

Microbial DNA and RNA from saliva

Collect and stabilize bacterial and viral nucleic acids (DNA and RNA) from saliva using a validated, CE-marked device for *in vitro* diagnostic use.

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



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

At-home collection combined with ease-of-use for optimized donor experience.

Convenient and cost-effective

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

Scalable for large studies

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

The benchmark for at-home collection of microbial DNA and RNA from saliva.

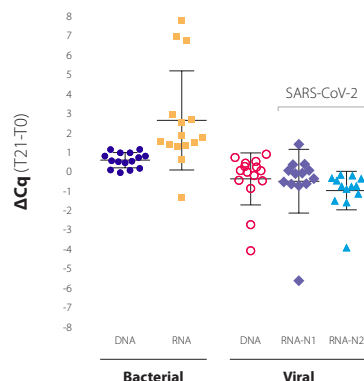
For the collection of nucleic acids from saliva

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DNAGENOTEK™

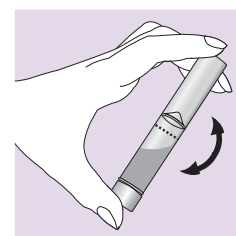
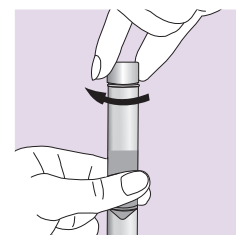
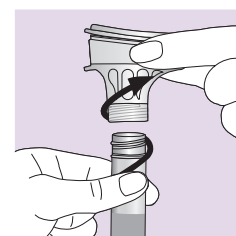
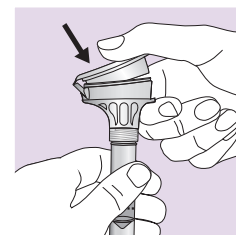
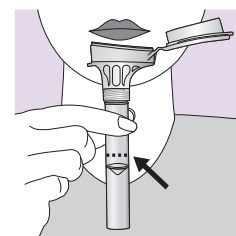
Difference in cycle quantification values
Room temperature (21 days)



All-in-one sample collection

OMNigene-ORAL stabilizes viral and bacterial nucleic acids (DNA and RNA) for target detection for up to **21 days** at room temperature.

Delta quantification cycle (ΔCq) analysis for candidate target genes across OMNigene-ORAL (OME-505) collected saliva samples. Nucleic acid extraction was performed at baseline (T0) following sample spike-in with a RNA virus (heat inactivated SARS-CoV-2) and a DNA virus and after storage at room temperature ($23 \pm 3^\circ\text{C}$) for 21 days (T21). Extracted nucleic acids were analyzed by RT-qPCR using primers and/or probes specific for bacterial DNA and RNA targets (N=15), viral DNA (N=15) and viral RNA (SARS-CoV-2 N1 and N2 genes, N=13). Data represented as scatter plot with Mean \pm SD.



For full collection instructions
visit www.dnagenotek.com

Specifications and attributes

Volume (chemistry / sample)	1 ml / 1 ml
Number of extractions per kit (250 μL per extraction)	8
Yields compatible with qPCR & RT-qPCR assays	✓
Freeze/thaw and temperature fluctuation stability	-20°C to $+50^\circ\text{C}$
Room temperature stability for the detection of microbial DNA and RNA, including SARS-CoV-2	21 days
Bar coded for full sample traceability (128C format)	✓

Safe collection and inactivation of SARS-CoV-2¹

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

>99%

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:
 $23 \pm 3^\circ\text{C}$

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 to sufficiently power your study.

Comprehension and execution²

Collection instructions

Successfully understood and performed critical steps

98.0%

Collection results

Provided sufficient yields to perform qPCR & RT-qPCR assays

98.0%

Differentiate your offerings to patients, customers or clinicians with a safe and validated CE IVD device.

¹ DNA Genotek, Inactivation of SARS-CoV-2, MK-01430

² DNA Genotek, internal validation

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.



OME-505
Cap



Clamshell and collection instructions



For the collection of
nucleic acids from saliva

Superior samples • Proven performance

DNAGENOTEK™

Patent (www.dnagenotek.com/legalnotices) PD-BR-00372 Issue 1/2020-09
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