DNAgenotek™

Product change notification

Product affected: ORAcollect•Dx

Catalog numbers/REFs: OCD-100 and OCD-100A

Effective date of change: October 27, 2022

Change description:

The ORAcollect®•Dx device intended use is being updated. The updated intended use is, ORAcollect•Dx is intended for the collection of saliva samples for diagnostic testing of human DNA. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using ORAcollect•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using ORAcollect•Dx can be transported and/or stored at ambient conditions.

Reason for change:

The U.S. Food and Drug Administration (FDA) has granted a general use 510(k) clearance for the ORAcollect•Dx family of products. DNA Genotek will be updating the product labeling to reflect an expanded intended use statement, which now includes over-the-counter (i.e., direct-to-consumer) use.

Customer action:

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

- If you have unused products: No action is required, you can continue to use the ORAcollect•Dx devices.
- If you have recently placed an order for ORAcollect•Dx devices but they have not been delivered: No action is required, the ORAcollect•Dx devices can be used once delivered.
- If you purchase customized ORAcollect•Dx devices: You will be contacted by your account manager to sign an updated customization requirements document (CRD).

For more information on how to incorporate ORAcollect•Dx devices in your genetic test offering, contact your account manager. Your account manager can share the advantages of leveraging the ORAcollect•Dx 510(k) for your test offering.

PD-PCN-00085 Issue 1/2023-02 © 2023 DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved.