Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution onthis issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please informus about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Affairs Specialist

Contact person of this notification	...Alice Wong.....
Department	... Marketing.....
Telephone	...6012-296 0320.....
Fax	...603 7772 0551.....
E-mail	... awong02@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
No 18, Jalan Tandang 51/205A,
Seksyen 51, 46050 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Tel : (603) 77728256
Fax : (603) 77720551
Website : www.beckmancoulter.com

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