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	...Stephanie Lim Shu Wen.....
Department	... Marketing.....
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December 02 2021

IMPORTANT PRODUCT NOTICE
AU/DxC AU Magnesium

REF	LOT	
OSR6189	All lots	All

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding Magnesium, REF OSR6189.

ISSUE:	Internal interference testing in accordance with current CLSI guideline EP07 version 3 was completed as part of the In Vitro Diagnostic Regulation (IVDR) remediation project. This testing was completed at lower and higher levels of analyte than specified in previous versions of the guideline. Beckman Coulter has determined that the lipemic interference for the Magnesium serum application failed to meet the performance specification as defined in the IFU as follows: *Interference less than 10% up to 500 mg/dL Intralipid* Two levels of magnesium pools (low and high) were tested. The low analyte pool with a concentration of 0.82 mmol/L was out of specification with a maximum bias of +30.38% at 500mg/dL of Intralipid. The high analyte pool with a concentration of 2.06 mmol/L was out of specification with a maximum bias of +13.56% at 500mg/dL of Intralipid. There is no lipemic interference specification with the urine application.
IMPACT:	A clinically significant interference due to intralipid concentration at 500mg/dL may cause a maximum positive bias up to 30.38% in low magnesium patient samples No clinically significant effect on high magnesium patient sample recovery was observed. Discontinuance or disposal of this product is not necessary. The impact is only to the clinical interpretation of magnesium results in the presence of lipemia.
ACTION:	Retain a copy of this letter as it serves as current labeling. Where LIH influence check settings are enabled, customers must update the lipemia influence check settings on their AU/DxC AU analyzers.

Beckman Coulter Inc.
250 S. Kraemer Boulevard
Brea, CA 92821

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	To determine if LIH influence check settings are enabled on your analyzer for Magnesium and to update your lipemia interference settings, perform the following action: **DxC 700 AU:** Select Menu List > Configuration Parameters > Specific Test Parameters > Test Volume and Methods > General > Edit. Update the LIH influence check for Magnesium Lipemia interference from +++++ to ++. **AU480 / AU680 / AU5800:** Select Menu > Parameters > Specific Test Parameters > General > Edit. Update the LIH influence check for Magnesium Lipemia interference from +++++ to ++. If LIH influence check settings are not enabled, review the new interference information in the IFU and assess whether changes are required to the reporting of magnesium results in the laboratory information system based on LIH flagging.
RESOLUTION:	The Magnesium IFU (BLOSR6189) Interference section will be updated with the following statement: *Lipemia: Interference less than 10% or 0.12mmol/L up to 200 mg/dL Intralipid* The Magnesium setting sheet (BSOSR6189) will be updated so that the lipemia influence check setting is reduced from +++++ to ++. This letter serves as current labeling pending update of IFU and setting sheet.

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.

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

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Rachel Davison
Vice President, Quality & Regulatory Affairs

Enclosure: Response Form

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