

FOLLOW-UP URGENT FIELD SAFETY NOTICE

UniCel DxI Immunoassay Systems*

* Includes the UniCel DxI 800 and UniCel DxI 600 systems, and the UniCel DxC 880i, 860i, 680i, and 660i integrated systems

Dear Beckman Coulter UniCel DxI Immunoassay System Customer:

This notice contains important information regarding an upcoming UniCel DxI system software release that needs your immediate attention.

The Access, Access 2, UniCel DxC 600i, and SYNCHRON LXI 725 Immunoassay Systems are not affected by this notice.

Within Urgent Field Safety Notice (FSN) PCA-16241 regarding DxI Thermal Sensitivity distributed in April 2011, Beckman Coulter implemented a required ambient operating temperature range of 18 °C to 30 °C for UniCel DxI Systems. Beckman Coulter will soon release UniCel DxI system software version 4.6.1 which includes updates related to the operating temperature ranges.

NOTE: The information in PCA-16241 was also provided in Field Safety Notice Product Correction (P/N B04823A), and/or the FSN provided on the *Room Temperature Operating Requirements* CD (P/N B05148).

ISSUE:

UniCel DxI software version 4.6.1 implements an instrument cabinet temperature requirement of 18 °C to 36 °C. Beckman Coulter is also updating the UniCel DxI system documentation to reflect the ambient operating temperature range of 18 °C to 30 °C implemented in PCA-16241.

IMPACT:

With UniCel DxI software version 4.6.1, the system monitors the temperature inside the instrument. After UniCel DxI software version 4.6.1 is installed, the UniCel DxI system will alert the operator and prevent test result reports whenever the temperature inside the instrument is not within the required range. To properly maintain the required temperature inside the instrument, you should continue monitoring and controlling the ambient operating temperature range at 18 °C to 30 °C.

ACTION:

- Once UniCel DxI software version 4.6.1 is installed, continue to ensure that the ambient temperature is maintained at 18 °C to 30 °C.
- If your laboratory is unable to maintain this ambient temperature range, contact your Beckman Coulter representative.



- Continue to follow the assay-specific requirements outlined in PCA-16241. See the attached Table 1: Assay Ambient Operating Temperature Restrictions. There have been no changes to these requirements.

RESOLUTION:

The UniCel DxI *Help* system and the *DxI Instructions for Use* manual that accompany UniCel DxI software version 4.6.1 have been updated to include the revised temperature range 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 any questions regarding this notice, please contact your local Beckman Coulter representative.

Sincerely,

A handwritten signature in black ink that reads 'Scott Cundy'.

Scott Cundy

VP, Quality and Regulatory Affairs

Enclosure: Response Form



Table 1: Assay Ambient Operating Temperature Restrictions

As reported in PCA-16241, Access AccuTnl (P/N 33340 and A78803) results should not be reported out of the laboratory when the ambient room temperature exceeds the required range in the table. All other affected Access assays should be recalibrated if the room temperature changes by more than the amount cited below from the room temperature at which the assay calibration was established.

Part Number	Product	Restricted temperature range	% Result error across restricted range	If temperature increases, assay result...
33340	Access AccuTnl	21 °C – 28 °C	24%	Decreases
A78803	Access AccuTnl	21 °C – 28 °C	24%	Decreases
33000	Access Vitamin B ₁₂	±4 °C	±8%	Increases
33210	Access AFP (100 test kit)	±4 °C	±10%	Increases
33211	Access AFP (300 test kit)	±4 °C	±10%	Increases
33410	Access Ultrasensitive Insulin	±4 °C	±6%	Increases
33540	Access Estradiol	±4 °C	±11%	Decreases
33560	Access Testosterone	±4 °C	±8%	Decreases
33580	Access Ultrasensitive hGH	±4 °C	±7%	Increases
33600	Access Cortisol	±4 °C	±6%	Decreases
33820	Access Fast TSH (Test IDs 246 and 11246 only)	±4 °C	±7%	Increases
33880	Access Free T4	±4 °C	±8%	Increases
34210	Access HAV IgM	±4 °C	±14%	Increases
34430	Access Rubella IgG	±4 °C	±11%	Increases
98200	Triage* BNP Test for Beckman Coulter Immunoassay Systems	±4 °C	±17%	Decreases
386371	Access CK-MB	±4 °C	±5%	Increases
A12985	Access TPO Antibody	±4 °C	±11%	Increases
A13422	Access Free T3	±4 °C	±13%	Increases
A16972	Access Intact PTH - Intraoperative Mode (Test IDs 215 & 11215 only)	±4 °C	±17%	Increases
A31588	Access Toxo IgG	±5 °C [‡]	±11%	Increases
A36097	Access Inhibin A	±4 °C	±8%	Decreases
A40702	Access CMV IgG	±5 °C [‡]	±18%	Increases
A48617	Access SHBG	±4 °C	±16%	Increases
A49752	Access Hybritech p2PSA	±6 °C	±16%	Decreases

[‡] Access Toxo IgG and Access CMV IgG Instructions for Use are already labeled for this temperature restriction

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