



بمقدم 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...1.1.1..... dated 20.1.6.1.22... Regarding NCMDR FSN of Elecsys ® Folate III from (mrf : Roche Diagnostics Middle East FZCO).

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. 111 / 2022

20 -11-1443 H

20 -06-2022

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Field Safety Notice of Elecsys ® Folate III from Roche Diagnostics Middle East FZCO

Source	GHC-Gulf Health Council.			
Product	Elecsys ® Folate III.			
Manufacturer	Roche Diagnostics Middle East FZCO.			
Affected	Instrument/System	Item	Description	Lot No.
	cobas e 411 analyzer	7559992190	Folate G3 Elecsys cobas e 100 V2	596881
	cobas e 601 module	7559992190	Folate G3 Elecsys cobas e 100 V2	648223
	cobas e 602 module	7559992160	Elecsys Folate III	596894
	cobas e 801 module	7027290190	Folate G3 Elecsys E2G 300	590062
	cobas e 402 analytical unit	5944295190	Folate RBC Elecsys cobas e 100	596898
			5944295160	Elecsys Folate RBC
Local Agent	National Pharmacy LLC.			
Reason	Roche issued a quality notification related to the medical device mentioned above because of signal loss issue.			
Action	1. 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

