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. 57 **dated** 31/03/2 **Regarding recall of LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test of from Roche Diagnostics**

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. 57 / 2020

14-07-1441 H

09-03-2020

Ref: 43/2020

Recall LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test of from Roche Diagnostics

Source of Recall	NCMDR National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15088
Product	LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test – IVD
Manufacturer	Roche Diagnostics Corp
Local Agent	New Source
The affected products	**GMMI** / **LOT** / **GTIN** **04391853190** / **E05866** / **00875197000467** **04391853190** / **F02378** / **00875197000467** **04391853190** / **F25957** / **00875197000467**
Reason for Recall	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	1. Kindly check your stock, contact your local agent for remedial action 2. Roche is requesting customers to discontinue the use of LINEAR ARRAY HPV (Human Papilloma Virus) Genotyping Test
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al RubaieDIRECTOR GENERAL

dg-padc@moh.gov.om : البريد الإلكتروني ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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