



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 180 dated 24/8/23 Regarding NCMDR Field Safety Corrective Action of Liquichek Pediatric Control from (mfr: Bio-Rad Laboratories Inc).

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. 1801 2023

08 -02-1445 H

24 -08-2023

Field Safety Corrective Action of Liquichek Pediatric Control from Bio-Rad Laboratories Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=19643
Product	Liquichek Pediatric Control.
Description	Multiple clinical chemistry constituent IVDs.
Manufacturer	Bio-Rad Laboratories Inc.
Local agent	Bahwan Healthcare Center LLC.
The affected products	Catalogue number: 354, 355, 353X Lot numbers: 74901, 44411, 44401, 44391, 44381, 74902, 44412, 44402, 44392, 44382, 74900, 44410, 44400, 44390, 44380 UDI numbers: 00847661000020, 00847661000037, 00847661001997
Reason	Bilirubin (Total, Direct, Indirect and Neonatal) and Phenylalanine may not meet the Thawed Unopened stability; or the Thawed Open Stability claims for Bilirubin (Total, Direct, Indirect and Neonatal) as printed in the package inserts.
Action	1. Users should obtain a revised copy of Liquichek Pediatric Control package insert through the Internet at http://myeinserts.qcnet.com which now include the revised stability claim in the STORAGE AND STABILITY section. 2. Discard all previous versions of the package insert for these lots of product and substitute with the revised package insert. 3. 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



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



Director General

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