Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
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.159**... dated** 31/08/20**Regarding NCMDR Field Safety Notice of Albumin Gen.2 and Bilirubin Total Gen.3 from (mfr: Roche Diagnostics).**

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**

ص . ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 159 / 2020

11 -01-1442 H

31 -08-2020

Field Safety Notice of Albumin Gen.2 and Bilirubin Total Gen.3 from Roche Diagnostics.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15305
Product	ALB2 (Albumin Gen.2) & BI LT3 (Bilirubin Total Gen.3)- IVD, Reagent.
Manufacturer	Roche Diagnostics.
Local agent	National Pharmacy LLC
The affected products	1) 05166861190 (ALB2) - cobas c 701/702 - Lot 33962301 2) 05795419190 (BILT3) - cobas c 701 /702 - Lot 36133801 2) Update ABL2 lots 43031001 (exp. 30-Nov-2020) and 43718901 (exp. 31-Jan-2021) and C4-2 lot 36870301 (exp 30-Sep-2020), removal of expired lots from version 2 (see attached).
Reason	Roche has received a number of complaints about Albumin Gen.2 (ALB2) reagent lot 33962301 and Bilirubin Total Gen.3 (BILT3) reagent lot 36133801 on cobas c 70 1/702 modules alleging low control recoveries of ALB2 and BILT3 outside of the laboratory acceptable control ranges. Customers observed a discoloration of R1 in ALB2 (yellow colour) and in some cases Sens.E calibration alarms were reported. Discoloration was also observed for R3 in BILT3. And Sens.E calibration alarm was issued at all times.
Action	1. Actions taken by Roche Diagnostics: All residual cassettes of BILT3 1ot 36133801 in the local warehouses should be blocked and discarded. 2. Actions to be taken by the customer/user: Each cassette of reagent lots: ALB2 lot 33962301 and BILT3 lot 36133801 must be calibrated before use. If the calibration and/or QC recovery is out of specification the cassette must be discarded. Each cassette of reagent lots: ALB2 lots 43031001 and 43718901 and C4-2 lot 36870301 must be calibrated and undergo QC before use (refer also to cobas 8000 Operator Manual). If the calibration and/or QC recovery is out of specification, the cassette must be discarded.
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 through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

dg-padc@moh.gov.om : ص . ب: ٣٩٣ مسقط-الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 062 08 19 001

Date submitted: 8/11/2020

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Manufacturer:	Roche Diagnostics
Device Type:	ALB2 (Albumin Gen.2) & BI LT3 (Bilirubin Total Gen.3)
Description:	IVD, Reagent
Medical Device Identifier:	1) 05166861190 (ALB2) - cobas c 701/702 - Lot 33962301 2) 05795419190 (BILT3) - cobas c 701 /702 - Lot 36133801 ..... **NCMDR Updated Codes:** Update ABL2 lots 43031001 (exp. 30-Nov-2020) and 43718901 (exp. 31-Jan-2021) and C4-2 lot 36870301 (exp 30-Sep-2020), removal of expired lots from version 2 (see attached).
Reason of Field Safety Corrective Action:	Roche has received a number of complaints about Albumin Gen.2 (ALB2) reagent lot 33962301 and Bi lirubin Total Gen.3 (BILT3) reagent lot 36133801 on cobas c 70 1/702 modules alleging low control recoveries of ALB2 and BILT3 outside of the laboratory acceptable control ranges. Customers observed a discoloration of R1 in ALB2 (yellow color) and in some cases Sens.E calibration alarms were reported. Discoloration was also observed for R3 in BILT3. And Sens.E calibration alarm was issued at all times.
Remedy Action:	Actions taken by Roche Diagnostics: All ALB2 cassettes of lot 33962301 have already been distributed. All residual cassettes of BILT3 1ot 36133801 in the local warehouses shou ld be blocked and discarded. Actions to be taken by the customer/user: • Each cassette of reagent lots: ALB2 lot 33962301 and BILT3 lot 36133801 must be calibrated before use. • If the calibration and/or QC recovery is out of specification the cassette must be discarded. In this case, no general recommendations wth respect to the review and follow up v..ere given. taking into account different possible scenarios (e.g. detectability via QC might be given, failed calibration. error appearance). I'vly specific questions raised by the users should be addressed individually, considering all relevant clinical information. ..... **NCMDR Updated Action:** Each cassette of reagent lots: ALB2 lots 43031001 and 43718901 and C4-2 lot 36870301 must be calibrated and undergo QC before use (refer also to cobas 8000 Operator Manual). If the calibration and/or QC recovery is out of specification, the cassette must be discarded.

Athorized Representative/Importer/Distributor:	FAROUK, MAAMOUN TAMER & COMPANY
Report Source:	NCMDR
Source Ref. Number:	75367F41561C1, 884FA9C038278
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	**Roche Diagnostics Corp.pdf**

View History

Product Name	ALB2 (Albumin Gen.2) C4-2 (Tina-quant Complement C4 ver.2)	
System	cobas c 701/702 module	
Product Description / GMMI	05166861190 (ALB2) cobas c 701/702 Lot 43031001 and 43718901 05991994190 (C4-2) cobas c 701/702 Lot 36870301	
Type of Action	Field Safety Corrective Action	
Change history	Version 1	Initial document
	Version 2	Updated affected lot 37437301
	Version 3	Update ABL2 lots 43031001 and 43718901 and C4-2 lot 36870301, removal of expired lots from version 2.

Dear Valued Customer,

In versions 1 and 2 of the FSN-CPS-2019-014, Roche communicated "to affected customers at that time" information about a number of complaints regarding Albumin Gen.2 (ALB2) and Bilirubin Total Gen.3 (BILT3) on cobas c 701/702 modules alleging control recovery below acceptable control ranges. Customers observed a low QC recovery and sometimes calibration failures for single cobas c pack large cassettes.

The lots listed in version 1 and 2 of the Field Safety Notification have already expired.

Recently we received and confirmed new customer complaints for C4-2 reagent lot 36870301 and ALB2 reagent lots 43031001 and 43718901 with the same error pattern and root cause.

Affected Lots			
SBN Version	Assay	Lot Number	Expiry Date
Version 1	ALB2	33962301	31-Aug-2019
	BILT3	36133801	29-Feb-2020
Version 2	ALB2	37437301	31-Jan-2020
Version 3	ALB2	43031001	30-Nov-2020
	ALB2	43718901	31-Jan-2021
	C4-2	36870301	30-Sep-2020

Table 1: Overview of affected lots of SBN Version 1-3