



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

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

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November 19, 2025

IMPORTANT PRODUCT NOTICE

UniCel Dxl 600 and 800 Analyzers

REF	Part Number	UDI
UniCel Dxl 600	A71460	15099590369224
UniCel Dxl 600	A30260	15099590341602
UniCel Dxl 800	973100	15099590265373 16954701000412
UniCel Dxl 800	A71456	15099590369194

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding UniCel Dxl 600 and UniCel Dxl 800 Access Immunoassay Analyzers running on a Windows 10 Operating System. Patient results are not impacted.

ISSUE:	<ul style="list-style-type: none"> • Beckman Coulter has determined that the UniCel Dxl 600 and UniCel Dxl 800 Access Immunoassay Analyzers listed above may unexpectedly transition from the Running mode to the Paused or Not Ready modes because the following errors occur more frequently than expected: <ul style="list-style-type: none"> ○ Air or excessive restriction has compromised wash buffer delivery, tests cannot run. ○ Process monitoring acquisition limit exceeded. ○ Process monitor general failure. ○ Wash carousel did not move: Timing issue. • This issue affects UniCel Dxl 600 and UniCel Dxl 800 Access Immunoassay Analyzers listed above running with a Windows® 10 Enterprise LTSC operating system. <p><small>® Windows is either a registered trademark or trademark of Microsoft Corporation in the United States and/or other countries.</small></p>
IMPACT:	<ul style="list-style-type: none"> • The system may cancel tests that are currently in progress when these errors occur. • Test result processing may be delayed if there is not enough sample volume to repeat a canceled test. • This issue does not cause erroneous test results.
ACTION:	<ul style="list-style-type: none"> • If your laboratory encounters this issue: <ul style="list-style-type: none"> ○ Perform the error recovery steps listed in the Event Log troubleshooting to resume normal operation.

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FA-25079



	<ul style="list-style-type: none"> ○ Repeat the testing for any canceled tests. ● Contact Customer Beckman Coulter Technical Support if repeated recovery attempts for an error listed above fail.
RESOLUTION:	Beckman Coulter is investigating resolution options for this issue.

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.

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>
- Contact your local Beckman Coulter Representative for replacement.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Signed by:

 Signer Name: Jennifer Chau
 Signing Reason: I approve this document
 Signing Time: 19-Nov-2025 | 2:18:43 PM PST
 CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, U.S. Quality Operations

Enclosure: Response Form

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