

# Product change notification

**Product affected:**  **ORAGENE™-DISCOVER** and  **ORAGENE™-Dx**

**Catalog number/SKU:** OGD-500, OGD-510, OGD-600, OGD-610, OGR-500, OGR-600, OGR-575, OGR-675

**Effective date of change:** November 1, 2024

## Change description:

The Oragene™-DISCOVER (OGR-500, OGR-600, OGR-575, OGR-675) and Oragene™-Dx (OGD-500, OGD-510, OGD-600, OGD-610) devices will undergo labeling changes. 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 still appears 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.

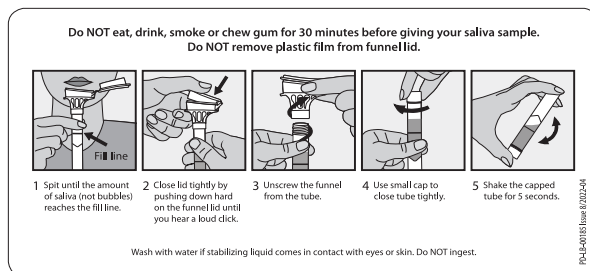
### Current primary package label (top-side)



### New primary package label (top-side)



### Current primary package label (underside)



### New primary package label (underside)



**Customer action:** No actions are required for Oragene™ products in your inventory, in distribution or in use, as there is no impact to product intended use, safety, performance, or regulatory compliance.

Contact [info@dnagenotek.com](mailto:info@dnagenotek.com) if you have any issues or concerns pertaining to this product change notification.