

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: Contains 1 collection kit.

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

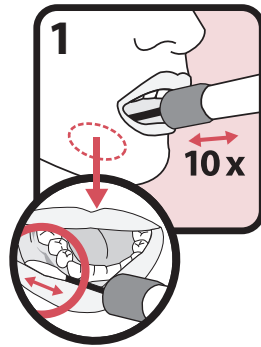
Storage: 15-25°C

Summary and explanation of the kit:

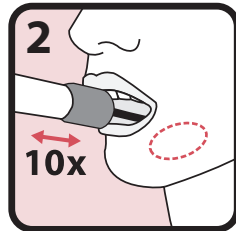
ORACollect[®]•RNA is a collection kit that provides the materials and instructions for collecting, stabilizing and maintaining during transport saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).

Label legend:

REF	Catalog number
MD	In vitro diagnostic medical device
M	Manufacturer
15°C-25°C	Storage instructions
U	Collect sample by (Use by)
LOT	Lot number
Rx	For Prescription Use Only



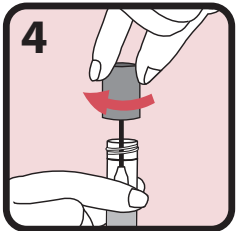
Open package and remove collector without touching sponge tip. Place sponge as far back in the mouth as comfortable and rub along the lower gums (see close up image) in a back and forth motion. Gently rub the gums 10 times. If possible, avoid rubbing the teeth.



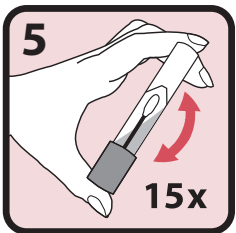
Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.



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 sample collection device has not been FDA cleared or approved.

This sample collection device has been authorized by FDA under an EUA.

This sample collection device 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.

This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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