Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 165 **dated** 28/11/24 **Regarding SFDA Field Safety Notice of Access hsTnI (reagent pack) from (mfr: Beckman Coulter Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

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

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سلطنة عمان
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Circular No. 165/ **2024**

26-05-1446 H
28-11-2024

Field Safety Notice of Access hsTnI (reagent pack) from Beckman Coulter Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/189
Product	Access hsTnI (reagent pack).
Manufacturer	Beckman Coulter Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	B52699.
Reason	In remote circumstances according Beckman Coulter, if a sample containing high cardiac troponin (cTnI) >55,000 pg/mL is tested using an Access assay other than Access hsTnI, cTnI carryover may occur if the next test performed, using the same probe on that instrument, is Access hsTnI on a different sample.
Action	1. Follow your established laboratory protocols for analyzing and retesting discrepant samples if an observed Access hsTnI test result does not align with the patient's clinical presentation. 2. Beckman Coulter recommends reviewing the content of the attachment with your laboratory and/or medical director to determine appropriate next steps. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

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

November 07, 2024

URGENT MEDICAL DEVICE RECALL

Access hsTnI Reagent Kit*

REF	LOT	
B52699	All	NA

*When run on the Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i,
UniCel DxC 680i, UniCel DxC 860i, UniCel DxC 880i and DxC 500i systems.
This Medical Device Recall does not affect the DxI 9000 Access Immunoassay Analyzer.

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

ISSUE:	• In remote circumstances, if a sample containing high cardiac troponin (cTnI) >55,000 pg/mL is tested using an Access assay other than Access hsTnI, cTnI carryover may occur if the next test performed, using the same probe on that instrument, is Access hsTnI on a different sample.
IMPACT:	• Carryover of cTnI may generate a falsely elevated Access hsTnI result in subsequent sample(s) which can impact patient care (potentially but not limited to unnecessary coronary imaging or diagnostic catheterization) if the result is near the medical decision points. • One internal study indicated the potential for carryover of 2-5 pg/mL from a high cTnI sample (~55,000 pg/mL).
ACTION:	• Follow your established laboratory protocols for analyzing and retesting discrepant samples if an observed Access hsTnI test result does not align with the patient's clinical presentation. • Beckman Coulter recommends reviewing the content of this letter with your laboratory and/or medical director to determine appropriate next steps.
RESOLUTION:	• Beckman Coulter is currently investigating options to resolve this issue.

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

Phone: 952.448.4848
Fax: 800.232.3828
www.beckmancoulter.com

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

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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,

Signed by:
Courtney Walton
Signer Name: Courtney Walton
Signing Reason: I approve this document
Signing Time: 07-Nov-2024 | 2:10:40 PM PST
A78060F7687943039615B491616B80F6

Courtney Walton
Senior Director of Quality Assurance and Regulatory Affairs
Beckman Coulter, Inc.

Enclosure: Response Form

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