P2007 SALIVA KIT

Igenomix®
PART OF VITROLIFE GROUP

Title: Saliva (instructions for use) (EN) | Index: SPA_L_I_KIT_019_EN | Version: 3.0 | Authorised By: Begoña Aguila and Arantxa Hervas Lorente | Authorised: 31-Aug-2026

INSTRUCTIONS FOR USE

This kit is designed for the collection, transport and preservation of saliva samples until they arrive at Igenomix's facilities. It is intended for use by the patient, allowing for self-collection of the sample. However, please note that this is not a self-testing kit; laboratory analysis will be conducted by Igenomix once they receive your sample. The kit does not contain any automated components -all steps must be performed manually as instructed-. Additionally, the kit is for single use only 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 SALIVA and ensure that it contains:

- 1 Oragene® DNA (CE-IVD) **(do not use if the product is near its expiration date)**.
- 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 saliva collection kit manufacturer's instructions: Oragene® DNA, Ref. OGD-510, DNA Genotek.

Store the kit at a temperature between 15 and 30°C until it is ready to be used.

Note: If the Oragene® DNA expiry date has elapsed or the package is damaged, dispose of it in accordance with current local regulations and contact Igenomix to receive a new kit.

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

Step 3: Sample collection

Warnings/Precautions:

Do not eat, drink, smoke and/or chew gum for 30 minutes before collecting your sample.

- Do not discard the plastic film of the funnel cap.
- Gently rub your cheeks. Produce saliva for 2-5 minutes before depositing it into the tube.

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
- This kit should only be used for transporting samples.

**Note: Not applicable if ordering through the portal.

Taking and returning the sample

If your kit contains two Oragene® DNA samples perform the following steps for each one.



1. Fill the funnel with saliva until the liquid amount (not bubbles) exceeds the line shown in image 1.



2. Hold the tube in an upright position. Push down to close the lid (as shown) until you hear a loud click.



3. Hold the tube in an upright position. Unscrew the funnel from the tube.



4. Seal the tube tightly with the small cap provided.



5. Shake the capped tube for about 5 seconds. The funnel you removed can be recycled or discarded.

   ***If QR stickers are available, attach one to the sample collection tube and the other to the Test Request Form (TRF).**

   If QR stickers are not available, clearly label the tube with the patient's initials and their date of birth.

   ***If the TRF is completed in the portal: enter the number that appears on the barcode on the sample form: "tube identification code" field.**



6. Insert the capped tube(s) into the secondary container(s) and seal tightly. Then place in the Igenomix kit box.



7. Finally include the previously filled out and signed informed consent and request forms. Then place the kit inside the plastic return shipping bag.

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Step 4:
Transporting the sample

- The saliva sample can be stored at room temperature for up to 3 weeks. Do NOT freeze or refrigerate the sample. We recommend returning the sample as soon as possible.
- 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**

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