



DNA from saliva

## Collect high-quality DNA samples for molecular diagnostics using an FDA cleared device.\*

ORAcollect®•Dx is a robust, painless and easy-to-use DNA collection kit. The unique design delivers samples that are superior to those collected with traditional flocked or cotton swabs, with DNA of higher quality and quantity. ORAcollect•Dx is a suitable alternative to blood collection and easily integrates into existing laboratory workflows.

- Fast, easy and reliable DNA sample collection in a clinic or at home
- Stabilized DNA at ambient temperature
- High-quality DNA for use in downstream molecular applications
- Flexible processing with seamless integration into existing workflows



Molecular diagnostic manufacturers could reduce the time and regulatory burden of their own FDA submissions by leveraging the 510(k) clearances of ORAcollect•Dx.

## Features and benefits

- Collection of sample is simple and gentle for donor
- Efficient and reliable collection in a clinic or at home
- DNA samples are able to withstand temperatures ranging from -20°C to 50°C (-4°F to 122°F) during collection and transportation
- Stabilization chemistry is non-toxic, bacteriostatic and prevents DNA degradation
- Compatible with high-throughput automated laboratory handling and barcode scanning for sample traceability

## Collection method comparison

	Flocked or cotton swab	ORACollect-Dx
No drying time required	x	✓
DNA stability	days	60 days
Liquid sample	x	✓
Standardized format for high-throughput processing	x	✓
Eliminates cross contamination	x	✓
Integrated barcode for sample traceability	x	✓
FDA cleared	x	✓
Microbial contamination	$T_0 = 14\%$ , $T_{30 \text{ days}} = 24\%^{**}$	$T_0 = 4\%$ , $T_{60 \text{ days}} = 4\%^{+}$
Median yield	0.7 $\mu\text{g}^{**}$	2.6 $\mu\text{g}^{+}$
Molecular weight	< 23 kb <sup>**</sup>	> 23 kb <sup>**</sup>

<sup>\*\*</sup> Panford-Walsh R, Doukhanine E. and Bouevitch A. (2011). Comparison of DNA from samples collected using ORACollect-DNA (OCR-100) vs. buccal swabs. DNA Genotek. PD-WP-00021.

<sup>+</sup> Data was obtained by testing 156 samples from 156 donors and DNA was extracted using the QIAamp® DNA Mini kit (QIAGEN®).

<sup>‡</sup> Data was obtained by testing 30 samples from 30 donors.

## Product specifications and contents

### Packaged product:

Dimensions: 241 mm x 102 mm x 19 mm

Approximate weight: 11 g

Shelf life: 24 months

Storage conditions: 15°C to 25°C (59°F to 77°F)

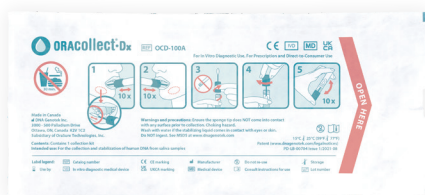
For full product specifications, refer to PD-BR-00240.



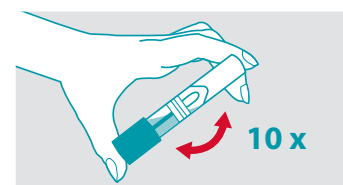
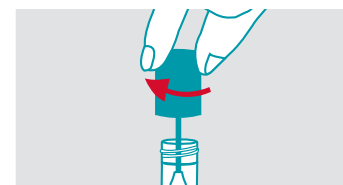
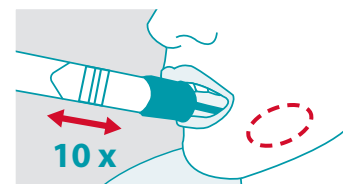
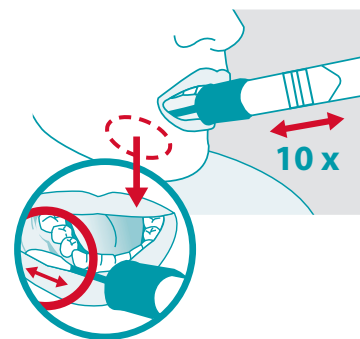
Collection device



Instructions for Use



Primary packaging



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

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

\* ORACollect-Dx (OCD-100A) is FDA cleared for *in vitro* diagnostic use, for prescription use (k152464) and over-the-counter (direct-to-consumer) use (k212745).

ORACollect 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 Prescription Use (k152464) and Over-the-Counter (Direct-to-Consumer) Use (k212745)

For In Vitro Diagnostic Use  
For collection of human DNA

Superior samples • Proven performance

Patent ([www.dnagenotek.com/legal/notice](http://www.dnagenotek.com/legal/notice)) PD-BR-00380 Issue 1/2022-11  
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