



DNA from saliva

EASY • PAINLESS • PROVEN

Collect high-quality DNA samples for direct genetic testing

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

Oragene™ Dx and ORAc collect™ Dx devices[†] are FDA 510(k) cleared for the collection, stabilization and transportation of DNA from saliva at ambient temperatures. Use Oragene™ Dx and ORAc collect™ Dx devices to streamline patient testing and scale diagnostic offerings.



Oragene™ Dx
Self-collection
device for saliva



ORAc collect™ Dx
Self-collection or assisted
collection device for saliva

- **Proven, reliable self-collection at the physician's office or at home***
- **Reduced time and complexity of FDA submissions by leveraging 510(k) clearances**
- **Decreased cost of sample transport, management and storage with ambient temperature DNA stability**
- **Designed to be compact and robust for transport via the postal system, enabling easy access to customers**
- **Increased efficiency and minimal sample handling with a tube format compatible with automated processing**
- **Proven high-quality DNA for use on microarray and sequencing platforms**
- **Comprehensive custom offerings, including branding and fulfillment services**

A faster, more affordable path to discovery



Product with
510(k) clearance

Products with 510(k) clearance (e.g., the Oragene™ Dx and the ORAc collect™ Dx devices) reduce the time needed to implement devices/assays in prescription or direct-to-consumer models



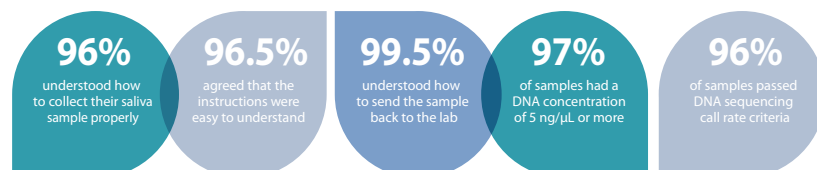
Product without
510(k) clearance

Considerable time and money spent revalidating devices that are not FDA cleared for general use

User comprehension studies

The Oragene™•Dx and ORAcollect™•Dx devices have both been rigorously tested in accordance with relevant industry standards for user-friendly, at-home DNA saliva collection and are proven for DTC and prescription use. Separate usability studies were conducted for the Oragene™•Dx device** and the ORAcollect™•Dx device.*** Most participants found the devices to be user-friendly.

ORagene™•Dx



ORAcollect™•Dx



| Features | Oragene™•Dx | ORAcollect™•Dx |
|---|-------------|----------------|
| Completely non-invasive | ✓ | ✓ |
| Standardized tube format for automated processing equipment | ✓ | ✓ |
| Sample stability at room temperature | 1 year | 2 months |
| Bacteriostatic solution | ✓ | ✓ |
| Compact format for mailing | ✓ | ✓ |

Safety data sheets (SDS) available at www.dnagenotek.com.

† FDA cleared for in vitro diagnostic use for direct-to-consumer applications, K192920 and K212745.

* The Oragene™•Dx and ORAcollect™•Dx DTC user comprehension studies (K192920 and K212745, respectively) were conducted to support a pre-market submission to FDA. These studies were conducted to assess the acceptability of saliva samples collected with the Oragene™•Dx or ORAcollect™•Dx devices for a direct-to-consumer application. The objective of the studies was to demonstrate that customers comprehend the instructions for use provided with the devices and can successfully provide a saliva sample at home with acceptable quality for use in genotyping.

**U.S. Food and Drug Administration. (2020). The Oragene™•Dx DTC user comprehension study, K192920. [PDF].

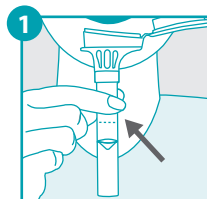
***U.S. Food and Drug Administration. (2022). The ORAcollect™•Dx DTC user comprehension study, K212745. [PDF].

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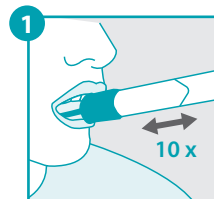
Collection steps



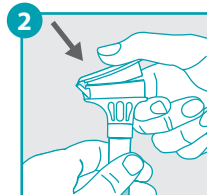
Spit to fill line



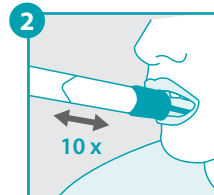
Swab right gum



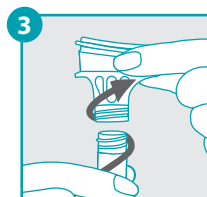
Close funnel



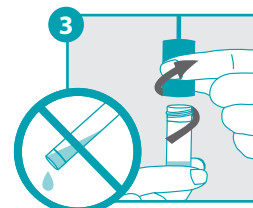
Swab left gum



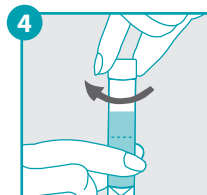
Remove funnel



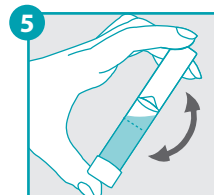
Remove swab



Screw on cap



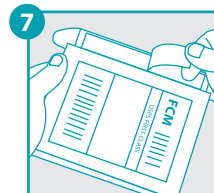
Shake 5 seconds



Seal in bag



Mail in box



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

Superior samples • Proven performance

DNAGENOTEK™

www.dnagenotek.com

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