

بتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

To:

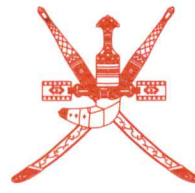
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of 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....41..... dated 28/2/22 Regarding NCMDR Recall of VIDAS® CMV IgM from (mrf: BioMerieux 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. 41/2022

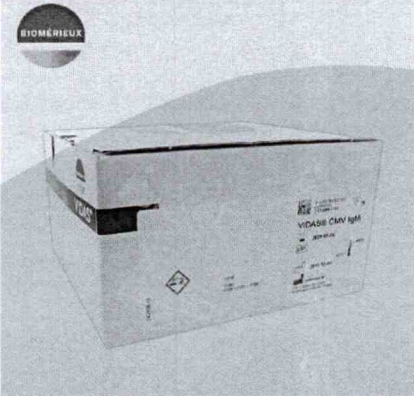
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28 -02-2022

بمودة بثقة
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Recall of VIDAS® CMV IgM from bioMérieux Inc.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16041
Product	VIDAS® CMV IgM..
Description	Cytomegalovirus (CMV) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA).
Manufacturer	BioMérieux Inc.
Affected	Refer to Table 1 "List of Affected Products" in the attached FSN.
Local Agent	Al Hashar Pharmacy.
Reason	Invalid Calibration leading to potential delayed results.
Action	<ol style="list-style-type: none">1. Stop using and destroy any stock of Lot 1008873250 and Lot 1008873260 of VIDAS® CMV IgM (Ref. 30205, 30205-01).2. You can continue to use the kits if the calibration is valid, regarding Lot 1008988860 and Lot 1009095380.3. Discuss any concerns you may have regarding delayed patients results obtained with your Laboratory Medical Director to determine the appropriate course of action.4. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaia
DIRECTOR GENERAL



Medical Devices Sector

قطاع الأجهزة الطبية

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NCMDR

National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 029 02 22 000

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Date submitted: 2/20/2022

Manufacturer:	bioMerieux Inc
Device Type:	VIDAS® CMV IgM
Description:	Cytomegalovirus (CMV) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
Medical Device Identifier:	Refer to Table 1 "List of Affected Products" in the attached FSN.
Reason of Field Safety Corrective Action:	Invalid Calibration leading to potential delayed results.
Remedy Action:	Refer to "Required Actions" in the attached FSN
Athorized Representative/Importer/Distributor:	Al-Jeel Medical & Trading Co. LTD
Report Source:	NCMDR
Source Ref. Number:	FB2DF4CC9237A
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 bioMerieux.pdf

[View History](#)