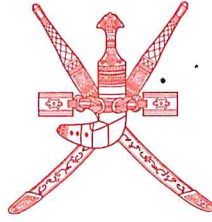


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطنة عُمان
وزارة الصحة
للمديرية العامة للصحة
والرقابة 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. 153 dated 26/8/20 Regarding NCMDR Field Safety Notice of Elecsys Anti-TPO Assay from (mfr: Roche Diagnostics GmbH).

Copy to:

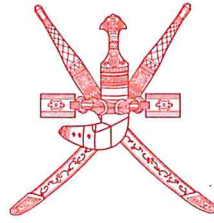
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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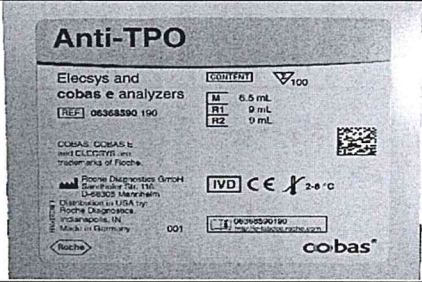
سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

Circular No. 153/2020

06 -1-1442 H

26 -08-2020

Field Safety Notice of/ Elecsys Anti-TPO Assay from Roche Diagnostics GmbH.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15291
Product	Elecsys Anti-TPO Assay.
Description	IVDs
Manufacturer	Roche Diagnostics GmbH.
Local agent	National Pharmacy LLC.
The affected products	Cobas e 411, cobas e 601, cobas e 602 Elecsys Anti-TPO 06368590 19 Elecsys Anti-TPO: all lots
Reason	The current method sheet claim for RF interference (no RF interference ≤ 1500 IU/mL) was not met. Re-testing showed that there is no RF interference ≤ 450 IU/mL (specifications of +/- 10% difference in recovery).
Action	Customers are advised to consider the updated claim for rheumatoid factors interference (no RF interference ≤ 450 IU/mL). Please make sure to refer to the latest version of the method sheet (V8) as soon as it becomes available.
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 Rubaie

DIRECTOR GENERAL

