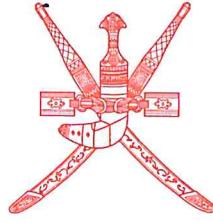


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
'and Drug Control
MUSCAT



سِلاطِنَا اَمَانَا
وَزَارَةُ الصِّحَّةِ
وَالرِّقَابَةِ الدَّوَلِيَّةِ
مَسْقَط

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. 6/2020 dated 1/1/2020 regarding NCMDR recall of Elecsys Troponin T hs for use on the cobas e 801 analytical unit (Mfr: Roche Diagnostics Corp)

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

Sultanate of Oman

Ministry of Health

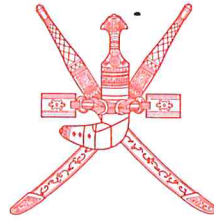
Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT

Circular No. 6 / 2020

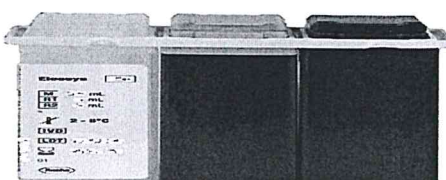
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سلطنة عمان
وزارة الصحة
المديرية العامة للصحة
والرقابة الدوائية
مسقط

Recall of Elecsys Troponin T hs for use on the cobas e 801 analytical unit from Roche Diagnostics

Source of Recall	NCMDR Recall		
Product	Elecsys Troponin T hs for use on the cobas e 801 analytical unit		
Manufacturer	Roche Diagnostics Corp		
The affected products	Product	Lot	
	Elecsys Troponin T hs (cobas e 801, 300 tests) - 08469873 190	419260, 436777	
	Elecsys Troponin T hs (cobas e 801, 300 tests) - 07028075 190	429178	
Reason for Recall	Roche informed about an increase in complaints concerning non-reproducible elevated results for Elecsys Troponin T hs lot 419260 on cobas e 801. <u>The issue appears as follows:</u> Either result of multiple determinations is non-reproducible elevated results compared to the other results of the same sample aliquot. The issue has been observed with both plasma and serum samples.		
Action	1. Kindly check your stock, contact your 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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om		

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

