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 9 **dated** 30/1/24 **Regarding NCMDR Field Safety Notice of Access hsTnl Reagent 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. 9 / 2024

18 -07-1445 H

30 -01-2024

Field Safety Notice of Access hsTnl Reagent from Beckman Coulter.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19890
Product	Access hsTnl Reagent.
Description	Troponin IVDs.
Manufacturer	Beckman Coulter.
Local agent	Muscat pharmacy & Stores LLC.
The affected products	Reference number: B52699 All lot numbers.
Reason	A residual risk for intra-assay carryover into an Access hsTnI reagent pack remains possible after upgrading to system software 7.0.0 and above. This risk is present when using the optional automated Access hsTnI Onboard Dilution (OBD) assay.
Action	1. Discontinue the use of Access hsTnI OBD assay on your UniCel DxI 600 and/or UniCel DxI 800 instruments by disabling the assay, please refer to the attachment for more information. 2. Beckman Coulter will implement a design change that removes DxI system onboard dilution information from the Access hsTnI reagent (IFU) and removes the OBD assay from the UniCel DxI 600 and UniCel DxI 800 instruments. 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

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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BECKMAN COULTER

September 13, 2023

URGENT FIELD SAFETY NOTICE

Access hsTnI Reagent

REF	Lot Number	⌛
B52699	All	Multiple

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that requires your immediate attention. Patient results may be affected. This letter is intended for UniCel DxI 600 and 800 customers who are running their systems with software version 7.0.0 or higher.

ISSUE:	• Beckman Coulter has determined that a residual risk for intra-assay carryover into an Access hsTnI reagent pack remains possible after upgrading to system software 7.0.0 and above. This risk is present when using the optional automated Access hsTnI Onboard Dilution (OBD) assay. • Clinically significant carryover into a reagent pack may occur when a sample with a cardiac Troponin I (cTnI) concentration greater than the S6 calibrator (~27,000 pg/mL) is diluted using the Access hsTnI OBD assay on a UniCel DxI 600 or UniCel DxI 800 immunoassay analyzer.
IMPACT:	• **When using the hsTnI OBD assay:** an Access hsTnI reagent pack that is used to test a sample with a (cTnI) concentration greater than the S6 calibrator (over range) may be subject to carryover. If this occurs, the carryover may impact the results for all subsequent samples tested from that reagent pack. • Carryover into a reagent pack may cause falsely elevated Access hsTnI results. • Manually diluted Access hsTnI samples run on the UniCel DxI 600 and UniCel DxI 800 are not impacted. • Samples run on an Access 2 system are not impacted.
ACTION:	• Discontinue the use of Access hsTnI OBD assay on your UniCel DxI 600 and/or UniCel DxI 800 instruments by disabling the assay. ○ For assistance with disabling the onboard dilution assay on the UniCel DxI 600 or UniCel DxI 800 standalone instrument, refer to Section 3.3 of the "*UniCel DxI Reference Manual*". ○ For assistance with disabling the onboard dilution assay on an integrated UniCel DxI 600 or UniCel DxI 800 instruments, refer to the IFU for "*UniCel DxC Synchron Access Clinical Systems Integrated Workstations*"; Chapter 10 System Setup, Configure the Chemistry, Delete a Chemistry.

BECKMAN COULTER

	• Additional testing may be performed on cTnI samples with a concentration greater than the S6 calibrator if these samples are manually diluted. Refer to the Instructions For Use (IFU) for manual dilution procedure. • At the discretion of your medical director, conduct a retrospective review of Access hsTnI results run after the Access hsTnI OBD assay after the software upgrade 7.0.0 was implemented.
RESOLUTION:	Beckman Coulter will implement a design change that removes DxI system onboard dilution information from the Access hsTnI reagent (IFU) and removes the OBD assay from the UniCel DxI 600 and UniCel DxI 800 instruments.

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 our Customer Support Center

- From our website: http://www.beckmancoulter.com

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Rachel Davison
Signer Name: Rachel Davison
Signing Reason: I approve this document
Signing Time: 14-Sep-2023 | 7:21:54 AM PDT
109D1D39B30B415BBEC3779EBF0205D5

Rachel Davison
Vice President Quality & Regulatory Affairs
Beckman Coulter Inc.

Enclosure: Response Form