February 11, 2022

URGENT FIELD SAFETY NOTICE *

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. • 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

ACTION:

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.

RESOLUTION:

- Beckman Coulter is continuing to investigate the root cause and resolution of 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 any of the affected product(s) 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 Technical Support:

From our website: http://www.beckmancoulter.com
Contact your local Beckman Coulter representative.

Beckman Coulter continues to investigate this issue and will report additional updates as they are available. We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Rachel Davison
Vice President of Regulatory Affairs and Quality Management

Enclosure: Response Form

CUSTOMER RESPONSE FORM

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Check the appropriate box below:

☐ I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken and records retained as part of our Laboratory Quality System documentation.

Or:

☐ We do not have this product.

Name and Address of Laboratory / Hospital / Organization / Institution:

_____

_____

Signed:_____ Date:_____

Name:_____ Title:_____

Tel: _____ Email: _____

Please return to:

Beckman Coulter is updating the customer address list for field action notifications. If the contact information on your notification is inaccurate, please update:

Customer Number:_____

Contact Name:_____ Title:_____

Tel: _____ Email: _____

Mailing Address:_____