

ERA - EMMA - ALICE - ENDOMETRIO - INSTRUCTIONS

These instructions should only be followed if your doctor has recommended for you to request the EndomeTRIO Kit from Igenomix (or any of the tests: ERA – EMMA – ALICE). Otherwise, please contact your doctor as these tests can only be prescribed by a specialist.



Step 1: Payment and Customer Enrollment Form

Patient must complete the Customer Enrollment Form (CEF) and complete the payment as described.

Collect:

- CEF (Must be signed by the Patient)
- Payment Bank Transfer Receipt

Send everything to supportspain@igenomix.com to receive the collection kit.



Step 2: Receipt of the Kit

Check the Kit and ensure that it includes the following materials:

- Cryotube with 1.5 ml of a transparent solution
- Rigid plastic blister (secondary container)
- Pipelle (check expiration date)
- Shipping bag (courier bag)



Step 3: Day of biopsy

Important guidance:

- After carefully reading the EndomeTRIO manual, the referring doctor should determine the cycle type, clinical treatment protocol and biopsy date. **Documents to require the test can be requested to: supportspain@igenomix.com**
- 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

Biopsy:

- A single endometrial biopsy is sufficient for an EndomeTRIO test (includes ERA, EMMA and ALICE)
- Sample size: it is important not to exceed the white line marked on the cryotube (provided by Igenomix). Larger samples may still be evaluated to determine whether the genetic material has been properly preserved. If this is not the case, a new sample will be requested.
- If an ERA test is requested (alone or together with the other tests), the endometrial biopsy must be taken according to the instructions provided in the EndomeTRIO manual (visit our website for additional info).
- * Label the tube with unique identifying information (one of the following options):
 - Option 1: Date of the biopsy, Patient initials or Full name and Date of Birth or
 - Option 2: Date of the biopsy, Patient initials or Full name and Unique Patient ID

Incorrectly labelled or unlabelled samples may be rejected.

After the Biopsy:

- The sample should be transferred immediately to the supplied cryotube and shaken vigorously for a several seconds.
- The cryotube containing the sample should be transferred to a refrigerator (4-8°C) immediately and must be stored there for at least 4 hours. After this time, samples may be sent to Igenomix at room temperature.
- ERA: Samples may also be kept in a refrigerator for up to 3 weeks or may be frozen at -20°C (after the first 4 hours at 4-8°C) if they are not being sent to Igenomix immediately following sample collection.
- EMMA and ALICE: As the microbiome can fluctuate over time, we recommend sending samples as soon as possible after collection. We do not recommend delaying the shipment of samples for more than a week.
- Place the plastic blister inside the kit box, along with the completed documentation, and put the Kit inside the plastic (courier) return bag (provided by Igenomix).

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**Step 4:**
Logistics

- Samples can be sent at room temperature
- We strongly recommend that samples are returned in the Kit provided by Igenomix.
- Transit at room temperature should not exceed 5 days in order to ensure the preservative action of the liquid in the cryotube. We recommend shipping the samples with a cold gelpack if outside temperatures exceed 35°C (never freeze the sample). For further details, please contact our Customer Support Department.

**Step 5:**
Sample pick up

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

- Contact us at supportspain@igenomix.com asking for a UPS courier pick-up indicating:
 - Name of the Clinic + Name of the person/s of the clinic to be contacted by the courier + Address of the clinic + Telephone Number of the clinic + Exact Day/time for courier pick-up
 - We will schedule the pick-up according to your indications.
- Contact us at least 48 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.
- 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.

**Step 6:**
Test results

The clinician that has requested the test will receive the results within 15 working days from sample reception by Igenomix.

The ERA report includes a recommendation for performing a personalized embryo transfer. The EMMA and ALICE report includes a suggested therapy in case it is needed. For some patients, another biopsy may be required (for ERA, EMMA, ALICE or EndometRIO). In this case, your doctor will inform you about the next steps.

**Additional information**

For any questions or concerns and to request sample collection

 **+34 963 905 310**

 **supportspain@igenomix.com**