

## Product change notification

**Product affected:**  **ORACollect™•RNA**

**Catalog numbers/SKUs:** OR-100

**Description:** ORACollect™•RNA

**Effective date of change:** By December 31, 2024

**Change description:** The ORACollect™•RNA (OR-100) device will undergo the following changes:

- The ORACollect™•RNA (OR-100) device is currently labeled for use under Emergency Use Authorization (EUA) within the United States for SARS-CoV-2. The device labeling will change to Research Use Only (RUO).
- The current ORACollect™•RNA package is made from poly film and Tyvek material. An alternate package, made from poly film and paper material, will be put into production. It is possible that you could receive product manufactured with either materials.
- The content on the ORACollect™•RNA kit will be updated by replacing English text with universal symbols. The instructions for use (IFU) will be updated to include 18 languages and the overall brand design will be refreshed.
- The ORACollect™•RNA device is currently manufactured with a red cap and a white label is applied to the tube. The updated device will be manufactured with a blue cap and the tube label will have a red stripe.

### Product images:

Current OR-100 device	Future OR-100 device
	

**Reason for change:** Demand for diagnostic COVID-19 testing has significantly declined following the pandemic. The EUA labeling on the ORACollect™•RNA (OR-100) device is no longer required to support COVID-19 testing, so the product will revert to its original RUO labeling.

The additional packaging and labeling changes are being implemented to support customers in non-English-speaking countries who use the device, and to source sustainable materials that are better for the environment.

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).

**Customer action:** No action is required.

If you have any questions about this product change notification, contact your account manager or email [info@dnagenotek.com](mailto:info@dnagenotek.com).