



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. 51 dated 23/3/22 Regarding NCMDR recall of ARCHITECT STAT Myoglobin Calibrators from (mrf: Abbott Laboratories 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



Circular No. 51 / 2022


بنقدم
Forward
with Confidence



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23 -03-2022

Recall of ARCHITECT STAT Myoglobin Calibrators from Abbott Laboratories Inc.

Source	NCMDR- Naciona Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16062
Product	ARCHITECT STAT Myoglobin Calibrators.
Description	Chemiluminescent microparticle immunoassay.
Manufacturer	Abbott Laboratories Inc.
Local Agent	Waleed Pharmacy & Stores LLC.
The affected products	List Number: 2K43-01 Lot Number: 166000 US/EU UDI: (01)00380740003272, (17)220531(10)166000
Reason	The calibrator lot did not meet acceptance criteria during ongoing stability testing. When a calibration is performed with this lot, controls may exceed the specified range in the Instructions for Use (IFU).
Action	1. Immediately contact Customer Support to order a replacement lot. 2. Discontinue use of and destroy any remaining inventory of lot 166000 according to your laboratory procedures. 3. 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

