



# Collect high quality DNA samples for molecular diagnostics with an FDA cleared device<sup>†</sup>.

Genetic testing starts with the collection of DNA samples. Use Oragene®•Dx for proven collection, stabilization and transportation of DNA from saliva.

- High quality, high quantity DNA<sup>†</sup>
- Fast and reliable self collection
- Long term room temperature sample stability
- Transport and store at room temperature
- Integrated 1D barcode + optional 2D bottom barcode for laboratory workflow efficiency

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.



To request free sample kits, go to www.dnagenotek.com





#### Your kit, your way.

The Oragene-Dx 610 combines ease-of-use and high quality samples with the ability to tailor the device to your needs. Tube length, anti-rotation features for automation and enhanced barcoding options give you ultimate flexibility for storage, sample processing and traceability. GenoFIND™ services are available to supplement your sample management needs.

| mid-size collection         | dard 610 kit with<br>ube barcode  | Compatible with manual processing   | Non-invasive   | Custom sample packaging  |
|-----------------------------|---|---|--|--|
| Largo-scalo Standa          |   | Automated de-capping<br>(low-medium throughput)     Sample tracking with     1D tube barcode  | Non-invasive At home or centralized collection Quick and easy self collection Instructions available in multiple languages Ship via standard postal system No cold chain required Compact design minimizes storage space | <ul> <li>Custom sample packaging for brand awareness</li> <li>Complete fulfillment capability</li> <li>Regulatory guidance</li> <li>Mailing accessories</li> <li>Wet lab services in a GLP/ CLIA accredited lab</li> </ul> |
| collection 1D tube • Option | dard 610 kit with<br>ube barcode<br>tional matching 2D<br>ttom barcode* | Automated de-capping<br>(high-throughput)     Sample tracking with<br>option for bed scanning |  |  |

### Kit contents and packaging specifications

For full specifications on weight and dimensions, refer to PD-BR-00233 on our website.

**Dimensions:** 14.0 x 7.5 x 2.8 cm

Weight: 37 g

Shelf-life: 30 months at room temperature

Sample stability: 12 months





Superior support, analysis

and reporting

## <sup>†</sup>Performance characteristics (representative data)\*\*

|                | Yield (μg)      | Concentration (ng/µL) | A <sub>260/280</sub> ratio |
|----------------|-----------------|-----------------------|----------------------------|
| Mean ± SD      | $36.0 \pm 41.1$ | $76.3 \pm 78.0$       | $1.7 \pm 0.1$              |
| Median         | 27.0            | 52.1                  | 1.7                        |
| 90% of samples | ≥7.5            | ≥ 16.0                | ≥ 1.6                      |

 $<sup>^{**}</sup>$  Data obtained by testing 45 samples from 45 individuals.

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

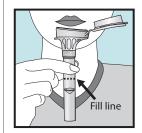
 $\dagger$  FDA cleared for in vitro diagnostic use; for prescription and direct-to-consumer use.

Oragene is a registered trademark, and GenoFIND is a trademark of DNA Genotek Inc.

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

Patent (www.dnagenotek.com/legalnotices)

## **Easy collection**











Full collection instructions can be found on our website.

