
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.

Contents: Kit contains 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.












Small cap may pose a choking hazard.

Storage: 15°C / 30°C

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).

Label legend:

	Collect sample by (Use by)
	In vitro diagnostic medical device
	Catalog number
	CE Marking
	Consult package insert
	Caution, consult instructions for use
	15°C / 30°C Storage instructions
	Manufacturer
	Authorized Representative
	Lot number
	For Prescription Use Only

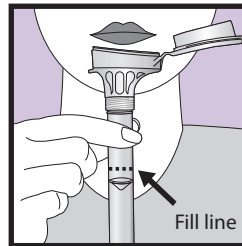
Collected specimen is potentially infectious and should be handled with appropriate biosafety practices.

Ship in accordance to applicable regulations covering transport of biological specimens.

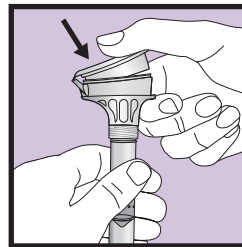
For donor collection instructions in other languages, see www.dnagenotek.com

USER INSTRUCTIONS

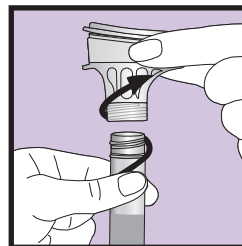
Most people take between 2 and 5 minutes to deliver a sample following steps 1 to 5.



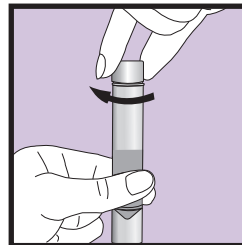
- 1** Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.



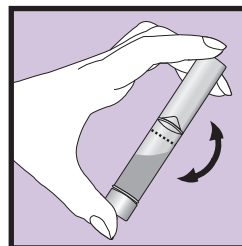
- 2** Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.



- 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.



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.

DNAGENOTEK™

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Superior samples • Proven performance

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Patent (www.dnagenotek.com/legalnotices)
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PD-PR-01059 Issue 1/2020-10