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 onthis 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 informus 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)
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November 05, 2025

UPDATED URGENT MEDICAL DEVICE RECALL

Bicarbonate

REF	LOT	
OSR6137	2681 2682 2683 2684 2685 2686 2687 2688 2689 2690 2693 2694 2695 2696	01-Nov-2025 01-Dec-2025 01-Jan-2026 01-Jan-2026 01-Feb-2026 01-Mar-2026 01-Apr-2026 01-May2026 01-Jun-2026 01-Jun-2026 01-Jul-2026 01-Sep-2026 01-Sep-2026 01-Oct-2026
OSR6237	2702 2703 2704 2705 2706 2707 2708 2709 2710 2712 2713 2714 2715 2716	01-Nov-2025 01-Dec-2025 01-Jan-2026 01-Jan-2026 01-Feb-2026 01-Mar-2026 01-Apr-2026 01-May-2026 01-Jun-2026 01-Jun-2026 01-Jul-2026 01-Sep-2026 01-Sep-2026 01-Oct-2026
OSR6637	2726 2728 2729 2730 2731 2732 2733 2734 2736 2737 2738 2739	01-Nov-2025 01-Jan-2026 01-Feb-2026 01-Mar-2026 01-Apr-2026 01-May-2026 01-Jun-2026 01-Jun-2026 01-Jul-2026 01-Sep-2026 01-Sep-2026 01-Oct-2026

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OSR6190 4 x 25mL R1 4 x 740 Tests on AU5800	2682 2683 2684 2685 2686 2687 2688 2689 2690 2691 2694 2696 2697	01-Nov-2025 01-Dec-2025 01-Jan-2026 01-Jan-2026 01-Feb-2026 01-Mar-2026 01-Apr-2026 01-May-2026 01-Jun-2026 01-Jun-2026 01-Jul-2026 01-Sep-2026 01-Oct-2026
OSR6290 4 x 50mL R1 4 x 1440 Tests on AU5800	2650 2651 2653 2654 2655 2656 2657 2661 2662 2663	01-Nov-2025 01-Dec-2025 01-Jan-2026 01-Feb-2026 01-Mar-2026 01-Apr-2026 01-Jun-2026 01-Sep-2026 01-Sep-2026 01-Oct-2026

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. You may have received this letter as part of a previous communication. This updated version includes additional information in relation to LDH concentrations based on the BEC LDH product code used; updates are highlighted in blue text.

ISSUE:	Beckman Coulter has received complaints for elevated results generated using Bicarbonate reagent when there are high levels of Lactate Dehydrogenase (LDH) in the test sample. Beckman Coulter has investigated and confirmed that the lots listed above of Bicarbonate reagent may generate Bicarbonate results that are biased high due to interference with LDH in the test sample. The level of LDH interference is not consistent across lots of Bicarbonate reagents. The magnitude of the impact varies depending on Bicarbonate lot in use and the level of LDH in the test sample.
IMPACT:	This issue does not affect Bicarbonate samples with LDH levels within the normal reference range for an adult patient.

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For the Bicarbonate reagent lots listed in **Table A**, a sample that is above the normal LDH reference range for an adult population or in the neonatal/infant ranges may report a false high Bicarbonate result.

This high bias increases with LDH concentration.

- At an LDH concentration of 600 U/L[1]* the observed shift was an increase in bicarbonate concentration up to 15%.
- At an LDH concentration of 2,000 U/L[2]* the observed shift was an increase in bicarbonate concentration up to 30%.

A patient may receive an incorrect diagnosis or incorrect treatment of acid-base disorders.

Table A

REF	LOT	⌛
OSR6137	2683	01 Jan 2026
	2684	01 Jan 2026
	2685	01 Feb 2026
	2686	01 Mar 2026
	2687	01 Apr 2026
	2688	01 May 2026
	2689	01 Jun 2026
	2690	01 Jun 2026
OSR6237	2704	01 Jan 2026
	2705	01 Jan 2026
	2706	01 Feb 2026
	2707	01 Mar 2026
	2708	01 Apr 2026
	2709	01 May 2026
	2710	01 Jun 2026
	2712	01 Jun 2026
OSR6637	2728	01 Jan 2026
	2729	01 Feb 2026
	2730	01 Mar 2026
	2731	01 Apr 2026
	2732	01 May 2026
	2733	01 Jun 2026
	2734	01 Jun 2026
OSR6190	2684	01 Jan 2026
	2685	01 Jan 2026
	2686	01 Feb 2026
	2687	01 Mar 2026
	2688	01 Apr 2026
	2689	01 May 2026
	2690	01 Jun 2026
	2691	01 Jun 2026
	2653	01 Jan 2026

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OSR6290	2654	01 Feb 2026
	2655	01 Mar 2026
	2656	01 Apr 2026
	2657	01 Jun 2026

For the Bicarbonate reagent lots listed in **Table B**, a sample with an LDH level greater than or equal to 2,000 U/L[2]* may report a false high Bicarbonate result.
Samples within the normal LDH reference range for an adult population or in the neonatal/infant ranges are unaffected.

This high bias increases with LDH concentration.

- At an LDH concentration of 2,000 U/L[2]* the observed shift was an increase in bicarbonate concentration up to 12%.

A patient may receive an incorrect diagnosis or treatment of acid-base disorders.

Table B

REF	LOT	
OSR6137	2681	01 Nov 2025
	2682	01 Dec 2025
	2693	01 Jul 2026
	2694	01 Sep 2026
	2695	01 Sep 2026
	2696	01 Oct 2026
OSR6237	2702	01 Nov 2025
	2703	01 Dec 2025
	2713	01 Jul 2026
	2714	01 Sep 2026
	2715	01 Sep 2026
	2716	01 Oct 2026
OSR6637	2726	01 Nov 2025
	2736	01 Jul 2026
	2737	01 Sep 2026
	2738	01 Sep 2026
	2739	01 Oct 2026
OSR6190	2682	01 Nov 2025
	2683	01 Dec 2025
	2694	01 Jul 2026
	2696	01 Sep 2026
	2697	01 Oct 2026
OSR6290	2650	01 Nov 2025
	2651	01 Dec 2025
	2661	01 Sep 2026
	2662	01 Sep 2026
	2663	01 Oct 2026

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	*Note: the LDH concentrations reported above were established using LDH Product code **OSR6127**. The LDH concentrations reported for a sample are dependent on the BEC LDH Product code used. Please see Table C below for concentrations corresponding to each BEC LDH Product code.

Table C

Relative LDH Concentrations by LDH Product Code (REF)

LDH REF	LDH Concentration[1]	LDH Concentration[2]
OSR6127	**600 U/L**	**2000 U/L**
OSR6126	1408 U/L	4694 U/L
OSR6128	662 U/L	2205 U/L

ACTION:	• Discontinue use and dispose all Bicarbonate OSR6x37/OSR6x90 lots listed in **Table A** in the **IMPACT** section of this letter, following your laboratory protocols and local regulations. Contact your local Beckman Coulter representative for replacement or re-imbursement. • For Bicarbonate OSR6x37/OSR6x90 lots listed in **Table B** in the **IMPACT** section, if elevated LDH levels are suspected, please assess results in conjunction with patient's LDH values. • Share the content of this letter with your laboratory and/or Medical Director to evaluate the requirement for a retrospective review of Bicarbonate results for neonatal patients and patients with elevated LDH levels.
RESOLUTION:	The Bicarbonate reagent IFU has been updated to provide guidance to the customer that samples with elevated Lactate Dehydrogenase (LDH) may cause falsely increased bicarbonate results and that if elevated LDH levels are suspected, please assess results in conjunction with patient's LDH values. Beckman Coulter • Is no longer distributing the affected lots outlined in **Table A** in the **IMPACT** section above. • Has implemented additional internal in-process release testing for all new lots of Bicarbonate reagent to ensure no significant interference for all patient populations with LDH within the normal reference range.

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.

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- From our website: http://www.beckmancoulter.com
- By phone:
  - Outside the United States and Canada, contact your local Beckman Coulter representative.
  - For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

Signer Name: Cheillan, Franck
Signing Reason: I approve this document
Signing Time: 05-Nov-2025 | 10:46:32 PM PST
6309FFDE61F340FA89FF6856007A4771

Franck Cheillan
Vice President, International Quality Operations

Enclosure: Response Form
Replacement order form