



August 21, 2023

Important Product Notice

UniCel Dxl 800 Access Immunoassay System
 UniCel Dxl 800 Access Immunoassay System with Spot B
 UniCel Dxl 600 Access Immunoassay System
 UniCel Dxl 600 Access Immunoassay System with Spot B
 Access 2 Immunoassay Analyzer

REF	Serial Number
973100, A71456, A30260, A71460, 81600N	Multiple

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter to notify your laboratory of a measured increase in the Cadmium levels for instrument parts that are used in Access 2, UniCel Dxl 600 and UniCel Dxl 800 immunoassay systems.

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that Access 2, UniCel Dxl 600 and UniCel Dxl 800 luminometer lock nuts fitted on multiple instrument serial numbers may contain Cadmium levels that are above the limit allowable by the Restriction of Hazardous Substances (RoHS). Beckman Coulter has determined that the UniCel Dxl 600 and UniCel Dxl 800 bulk feeder II chute block sensor fitted on multiple instrument serial numbers may contain Cadmium levels that are above the limit allowable by the Restriction of Hazardous Substances (RoHS).
IMPACT:	<ul style="list-style-type: none"> These elevated Cadmium levels do not affect patient, quality control, calibration, or system check results. These elevated Cadmium levels are not a safety risk to laboratory personnel who might contact an affected luminometer lock nut or bulk feeder II chute block sensor. Your laboratory may continue normal operation of any immunoassay system affected by this issue.
ACTION:	<ul style="list-style-type: none"> No action is necessary by end users.
RESOLUTION:	<ul style="list-style-type: none"> Due to the environmental hazard of Cadmium, Beckman Coulter will dispose of all affected luminometer lock nuts, bulk feeder II chute sensor blocks, and/or the instruments that contain these parts, according to the applicable regulations. During the next semi-annual preventative maintenance or repair visit, a Beckman Coulter service representative will:

	<ul style="list-style-type: none">○ Replace any affected UniCel DxI 600 and UniCel DxI 800 bulk feeder II chute sensor block with a RoHS-compliant block.○ Due to the extended instrument downtime (loss of diagnostic capacity for up to a day) caused by extensive disassembly required to replace the luminometer lock nuts and extremely limited exposure risk, Beckman Coulter will affix an alert label to the back of any Access 2, UniCel DxI 600, and UniCel DxI 800 instruments that contain the affected luminometer lock nuts. This label notifies laboratory personnel that the luminometer lock nut Cadmium levels are above the allowable RoHS limit, and that the part will not be replaced.○ Upon decommissioning of the instrument, Beckman Coulter will dispose of the affected part per applicable regulations.
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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.

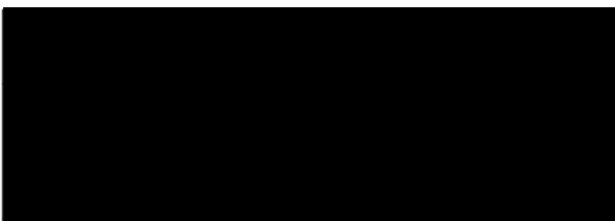
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center.

- From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Enclosure: Response Form

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