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	Chong Chuen Ling.....
Department	... Marketing.....
Telephone	...6012 982 6529.....
Fax	...603 7772 0551.....
E-mail	... cchong01@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
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March 05, 2025

URGENT MEDICAL DEVICE RECALL

DxC 500i Clinical Analyzer

Product	Analyzer Module	REF	UDI	Software
DxC 500i Clinical Analyzer	Access 2 Module, DxC 500i	C13252	15099590742331	SW v1.3.0 and 1.3.2

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.

ISSUE:	Beckman Coulter has determined that during Installation of the DxC 500i Clinical Analyzer by the Service Engineer, if the analyzer was configured with regional settings, where the region uses commas as decimal identifiers, information within the APF (Assay Protocol File) will load decimal numerals as whole numbers (example 1.25 will load as 125).
IMPACT:	• The only assay impacted by this issue is Access Toxo IgM II assay (REF34470) • Falsely non-reactive results may be generated for Access Toxo IgM II on the DxC 500i analyzer
ACTION:	• Your laboratory should cease running Access Toxo IgM II assay (REF34470) on the DxC 500i analyzer until an assessment is completed by your Field Service Engineer. • Beckman Coulter recommends sharing the content of this letter with your laboratory and/or Medical Director to determine if a review of previous patient test results should be conducted.
RESOLUTION:	Your Beckman Coulter service representative will contact you to arrange an assessment of your system.

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.

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

If you have any questions regarding this product, please contact your local Beckman Coulter Representative, or use the following link for a listing of local contact information.

https://www.beckmancoulter.com/en/support/contact-us

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: 05-Mar-2025 | 3:52:05 PM PST
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President Quality & Regulatory Affairs

Enclosure: Response Form