

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطَنَة عُمان
وَزَارَة الصِّحَة
وَالرِّقَابَة الدَّوْلِيَّة
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...^{1.52}... dated ^{27/15/12}... Regarding Safety Alert of Rotor-Gene Q Software Version 2.3.4 (Mfr: QIAGEN 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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Circular No. 102 / 2020

04 - Shwaa - 1441 H

27 - May - 2020

Safety Alert of Rotor-Gene Q Software Version 2.3.4 from QIAGEN GmbH

Source	GHC (Gulf Health Council) https://services.dha.gov.ae/sheryan/wps/portal/home/circular-details?circularRefNo=CIR-2020-00000087&isPublicCircular=1&fromHome=true		
Product	Rotor-Gene Q Software Version 2.3.4		
Manufacturer	QIAGEN GmbH		
The affected products	Product name	All serial number later than:	Catalogue number
	Rotor-Gene Q 5Plex	R0919104	9001700
	Rotor-Gene Q 6Plex	R0919115	9001720
	Rotor-Gene Q MDx	R0910300	9002020
Reason	QIAGEN has identified an issue with Rotor-Gene Q Software Version 2.3.4. This issue has been observed only when using the Rotor-Gene Q with software version 2.3.4 while using the Export function of the Laboratory Information Management Systems (LIMS) for Quantitative analysis. Which could lead to a false negative result, which could lead to serious medical consequences such as the suspension or non-initiation of treatment.		
Action	1- Discontinue use of the Rotor-Gene Q instrument with the above mentioned specific conditions. 2- Contact the local agent to upgrade to the latest version of the Rotor-Gene Q software which resolves the issue-version 2.3.5.		
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

Directorate General of Pharmaceutical Affairs & Drug Control
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