



## Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah  
Regulatory Affairs Specialist

<b>Contact person of this notification</b>	Chong Chuen Ling.....
<b>Department</b>	... Marketing.....
<b>Telephone</b>	... 6012 982 6529.....
<b>Fax</b>	...603 7772 0551.....
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Dec 13, 2024

**IMPORTANT PRODUCT NOTICE**

CK-MB Calibrator

REF	LOT	
ODR30034	1059A	2025-06-01

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding an incorrect expiry date in the 2-dimensional (2D) barcode value assignment sheet for **CK-MB Calibrator REF ODR30034, Lot 1059A**. There is no impact to results.

<b>ISSUE:</b>	Beckman Coulter (BEC) have identified that the 2D barcode on the CK-MB calibrator (ODR30034), <b>Lot 1059A</b> value assignment sheet (VAS) incorrectly encodes the expiry date as 01-Sep-2025. The correct expiry date is 01-Jun-2025, as printed on the calibrator kit and vial labels.
<b>IMPACT:</b>	The 2D barcode value assignment sheet is intended for use with the DxC 700 AU, DxC 500 AU and DxC 500i analyzers only. When the 2D barcode on the CK-MB calibrator ODR30034, <b>Lot 1059A</b> VAS is scanned, it will populate an incorrect expiry date of 01-Sep-2025 on the analyzer, 3 months beyond the correct expiry date of 01-Jun-2025. Therefore, the analyzer will not alert appropriately for the expired material. However, BEC internal real-time stability studies have shown that the CK-MB calibrator remains stable for up to 7 months beyond its expiry date. Therefore, there is no impact to patient results generated using ODR30034, <b>Lot 1059A</b> .
<b>ACTION:</b>	A retrospective review of results is not recommended. The ODR30034 CK-MB Calibrator VAS for Lot 1059A will be updated with the correct expiry date and made available on the Beckman Coulter Website <a href="https://www.beckmancoulter.com/support/tech-docs">https://www.beckmancoulter.com/support/tech-docs</a> . <ul style="list-style-type: none"> <li>• Search for document number ODR30034_1059 to download and print as required.</li> <li>• Enter the correct expiry date of 01-Jun-2025 for ODR30034, <b>Lot 1059A</b> by scanning the 2D barcode on the updated VAS or by manual entry.</li> </ul>



	<ul style="list-style-type: none"> <li>Dispose of the current ODR30034 CK-MB Calibrator VAS for Lot 1059A contained in the kit box.</li> </ul>
<b>RESOLUTION:</b>	The updated VAS will be made available on the BEC website. No other lots are impacted.

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 or

- From our website: <http://www.beckmancoulter.com>
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Signed by:  
  
 Signer Name: Cartha Donovan  
 Signing Reason: I approve this document  
 Signing Time: 13-Dec-2024 | 2:49:19 AM PST  
 FC8790FF4BB84911B7E9B8C4F430830A

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Cartha Donovan  
 Senior Director, Quality & Regulatory Affairs

Enclosure: Response Form

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