



## DNA from Saliva

EASY • PAINLESS • PROVEN

### Collect high quality DNA samples for molecular diagnostics

Launching a personalized medicine product or service entails sound sample management, planning and execution. Ensure that your approach includes streamlined end-to-end sample integration for collection at home or in the clinic right through to downstream processing and analysis.

Oragene•Dx is an FDA cleared device<sup>†</sup>. Molecular diagnostic test manufacturers can reduce the time and regulatory burden of their own FDA submissions by leveraging the 510(k) clearance of Oragene•Dx.

- **Improve patient care with easy-to-use and painless sample collection**
- **Collect DNA with a median  $A_{260/280}$  of 1.7<sup>‡</sup>**
- **Decrease cost and complexity of sample transport, management and storage with room temperature stability of samples**
- **Improve processing efficiency with a tube format that seamlessly integrates with automated platforms**



*Sample ready for transport, storage and processing*

**Collection device**

**For more information contact [info@dnagenotek.com](mailto:info@dnagenotek.com)**

## Features

- Non-invasive, reliable self-collection or assisted collection of samples
- Improve patient convenience while eliminating phlebotomy costs
- Ideal for use with all patients, 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 postal system
- Decrease cost and complexity of sample transport, management and storage with one year room temperature stability of samples
- Increase efficiency and minimize sample handling with a compatible tube format for high-throughput processing

## ORAgene-Dx product line comparison

	ORAgene-Dx OGD-500	ORAgene-Dx OGD-575 (Assisted collection)
Completely non-invasive	✓	Minimally
Standardized tube format for automated processing equipment	✓	✓
Sample stability at room temperature	1 year	1 year
Bacteriostatic solution	✓	✓
Compact format for mailing	✓	✓

## Performance characteristics

		ORAgene-Dx OGD-500**	ORAgene-Dx OGD-575††
Yield (µg)	Mean ± SD	58.5 ± 47.0	13.5 ± 8.8
	Median	48.4	11.0
	95% of samples	≥ 13.1	≥ 3.8
Concentration (ng/µL)	Mean ± SD	68.1 ± 55.3	41.1 ± 24.6
	Median	55.3	33.2
	95% of samples	≥ 16.0	≥ 11.2
A <sub>260/280</sub> ratio	Mean ± SD	1.7 ± 0.1	1.7 ± 0.1
	Median†	1.7	1.7
	95% of samples	1.5 – 1.9	1.6 – 1.9

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

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

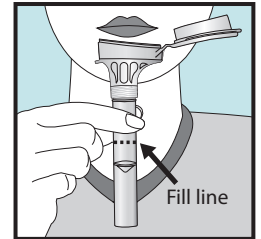
Material Safety Data Sheet (MSDS) available at [www.dnagenotek.com](http://www.dnagenotek.com)

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

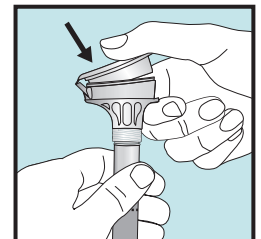
† FDA cleared for in vitro diagnostic use with results from eSensor® Warfarin Sensitivity Saliva Test.

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

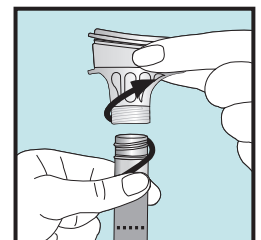
## Easy collection††



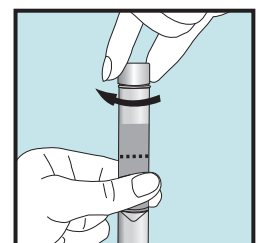
Spit until the amount of saliva (not bubbles) reaches the fill line.



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 No. 7,482,116;  
European Patent No. 1 513 952  
and patent pending  
Canadian Design Nos.  
127470; 132896; 132897  
U.S. D631,554 S and D640,795 S  
Community Design Nos.  
001095186-0001; -0002; -0003