



28 April 2015

FOLLOW-UP URGENT FIELD SAFETY NOTICE

UniCel DxI Immunoassay Systems*

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

Attention Beckman Coulter Customer,

This follow up notice contains important information regarding changes to the UniCel DxI Immunoassay Systems Instructions for Use (IFU) that needs your immediate attention.

In Product Corrective Action Notification (PCA 16241) Beckman Coulter recommended temperature restrictions to address the impact of room temperature changes on certain assays run on UniCel DxI Immunoassay Systems. The UniCel DxI Immunoassay Systems Instructions for Use (IFU) has been updated to include these temperature restrictions in Appendix A Temperature-Sensitive Assays. An updated version of the UniCel DxI Immunoassay Systems IFU is available on the Beckman Coulter website (<http://www.beckmancoulter.com>).

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,

A handwritten signature in black ink that reads 'Noreen Galvin'.

Noreen Galvin, Ph.D.
Vice President Quality & Regulatory Affairs

Enclosure: Response Form

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