

URGENT FIELD SAFETY NOTICE

DxA 5000 Automation System

REF	LOT	
B50516	N/A	N/A

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:	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.

The national competent authority has been informed of this field safety corrective action.

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.

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 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,

A handwritten signature in blue ink, appearing to read 'Franck Cheillan', with a long horizontal line extending to the right.

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

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