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	Chong Chuen Ling.....
Department	... Marketing.....
Telephone	...6012 982 6529.....
Fax	...603 7772 0551.....
E-mail	... cchong01@beckman.com .....

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July 13, 2023

URGENT MEDICAL DEVICE RECALL
AU/DxC AU Immunoglobulin A (IgA)

REF	LOT	
OSR61171	All lots	All

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:	During internal interference testing, lipemic interference failed to meet the performance specification in the IFU. Low (~1.0 g/L) and high (~5.0 g/L) levels of IgA analyte concentration pools were tested at 0 mg/dL and 1,000 mg/dL Intralipid. For customers following IFU BAOSR6X171, testing failed to meet specifications outlined in the IFU for both IgA analyte concentration pools. At 1,000 mg/dL Intralipid, the low analyte concentration pool (~1.0 g/L) exhibited a maximum negative bias of -13.44% or an absolute value of -0.15 g/L, and the high analyte concentration pool (~5.0 g/L) exhibited a maximum negative bias of -13.3% or an absolute value of -0.58 g/L. For customers following IFU BLOSR6X171, testing failed to meet specifications outlined in the IFU for the high IgA analyte concentration pool only. At 1,000 mg/dL Intralipid, the high analyte concentration pool (~5.0g/L) IgA showed a maximum negative bias of -13.3% or -0.58 g/L.
IMPACT:	Patient samples with high levels of lipemia may cause a negative bias to the IgA results. This may result in a false low result or cause a high result to report as normal. Where LIH Influence check settings are in use, levels of lipemia with turbidity equivalent to 1,000 mg/dL will flag. LIH Influence check settings facilitate the automated assessment of sample suitability on the AU/DxC AU analyzers.
ACTION:	• 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. • Discontinuance or disposal of this product is not necessary. • Per the IFU, avoid highly lipemic samples when using the IgA assay.

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	• No update is required to the LIH influence check settings on the analyser, where in use.
RESOLUTION:	The OSR61171 IgA IFU's Interference sections will be updated with the following statement: BAOSR6x171 *Lipemia: Interference less than 10% or 22mg/dL up to 550mg/dL Intralipid.* *BLOSR6X171* *Lipemia: Interference less than 10% or 0.22g/L up to 550mg/dL Intralipid.*

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 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
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Cartha Donovan
Senior Director, Quality & Regulatory Affairs

Enclosure: Response Form

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