

For In Vitro Diagnostic Use

Instructions for sample collection:



Collection precautions:

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

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

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

Contents: 1 kit containing 1 mL stabilizing liquid

Warnings 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. Do NOT ingest. See SDS at www.dnagenotek.com

Report any serious incident to DNA Genotek and the competent authority in your country.

Storage: 15°C/25°C (59°F/77°F)

Summary and explanation of the kit: ORAcollect.DNA is a self-collection kit that provides the materials and instructions for collecting human oral samples.

Label legend:

Catalog number

IVD In vitro diagnostic medical device**

CE CE marking ĽĶ **UKCA** marking Manufacturer MD Medical device* (2) Do not reuse

Consult instructions for use

Use by LOT Lot number

EC REP European Authorized Representative CH REP Swiss Authorized Representative Unique Device Identifier UDI

15°C 1/25°C Storage instructions

Per applicable regulatory requirements, the device contains a swab component, which is a *medical device, and a collection tube component, which is an **in vitro device.



FNGLISH

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 15 times.





DNAgenotek[™]

■ DNA Genotek Inc. 3000 - 500 Palladium Drive

Ottawa, ON, Canada K2V 1C2



For In Vitro Diagnostic Use

Superior samples

info@dnagenotek.com

www.dnagenotek.com

Proven performance

Toll-free (North America): 1.866.813.6354

Tel.: +1.613.723.5757 • Fax: +1.613.723.5057



Novosanis NV, Bijkhoevelaan 32c, 2110 Wijnegem, Belgium Email: EUAR@novosanis.com

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



CH REP Arazy Group Swiss GmbH, Bruderholzallee 53, 4059 Basel, Schweiz Email: swiss.ar@arazygroup.com Australian Sponsor: Emergo Australia, Level 20, Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000 Australia

ORAcollect. DNA is not available for sale in the United States

ORAcollect and DNA Genotek are trademarks 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)

© 2024 DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved.

