DNAgenotek™

Product change notification

Products affected: ORAcollect™•RNA

Catalog numbers/SKUs: ORE-100

Effective date of change: By December 31, 2024

Change description: The ORAcollect™•RNA (ORE-100) device and packaging will undergo the following changes:

- The current ORE-100 device package is made from poly-film and Tyvek materials. An alternate package made from poly-film and paper will be put into production. It is possible that you could receive product manufactured with either of the materials.
- The ORE-100 device is currently manufactured with a red cap and with a white label applied to the tube. The device will be manufactured with a blue cap and the tube label will be white with a red stripe.
- The package design has been refreshed, collection steps have been removed and text has been converted to symbols.
- The ORE-100 device is currently dually labeled as an In Vitro Diagnostic device (IVD) for use under Emergency Use Authorization (EUA) within the United States for SARS-CoV-2 and as a Medical Device (MD) with UKCA and CE marks. The device labeling will be updated to remove the EUA and IVD labeling. The device will remain labeled as a Medical Device (MD) with UKCA and CE marks.

Product images:

	Current ORAcollect™•RNA (ORE-100) device and packaging	New ORAcollect™•RNA (ORE-100) device and packaging
Cap color and tube label		
Package design		
Device labeling	CE IVD MD UKCA For IVD, Rx and For Use Under Emergency Use Authorization	CE UKCA MD

Reason for change:

The packaging material change is being implemented to source sustainable materials that are better for the environment. The packaging design changes are being made to refresh the brand with a sleeker overall design.

The cap color change is being implemented to improve product quality and to provide manufacturing efficiencies. The red stripe on the tube label is designed to provide a visual differentiator from other ORAcollect™ products (e.g., ORAcollect™•Dx, ORAcollect™•DNA devices).

Demand for diagnostic SARS-CoV-2 testing has significantly declined following the pandemic. The EUA labeling on the ORE-100 device is no longer required to support SARS-CoV-2 testing. The IVD labeling is being removed to increase clarity, since DNA Genotek Inc. has received feedback that the dual IVD/MD labeling has caused confusion.

Customer action:

- For customers in the United States, ORE-100 will no longer be available for purchase after the effectivity date. If you have ORE-100 devices labeled for EUA in your inventory, they can be used until the expiry date as stated on the device.
- If you are purchasing the ORE-100 device from a country outside of the United States that recognizes the device as an MD, no action is required.
- If you are purchasing the ORE-100 device from a country outside of the United States that recognizes the device as an IVD, you can continue to use the devices in your inventory. However, the devices will no longer be available for sale in these countries after the effectivity date. Contact your account manager to discuss alternate device options.
- Update your documentation and/or internal processes, as required.

If you have any questions about this product change notification, contact your account manager or email **info@dnagenotek.com**.