



سنقدم بثقة
Moving Forward
with Confidence



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 248 dated 26/11/2023 Regarding NCMDR Field Safety Notice of Total Bilirubin Vanadate Oxidation Method from (mfr: Randox Laboratories Ltd).

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



نتقدم بثقة
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Circular No. 2481/2023

12 -05-1445 H

26 -11-2023

Field Safety Notice of Total Bilirubin Vanadate Oxidation Method from Randox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19768
Product	Total Bilirubin Vanadate Oxidation Method.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue number: BR8377 GTIN: 05055273214772 Catalogue number: BR9766 GTIN: 05055273208337 Catalogue number: BR4061 GTIN: 05055273214765
Reason	Elevated patient results using Plasma (Lithium Heparin) samples with Total Bilirubin reagent (TBil) Vanadate Oxidation Method for the above catalogue numbers.
Action	1. Total Bilirubin Vanadate Oxidation Method can only to be used on Serum samples. 2. Review results generated with Plasma (lithium heparin) samples in line with the clinical profile of the patient. 3. Randox are currently investigating Plasma (lithium heparin) sample interference with the sample collection and preparation steps and will complete a further notice to update our Instructions for Use (IFU). 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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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