



## Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah  
Regulatory Affairs Specialist

<b>Contact person of this notification</b>	... Minella Liam.....
<b>Department</b>	... Marketing.....
<b>Telephone</b>	... 6017 2328 611.....
<b>Fax</b>	...603 7772 0551.....
<b>E-mail</b>	... lmliam@beckman.com .....

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November 19, 2025

**URGENT MEDICAL DEVICE RECALL**

UniCel Dxl 600 and 800 Analyzers

REF	Part Number
UniCel Dxl 600	A71460; A71461; A30260
UniCel Dxl 800	973100; A71456; A71457; A25288

Attention Beckman Coulter Customer,

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

<b>ISSUE:</b>	Beckman Coulter has determined that, due to a potential communication issue, the analyzers listed above may not successfully restart following a standard shutdown, even after multiple attempts. If this issue occurs, the instrument will be unable to complete initialization and transition to <b>Ready</b> mode.
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>If communication is not established after your laboratory follows the normal restart process documented in the "Unicel Dxl Access Immunoassay System Instructions for Use" (IFU):                             <ul style="list-style-type: none"> <li>The system mode area in the upper left of the software user interface will be red, but the <b>Not Ready</b> mode is not displayed.</li> <li>The instrument will not process patient samples, QCs or calibrators.</li> </ul> </li> <li>In a worst-case scenario, inappropriate delay in treatment or early discharge of affected patient puts the patient at increased risk of missed diagnosis and delayed treatment of acute myocardial infarction.</li> <li>This issue does not affect test results.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Follow the restart process documented in Section 2 of the "Unicel Dxl Access Immunoassay System Instructions for Use".</li> <li>If your analyzer continues to experience this issue, please contact Beckman Coulter Technical Support.</li> <li>Beckman Coulter recommends posting this letter on or near the affected analyzers.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter is currently investigating this issue.</li> <li>This issue will be addressed in a future software update.</li> </ul>

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 products listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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,

Signed by:  
*Jennifer Chau*

 Signer Name: Jennifer Chau  
Signing Reason: I approve this document  
Signing Time: 19-Nov-2025 | 2:20:09 PM PST  
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau  
Vice President, U.S. Quality Operations

Enclosure: Response Form

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