

	<b>Title</b>	<b>CODE</b> US_M_P_009_EN	<b>VERSION</b> 1.0
	<b>USER MANUAL</b>	<b>Author (Name):</b> Belén Arnau, Adedoyin Akinwale, Refik Kayali, Sue Robles, Francisco Dueñas	<b>Date of issue:</b> April/29/2019
		<b>Authorized by (Name):</b> Brynn Levy, Cengiz Cinnioglu, Victor Llinares	<b>Date of next review:</b> April/29/2020
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# USER MANUAL

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## 1.0 IGENOMIX USA

### 1.1 INTRODUCTION

Igenomix USA is a private medical testing laboratory specializing in reproductive genetic services and is part of a multinational company (Igenomix SL) with headquarters in Valencia, Spain. There are three Igenomix laboratories in the USA: Los Angeles (LA), New York (NY) and Miami labs. The laboratories currently perform four tests in-house: Preimplantation Genetic Testing for Aneuploidy (PGT-A) (LA, NY, Miami), and Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR) (LA, NY, Miami), Products of Conception (POC) (LA, NY, Miami), Endometrial Receptivity Analysis (ERA) (Miami). The laboratory offers other services that are currently outsourced to the headquarters in Spain including testing Preimplantation Genetic Testing for Monogenic Disorders (PGT-M), Sperm Aneuploidy Testing (SAT), Endometrial Receptivity Analysis (ERA).

### 1.2 LABORATORY OPENING TIMES

Laboratories are open 24/7 based on an as-needed basis to best service our client's need.

### 1.3 CONTACT DETAILS

General Enquiries:

Email:

[infousa@igenomix.com](mailto:infousa@igenomix.com)

Tel: 305-5014948

Laboratory enquiries:

Email:

LA lab: [lablosangeles@igenomix.com](mailto:lablosangeles@igenomix.com)

NY lab: [labnewyork@igenomix.com](mailto:labnewyork@igenomix.com)

Miami lab: [labmiami@igenomix.com](mailto:labmiami@igenomix.com)

Tel: 305-5014948

### 1.4 ADDRESS

Miami

7955 NW 12th St. Suite 415

Miami, FL 33126

Phone: +1 (305) 501-4948

Fax: +1 (786) 401-7546

Los Angeles


383 Van Ness Ave.

Suite 1605

Torrance, CA 90501

New York

30 Montgomery Street

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Suite 270  
Jersey City, NJ 07302

## 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 US website and can also be requested by email at: [infousa@igenomix.com](mailto:infousa@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 [infousa@igenomix.com](mailto:infousa@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 HIPAA REGULATIONS.

### 2.2 TESTS OFFERED


#### 2.2.1 Tests performed in-house

The laboratory currently performs four tests in-house: Preimplantation Genetic Testing for Aneuploidy (PGT-A) (LA, NY, Miami), and Preimplantation Genetic Testing for Chromosomal Rearrangements (PGT-SR)(LA, NY, Miami), Endometrial Receptivity Analysis (ERA) (Miami), and Products of Conception (POC) (LA, NY, Miami).

#### **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” and “padding” 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

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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 analyzed 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. Please also include the provided padding in the shipment of samples.

Turnaround time: Report turnaround time (TAT) is 7 days following sample reception.


### **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 trophoctoderm cells from a blastocyst biopsy. Currently, PGT-SR at Igenomix USA has been validated to detect chromosomal abnormalities that are  $\geq 6\text{Mb}$ .

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” and “padding” 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

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“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 analyzed 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. Please also include the provided padding in the shipment of samples.

Turnaround time: Report turnaround time (TAT) is 7 days following sample reception.


**Important notes:**

- Unlabeled 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.

**Endometrial Receptivity Analysis (ERA)**

Description: The lack of synchronization 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 personalized embryo transfer (pET), synchronizing 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

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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 15 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 7 days following sample reception.

### **Important notes:**

- Unlabeled 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 US is responsible in ensuring that Reports for outsourced tests are provided to the clinician/healthcare professional making the initial request

### **2.2.2 Outsourced tests**

The laboratory currently offers other tests that are outsourced to the headquarters in Spain including Preimplantation Genetic Testing for Monogenic Disorders (PGT-M), Endometrial Receptivity Analysis (ERA), and Sperm Aneuploidy Testing (SAT).

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### **Preimplantation Genetic Testing for Monogenic Diseases (PGT-M)**

Description: PGT-M may be performed on embryos during in vitro fertilization (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 CMS/CAP 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 US. 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 favorable 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:



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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” and “padding” 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 analyzed 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°C freezer and 4°C fridge respectively until sending them along with the samples back to the laboratory. Please also include the provided padding in the shipment of samples.

Turnaround time (TAT): The setup of a protocol (PGT-M workup) is case-dependent and varies between 3 to 6 weeks. Once the samples arrive at the laboratory, the report TAT

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is 15 days.

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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 15 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.

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Turnaround time: Report TAT is 15 days.

### 3.0 REFERRALS

Before referrals can be made, clinics need to complete the “Clinic Enrolment Form (CEF)” which can be requested by email from [infousa@igenomix.com](mailto:infousa@igenomix.com). Once the form is completed it should be sent by email to [infousa@igenomix.com](mailto:infousa@igenomix.com). Biopsy worksheet (embryo manifest) needs to be completed and included in the kit along with the sample to be sent to the laboratory. Embryo biopsy worksheet form can be requested by email from [infousa@igenomix.com](mailto:infousa@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 the corresponding lab email addresses prior to sending the sample (please email [infousa@igenomix.com](mailto:infousa@igenomix.com) or call 305-501-4948 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 consent forms must be signed by the patient.

The consent forms (Consent and HIPAA) must be signed by the patient. Report will not be released until all forms (Requisition, consent and HIPAA) are on file.

### 4.0 ACCREDITATION AND ENROLMENT IN EXTERNAL ASSESSMENT SCHEMES

The laboratory participates annually in Genomics Quality Assessment (GenQA) schemes, American Association of Bioanalysts (AAB) Proficiency Tests and performs internal proficiency tests.