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	...Alice Wong.....
Department	... Marketing.....
Telephone	...6012-296 0320.....
Fax	...603 7772 0551.....
E-mail	... awong02@beckman.com .....

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Docusign Envelope ID: 3B11BFDD-A7C6-415E-A71B-0C7EFE78C8C2

September 04, 2024

IMPORTANT PRODUCT NOTICE

DxH 500 Series Control

REF	LOT
B36872	All

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding the DxH 500 Series Control. There is no impact to patient results.

ISSUE:	Beckman Coulter has become aware of an increase in customer complaints regarding the DxH 500 Series Control exhibiting a “PLT1: Debris" message and Review (R) flags on PLT and MPV parameters.
IMPACT:	• Customers may experience an increase in DxH 500 Series Control R flagging. • There is no impact to accuracy of the PLT and MPV results of the DxH 500 Series Controls. • There is no impact to the accuracy of patient results.
ACTION:	• If the DxH 500 Series Controls produce a “PLT1: Debris” message with R flags and the PLT and MPV parameters are within the acceptable range, accept the controls results. • If the DxH 500 Series Controls produce a “PLT1: Debris” message with R flags and the PLT and/or MPV parameters are *not* within the acceptable range, review Chapter 4, Quality Control, *If a Control is OUT* section, in the DxH 500 Series Instructions for Use* for troubleshooting. • No retrospective review of QC or patient sample results is necessary.
RESOLUTION:	• Beckman Coulter is actively investigating the issue. • This letter serves as labeling supplement.

(*) Part numbers for the DxH 500 Series Instructions for Use.

	US	OUS
•	DxH 500 (PN# C42118)	DxH 500 (PN# B95837)
•	DxH 520 (PN# C41838)	DxH 520 (PN# B85528)
•	DxH 560 (PN# C48648)	DxH 560 (PN# C31608)

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 with 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 or your local Beckman Coulter representative:

- From our website: http://www.beckmancoulter.com
- By phone: Call 1-800-526-7694 in the United States and Canada.
  - Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for any inconvenience that this may have caused your laboratory.

Sincerely,

Signed by:

Jennifer Chau

Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 04-Sep-2024 | 1:29:43 PM PDT

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Jennifer Chau
Vice President, QRA Hematology, UA, LS, CDSS & GQM

Enclosure: Response Form

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