




February 01, 2023

## IMPORTANT PRODUCT NOTICE

### AQUIOS IMMUNO-TROL Cells

REF	LOT	
B23535	6170210K 6170215K	2023-03-11 2023-04-22

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the incorrect product name on the packaging box label for AQUIOS IMMUNO-TROL Cells for the lot numbers listed above. Patient results are not impacted.

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>The product name on the packaging box label for AQUIOS IMMUNO-TROL Cells is incorrect.</li> <li>The label states AQUIOS IMMUNO-TROL <b>Low</b> Cells instead of AQUIOS IMMUNO-TROL Cells.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>No impact to patient results.</li> <li>Beckman Coulter confirms that the kit contents of AQUIOS IMMUNO-TROL Cells (Part Number B23535), including label on the vial, barcodes, and the assay sheet are correct for the lots mentioned above.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Customers may continue to use the lot numbers listed above of AQUIOS IMMUNO-TROL Cells per AQUIOS CL Instructions for Use (Part Number B21896) until their expiration date.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Label has been corrected and new lots do not have this issue.</li> <li>Beckman Coulter is working on determining root cause and corrective actions required to prevent recurrence of this issue.</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 we are assured you have received this important communication.


If you have any questions regarding this notice, please contact our Customer Support Center or your local Beckman Coulter representative:

- From our website: <http://www.beckman.com>
- By phone: call 800-369-0333 in the United States and Canada.
  - Outside the United States and Canada, contact your local Beckman Coulter representative.



We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:  
  
Signer Name: Nancy Nadler  
Signing Reason: I approve this document  
Signing Time: 01-Feb-2023 | 12:54:03 PM PST  
35F6C4BF25B8477F89D87D93E7900BAE

Nancy Nadler  
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form

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