

NEW BORN SCREENING BLOOD CARD KIT

INSTRUCTIONS

The intended use of this kit is the collection and conservation of the sample until it reaches the Igenomix facilities. These instructions are addressed to the Health Care Professional only.



Step 1: Contact us

Call +34 965 028 150 or send an email to teayudamos@igenomix.com for queries regarding any of the following:

- Further information about the test
- Request the test
- Request a pick up of the kit after collecting the sample



Step 2: Receipt of the kit

Check the kit and make sure that it includes the following:

- A QIAcard Bloodstain blood collection filter paper card.
- Test Requisition Form and Consent Form.
- Biohazard plastic bag.
- Shipping bag (courier bag).

Note 1: Kit must be stored at room temperature. Open the kit with sterile gloves to avoid contamination. In case the expiration date of the kit has passed and/or the package is damaged in a way that the sterilization may be compromised, dispose it according to the local legislation and contact Igenomix to receive a new kit.

Note 2: Don't dispose the kit cardboard envelope. After taking the sample, this envelope will be used to send it to Igenomix.



Step 3: Sample Collection

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

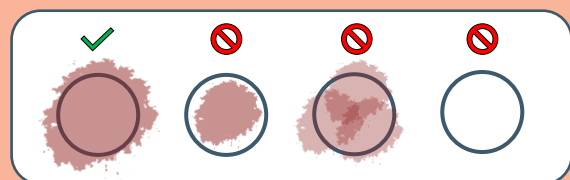
- Samples are accompanied by all required documentation:
 - Test Requisition Form
 - Informed Consent
- Sample documentation has been correctly completed:
 - Mandatory fields have been completed
 - Patient and clinician signatures are included

Please, note the following:

- Stain the circles completely. It is preferable to have two circles completed than four incompleting.
- Only apply one blood drop per collection circle.
- Do not press the filter paper against the puncture area.
- Do not apply too much pressure to the puncture area. This will avoid haemolysis and the collection of other tissue fluids.
- Do not touch the blood stains on the filter card with hands or any other object.

Instructions for sample collection:

1. Apply gentle pressure around the puncture area to increase the blood flow. Recommended puncture area: heel for newborn and ring finger for children and adults.
2. Hold the blood collection card by the corners and place the blood drop in the middle of the first circle, filling the area, as shown in the diagram below.



3. Repeat the process three more times, until all four circles are completely filled.
4. Allow the card to dry at room temperature for at least 3-4 hours in a horizontal position. Label the sample with the patient name.
5. Once the sample is dried, place the card in the plastic bag marked as Biohazard. Then, introduce it, at the same time, in the kit envelope and the envelope in the courier bag.

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Step 4: Logistics

- Send the sample at room temperature.
- We recommend that samples are returned in the kit provided by Igenomix. If, for any reason it has been discarded, contact the pick up service before proceeding.
- The sample must be placed in the biohazard plastic bag which then must be placed in the kit envelope.
- Place the completed consent form, test requisition form and biohazard bag inside the kit envelope.
- Place the kit envelope in the courier envelope that is provided by Igenomix.
- Any serious incident related to the materials in the kit must be notified by e-mailing vigilance@igenomix.com and the local health authority where the user and/or the patient resides.



Step 5: Sample pick up

To ensure sample integrity is not compromised, please adhere to the following hours of operation:

- Pickups in Spain: From Monday to Thursday. Contact us for a Friday pick up.
- Pickups outside Spain (Europe): From Monday to Wednesday (all day) and Thursday until 12 am. Contact us for different timeframes.
- Holidays may cause service disruptions. In the event of any disruption, Igenomix will notify you of any changes that apply to the pickups.
- We recommend that you ship the samples as soon as possible, in order to guarantee the quality of the sample.

To arrange the pick up, please contact:



+34 96 502 34 60



pickup@igenomix.com



Step 6: Test Results

Igenomix will send the test results to you or to the clinician that has requested the test

The results of the test will be available within the period agreed.



Additional information

To request additional information or to solve doubts, please do not hesitate to contact us:



+34 965 028 150



teayudamos@igenomix.com