IGENOMIX DUBAI LABORATORY DIRECTORY OF TEST SERVICES

1 IGENOMIX LABORATORY

1.1 INTRODUCTION

IGENOMIX FZ LLC (**DHA License Number**: **8454809**) is a private medical laboratory specializing in reproductive genetic services and is part of the globally recognized **Vitrolife Group**. Based on science and advanced research capabilities, the aim of Vitrolife Group is to deliver products and services for the entire reproductive-health journey, providing consistent performance and guaranteed quality.

IGENOMIX FZ LLC provides advanced genetic testing in support of reproductive health, including in-house laboratory services such as Preimplantation Genetic Testing for Monogenic Diseases (**PGT-M**), Preimplantation Genetic Testing for Aneuploidy (**PGT-A & PGT-A Plus**), **Baby Gender** (21, 18, 13, X and Y Chr), Preimplantation Genetic Testing for Structural Rearrangements (**PGT-SR & PGT-SR Plus**), and Products of Conception (**POC**). Additionally, the laboratory offers outsourced testing services including Endometrial Receptivity Analysis (**ERA**), Endometrial Microbiome Metagenomic Analysis (**EMMA**), and the Analysis of Infectious Chronic Endometritis (**ALICE**).

1.2 LABORATORY OPENING HOURS, CONTACT DETAILS, AND ADDRESS

LABORATORY SAMPLE RECEPTION	Monday to Friday: 9:00 AM – 6:00 PM Weekends and Holidays: Support available subject to operational requirements.
CUSTOMER SUPPORT SERVICE	Monday to Friday: 9:00 AM – 6:00 PM Weekends and Holidays: Support available subject to operational requirements
LABORATORY OPERATIONS	Monday to Friday: 9:00 AM – 6:00 PM Weekends, Holidays and after working hours: Support available subject to operational requirements.
CONTACT METHODS	**Email** supportme@vitrolifegroup.com **Toll-Free** 800 50342 **Landline** +971 4551 9465 **WhatsApp** +971 55 515 7021
ADDRESS	Unit 501-502, 503 and 512, Building 40, Dubai Health Care City, P.O. Box 66566 Dubai, UAE.
WEBSITE	www.igenomix.net
NOTE	For support outside regular working hours or for urgent matters (including weekend/holiday services), please contact WhatsApp or call to confirm availability. All communications will be responded to as promptly as possible during service hours.

2 MAIN ACTIVITIES

2.1 GENERAL INFORMATION

All genetic tests are performed based on clinical appropriateness. Comprehensive information about the various tests available can be found on the Genetic Laboratory UAE | Genetic Lab Dubai | Igenomix ME website.

For additional clarification or interpretation of genetic test reports, please contact us at: supportme@vitrolifegroup.com and me-gc@igenomix.com.

2.2 COMPLAINT PROCEDURE

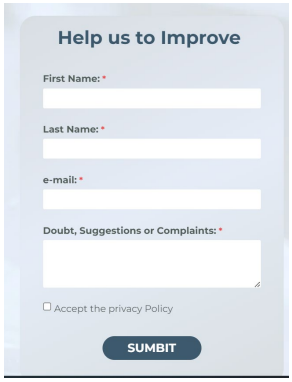
The laboratory is dedicated to consistently providing the highest quality services to ensure both patient safety and customer satisfaction.

For your convenience, you can submit complaints or concerns regarding our services through multiple channels. Upon receipt, your complaint will be promptly forwarded to the relevant team members for appropriate action.

Contact Information

Email	supportme@vitrolifegroup.com
Toll-Free	800 50342
Landline	+971 4551 9465
WhatsApp	+971 55 515 7021

Or through the complaint form available in the Quality section on our website https://www.igenomix.net/quality/#suggestion-complaint .



All complaints will receive a response within two business days.

- If you require urgent assistance, please specify this in your communication so we can prioritize accordingly.
- Should you need updates or clarification on your case, feel free to contact us through any of our listed channels.

2.3 LABORATORY POLICY ON PROTECTION OF PERSONAL INFORMATION

The laboratory follows strict policies on Information Governance and maintains a data protection infrastructure in line with Local regulation.

Further information about Igenomix Privacy Policy can be found on the Genetic Laboratory in UAE | Genetic Lab in Dubai | Igenomix ME

2.4 REQUIREMENTS PRIOR TO SENDING A SAMPLE

To ensure accurate sample processing, secure shipment, and timely reporting, follow these general requirements before sending samples to Igenomix for any test service.

2.4.1 Clinic Enrolment and Registration –First Step

Before a new clinic can begin sending samples to Igenomix, completion of the Clinic Enrolment Form is a mandatory first step. This process ensures your clinic is registered in the Igenomix LIS, allowing for secure sample tracking, data management, and compliant communication.

1. Contact Customer Support at supportme@vitrolifegroup.com to obtain the Clinic Enrolment Form.
2. Fill out all required details as instructed on the form.
3. Return the completed form via email to supportme@vitrolifegroup.com and finance.me@igenomix.com.
4. Igenomix will confirm your clinic's registration and now you shall be able to send test requests.

Important Note:

No samples/test request can be accepted from a clinic until this registration process is completed and confirmed. This ensures all patient data, sample records, and reporting are correctly managed from the start.

2.4.2 Documentation and Notification Instructions

Complete and include the following forms before sample collection:

1. **Test Requisition Form (TRF)**
2. **Consent Form**
3. **Biopsy Worksheet (required for all PGT-test services)**

If you do not have the necessary forms, request them from Customer Support (supportme@vitrolifegroup.com) at least one week before sample collection.

All the forms clearly state the mandatory fields to be completed. The Test Requisition Form must be signed by the referring Physician. The Informed Consent form must be signed by the patient.

Advance Notification

Notify Igenomix at supportme@vitrolifegroup.com, 24–48 hours prior for sample shipment or collection, including:

1. **Requested test services**
2. **Patient name and Medical Record Number**
3. **Accurate number of samples**

Submission of Documentation

1. All required documents hardcopies must be included in the kit provided by Igenomix.
2. If submitting documentation electronically, email all completed forms to Igenomix at supportme@vitrolifegroup.com before the samples are shipped or arrive at Igenomix.
3. Ensure all documents are completed for mandatory information.
4. Confirm receipt of your documents with Igenomix to prevent processing delays.
5. Electronic forms must be submitted in secure, standard file formats (e.g., PDF) and comply with data protection requirements.

Special Requests:

For any special instructions or requests concerning your samples or test service, email Customer Support supportme@vitrolifegroup.com OR **What's app Bot :+971 55 515 7021** at least 24–48 hours before your samples are expected to arrive at the Igenomix laboratory. Clearly specify the nature of your request, reference the relevant patient information (name and Medical Record Number), and confirm receipt with Customer Support to ensure your instructions are accurately followed and avoid processing delays.

Risks of Non-Compliance

1. Insufficient prior information about expected samples from the clinic may prevent Igenomix from accurately matching shipped and received samples, potentially compromising the chain of custody and the integrity of testing.
2. Not informing Igenomix of the exact number of expected samples can increase the risk of samples being lost or misplaced during transit or processing.
3. Failure to provide written special instructions in advance may result in incorrect sample handling or processing.
4. Incomplete or incorrect sample identification can lead to misidentification errors.
5. Inadequate documentation can reduce traceability throughout shipment and sample reception.
6. Failure to communicate promptly may cause delays in sample examination and reporting.
7. Not submitting a sample collection request to Customer Support may result in delayed pickup, missed deadlines, miscommunication, and inaccurate record-keeping.
8. To avoid these risks, please ensure all documentation and notifications are complete and submitted according to this instruction.

2.4.3 Professional user validation for PGT tests ('DRY RUN'):

Validation ("dry run") is strongly recommended for all embryologists performing embryo biopsy or tubing for Preimplantation Genetic Testing (PGT) procedures.

Embryologist Dry Run/Validation – Purpose:

The embryologist "dry run" or validation process is designed to evaluate an individual's ability to carry out all critical steps of embryo biopsy and sample preparation (tubing) for Preimplantation Genetic Testing (PGT) using Igenomix KIT & protocols. This process is essential to ensure consistent, high-quality results and reduce the risk of technical errors or sample contamination in clinical settings.

- Validation certificate and report are provided only after successful completion of a dry run coordinated with our

laboratory. A validation/dry run report is issued after the analysis and signed by a senior member of laboratory staff or the Laboratory Director.

- Embryologists who have been previously validated by an accredited diagnostic laboratory may be approved for clinical sample processing, subject to the Laboratory Director's review and authorization. In such cases, the clinic must provide relevant certification or documentation when requested. However, if the percentage of informativity in Preimplantation Genetic Testing (PGT) cases decreases considerably, it is strongly recommended to conduct a "dry run test" to evaluate and address potential issues.
- Each clinic must ensure that only validated embryologists are assigned to perform embryo biopsy or tubing for all PGT procedures. The clinic is also responsible for notifying our laboratory whenever new staff are introduced and for initiating the validation ("dry run") request as needed.
- Certificates cannot be retrospectively issued if a dry run or validation was not performed with our laboratory.
  - Validation certificates/report are issued based on the original context of the study (embryologist and clinic/organization at the time of validation).
  - If an embryologist previously validated by Igenomix (locally or at another group laboratory) moves to a new clinic, their prior validation is recognized for technical acceptance of samples, provided records are available.
  - However, a new certificate/report reflecting the current clinic name will only be issued if a repeat validation (dry run) is coordinated and completed under the new clinic's details. Retrospective certificate/reports with updated clinic names cannot be provided unless a corresponding study is performed.
  - For regulatory or accreditation purposes, clinics may reference the original validation certificate for the embryologist concerned.

How to Request Instructions and Documents

To initiate a dry run or validation process, please refer to the following documents:

DUB_L_I_PGT_002_EN: Instructions – PGT Tubing/Loading: Guidance on tubing using Igenomix kits and protocols

DUB_L_F_PGT_003_EN: PGT Dry Run Lab Setup & Embryologist Collection Form: Details of sample staff & clinic for validation study

DUB_L_I_PGT_003_EN: PGT Instructions – Dry Run: Procedure for collecting validation samples

Contact Details

For validation protocol instructions or certificate requests:

General Support: supportme@vitrolifegroup.com

Protocol Queries: embryology@igenomix.com

2.5 Sample Transportation Requirements in general:

IMP NOTE: Failure to follow these guidelines may result in delays, sample rejection, or regulatory issues.

Requirement	Description / Instructions
Pick-ups in UAE	Sample collection is available Monday through Sunday. Request courier pick-up at least 24 hours before desired collection. For scheduling/support, email: supportme@vitrolifegroup.com.
Pick-ups outside UAE	Contact us to arrange courier pick-up according to your location. Submit pick-up request at least 24 hours in advance. Before shipment, ensure your package includes all required documents: Airway Bill, Commercial Invoice, and Non-Declaration shipping documents (provided by Igenomix prior to collection).
Packaging & Labelling	Samples must be securely packed according to ADR "Packaging Instructions P650" (three-layer system: primary receptacle, secondary packaging, outer packaging). Clearly label as 'Exempt Human Specimen UN3373'. Ship via first class mail or secure courier (DHL, UPS, FedEx, etc.). These requirements apply to all shipments both within UAE and internationally.
General Packaging	Package all samples securely and send to the Igenomix laboratory address (refer to Section 1.0 for current address details).
Notification	Email supportme@vitrolifegroup.com to notify Igenomix when samples have been sent.
Additional Information	Service disruptions may occur on holidays; Igenomix will communicate any changes to pick-up schedules promptly. Contact support for any uncertainties about transportation or documents.

2.6 LABORATORY CRITERIA FOR ACCEPTING AND REJECTING SAMPLES

To maintain testing accuracy and patient safety, the laboratory adheres to strict criteria for accepting, rejecting, or temporarily holding samples. All samples are thoroughly reviewed before processing.

Sample Rejection Criteria

A sample may be rejected under the following circumstances:

a) Incorrect, missing, illegible, or damaged labelling or containers. This includes:

- Unlabelled sample containers
- Mislabelled or incorrectly identified samples
- Labels that are smeared, faded, or otherwise illegible
- Tubes or containers that are cracked, leaking, or otherwise damaged
- Use of expired sample collection materials.

b) Failure to meet specific test requirements, including:

- Inadequate timing for sample collection
- Insufficient sample quality or quantity
- Non-compliance with required patient biological status as outlined in test instructions

c) Non-validated primary containers or tubes (containers not validated by Igenomix).

d) Absence of dry ice or ice packs when temperature control is required.

e) Abnormal or questionable sample appearance.

f) Damaged secondary containers.

Standby Status Criteria

Samples may be placed on standby (not processed) rather than rejected in the following scenarios:

a) Incomplete sample documentation (Test Requisition Form and Informed Consent not fully completed).
b) Documentation missing (samples not accompanied by required forms).
c) Mandatory fields (*asterisked on forms) not completed.
d) Documentation not approved by Igenomix (e.g., forms in other languages, outdated forms, unauthorized logos).
e) Missing patient and/or physician signature on required documents.

Samples on standby or rejected are logged as an incident. Further action will proceed only after the issue is resolved and corrective measures have been taken.

Process Flow

a) Sample Receipt and Initial Review: All samples are inspected upon arrival for integrity, correct labelling, documentation, and conformity to test requirements.

b) Sample Classification

Each sample is classified as:

- Accepted: Ready for processing.
- Rejected: Not suitable for processing; reasons documented.
- Standby (Hold): Pending resolution of minor issues (e.g., incomplete documentation).

c) Incident Registration: Any sample placed on hold or rejected is registered in the incident management system.

All relevant details (sample ID, reason, time/date) are logged for audit trail and traceability.

d) User Communication: The sender (client/user) is promptly notified about the status of their sample and necessary actions (with specific feedback on issues if any).

e) Corrective Actions: Appropriate corrective measures are initiated to resolve issues, such as:

- Requesting missing or corrected documentation.
- Clarifying labelling discrepancies.
- Replacing damaged or non-compliant containers.

f) Follow-up and Resolution:

- Ongoing updates are provided to the user.
- Once corrective actions are complete, the sample is re-evaluated for acceptance.
- If unresolved, the sample is permanently rejected; resolution details are communicated to the user.

3 TESTS OFFERED

3.1 Tests performed in-house.

3.1.1 Preimplantation Genetic Testing for Monogenic Diseases (PGT-M)

PGT-M test description:	Preimplantation Genetic Testing for Monogenic (Single Gene) disorders, commonly referred to as PGT-M, is performed on embryos created via in vitro fertilization (IVF) to identify those unaffected by specific inherited conditions. The procedure requires a small amount of DNA from each embryo and relies on the analysis of familial variant(s) and/or informative Short Tandem Repeat (STR) and Single Nucleotide Polymorphism (SNP) markers, as defined by a prior pre-PGT-M study. This analysis is typically conducted using fluorescent PCR. These approaches require only a few cells from each embryo, allowing precise detection of inherited gene variants and HLA haplotypes. The main objective of PGT-M is to help at-risk families reduce the chance of transmitting a genetic disorder and to avoid the emotional and ethical challenges that may arise from prenatal diagnosis and potential pregnancy termination. Genetic counselling and informed consent are recommended prior to testing, and patients should be made aware of the limitations and possible risks of misdiagnosis. Confirmatory prenatal testing may be advised following embryo transfer to ensure diagnostic accuracy.

Pre-requirements for accepting a PGT-M case:

Step	Process Description
1. Case Initiation	The clinic, doctor, begins the process by submitting an initial inquiry for PGT-M via email to supportme@vitrolifegroup.com and me-gc@igenomix.com. This inquiry should include basic identifiers for the patient and partner.
2. Data Collection & Inheritance Assessment	The genetic counsellor conducts a comprehensive review by collecting medical history, reproductive history, and detailed family history. Genetic reports for the affected partner and selected family members are gathered. The counsellor also identifies the relevant gene and mutation and assesses the inheritance pattern (autosomal dominant, autosomal recessive, X-linked) as well as HLA matching if applicable.
3. Documentation Submission	The clinic emails a test requisition and carrier testing/mutation report to me-gc@igenomix.com. The report must clearly state the gene and mutation responsible for the condition being tested for PGT-M. Family history regarding the disease is also required for proper assessment.
4. Case Discussion with Genetic Counsellor	A counselling session is scheduled by clinic with the genetic counsellor to review all collected data, clarify outstanding questions, discuss the procedure and its implications, and align on next steps.
5. Outcome Communication	The genetic counsellor informs the clinic or doctor of the case outcome (acceptance or rejection). If accepted, the counsellor communicates details of sample requirements or any additional information needed to proceed.
6. Sample Collection & Submission	The clinic or doctor prepares and submits the required biological samples for **pre-PGT-M** as outlined in the instructions **DUB_L_I_PGT_012_EN: Pre PGT-M Instructions**. Samples must meet specified handling and quality standards.
7. Pre-PGT-M Execution	The laboratory performs **pre-PGT-M** testing and analysis to evaluate the quality and feasibility of proceeding with **PGT-M** based on the collected samples.
8. Feasibility Confirmation & Next Steps	After pre-PGT-M analysis, if the results are favourable, Igenomix Laboratory confirms the technical feasibility of proceeding with PGT-M. The genetic counsellor formally communicates the possibility of PGT-M to the clinic, allowing the case to advance to embryo testing according to the agreed protocol.

	09. Documentation & Follow-Up | The genetic counsellor updates the case file with all decisions, outcomes, and contact details, and arranges any necessary follow-up actions for ongoing support.
Pre PGT-M sample requirements:	In the referral response, the Igenomix laboratory will confirm the sample requirements for Pre-PGT-M. **1. Blood Samples** 4 ml of blood must be sent in EDTA (purple-top) tube(s) Store the sample at room temperature (15–25°C) until transport. **2. Buccal Samples** In some special cases, example:- where the blood transfusion is done in patient then GC will recommend for buccal swab samples. However, in 99% of cases only Blood samples in EDTA will be accepted. Gently rub the dry buccal swab against the inner cheek for 30 seconds to collect epithelial cells. Allow the swab to air dry and store at room temperature (15–25°C) until transport. **3. Stored DNA** In some special cases extracted POC DNA samples in case of deceased children previously tested in family might be requested upon case review by GC. For each DNA sample, we require 50-70ng of the DNA with a minimum concentration of 15-20 ng/µl, store at room temperature (15–25°C) until transport. Refer to **DUB_L_I_PGT_012_EN: Pre PGT-Instruction** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com
PGT-M sample requirement	Requires trophectoderm biopsy on blastocyst stage (day 5/6/7), with day 3 single-cell biopsy possible only after consultation and approval by the Igenomix laboratory. Storage temperature required: -20 °C. Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction and DUB_L_I_PGT_002_EN: Instructions - PGT Tubing** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com
Sample Transportation and KIT	Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample collection. Igenomix provides a PGT Kit and a thermal box with a cool-rack for the shipment of biopsies. Freeze the ice packs, and cool-rack before the shipment.
Turnaround time (TAT)	The Physician that has requested the test will receive the results. Pre-PGT-M results will be available within **4 weeks** for common mutations and **6-8 weeks** for the non-frequent mutations, from receipt of samples by Igenomix. PGT-M results will be available within **10 working days** from receipt of samples by Igenomix.
Pre PGT-M Reporting	**For pre-PGT-M the following results can be obtained:** - Fully Informative (FI): Each of the wild-type and mutant alleles in both members of the couple are unique. - Semi Informative (SI): The wild-type and mutant alleles have unique polymorphic marker, but one of the values is equivalent between both members of the reproductive couple. - Non-Informative (NI): The wild-type and mutant alleles have the same polymorphic marker in the individual carrying the mutation. - Not Applicable (NA): The individual does not carry a mutation or is carrying a mutation/variant in homozygous state and so informativity is not applicable.
PGT-M Reporting	**For PGT-M the following results can be obtained, for each embryo, as a result of performing this test:** - Normal: Embryo found not to inherit the "at risk haplotype". This embryo is expected to be unaffected by the indicated genetic mutation.

	- Carrier: Embryo found to inherit one parental "at risk haplotype". This embryo is expected to be a carrier for the tested genetic mutation, in the same way as the carrier parent(s). - Abnormal: Embryo found to inherit the parental "at risk haplotype". This embryo is expected to be affected by the indicated disorder. - At risk: This embryo has inherited the haplotype linked to the tested indication and is at risk of being affected. - Seek genetic counselling: Genetic counselling is recommended to discuss the risks of transferring this embryo. - No DNA detected: DNA was not detected, due to the absence of, or degraded DNA. - Non-informative: A reliable result could not be achieved due to factors such as Allele Drop Out (ADO), parental/external contamination, recombination, and others.

For further details on how to send the samples, please review the test instructions included on the Igenomix website or contact Igenomix Customer Support service (see section 1.2).

3.1.2 Preimplantation Genetic Testing for Aneuploidy (PGT-A) and PGT-Plus

PGT-A test description:	Preimplantation Genetic Testing for Aneuploidy (PGT-A) is a genetic screening performed on embryos during IVF to identify those with abnormal chromosome numbers. By analyzing a small sample of cells from each embryo, PGT-A examines all 24 chromosomes using Next Generation Sequencing (NGS) technology. This comprehensive test helps clinicians and patients select embryos with the highest chance of implantation and healthy development to term.
PGT-A Plus test Description	PGT-A Plus is an optional analysis that includes PGT-A for 24 chromosome aneuploidy screening and adds ploidy assessment, cohort check and contamination testing. Triploidy (when there is an additional set of all chromosomes) and haploidy (when there is only a single set of all chromosomes) are the most common ploidy abnormalities and are incompatible with normal growth and development. PGT-A Plus includes a QC analysis for embryos, confirming that embryos within a cohort demonstrate the expected sibling relatedness and assessing for DNA contamination. This analysis can reduce the risk of misdiagnosis and provide additional reassurance about the IVF process.
PGT-A sample requirement	**PGT-A test:** Permit both single-cell (blastomere) biopsy on day 3 of embryo development and trophectoderm biopsy at the blastocyst stage (day 5/6/7). Storage temperature required: -20 °C. Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction and DUB_L_I_PGT_002_EN: Instructions - PGT Tubing** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com.
PGT-A Plus sample requirement	PGT-A Plus: Typically require trophectoderm biopsy at the blastocyst stage (day 5/6/7). Storage temperature required: -20 °C. Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction and DUB_L_I_PGT_002_EN: Instructions - PGT Tubing** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample collection. Igenomix provides a PGT Kit and a thermal box with a cool-rack for the shipment of biopsies. Freeze the ice packs, and cool-rack before the shipment.

Turnaround time (TAT)	The Physician that has requested the test will receive the results. For PGT-A samples with Frozen Embryo Transfer (FET) cycle, results will be available within **7 working days** from receipt of samples by Igenomix. For PGT-A samples with fresh transfer results will be available on the morning of the next day following the receipt of samples by Igenomix For PGT-A Plus samples Report turnaround time (TAT) is **15 working days** following reception of samples and all required documents
PGT-A Reporting	Igenomix uses an internal validated algorithm (García-Pascual.C, et.al., 2020) for whole chromosome aneuploidies, partial deletion/duplications and mosaicism calling. The following results can be obtained: • **Euploid:** A result of "euploid" indicates that no chromosomal copy number changes were detected in the embryo biopsy. The embryo is expected to have the typical number of chromosomes necessary for normal growth and development. Embryos with less than 30% whole chromosome copy number variation and less than 50% segmental chromosome copy number variation will be reported as euploid. Euploid embryos have the highest chances of reproductive success and are recommended for transfer. • **Aneuploid:** A result of "aneuploid" indicates that a chromosomal copy number change was detected in the embryo biopsy. Aneuploidy is reported when there is a trisomy (three copies) or monosomy (a single copy) of a chromosome or chromosome segment. Embryos with greater than 70% chromosomal copy number variation will be reported as aneuploid. The reproductive potential of uniformly aneuploid embryos is low. • **Segmental aneuploid**: A result of "partial trisomy" or "partial monosomy" indicates that an imbalance of a chromosome segment was detected in the embryo biopsy. The breakpoints of the segmental aneuploidy and the fragment size in megabases (Mb) are provided following the p or q, which refer to the short or long arm of the chromosome, respectively. Segmental aneuploidy is detectable when a chromosomal imbalance is greater than 10 Mb and when the copy number variation is greater than 50%. Emerging evidence suggests that segmental aneuploidies may be mitotic in origin. • **Low mosaic:** An embryo is reported as mosaic when there is an intermediate chromosomal copy number change detected in the biopsy. An embryo with a mosaic result is at increased risk of being mosaic and may have more than one chromosomally distinct cell line. The level of mosaicism may vary in each biopsy and cannot predict the level of mosaicism in the embryo as a whole. Chromosomes reported as "low mosaic" have between 30% and 50% copy number variation in the biopsy. Low mosaic copy number variations will be reported for autosomes (1-22). Due to technical and biological limitations, low mosaicism for segmental imbalances and sex chromosomes cannot be reliably detected and may not be reported. Embryos reported as low mosaic have been shown to have significant reproductive potential. Whereas some studies suggest that they may have slightly lower implantation rates and higher risk of miscarriage (PMID: 33685629), the Igenomix non-selection study has shown clinical outcomes equivalent to euploid embryos (PMID: 34798051). Concordance studies show that biopsies with a low mosaic result are most likely to be concordant with a euploid inner cell mass (ICM) (PMID: 34798051). The 2021 PGDIS Position Statement on the Transfer of Mosaic Embryos states that mosaic embryos should not be disregarded in terms of suitability for transfer with good counseling (https://pgdis.org/docs/PositionStatement.pdf). The risk for mosaicism to persist throughout pregnancy or until birth, following transfer of an embryo reported as low mosaic, is reported to be low. • **High mosaic:** An embryo is reported as mosaic when there is an intermediate chromosomal copy number change detected in the biopsy. An embryo with a mosaic result is at an increased risk of being mosaic and may have more than one chromosomally distinct cell line. The level of mosaicism may vary in each biopsy and cannot predict the level of mosaicism in the embryo as a whole. Chromosomes reported as "high mosaic" have between 50% and 70% copy number variation in the biopsy. High mosaic copy number variations will be reported for autosomes (1-22), sex

chromosomes and segmental aneuploidies. Clinical outcome data from transfer of high mosaic embryos is still emerging, and there are no non-selection studies for the transfer of high mosaic embryos. Embryos reported as high mosaic may have some reproductive potential but with lower implantation rates and higher risk of miscarriage in comparison with euploid and low mosaic embryos (PMID: 33685629). The 2021 PGDIS Position Statement on the Transfer of Mosaic Embryos states that mosaic embryos should not be disregarded in terms of suitability of transfer with good counseling (https://pgdis.org/docs/PositionStatement.pdf). The risk for mosaicism to persist throughout pregnancy or until birth, following transfer of an embryo reported as high mosaic, is reported to be low; however, concordance studies show that biopsies with a high mosaic result are more likely to correspond with an aneuploid inner cell mass (ICM) (PMID: 34798051).

- **Complex mosaic:** An embryo is reported as "complex mosaic" when intermediate copy number variations in 2-5 chromosomes are detected in the biopsy sample. Embryos will not be reported as mosaic if there are one or more chromosomes with a full copy number change. If all chromosomes are in the low mosaic range, see "low mosaic" interpretation above. If one or more chromosomes are in the high mosaic range, see "high mosaic" interpretation above. Data on reproductive outcomes following transfer of embryos reported as complex mosaic is limited. Complex mosaics may have similar or slightly reduced chance of reproductive success compared to their single chromosome mosaic equivalent.
- **Complex aneuploid:** An embryo is reported as "complex aneuploid" when copy number variations in 2-5 chromosomes, at least one of which involves a full copy number change, are detected in the biopsy sample. If there is at least one chromosome with a full copy number change, mosaicism will not be reported.
- **Chaotic:** An embryo is reported as "chaotic" when copy number variations in 6 or more chromosomes are detected in the biopsy sample. The predictive value of the chaotic result may be reduced. Rebiopsy and retesting can be considered depending on blastocyst quality.
- **No DNA detected:** A result of "no DNA detected" is consistent with a biopsy sample containing enucleated cells. In some cases, cells may be lost during the washing procedure or may not be successfully transferred into the liquid buffer. Lastly, DNA might not be detected if it has degraded. Rebiopsy and retesting can be considered depending on blastocyst quality.
- **Non-informative:** When a reliable result cannot be achieved with high confidence, "non-informative" will be reported for that embryo. Rebiopsy and retesting can be considered according to blastocyst quality.
- **Morphology:** The morphology (embryo grade) included on this report is assessed and provided by the IVF center. Morphology is not determined by Igenomix.
- **MitoScore Ranking:** In euploid embryos with proper morphology, implantation could be improved using MitoScore. The last column shows the suggested according to the MitoScore value, that should be considered only after taking into account aneuploidy screening result and embryo morphology. Until the MitoScore RCT is done, the priority for the transfer should be always the morphology after a chromosomally normal embryo.
- **MitoScore Data Interpretation:** An increased amount of mitochondrial DNA in euploid embryos is related to poor implantation potential and may be indicative of reduced energetic reserve during oocyte maturation. The mitochondrial score ("MitoScore") is a value that represents the normalized mitochondrial DNA content in euploid embryos and mitochondrial DNA analyzed support the hypothesis that mitochondrial DNA copy number in the embryo is not a direct indicator of energetic capability, rather it is an index stress and thus it can potentially be used to predict their implantation capacity (Diez-Juan A, Rubio C et al. 2015). Healthy embryos split the total amount of mitochondrial DNA equally among all cells present during division. In embryos experiencing energetic stress, the mitochondrial biogenesis increases during early development compensating the mitochondrial DNA reduction caused by cell division. Thus, increased mitochondrial DNA in euploid embryos is an indication of reduced amount of energetic reserve during oocyte maturation that is reflected in reduced implantation rate.

	Nowadays, the NGS technique is used for the quantification of mitochondrial DNA. The value obtained and the algorithm designed and developed by Igenomix are the first version of this test. Given the evolution of the NGS and subsequent bioinformatic development, the predictive value of this test is considered experimental, and will be periodically adjusted by enhancements and updates, as capture of the mitochondrial DNA sequence improves. The optimizations of the test are and will be validated in a prospective, randomized, multicenter study that will determine the clinical value and its application as an independent test. It should be noted that small variations in the value of MitoScore are not relevant in the transfer priority.
PGT-A Plus Reporting	Additional to the PGT-A results, the following results can be obtained for each embryo when PGT-A Plus (ploidy and embryo QC) is requested: Ploidy and contamination results: • **Diploid:** Ploidy analysis is consistent with 2 sets of chromosomes and a diploid state (2N). Contamination was not detected. Diploidy is required for normal growth and development. Diploid embryos may be euploid or have chromosome copy number variations. • **Triploid:** Ploidy analysis confirms 3 sets of chromosomes and a triploid state (3N). Triploid embryos may have additional gains or losses of some chromosomes. Triploidy Is incompatible with normal growth and development, usually resulting in implantation failure, miscarriage, or molar pregnancy. • **Haploid:** Ploidy analysis is consistent with 1 set of chromosomes and a haploid state (1N). Haploid embryos may have additional gains or losses of some chromosomes. Haploidy is incompatible with normal growth and development. • **Ploidy Non-informative:** The ploidy analysis is non-informative. In normalized fertilized oocytes (2PN/2PB), the incidence of triploidy or haploidy is typically low (<1%; PMID: 30383227, 3190515) and embryos are most likely to be diploid. Contamination analysis is similarly non-informative. Embryo re-biopsy and retesting can be considered for embryos in which there is concern for triploidy or haploidy, such as for abnormally fertilized oocytes or for a reproductive history involving triploidy/molar pregnancy. • **Contamination detected:** Admixture of exogenous DNA is detected in the sample analyzed. The presence of exogenous DNA in the sample suggests that the NGS result might not be representative of the chromosomal status of the embryo. A euploid result with DNA contamination is not conclusive and possibility of aneuploidy, mosaicism, triploidy, or haploidy cannot be ruled out. Any intermediate copy number (mosaic) variation of an autosome observed by NGS will be interpreted as uniform aneuploidy. If variations consistent with XX/XY admixture are observed, the sex chromosomes will be considered non=informative. The ploidy status of an embryo with contamination detected cannot be determined. Rebiopsy and retesting can be considered for embryos with a euploid result, depending on blastocyst quality. Cohort check results: • **Consistent:** The sample demonstrates the expected genetic relatedness to other samples submitted for the patient, suggesting that the sample belongs to the patient's cohort of embryos. The result for the sample analyzed is expected to represent the embryo. • **Inconsistent:** A genetic relationship was not established between the sample and other samples submitted for the patient. When the cohort check is inconsistent, the sample might not represent the intended embryo. The NGS result may not be applicable and is not reported. Rebiopsy and retesting can be considered depending on blastocyst quality. • **Non-informative**: Genetic relatedness analysis between the sample and other samples in the patient's cohort was non-informative. Low DNA quality, the presence of copy number variations in the biopsy, and genetic variation can result in a non-informative analysis. This result does not suggest the need for rebiopsy or retesting. • **N/A**: Not applicable. The cohort check is not performed (i) for embryos with haploid or triploid results; (ii) for contaminated samples; (iii) when there is only one embryo available for analysis; (iv) or when insufficient DNA is detected.

3.1.3 Preimplantation Genetic Testing for structural rearrangements (PGT-SR)/ PGT-SR Plus

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 parental chromosomal rearrangement. This method uses NGS to analyses all 24 chromosomes and requires multiple trophectoderm cells from a blastocyst biopsy. Currently, PGT-SR at Igenomix USA has been validated to detect chromosomal abnormalities that are ≥ 6Mb
PGT-SR Plus Description	PGT-SR Plus is an optional analysis that includes PGT-SR and adds ploidy assessment, cohort check and contamination testing. Triploidy (when there is an additional set of all chromosomes) and haploidy (when there is only a single set of all chromosomes) are the most common ploidy abnormalities and are incompatible with normal growth and development. PGT-SR Plus includes a QC analysis for embryos, confirming that embryos within a cohort demonstrate the expected sibling relatedness and assessing for DNA contamination. This analysis can reduce the risk of misdiagnosis and provide additional reassurance about the IVF process.
Pre-requirements for accepting a PGT-SR case:	Before starting a PGT-SR cycle, the couple needs to submit the karyotype report detailing the structural chromosomal anomaly to their prescribing physician. The report is then reviewed by Igenomix staff, who may request a pre-PGT-SR genetic study if necessary. This preliminary study analyses a DNA sample from the individual carrying the chromosomal abnormality to determine if PGT-SR is suitable for their case and to develop an appropriate diagnostic approach for the cycle
Pre PGT-SR sample requirement	For pre-PGT-SR (if required), 4 mL of peripheral blood (in EDTA or Heparin-Lithium tubes, as requested by the Igenomix staff to the prescribing physician) from the carrier of the structural chromosomal abnormality (and/or other family members if required) are needed. Based on the outcome of the pre-PGT-SR, the laboratory will inform the IVF clinic by email whether PGT-SR can be offered.
PGT-SR sample requirement	Typically require trophectoderm biopsy at the blastocyst stage (day 5/6/7). PGT-SR allows single-cell biopsy on day 3 only for Robertsonian translocation cases, followed by fresh transfer, only after consultation and approval by the Igenomix laboratory. Storage temperature required: -20 °C. Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction and DUB_L_I_PGT_002_EN: Instructions - PGT Tubing** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com.
PGT-SR Plus sample requirement	PGT-SR Plus: Typically require trophectoderm biopsy at the blastocyst stage (day 5/6/7). Storage temperature required: -20 °C. Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction and DUB_L_I_PGT_002_EN: Instructions - PGT Tubing** for more details. For access to this, please contact Igenomix Customer Support at supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_PGT_013_EN: PGT Kit Test Instruction** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample collection. Igenomix provides a PGT Kit and a thermal box with a cool-rack for the shipment of biopsies. Freeze the ice packs, and cool-rack before the shipment.
Turnaround time (TAT)	The Physician that has requested the test will receive the results. For pre-PGT-SR, results will be available within 4 weeks from receipt of samples by Igenomix. For PGT-SR samples results will be available within **10 working days** from receipt of samples by Igenomix.

	For PGT-SR Plus Report turnaround time (TAT) is **15 working days** following reception of samples and all required documents
Pre PGT-SR Reporting	For pre-PGT-SR there are two possible results: • The structural alteration that is the subject of study for pre-PGT-SR can be detected; therefore, PGT-SR can be offered. • The structural alteration that is the subject of study for the pre-PGT-SR cannot be detected, therefore, The PGT-SR cannot be offered.
PGT-SR Reporting	For PGT-SR, Igenomix uses an internal validated algorithm for whole chromosome aneuploidies, partial deletion/duplications and mosaicism calling. The following results can be obtained as a result of performing this test: • **Euploid/balanced:** A result of "euploid/balanced" indicates that no chromosomal imbalances or copy number changes were detected in the embryo biopsy. PGT-SR is unable to distinguish carriers and non-carriers of the balanced rearrangement. The embryo is expected to have the necessary number of chromosomes and/or the necessary amount of genetic material to support normal growth and development. Embryos with less than 30% full chromosome copy number variation and less than 50% segmental chromosome copy number variation will be reported as euploid/balanced. Euploid/balanced embryos have the highest chances of reproductive success and are recommended for transfer. • **Aneuploid:** A result of "aneuploid" indicates that a chromosomal copy number change was detected in the embryo biopsy. Aneuploidy is reported when there is a trisomy (three copies) or monosomy (a single copy) of a chromosome or chromosome segment. The aneuploidies detected are presumed to be unrelated to the chromosomal rearrangement carried by the gamete source. Embryos with greater than 70% copy number variation will be reported as aneuploid. The reproductive potential of uniformly aneuploid embryos is low. • **Segmental aneuploid:** A result of "partial trisomy" or "partial monosomy" indicates that an imbalance of a chromosome segment was detected in the embryo biopsy. The breakpoints of the segmental aneuploidy and the fragment size in megabases (Mb) are provided following the p or q, which refer to the short or long arm of the chromosome, respectively. Reported segmental aneuploidies are at least 6 Mb in size and are detectable when the copy number variation is greater than 50%. Emerging evidence suggests that sporadic segmental aneuploidies may be mitotic in origin. Embryos with segmental imbalances related to the balanced rearrangement will be classified as aneuploid/unbalanced (see above). Segmental imbalances related to the balanced rearrangement are unlikely to be mosaic and are expected to have high predictive value. • **Low mosaic:** An embryo is reported as mosaic when there is an intermediate chromosomal copy number change detected in the biopsy. An embryo with a mosaic result is at increased risk of being mosaic and may have more than one chromosomally distinct cell line. The level of mosaicism may vary in each biopsy and cannot predict the level of mosaicism in the embryo as a whole. Chromosomes reported as "low mosaic" have between 30% and 50% copy number variation in the biopsy. Low mosaic copy number variations will be reported for autosomes (1-22). Due to technical and biological limitations, low mosaicism for segmental imbalances and sex chromosomes cannot be reliably detected and may not be reported. Embryos reported as low mosaic have been shown to have significant reproductive potential. Whereas some studies suggest that they may have slightly lower implantation rates and higher risk of miscarriage (PMID: 33685629), the Igenomix non-selection study has shown clinical outcomes equivalent to euploid embryos (PMID: 34798051). Concordance studies show that biopsies with a low mosaic result are most likely to be concordant with a euploid inner cell mass (ICM) (PMID: 34798051). The 2021 PGDIS Position Statement on the Transfer of Mosaic Embryos states

that mosaic embryos should not be disregarded in terms of suitability for transfer with good counseling (https://pgdis.org/docs/PositionStatement.pdf). The risk for mosaicism to persist throughout pregnancy or until birth, following transfer of an embryo reported as low mosaic, is reported to be low.

- **High mosaic:** An embryo is reported as mosaic when there is an intermediate chromosomal copy number change detected in the biopsy. An embryo with a mosaic result is at increased risk of being mosaic and may have more than one chromosomally distinct cell line. The level of mosaicism may vary in each biopsy and cannot predict the level of mosaicism in the embryo as a whole.

  Chromosomes reported as "high mosaic" have between 50% and 70% copy number variation in the biopsy. High mosaic copy number variations will be reported for autosomes (1-22), sex chromosomes and segmental aneuploidies. Clinical outcome data from transfer of high mosaic embryos is still emerging, and there are no non-selection studies for the transfer of high mosaic embryos. Embryos reported as high mosaic may have some reproductive potential but with lower implantation rates and higher risk of miscarriage in comparison with euploid and low mosaic embryos (PMID: 33685629).

  The 2021 PGDIS Position Statement on the Transfer of Mosaic Embryos states that mosaic embryos should not be disregarded in terms of suitability of transfer with good counseling (https://pgdis.org/docs/PositionStatement.pdf). The risk for mosaicism to persist throughout pregnancy or until birth, following transfer of an embryo reported as high mosaic, is reported to be low; however, concordance studies show that biopsies with a high mosaic result are more likely to correspond with an aneuploid inner cell mass (ICM) (PMID: 34798051).
- **Complex mosaic:** An embryo is reported as "complex mosaic" when intermediate copy number variations in 2-5 chromosomes are detected in the biopsy sample. Embryos will not be reported as mosaic if there are one or more chromosomes with a full copy number change. If all chromosomes are in the low mosaic range, see "low mosaic" interpretation above. If one or more chromosomes are in the high mosaic range, see "high mosaic" interpretation above. Data on reproductive outcomes following transfer of embryos reported as complex mosaic is limited. Complex mosaics may have similar or slightly reduced chance of reproductive success compared to their single chromosome mosaic equivalent.
- **Complex aneuploid:** An embryo is reported as "complex aneuploid" when copy number variations in 2-5 chromosomes, at least one of which involves a full copy number change, are detected in the biopsy sample. If there is at least one chromosome with a full copy number change, mosaicism will not be reported.
- **Chaotic:** An embryo is reported as "chaotic" when copy number variations in 6 or more chromosomes are detected in the biopsy sample. The chromosomes involved in the chaotic aneuploid result may or may not be related to the balanced rearrangement. The predictive value of the chaotic result may be reduced. Rebiopsy and retesting can be considered depending on blastocyst quality.
- **No DNA detected:** A result of "no DNA detected" is consistent with a biopsy sample containing enucleated cells. In some cases, cells may be lost during the washing procedure or may not be successfully transferred into the liquid buffer. Lastly, DNA might not be detected if it has degraded. Rebiopsy and retesting can be considered depending on blastocyst quality.
- **Non informative:** When a reliable result cannot be achieved with high confidence, "non-informative" will be reported for that embryo. Rebiopsy and retesting can be considered according to blastocyst quality.
- **MitoScore Ranking**: In euploid embryos with proper morphology, implantation could be improved using MitoScore. The last column shows the suggested according to the MitoScore value, that should be considered only after taking into account aneuploidy screening result

	and embryo morphology. Until the MitoScore RCT is done, the priority for the transfer should be always the morphology after a chromosomally normal embryo. • **MitoScore Data Interpretation:** An increased amount of mitochondrial DNA in euploid embryos is related to poor implantation potential and may be indicative of reduced energetic reserve during oocyte maturation. The mitochondrial score MitoScore is a value that represents the normalized mitochondrial DNA content in euploid embryo transfers and mitochondrial DNA analyzed support the hypothesis that mitochondrial DNA copy number in the embryo is not a direct indicator of energetic capability, rather it is an index stress and thus it can potentially be used to predict their implantation capacity (Diez-Juan A, Rubio C et al. 2015). Healthy embryos split the total amount of mitochondrial DNA equally among all cells present during division. In embryos experiencing energetic stress, the mitochondrial biogenesis increases during early development compensating the mitochondrial DNA reduction caused by cell division. Thus, increased mitochondrial DNA in euploid embryos is an indication of reduced amount of energetic reserve during oocyte maturation that is reflected in reduced implantation rate. Nowadays, the NGS technique is used for the quantification of mitochondrial DNA. The value obtained and the algorithm designed and developed by Igenomix are the version 1 of this test. Given the evolution of the NGS and subsequent bioinformatic development, the predictive value of this test is considered experimental, and will be periodically adjusted by enhancements and updates, as capture of the mitochondrial DNA sequence improves. The optimizations of the test are and will be validated in a prospective, randomized, multi-center study that will determine the clinical value and its application as an independent test. It should be noted that small variations in the value of MitoScore are not relevant in the transfer priority.
PGT-SR Plus Reporting	Additional to the PGT-SR results, the following results can be obtained for each embryo when PGT-SR Plus (ploidy and embryo QC) is requested: Ploidy and contamination results: • **Diploid:** Ploidy analysis is consistent with 2 sets of chromosomes and a diploid state (2N). Contamination was not detected. Diploidy is required for normal growth and development. Diploid embryos may be euploid or have chromosome copy number variations. • **Triploid:** Ploidy analysis confirms 3 sets of chromosomes and a triploid state (3N). Triploid embryos may have additional gains or losses of some chromosomes. Triploidy Is incompatible with normal growth and development, usually resulting in implantation failure, miscarriage, or molar pregnancy. • **Haploid:** Ploidy analysis is consistent with 1 set of chromosomes and a haploid state (1N). Haploid embryos may have additional gains or losses of some chromosomes. Haploidy is incompatible with normal growth and development. • **Ploidy Non-informative:** The ploidy analysis is non-informative. In normalized fertilized oocytes (2PN/2PB), the incidence of triploidy or haploidy is typically low (<1%; PMID: 30383227, 3190515) and embryos are most likely to be diploid. Contamination analysis is similarly non-informative. Embryo re-biopsy and retesting can be considered for embryos in which there is concern for triploidy or haploidy, such as for abnormally fertilized oocytes or for a reproductive history involving triploidy/molar pregnancy. • **Contamination detected:** Admixture of exogenous DNA is detected in the sample analyzed. The presence of exogenous DNA in the sample suggests that the NGS result might not be representative of the chromosomal status of the embryo. A euploid result with DNA contamination is not conclusive and possibility of aneuploidy, mosaicism, triploidy, or haploidy cannot be ruled out. Any intermediate copy number (mosaic) variation of an autosome observed by NGS will be interpreted as uniform aneuploidy. If variations consistent with XX/XY admixture are observed, the sex chromosomes will be considered non=informative. The ploidy status of an embryo with contamination detected cannot be determined. Rebiopsy and retesting can be considered for embryos with a euploid result, depending on blastocyst quality.

	Cohort check results: • **Consistent:** The sample demonstrates the expected genetic relatedness to other samples submitted for the patient, suggesting that the sample belongs to the patient's cohort of embryos. The result for the sample analyzed is expected to represent the embryo. • **Inconsistent:** A genetic relationship was not established between the sample and other samples submitted for the patient. When the cohort check is inconsistent, the sample might not represent the intended embryo. The NGS result may not be applicable and is not reported. Rebiopsy and retesting can be considered depending on blastocyst quality. • **Non-informative:** Genetic relatedness analysis between the sample and other samples in the patient's cohort was non-informative. Low DNA quality, the presence of copy number variations in the biopsy, and genetic variation can result in a non-informative analysis. This result does not suggest the need for rebiopsy or retesting. • **N/A:** Not applicable. The cohort check is not performed (i) for embryos with haploid or triploid results; (ii) for contaminated samples; (iii) when there is only one embryo available for analysis; (iv) or when insufficient DNA is detected.

3.1.4 Embryo priority test (EMBRACE)

EMBRACE Description	EMBRACE is a non-invasive test used in combination with in vitro fertilization (IVF) treatments to prioritize embryos for transfer. Embryos release small DNA fragments (cell-free DNA) into the culture media in which they are grown. The analysis of the cell-free DNA in the culture medium gives an estimate of the embryo's chromosomal content. The assessment is most effective during the embryo's later stage of development, at least 6 days after egg retrieval. EMBRACE analyzes the embryonic cell-free DNA released by a blastocyst-stage embryo into the media in which it has been cultured. The number of chromosomes is assessed, without a biopsy, in order to identify embryos with the best chance of resulting in a healthy baby. This information can be used to establish the order of priority for embryo transfer. The Igenomix USA prioritization system is based on a multicenter study comparing the chromosome screening results from trophectoderm biopsies (cells collected from the outer edge of a blastocyst) and from the embryonic cell-free DNA present in the culture media of more than 1,301 blastocysts (Rubio et al., 2019, 2020). For each culture medium result, the probability for the blastocyst to have a normal/euploid trophectoderm result was calculated and represented as the Euploidy Score. The embryos with higher Euploidy Scores are prioritized as the first candidates for transfer. The goal of the assessment is to allow all embryos to remain candidates for transfer and not to exclude any embryos with reproductive potential.
EMBRACE sample requirement	Refer to **DUB_L_I_PGT_004_EN: EMBRACE-IVF Lab Protocol / DUB_L_I_PGT_008_EN: EMBRACE - IVF Lab Protocol (Embryoscope), DUB_L_I_PGT_006_EN: EMBRACE Test Instructions**, for detailed instruction on EMBRACE sample requirement and protocol for sample collection and handling. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The protocol specifies that spent blastocyst culture medium should be collected from embryos at the blastocyst stage, on either day 6 or day 7 of development with a small volume of 5-15 microlitres. Samples must be promptly centrifuged and frozen at -20°C for at least 24 hours prior to shipment to ensure integrity.
Sample Transportation and KIT	Refer to **DUB_L_I_PGT_006_EN: EMBRACE Test Instructions** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or

	requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic must notify the laboratory before a sample is ready and the laboratory will offer to arrange for sample collection. The PGT kit provided by Igenomix must be used for the shipment, including the cooler box: freeze the ice packs, cool-rack and biopsied samples before the shipment.
Professional user validation for EMBRACE tests (DRY RUN):	We recommend performing a "validation" or "dry run" for every IVF laboratory. This process aims to provide reduce the likelihood of difficulties with clinical cases that could lead to a failure to determine a result(s) for the culture media. Refer to **DUB_L_I_PGT_004_EN: EMBRACE-IVF Lab Protocol/ DUB_L_I_PGT_008_EN: EMBRACE - IVF Lab Protocol (Embryoscope), DUB_L_I_PGT_010_EN: EMBRACE - Dry Run with PGT-A (Embryoscope), DUB_L_I_PGT_007_EN: EMBRACE_Dry Run without PGT-A, DUB_L_I_PGT_009_EN: EMBRACE - Dry Run without PGT-A (Embryoscope)**. Instructions on how to complete a "validation run" can be requested by email to the Customer Support service at supportme@vitrolifegroup.com. A validation/dry run report is issued after the analysis and signed by a senior member of laboratory staff or the Laboratory Director.
Turnaround time (TAT)	The Physician that has requested the test will receive the results. For EMBRACE samples all cases will be with Frozen embryo transfer (FET) cycle and results will be available within 7 working days from receipt of samples by Igenomix.
EMBRACE Reporting	Igenomix uses an internal validated algorithm for whole chromosome aneuploidies and partial deletion/duplications. This algorithm estimates the euploidy score of each medium. As a result, a priority order is established for each medium according to the euploidy score based on the results that can be obtained, for each culture media: • **Normal/euploid**: when there are two copies of each chromosome pair, and no partial deletion/duplications ≥10Mb in size are detected. • **Abnormal/aneuploid:** when there is an abnormal copy number for one or more chromosomes and/or partial deletion/duplications ≥10Mb in size are detected. There are different combinations of chromosomal abnormalities and each of them is associated to a different euploidy score. • **No DNA detected:** when insufficient DNA is detected in the sample. • **Non informative:** when the quality of the sample is suboptimal and leads to an NGS result below the required quality thresholds. In samples with no DNA-detected or non-informative a euploid score is given to each sample according to the aneuploidy risk associated to the corresponding female age.

3.1.5 Testing for Products of Conception (POC)

POC Test 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.
Pre-requirements for accepting a POC case:	No specific pre-requirements are needed in order accept a case. Specific test indications and relevant clinical information can be reported in the test requisition form.
POC sample requirement	Tissue from the lost pregnancy is required. A tissue sample with a minimum size of 3x3 mm, preferably without blood, must be placed in a specimen pot (usually provided by the laboratory) and covered with saline solution. In addition, and as a control to test for maternal contamination and polyploidy (when appropriate) by STR analysis, 1x4ml of peripheral blood from the mother in EDTA tubes (provided by the laboratory) is required.

	Instructions on how to prepare a sample are available (**DUB_L_I_POC_001_EN: Instructions_POC_EN**) and can be downloaded from the Igenomix website or requested by email at supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_POC_001_EN: Instructions_POC** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic needs to notify Igenomix when a sample will be ready, and the laboratory will offer to arrange for sample collection. Transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature. We recommend shipping the samples with a cold gel pack if outside temperatures exceed 35°C. Avoid freezing the sample when introducing the cold gel pack.
POC Turnaround time (TAT)	The Physician that has requested the test will receive the results within **10 working days** from sample reception by Igenomix.
POC Reporting	The following results can be obtained as a result of performing this test: • **Normal/Euploid:** A normal result indicates the presence of two copies of every chromosome, including 22 pairs of autosomes and a pair of sex chromosomes. A normal result will be reported if two copies for each autosome (1 through 22) and two sex chromosomes (XX for female or XY for male) are found. • **Monosomy:** Monosomy is a state in which one chromosome of a normal pair is absent. The majority of monosomies are not compatible with life. Monosomy will be reported if any chromosome is missing. The report will show "abnormal" in the result field, followed by "monosomy" before the affected autosome (chromosomes 1-22) and "X0" or "Y0" if the sex chromosomes are affected. • **Trisomy:** Trisomy is a state in which one chromosome of a normal pair is duplicated. The majority of trisomies are not compatible with life. Trisomy will be reported if there are any extra chromosomes detected. The report will show "abnormal" in the result field, followed by "trisomy" before the affected autosome (chromosomes 1-22) and "XXX, XXY, or XYY" if the sex chromosomes are affected. • **Partial monosomy/trisomy:** Partial monosomy or trisomy are referred to the deletion (loss) or duplication (gain) of a piece of chromosome, respectively. Partial monosomies or trisomies diagnosed in a fetus or live birth are generally associated with physical or cognitive abnormalities. The report will show "abnormal" in the result field, followed by "partial monosomy" or "partial trisomy" before the affected chromosome, arm (p, q), cytoband and fragment size in megabases (Mb). • **Haploid/triploid/tetraploid:** Haploid is a state in which there is only one copy of every chromosome instead of the normal two. Triploid is a state in which there are three copies of every chromosome instead of the normal two. Tetraploid is a state in which there are four copies of every chromosome instead of the normal two. The report will show "abnormal" in the result field, followed by "haploid/triploid/tetraploid" and the information of the sex chromosomes. • **Maternal Cell Contamination (MCC):** Despite taking multiple dissections, a POC sample may still only yield maternal information. Results reflecting maternal cell contamination are not actionable. • **Non-informative:** If the quality of the sample is suboptimal, we may be unable to obtain results. This is most likely to occur because of DNA degradation following improper storage or shipment conditions.

4.0 OUTSOURCED TEST

Igenomix offers different tests that are currently outsourced including: Endometrial Receptivity Analysis (ERA), Endometrial Microbiome Metagenomic Analysis (EMMA), Analysis of Infectious Chronic Endometritis (ALICE);

4.1 ERA

ERA Description	The lack of synchronization between the embryo, which must be ready to be implanted and endometrial receptivity is believed to be one of the causes of recurring implantation failure. ERA is a test that was 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 (through NGS) on material biopsied from the endometrium. Following the analysis, a specific computational predictor classifies the samples according to their expression profile in the corresponding endometrial stage (proliferative, pre-receptive, receptive, late receptive or post-receptive). This data will enable a personalized embryo transfer (pET), synchronizing endometrial receptivity with an embryo prepared for implantation.
Pre-requirements for accepting an ERA case:	No specific pre-requirements are needed in order accept an ERA case. We strongly encourage you to carefully read the "ERA-EMMA-ALICE Manual" for further information in addition to the specific ERA-EMMA-ALICE test instructions. You can download these documents from the Igenomix website (https://www.igenomix.net/).
ERA sample requirement	Endometrial tissue (~70mg by mass or ~7mm by size) placed in a cryotube containing RNA stabilizing solution (1,5 ml) provided by the laboratory. The ERA test requires an endometrial biopsy that should be carried out on day LH+7/HCG+7 (natural cycle) or day P+5 (Hormone Replacement Therapy cycle), or following the usual clinical protocol for blastocyst transfer. The cryotube containing the sample must be refrigerated (4-8 °C) for a minimum of 4 hours before shipping. For shipment, the cryotube containing the endometrial biopsy must be placed inside a blister as secondary container. In order to obtain a fully confident test result, the **DUB_L_I_ERA_002_EN: ERA-EMMA-ALICE - Manual EndomeTRIO - EN** details must be strictly followed. This document can be downloaded either from the Igenomix website (https://www.igenomix.net/) or requested by email to the Customer Support service at supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_ERA_001_EN: Instructions_ERA,** for detail instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic needs to notify Igenomix when a sample will be ready, and the laboratory will offer to arrange for sample collection. Transportation will be conducted in custom-made kits provided by the laboratory. Carriage is at Room Temperature. We recommend shipping the samples with a cold gel pack if outside temperatures exceed 35°C. Avoid freezing the sample when introducing the cold gel pack. To maintain sample stability, transit at room temperature should not exceed 5 days in order to ensure the preservative action of the liquid in the cryotube.
Turnaround time (TAT)	The clinician that has requested the test will receive the results within **15 working days** from sample reception by Igenomix.
ERA Reporting	The result of the test can be: • **Receptive (R):** This gene expression profile is compatible with a normal, receptive endometrium. In this case, we recommended performing a blastocyst(s) transfer following the same protocol utilized during this Endometrial Receptivity Analysis (ERA) test. • **Late Receptive (eT):** This gene expression profile means that the endometrium is at the end of the receptive stage. In this case, we recommend advancing the embryo transference 12 hours regarding the moment in which the biopsy was taken.

	• **Proliferative (F):** This gene expression profile is concordant with an endometrium at a proliferative stage. We recommend that you contact the ERA laboratory to evaluate the protocol in which this endometrial biopsy was performed. • **Pre-receptive (PREd1/PREd2):** This gene expression profile is concordant with an endometrium at a pre-receptive stage due to the potential displacement of the window of implantation. For some results, we may require analysis of a second biopsy on the recommended day to be able to provide a transfer timing recommendation. • Post-receptive (T): This gene expression profile is concordant with an endometrium at a post-receptive stage due to the potential displacement of the window of implantation. To confirm this result, analysis of a second biopsy on the recommended day is required. • **Non-informative:** The profile analyzed does not match the control gene expression profiles present in the ERA predictor. We recommend that you contact the ERA laboratory to evaluate the protocol in which this endometrial biopsy was performed. • **Insufficient RNA:** It was not possible to determine the gene expression profile of the sample because there was not enough genetic material. A new endometrial biopsy is required. • **Invalid RNA:** It was not possible to determine the gene expression profile of the sample due to the poor quality of genetic material obtained. A new endometrial biopsy is required. The ERA report for most samples includes a recommendation for performing a personalized embryo transfer (pET). For some patients, as indicated above, another biopsy may be required.

4.2 Endometrial Microbiome Metagenomic Analysis (EMMA)

EMMA Description	A molecular test that provides microbiota information in endometrial tissue by analyzing a customized panel of bacteria. It includes information about Lactobacillus and potentially pathogenic bacteria of the reproductive tract, some of them related to Chronic Endometritis. This method is based on detecting bacterial DNA through real-time polymerase chain reaction (RT-PCR) which translates into different profiles that have been linked to the success of pregnancy. Igenomix reserves the right to analyse EMMA samples using NGS technology, subject to prior notification and information to the customer. EMMA can be beneficial for any woman wishing to conceive, especially those with recurrent implantation failure and recurrent pregnancy loss, by analyzing the microbial environment of the uterine cavity including the most frequently bacterial pathogens that cause Chronic Endometritis (CE). The EMMA test always includes the ALICE test.
Pre-requirements for accepting an EMMA case:	No specific pre-requirements are needed in order accept an EMMA case. We strongly encourage you to carefully read the "ERA-EMMA-ALICE Manual" for further information in addition to the specific ERA-EMMA-ALICE test instructions. You can download these documents from the Igenomix website How to send a sample - Middle East (igenomix.net)
EMMA sample requirement	A single endometrial biopsy is sufficient for the EndomeTRIO test (includes ERA, EMMA, and ALICE). If the clinic's standard ERA protocol includes a double biopsy, please note that microbiome analysis will only be performed on the first biopsy. If an ERA test is requested, the endometrial biopsy must be taken according to the ERA timing provided in the EndomeTRIO manual (120 hours of progesterone exposure in an HRT cycle or 168 hours after hCG administration in a natural cycle or following the routine protocol for blastocyst transfer). It is imperative to properly control endogenous progesterone by ensuring levels are <1ng/ml within the 24 hours prior to the first intake of exogenous progesterone (in HRT cycles). If only an EMMA test is requested, the endometrial biopsy may be taken following the same protocol as for ERA or between days 15 and 25 of a natural cycle (only for patients with regular

	cycles between 26-32 days). If the patient does not have regular cycles, we recommend performing an HRT cycle and taking the sample during the progesterone intake days, preferably at day P+5. Alternatively, ovulation can be controlled, and the sample can be taken between LH/hCG+2 and LH/hCG+12, or between Ov+1 and Ov+11. Another option is to collect the sample while the patient is on Oral Contraceptive Pills (OCPs) between day 14-21 of active pills (if the patient takes placebo pills) or after day 14 and onwards if taking active pills continuously (note: not as all OCPs are valid for EMMA testing, we recommend checking it with our specialists before scheduling the biopsy). The endometrial biopsy must be taken from the uterine fundus. Sample size should be approx. 70 mg and not exceed the white line marked on the Igenomix cryotube. Larger samples may still be evaluated to determine if the genetic material has been properly preserved. If this is not the case, a new sample will be requested. Ensure that the sample is made up of endometrial tissue and not solely blood or mucus. Label the cryotube with the patient's full name, DOB, and date of biopsy. As the microbiome can fluctuate over time, the samples should be sent as soon as possible, following the minimum 4-hour refrigeration period. In order to obtain a fully confident test result, the ERA-EMMA-ALICE Manual details must be strictly followed. This document can be downloaded either from the ERA-EMMA-ALICE website (How to send a sample - Middle East (igenomix.net)), the Igenomix website or requested by email supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_ERA_001_EN: Instructions_ERA,** for detailed instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic needs to notify to Igenomix when a sample will be ready, and the laboratory will offer to arrange for sample collection. Transportation will be conducted in custom-made kits provided by the laboratory. Shipment can be at Room Temperature. We recommend shipping the samples with a cold gel pack if outside temperatures exceed 35 ^{o}C. To maintain sample stability, transit at room temperature should not exceed 5 days to ensure the preservative action of the liquid in the cryotube.
Turnaround time (TAT)	The Physician that has requested the test will receive the results within **15 Working days** from sample reception by Igenomix.
EMMA Reporting	The EMMA report will provide information about the overall microbial health of the uterine cavity. This includes: • One table showing information about detection of DNA from Lactobacillus spp and for species (L. crispatus, L gasseri, L. iners and L. jensenii) • One table showing the reference ranges for 16 species of common reproductive tract pathogens (*Actinomyces israelii, Atopobium vaginae, Bacteroides fragilis, Bifidobacterium spp, Clostridium sordelii, Fusobacterium nucleatum, Gardnerella vaginalis, Haemophilus ducreyi, Mobiluncus spp, Mycobacterium tuberculosis, Peptostreptococcus anaerobius, Porphyromonas asaccharolytica, Prevotella bivia, Prevotella disiens, Sneathia spp* and *Treponema pallidum*) and the values obtained in the endometrial sample. • One table with ALICE results, showing the reference ranges for 10 species of pathogens causing chronic endometritis (CE) (*Streptococcus agalactiae* (group B) and *Streptococcus viridans*, *Staphylococcus aureus, Enterococcus faecalis, Mycoplasma hominis, Mycoplasma genitalium, Escherichia coli, Klebsiella pneumoniae, Ureaplasma urealyticum, Chlamydia trachomatis* and *Neisseria gonorrhoeae*) and the values obtained in the endometrial sample. • In cases in which there are no pathogens detected out of their reference range, if at least one of the Lactobacillus species or Lactobacillus spp are detected, this is considered a normal result.

	• In case that DNA from *Haemophilus ducreyi, Mycobacterium tuberculosis, Treponema pallidum, Neisseria gonorrhoeae* and/or *Chlamydia trachomatis* is detected in the endometrial sample, an additional confirmatory test could be recommended according to endometrial profile. Infections caused by these bacteria are mandatory notification to the local Health Authorities in different countries. In the case that these pathogens are identified, it is the doctor's responsibility to declare these infections. • In case that DNA from *Actinomyces israelii, Clostridium sordelii* and/or *Fusobacterium nucleatum* is detected in the endometrial sample, an additional confirmatory test and follow-up by a physician will be recommended. • Values of pathogens out of the reference range are identified with an asterisk and highlighted in bold. • EMMA report includes a suggested therapy (if needed) considering each specific bacterium detected out of the reference range, to achieve a *Lactobacillus*-dominated reproductive tract, increasing the chances of achieving pregnancy, as is describes in the scientific literature. However, is the medical professional who must consider the possible prescription of an antibiotic and/or probiotic treatment in conjunction with the available clinical findings of each patient. In the case of prescribed treatment, it is also recommended to analyze a new biopsy after its completion to confirm normalized values of pathogens. The new sample must be taken following the standard test protocol. In some other cases, for some patients, another biopsy may be suggested.

4.3 Analysis of Infectious Chromic Endometritis (ALICE)

ALICE Description	ALICE is a molecular test performed using RT-PCR, which detects the presence of DNA from potentially pathogenic bacteria that most frequently cause chronic inflammation of the endometrium, known as Chronic Endometritis (CE). This disease has been linked to infertility and obstetric complications. Igenomix reserves the right to analyses ALICE samples using NGS technology, subject to prior notification and information to the customer. ALICE can be helpful in determining which pathogenic bacteria are present in the uterine cavity and which may be the cause of chronic endometritis. These results may help determine the most appropriate treatment to eliminate the potential pathogens causing the disease.
Pre-requirements for accepting an ALICE case:	No specific pre-requirements are needed in order accept an ALICE case. We strongly encourage you to carefully read the "ERA-EMMA-ALICE Manual" for further information in addition to the specific ERA-EMMA-ALICE test instructions. You can download these documents from the Igenomix website How to send a sample - Middle East (igenomix.net)
ALICE sample requirement	A single endometrial biopsy is sufficient for the EndomeTRIO test (includes ERA, EMMA, and ALICE). If the clinic's standard ERA protocol includes a double biopsy, please note that microbiome analysis will only be performed on the first biopsy. If an ERA test is requested, the endometrial biopsy must be taken according to the ERA timing provided in the EndomeTRIO manual (120 hours of progesterone exposure in an HRT cycle or 168 hours after hCG administration in a natural cycle, or following the routine protocol for blastocyst transfer). It is imperative to properly control endogenous progesterone by ensuring levels are <1ng/ml within the 24 hours prior to the first intake of exogenous progesterone.

	If only the ALICE test is requested, the endometrial biopsy may be taken following the same protocol as for ERA or between days 15 and 25 of a natural cycle (only for patients with regular cycles between 26-32 days). If the patient does not have regular cycles, we recommend performing an HRT cycle and taking the sample during the progesterone intake days, preferably at day P+5. Alternatively, ovulation can be controlled, and the sample can be taken between LH/hCG+2 and LH/hCG+12, or between Ov+1 and Ov+11. Another option is to collect the sample while the patient is on Oral Contraceptive Pills (OCPs) between day 14-21 of active pills (if the patient takes placebo pills) or after day 14 and onwards if taking active pills continuously (note: not as all OCPs are valid for ALICE testing, we recommend checking it with our specialists before scheduling the biopsy). The endometrial biopsy must be taken from the uterine fundus. Sample size should be approx. 70 mg and not exceed the white line marked on the Igenomix cryotube. Larger samples may still be evaluated to determine if the genetic material has been properly preserved. If this is not the case, a new sample will be requested. Ensure that the sample is made up of endometrial tissue and not solely blood or mucus. Label the cryotube with the patient's full name, DOB, and date of biopsy. As the microbiome can fluctuate over time, the samples should be sent as soon as possible, following the minimum 4-hour refrigeration period. In order to obtain a fully confident test result, the ERA-EMMA-ALICE Manual details must be strictly followed. This document can be downloaded either from the ERA-EMMA-ALICE website (How to send a sample - Middle East (igenomix.net)), the Igenomix website or requested by email supportme@vitrolifegroup.com.
Sample Transportation and KIT	Refer to **DUB_L_I_ERA_001_EN: Instructions_ERA,** for detailed instruction on sample transportation requirement. This document can be found and downloaded from the website or requested by email to the Customer Support service at supportme@vitrolifegroup.com. The clinic needs to notify to Igenomix when a sample will be ready, and the laboratory will offer to arrange for sample collection. Transportation will be conducted in custom-made kits provided by the laboratory. Shipment can be at Room Temperature. We recommend shipping the samples with a cold gel pack if outside temperatures exceed 35 ^{o}C. To maintain sample stability, transit at room temperature should not exceed 5 days to ensure the preservative action of the liquid in the cryotube.
Turnaround time (TAT)	The Physician that has requested the test will receive the results within **15 Working days** from sample reception by Igenomix.
ALICE Reporting	The ALICE report will provide information about the bacteria that most frequently cause chronic inflammation of the endometrium, known as Chronic Endometritis (CE). This includes: • The ALICE report shows a table with the reference ranges for 10 species of reproductive tract pathogens most often related to chronic endometritis (*Streptococcus agalactiae* (group B) and *Streptococcus viridans, Staphylococcus aureus, Enterococcus faecalis, Mycoplasma hominis, Mycoplasma genitalium, Escherichia coli, Klebsiella pneumoniae, Ureaplasma urealyticum, Chlamydia trachomatis and Neisseria gonorrhoeae*) and the values obtained in the endometrial sample. Values of pathogens out of the reference range are identified with an asterisk and highlighted in bold. • In case *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis* are out of the normal range, an additional confirmatory test will be recommended. Infections caused by these bacteria are mandatory notification to the local Health Authorities in different countries. In the case that these pathogens are identified, it is the doctor's responsibility to declare these infections. • ALICE report includes suggested therapy (if needed) taking into account each specific bacterium detected out of the reference range, to increase the chances of achieving a healthy pregnancy as described in the scientific literature. However, is the medical professional who must consider the possible prescription of an antibiotic and/or probiotic treatment in

	conjunction with the available clinical findings of each patient. In the case of prescribed treatment, it is also recommended to analyze a new biopsy after its completion to confirm normalized values of pathogens. The new sample must be taken following the standard test protocol. In some other cases, for some patients, another biopsy may be suggested

5 CERTIFICATION, ACCREDITATION AND EXTERNAL ASSESSMENT SCHEMES

IGENOMIX LABORATORY is Commercially, and Operationally Licensed by Dubai Health Authority (DHA) as a Medical Laboratory specialized in Molecular Genetics. We are also CAP certificated (College Of American Pathology), since 2016 (CAP NUMBER 9051461, AU-ID: 1753304) for the PGT-A, PGT-SR & PGT-M tests, In addition, POC are included in the scope in 2024. The laboratory annually participates in External Quality Assessments (EQA) (also known as Proficiency Testing, PT) with internationally recognized schemes accredited to ISO 17025 or offered by CAP organizations.

For some tests, no EQA scheme is available. For these tests, the lab performs an internal Alternative Assessment (AA) twice a year to provide objective evidence for the acceptability of examination results.

All tests that are included in certification/accreditation schemes participate in any assessment program (either PT or AA) that may further assist in the continued assessment of the reliability of the offered tests by Igenomix.