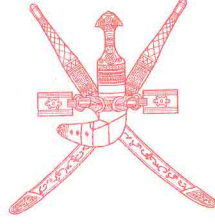


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
والدواء العامة للصحة
والرعاية الدوائية
مسقط

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. **221**..... dated **29/11/20**.. Regarding NCMDR Recall of ARCHITECT EBV VCA IgM Calibrator from (mfr: Abbott).

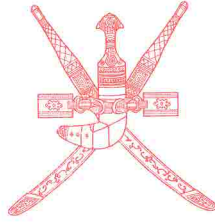
Copy to:

- 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

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مسقط

Circular No. 221 / 2020

13 -4-1442 H

29 -11-2020

Recall of Architect EBV VCA IgM Calibrator from Abbott.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15418
Product	Architect EBV VCA IgM Calibrator.
Description	IVD Test Reagent/Kits, Serology, Virus, Epstein-Barr, IgM Antibody.
Manufacturer	Abbott.
Local Agent	Mustafa Sultan Science & INDU.CO.LLC
The affected products	List Number: 3P66-01 Lot Number: 08159BE00
Reason	May show reduced RLU (Relative Light Units) signal.
Action	1. Immediately discontinue use of, and destroy, any remaining inventory of Architect EBV VCA IgM Calibrator lot 08159BE00 according to your local guidelines and your laboratory procedure. 2. In the event you are currently using or have inventory of this lot, immediately contact the manufacturer for replacement material. 3. Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results. 4. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

