



Collect high quality DNA samples for molecular diagnostics

ORAcollect®•Dx is a robust, painless and easy-to-use DNA collection kit. ORAcollect•Dx is designed to collect, stabilize and protect DNA samples. Unlike buccal swabs, ORAcollect•Dx samples yield larger amounts of high quality human DNA and integrates easily into existing laboratory workflows.

DNA collection with ORAcollect•Dx provides:

- A fast, easy and reliable DNA sample with no drying time required
- Stabilized DNA at ambient temperature
- High quality DNA for use in downstream molecular applications
- Flexible processing with seamless integration into existing workflows

ORAcollect•Dx is an FDA cleared device[†]. Molecular diagnostic and laboratory developed test manufacturers can reduce the time and regulatory burden of their own FDA submissions by leveraging the 510(k) clearance of ORAcollect•Dx.







Features

ORAcollect•Dx is a superior alternative to buccal swabs and offers several advantages:

- Collection of sample is simple and gentle for donor
- · Efficient collection is ideal for clinical workflows
- · DNA integrity is maintained at ambient temperature for transportation via regular post
- Bacteriostatic reagent inhibits growth of bacteria from time of sample collection to processing
- Liquid sample (no cutting of tips) eliminates manual steps, reduces the chance of errors and cross contamination, while facilitating efficiency in the lab
- High quality DNA sample enables downstream analysis with proven clinical utility
- Format optimizes laboratory efficiency
 - Use with liquid handling robots
 - Minimal hands on technician time
 - Compatible with standard labware
 - Integrated barcode on tube for workflow efficiency and sample traceability

Collection method comparison

Attributes	Buccal swabs	ORAcollect•Dx
No drying time required	*	\checkmark
Specimen stability at ambient temperature	days	months
Liquid sample	*	\checkmark
Standardized format for high-throughput processing	×	✓
Eliminates cross contamination	×	✓
Integrated barcode for sample traceability	×	✓
FDA cleared	×	✓
Microbial contamination	$T_0 = 14\%, T_{30 \text{ days}} = 24\%$ ‡	$T_0 = 4\%, T_{60 \text{ days}} = 4\%^{**}$
Median yield	0.7 μg [‡]	2.6 μg*
Molecular weight	$<$ 23 kb^{\ddagger}	$>$ 23 $\mathrm{kb^{\dagger}}$

[‡] 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.

OCD-100A kit contents



in the LICA

Product specifications

Pre-use with packaging:

Dimensions: $10.2 \times 24.1 \times 1.8$ cm

Weight: 11 g Shelf-life: 24 months

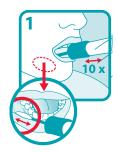
Post sample collection specifications

Storage conditions: Room temperature Sample stability: 60 days

For full specifications on weight and

dimensions, refer to PD-BR-00240 on our website.

Easy collection



Place sponge comfortably in mouth and rub lower gums 10 times back and forth.



Repeat rubbing motion on the opposite side of the mouth.



Holding the tube upright, unscrew the cap from the tube.



Turn the cap upside down, insert the sponge into the tube and close tightly.



Invert the capped tube and shake vigorously 10 times.

ORAcollect®•Dx has been cleared for in vitro diagnostic use in the U.S.A.

 $\ \, + \ \, \text{FDA cleared for in vitro diagnostic use with the eSensor} \, \, \text{Warfarin Sensitivity Saliva Test.}$

*ORAcollect is a registered trademark of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners. Patent (www.dnagenotek.com/legalnotices)

Collector

^{*} Data was obtained by testing 156 samples from 156 donors and DNA was extracted using the QIAamp® DNA Mini kit (QIAGEN®).

^{**} Data was obtained by testing 30 samples from 30 donors.