

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 saliva sample.

Contents: 1 kit containing 1 mL stabilizing liquid.

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

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

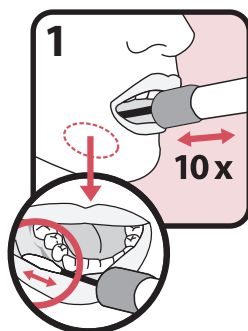
Storage: 15]25°C (59°F I 77°F)

Summary and explanation of the kit:

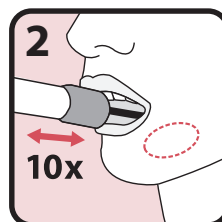
ORACollect®RNA is a collection kit that provides the materials and instructions for collecting, stabilizing and maintaining during transport saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).

Label legend:

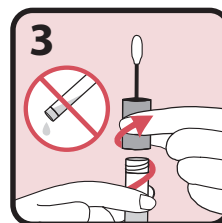
REF	Catalog number
IVD	In vitro diagnostic medical device
Manufacturer	Manufacturer
15°C I 25°C	Storage instructions
59°F I 77°F	
Collect sample by (Use by)	
LOT	Lot number
Rx	For Prescription Use Only



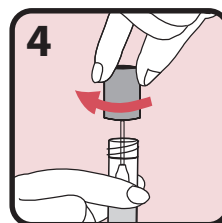
Open package and remove collector without touching sponge tip. Place sponge as far back in the mouth as comfortable and rub along the lower gums (see close up image) in a back and forth motion. Gently rub the gums 10 times. If possible, avoid rubbing the teeth.



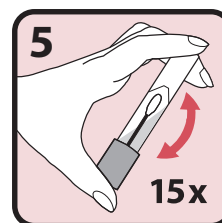
Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.



Hold the tube upright to prevent the liquid inside the tube from spilling. Unscrew the 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.



For IVD, Rx and For Use Under Emergency Use Authorization.

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA.

This product has been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens; and.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

DNAGENOTEK™

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

Superior samples • Proven performance

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

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