Product change notification

Products affected: ORAgene•Dx For collection of human DNA

Catalogue Number: OGD-5XX

Description: Oragene®•Dx

Transition Period: June 1 – September 24, 2016

Customer action: No action required

Reason for change:

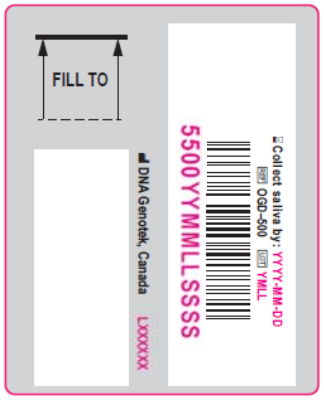
The U.S. Food and Drug Administration (FDA) has established a unique device identification (UDI) system to adequately identify medical devices through their distribution and use. Class II medical devices must be in compliance by September 24th, 2016. Oragene•Dx collection devices are subject to this regulation.

Change description:

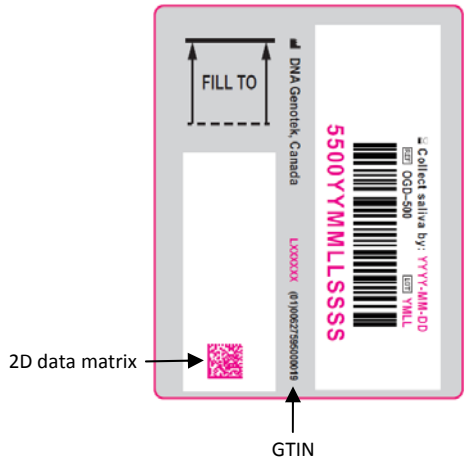
DNA Genotek is implementing a UDI on all Oragene•Dx collection devices. The UDI will be a 2D data matrix (5mm x 5mm) located on the collection tube label. An image detailing the change is shown below for representational purposes. DNA Genotek's Global Trade Identification Number (GTIN) which is embedded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

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

Existing



New



*Pink denotes variable content

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

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