July 21, 2025

UPDATED URGENT FIELD SAFETY NOTICE – FSN-24062-C

Access hsTnI 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

Dear Beckman Coulter Customer,

Beckman Coulter is initiating **an update to the field action (FA-24062)** for the product listed above. This letter contains important information that needs your immediate attention. All updates to this field action letter are outlined in Blue.

ISSUE:

- In remote circumstances, if a sample containing high cardiac troponin (cTnI) 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.
- Following additional feedback, Beckman Coulter is providing representative data for the magnitude of carryover observed in internal studies.

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.
- In internal studies conducted on the Access 2 and DxI 800, Beckman Coulter observed the following potential magnitude of cTnI carryover from a previous sample tested on an assay other than Access hsTnI:

High cTnI concentration (pg/mL)	Access 2 maximum observed carryover (pg/mL [ng/L])	DxI 800 maximum observed carryover (pg/mL [ng/L])
~27,000	3.2	2.5
~50,000	4.5	3.2
~110,000	9.3	3.6

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<table>
<tr><td></td><td>
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<tr><td>~150,000</td><td>19.6</td><td>4.5</td></tr>
<tr><td>~270,000</td><td>22.3</td><td>7.6</td></tr>
<tr><td>~500,000</td><td>44.9</td><td>39.6</td></tr>
<tr><td>~1,000,000</td><td>77.8</td><td>67.7</td></tr>
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Based on the data observed, the highest concentrations of cTnI tested that did not generate any clinically significant carryover was ~27,000 pg/mL and carryover of 2-5 pg/mL was observed from a high cTnI sample ~55,000 pg/mL.
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<tr><td>ACTION:</td><td>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.</td></tr>
<tr><td>RESOLUTION:</td><td>Beckman Coulter is currently developing additional software modifications as a comprehensive carryover solution for all affected instruments identified at the top of this notification.
The Access hsTnI IFU will be updated with a new limitation statement indicating samples with cTnI concentrations >27,000 pg/mL may lead to carryover if the next test(s) performed using the same reagent probe is Access hsTnI.</td></tr>
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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 with a copy of this letter.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologise for the inconvenience that this caused your laboratory.

Yours sincerely,

Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe