

May 25, 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	ORAc collect™•Dx, ORAc collect™•RNA
Catalog number/SKU	OCD-100, OCD-100.XXX, OCD-100A, OCD-100A.XXX, ORE-100

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 currently being manufactured and shipped can be used as labeled, per the “Collect sample by/Use by” date listed on the collection device tube label. Additionally, we can advise you that unused products with the lot numbers listed below may also be used as labeled, per the “Collect sample by/Use by” date listed on the collection device tube label. Consult the lot numbers listed below to identify whether this updated notification applies to your product inventory.

Product name	Catalog/SKU	Lot number
ORAc collect™•Dx	OCD-100, OCD-100.XXX	ZC102, ZC105, ZC106, ZC107, ZC109, ZC108, ZC110, ZC112, ZC111, ZC113, ZC114, ZC118, ZC119, ZC121, ZC124, ZD100, ZD101, ZD102, ZD105, ZD106, ZD107, ZD108, ZD110, ZD111, ZD112, ZD113, ZE103
ORAc collect™•Dx	OCD-100A, OCD-100A.XXX	ZD114, ZE111
ORAc collect™•RNA	ORE-100	ZE116

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

DNA Genotek recommends the following actions, depending on the scenario that applies to you:

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

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

2. You have unused products with lot numbers other than those listed above AND with “Collect sample by/Use by” dates between September 16, 2022, and May 24, 2024:

- The pre-collection shelf life has been reduced by 12 months. You should use the products by the date that is 12 months prior to the “Collect sample by/Use by” date listed on the collection device tube label. Alternatively, contact your account manager for replacement devices.

3. You have unused products with lot numbers other than those listed above AND with “Collect sample by/Use by” dates on or before September 16, 2022:

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

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

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

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