



May 31, 2023

URGENT FIELD SAFETY NOTICE – FSN-23021

Dxl 9000 Access Immunoassay Analyzer

REF	Software Versions
C11137	1.14.0.115

Dear 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:	<ul style="list-style-type: none">Beckman Coulter has determined that the Dxl 9000 Access Immunoassay Analyzer software version listed above will not accurately count the number of tests that remain in a reagent pack if the system goes into the red stopped state while loading the reagent pack.This issue may occur if a System Event occurs while loading a new unopened reagent pack on a Dxl 9000 analyzer. This System Event would need to occur during a 0-2 second window of this process.If this issue does occur, the Dxl 9000 analyzer cannot properly account for tests that are used from the reagent pack. The analyzer will continue to use the reagent pack for sample processing, even if all the reagents in the pack are depleted.
IMPACT:	<ul style="list-style-type: none">The test results obtained from an affected reagent pack may be falsely elevated for competitive assays, or falsely decreased for sandwich assays. This information can be found in the product IFU.Affected test results may display a warning flag, such as: OVR, LOW or IND.
ACTION:	<ul style="list-style-type: none">When loading reagent packs on the Dxl 9000 analyzer:<ol style="list-style-type: none">Confirm that the reagent load is complete (indicated by the reagent cover unlocking).Wait for the load door to unlock.If a System Event occurs while loading reagent packs and places the analyzer in the Stopped mode:<ol style="list-style-type: none">Resolve the System Event

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

	<ol style="list-style-type: none"> 2. Unload and reload all reagent packs currently on board the analyzer. 3. Reinitialize the analyzer before resuming sample processing. <ul style="list-style-type: none"> • Perform a retrospective review of any results that have consecutive OVR, Low or IND Flags generated from a reagent pack with test counts that are greater than the number specified for the assay.
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter has identified the root cause of this issue and will implement the correction with the next software release. • Your service representative will contact you to schedule your software upgrade when it is available.

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.

Yours sincerely,



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

Enclosed: Vigilance Response Form