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

سلطنة عمان
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.....93**..... dated** 20/05/20**Regarding NCMDR recall of** LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test In vitro diagnostic device. **(Mfr:** Roche Diagnostics Corp**)**

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**

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

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Circular No. 93 **/ 2020**

26 -Ramadhan -1441 H

20 - may - 2020

Field Safety Corrective Actions of LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test IVD device.from Roche Diagnostics Corp

Source	**(NCMDR) National Center for Medical Devices Reporting** https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15143
Product	LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test In vitro diagnostic device.
Manufacturer	Roche Diagnostics Corp
The affected products	1) LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test - GMMI: 04391853190 - Lot No.: E05866 - GTIN: 00875197000467 2) LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test - GMMI: 04391853190 - Lot No.: F02378 - GTIN: 00875197000467 3) LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test - GMMI: 04391853190 - Lot No.: F05629 - GTIN: 00875197000467 4) LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test - GMMI: 04391853190 - Lot No.: F25957 - GTIN: 00875197000467
Local Agent	National Pharmacy
Reason	Internal quality data sources have demonstrated that the aforementioned batches may not be performing as intended and may result in false HPV DNA not detected for HPV genotype 31.
Action	Roche is requesting customers to discontinue the use of LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test, CE-IVD (M/N 04391853190; batch numbers E05866*, F02378, F05629 and F25957) and discard any remaining inventory, immediately. In addition, Roche is requesting affiliates to discard any local inventory. Contact the local Agent to do the necessary action.
Product image	
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

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

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