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

سلطنة عُمان
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 83 dated 30/4/2023 Regarding NCMDR Recall of AU / DxC AU Bicarbonate Reagent OSR6x90 from (mfr: Beckman Coulter).

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

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

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Circular No. 83 / 2023

09 -10-1444 H

30 -04-2023

Recall of AU / DxC AU Bicarbonate Reagent OSR6x90 from Beckman Coulter.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19500
Product	AU / DxC AU Bicarbonate Reagent OSR6x90.
Description	IVD.
Manufacturer	Beckman Coulter.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Refer to " Table A" in the attachment.
Reason	A premature decrease in calibration ODs.
Action	1. Safely dispose of Bicarbonate OSR6x90 lots listed in Table A. 2. Contact your local Beckman Coulter for replacement. 3. Refer to "Action" in the attachment for more information. 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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March 30, 2023

URGENT FIELD SAFETY NOTICE

AU / DxC AU Bicarbonate Reagent OSR6x90

REF	LOT	⌛
OSR6190	All lots	All
OSR6290	All lots	All

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:

Beckman Coulter has confirmed a premature decrease in calibration ODs for the following lots of Bicarbonate OSR6x90:

Table A

REF	LOT	⌛
OSR6190	2631 2632 2633	01 Aug 23 01 Aug 23 01 Sep 23
OSR6290	2628 2629	01 Aug 23 01 Sep 23

It is possible that all Bicarbonate lots may also be impacted by this issue, therefore all lots are subject to this field action.

IMPACT:

The abnormal decrease in calibrator ODs may result in calibration failures and/or QC failures. The risk of generating falsely elevated, clinically impactful patient test results is remote.

Data analysed internally has determined that, if the failure mode is generated, a positive shift of between 2 and 8 mEq/L for patient samples in the range of 20 – 39 mEq/L, would be observed.

It is possible that all Bicarbonate lots may also be impacted by this issue, therefore action is required and outlined in the following section.

ACTION:

- Safely dispose of Bicarbonate OSR6x90 lots listed in Table A in the **Issue** section of this letter. Beckman Coulter have confirmed that

these specific lots *are* impacted by premature calibration OD decrease.

- Contact your local Beckman Coulter representative for replacement and re-imbursement.

- Retrospective review of patient data is not required due to the remote possibility of generating falsely elevated, clinically impactful results which could cause a change in treatment. However, Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results.

- To avoid generation of elevated data on other lots of Bicarbonate OSR6x90, the Calibration OD range **Low** has been adjusted. Please take action to update the Calibration OD range on your analyzer with the updated values outlined in the table below.

	Current OD Range Low	**Updated OD Range Low**
Point-1	0.0500	**0.0750**
Point-2	0.1000	**0.1550**

- To change the Calibration OD Range Low on your AU / DxC AU analysers, follow the below outlined instructions:

DxC 700 AU:

- Select **Menu List > Calibration > Calibration Setup> General**
- Select the **Test Name** and scroll to the Bicarbonate test
- Select **Edit**.
- For OD Range Low, enter updated values for **Point-1** and **Point-2**
- Confirm that information is correct, then select **Save**.

AU480/AU680/AU5800: Select **Menu List > Parameters > Calibration Parameters > Calibration Specific > General**

- Select the **Test Name** and scroll to the Bicarbonate test
- Select **Edit**.
- For OD Range Low, enter updated values for **Point-1** and **Point-2**
- Confirm that information is correct, then select **Confirm**.

- After making the change to the Calibration OD range Low values, Calibrate the bicarbonate test and confirm QC is acceptable before proceeding.

	• In the event of a calibration failure or sudden shift in control values, attempt to re-calibrate the assay. If re-calibration or QC fails, discard the reagent bottle and replace with a bottle from a different lot.
RESOLUTION:	The Bicarbonate Setting Sheet BSOSR6X90 has also been revised to align with this updated Calibration OD Range. BSOSR6X90.04 will be available on the Beckman Coulter website under *Technical Documents*. Beckman Coulter is currently investigating the root cause of this issue. Beckman Coulter will continue to monitor the situation moving forward and keep you informed of any further developments.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact:

- From our website : http://www.beckmancoulter.com
- You may request replacement product by contacting your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Cartha Donovan
Senior Director, Quality & Regulatory Affairs

Enclosure: Response Form