OMNIgene®•ORAL

OME-505

For IVD Use, For Rx Use. For Use Under Emergency Use Authorization

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.

CE IVD

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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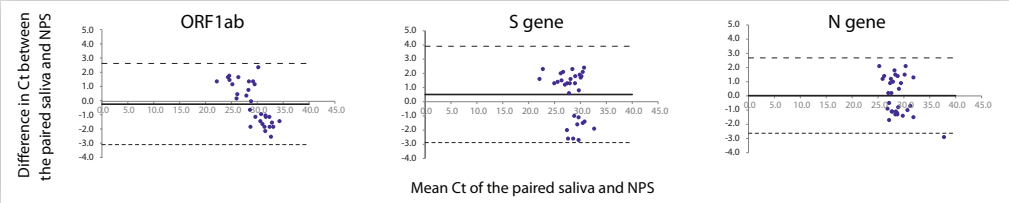
DNAgenotek™

OMNIgene•ORAL

OME-505

All-in-one sample collection

OMNIgene•ORAL provides high quality saliva samples for use in SARS-CoV-2 detection.[1]



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[2]	-20°C to +50°C
Room temperature stability for the RNA detection of SARS-CoV-2[1]	**3 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 (59°F to 86°F)
Post-collection: 23±3°C

Safe collection and inactivation of SARS-CoV-2[3]

Successful inactivation of SARS-CoV-2 in collected and stabilized samples	**> 99%**

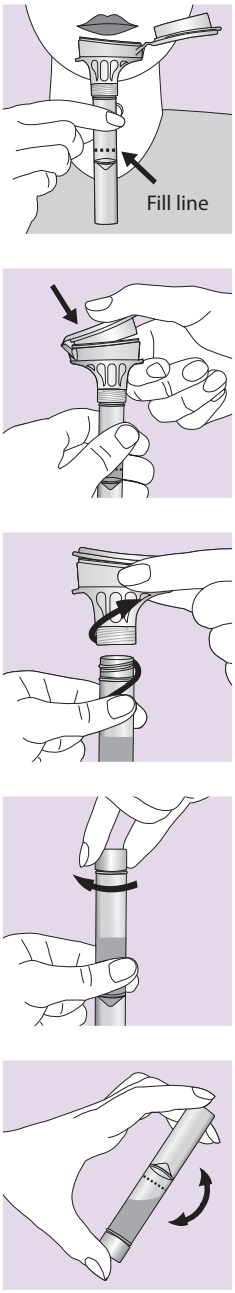
Improve donor care and maximize compliance

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[2]

Collection instructions Successfully understood and performed critical steps	**98.0%**
Collection results Provided sufficient yields to perform RT-qPCR assays	**98.0%**

Collection instructions



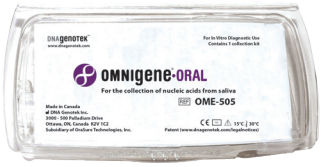
For full collection instructions, visit ***www.dnagenotek.com***

[1] P23 Labs, LLC, Emergency Use Authorization (EUA) summary for the P23 Labs TaqPath SARS-CoV-2 assay
[2] DNA Genotek, internal validation
[3] 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.



Clamshell and collection instructions

CE IVD

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 2/2021-04