



13th May 2016

URGENT MEDICAL DEVICE RECALL
ALT OSR6X07
Glucose-Stat OSR6X40

REF	LOT	
OSR6X07 OSR6X40	All Lots	N/A

Attention Beckman Coulter AU Customer,

Beckman Coulter is initiating a field safety corrective action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<p>Previously unknown drug interferences from Sulfasalazine and Sulfapyridine have been identified.</p> <p>No customer complaint has been received for this particular issue.</p>
IMPACT:	<p>There is a possibility that drug interferences from administration of Sulfasalazine to patients may generate false low ALT results (OSR6X07) and false low Glucose-Stat results (OSR6X40). Sulfapyridine may generate false high Glucose-Stat results (OSR6X40).</p> <p>Interference seen with 300mg/L Sulfasalazine showed a negative bias of up to 35% for the low ALT control and up to 29% for the high ALT control.</p> <p>Interference seen with 300mg/L Sulfasalazine showed a negative bias of up to 25% (or 1.3 mmol/L) for the low Glucose-Stat control and up to 13% (or 1.6mmol/L) for the high Glucose-Stat control.</p> <p>Interference seen with 300mg/L Sulfapyridine showed a positive bias of up to 21% (or 1.1 mmol/L) for the low Glucose-Stat control and up to 9% or (1.1mmol/L) for the high Glucose-Stat control.</p>
ACTION:	<p>No action is required by your laboratory. No retrospective review of results is recommended.</p>
RESOLUTION:	<p>The following statement has been added to the Interfering Substances section of the IFUs for ALT (BLOSR6X07) and Glucose-Stat (BLOSR6X40)</p> <p><i>"Patients treated with Sulfasalazine may generate a false low result for <SPECIFIC ANALYTE>"</i></p> <p>The following statement has been added to the Interfering Substances section of the IFUs of Glucose-Stat (BLOSR6X40)</p> <p><i>"Patients treated with Sulfapyridine may generate a false high result for Glucose-Stat"</i></p>



The updated IFUs are available on the Beckman Coulter website under *Technical Documents*. Please search using the *Reagent/Calibrators/Controls* option.

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 Center

- From our website, <http://www.beckmancoulter.com/customersupport/support>
- Outside the United States and Canada, call +353-65-6831111 or contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Marie O'Rourke
Group Quality & Representative Affairs Manager

Enclosure: Response Form

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