December 5, 2018

URGENT FIELD SAFETY NOTICE

UniCel DxI 600 and 800 Access Immunoassay Systems and
UniCel DxC 660i, 680i, 860i, 880i Synchron Access Clinical Systems

REF	SOFTWARE VERSIONS
UniCel DxI 600 Systems (A30260, A71460, A71461, A92060) UniCel DxI 800 Systems (973100, A71456, A71457, A84545, A25288, A25285) UniCel DxC 660i, 680i, 860i, 880i Synchron Access Clinical Systems (A64871, A64903, A64935, A59102)	5.2, 5.3.0, 5.3.1

Only instruments that are connected to an automation line and running any of the indicated software versions are affected. Access 2 systems are NOT affected.

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	• Beckman Coulter has determined that UniCel DxI 600 and 800 system software versions 5.2, 5.3.0, and 5.3.1 contain a defect that has the potential to cause erroneous results when the instrument is operated while connected to an automation line **(software versions 5.1 or earlier are not affected)**. Note: Your system software version is shown at the bottom-left of your system's Main Menu (See images below for location)  • When racks are front-loaded onto the DxI sample presentation unit (SPU) while samples from the automation line are being processed, a scheduling error within the software can cause mishandling of samples during the creation of an aliquot and lead to incorrect results being generated. • The defect only occurs when sample racks are front-loaded through the SPU on a UniCel DxI 600 or 800 system that is simultaneously testing automation line samples.

IMPACT:	• **Access 2 systems, DxI stand-alone and DxI integrated instruments are not affected.** • The issue will not occur during regular automation line operation if samples are not loaded at the same time through the SPU. • The issue does not occur when racks are loaded on the SPU if the DxI instrument is not simultaneously testing samples from the automation line. • Any assays and any sample types (patient samples, quality control, and calibrators) run on the DxI are susceptible to this error. • Affected samples typically yield non-reproducible falsely decreased results by up to 100%, however the potential for falsely elevated results cannot be ruled out. • All tests processed from an affected sample aliquot have the potential to be impacted.
ACTION:	• In order to prevent this error from occurring, **do not load racks onto the SPU while samples are being processed from the automation line.** • Either of the following options can be followed to avoid the error: 1) Pause the automation line before loading of any racks onto the SPU. a) To pause the automation line and load racks on the SPU, use the following steps: i) Set the Lab Automation System (LAS) Mode to “Offline” (1) Return to the Main Menu (F9) (2) Select Configure (F8) (3) Select LIS/LAS (F6) (4) Select LAS (F2) (5) In the dropdown menu, select “Offline” and press OK (F1) ii) Load samples onto the SPU iii) Wait until all racks from the SPU are fully aspirated and moved to the off-load area b) To resume processing using the automation line, follow Step (i) above and select “Online” from the dropdown menu. 2) As an alternative to pausing automation line operation, racks can be loaded onto the SPU of any stand-alone instrument (if available). • Interpret results in light of the total clinical presentation of the patient including: symptoms, clinical history, data from additional tests, and other appropriate information. • Review this letter with your Medical Director to determine if any further actions are warranted, including a review of results previously generated by affected systems.
RESOLUTION:	• Beckman Coulter will implement a correction in the next software release. • Your service representative will contact you to schedule your software upgrade when available. • Refer to the Questions and Answers document for additional information.

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 Support Center:

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

David G. Davis
Senior Director, Regulatory Affairs

Enclosure: Response Form

FSN-000162 Questions and Answers

1) **Are the Access 2 instruments in my laboratory affected by this issue?**

   A: No, Access 2 instruments are not affected since they run different software than the DxI systems and Access 2 systems cannot be connected to an automation line.

2) **The DxI (or DxC Synchron) instrument(s) in my laboratory match the REF number listed, but they are not connected to an automation line, are these instruments affected?**

   A: No, the instruments listed are ONLY affected when they are connected to a laboratory automation system AND are running any of the software versions listed.

3) **My DxI is on our automation line, but the Main Menu says "5.1" for the software version, am I affected?**

   A: No your system is not affected. The instruments listed are ONLY affected when they are connected to a laboratory automation system AND are running any of the software versions listed (5.2, 5.3.0, or 5.3.1). Unaffected software versions will not be changed.

4) **What sample results are affected by this issue?**

   A: Any sample loaded on the SPU or from the automation line is susceptible. All sample types including patient samples, quality control, and calibrators are susceptible to this error. However, not all samples are always affected. The issue can only occur when:

   a) Sample racks are front-loaded through the sample presentation unit, AND
   b) The instrument is processing/aliquotting samples from the automation line, AND
   c) The instrument is running software versions 5.2, 5.3.0, or 5.3.1

5) **Does the instrument need to be in "Ready" mode to turn the automation line offline?**

   A: No, you can turn the LAS to "Offline" when the instrument is in any operating mode other than "Not Ready."

6) **We load all STAT samples and/or QC through the SPU on our automation connected instrument, will this impact or delay my results?**

   A: Beckman Coulter recommends following the actions to turn the LAS offline prior to loading any sample racks on the SPU. There should only be minimal delay (about 30 – 60 sec.) to sample turn-around-time when this action is carried out.

7) **Can I downgrade my system software back to version 5.1 until a fix is released?**

   A: No, due to computer operating system capability and compatibility, systems running the affected software versions cannot be reverted back to version 5.1 and Beckman Coulter does not support this customer action.

8) **Should we review all previous results generated by the affected software versions?**

   A: Your Medical Director should determine whether any review of prior results is required.