



DNA from Saliva

EASY • PAINLESS • PROVEN

Collect high quality DNA samples for molecular diagnostics

Genetic analysis and testing starts with the collection of DNA samples. Oragene[®]Dx is ideal for use with molecular diagnostic applications that require DNA to derive a result. Genetic testing companies may improve their efficiency, decrease costs and increase the number of tests conducted by offering a completely non-invasive, reliable and easy-to-use sample collection method.

Oragene[®]Dx is an FDA cleared device[†]. 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[‡]**
- **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

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 a 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 | ✓ | ✓ |

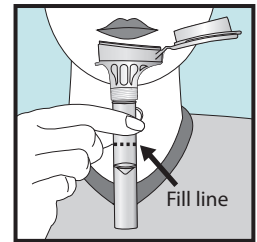
Performance characteristics

| | | 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 _{260/280} 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 |

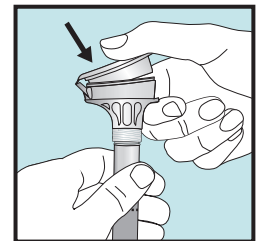
** Data obtained by testing 450 samples from 245 individuals.

† Data obtained by testing 43 samples from 43 individuals.

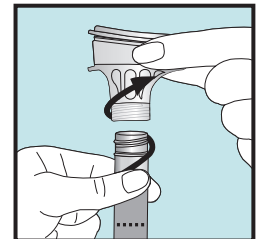
Patient friendly collection^{††}



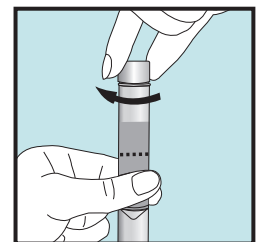
Spit until the amount of saliva (not bubbles) reaches the fill line.



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.

Material Safety Data Sheet (MSDS) available at 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.

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