



STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

URGENT MEDICAL DEVICE RECALL UniCel DxH 800

Description:	FA-28817 URGENT MEDICAL DEVICE RECALL UniCel DxH 800 and DxH 600 IMMEDIATE ACTION REQUIRED
Implementation Date:	5/1/17
Performing Locations:	<p>Click on the boxes that apply:</p> <p><input checked="" type="checkbox"/> Alamance Regional <input type="checkbox"/> Annie Penn Hospital <input type="checkbox"/> Moses Cone Hospital <input type="checkbox"/> Med Center at High Point <input type="checkbox"/> Wesley Long Hospital <input type="checkbox"/> Women's Hospital</p>
Affected Locations:	<p>Click on the boxes that apply:</p> <p><input checked="" type="checkbox"/> Alamance Regional <input type="checkbox"/> Annie Penn Hospital <input type="checkbox"/> Moses Cone Hospital <input type="checkbox"/> Med Center at High Point <input type="checkbox"/> Wesley Long Hospital <input type="checkbox"/> Women's Hospital</p>
Affected Departments:	<p>Click on the boxes that apply:</p> <p><input type="checkbox"/> Blood Bank <input type="checkbox"/> Cytology <input type="checkbox"/> Flow Cytometry <input type="checkbox"/> Histology <input type="checkbox"/> Microbiology <input type="checkbox"/> Phlebotomy <input type="checkbox"/> Point of Care <input checked="" type="checkbox"/> Rapid Response Lab <input type="checkbox"/> Respiratory Therapy <input type="checkbox"/> Specimen Processing</p>
Specimen Type:	EDTA

Updated Clinical Lab Procedures:	N/A
Retired Clinical Lab Procedures:	N/A
Notification to Client:	<p>Click on the boxes that apply: <input checked="" type="checkbox"/> Section Not Applicable <input type="checkbox"/> Memo Needed</p> <p>Distribution of Memo: <input type="checkbox"/> Medical Staff <input type="checkbox"/> Allied Health Professionals (PA, Nurse Practitioners) <input type="checkbox"/> Anesthesia <input type="checkbox"/> Annie Penn (Primary Source Physicians) <input type="checkbox"/> Dentist <input type="checkbox"/> Emergency Department/Urgent Care Centers <input type="checkbox"/> Family Practice <input type="checkbox"/> Infectious Docs #ID Docs (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam) <input type="checkbox"/> OB/GYN <input type="checkbox"/> Pathology <input type="checkbox"/> Pediatricians <input type="checkbox"/> Psych <input type="checkbox"/> Radiology <input type="checkbox"/> Surgery</p> <p><input type="checkbox"/> #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager) <input type="checkbox"/> Pharmacy - Send to DeAnne Brooks & Jim Hasspacher <input type="checkbox"/> #IM Residents <input type="checkbox"/> Kim Helsabeck <input type="checkbox"/> Phlebotomy Managers and Supervisors <input type="checkbox"/> Point of Care: Sheila, Kim & Marty</p>
Accreditation Section:	<p>Click on the boxes that apply: <input checked="" type="checkbox"/> Section Not Applicable <input type="checkbox"/> CAP Test menu change needed <input type="checkbox"/> CMS Analyte form change needed <input type="checkbox"/> Proficiency Testing surveys changes needed or ordered</p>
Laboratory IT section:	<p>Click box and type needed changes/additions: <input type="checkbox"/> Section Not Applicable <input type="checkbox"/> LIS changes <input type="checkbox"/> Reference range change/addition</p>

	<input type="checkbox"/> Technical Failure change/addition <input type="checkbox"/> Critical Value change/add <input type="checkbox"/> Text comments needed <input type="checkbox"/> Specimen collection instructions <input type="checkbox"/> Need to monitor TAT <input type="checkbox"/> CPT code for tests(s) Narrowed Abs Neutrophil range from 1.4 - 6.5 to 2.0 – 5.0
Technical Staff Update:	Repeat specimen outside range if Diff matches release results if not do manual Diff
STOP Initiator:	John Rizzo
Medical Director Signature:	Quality Department will obtain signature: <i>Sara C Rubinas M.D. 5/5/17</i> <i>May 1 2017 5/5/17</i>



April 24, 2017

URGENT MEDICAL DEVICE RECALL

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

Attention Beckman Coulter Customer,

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:	<p>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.</p> <p>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.</p>
IMPACT:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.

FA-28817

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](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.

A handwritten signature in black ink, appearing to read "Marwan Fathallah".

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Encl: Response form

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