



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

Contact person of this notification	... Minella Liam.....
Department	... Marketing.....
Telephone	... 6017 2328 611.....
Fax	...603 7772 0551.....
E-mail	... lmliam@beckman.com

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
No 18, Jalan Tandang 51/205A,
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October 29, 2025

URGENT MEDICAL DEVICE RECALL

Access 2 Reaction Vessels

REF	LOT	
81901	P243943, P243971, P244202 P244344, P244345, P250001, P250002, P250003, P250004 and P250005	N/A

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.

ISSUE:	Beckman Coulter has determined that Access 2 RVs lots listed above may contain manufacturing deformities. The bottom (round end) of the RV may have a small protrusion or hair like deformity.
IMPACT:	The deformed RVs may cause an increased rate of the following instrument errors, putting the instrument in a Not Ready mode, and delay processing of patient samples. <ul style="list-style-type: none"> • No RV in Pipetting position 1 or 2 • Wash Carousel Motion Error • Rake Motion Error • Shuttle Motion Error
ACTION:	Check your inventory of Access 2 RVs for the lots listed at the top of this letter. <ul style="list-style-type: none"> • If you have the lots listed above contact Beckman coulter for replacement RVs. • You may continue to use the lots listed above until you have received a sufficient supply of replacement RVs. Once replacement RVs arrive, then dispose of the lots listed above according to your local regulations. • If you do not have the RV lots listed above, then no further action is needed. Retrospective review of results is not necessary because this issue does not affect individual patient results.

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

phone: 952.448.4848
www.beckmancoulter.com

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Customer Letter



	Please contact your local Beckman Coulter representative for replacement product requests.
RESOLUTION:	The lots listed above are no longer being shipped to customers.

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.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:


- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center:

- From our website: <http://www.beckmancoulter.com>
- Contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

 Signer Name: Ian Pilcher
 Signing Reason: I approve this document
 Signing Time: 29-Oct-2025 | 9:32:13 AM PDT
 73C58D9A69DC485EA887E365533D3D7D

Ian Pilcher
Director Regulatory Affairs, Clinical Chemistry & Immunoassay

Enclosure: Response Form
Product Replacement Form

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