

BLOOD KIT INSTRUCTIONS

This kit is specifically intended for the collection, preservation and transport of blood samples until they arrive at Igenomix's facilities. It is designed to be used exclusively by trained medical professionals within a medical setting and is not meant for self-testing or at-home use. The kit does not contain any automated components and all procedures must be carried out manually by healthcare staff. Additionally, it is a single-use kit and should not be reused.



Step 1: Contact us

For EU - By telephone at +34 963 905 310 or contact us by email at **supportspain@igenomix.com**

For UK - Contact us by email at support.uk@igenomix.com

- Request more information about the test.
- Request documentation in print format or in other languages, free of charge.



Step 2: Receipt of the Kit

Review the contents of the kit BLOOD and ensure that it contains:

- 1 EDTA tube (CE-IVD) (**Do not use if the product is near its expiration date, taking into account estimated logistics and delivery times.**) + 1 rigid plastic blister
- Courier Shipping bag.
- Test request and informed consent sheet can be downloaded from the website or completed in the Portal.
- Igenomix QR code stickers*.

For further information, check the tube manufacturer's instructions: BD Vacutainer® Plus EDTA tube, Ref. 368857, BD.

Store the Kit at room temperature, below 25°C, prior to use.

Note: If the tube expiry date has elapsed or the package is damaged, thus compromising the sterility of the material, dispose of it in accordance with valid local regulations and contact Igenomix to receive a new Kit.

*** Attach one QR sticker to the EDTA tube and the other to the Test Request Form. Alternatively, if requesting the test through the portal please enter the QR code number into the portal.**



Step 3: Sample collection

Warnings/Precautions:

If applicable to the patient, please ensure that you inform us of any:

1. Bone marrow transplant,
2. Blood transfusion (<60 days) and/or
3. Congenital or acquired chimerism.

Fasting is not required.

Missing or incomplete documentation may lead to sample rejection. Ensure that:

- Samples are accompanied by their Test Requisition Form and Informed Consent*
- Sample documentation has been completed correctly
- Mandatory fields in the sample documentation, identified with an asterisk (*), have been completed.
- Patient and clinician signatures are included

*Note: Not applicable if ordering through the portal.

Sample collection:

- EDTA tube: Collect 3ml of blood. If there is not enough blood in the tube, our laboratory may not accept the sample. Should this occur, in order to process the sample, the laboratory will contact the clinic. For new-borns, collect at least 1ml; 3ml is the recommended amount.
- After blood draw, immediately mix the contents by gently inverting 8 to 10 times.
- Do not freeze the tube after the sample is taken.

After taking the sample:

- **If using the portal: place one QR code sticker to the sample collection tube and label the tube with patient initials and date of birth.** Enter the number that appears on the QR code into the clinic information (step 3), 'tube identification code' field.
- **If using test request form: place one QR code sticker to the sample collection tube and the other to the test request form.**
- If QR code stickers are not available, clearly label the tube with at least two identifiers, such as patient initials and date of birth.
- If the tube is not properly labelled, our laboratory may not accept the sample.
- Place the EDTA tube inside the rigid plastic blister and insert them in the kit. If using paper copies, include the previously filled out and signed informed consent and request forms. Then place the box inside the plastic return shipping bag.
- If the sample is not going to be sent immediately after it is taken, store the sample in the fridge (never in the freezer) at 4°C until shipping.

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Step 4: Transporting the sample

- Samples can be sent at room temperature (do not send frozen samples). If samples are not sent immediately, they must not be stored for more than 48h prior to shipping.
- We recommend using the cardboard packaging provided by Igenomix for returning the sample.
- When the outdoor temperature is higher than 30°C, additional measures must be taken to prevent deterioration of the sample during transport. We recommend using cold packs or similar devices, at all times ensuring that the sample does not become frozen. If in doubt, please contact our customer service department.



Step 5: Sample pick-up

To prevent the sample stability from being compromised, which could lead to a test failure or the need to take another sample, we recommend following these instructions:

For picking up the sample in the European Union:

Pick-ups in Spain:

 **+34 965 023 460**  **pickup@igenomix.com**

- Monday to Friday.
- A 3-hour margin of time is required to arrange for sample pick-ups.

Pick-ups in Italy:

 **+39 0424472449**  **supportitalia@igenomix.com**

- Monday to Friday
- A 24-hour margin of time is required to arrange for sample pick-ups.

Pick-ups in other countries of the European Union. Use contact info from pick-ups in Spain and take into account the following:

- Check availability with our customer service department.
- A 24-hour margin of time is required to arrange for sample pick-ups.
- Check that the return bag for the courier bears an adhesive label stating UN3373 or Exempt Human Specimen in a visible place.

For picking up the sample in the UK:

 **support.uk@igenomix.com**

- Domestic same-day collection is available for requests made prior to 13:30, Monday to Thursday.
- Arrange the courier by email up to 5 days in advance or on the day of draw.

Holidays: The aforementioned days may differ in the event of holidays. In such cases, our customer service department will notify you in advance of the available pick-up days.

We recommend sending samples as quickly as possible in order to ensure the quality of the sample.



Step 6: Test results

Igenomix will send the test results to the requesting clinician. The test results will be available within a period that depends on the requested service. For further information, please contact our customer service department.

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Additional information

In the event of serious incidents:

Any serious incident involving the materials supplied in this kit must be promptly reported to vigilance@igenomix.com and to the appropriate health authority in the Member State where the user or patient is located.

Symbols key:



Manufacturer



Use-by date



European Conformity



In vitro diagnostic medical device



Keep away from sunlight



Temperature limit



Do not use if the package is damaged



Do not re-use



Keep dry



Consult instructions for use



Authorised Representative



Importer



IGENOMIX SPAIN.LAB; S.L.U.
Calle Narcís Monturiol Estarriol n°11
Parcela B, Edificio Europark,
Parque Tecnológico de Paterna
46980 - Paterna - Valencia, Spain



MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland