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 onthis 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 informus 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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Docusign Envelope ID: 7DF732BC-A94F-47E3-B7FE-542B61C6B14A

BECKMAN COULTER

September 12, 2025

URGENT MEDICAL DEVICE RECALL

DxI 9000 Access Immunoassay Analyzer

REF	⌛
C11137	SW 1.22 and below

Attention Beckman Coulter Customer,

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

ISSUE:	• Beckman Coulter has determined that the analyzer may fail to apply a dilution factor to tests associated with a manually diluted sample when the tests are ordered through the Test Order Entry page and a unique sample ID is not used.
	• The issue occurs under the following conditions:
	1. A sample is presented to the analyzer from the sample handler or an automation system.
	2. While tests associated with the sample are in progress:
	  • The sample is manually diluted.
	  • Additional tests are ordered through the Test Order Entry page, and a dilution factor is entered.
	  • The sample ID used for the original test requests is also used for the tests ordered with the diluted sample.
	3. When tests ordered for the diluted sample are complete, the user interface correctly displays the dilution factor that was entered on the Test Order Entry page. However, the analyzer does not apply the dilution factor to the result.
	• Automated dilutions and tests ordered using the **Dilute and Rerun** feature are not affected by this issue.

IMPACT:	• This issue can lead to a falsely low or falsely elevated result when not using a unique sample ID for manual dilutions. Examples:
	  ○ **Falsely Low:** An undiluted estradiol test (dilution factor =1) is in progress. A progesterone test is ordered using the same sample ID as the estradiol test, but with a manual dilution factor of 10. Because the dilution factor of 1 from the first test is applied to the progesterone result, the progesterone result is falsely low.
	  ○ **Falsely Elevated:** A progesterone test using a manually diluted sample (dilution factor =10) is in progress**.** A second test, estradiol, is ordered using the same sample ID as the progesterone test, but without dilution (dilution factor =1). Because the dilution factor of 10 from the first test is applied to the estradiol result, the estradiol result is falsely elevated.
	Note: Estradiol and progesterone are used as examples, but this issue may occur with any Access assay that allows manual dilution.

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	• This issue may generate inconsistent test results within the laboratory, which could lead to a delay in reporting patient results. • The potential risks are dependent on the assays being used, with the worst-case risks associated with the diagnosis and treatment of acute myocardial infarction (AMI).
ACTION:	• When ordering tests for a manually diluted sample through the Test Order Entry page, a unique sample ID is required. • Alternatively, use the **Dilute and Rerun** feature or an automated dilution to measure diluted samples. Refer to Rerunning a Test with a Diluted Sample in the System Help for more information. • Beckman Coulter suggests sharing this letter with your Medical Director to determine if performing a retrospective review of results is necessary.
RESOLUTION:	• Beckman Coulter is investigating the root cause of this issue and will implement a correction with a future software release. • Your Beckman Coulter service representative will contact you to schedule the software upgrade when it is available.

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 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 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: 12-Sep-2025 | 1:48:15 PM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, US Quality Operations

Enclosure: Customer Response Form

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