR), Mitoscore and a non-invasive PGT-A (EMBRACE). The laboratory offers other services currently outsourced to the headquarters in Spain and to Igenomix Italy. The tests outsourced to Igenomix SL are testing for Products of Conception (POC), a suite of Carrier Screening tests (CGT), Sperm Aneuploidy Testing (SAT), non-invasive prenatal tests (NACE/NACE 24), Genomic Precision Diagnostics (GPDx) Endometrial Receptivity Analysis (ERA), Endometrial Microbiome Metagenomic Analysis (EMMA), and Analysis of Infectious Chronic Endometritis (ALICE) [Last three tests are also offered as a package known as EndomeTRIO]. In addition, Karyotyping, CGT Essential and Y chromosome microdeletions are outsourced to Igenomix Italy. Igenomix UK is accredited to ISO 15189 (2012) (Medical Laboratories- 10131) for the in-house tests and maintains a data protection infrastructure in line with the UK GDPR. Igenomix is registered with the CQC under Diagnosis/Screening category.

To ensure that the needs and requirements of users are met, Igenomix UK Ltd undertakes to develop continual quality improvement by:

- 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 consistent 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 internally within Igenomix UK, with users of the service, and with other interested parties, including other Igenomix affiliates.
- 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 UK Ltd will comply with the standards set by ISO15189:2012 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 the 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 utilise 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 ISO 15189 accreditation standards.
- Continuing compliance with the CQC regulations.

Dr Roy Pascal Naja
Laboratory Director
Date: 25/01/2022

Prof. Alan Thornhill
Country Manager
Date: 25/01/2022