



April 07, 2023

URGENT FIELD SAFETY NOTICE – FSN-000884

AU / DxC AU Bicarbonate Reagent OSR6x90 /OSR6x37

REF	LOT	
OSR6190	All lots	All
OSR6290	All lots	All
OSR6137	All Lots	All
OSR6237	All Lots	All

Dear 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 confirmed a premature decrease in calibration ODs for the following lots of Bicarbonate OSR6x90 / OSR6x37:</p> <table border="1"><thead><tr><th colspan="3">Table A</th></tr><tr><th>REF</th><th>LOT</th><th></th></tr></thead><tbody><tr><td rowspan="3">OSR6190</td><td>2631</td><td>01 Aug 23</td></tr><tr><td>2632</td><td>01 Aug 23</td></tr><tr><td>2633</td><td>01 Sep 23</td></tr><tr><td rowspan="2">OSR6290</td><td>2628</td><td>01 Aug 23</td></tr><tr><td>2629</td><td>01 Sep 23</td></tr><tr><td rowspan="2">OSR6137</td><td>2629</td><td>01 Aug 23</td></tr><tr><td>2630</td><td>01 Sep 23</td></tr><tr><td rowspan="2">OSR6237</td><td>2649</td><td>01 Aug 23</td></tr><tr><td>2650</td><td>01 Aug 23</td></tr></tbody></table> <p>It is possible that all Bicarbonate lots may also be impacted by this issue, therefore all lots are subject to this field action.</p>	Table A			REF	LOT		OSR6190	2631	01 Aug 23	2632	01 Aug 23	2633	01 Sep 23	OSR6290	2628	01 Aug 23	2629	01 Sep 23	OSR6137	2629	01 Aug 23	2630	01 Sep 23	OSR6237	2649	01 Aug 23	2650	01 Aug 23
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IMPACT:	<p>The abnormal decrease in calibrator ODs may result in calibration failures and/or QC failures. The risk of generating falsely elevated, clinically impactful patient test results is remote.</p>																												

Beckman Coulter Diagnostics Limited
Lismeehan
O'Callaghans Mills
County Clare
Ireland

Telephone +353 65 6831100
Fax +353 65 6831122
e-mail infoie@beckman.com
Website www.beckmancoulter.co.uk

Directors: Pasquale Della Puca (ITL), Robert Young (UK), Paul Henry (IRE)
Registered in Ireland no 485929
Registered Office: 70 Sir John Rogerson's Quay, Dublin 2, Ireland

Data analysed internally has determined that, if the failure mode is generated, a positive shift of between 2 and 8 mEq/L for patient samples in the range of 20 – 39 mEq/L, would be observed.

It is possible that all Bicarbonate lots may also be impacted by this issue, therefore action is required and outlined in the following section.

ACTION:

- Safely dispose of Bicarbonate OSR6x90 and OSR6x37 lots listed in Table A in the **Issue** section of this letter. Beckman Coulter have confirmed that these specific lots *are* impacted by premature calibration OD decrease.
- Contact your local Beckman Coulter representative for replacement and reimbursement.
- Retrospective review of patient data is not required due to the remote possibility of generating falsely elevated, clinically impactful results which could cause a change in treatment. However, Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results.
- To avoid generation of elevated data on other lots of Bicarbonate OSR6x90 and OSR6x37, the Calibration OD range **Low** has been adjusted. Please take action to update the Calibration OD range on your analyser with the updated values outlined in the table below.

	Current OD Range Low	Updated OD Range Low
Point-1	0.0500	0.0750
Point-2	0.1000	0.1550

- To change the Calibration OD Range Low on your AU / DxC AU analysers, follow the below outlined instructions:

DxC 700 AU:

- Select **Menu List > Calibration > Calibration Setup> General**
- Select the **Test Name** and scroll to the Bicarbonate test
- Select **Edit**.
- For OD Range Low, enter updated values for **Point-1** and **Point-2**
- Confirm that information is correct, then select **Save**.

AU480/AU680/AU5800: Select **Menu List > Parameters > Calibration Parameters > Calibration Specific > General**

- Select the **Test Name** and scroll to the Bicarbonate test
- Select **Edit**.
- For OD Range Low, enter updated values for **Point-1** and **Point-2**
- Confirm that information is correct, then select **Confirm**.
- After making the change to the Calibration OD range Low values, calibrate the bicarbonate test and confirm QC is acceptable before proceeding.

	<ul style="list-style-type: none">• In the event of a calibration failure or sudden shift in control values, attempt to re-calibrate the assay. If re-calibration or QC fails, discard the reagent bottle and replace with a bottle from a different lot.
RESOLUTION:	<p>The Bicarbonate Setting Sheets BSOSR6X90 (OSR6x90) and BASOSR6X37 (OSR6X37) has also been revised to align with this updated Calibration OD Range. BSOSR6X90 and BASOSR6X37 will be available on the Beckman Coulter website under <i>Technical Documents</i>.</p> <p>Beckman Coulter is currently investigating the root cause of this issue. We will continue to monitor the situation moving forward and keep you informed of any further developments.</p>

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 that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

Contact your local Beckman Coulter Representative to arrange for a replacement lot on 0870 243 6001 – Option 1 or bcieorders@beckman.com.

We apologise for the inconvenience that this caused your laboratory.

Yours sincerely,



Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe
Tel +44 (0) 1494 429184/+44 (0)1494 429219

Enclosed: Vigilance Response Form