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.. 38 ..... dated ..21/2/22.. Regarding NCMDR FSCA of Access hsTnI Reagent from (mrf: 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

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
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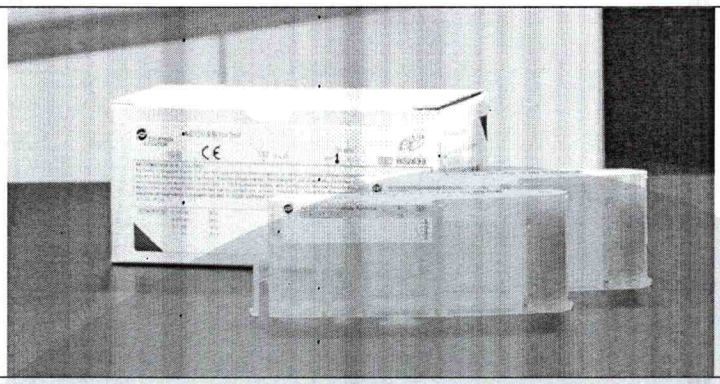
سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 38 **/ 2022**

20-07-1443 H

21-02-2022

Field Safety Corrective Action of Access hsTnI Reagent from Beckman Coulter.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16028
Product	Access hsTnI Reagent.
Description	IVD.
Manufacturer	Beckman Coulter.
Affected	REF: B52699 Lot: All Includes the Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.
Local Agent	Muscat Pharmacy & Stores LLC.
Reason	Potential sample-to-sample carryover with the Access hsTnI (High Sensitivity Troponin I) assay. The letter also addresses the Access hsTnI intra-assay carryover issue.
Action	1. Refer to "Action" in the attached FSN. 2. Contact the local agent for remedial action.
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 contact 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

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الاجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 017 02 22 000

Back

Date submitted: 2/10/2022

Manufacturer:	Beckman Coulter
Device Type:	Access hsTnI Reagent.
Description:	IVD
Medical Device Identifier:	REF: B52699 Lot: All Includes the Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.
Reason of Field Safety Corrective Action:	Potential sample-to-sample carryover with the Access hsTnI (High Sensitivity Troponin I) assay. The letter also addresses the Access hsTnI intra-assay carryover issue.
Remedy Action:	Refer to "Action" in the attached FSN.
Athorized Representative/Importer/Distributor:	Beckman Coulter Saudi Arabia Co Ltd
Report Source:	NCMDR
Source Ref. Number:	7178AC86A02BB
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Beckman Coulter..pdf

View History

BECKMAN COULTER

February 04, 2022

URGENT MEDICAL DEVICE RECALL*

Access hsTnI Reagent

REF	LOT	
B52699	All	Multiple

* Includes the Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.

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. This letter notifies you of potential sample-to-sample carryover with the Access hsTnI (High Sensitivity Troponin I) assay. The letter also addresses the Access hsTnI intra-assay carryover issue that was previously documented in FA-000604.

ISSUE:	• FA-000604, which was distributed in August 2021, notified customers of possible intra-assay carryover. The letter communicated that clinically significant carryover into a reagent pack (into-pack) can occur if an Access hsTnI test is performed after a sample with a cTnI concentration >270,000 pg/mL (ng/L) and uses the same reagent pipettor. • A subsequent investigation has determined that **sample-to-sample** carryover may also occur under certain conditions confirming that intra-assay carryover encompasses into-pack and **sample-to-sample** carryover. • Through these subsequent studies, BEC determined that clinically significant **sample-to-sample** carryover can occur in hsTnI samples that are tested after a sample with a cTnI concentration >55,000 pg/mL (ng/L).
IMPACT:	• Intra-assay carryover may lead to falsely elevated hsTnI results. • An Access hsTnI reagent pack that is sampled immediately after a >270,000 pg/mL (ng/L) cTnI sample may demonstrate into-pack carryover, which will impact the results for all subsequent samples tested from that reagent pack or possibly a different hsTnI pack. • An Access hsTnI sample that is started between aspiration and result of a high hsTnI sample (>55,000 pg/mL (ng/L)) may be affected by **sample-to-sample** carryover from the high sample. This **sample-to-sample** carryover does not affect the reagent pack or the primary sample tube.

<table>
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- Technical investigations have determined that the extent of total intra-assay carryover (into pack and **sample-to-sample** carryover) are directly proportional to the cTnI concentration that is present in the high sample. Internal studies were performed to estimate the magnitude of total intra-assay carryover. A summary of the findings is presented in the following table.

Observed High Sample TnI Concentration (pg/mL)	Expected Intra-assay Carryover (pg/mL)	95% Prediction Limit for Individual Carryover Events (pg/mL)
55,000	1.6	3.3
270,000	6.5	20.9

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<tr><td>ACTION:</td><td>

1. If an hsTnI result ≤ 55,000 pg/mL (ng/L) is observed, no mitigation is necessary. Follow your standard laboratory procedure for reporting results.
2. If an hsTnI result > 55,000 pg/mL (ng/L) but less than the top of the diluted range (~270,000 pg/mL (ng/L)) is observed, perform the following steps:
   i. Repeat each positive or delta check hsTnI sample run between the time when the high sample was first introduced to the system and final result was obtained.
   ii. Continue normal operation.
3. If an hsTnI result >270,000 pg/mL (ng/L) is observed, perform the following steps:
   i. Remove and discard all open Access hsTnI reagent packs.
      - Contact your Beckman Coulter representative if you need replacements for the discarded Access hsTnI reagent packs.
   ii. Load a single Access hsTnI reagent pack.
   iii. Run your current low level hsTnI QC on all reagent pipettors configured for hsTnI to verify that there is no further carryover. **NOTE:** UniCel DxI operators can test all configured reagent pipettors by setting up a QC file.
   iv. If the QC result is within the laboratory's defined ranges for each pipettor configured, repeat each positive or delta check hsTnI sample that was tested after the >270,000 pg/mL (ng/L) cTnI sample and then continue normal operation. Load additional reagent packs if it is appropriate for your laboratory's testing requirements.
   v. If the QC result is not within the acceptable range, contact Beckman Coulter Customer Technical Support for further assistance.

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<tr><td>RESOLUTION:</td><td>

- Beckman Coulter is continuing to investigate the root cause and resolution of this issue.

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</table>

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 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 Customer Technical Support:

- From our website: http://www.beckmancoulter.com
- Outside the United States, contact your local Beckman Coulter representative.

For customers in Canada, if you need replacement product:

- Complete the attached "Replacement Order Form" and email to Beckmancoultercanada@beckman.com or fax to (866) 294-7850 OR
- Call Client Services at (800) 463-7828

For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Rachel Davison
Vice President of Regulatory Affairs and Quality Management

Enclosure: Response Form