![Beckman Coulter logo]

9 February 2015

FOLLOW-UP URGENT FIELD SAFETY NOTICE

Access 2 Systems*
Includes the Access 2 Immunoassay System and the UniCel DxC 600i Synchron Access Clinical System

Attention Beckman Coulter Customer,

Beckman Coulter is pleased to announce we are releasing Access 2 system software version 3.4.2 and Access 2i (UniCel DxC 600i System) software version 6.2.2 to address the reagent pack volume issues discussed in the PCA-14932 notification that was distributed August 13, 2010.

PCA-14932 discussed the risks associated with assay reagent packs that were loaded incorrectly, or reagent packs that were inappropriately transferred between two systems (pack sharing). With these software versions, the new Reagent Pack Monitoring feature enables the Access 2 system pressure monitoring hardware to detect packs with insufficient volume, as well as packs that are improperly loaded or missing. Your service representative will contact you to schedule installation of the new software.

The national competent authority has been informed of this follow-up 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 any of the affected instrument systems have been moved 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 your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Vice President Quality & Regulatory Affairs

Enclosure: Response Form

Beckman Coulter, the stylized logo, Access, and UniCel are trademarks of Beckman Coulter, Inc., and are registered with the USPTO

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