


December 15<sup>th</sup>, 2022**IMPORTANT PRODUCT NOTICE**

## VersaLyse Lysing Solution

REF	LOT	
A09777	200504	13 Feb 2025

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding Lysis deficiency issue for the product described above.

<b>ISSUE:</b>	Beckman Coulter has identified a deficiency in the Lysing reagent with the lot of product listed above. According to internal testing performed, the lysis of Red Blood Cells is determined to be insufficient and incomplete after 10 minutes of incubation. This issue is limited only to Lot No: 200504
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>As a result of insufficient RBC lysis, variable or incorrect flow cytometry scatter patterns may occur leading to potential improper identification of White Blood Cells.</li> <li>In the worst case scenario, this issue may potentially result in erroneous and/or inconsistent results leading to retest and blood redraw and/or extra marrow aspirate or biopsy.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Please stop using any remaining inventory of the affected lot listed above and safely discard as per local regulations. Please contact your local Beckman Coulter representative for replacement product.</li> <li>According to the IFU, the efficiency of the lysis can be confirmed by visual inspection. The customer is able to detect the issue prior to processing the sample for acquisition. Beckman Coulter therefore recommends retrospective review of results is not required.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter is implementing enhanced quality control testing as a short term control to ensure adequate performance of subsequent lots.</li> <li>Further investigation is in progress to determine root cause and to implement additional control measures to prevent recurrence of the reported 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(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

- From our website: <http://www.beckman.com>
- By phone: call 1-800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.
  - For customers in the United States, if you need replacement product:
    - Complete the attached "Replacement Order Form" and email to [askbeckman@beckman.com](mailto:askbeckman@beckman.com) or fax to (866) 294-7850 OR
    - Call Client Services at (800) 526-3821
  - For customers in Canada, if you need replacement product:
    - Complete the attached "Replacement Order Form" and email to [Beckmancoultercanada@beckman.com](mailto:Beckmancoultercanada@beckman.com) or fax to (866) 294-7850 OR
    - Call Client Services at (800) 463-7828
  - For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:  
  
Signer Name: Sudharsan Sathyamurthy  
Signing Reason: I approve this document  
Signing Time: 15-Dec-2022 | 10:31:04 AM PST  
1736351638674E5BAA94C152EEC8D0A1

Sudharsan Sathyamurthy  
Director QRA, Beckman Coulter Life Sciences

Enclosure: Response Form  
Replacement Order Form

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