

PGT-A, PGT-SR & PGT-M - INSTRUCTIONS



Step 1: Contact us

Call **+34 963 905 310** or send us an email at:

PGT-A & PGT-SR: **supportspain@igenomix.com, labpgsspain@igenomix.com or embryology@igenomix.com**
PGT-M: **supportspain@igenomix.com, pgdmonogenicspain@igenomix.com or embryology@igenomix.com**

- Get more information about the test
- Request your test
- Request a pick-up

Prior to starting a PGT cycle, it is important that you understand the documentation requirements. This will depend on the services that you require:

- If Igenomix biopsy and tubing services are **not** required:
 - For PGT fresh embryo transfers: fill out the test requisition form in advance of the embryo biopsy and submit the form by email to labsamples@igenomix.com, labpgsspain@igenomix.com and embryology@igenomix.com.
 - For PGT frozen embryo transfers: it is not necessary to send the test requisition form/biopsy worksheet in advance.
- If the biopsy service is required: send the test requisition form/biopsy worksheet with as many fields completed as possible. This should be completed and sent when the patient is starting the COS (Controlled Ovarian Stimulation).

If you do not have the test requisition form/biopsy worksheet, please inform us about the following information at least one week before the biopsy. Send the information to embryology@igenomix.com with the following details:

- Unique patient ID/Medical Record Number and patient initials
- Start-date of controlled ovarian stimulation
- Possible date of transvaginal oocyte retrieval

All documents (test requisition form and biopsy worksheet) must be included in the box provided by Igenomix.

Basic Concepts

• **PGT-SR (Preimplantation Genetic Testing for Structural Rearrangements)**

- A prior genetic consultation with Igenomix is required (labpgsspain@igenomix.com) to assess the possibility and method of PGT-SR. The outcomes following the assessment can be:
 - * Direct PGT-SR, with no need of prior study.
 - * A prior study for assessment (pre-PGT-SR) may be necessary: in this case, a blood sample from the carrier in an EDTA tube is required in order to perform NGS analysis and evaluate the possibility of detecting potential imbalances in the embryos.
- The PGT-SR protocol only permits blastocyst biopsy on day 5/6/7 of development and deferred transfer. A biopsy of 4-8 trophectoderm cells is required. Day 3 biopsy and fresh transfer is only available for Robertsonian translocations.

• **PGT-A (Preimplantation Genetic Testing for Aneuploidies):**

- The PGT-A protocol permits both types of biopsy: single cell biopsy on day 3 of development and trophectoderm biopsy.

• **PGT-M (Preimplantation Genetic Testing for Monogenic Disease):**

- A previous consultation with Igenomix is required (pgdmonogenicspain@igenomix.com) to assess the possibility and strategy of PGT-M.
 - * A prior study (pre-PGT-M) is always required. Blood or buccal swabs from the couple and other family members will be requested during the answer to the genetic consultation.
- The PGT-M protocol permits blastocyst biopsy on day 5/6/7 of development. A biopsy of 4-8 trophectoderm cells is required. Ask for the possibility of day 3 biopsy if needed.

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Step 2: Receipt of the Kit

Check the Kit (IMPORTANT: use of gloves when handling the contents to avoid any contamination) and ensure that it includes the following:

- 2-3 gel packs (must be stored in a freezer at -20°C for a minimum of 24 hours before the sample is sent).
- 1 cool rack inside an envelope kept at -20°C until it is used. Do not remove the cool rack from the envelope until the time of use.
- 1 pack containing:
 - Washing/loading solution; verify the expiration date of the reagent and store at 4°C.
 - Bag with eppendorf PCR tubes 0.2 ml. These can be stored along with the washing/loading solution in the fridge at 4°C, without opening the bag until the time of use.



Note: Don't discard the kit. The kit will be used to return the samples to Igenomix once the biopsy has been taken.



Step 3: Important guidance

The following cases may lead to sample rejection:

- Samples not accompanied by their documentation (Test Requisition Form and Informed Consent)
- Sample documentation (Test Requisition Form and Informed Consent) has not been correctly completed
- Mandatory fields in sample documentation, identified on the forms with an asterisk (*), have not been completed
- Missing patient and/or clinician signature on the Test Requisition and Informed Consent
- Missing karyotype in the Test Requisition Form for PGT-SR cases.

Ensure to include the identity of the person that performs the biopsy.



Step 4: Tube labelling

Label the tubes with unique identifying information (one of the following options). Ensure all tubes are labeled.

Blood samples (pre-PGT-SR)

- Option 1: Patient initials or Full name and Date of Birth or
 - Option 2: Patient initials or Full name and Unique Patient ID
- Incorrectly labelled or unlabelled samples may be rejected.

If shipping is not performed immediately, we recommend storing the sample(s) in the fridge (4°C) until the shipment is performed.

Blood samples (pre-PGT-M)

Please contact our Customer Support Department for further details for the pre-PGT-M samples.

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Embryo samples (PGT-A, PGT-SR, PGT-M)

- Identify the samples as described in the Tubing/Loading protocol. Please contact our Customer Support Department for further details.
- Place the cool rack with all samples inside a freezer (-20°C) for at least one hour before the shipment.
- If the shipment is not organised for the same day as the biopsy, we recommend keeping the rack with the samples at -20°C until the shipment is performed.

Note: For unused solutions (remains of washing/loading solution) and empty receptacles (i.e. washing/loading container), Igenomix recommends use of authorized disposal organizations to ensure the disposal of waste complies with any local regulations.



Embryo samples (PGT-A, PGT-SR, PGT-M)

Insert the cool rack with the samples (previously frozen at -20°C) for at least one hour before the shipment into a bag that is provided in the Kit (provided by Igenomix). Put the cooled rack between the gel packs, in the same way that they were received. To keep the rack cool during the shipment, it is very important to use the gel packs provided by Igenomix. Fold and place the Test Requisition & Consent Form and the sample inside the kit. Documents must be correctly completed and signed.

Blood samples (Pre-PGT-SR and Pre-PGT-M)

1. We recommend including a cold gelpack inside the Kit if outside temperatures exceed 35°C. Take care to avoid freezing the sample when adding the gelpack. For further details, please contact Customer Support.
2. Place the blood sample in a plastic container to avoid any damage during the shipment. The plastic container should be placed into a padded envelope or box to avoid movement of the tube during the shipment.
3. Fold and place the Test Requisition & Consent Form and the sample inside the Kit. Documents must be correctly completed and signed. Put the kit inside the shipping bag (courier bag).

To ensure sample integrity is not compromised, which may lead to test failure and another sample collection, please adhere to the following hours of operation:

Blood sample collection (pre-PGT-SR and pre-PGT-M)/Embryo sample collection (PGT-A, PGT-SR, PGT-M)

- Pick-ups in Spain:
 - From Monday to Thursday
 - Contact us at least 3 hours before your preferred collection time to request a courier
 - Contact us for collections on Friday
- Pick-ups outside Spain:
 - Contact us and we will schedule the pick-up according to your location
 - Contact us at least 24 hours before your preferred collection time to request a courier
 - Ensure that the shipping bag (courier bag) includes an UN3373 or Exempt Human Specimen label and it is visible
 - International collection for PGT in fresh transfer cycles is not currently available
- Holidays may cause service disruptions. In the event of any disruption, Igenomix will notify you of any changes that apply to the pickups.
- For PGT cases with fresh transfer, it is mandatory to receive the samples at Igenomix no later than 9am of the day after the biopsy.

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Step 6: Test results

The **clinician that has requested the test** will receive the results of the sample from Igenomix.

- pre-PGT-SR samples:

Results will be available within **4 weeks** from receipt of samples by Igenomix.

- pre-PGT-M samples:

Results will be available within **3 weeks** for common mutations and **6 weeks** for the non-frequent mutations, from receipt of samples by Igenomix.

- PGT-A & PGT-SR samples with deferred transfer:

Results will be available within **7 working days** from receipt of samples by Igenomix.

- PGT-A & PGT-SR (Robertsonian translocation only) samples with fresh transfer:

Results will be available on the morning of the day following the receipt of samples by Igenomix.

- PGT-M samples:

Results will be available within **10 working days** from receipt of samples by Igenomix.



Additional information

For any questions or concerns and to request sample collection

+34 965 023 460

 pickup@igenomix.com

Please contact our Customer Support Department for further details for the **pre-PGT-M** instructions.