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	...Stephanie Lim Shu Wen.....
Department	... Marketing.....
Telephone	...601 2982 6560.....
Fax	...603 7772 0551.....
E-mail	... SWLIMc@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
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June 2, 2023

URGENT MEDICAL DEVICE RECALL

DxA 5000 Automation System

REF	LOT	
B50516	N/A	N/A

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:	The DxA Software has configuration settings to identify tests that are not to be performed based upon a specific tube type. The DxA does NOT communicate this to the Remisol middleware software quickly enough to prevent the test to be run.
IMPACT:	Tests may be erroneously performed. In cases where a tube contains an additive which could interfere with a test, the test result may be incorrect.
ACTION:	Inspect tubes routed to error regions and confirm that the tube type was appropriate per the assay IFU for the test performed.
RESOLUTION:	A software update is in progress and will be released to address the issue. Your Beckman Coulter Field Service Engineer will perform the installation.

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.

Beckman Coulter Biomedical GmbH
Sauerbruchstraße 50, 81377 München, Germany, Tel. +49 (0) 89 579589-0, Fax: +49 (0) 89 579589-3501
Geschäftsführer/Managing Directors: Ross Michael Bell, Orlaith Anne Lawler

If you have any questions regarding this notice, please contact our Customer Support Center or your local Beckman Coulter Representative:

- From our website: http://www.beckmancoulter.com
- Contact your local Beckman Coulter representative

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Franck Cheillan
Vice President, Quality & Regulatory Affairs
Beckman Coulter Biomedical GmbH

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