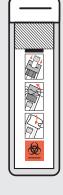


Saliva Collection Kit contents:





Bio-Specimen Bag

Instructions for Use

ORAcollect®·Dx (OCD-100.014)

in pouch, with your unique barcode on the tube



Record Card for you to keep with your unique barcode





By using the AlphalD At Home Genetic Health Risk Service, you agree to the Terms of Service at www.AlphalDAtHome.com/Terms-of-Service/

Please note: The AlphalD At Home Genetic Health Risk Service is FREE. This includes the collection device, shipping, lab processing and access to your results. You or your insurance will not be billed.

Label legend:

In vitro diagnostic medical device
Manufacturer

Caution, consult Instructions for Use

Collect sample by (Use by) Catalog number

Lot number 59°F ∤ 77°F Storage instructions

(15°C / 25°C)

REF

ORAcollect®-Dx

REF OCD-100.014

M DNA Genotek Inc.

3000-500 Palladium Drive

Ottawa, ON, Canada K2V 1C2

ORAcollect®-Dx (OCD-100.014) is made for Progenika Biopharma, S.A. by DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc. Patent (www.dnagenotek.com/legalnotices)

 $\label{eq:linear_problem} \mbox{Al Home Genetic Health Risk Service is provided by Progenika Biopharma, S.A. A Grifols company.}$

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Saliva Collection Kit

Instructions for Use

Read all instructions prior to getting started.

Collection precautions:

Do 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 for ORAcollect®-Dx (OCD-100.014):

ORAcollect®•Dx is intended for use in the collection of saliva samples for diagnostic testing of human DNA. Saliva samples may be collected by a health care professional or non-health care professional, such as a lay user. Saliva samples collected using ORAcollect®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using ORAcollect®•Dx can be transported and/or stored at ambient conditions.

IVD





Warnings and precautions for ORAcollect®-Dx (OCD-100.014):

- Read all instructions carefully prior to sample collection; not following instructions may result in inadequate sample and impact DNA yield and your results.
- For direct-to-consumer use with the AlphalD™ At Home Genetic Health Risk Service.
- For use in individuals 18 years of age and older.
- Choking hazard. Caution should be used when inserting sponge into the mouth.
- Sample donors with xerostomia (dry mouth) may not collect an adequate sample using these instructions, resulting in lower DNA yield and an invalid sample for use.
- If stabilizing liquid comes in contact with eyes or skin, wash with water. Do NOT ingest. See the Safety Data Sheet at https://www.AlphalDAtHome.com/safety_data_sheet.pdf

Information on the AlphaID™ At Home Genetic Health **Risk Service:**

For information on the AlphalD™ At Home Genetic Health Risk Service, please visit www.AlphalDAtHome.com.

Procedure



Register your kit

Before you collect your sample, register your unique barcode on the secure, confidential and HIPAA compliant website www.AlphalDAtHome.com/REGISTER/

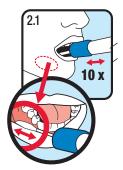
IMPORTANT: You must register your kit to access your report. Collect and mail your sample at your earliest convenience.



Collect sample

Open the package and remove the **Saliva Collection Device** without touching the sponge tip. Collect the sample following the instructions below:





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 other 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.



Seal sample

Place the tube containing your saliva sample into the **Bio-Specimen Bag** provided and seal tightly.



Place in Mailer Box

Place one sealed saliva sample into the Mailer Box.

IMPORTANT:

Keep the Record Card containing your unique barcode.



KEEP



Seal box

Using the adhesive strip located on the Mailer Box, seal the box tightly across its entire length.



Mailing instructions

Place the boxed sample into the mail or take it to the nearest postal location. A prepaid return label is located on the back of the Mailer Box.

Your service result report is kept confidential and can only be accessed with your unique barcode and password on the secure website https://www.AlphalDAtHome.com/ View-Report/



Questions?

For questions, contact Customer Support at 1-844-891-3030.

