DNAgenotek™

Product change notification

Product affected: ORAcollect™•Dx and ORAcollect™•DNA

Catalog number/SKU: OCD-100, OCR-100

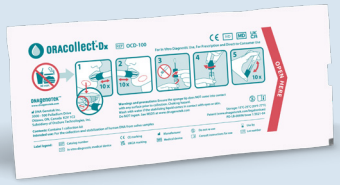
Effective date of change: By December 31, 2024

Change description:

The ORAcollect™•Dx (OCD-100, OCD-100A) and ORAcollect™•DNA (OCR-100) devices and packaging will undergo the following changes:

1. The current primary package is made from poly-film and Tyvek materials. An alternate package made from poly-film and paper materials will be put into production. The packaging material change is being implemented to source more sustainable materials that are better for our environment. It is possible that you could receive product manufactured with either of the materials.

2. A change to the primary package design is being implemented to refresh our brand. Notable changes include the removal of the collection steps and English text has been converted to symbols. All of the required regulatory and product information remains on the product labeling; however the information may be found in different areas of the primary package label and instructions for use.

	Current primary packaging design	New primary packaging design
ORAcollect™•Dx (OCD-100)		
ORAcollect™•Dx (OCD-100A)		
ORAcollect™•DNA (OCR-100)		

3. The ORAcollect™•Dx (OCD-100, OCD-100A) and ORAcollect™•DNA (OCR-100) devices are dually labeled as Medical Devices (MD) and In Vitro Diagnostic (IVD) devices and are UKCA and CE marked. The ORAcollect™•Dx (OCD-100, OCD-100A) devices are additionally FDA cleared For Prescription Use and Direct-to-Consumer Use within the United States. To reduce any confusion created by the dual IVD and MD device labeling, we have created separate labels.

PD-PCN-101 v1/2024-08

DNAgenotek™

Device labeling will be updated and shipped following the depletion of existing inventory. It is possible you may receive devices with the new labeling prior to the December 31, 2024, effectivity date.

	Current labeling	New labeling
ORAcollect™•Dx (OCD-100 OCD-100A)	CE IVD MD UKCA	IVD
ORAcollect™•DNA (OCR-100)	CE IVD MD UKCA	CE MD UKCA

Customer action:

No actions are required for products in your inventory, in distribution or in use related to the primary packaging material or design changes.

For the ORAcollect™ device IVD and MD regulatory labeling split, we recommend you review the following guidance to determine whether action is required:

1. If internal documentation/process updates are required:
   - Contact your account manager to request the required documentation to support your updates.
2. If you have unused ORAcollect™•Dx (OCD-100, OCD-100A) or ORAcollect™•DNA (OCR-100) devices with the current labeling:
   - No action is required. The devices can be used until the specified expiration date on the devices.
3. For customers within the USA distributing ORAcollect™•Dx (OCD-100, OCD-100A) devices/tests domestically:
   - No action is required.
4. For customers within the USA distributing ORAcollect™•Dx (OCD-100, OCD-100A) devices/tests to the European Union (EU) and other countries that recognize CE marking:
   - Contact your account manager to update your upcoming orders and/or purchase plan.
5. For customers within the USA distributing ORAcollect™•Dx (OCD-100, OCD-100A) devices/tests to countries other than the USA, EU and countries that recognize CE marking:
   - Contact your account manager to discuss the current marketing authorization status and ORAcollect™ device recommendation for the country in which you are distributing the devices.
6. For customers within the EU and customers in other countries that recognize CE marking who are distributing ORAcollect™•DNA (OCR-100) devices domestically:
   - No action is required.
7. For customers within the EU and customers in other countries that recognize CE marking who are purchasing ORAcollect™•Dx (OCD-100, OCD-100A) devices for domestic distribution:
   - Contact your account manager to update your upcoming orders and/or purchase plan.
8. For customers outside of the USA, EU and countries that recognize CE marking distributing ORAcollect™•Dx (OCD-100, OCD-100A) or ORAcollect™•DNA (OCR-100) devices to other countries:
   - Contact your account manager to discuss the current marketing authorization status and ORAcollect™ device recommendation for the country in which you are distributing the devices.

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