

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,

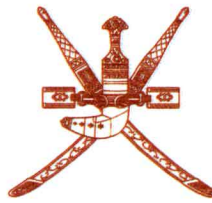
Please find attached our Circular No 50 dated 16/3/2023 Regarding NCMDR FSN of Access 2 Immunoassay System from (mfr: Beckman Coulter).

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. 50/2023


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16 -03-2023

ننقدم بثقة  
Moving Forward  
with Confidence



### Field Safety Notice of Access 2 Immunoassay System from Beckman Coulter

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18464">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18464</a>
Product	Access 2 Immunoassay System.
Description	Analyzers, Laboratory, Immunoassay.
Manufacturer	Beckman Coulter.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Reference No. 81600N Serial No. 573521 – 573594 & 570588 Reference No. 386220 Serial No. 507670, 508446, 508576, 508579, 508654, 509990, 510019, 510173, 510775, 511812, 512130, 572193, 572651, 800795
Reason	Communication Failures between System Connected to LIS or Middleware (Host) System May Occur.
Action	1. Schedule a field service visit if your laboratory must connect its Access 2 system(s) to an LIS or host system. 2. No action is necessary if you do not need to connect the Access 2 system to the LIS or host 3. Contact the local agent for remedial 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 through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General