

**Intended use/purpose:** OMNigene<sup>®</sup>•ORAL is intended for the collection and stabilization of nucleic acids from saliva.

**Intended user:** This product is intended for use in adults.

**Contents:** 1 kit containing stabilizing liquid.

**Warnings and precautions:** Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at [www.dnagenotek.com](http://www.dnagenotek.com).

Small cap may pose a choking hazard.

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

**Storage:** 15°C/ 30°C (59°F/ 86°F)

### Summary and explanation of the kit:

OMNigene-ORAL 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).

### Collection precautions:

**Do NOT eat, drink, smoke, or chew gum for 30 minutes before giving your sample.**

**Do NOT remove the plastic film from the funnel lid.**

### Label legend:

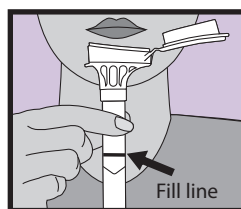
REF	Catalog number
CE	CE marking
IVD	In vitro diagnostic medical device
UKCA	UKCA marking
Do not re-use	Do not re-use
Consult package insert	Consult package insert
Caution, consult instructions for use	Caution, consult instructions for use
Manufacturer	Manufacturer
European Authorized Representative	European Authorized Representative
Swiss Authorized Representative	Swiss Authorized Representative
Collect sample by (Use by)	Collect sample by (Use by)
Lot number	Lot number
UDI	Unique Device Identifier
15°C/ 30°C	Storage instructions
59°F/ 86°F	

## USER INSTRUCTIONS

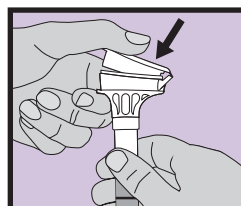
Read all instructions prior to collection.

### Procedure:

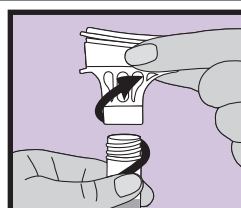
**Most people take between 2 and 5 minutes to deliver a sample following steps 1 to 5.**



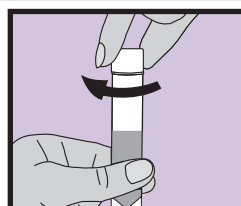
- 1 Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.



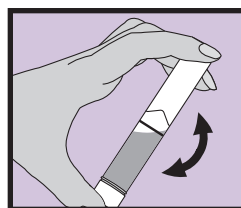
- 2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.



- 3 Hold the tube upright. Unscrew the funnel from the tube.



- 4 Use the small cap to close the tube tightly.



- 5 Shake the capped tube for 5 seconds. Discard or recycle the funnel.

*Collected specimen is potentially infectious and should be handled with appropriate biosafety practices.*

*Ship in accordance with applicable regulations covering transport of biological specimens.*



For IVD, For Prescription Use Only 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.

**DNagenotek<sup>™</sup>**

*Superior samples • Proven performance*

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OMNigene is a registered trademark and DNA Genotek is a trademark 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](http://www.dnagenotek.com).

Patent ([www.dnagenotek.com/legal/notice](http://www.dnagenotek.com/legal/notice))

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