



October 29, 2025

URGENT FIELD SAFETY NOTICE

Access 2 Reaction Vessels

REF	UDI**	LOT	
81901	15099590180249	P243943, P243971, P244202 P244344, P244345, P250001, P250002, P250003, P250004 and P250005	N/A

Single Registration Number (SRN): US-MF-000010288

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective 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. • 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. • 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

FA-25078
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.

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:

- From our website: <http://www.beckmancoulter.com>
- You may request replacement product by contacting 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 | 9:32:07 AM PDT
 73C58D9A69DC485EA887E365533D3D7D

Ian Pilcher
 Director Regulatory Affairs, Clinical Chemistry & Immunoassay

Enclosure: Response Form
 Product Replacement Form

Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

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

phone: 952.448.4848
www.beckmancoulter.com

FA-25078
 Customer Letter