




June 12, 2023

URGENT FIELD SAFETY NOTICE

DxA 5000 Automation System

REF	LOT	
B50516	N/A	N/A

Dear 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 that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologise for the inconvenience that this caused your laboratory.

Beckman Coulter Diagnostics Limited
Lismeehan
O'Callaghans Mills
County Clare
Ireland

Telephone +353 65 6831100
Fax +353 65 6831122
e-mail infoie@beckman.com
Website www.beckmancoulter.co.uk

Directors: Pasquale Della Puca (ITL), Robert Young (UK), Paul Henry (IRE)
Registered in Ireland no 485929
Registered Office: 70 Sir John Rogerson's Quay, Dublin 2, Ireland

Yours sincerely,



Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe
Tel +44 (0) 1494 429184/+44 (0)1494 429219

Enclosed: Vigilance Response Form