



DNA from Saliva

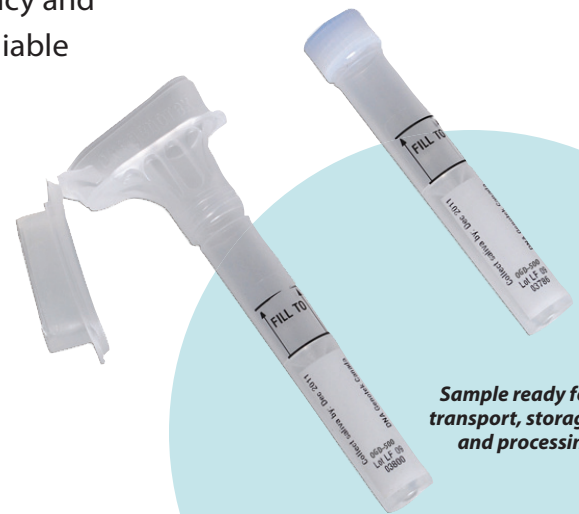
EASY • PAINLESS • PROVEN

Collect high quality DNA samples for HLA typing

Genetic analysis and testing starts with the collection of DNA samples. Oragene®•Dx is ideal for use with HLA typing applications that require DNA to derive a result. Transplant centers and marrow donor registries can improve access to potential donors, improve efficiency and decrease costs by offering a completely non-invasive, reliable and easy-to-use sample collection method.

Oragene•Dx is an FDA cleared[†] device. Use Oragene•Dx for proven collection, stabilization and transportation of DNA from saliva.

- **Non-invasive, reliable self-collection of DNA samples from saliva**
- **Increase access to potential family members and/or unrelated donors with mail based or event-based sample collection**
- **Ideally suited for HLA typing applications**
- **Decrease cost and complexity of sample transport, management and storage with room temperature stability of samples**
- **Improve processing efficiency with a liquid sample and tube format that seamlessly integrates with automated platforms**



Sample ready for transport, storage and processing

Collection device

For more information contact info@dnagenotek.com

FDA 510(k) clearance of Oragene•Dx enables diagnostic test manufacturers to streamline their own regulatory submissions and provide added flexibility in offering their patients/donors the option of non-invasive, reliable and easy sample collection with Oragene•Dx saliva sample collection.

For In Vitro Diagnostic Use

For collection of human DNA

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DNAgenotek



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Features

- Non-invasive, reliable self-collection or assisted collection of samples
- Improve donor convenience while eliminating phlebotomy costs
- Ideal for use with all donors, including those who will not comply with blood collections
- Reliable for use in any collection environment: in the clinic, at the physician's office or at home
- Compact and robust design for transport via the standard postal system
- Decrease cost and complexity of sample transport, management and storage with one year room temperature stability of samples
- Suitable for molecular diagnostic applications, such as HLA low, intermediate and high resolution typing
- Increase efficiency and minimize sample handling with a liquid sample and tube format that seamlessly integrates with automated platforms or facilitates DNA extraction in manual environments

ORAgene-Dx product line comparison

	ORAgene-Dx OGD-500	ORAgene-Dx OGD-510	ORAgene-Dx OGD-575 (Assisted collection)
Sample collection	2 mL saliva	1 mL saliva	0.75 mL saliva via sponge
Standardized tube format for automated processing equipment	✓	✓	✓
Sample stability at room temperature	1 year	1 year	1 year
Bacteriostatic solution	✓	✓	✓
Compact format for mailing	✓	✓	✓

Performance characteristics

		ORAgene-Dx OGD-500**	ORAgene-Dx OGD-510††	ORAgene-Dx OGD-575‡‡
Yield (µg)	Mean ± SD	58.5 ± 47.0	28.8 ± 28.1	13.5 ± 8.8
	Median	48.4	20.7	11.0
	95% of samples	≥ 13.1	≥ 4.3	≥ 3.8
Concentration (ng/µL)	Mean ± SD	68.1 ± 55.3	62.2 ± 64.1	41.1 ± 24.6
	Median	55.3	45.6	33.2
	95% of samples	≥ 16.0	≥ 9.0	≥ 11.2
A _{260/280} ratio	Mean ± SD	1.7 ± 0.1	1.7 ± 0.1	1.7 ± 0.1
	Median	1.7	1.7	1.7
	95% of samples	1.5 – 1.9	1.5 – 1.9	1.6 – 1.9

** Data obtained by testing 450 samples from 245 individuals.

†† Data obtained by testing 60 samples from 60 individuals.

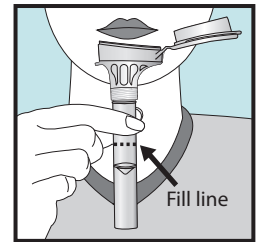
‡‡ Data obtained by testing 43 samples from 43 individuals.

ORAgene-Dx has been cleared for in vitro diagnostic use in the U.S.A.

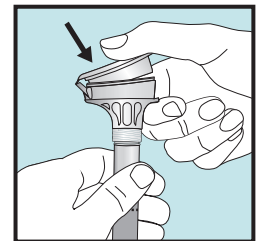
† FDA cleared for in vitro diagnostic use with the eSensor® Warfarin Sensitivity Saliva Test.

*ORAgene is a registered trademark of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners.

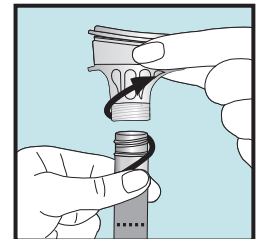
Donor/patient friendly collection[‡]



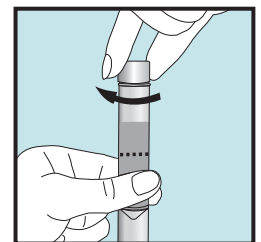
Spit until the amount of saliva (not bubbles) reaches the fill line.



Close lid tightly by pushing down hard on the funnel lid until you hear a loud click.



Unscrew the funnel from the tube.



Close tube tightly with small cap. Shake for 5 seconds.

[‡] Does not apply to OGD-575.

U.S. Patent Nos. 8,221,381 and 7,482,116; European Patent Nos. 1 513 952 and 1 956 969; Canadian Patent No. 2,488,769; Patent pending; Canadian Design Nos. 127470; 132896; 132897 U.S. D631,554 S and D640,795 S Community Design Nos. 001095186-0001; -0002; -0003