Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.. 60 ..... dated 27/3/22 Regarding NCMDR FSCA of ORAcollect™•DNA from (mrf: DNA Genotek Inc).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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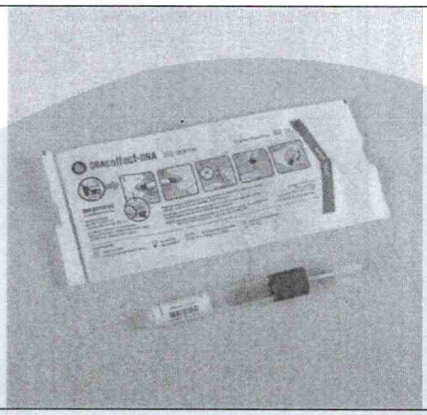
Circular No. 60/2022

24 -08-1443 H
27 -03-2022

Field Safety Corrective Action of ORAcollect™•DNA from DNA Genotek Inc.

Source	NCMDR- Nationa Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16076
Product	ORAcollect™•DNA.
Description	IVD.
Manufacturer	DNA Genotek Inc..
The affected products	Catalog number/SKU: OCR-100.
Reason	May experience higher-than-expected stabilizing liquid evaporation. As a result, in a small subset of products, the amount of available stabilizing liquid may be lower than expected. This may impact the current "Collect sample by/Use by" date (i.e. the shelf life), which is indicated on the collection device tube label.
Action	1. Refer to "Action(s) to be taken by customer or user" in the attached FSN. 2. Contact the local agent for remedial action.
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
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P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

DNAgenotek™

February 18, 2022

RE: Update to Pre-Collection Device Shelf Life

Dear Valued Customer,

We are providing this notification to advise you of a finding related to the following product(s) you have ordered from us.

Product affected:

Product name	ORAcollect™•DNA
Catalog number/SKU	OCR-100

Background:

Routine internal testing at DNA Genotek Inc. ("DNA Genotek") determined that certain manufactured products, listed above, may experience higher-than-expected stabilizing liquid evaporation. As a result, in a small subset of products, the amount of available stabilizing liquid may be lower than expected. This may impact the current "Collect sample by/Use by" date (i.e. the shelf life), which is indicated on the collection device tube label. DNA Genotek internal data shows that despite the potential increase in evaporation, the performance of the device relating to DNA collection, stability and DNA quality is not impacted. DNA concentration may be higher than expected. Additionally, to date there have been no reports from customers or users that indicate impact on the safety or performance of products listed above.

Action taken by manufacturer:

DNA Genotek has identified the cause and is taking steps to correct this issue. We are informing you of this quality issue so that you can assess and understand the potential impact to your processes. Additionally, we are notifying the appropriate regulatory agencies as required.

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 successfully processed samples using these products:**
   - No action is required.
2. **You have unused products:**
   - 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.

DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.

Toll-free (North America): 1.866.813.6354
Tel.: +1.613.723.5757
info@dnagenotek.com
www.dnagenotek.com

DNAgenotek™

3. **You have ordered products but have not received them:**
    - 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. Should there be any delay in the shipment or delivery of your order, your account manager will reach out to you.
4. **The processing lab is having difficulty recovering the minimum input volume required for the sample extraction:**
    - If you do not have sufficient volume for your workflow, contact our Technical Support team at support@dnagenotek.com.

Please acknowledge receipt of this advisory letter by completing this ONLINE FORM. Should you have additional questions or concerns pertaining to this letter, contact your DNA Genotek account manager or, for technical assistance, contact our Technical Support team at support@dnagenotek.com.

Sincerely,

Austin Udocor
Regulatory Affairs, DNA Genotek

DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.

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