August 06, 2018

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION

PRODUCT	REF	Software Versions
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802, B68304, B66445, B63322	3.2.0 and below
UniCel DxH 600 Coulter Cellular Analysis System	B23858	1.3.0 and below

Attention Beckman Coulter Customer,
*Copy: Chairman Medical Board/Head of Departments of Affected consignees

**Applicable to Affected consignees of Singapore only*

Beckman Coulter is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention. Patient results may be affected. No injury has been reported in association with this issue.

ISSUE:	Beckman Coulter has confirmed complaints of sporadic erroneously elevated platelet results without flags or system messages. Other parameters are not affected by this issue.
IMPACT:	• The platelet parameter may be erroneously elevated without flags or system messages. • Erroneously elevated results could be reported out of the laboratory.
ACTION:	During patient's follow-up, consider unexpected elevated platelet levels as possible erroneous results due to this failure. Ensure implementation of the following actions: • Use all available features to assess patient results, including reference ranges, action and critical limits, instrument system flags, codes, messages, delta checks, XM, and decision rules. • Follow your laboratory's standard operating procedure for confirming unexpected results. • Communicate to your medical director the need to avoid patient treatment based solely on any single test result, and to interpret all results in the context of other clinical and laboratory features. • Consult with your Medical Director to determine if a retrospective review of results is warranted.
RESOLUTION:	• DxH 800 version 3.2.1 and DxH 600 version 1.3.1 are not affected by this issue. Beckman Coulter will be prioritizing the upgrades for your systems. • Alternatively, Beckman Coulter is working on the development of a self-installable software patch option, in lieu of the software upgrade, to expedite resolution and minimize impact on laboratory workflow.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have transferred any of the affected product(s) listed above to other laboratories, please provide them with a copy of this letter.

So that we are assured you have received this important communication, 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 Beckman Coulter Customer Support Center:

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

We apologize for any inconvenience to your laboratory.

Sincerely,

[redacted]

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs