December 21, 2016

URGENT MEDICAL DEVICE RECALL
Resolution Section Updated

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

Dear Beckman Coulter DxH Customer,

Beckman Coulter is sending you this letter regarding a documentation update for the blast Suspect Messages. The Suspect message information has been updated for clarity.

ISSUE:	Beckman Coulter has determined that additional clarification for the Blast Suspect messages is necessary. In rare situations, the UniCel DxH 800 and DxH 600 Coulter Cellular Analysis System may not flag or detect blasts in some blood samples. This is due to limitations in the available technology as well as sample limitations.
IMPACT:	In these situations there could be a delay in the diagnosis and treatment of conditions associated with blasts in the peripheral blood.
ACTION:	Please refer to the following modified information for both the Suspect messages and Limitation sections for the Differential: Blasts are detected, but not enumerated, by internal algorithms using acquired events, histogram and dataplot patterns, and sophisticated statistical methods for all available data for the sample analyzed. A standard trigger value or limit corresponding to enumeration on peripheral smear cannot be established because: • Laboratories differ in their desired sensitivity to abnormal flagging and messaging. • Laboratories differ in their definition of blasts. • Mature and immature abnormal cell types may be identified as blasts. • Blasts can be rare events. Blasts can represent a mixed population of cells often associated with specimen abnormalities that alter the white cell population's pattern distribution in dataplots and histograms away from a normal distribution. The presence of blast cells may trigger other available Suspect messages, and not all blood samples that contain blasts may report a Suspect message. A blast Suspect message is not diagnostic. The user should not rely upon instrument results alone to replace the need for manual microscopic review of blood samples, if indicated by other clinical and laboratory features of the patient. Further diagnostic procedures and clinical evaluation must be evaluated for diagnosis.

Beckman Coulter, Inc.
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Miami, FL 33196-2500

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

	Refer to your Instructions for Use REF B26647, Chapter 6, Data Review, Processing Results, for complete information on all available messaging and flagging options on the system.
RESOLUTION:	• The Instructions for Use, B26647, will be updated to Revision AE in March 2017. • The modified information is temporarily available within the online ReadMefile, **B44444 ~~AD~~ AE**, available on the Beckman Coulter website at https://www.beckmancoulter.com/wsrportal/page/techdocSearch

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(s) listed above 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, please contact our Customer Support Center:

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

Thanks for your attention to this matter.

Sincerely,

[redacted]

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosures: Response Form

FA-29740-B

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