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PIONEERS IN **REPRODUCTIVE GENETICS**

User Manual

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Table of Contents

1.0 IGENOMIX UK

1.1 INTRODUCTION

Igenomix UK Ltd is a private medical testing laboratory (Company No.10675550) specialising in reproductive genetic services and is part of a multinational company (Igenomix SL) with headquarters in Valencia, Spain. The laboratory currently performs four tests in-house: Preimplantation Genetic Testing for Monogenic Disorders (PGT-M), Preimplantation Genetic Testing for Aneuploidy (PGT-A), and Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR). The laboratory offers other services that are currently outsourced to the headquarters in Spain including testing for Products of Conception (POC), a Carrier Genetic Test (CGT), Sperm Aneuploidy Testing (SAT), a non-invasive prenatal test (NACE/NACE extended 24), 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].

1.2 LABORATORY OPENING TIMES

The laboratory is open Monday – Friday 9:00am to 5:00pm

1.3 CONTACT DETAILS

Key members of staff:
Prof. Alan Thornhill, PhD. State Registered Clinical Scientist (Clinical Embryology). Country Manager UK.
Dr Roy Pascal Naja, MSc, PhD. State Registered Clinical Scientist (Genetics). Laboratory Director UK.
Dr Araz Raberi, MSc, PhD. Senior Laboratory Specialist and Quality Manager
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1.4 ADDRESS

Igenomix UK Ltd
Surrey Technology Centre
40 Occam Road
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2.0 MAIN ACTIVITIES

2.1 GENERAL INFORMATION

Genetic tests are carried out as clinically appropriate. Additional information regarding the different tests offered is available to users on the Igenomix UK website and can also be requested by email to: info.uk@igenomix.com or support.uk@igenomix.com. Further interpretation of the report is available to users by calling the laboratory and requesting to speak with a senior member of staff. The laboratory is committed to delivering service of the highest quality at all times to ensure patient safety and customer satisfaction. Any comments, suggestions or complaints about the service should be sent to info.uk@igenomix.com & support.uk@igenomix.com, after which they will be passed to the relevant members of staff. The laboratory follows strict policies on Information Governance and maintains a data protection infrastructure in line with REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ('GDPR').

2.2 TESTS OFFERED

2.2.1 Tests performed in-house

The laboratory currently performs Three tests in-house: Preimplantation Genetic Testing for Monogenic Diseases (PGT-M), Preimplantation Genetic Testing for Aneuploidy (PGT-A) and Preimplantation Genetic Testing for Chromosomal Rearrangements (PGT-SR).

Preimplantation Genetic Testing for Monogenic Diseases (PGT-M)

Description: PGT-M may be performed on embryos during in vitro fertilisation (IVF) treatment to test for single gene diseases. PGT-M, requiring only a small number of cells, identifies which embryos are not at an increased risk of developing the disease. The goal of PGT-M is to help couples start a "healthy" family and avoid the difficult choice of having to terminate a pregnancy if a "positive" result is obtained through prenatal diagnosis. PGT-M is performed by using a genome-wide linkage technique known as Karyomapping.

Pre-requirements for accepting a PGT-M case:

Prior to offering PGT-M, a "genetics report" (issued from an ISO 15189 accredited laboratory or equivalent) for the affected partner and for certain family members with known disease status must be available and sent to the laboratory of Igenomix UK. The report must clearly identify the gene responsible for the disease/disorder to be tested by PGT-M. A case-discussion with a senior member of laboratory staff will be required in certain instances. The scenarios where Karyomapping can be considered as a method for PGT-M include the following:

- Autosomal dominant disorders where a family member with tested genetic status (affected or normal and known as a reference) is available to provide a sample.
  The reference is chosen in the order of preference as follows:
  1. Child of the couple
  2. Parent of the affected member of the couple
  3. Sibling of the affected member of the couple.

- Autosomal recessive disorder where a child known to be affected or normal is available to provide a sample to be used as a reference. If a child is not available, then samples are required from the parents of the couple or their siblings (least favourable scenario).
- X-linked disorder where a member of the family with tested genetic status is available to provide a sample. The reference is chosen in the order of preference as follows:
  1. Child of the couple.
  2. Parent of the affected member of the couple
  3. Sibling of the affected member of the couple.

Note: The sex of the embryos will be disclosed in the case of X-linked disorders.

Note: Karyomapping will detect meiotic aneuploidies which will be reported. However, Karyomapping is not currently validated for aneuploidy screening.

In the cases where a reference is not available and where the informativity of the Karyomapping platform did not reach the accepted threshold (e.g. the couple is consanguineous) then a mutation detection system will be developed and coupled with Karyomapping.

Sample requirements:

For the PGT-M workup, peripheral blood (in EDTA tubes) and/or a buccal swab (less recommended) from the prospective parents and other relevant family members is needed. Based on the outcome of the PGT_M workup, the laboratory will inform the IVF clinic by email whether Karyomapping is suitable for embryo diagnosis or not. The patients can then start their treatment towards PGT-M or seek alternative treatment which can be further discussed with a senior member of laboratory staff

For PGT-M, 5-6 cells are required for a day five biopsy. The solution used for "washing/tubing" the biopsied cells is provided by the laboratory. The biopsied cells must be "tubed" in sterile 0.2ml microcentrifuge tubes provided by the laboratory. The lid of these tubes must be labelled with the female patient initials followed by the embryo number. All 0.2ml tubes must be placed in a "plate/rack" (provided by the laboratory) with the lid labelled with the patient name, patient date of birth and the unique patient ID number. The "plate/rack" in turn is placed in a sterile plastic bag in a cooler with "ice packs" also provided by the laboratory. Further information on how to prepare a sample is found in the "Washing_Tubing Instructions" that can be downloaded from the website or requested by email. The "Embryo Biopsy Worksheet" and "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in a sleeve and in the cooler prior to transport.

User validation: Following the enrolment of a new clinic (see section 3), a "validation" or "dry" run is performed for every embryologist involved in embryo biopsy for PGT-M. Instructions on how to complete a "validation run" (Embryo Biopsy_Tubing Validation Instructions and Washing_Tubing Instructions) can be downloaded from the website or requested by email. A "validation/dry" run report is issued after the run is analysed and signed by a senior member of laboratory staff or the Laboratory Director. Clinical samples

taken by an embryologist will only be processed after his/her successful completion of a "validation/dry run". In certain cases, and after discussion with the Laboratory Director, user validation is not needed for every embryologist performing a biopsy. This includes embryologists that have been previously validated for biopsy by an ISO 15189 (or equivalent) accredited diagnostic laboratory.

Transportation to the laboratory:

For the PGT-M workup, blood samples and/or buccal swabs should be sent to the laboratory by either first class mail or a similar secure service (DHL, UPS…) and packed according to UN packing requirement PI 650 and clearly labelled 'diagnostic specimen UN3373' (this service is not offered by the laboratory but outsourced to a third-party logistics company).

For PGT-M, the clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. Carriage is at Room Temperature.

Note: Please remove the "ice packs" and "biopsy kit" from the kit once received and store them at -20^{o}C freezer and 4^{o}C fridge respectively until sending them along with the samples back to the laboratory.

Turnaround time (TAT): The setup of a protocol (PGT-M workup) is case-dependent and varies between 20 working days to 30 working days. Once the samples arrive at the laboratory, the report TAT is 10 working days.

Preimplantation Genetic Testing for Aneuploidy (PGT-A)

Description: PGT-A is a genetic test that may be performed on embryos during IVF treatment to screen for numerical chromosomal abnormalities. Chromosomally normal embryos are most likely to implant and develop to term. PGT-A helps clinicians and patients undergoing IVF decide which embryos to transfer. The method, requiring only a small number of cells, is comprehensive as it analyses all 24 chromosomes for chromosomal copy number using Next Generation Sequencing (NGS).

Sample requirements: For PGT-A, 5-6 cells are required for a day five biopsy. The solution used for "washing/tubing" the biopsied cells is provided by the laboratory. The biopsied cells must be "tubed" in sterile 0.2ml microcentrifuge tubes provided by the laboratory. The lid of these tubes must be labelled with the female patient initials followed by the embryo number. The "plate/rack" in turn is placed in a sterile plastic bag in a cooler with "ice packs" also provided by the laboratory. Further information on how to prepare a sample is found in the "Washing_Tubing Instructions" that can be downloaded from the website or requested by email. The "Embryo Biopsy Worksheet" and "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in a sleeve and in the cooler prior to transport.

User validation: Following the enrolment of a new clinic (see section 3), a "validation" or "dry" run is performed for every embryologist involved in embryo biopsy for PGT-A. Instructions on how to complete a "validation run" (Embryo Biopsy_Tubing Validation Instructions and Washing_Tubing Instructions) can be downloaded from the website or requested by email. A "validation/dry run" report is issued after the run is analysed and signed by a senior member of laboratory staff or the Laboratory Director. Clinical samples taken by an embryologist will only be processed after his/her successful completion of a "validation/dry run". In certain cases, and after discussion with the Laboratory Director,

user validation is not needed for every embryologist performing a biopsy. This includes embryologists that have been previously validated for biopsy by an accredited diagnostic laboratory.

Transportation to the laboratory: The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. Carriage is at Room Temperature.

Note: Please remove the "ice packs" and "biopsy kit" from the kit once received and store them at -20^{o}C freezer and 4^{o}C fridge respectively until sending them along with the samples back to the laboratory.

Turnaround time: Report turnaround time (TAT) is 10 working days following sample reception.

Reporting mosaicism: If requested by the clinic/user, Igenomix UK will report mosaicism for whole chromosome aneuploidies. "Mosaic samples" will be reported as either "low mosaic aneuploid" defined as having > 30% and < 50% mosaicism or "High mosaic aneuploid" defined as having > than 50% and < than 70% mosaicism.

- For all chromosomes, mosaic aneuploidy levels below 30% will be reported as euploid.
- For all chromosomes, mosaic aneuploidy levels above 70% will be reported as abnormal.
- For chromosomes 13, 18, 21 and the sex chromosomes mosaic aneuploidy above 30% will be reported as abnormal.

Preimplantation Genetic Testing for structural rearrangements (PGT-SR)

Description: PGT-SR is a genetic test to detect specific chromosomal imbalances in embryos arising from parental chromosomal rearrangements. The test will also detect numerical chromosomal abnormalities not associated with the parental chromosomal rearrangement. This method uses NGS to analyse all 24 chromosomes and requires multiple trophectoderm cells from a blastocyst biopsy. Currently, PGT-SR at Igenomix UK has been validated to detect chromosomal abnormalities that are ≥ 13Mb.

Sample requirements: Prior to offering PGT-SR, a "genetics report" (karyotype) that clearly identifies the chromosomal rearrangement to be tested for is required, and if appropriate, a case-discussion with a senior member of staff.

For PGT-SR, 5-6 cells are required for a day five biopsy. The solution used for "washing/tubing" the biopsied cells is provided by the laboratory. The biopsied cells must be "tubed" in sterile 0.2ml microcentrifuge tubes provided by the laboratory. The lid of these tubes must be labelled with the female patient initials followed by the embryo number. The "plate/rack" in turn is placed in a sterile plastic bag in a cooler with "ice packs" also provided by the laboratory. Further information on how to prepare a sample is found in the "Washing_Tubing Instructions" that can be downloaded from the website or requested by email. The "Embryo Biopsy Worksheet" and "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in a sleeve and in the cooler prior to transport.

User validation: Following the enrolment of a new clinic (see section 3), a "validation" or "dry" run is performed for every embryologist involved in embryo biopsy for PGT-A. Instructions on how to complete a "validation run" (Embryo Biopsy

_Tubing Validation Instructions and Washing_Tubing Instructions) can be downloaded from the website or requested by email. A "validation/dry run" report is issued after the run is analysed and signed by a senior member of laboratory staff or the Laboratory Director. Clinical samples taken by an embryologist will only be processed after his/her successful completion of a "validation/dry run". In certain cases, and after discussion with the Laboratory Director, user validation is not needed for every embryologist performing a biopsy. This includes embryologists that have been previously validated for biopsy by an accredited diagnostic laboratory.

Transportation to the laboratory: The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. Carriage is at Room Temperature.

Note: Please remove the "ice packs" and "biopsy kit" from the kit once received and store them at -20°C freezer and 4°C fridge respectively until sending them along with the samples back to the laboratory.

Turnaround time: Report turnaround time (TAT) is 10 working days following sample reception.

Reporting mosaicism: If requested by the clinic/user, Igenomix UK will report mosaicism for whole chromosome aneuploidies. "Mosaic samples" will be reported as either "low mosaic aneuploid" defined as having > 30% and < 50% mosaicism or "High mosaic aneuploid" defined as having > than 50% and < than 70% mosaicism. For all chromosomes, mosaic aneuploidy levels below 30% will be reported as euploid except for 13, 18, 21 and the sex chromosomes which will be reported as abnormal. Also, any mosaic aneuploidy levels above 70% will be reported as abnormal.

Important notes:

- Unlabelled or damaged samples will not be accepted.
- Samples not accompanied by the relevant "Test Requisition Form" will not be processed. The report for samples accompanied by an incomplete "Test Requisition Form" will not be released until the form is completed (see section 3).
- When the outside ambient temperature exceeds 35°C please contact the laboratory for further instructions on how to send the samples.

2.2.2 Outsourced tests

The laboratory currently offers other tests that are outsourced to the headquarters in Spain including Endometrial Receptivity Analysis (ERA), a non-invasive prenatal test (NACE), a Carrier Genetic Test (CGT), Endometrial Microbiome Metagenomic Analysis (EMMA), Analysis of Infectious Chromic Endometritis (ALICE), Testing for Products of Conception (POC) and Sperm Aneuploidy Testing (SAT).

Endometrial Receptivity Analysis (ERA)

Description: The lack of synchronisation between the embryo ready to be implanted and endometrial receptivity is believed to be one of the causes of recurring implantation failure. ERA is a test that has been developed and patented in 2009 by IGENOMIX after more than 10 years of research and development. The ERA test helps to evaluate the woman's endometrial receptivity and thus identify a 'window of implantation' from a molecular perspective. The test analyses the expression levels of 248 genes linked to the status of endometrial receptivity, using RNA sequencing (NGS) on material biopsied from the endometrium. Following the analysis, a specific computational predictor classifies the samples according to their expression profile as "Receptive" or "Non-Receptive". This data will enable a personalised embryo transfer (pET), synchronising endometrial receptivity with an embryo prepared for implantation.

Sample requirements: Endometrial tissue (~30-50mg by mass or ~5-10mm by size) placed in a cryotube containing RNA stabilizing solution provided by the laboratory. The cryotube containing the sample must be refrigerated (4-8°C) for a minimum of 4 hours before shipping. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the ERA kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 10 working days.

Endometrial Microbiome Metagenomic Analysis (EMMA)

Description: An "endometrial microbiome" is composed of various microorganisms co-existing in balanced proportions in the endometrium/uterine cavity. Of these microorganisms, the bacterium Lactobacillus is essential in predicting a "healthy" uterine cavity when present at certain levels. Recent studies have demonstrated that dysbiosis of the uterine cavity is associated with poor reproductive outcomes in assisted reproductive treatment patients. This suggests that altered endometrial Lactobacilli levels (and the presence of other bacteria) could play a role in infertility.

The indication for EMMA is Recurrent Implantation Failure (RIF); however, EMMA can be beneficial for any patient wishing to conceive.

EMMA can be performed between days 15 and 25 of the natural cycle, or during the uterine secretory phase in a HRT cycle.

EMMA uses NGS to analyse the complete endometrial microbiome profile for an endometrial tissue sample. The test is based on DNA extraction followed by amplification and barcoded sequencing of the bacterial 16S ribosomal RNA gene.

Sample requirements: Endometrial tissue (~30-50mg/~5-10mm) placed in a cryotube containing RNA stabilizing solution provided by the laboratory. The cryotube containing the sample must be refrigerated (4-8°C) for a minimum of 4 hours before shipping. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the ERA kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 10 working days.

Analysis of Infectious Chromic Endometritis (ALICE)

Description: The best example of pathology caused by an altered "endometrial microbiome" is chronic endometritis (CE). CE is a persistent inflammation of the endometrial lining, caused by infection of the uterine cavity, mainly by bacterial pathogens.

ALICE detects the most frequent bacteria that cause CE. It is a subset test of EMMA that can be ordered as a stand-alone test.

The indication for ALICE is Recurrent Implantation Failure (RIF); however, ALICEcan be beneficial for any patient wishing to conceive.

ALICE can be performed between days 15 and 25 of the natural cycle, or during the uterine secretory phase in a HRT cycle.

ALICE uses NGS to analyse the complete endometrial microbiome profile for an endometrial tissue sample and reports the presence and percentage of specific pathogenic bacteria. The test is based on DNA extraction followed by amplification and barcoded sequencing of the bacterial 16S ribosomal RNA gene.

Sample requirements: Endometrial tissue (~30-50mg/~5-10mm) placed in a cryotube containing RNA stabilizing solution provided by the laboratory. The cryotube containing the sample must be refrigerated (4-8°C) for a minimum of 4 hours before shipping. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the ERA kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 10 working days.

NACE & NACE extended 24

Description: Unlike invasive prenatal diagnosis that can pose a risk to an ongoing pregnancy, NACE is a non-invasive prenatal genetic screening test. NACE uses the latest sequencing technology (NGS) to analyse fetal DNA compared to maternal DNA in order to detect certain fetal anomalies with high precision and reliability. Two versions of the test exist: NACE and NACE Extended 24. NACE is designed to detect fetal Trisomy 21, 18, 13 and sex chromosome aneuploidies and NACE Extended 24 is designed to detect fetal chromosome aneuploidies in all 24 chromosomes and six additional microdeletions.

Sample requirements: 1x 10ml of peripheral blood in a Streck tube (or equivalent) provided by the laboratory. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the NACE kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 10 working days.

Carrier Genetic Test (CGT)

Description: CGT is a genetic test designed to detect carriers of known pathogenic mutations that pose risks for future progeny of having a serious genetic disorder. A "positive" result indicates the presence of one or more mutations in the individual. In that case, the test is highly recommended to the individual's partner if the couple wishes to have a child. Alternatively, both partners can be tested simultaneously.

If both are carriers of a mutation in the same single gene, there is high risk of having a child affected by a genetic disease. In these cases, there are options to conceive healthy children, such as PGT-M or gamete donation. It is also possible to conceive naturally and resort to prenatal diagnosis. A negative result indicates that the person does not carry any of the mutations studied. The test uses NGS.

Sample requirements: 1x 4ml of peripheral blood in EDTA tubes provided by the laboratory. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the CGT kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 25 working days.

Sperm Aneuploidy Testing (SAT)

Description: The Sperm Aneuploidy Test (SAT) is a diagnostic test that helps to assess male infertility by measuring the percentage of spermatozoa with chromosomal abnormalities in a semen sample. The SAT result provides an estimation of the transmission risk of chromosomal abnormalities to the offspring. The test specifically analyses the chromosomes most commonly observed in spontaneous miscarriages and affected offspring with chromosomal abnormalities (chromosomes 13, 18, 21, X and Y). The test uses Fluorescence In Situ Hybridization (FISH).

Sample requirements: 1x 10 ml of semen suspended in culture media in a conical tube placed inside a padded envelope (not provided by the laboratory). The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in the SAT kit.

Transportation to the laboratory: The clinic needs to notify the laboratory before a sample is ready and the laboratory will offer to arrange sample pickup. Carriage is at Room Temperature.

Turnaround time: Report TAT is 15 working days.

Testing for Products of Conception (POC)

Description: POC is a genetic test that can provide information to help determine the reason for a miscarriage. Most miscarriages are caused by chromosome abnormalities. POC testing, performed on tissue retrieved from the lost pregnancy, is comprehensive as it analyses all 24 chromosomes for gross chromosomal abnormalities using NGS.

Sample requirements: Biopsied tissue from the lost pregnancy is required. The tissue must be placed in a specimen pot (provided by the laboratory) containing saline solution. In addition, and as a control to test for maternal contamination (when appropriate), 1x4ml

of peripheral blood in EDTA tubes (provided by the laboratory) is required. Instructions on how to prepare a sample are available (POC Instructions) and can be downloaded from the website or requested by email. The "Test Requisition Form" (that can be downloaded from the website or requested by email) must be completed and placed in a sleeve and in the cooler.

Transportation to the laboratory: The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample pickup. The transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature.

Turnaround time: Report TAT is 10 working days following sample reception.

Important notes:

- Unlabelled or damaged samples will not be accepted.
- Samples not accompanied by the relevant "Test Requisition Form" will not be processed. The report for samples accompanied by an incomplete "Test Requisition Form" will not be released until the form is completed (see section 3).
- When the outside ambient temperature exceeds 35°C please contact the laboratory for further instructions on how to send the samples.
- Igenomix UK is responsible in ensuring that Reports for outsourced tests are provided to the clinician/healthcare professional making the initial request

3.0 REFERRALS

Before referrals can be made, clinics need to complete the "Clinic Enrolment Form (CEF)" which can be downloaded from the Igenomix UK website or requested by email from info.uk@igenomix.com and support.uk@igenomix.com. Once the form is completed it should be sent by email to info.uk@igenomix.com and support.uk@igenomix.com. For all tests, the Test Requisition Form and Informed Consent Form (if applicable) need to be completed, placed in a plastic sleeve and included in the kit along with the sample to be sent to the laboratory. These forms can be downloaded from the Igenomix UK website or requested by email from info.uk@igenomix.com and support.uk@igenomix.com.

For PGT-SR and PGT-M: the Test Requisition Form and a genetics report (specifying the pathogenic mutation(s)/chromosomal abnormality) need to be sent by email to lab.uk@igenomix.com prior to sending the sample (please email lab.uk@igenomix.com or call +44(0)2080689410 for additional information).

All the forms clearly state the mandatory fields to be completed. The Test Requisition Form must be signed by the referring clinician. The Informed Consent form (if applicable) must be signed by both the patient and the referring clinician.

4.0 ACCREDITATION AND ENROLMENT IN EXTERNAL ASSESSMENT SCHEMES

The laboratory is accredited for ISO 15189:2012 by UKAS and the scope of accreditation is detailed in the following link: https://www.ukas.com/wp-

content/uploads/schedule_uploads/00007/10131%20Medical%20Multiple.pdf . The laboratory participates annually in Genomics Quality Assessment (GenQA) schemes.