



May 29, 2024

### URGENT FIELD SAFETY NOTICE

Access Dxl 9000 Immunoassay Analyzer

REF	Serial Numbers	UDI-DI:
C11137	See Appendix	15099590732103

Single Registration Number (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.

<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>

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;

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Enclosures:  
Appendix  
Response Form



## **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.



**CUSTOMER RESPONSE FORM**

Access Dxl 9000 Immunoassay Analyzer

REF	Serial Numbers
C11137	See Letter Appendix

**Check the appropriate box below:**

- I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken, and records retained as part of our Laboratory Quality System documentation.

Or:

- We do not have this product. I have read and understood the information within the accompanying Beckman Coulter Notification and have retained this record as part of our Laboratory Quality System documentation.

Name and Address of Laboratory / Hospital / Organization / Institution:

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Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Tel: \_\_\_\_\_ Email: \_\_\_\_\_

Beckman Coulter Customer Number: \_\_\_\_\_

Please return to: Beckman Coulter, Inc.  
 250 S. Kraemer Blvd  
 Mail Stop B1. SW.01  
 Brea, California 92821  
 Attn: Regulatory Affairs  
 Fax number: (714) 961-4234  
 Email: [regaffairsfax@beckman.com](mailto:regaffairsfax@beckman.com)

Beckman Coulter is updating the customer address list for field action notifications. If the contact information on your notification is inaccurate, please update:

Customer Number: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Title: \_\_\_\_\_

Tel: \_\_\_\_\_ Email: \_\_\_\_\_

Mailing Address: \_\_\_\_\_