



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,
Seksyen 51, 46050 Petaling Jaya
Selangor Darul Ehsan, Malaysia

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Website : www.beckmancoulter.com



October 07,2025

URGENT MEDICAL DEVICE RECALL
Bicarbonate

REF	LOT	
OSR6137	2681	01-Nov-2025
	2682	01-Dec-2025
	2683	01-Jan-2026
	2684	01-Jan-2026
	2685	01-Feb-2026
	2686	01-Mar-2026
	2687	01-Apr-2026
	2688	01-May2026
	2689	01-Jun-2026
	2690	01-Jun-2026
	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
	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
	2713	01-Jul-2026
	2714	01-Sep-2026
	2715	01-Sep-2026
2716	01-Oct-2026	
OSR6637	2726	01-Nov-2025
	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
	2736	01-Jul-2026
	2737	01-Sep-2026
	2738	01-Sep-2026
	2739	01-Oct-2026



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

ISSUE:	<p>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.</p> <p>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.</p>
IMPACT:	<p>This issue does not affect Bicarbonate samples with LDH levels within the normal reference range for an adult patient.</p> <p>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.</p> <p>This high bias increases with LDH concentration.</p>



- At an LDH concentration of 600 U/L the observed shift was an increase in bicarbonate concentration up to 15%.
- At an LDH concentration of 2,000 U/L 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
OSR6637	2712	01 Jun 2026
	2728	01 Jan 2026
	2729	01 Feb 2026
	2730	01 Mar 2026
	2731	01 Apr 2026
	2732	01 May 2026
	2733	01 Jun 2026
OSR6190	2734	01 Jun 2026
	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	
OSR6290	2653	01 Jan 2026
	2654	01 Feb 2026
	2655	01 Mar 2026
	2656	01 Apr 2026
	2657	01 Jun 2026



	<p>For the Bicarbonate reagent lots listed in Table B, a sample with an LDH level greater than or equal to 2,000 U/L 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.</p> <p>This high bias increases with LDH concentration.</p> <ul style="list-style-type: none"> At an LDH concentration of 2,000 U/L the observed shift was an increase in bicarbonate concentration up to 12%. <p>A patient may receive an incorrect diagnosis or treatment of acid-base disorders.</p> <table border="1" data-bbox="446 651 1416 1675"> <thead> <tr> <th colspan="3">Table B</th> </tr> <tr> <th>REF</th> <th>LOT</th> <th></th> </tr> </thead> <tbody> <tr> <td rowspan="6">OSR6137</td> <td>2681</td> <td>01 Nov 2025</td> </tr> <tr> <td>2682</td> <td>01 Dec 2025</td> </tr> <tr> <td>2693</td> <td>01 Jul 2026</td> </tr> <tr> <td>2694</td> <td>01 Sep 2026</td> </tr> <tr> <td>2695</td> <td>01 Sep 2026</td> </tr> <tr> <td>2696</td> <td>01 Oct 2026</td> </tr> <tr> <td rowspan="6">OSR6237</td> <td>2702</td> <td>01 Nov 2025</td> </tr> <tr> <td>2703</td> <td>01 Dec 2025</td> </tr> <tr> <td>2713</td> <td>01 Jul 2026</td> </tr> <tr> <td>2714</td> <td>01 Sep 2026</td> </tr> <tr> <td>2715</td> <td>01 Sep 2026</td> </tr> <tr> <td>2716</td> <td>01 Oct 2026</td> </tr> <tr> <td rowspan="5">OSR6637</td> <td>2726</td> <td>01 Nov 2025</td> </tr> <tr> <td>2736</td> <td>01 Jul 2026</td> </tr> <tr> <td>2737</td> <td>01 Sep 2026</td> </tr> <tr> <td>2738</td> <td>01 Sep 2026</td> </tr> <tr> <td>2739</td> <td>01 Oct 2026</td> </tr> <tr> <td rowspan="4">OSR6190</td> <td>2682</td> <td>01 Nov 2025</td> </tr> <tr> <td>2683</td> <td>01 Dec 2025</td> </tr> <tr> <td>2694</td> <td>01 Jul 2026</td> </tr> <tr> <td>2696</td> <td>01 Sep 2026</td> </tr> <tr> <td rowspan="5">OSR6290</td> <td>2697</td> <td>01 Oct 2026</td> </tr> <tr> <td>2650</td> <td>01 Nov 2025</td> </tr> <tr> <td>2651</td> <td>01 Dec 2025</td> </tr> <tr> <td>2661</td> <td>01 Sep 2026</td> </tr> <tr> <td>2662</td> <td>01 Sep 2026</td> </tr> <tr> <td></td> <td>2663</td> <td>01 Oct 2026</td> </tr> </tbody> </table>	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	OSR6290	2697	01 Oct 2026	2650	01 Nov 2025	2651	01 Dec 2025	2661	01 Sep 2026	2662	01 Sep 2026		2663	01 Oct 2026
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<p>ACTION:</p>	<ul style="list-style-type: none"> Discontinue use and dispose all Bicarbonate OSR6x37/OSR6x90 lots listed in Table A in the ISSUE section of this letter, following your laboratory protocols and local regulations. Contact your local Beckman Coulter representative for replacement or reimbursement. 																																																																		



	<ul style="list-style-type: none"> • For Bicarbonate OSR6x37/OSR6x90 lots listed in Table B in the ISSUE 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:	<p>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.</p> <p>Beckman Coulter</p> <ul style="list-style-type: none"> • Is no longer distributing the affected lots outlined in Table A in the ISSUE 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.

- 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: 07-Oct-2025 | 9:51:38 AM PDT
6309FFDE61F340FA89FF6856007A4771

Franck Cheillan
Vice President, International Quality Operations

Enclosure: Response Form
Replacement order form

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