

## Collection and stabilization of SARS-CoV-2 (COVID-19) RNA

### Collect and stabilize RNA from saliva using a collection device authorized by FDA for use in SARS-CoV-2 testing.†

OMNigene®ORAL is an all-in-one solution for collection, stabilization, storage and transportation of saliva samples at ambient temperature for use in the detection of viral RNA targets (SARS-CoV-2).



**Non-invasive method that allows donors to collect a saliva sample at home without the challenges associated with clinical or hospital settings.**



#### Painless and intuitive

Validated at-home collection method designed for optimized user experience.

#### Convenient and cost-effective

Eliminates the need for post-collection freezer storage and cold-chain transport.

#### Enables large-scale collection

Unique bar code to improve automated lab procedures, workflow efficiencies and sample traceability.



**The benchmark for successful at-home collection of saliva samples.**

For the collection of saliva specimens suspected of containing SARS-CoV-2 RNA

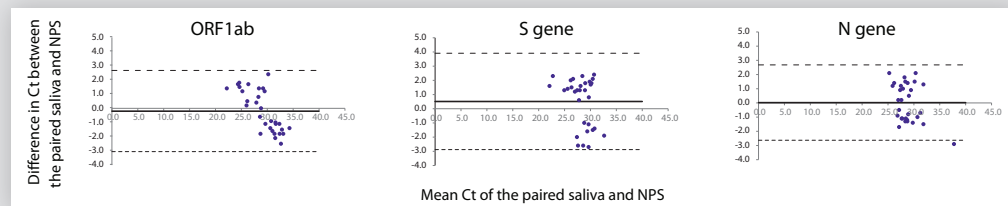
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**DNAGENOTEK™**

## All-in-one sample collection

OMNigene-ORAL stabilizes SARS-CoV-2 RNA for target detection for up to **5 days** at room temperature.<sup>1</sup>



Evaluation of Ct value differences among paired samples collected from the same patient within 10 minutes using saliva (OMNigene-ORAL) and a nasopharyngeal swab (NPS) (Copan ESwab 480C).

Adapted from "Emergency Use Authorization (EUA) summary for the P23 Labs TaqPath SARS-CoV-2 assay" by P23 Labs, 2020.

## Specifications and attributes

Volume (chemistry/sample)	1 mL/1 mL
Number of extractions per kit (250 µL per extraction)	8
Yields compatible with RT-qPCR assays	✓
Freeze/thaw and temperature fluctuation stability <sup>2</sup>	-20°C to +50°C
Room temperature stability for the RNA detection of SARS-CoV-2 <sup>1</sup>	5 days
Bar coded for full sample traceability (128C format)	✓

### Packaged product:

Dimensions: 14.0 cm x 8.0 cm x 2.8 cm  
Weight: 37.13 g  
Shelf life: 24 months

### Collection device:

Height (capped): 98.25 mm  
Tube height: 93 mm  
Tube diameter: 16 mm  
Cap diameter: 18 mm  
Net weight: 6.04 g

### Storage conditions:

Pre-collection: 15°C to 30°C  
Post-collection: 23±3°C

## Safe collection and inactivation of SARS-CoV-2<sup>3</sup>

Successful inactivation of SARS-CoV-2 in collected and stabilized samples

**> 99%**

## Improve donor care and maximize compliance

A collection method combining an intuitive design and clear concise instructions favors a high percentage of successful sample collections and increases overall usability and compliance.

## Comprehension and execution<sup>2</sup>

### Collection instructions

Successfully understood and performed critical steps

**98.0%**

### Collection results

Provided sufficient yields to perform RT-qPCR assays

**98.0%**

<sup>1</sup> P23 Labs, LLC, Emergency Use Authorization (EUA) summary for the P23 Labs TaqPath SARS-CoV-2 assay

<sup>2</sup> DNA Genotek, internal validation

<sup>3</sup> DNA Genotek, Inactivation of SARS-CoV-2 in samples collected using Oragene, ORAcollect and OMNigene products from DNA Genotek, MK-01430

### † 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.

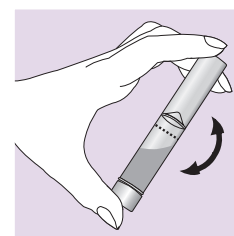
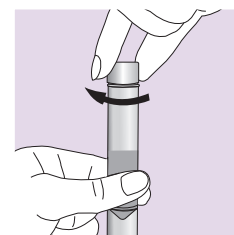
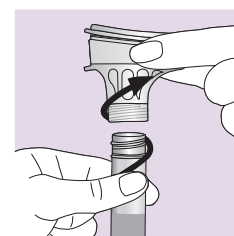
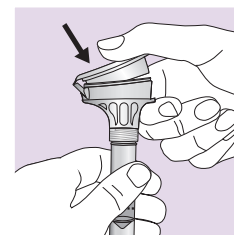
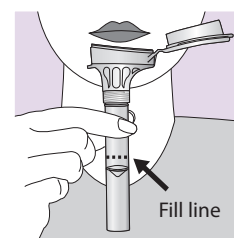
This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1),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

Some DNA Genotek products may not be available in all geographic regions.

\*OMNigene-ORAL (OME-505) is CE marked for In Vitro Diagnostic Use.

\*OMNigene is a registered trademark and DNA Genotek™ is a trademark of DNA Genotek Inc.

All other brands and names contained herein are the property of their respective owners.



For full collection instructions, visit [www.dnagenotek.com](http://www.dnagenotek.com)



Clamshell and collection instructions



**For the collection of saliva specimens suspected of containing SARS-CoV-2 RNA**

*Superior samples • Proven performance*

**DNAGENOTEK™**

Patent (www.dnagenotek.com/legalnotices) PD-BR-00374 Issue 1/2021-01  
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