



Product change notification

Academic research customers in the United States

Products affected:

Part number: OG-500, OG-575, OG-250

Description: Oragene®•DNA saliva collection products

Customers affected: Academic research customers in the United States

Effective date of change: February 14, 2012

Customer action required: Notify procurement office of update to catalogue numbers

Change description:

DNA Genotek will be changing the brand name and labelling of our Oragene•DNA product within the United States for our academic research customers to **Oragene•DISCOVER**. The product labelling will specify that the product is **For Research Use Only** and **Not for use in diagnostic procedures**.

The new product numbers will be as follows:

- OGR-500 (previously OG-500)
- OGR-575 (previously OG-575)
- OGR-250 (previously OG-250)

There will be no change to pricing, manufacturing specifications or performance characteristics for these products. As such, it is not necessary to re-validate your extraction method or downstream analysis with these new products.

Reason for change:

DNA Genotek is introducing the Oragene•DISCOVER line of products within the United States to differentiate it from our new Oragene•Dx line of products that is intended for diagnostic use within the United States. Oragene•Dx products are FDA 510(k) cleared (class II) medical devices[†]. If you are using Oragene•DNA for clinical purposes, please contact your DNA Genotek Account Manager to request information on the Oragene•Dx product family.

Transition date: February 14, 2012

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



*Oragene is a registered trademark of DNA Genotek Inc.
Oragene•DNA is not available for sale in the United States.
Oragene•DISCOVER is for research use only, not for use in diagnostic procedures.
Oragene•Dx has been cleared for in vitro diagnostic use in the U.S.A.
[†] FDA cleared for in vitro diagnostic use with the eSensor® Warfarin Sensitivity Saliva Test.

