

URGENT FIELD SAFETY NOTICE

Dxl 9000 Access Immunoassay Analyzer

REF	UDI**	Serial Number
C11137	15099590732103	See Appendix A

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.

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that a Dxl 9000 Access Immunoassay Analyzer containing tip stocker interface (TSI) and reagent storage interface (RSI) boards with the firmware version 1.1.0.0 can cause sub-system communication failures.
IMPACT:	<ul style="list-style-type: none"> If the analyzer experiences the issue described above, it can lead to the analyzer entering the red, or <i>Stopped</i>, system status due to Reagent Storage and Tip Stoker "axis is out of tolerance" errors. Any in process tests that require addition of reagent at the time of the error are cancelled. There could be a delay in reporting patient test results to the physician
ACTION:	<ul style="list-style-type: none"> If the error occurs: <ol style="list-style-type: none"> Confirm that the Dxl 9000 Access Immunoassay Analyzer is in either the <i>Paused</i> or <i>Stopped</i> system state. Select the System state button in the lower left corner of the user interface. Select Initialize. When initialization is complete, the analyzer returns to the green, or <i>Running</i>, state. If your laboratory has experienced the issue and it is not resolved by initializing the analyzer, contact your Beckman Coulter representative and schedule a service visit.
RESOLUTION:	<ul style="list-style-type: none"> Beckman Coulter has identified the root cause of this issue and is no longer distributing affected TSI-RSI boards. A Beckman Coulter service representative will schedule a visit to replace any affected TSI-RSI boards on your Dxl 9000 Access Immunoassay Analyzer.

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:

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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

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

Enclosure: Response Form

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FA-001170

Appendix A

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300161	300304
300164	300313
300167	300314
300169	300317
300175	300318
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300179	300322
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300197	300338
300201	300339
300202	300341
300204	300351
300210	300362
300216	300364
300217	300368
300218	300370
300220	300373
300224	300374
300225	300375
300233	300379
300234	300380
300236	300385
300237	300386
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