

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 on this 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 inform us 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	... Minella Liam.....
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March 12, 2025

URGENT FIELD SAFETY NOTICE

Dxl 9000 Immunoassay Analyzer

REF	UDI**	
C11137	15099590732103	SW 1.20.0 and below

(SRN): US-MF-000010288

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:	<ul style="list-style-type: none"> This issue affects Dxl 9000 analyzers that are run with the system software versions listed above and are connected to a host system (laboratory information system (LIS) or middleware). If a Dxl 9000 analyzer has accumulated canceled QC test results that were not sent to the host system, the analyzer may lose communication with the host system. The lost connection cannot be restored by routine troubleshooting. Sample processing is affected when the Dxl 9000 analyzer loses communication with the host system.
IMPACT:	<ul style="list-style-type: none"> The Dxl 9000 analyzer responds in one of the following ways when it loses communication with the host system: <ul style="list-style-type: none"> No event message is generated: The analyzer may discharge sample tubes to the sample output area, or the samples may remain in the sample aspiration area. The analyzer cannot process additional tests using normal troubleshooting procedures. OR An event message is generated that warns your laboratory that the LIS is Disconnected. The analyzer does not aspirate patient samples, but the sample tube is discharged to the sample output area. Either response interrupts sample processing, which delays reporting patient test results and may subsequently delay patient treatment.
ACTION:	<p>To Prevent the Issue:</p> <p>Each time that the Cleaning Routine maintenance procedure is due, Beckman Coulter recommends that your laboratory perform the steps provided in Appendix A before performing the Cleaning Routine.</p>



	<p>If the Issue Occurs:</p> <ul style="list-style-type: none"> • If the DxI 9000 analyzer loses communication with the host system and does not generate an event message, perform the steps provided in Appendix A to restore communication with the host system. • If the DxI 9000 analyzer loses communication and generates an event message, follow the system event troubleshooting steps on the user interface to restore the LIS connection. If the troubleshooting steps do not resolve the event, perform the steps provided in Appendix A to restore communication with the host system. • Samples can be run on a different analyzer to prevent further delay to reporting patient results. •
RESOLUTION:	<ul style="list-style-type: none"> • Beckman Coulter has identified the root cause of this issue and will implement the correction with a future software release. • Your Beckman Coulter service representative will contact you to schedule the software upgrade when 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 we are assured you have received this important communication.

If you have any questions regarding this notice, please contact Customer Support Center:

From our website: <http://www.beckmancoulter.com>

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: 12-Mar-2025 | 11:40:04 AM PDT

CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau

Vice President, QRA Hematology, UA, LS, CDSS & GQM

Enclosure: Response Form, Appendix A

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Mitigation Steps Outlined in Appendix A of the Field Action Letter

Appendix A: FA-25027

Follow the steps below to restore communication between the Dxl 9000 Immunoassay Analyzer and the host system.

1. Be sure that the analyzer is in the green running state but is not actively processing samples. Refer to the *Monitoring Sample Status* topic in the System Help or IFU for more information.
2. Select **Menu > System Configuration > LIS**.
3. In the LIS Protocol area, select **Disabled**.
4. Activate the draft configuration. Refer to *Activating a Draft Configuration* topic in the System Help or IFU for more information.
5. Restart the analyzer computer. Refer to the *Restarting the Analyzer Computer* procedure located in the System Help or IFU for more information.
6. Select **Menu > System Configuration > LIS**.
7. In the LIS Protocol area, select **CLSI LIS01-A/LIS02-A (ASTM)**.
8. Activate the draft configuration. Refer to *Activating a Draft Configuration* topic in the System Help or IFU for more information.
9. Send test results to the host system to confirm that communication has been restored.

If communication with the host system is not restored, contact your Beckman Coulter representative and schedule a service visit.