e BECKMAN COULTER

December 1, 2015

URGENT FIELD SAFETY NOTICE

PRODUCT		SOFTWARE VERSION
Unicel® Dx.H™ 800 Coulter® Cellular Analysis System	629029, B24465,B24802	3.0.2.0
Unicel® *DxWM* SMS Coulter® Cellular Analysis System	775222	3.0.2.0
Unicel® Dx.H™ 600 Coulter® Cellular Analysis System	B23858	1.1.1.0

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety co1Tective action for the products listed above regarding the possibility of sample misidentification. This notice pertains to systems configured as a stand-alone Dx.H SlideMaker Stainer, DxH 800 or DxH 600, or as a workcell with multiple DxH 800s without a Dx.H Slidemaker Stainer. This letter contains important information that needs your immediate attention.

ISSUE:	During internal testing, Beckman Coulter detennined that the software for the DxH systems noted above allows the creation of multiple orders with the same Specimen identification (ID) but different Patient identification when manually editing pending orders at the System Manager. The issue does not occur for edits ofreleased results or for test orders requested through host transmission. • A duplicate Specimen ID can be manually edited into an existing pending test order at the DxH System Manager' s Worklist - Pending or Worklist - Review tab. • The software does not reject the edit or generate a message stating that duplicate Specimen IDs are not allowed. • The software prompts the user to verify the change in Specimen ID with the following message: *Change Specimen ID for the current specimen?* *Select OK to change the Specimen ID, the change wil! take effect immediately.* ***<0!(>*** *<Cancel>* • Upon selecting **OK,** a duplicate Specimen ID will be assigned to the edited test order. The system will now have two active test orders for the same Specimen ID, one with a possible Specimen ID to Patient ID mismatch. • After processing, inc01Tect results may be observed at the System Manager, on printed rep011s, in transmission, and in exported files.
IMPACT:	The issue creates the potential for sample misidentification and possibility of releasing e1Toneousresults.
ACTION:	Do not edit the Specimen ID fora pending test order at the System Manager's Worklist - Pending or Worklist - Review tabs.
RESOLUTION:	The issue will be c01Tected in the next software release in early 2016.

FSN- 26617

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Pr.oduct Information : (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet : www.beckm ancoulter .com

The national competent authority has been info1med of this field safety conective action.

Share this information with your laborato1y staff and retain this notice as part of your laboratory Quality System documentation. Ifyou have fo1warded any of the affected product(s) listed above to another laborat01y, please provide thema copy of this letter.

Please complete and return the enclosed Response Form within 10 days so that we are assured you have received this imp01tant communication.

Ifyou have any questions regarding this notice, please contact our Customer Support Center

- Via our website, http://www.beckmancoulter.com/customersuppo rt/supp01t
- Or contact your local Beckman Coulter Representative.

We apologize for the inconvenience to your laborat01y.

Sincerely,

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Vice President, Quality Assurance and Regulat01y Affairs

Enclosure: Response Form