



May 24, 2023

### URGENT FIELD SAFETY NOTICE

Dxl 9000 Access Immunoassay Analyzer

REF	Software Versions
C11137	1.14.0.115

Attention 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 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.</li> <li>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.</li> <li>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.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Affected test results may display a warning flag, such as: OVR, LOW or IND.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>When loading reagent packs on the Dxl 9000 analyzer:               <ol style="list-style-type: none"> <li>Confirm that the reagent load is complete (indicated by the reagent cover unlocking).</li> <li>Wait for the load door to unlock.</li> </ol> </li> <li>If a System Event occurs while loading reagent packs and places the analyzer in the <b>Stopped</b> mode:               <ol style="list-style-type: none"> <li>Resolve the System Event</li> <li>Unload and reload all reagent packs currently on board the analyzer.</li> <li>Reinitialize the analyzer before resuming sample processing.</li> </ol> </li> </ul>



	<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter has identified the root cause of this issue and will implement the correction with the next software release.</li> <li>Your service representative will contact you to schedule your software upgrade when it is available.</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,

...  
 Vice President Quality & Regulatory Affairs  
 Beckman Coulter Inc.  
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Enclosure: Response Form

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