ORAcollect•RNA

REF ORE-100

ENGLISH

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.

Intended use: For the collection and stabilization of RNA from human saliva samples

Contents: Contains 1 collection kit

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

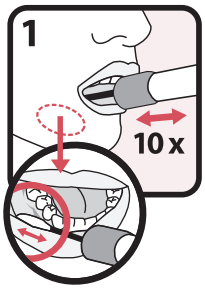
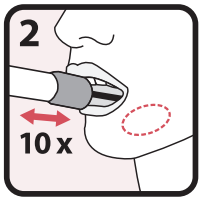
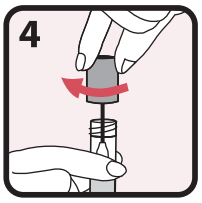
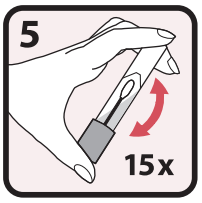
Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com

Storage: 15°C-25°C

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

Label legend:

REF	Catalog number
Rx	For Prescription Use Only
IVD	In vitro diagnostic medical device
CE	CE marking
UKCA	UKCA marking
	Manufacturer
MD	Medical device
	Do not re-use
	Consult instructions for use
	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 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.

CE IVD MD UKCA

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 for the collection and maintenance of saliva specimens as an aid in detection of nucleic acid from SARS-CoV-2, 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 in vitro diagnostics for detection and/or diagnosis of COVID-19 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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