



GPDx

Genomic Precision
Diagnostic

Igenomix[®]
WITH SCIENCE ON YOUR SIDE

NEWBORN SCREENING - INSTRUCTIONS



Step 1: Contact us

Call **(+44) 020 8068 8176** or send an email to **support.uk@igenomix.com** to request more information, kits, or a collection.



Step 2: Receipt of the kit

Check the kit box and ensure that it includes:

- 2x DNAgenotek collector tubes
- Courier return envelope
- 2x blister packs

Additional documentation required:

The Test Requisition & Consent Form can be downloaded from:

<https://igenomix.co.uk/send-a-sample>



Step 3: Sample collection

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

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

Buccal swab:

- Two buccal swabs/collector tubes are needed for this test.
- **IMPORTANT:** Carefully review and follow the steps in the ORAcollection OCR-100 collection instructions (page 3) for sample collection. Ensuring that both lower gums are swabbed 10 times each.

After the sample collection:

- Label both collector tubes with two unique identifiers, e.g.
 - Patient initials/full name and date of birth, **OR**;
 - Patient initials/full name and unique patient ID.
- Seal the collector tubes, invert, and shake vigorously 15 times.
- Collector tubes should be stored at 15-25°C (room temperature).

Packaging the sample:

- Put each of the collector tubes inside a rigid plastic blister pack, then place these in the original kit box.
- Fold and place the Test Requisition & Consent Form inside the kit box.
- Place the kit box inside the courier return envelope.
- Seal the courier return envelope.

Samples that have not been collected, stored, and/or packaged according to the instructions in this document may be rejected.



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Step 4: Logistics

- Send the package at room temperature.
- Only send samples using the kit provided by Igenomix.
- Remember that both collector tubes must be packaged within the rigid plastic blister packs and the original kit box, with the completed Test Requisition & Consent Form before placing them in the courier return envelope.
- If outside temperatures exceed 35°C, we recommend including a cold gel pack inside the kit box. For further details, please contact our Customer Support Team.



Step 5: Sample shipment

Requesting a collection

- Contact support.uk@igenomix.com in advance to arrange a collection.
- Domestic same-day collection is usually available **Monday-Thursday** for requests made prior to 13:30.

Waybill documents

You will receive the waybill documents by email. There are two of these documents:

- The package waybill document has three barcodes and should be placed in the dedicated document compartment, which can be found on the courier return envelope. Seal the compartment.
- The courier waybill document has one barcode and should be handed to the courier when they arrive.

Important considerations

- Ensure that the 'UN3373' sign is uncovered and visible on the courier return envelope.
- Check that the package is well sealed before shipment.
- Igenomix will notify you of any disruption (e.g. holidays) which may affect collections.
- We recommend shipping samples as soon as possible.



Step 6: Test results

Results will be delivered by secure email to the address(es) indicated in the test documentation. Results will be available within **25 calendar days** of receipt of samples at Igenomix.



Step 7: Additional information

For any questions, further information and to request sample collection:

(+44) 020 8068 8176

 **support.uk@igenomix.com**



NEWBORN SCREENING - INSTRUCTIONS

Collection instructions

Collection precautions:

Ensure the sponge tip does NOT come in contact with any surface prior to collection.

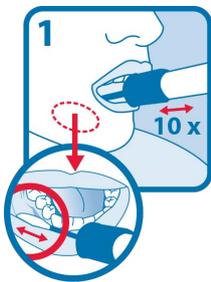
Donor should not drink for 30 minutes before collecting oral sample.

Warning and precautions: Choking hazard. Caution should be used when inserting sponge into the mouth

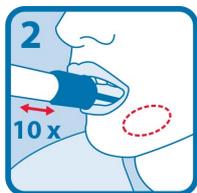
Wash with water if stabilizing liquid comes in contact with eyes or skin.

Storage: 15°C–25°C

Intended use: This product is designed for the collection and stabilization of DNA from human oral samples



Open package and remove collector without touching sponge tip. Place sponge as far back in the mouth as comfortable and rub along the lower gums (see close up image) in a back and forth motion. Gently rub the gums 10 times.



Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.



Hold the tube upright to prevent the liquid inside the tube from spilling. Unscrew the blue cap from the collection tube without touching the sponge



Turn the cap upside down, insert the sponge into the tube and close cap tightly.



Invert the capped tube and shake vigorously 15 times.