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.....
Telephone	...601 2982 6560.....
Fax	...603 7772 0551.....
E-mail	... SWLIMc@beckman.com .....

Beckman Coulter Malaysia Sdn Bhd. (861038-K)
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December 09 2021

IMPORTANT PRODUCT NOTICE
AU/DxC AU Uric Acid

REF	LOT	
OSR6x98	All lots	All

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding Uric Acid, REF OSR6x98.

ISSUE:	During internal interference testing completed as part of the In Vitro Diagnostic Regulation (IVDR) remediation project, Beckman Coulter has determined that Uric Acid failed to meet the conjugated bilirubin interference specification for the serum application as defined in the IFU: *Interference less than 10% up to 20 mg/dL or 342 µmol/L conjugated bilirubin* Two levels of Uric Acid serum pools (low and high) were tested. The low analyte pool with a concentration of 238 µmol/L was out of specification with a maximum bias of -11.06% at 20 mg/dL of conjugated bilirubin. The high analyte pool with a concentration of 416 µmol/L was out of specification with a maximum bias of -10.92% at 20 mg/dL of conjugated bilirubin. There is no conjugated bilirubin interference specification with the urine application.
IMPACT:	An interference due to a 20 mg/dL or 342 µmol/L conjugated bilirubin concentration may cause a: • maximum negative bias up to -11.06% in low uric acid patient samples. • maximum negative bias up to -10.92% in high uric acid patient samples. This bias is not clinically significant.
ACTION:	Retain a copy of this letter as it serves as current labeling. The worst-case result for this failure is within the total allowable error (14% per RiliBÄK) for Uric Acid and therefore would not be expected to produce a result that is clinically significantly different from the true value. A retrospective review of results is not recommended but is left to the discretion of the Laboratory Director.

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

Telephone: (714) 993-5321
Facsimile: (714) 961/4234
Internet: www.beckmancoulter.com

RESOLUTION:	The Uric Acid IFU (BLOSR6x98) Interference section will be updated with the following statement: *Interference less than 12% or 35 µmol/L up to 20 mg/dL or 342 µmol/L conjugated bilirubin.*

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,

Cartha Donovan
Director Quality & Regulatory Affairs

Enclosure: Response Form

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