DNAgenotek™

Product change notification

Product affected: ORAgene™•Dx

Catalog number/SKU: OGD-575, OGD-675

Effective date of change: November 1, 2024

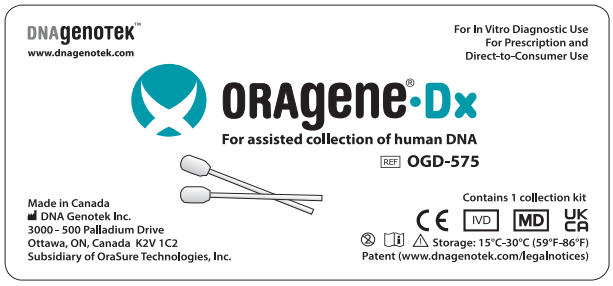
Change description:

The Oragene™•Dx (OGD-575, OGD-675) devices will undergo the following changes:

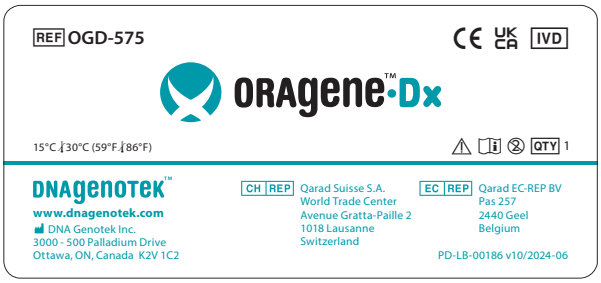
1. The Oragene™•Dx (OGD-575, OGD-675) devices are dually labeled as Medical Devices (MD) and In Vitro Diagnostic (IVD) devices. Device labeling will be updated to remove MD labeling. Device labeling will be updated and shipped following the depletion of existing inventory.
2. Printing will be removed from the underside of the primary package label to increase manufacturing efficiencies enabling DNA Genotek to respond to increased product demand. All of the required regulatory and product information remains on the product labeling; however, the information may be found in different areas of the product labeling (e.g., instructions for use). You may receive orders with the current labeling until inventory becomes depleted.

An example of the changes to labeling is provided below.

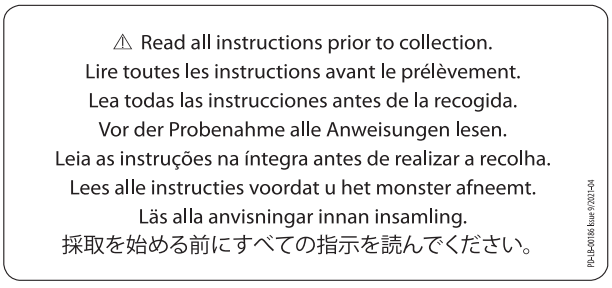
Current primary package label (top-side)



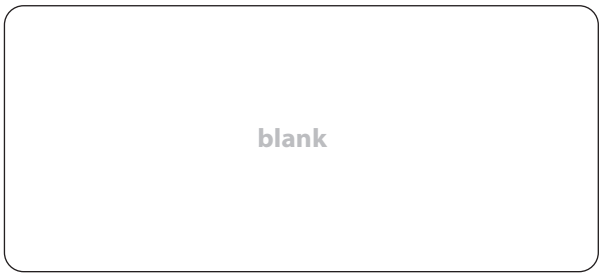
New primary package label (top-side)



Current primary package label (underside)



New primary package label (underside)



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

For the regulatory labeling change, you should determine whether internal documentation/process updates are required and, if necessary, contact your account manager to request the required documentation to support the required updates.

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