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 on this 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 inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Yours Sincerely,

Teoh Siang Yee

Sr Quality Specialist

Contact person of this notification	... Stephanie Lim Shu Wen…….
Department	... Marketinq.... ... ... ……
Telephone	... 601 2982 6560..... ... ……
Fax	... 603 7772 0551..... ……
E-mail	... SWLIM@beckman.com.....

Beckman Coulter Malaysia Sdn. Bhd. (as103s-K)
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October 18, 2021

IMPORTANT PRODUCT NOTICE

Product	REF
COULTER 4C-ES Cell Controls	7547187, 7547188, 7547189, 7547190

Dear Beckman Coulter Customer,

Beckman Coulter is sending you this letter regarding an issue with flagging on White Blood Cell (WBC) values and differential parameters for COULTER 4C-ES Cell Controls. Patient results are not affected.

ISSUE:	Beckman Coulter has confirmed intermittent asterisk (*) flags on WBC and differential parameters for the Abnormal Low control. Control results are recovering within values in the Table of Expected Results included in the product packaging.
IMPACT:	• Patient results are not affected. • A delay in the reporting of patient results is not expected to occur. • Normal and Abnormal High controls are not affected.
ACTION:	• If the recovered results for the WBC and differential parameters are within the values in the Table of Expected Results for the Abnormal Low control, values can be accepted. • If the recovered results are not within the values stated in the Table of Expected Results for the Abnormal Low Control, perform the actions in Table 6.4 of your instrument's Instructions for Use. • Follow your laboratory protocol for asterisk (*) flags on patient samples.
RESOLUTION:	An investigation is in process to determine the root cause of this issue.

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, 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, contact Beckman Coulter Customer Support Center:

- From our website: http://www.beckmancoulter.com
- Via phone, call 800-526-7694 in the United States and Canada.
- Outside of the United States and Canada, contact your local Beckman Coulter Representative.

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

Sincerely,

Roger Janczak
Vice President, Quality and Regulatory Affairs
Enclosure: Response Form