

Product change notification

Products affected:  **ORAc collect•RNA**

Catalog number/SKU: OR-100 and ORE-100

Description: ORAc collect®•RNA

Effective date of change: April 1, 2021

Change description: Customers purchasing the ORAc collect•RNA kit with SKU OR-100 will be transitioned to the ORE-100 SKU. The OR-100 and ORE-100 kits are functionally equivalent and both have received FDA Emergency Use Authorization for SARS-CoV-2 testing.

Product images

OR-100



ORE-100



Reason for change: Due to the high demand for ORAc collect•RNA kits for SARS-CoV-2 testing and in our best effort to respond to global testing needs, DNA Genotek is streamlining manufacturing to a single ORAc collect•RNA SKU (ORE-100) to maximize production.

Customer action: Identify which of the following actions apply to you. Contact your DNA Genotek account manager for all questions.

- If you currently have OR-100 kits: No action. Products in inventory can be used.
- If you have a pending OR-100 kit order expected to ship on or before April 1, 2021: DNA Genotek client services will inform you by email if you will be receiving ORE-100 kits. If your order will be fulfilled with OR-100 kits, you will not be notified.
- If you have a pre-scheduled OR-100 kit order expected to ship after April 1, 2021: No action. DNA Genotek client services will automatically update your pre-scheduled orders and will ship you ORE-100 kits.
- If you have completed validations or have received EUA for your test using OR-100 or OR-100.025 kits: Request a Certificate of Exclusivity and Equivalence from your DNA Genotek account manager and amend your regulatory files as required.

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