April 24, 2017

MEDICAL DEVICE FIELD ACTION NOTIFICATION

PRODUCT	REF	SOFTWARE VERSION
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802,B68304, B66445, B63322	All
UniCel DxH 600 Coulter Cellular Analysis System	B23858	All

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

*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:	There is a possibility of a data acquisition disruption that may cause an unusual light scatter event pattern for the white blood cell differential that may not have a system flag and/or message. The events associated with the unusual light scatter pattern may be incorrectly removed from analysis which can result in an erroneous differential result. In most cases, system flags and/or messages have accompanied the erroneous results, indicating the need to review the results. In rare instances, system flags and/or messages might be absent
IMPACT:	• An erroneous, automated White Blood Cell (WBC) differential result might be reported. The WBC count is correctly reported. • The most significant clinical impact might be an incorrect neutrophil count potentially leading to errors in patient management.
ACTION:	• Use all available features to assess patient results, including reference ranges, action and critical limits, instrument system flags, codes, messages, delta checks, and decision rules. • Follow all Instructions for Use pertaining to flow cell error and warning messages, and ensure daily Shutdown is performed. • Follow your laboratory's standard operating procedure for confirming unexpected results. • Communicate to your Laboratory 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:	Beckman Coulter is working on a resolution to detect and flag these unexpected light scatter patterns.

Beckman Coulter, Inc.
11800 S.W. 147th Avenue
Miami, FL 33196-2500

Mailing Address:
11800 S.W. 147th Avenue
P.O. Box 169015
Miami, FL 33116-9015

Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet : www.beckmancoulter.com

Please share this information with your laboratory staff and retain this notification as part of your laboratory quality system documentation. If you have forwarded the affected product to another laboratory,

Please provide them with a copy of this letter.
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 our Customer Support Center
- Via our website at Http://www.beckmancoulter.com/customersupport/support
- Via phone at 800-526-7694 in the United States and Canada
- Outside the U.S. and Canada, contact your local Beckman Coulter representative.

Thanks for your attention to this matter.

Sincerely,

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosures: Response Form

FA-28817