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



سلطنة عُـمان وزارة الصـحـة الـمـديـريـة الـعـامـة للـصـيـدلــة والـرقــابـة الـدوائـيــة مـسـقـط

To:

Moving Forward

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. 3.7....... dated .1.7.2.2.2. Regarding NCMDR recall of VITROS Immunodiagnostic Products HIV Combo Reagent Pack from (mrf: Ortho-Clinical 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





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



سلطنة عُهان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

Circular No. 37/2022

16-07-1443 H

17 -02-2022



Recall of VITROS Immunodiagnostic Products HIV Combo Reagent Pack from Ortho-Clinical Diagnostics

Source	NCMDR-National Center for Medical Device Reporting
D 1	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16016
Product	VITROS Immunodiagnostic Products HIV Combo Reagent Pack.
Description	IVD.
Manufacturer	Ortho-Clinical Diagnostics.
Affected	Product Code (UDI): 6842779 (10758750031061) (xUS/CA) Affected Lot Numbers: 0520, 0530, 0540, 0570, 0580; Expiry: Expired 0590; Expiry: 07MAR2022 0630; Expiry: 11JUN2022 0640; Expiry: 18JUL2022
Local Agent	Al Hashar Pharmacy.
Reason	False Repeat Reactive Results.
Action	 If customers have an affected lot that is still within expiration date, they may request replacement/credit. Contact the local agent for remedial action.
Product Image	Healthcare professionals are encouraged to report any adverse events Suspected to be associated
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





