

## INSTRUCTIONS FOR CLINICS AND SAMPLE COLLECTION CENTRES

This kit is intended for use in collection and preservation of samples until they arrive at Igenomix's facilities. These instructions are intended for medical workers. The kit will transport blood samples. The materials included in this kit can only be used by a medical professional, always in medical settings. This is not a self-assessment kit. This kit is not automated.



### Step 1: Contact us

Call + 966 549109444 or contact us by email at [supportme@vitrolifegroup.com](mailto:supportme@vitrolifegroup.com)

- Request more information about the test
- Arrange
  - Resolve any questions about the report
  - Request documentation in print format or in other languages, free of charge



### Step 2: Receipt of the Kit

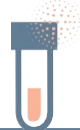
Review the contents of the niPOC kit and ensure that it contains:

- STRECK tube (do not use the tube if it is close to expiry) (CE-IVD).
- Shipping bag (courier).
- Plastic receptacle (secondary container).
- Test request and informed consent sheet.

For further information, check the tube manufacturer's instructions: Cell-free DNA BTC® CE, Ref. 35414, STRECK

**Store the Kit at room temperature, below 30 °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.



### Step 3: Sample collection

#### Warnings/Precautions:

**•IMPORTANT: It is essential that the blood sample be collected before the evacuation of the foetal remains takes place.**

If pharmacological treatment is being used for the evacuation, the sample should be taken prior to taking the medication.

•In the Clinical Information section of the Test Request Form (TRF), report whether any of the following situations may apply:

1. In heparin treatment for low molecular weight.
2. The patient has received a blood transfusion.
3. The patient has received a bone marrow transplant.
4. History of cancer.
5. Presence of a vanishing twin.
6. Congenital or acquired chimera.

•The following may lead to our laboratory rejecting the sample:

- The documentation (request and informed consent form) has not been properly completed.
- The mandatory fields marked with an asterisk (\*) have not been filled in.
- The signature of the patient or the requesting doctor is missing on the request and informed consent form.

•This kit should only be used for transporting samples.

#### Sample collection (always use gloves):

- STRECK tube: Sample volume (maternal blood) between 7ml (minimum) and 10ml (maximum). Samples containing a volume that is less than the minimum indicated and/ or in tubes other than the ones provided by Igenomix (STRECK tube) may not be accepted by our laboratory.
- After the sample is taken, immediately mix the contents by tipping the tube gently 180°, 8 to 10 times.

#### After taking the sample:

- Do not freeze the tube after the sample is taken.
- Label the tube with the following identification details (option 1 or option 2):
  - The patient's initials or full name and date of birth or
  - The patient's initials or full name and medical record number.

If the tube is not properly labelled, our laboratory may not accept the sample.

- Place the STRECK tube inside the secondary packaging and then, inside the Igenomix kit. Put the kit inside the shipping bag.
- The sample remains stable for 5 days at room temperature. If kept refrigerated the sample remains stable for 10 days.

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**Step 4:**  
**Transporting the sample**

- Samples can be sent along with cool gel packs
- When the outdoor temperature is higher than 35 °C, additional measures must be taken to prevent deterioration of the sample during transport. We recommend using cold gel packs or similar devices, at all times ensuring that the sample does not become frozen. If in doubt, please contact our customer service department. [supportme@vitrolifegroup.com](mailto:supportme@vitrolifegroup.com)

**Step 5:**  
**Sample pick-up**

For Picking up the sample in Saudi Arabia:



+966 549109444



[supportme@vitrolifegroup.com](mailto:supportme@vitrolifegroup.com)

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

**Pickups in Saudi Arabia :**

- From Sunday to Thursday.
- Contact us at least 24 hours before your preferred collection time to request a courier

**Pickups outside Saudi Arabia :**

- Check availability with our customer service department
- Contact us at least 24-48 hours before your preferred collection time to request a courier.
- Ensure that the shipping bag (courier bag) includes Airway Bill, Commercial Invoice and Non-Declaration shipping documents that will be provided to you prior of the collection request.

**Holidays:** May cause service disruptions. In the event of any disruption, our customer service department notify you in advance of the available pick-up days.

We recommend sending sample 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 doctor. Test results will be available within **15 working days** of receipt of the sample at Igenomix.

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## Additional information

**In the event of serious incidents:**

Any serious incident that may occur in relation to the materials included in the Kit supplied must be reported to [supportme@vitrolifegroup.com](mailto:supportme@vitrolifegroup.com) and [facilitymanagementKSA@vitrolifegroup.com](mailto:facilitymanagementKSA@vitrolifegroup.com) and to the competent health authority in the Member State where the user and/or patient is located.

## Symbols key:



Manufacturer



Expiry date



European Conformity



Medical device for in vitro testing



Keep away from sunlight



Temperature limit



Do not use if the package is damaged



Contains human blood or plasma-derived



products Do not reuse



Keep dry



Check the instructions for use.