



بمقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

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 200 dated 24/9/2023 Regarding NCMDR recall of ORTHO Sera Anti-Lea Murine Monoclonal IgM from (mfr: 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



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



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Circular No. 2001 2023

08 -03-1445 H

24 -09-2023

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Recall of ORTHO Sera Anti-Lea Murine Monoclonal IgM from Ortho-Clinical Diagnostics

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=19685
Product	ORTHO Sera Anti-Lea Murine Monoclonal IgM.
Description	An in vitro diagnostic medical device (IVD).
Manufacturer	Ortho-Clinical Diagnostics.
Local Agent.	AL Hashar Pharmacy LLC.
The affected products	GTIN: 10758750013234 Alba code: FD212B Ortho code: 6904497 Lot numbers: V239361, V243312, V255872
Reason	Some lots of ORTHO Sera Anti-Lea have shown unexpected negative results with Lea antigen positive red cells.
Action	1. The reagents listed should be removed from use and discarded. It is recommended that a review of previous donor and patient testing performed with these lots of antisera should be conducted. 2. Repeat testing should be conducted using an alternative lot of antisera if previously obtained results appear anomalous. 3. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

