# Product change notification

**Products affected:** ORAcollect®

**Catalog number:** OC-100
**Description:** ORAcollect®

**Effective date of change:** September 2016

## Customer actions:

- Notify purchasing department of change to product name and catalogue number.
- Consult your DNA Genotek Account Manager prior to placing your next order.

## Reason for change:

ORAcollect is being rebranded to ORAcollect•Dx to coincide with receipt of 510(k) clearance from the United States Food and Drug Administration (FDA). ORAcollect•Dx was cleared by the FDA as a class II IVD medical device (K152464) on May 26, 2016.

In compliance with FDA Unique Device Identifier (UDI) requirements for class II IVD medical devices, ORAcollect•Dx will bear a UDI.

## Change description:

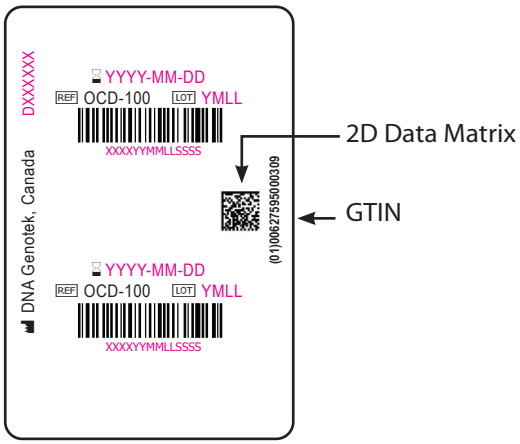
DNA Genotek is rebranding ORAcollect to ORAcollect•Dx within the United States. The respective catalogue number will change from OC-100 to OCD-100. There is no change to pricing or product performance as a result of this rebranding. If you are currently using ORAcollect you may continue to use your current inventory. New product shipments of ORAcollect•Dx will begin after September 2016; our website will be updated with new brand and catalogue number.

ORAcollect•Dx UDI will be 2D data matrix (5 mm × 5 mm) located on the collection tube label. An image detailing the change is shown below for representational purposes. DNA Genotek's Global Trade Identification Number (GTIN) which is embedded within the UDI will also appear on the tube label in human-readable format.

The existing 128C barcode on the tube label is not affected by the addition of UDI and should continue to be used for sample traceability.

**Existing**


**New**




Denotes variable content

Please contact **info@dnagenotek.com** if you have any issues or concerns pertaining to this product change notification.