

SAMPLE COLLECTION MANUAL

SEE THE UPDATED TEST CATALOG AT
www.unilabs.pt/en/specialties/medical-genetics/tests-catalogue
AND CHECK IF THERE ARE SPECIFIC REQUIREMENTS FOR THE
TEST YOU ARE REQUESTING

- 1.** Confirm the completion of the Unilabs request form, including personal information with at least two identifiers, and family medical history, specifying the type and reason for the test.
- 2.** To ensure the stability of DNA samples during shipping, make sure they are properly stored in sterile tubes, hermetically sealed. Use tubes that are resistant to low temperatures and pressure, with screw caps that ensure a secure closure to prevent sample loss and/or contamination. Label with the patient's identification, preferably with at least with two distinct identifiers.
- 3.** If the sample is collected the day before or over the weekend, we recommend keeping the sample container at room temperature (between 15°C and 25°C) until it is sent, away from sources of cold and heat. Additionally, use isothermal packaging and include dry ice or gel packs to preserve the integrity of the samples during transport, if needed.

To find answer to the most frequent questions, please visit
www.unilabs.pt/en

For additional information, please send us an email to
genetics.customercare@unilabs.com
or call **+351 222 406 406**,
from Monday to Friday
08h30 am - 5h30 pm (GMT/UTC + 00:00)

MOLECULAR DIAGNOSTICS AND CLINICAL GENOMICS

It is recommended to consult the collection instructions for the desired test at:
<https://www.unilabs.pt/en/specialties/medical-genetics/tests-catalogue>

Sample Type	Methodology	Volume / Concentration	Container	Optimal period (days)*
Peripheral blood	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	≥ 3mL	EDTA	5
	Transcript quantification	≥ 10mL	EDTA / PAXgene	2 (EDTA) / 5 (PAXgene)
	RT-PCR	≥ 4mL		
DNA	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	≥ 20µL (50ng/µL)	Eppendorf Safe-lock / Criotube	<26 weeks at room temp. according to CLSI guidelines
Bone marrow	Sanger sequencing	≥ 1mL	EDTA	24h
	Transcript quantification		EDTA / PAXgene	
	RT-PCR			
Amniotic fluid ^a	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	≥ 7mL	Sterile tube with leak resistant screw cap (do NOT use urine collection tubes)	4
Chorionic villi ^a	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	Variable/ According to collection	Sterile tube provided by Unilabs	4
Fibroblasts cell culture ^a	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	2 confluent flasks	Flasks T25 / TPP	2
Saliva	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	See attached manufacturer's instructions	Kit Oragene Ref. OGD-600	n/a
Buccal Swab	Sequencing (NGS and Sanger) Fragment analysis Deletion/duplication analysis QF-PCR	See attached manufacturer's instructions	Kit Oragene Ref. OGD-100 Kit Copan	n/a

^a Maternal blood sample is necessary for investigation of maternal cell contamination.

^b In methylation studies, this type of sample is not applicable.

* If the optimal timeframe for sample reception is not met, the laboratory will assess whether the sample should be processed or not.

CYTOGENETICS

Methodology	Sample Type	Volume / Concentration	Container	Optimal period (days)*
Array CGH	Peripheral blood	≥ 3mL	EDTA	5
	DNA	≥ 20µL (50ng/µL)	Eppendorf Safe-lock/ Criotube	<26 weeks at room temp. according to CLSI guidelines
	Amniotic fluid ^a	≥ 5mL	Sterile tube with leak resistant screw cap (do NOT use urine collection tubes)	4
	Chorionic villi ^a	Variable/ According to collection	Sterile tube provided by Unilabs	4
	Fibroblasts cell culture	2 confluent flasks	Flasks T25/TPP	2
FISH * and Karyotype*	Peripheral blood	≥ 3mL	Lithium heparin	5
	Bone marrow	≥ 1mL		24h
	Amniotic fluid ^a	≥ 5mL	Sterile tube with leak resistant screw cap (do NOT use urine collection tubes)	4
	Chorionic villi ^a	≥ 30mg	Sterile tube provided by Unilabs	4
	Fibroblasts cell culture	2 confluent flasks	Flasks T25/TPP	2
	Suspension of simulated fixed cells	1 tube per culture	Sterile tube with leak resistant screw cap	n/a
	Suspension of unstimulated fixed cells (oncology)			
	Slides, not colored	2 slides per probe	Slide container	4
	Slides, not colored	3 slides per culture		4
	Fresh tissue	≥ 1cm ²	In saline solution and ampicillin or amoxicillin (1g/L)	4
	Paraffin block	—	Block processed in buffered formaldehyde	n/a

^a Maternal blood sample is necessary for investigation of maternal cell contamination.

* If the optimal timeframe for sample reception is not met, the laboratory will assess whether the sample should be processed or not.

PRENATAL SCREENING

HARVEST IN FILTER PAPER

1. Gently massage the finger (ring or middle). Warming the finger causes vasodilation.
2. Select the fingertip as the location for puncture. Clean the area with alcohol and dry with sterile gauze
3. Lancet with a sterile scalpel (supplied by Unilabs)
4. Put the finger down to increase blood flow. Let the second drop form. You do not have to press the finger too hard.
5. With the finger facing down, touch each circle to a drop of blood. Blood should cover at least 75% of both sides of each of the five circles. Apply one drop to each circle, and just ONE drop.
6. Allow the blood drops to dry at room temperature (at least 60 minutes) in the horizontal position. Protect from direct sunlight or heat. Do not overlap filter paper during drying.
7. After drying, place the filter paper in the small envelope provided and then in a largest envelope along with the request form (provided by Unilabs)
8. Store the sample in a cool and dry place until transport.

Accepted**Rejected**



Before proceeding with the dose, please read the instructions described below carefully:

PROCEDURE:

1. Collect the blood sample into a **Streck** tube (ref.: Cell-Free DNA BCT® CE).
2. Identify the Streck Tube with at least 2 identifications, for example, patient's name and date of birth;
3. Clean the region of sampling and harvest by venipuncture between 7–10 mL of blood into the Streck tube;
4. Immediately after sampling, carefully rotate the tube 8-10 times (inadequate or late mixture may affect the test result);
5. Sample should be stored and shipped at room temperature (20-25°C, 68-77°F);
6. Make sure the tube arrives within 5 days after sample collection to:

Unilabs | CGC - Centro de Genética Clínica e Patologia S.A.

Rua Manuel Pinto de Azevedo, 173
4100-321 Porto



ATTENTION, THE TEST CANNOT BE PERFORMED IF:

- Blood sample volume is below 7 mL;
- The tube is not identified appropriately;
- The Requisition **tomorrow** Form is not properly completed and signed by the health professional;
- The sample arrived 5 days after collection.


Collection precautions:

Donor should NOT eat, drink, smoke or chew gum for 30 minutes before collecting saliva sample.

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

Intended use: ORAc collect•Dx is intended for use in the non-invasive collection of saliva samples. Human DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. Saliva samples collected using ORAc collect•Dx are stabilized and can be transported and/or stored long-term at ambient conditions.

Contents: Kit contains stabilizing liquid.

Warnings and precautions:

- Rx only. For professional use.
- Read all instructions carefully prior to sample collection; deviation may result in inadequate sample and impact DNA yield.
- Choking hazard. Caution should be used when inserting sponge into the mouth.
- Donors with xerostomia (dry mouth) may not collect adequate sample using these instructions resulting in lower DNA yield and an invalid sample for use.
- Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com

Storage: 15°C-25°C

Label legend:

REF	Catalog number
IVD	In vitro diagnostic medical device
CE	CE marking
UKCA	UKCA marking
Manufacturer	Manufacturer
MD	Medical device
Do not re-use	Do not re-use
Consult instructions for use	Consult instructions for use
Collect sample by (Use by)	Collect sample by (Use by)
LOT	Lot number
EC REP	Authorized Representative



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. If possible, avoid rubbing the teeth.



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 stabilizing liquid inside the tube from spilling. Unscrew the blue cap from the collection tube without touching the sponge.

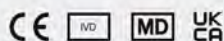


Turn the cap upside down, insert the sponge into the tube and close cap tightly.



Invert the capped tube and shake vigorously 10 times.

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For In Vitro Diagnostic Use



Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

UK Responsible Person: Emergo Consulting (UK) Limited c/o Cr360 – UL International, Compass House, Vision Park Histon, Cambridge, CB24 9BZ

Australian Sponsor: Emergo Australia, Level 20, Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000 Australia

ORAc collect is a registered trademark and DNA Genotek is a trademark of DNA Genotek Inc. Some DNA Genotek products may not be available in all geographic regions; contact your sales representative for details. All DNA Genotek protocols, white papers and application notes are available in the support section of our website at www.dnagenotek.com.

Patent (www.dnagenotek.com/legalnotices)

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DNAGENOTEK™

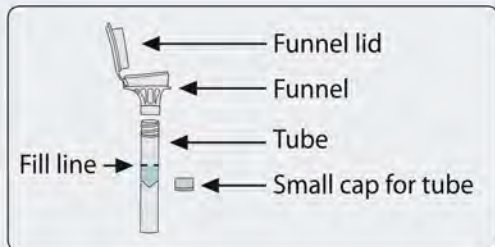
*Superior samples
Proven performance*

DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2

Toll-free (North America): 1.866.813.6354
Tel.: +1.613.723.5757 • Fax: +1.613.723.5057
info@dnagenotek.com
www.dnagenotek.com

USER INSTRUCTIONS

Read all instructions prior to collection



Collection precautions:

Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva sample.

Do NOT remove the plastic film from the funnel lid.

Intended use: For the collection of human DNA from saliva samples.

Contents: Kit contains stabilizing liquid.

Warnings and precautions: Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com.

Small cap may pose a choking hazard.

Storage: 15°C / 30°C

Summary and explanation of the kit:

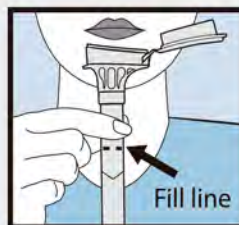
Oragene•DNA is a self-collection kit that provides the materials and instructions for collecting and stabilizing saliva specimens.

Label legend:

	Consult package insert
	Collect saliva by (Use by)
	In vitro diagnostic medical device
	Catalog number
	CE Marking
	Caution, consult instructions for use
	Storage instructions
	Authorized Representative
	Manufacturer
	Lot number

Procedure:

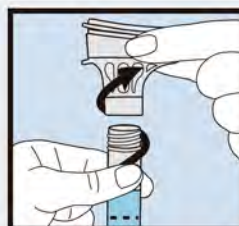
Most people take between 2 and 5 minutes to deliver a saliva sample following steps 1 to 5.



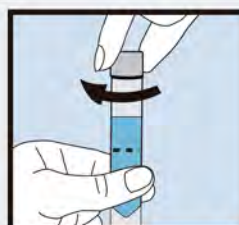
- 1 Spit into funnel until the amount of liquid saliva (not bubbles) reaches the fill line shown in picture #1.



- 2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the saliva. Make sure that the lid is closed tightly.



- 3 Hold the tube upright. Unscrew the funnel from the tube.

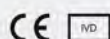


- 4 Use the small cap to close the tube tightly.



- 5 Shake the capped tube for 5 seconds. Discard or recycle the funnel.

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For In Vitro Diagnostic Use

DNAgenotek



Made in Canada
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3000 - 500 Palladium Drive
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Superior samples
Proven performance

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info@dnagenotek.com
www.dnagenotek.com



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Australian Sponsor: Emergo Australia, Level 20, Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000 Australia

Oragene•DNA is not available for sale in the United States.

*Oragene is a registered trademark of DNA Genotek Inc.

Some DNA Genotek products may not be available in all geographic regions, contact your sales representative for details. All DNA Genotek protocols, white papers and application notes, are available in the support section of our website at www.dnagenotek.com.

Patent (www.dnagenotek.com/legal/notice)

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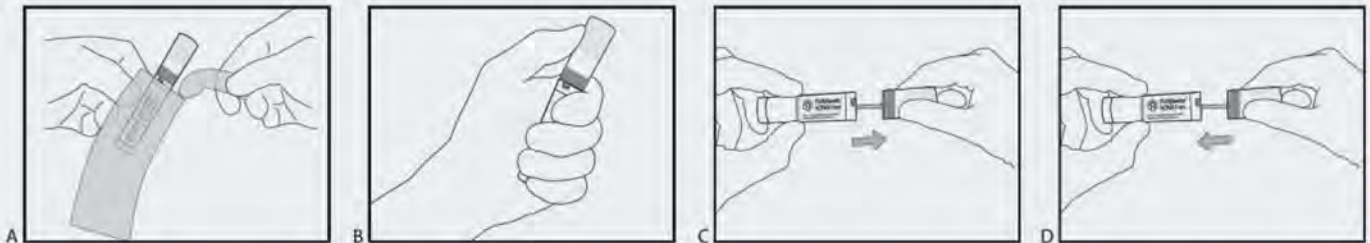
FLOQSwabs®
hDNA Free

HPC152 Rev.00 Date 2019.02

NOTE: The sample must be collected immediately after opening the transparent bag.

NOTE: Do not force or excessively press or bend the swab when taking the sample from the patient, as this may result in accidental breakage of the shaft. The swab shaft has a moulded breakpoint in proximity of the tip, which allows intentionally breaking the swab inside a test tube.

1. Put on gloves, open the bag and remove the plastic tube (Figure 1A).
2. To facilitate the opening of the tube cap, hold the swab by the plastic tube with one hand and with your thumb press the top of the white cap (Figure 1B).
3. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface (Figure 1C).
4. Collect the sample. During sampling, the swab end (tip) shall only come in contact with the collection site, so as to reduce contamination risks.
5. Once you have taken the sample, put the swab back into the plastic tube and securely close it (Figure 1D).
6. Identify the collected sample. Send the sample to the laboratory for testing as soon as possible.



WASTE DISPOSAL

Unused swabs may be considered as non hazardous waste and disposed of accordingly.

Dispose of used swabs as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

Table of Symbols

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Consult the instructions for use
	Do not reuse		Batch code (lot)
	Catalogue number		Contents sufficient for <n> tests
	Temperature limits		Do not use if the packaging is damaged
	Use before		Non-sterile

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