

OGD-575

FILL TO

DNA from saliva

Collect high-quality DNA samples for molecular diagnostics

Genetic testing relies on superior DNA samples determined by yield and purity. Use Oragene[™]•Dx for proven collection, stabilization and transportation of DNA from saliva. Oragene[™]•Dx is an FDA-cleared device.[†]

- Painless, non-invasive collection
- Alternative for donors unable to provide direct saliva samples
- Oragene[™]•Dx saliva samples are stable for long-term room temperature storage

Molecular diagnostic test manufacturers could reduce the time and regulatory burden of their own FDA submission by leveraging the 510(k) clearance of Oragene[™]•Dx.









Easy collection and transportation Oragene[™]•Dx solution is bacteriostatic Standardized tube format and 1D barcode

DNAGENOTEK[™]

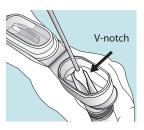
DNA Genotek Inc. 3000 - 500 Palladium Drive Ottawa, ON, Canada K2V 1C2 Subsidiary of OraSure Technologies, Inc. Toll-free (North America): 1.866.813.6354 Tel: +1.613.723.5757 • Fax: +1.613.723.5057 www.dnagenotek.com info@dnagenotek.com

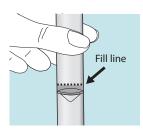
For In Vitro Diagnostic Use For assisted collection of human DNA

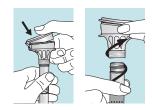


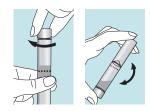
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Easy collection









For full collection instructions, visit www.dnagenotek.com

Features

- · Non-invasive, reliable self-collection or assisted collection of samples
- · Ideal for donors who are unable to provide direct saliva samples
- · DNA from saliva is a proven alternative to DNA from blood for downstream applications
- Increase donor compliance by 200%^{1,2} over blood collections
- Oragene[™]•Dx solution is bacteriostatic, prevents human DNA degradation
- Samples remain stable at room temperature reducing storage costs
- Robust sample stability across temperatures ranging from -20°C to 50°C during collection and transport increases sample transport options, including postal service
- Increase workflow efficiency and minimize sample handling with a standardized tube format and integrated 1D barcode
- · Branding and customized packaging available to create a unique end-customer experience

Performance characteristics (representative data)*

	Yield (µg)	Concentration (ng/µL)	A _{260/280} ratio
Mean ± SD	13.5 ± 8.8	41.1 ± 24.6	1.7 ± 0.1
Median	11.0	33.2	1.7
95% of samples	≥ 3.8	≥ 11.2	1.6 - 1.9

*Data obtained by testing 43 samples from 43 individuals.

OGD-575 kit contents

Product specifications

Pre-use with packaging:

Dimensions: 14.0 cm x 8.0 cm x 2.8 cm Weight: 36 g Shelf life: 30 months at room temperature**

Post-collection specifications

Standard false bottom tube:

Tube diameter: 16 mm Tube height (without cap): 93 mm

1 Hansen TV, Simonsen MK, Nielsen FC, et al. (2007). Collection of blood, saliva, and buccal cell samples in a pilot study on the Danish nurse cohort: 2 Galbete C, Toledo J, Martínez-González MA, et al. (2013). Lifestyle factors modify obesity risk linked to PPARG2 and FTO variants in a elderly population:

A cross-sectional analysis in the SUN Project. *Genes Nutr.* 8(1):61-67. doi:10.1007/s12263-012-0296-4 Patent (www.dnagenotek.com/legalnotices)

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

Oragene[™]•Dx has been cleared for in vitro diagnostic use in the U.S.A

**Shelf life is 30 months from date of manufacture at specified storage condition.

+FDA cleared for in vitro diagnostic use; for prescription and direct-to-consumer use

Oragene™•Dx is a registered trademarks of DNA Genotek Inc., registered in various jurisdictions.

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

In regions outside the U.S., the stability claim for DNA is 5 years. For U.S. customers only, see PD-HB-1 at www.dnagenotek.com.



Superior samples • Proven performance

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CE R For In Vitro Diagnostic Use

