



November 07, 2024

URGENT FIELD SAFETY NOTICE

Access hsTnl Reagent Kit*

REF	LOT		UDI
B52699	All	NA	15099590693183

*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 Urgent Field Safety Notice does not affect the DxI 9000 Access Immunoassay Analyzer

Single Registration Number (SRN): FR-MF-000011121

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:	<ul style="list-style-type: none"> In remote circumstances, if a sample containing high cardiac troponin (cTnl) >55,000 pg/mL is tested using an Access assay other than Access hsTnl, cTnl carryover may occur if the next test performed, using the same probe on that instrument, is Access hsTnl on a different sample.
IMPACT:	<ul style="list-style-type: none"> Carryover of cTnl may generate a falsely elevated Access hsTnl 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 cTnl sample (~55,000 pg/mL).
ACTION:	<ul style="list-style-type: none"> Follow your established laboratory protocols for analyzing and retesting discrepant samples if an observed Access hsTnl 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:	<ul style="list-style-type: none"> Beckman Coulter is currently investigating options to resolve this issue.



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 the affected product 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,

Signed by:
Courtney Walton
Signer Name: Courtney Walton
Signing Reason: I approve this document
Signing Time: 13-Nov-2024 | 9:30:28 AM PST
A78060F7687943039615B491616B80F6

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

Enclosure: Response Form

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