

June 9, 2022

RE: Update to Notification about Pre-Collection Device Shelf Life

Dear Valued Customer,

We are providing an important update to the previous notification titled Update to Pre-Collection Device Shelf Life, dated February 18, 2022, regarding reduced pre-collection device shelf life dating for the following products:

Product affected:

Product name	ORACollect™•DNA, ORACollect™•RNA
Catalog number/SKU	OCR-100, ORE-100
Lot number	YB505, YC520, YD535, YF531, YF532, YF533, YH530, YI503, YJ507, XL517, YF527, YJ530, ZB119,

Background:

DNA Genotek Inc. (“DNA Genotek”) notified you that routine internal testing had found that certain manufactured products, listed above, may experience higher-than-expected stabilizing liquid evaporation in a small subset of devices. At that time, we advised you to use the product by the date that is 12 months prior to the “Collect sample by/Use by” date listed on the collection device tube label.

Notification update:

Thank you for your patience while DNA Genotek worked to identify and resolve the root cause of the pre-collection product shelf life issue. The root cause was identified to be within one of DNA Genotek’s manufacturing processes. The necessary corrective actions were implemented and testing has confirmed the actions to be effective. Additionally, DNA Genotek has implemented actions to ensure we continue to provide you with products of the highest quality.

This notification serves to inform you that products not listed above can be used as labeled, per the “Collect sample by/Use by” date listed on the collection device tube label.

Action(s) to be taken by customer or user:

1. You have unused products with lot numbers listed above:

- Discard product. Contact your account manager for replacement devices.

2. You have unused products with lot numbers other than those listed above

- No action. The products can be used as labeled, per the “Collect sample by/Use by” date listed on the collection device tube label.

3. You have ordered products but have not received them:

- No action is required. The “Collect sample by/Use by” date listed on the device is accurate.



Should you have additional questions or concerns pertaining to this letter, contact your DNA Genotek account manager. For technical assistance contact our Technical Support team at support@dnagenotek.com.

Sincerely,

Austin Udocor
Regulatory Affairs, DNA Genotek