



June 06, 2024

**URGENT FIELD SAFETY NOTICE – FSN-24032**  
Dxl 9000 Access Immunoassay Analyzer

REF	Serial Numbers
C11137	See Appendix

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.

<b>ISSUE:</b>	<ul style="list-style-type: none"><li>• Beckman Coulter has determined that USB 2.0 cables used in the Dxl 9000 Immunoassay Analyzers listed in the appendix could oxidize over time and negatively affect electrical conductivity.</li><li>• A USB 2.0 cable with oxidized connectors may intermittently cause a loss in communication between subsystems within the analyzer.</li><li>• The Dxl 9000 Access Immunoassay Analyzer may enter the red system status due to this issue and cancel all in-progress tests. The exact error displayed varies depending on the subsystem the system software was attempting to communicate with at the time.</li></ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"><li>• The system software establishes communication with all subsystems during software startup. If connection is lost, the analyzer cannot reestablish communication until the system software is restarted.</li><li>• If the system software loses connection with a subsystem and must be restarted, there may be a delay reporting patient test results which could lead to a delay in patient treatment.</li></ul>
<b>ACTION:</b>	<ul style="list-style-type: none"><li>• Your Beckman Coulter service representative will contact you to replace parts affected by this issue.</li><li>• Contact your Beckman Coulter representative if your laboratory has experienced any errors pertaining to communication failures.</li></ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>• Beckman Coulter will replace all affected USB 2.0 cables.</li></ul>

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 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](mailto:techsupportie@beckman.com).

We apologise for the inconvenience that this caused your laboratory.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'AB', with a long horizontal line extending to the right.

Andy Brown  
Quality & Regulatory Affairs Manager, Northern Region Europe

Enclosed: Vigilance Response Form  
Appendix

## **Appendix**

Affected serial numbers:

300117, 300116, 300137, 300138, 300139, 300129, 300141, 300143, 300142, 300151, 300152, 300128, 300156, 300153, 300154, 300135, 300164, 300180, 300155, 300167, 300166, 300158, 300171, 300179, 300169, 300182, 300176, 300183, 300198, 300192, 300133, 300188, 300161, 300134, 300190, 300209, 300212, 300211, 300149, 300148, 300150, 300130, 300172, 300197, 300160, 300189, 300170, 300181, 300195, 300194, 300224, 300222, 300168, 300210, 300233, 300207, 300205, 300221, 300203, 300240, 300199, 300200, 300136, 300196, 300178, 300220, 300208, 300126, 300213, 300206, 300219, 300214, 300217, 300215, 300229, 300255, 300257, 300202, 300254, 300223, 300258, 300259, 300218, 300201, 300234, 300237, 300249, 300260, 300238, 300243, 300261, 300231, 300191, 300131, 300236, 300264, 300263, 300193, 300239, 300230, 300235, 300245, 300216, 300247, 300242, 300226, 300270, 300271, 300269, 300174, 300251, 300241, 300232, 300204, 300227, 300228, 300256, 300266, 300281, 300282, 300253, 300244, 300272, 300246, 300145, 300123, 300147, 300297, 300157, 300275, 300284, 300286, 300248, 300273, 300252, 300144, 300146, 300165, 300177, 300173, 300250, 300268, and 300140.