



DNA from Saliva

EASY • PAINLESS • PROVEN

Collect high quality DNA samples for direct-to-consumer genetic testing

Launching a direct-to-consumer service entails implementing a reliable sample collection method, proven science, strong brand differentiation and scalable sample management logistics.

Oragene•Dx is an all in one system for the collection, stabilization and transportation of DNA from saliva. Use Oragene•Dx to launch and build a flexible and streamlined direct-to-consumer business.

- **Oragene•Dx is an FDA cleared device[†]**
- **Proven reliable self-collection at the physician's office or at home^{**}**
- **Reduce the time and complexity of an FDA submission by leveraging the 510(k) clearance of Oragene•Dx**
- **Decrease cost of sample transport, management and storage with ambient temperature DNA stability**
- **Compact and robust design for transport via the postal system enables easy access to customers**
- **Increase efficiency and minimize sample handling with a tube format compatible with automated processing**
- **High quality DNA proven for use on microarray and sequencing platforms[‡]**



Sample ready for transport, storage and processing

Collection device

For more information contact info@dnagenotek.com

Oragene•Dx is proven for Prescription Use and Direct-to-Consumer (DTC) at home DNA saliva collection. Data obtained from a Saliva Collection Usability Study** (involving 212 naïve, adult, general population donors receiving a typical DTC saliva collection kit including instructions and two-way mailing box for return shipping) revealed the following:

Proven easy to use**

- 96.5% of donors agreed or strongly agreed that the instructions were easy to understand
- 96% of donors understood how to collect their saliva sample properly
- 99.5% of donors understood how to send the sample back to the laboratory
- 100% of donors understood where and how to contact technical support for any questions

Proven technical performance**

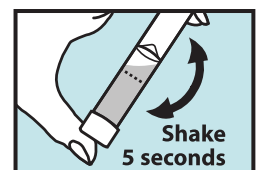
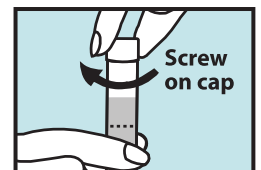
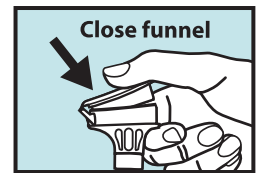
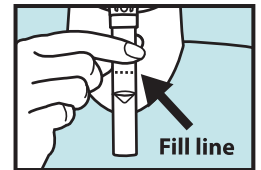
- 95% of samples passed sample weight criteria (between 1-4 mL of total sample volume)
- 97% of samples had a DNA concentration of 5 ng/μL or more
- 96% of samples passed DNA sequencing call rate criteria

Oragene•Dx product features

	Oragene•Dx
Completely non-invasive	✓
Standardized tube format for automated processing equipment	✓
Sample stability at room temperature	1 year
Bacteriostatic solution	✓
Compact format for mailing	✓

Material Safety Data Sheet (MSDS) available at www.dnagenotek.com

Easy collection



† FDA cleared for in vitro diagnostic use for direct-to-consumer applications, K192920.

** Based upon results derived from *The Oragene•Dx DTC User Comprehension Study*, K192920.

** *The Oragene•Dx DTC User Comprehension Study*, K192920 was conducted to support a pre-market submission to FDA. The study was conducted to assess the acceptability of saliva samples collected with the Oragene•Dx device for a direct-to-consumer application. The objective of the study was to demonstrate that customers comprehend the instructions for use provided with the Oragene•Dx device and can successfully provide a saliva sample at home with acceptable quality for use in genotyping.

Oragene® is a registered trademark of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners. Patent (www.dnagenotek.com/legalnotices)



For In Vitro Diagnostic Use
For Prescription Use and
Direct-to-Consumer Use

Superior samples • Proven performance

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