

August 08, 2016

URGENT MEDICAL DEVICE RECALL

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 Customer,

Beckman Coulter is initiating a field action that needs your immediate attention. There is a possibility of specimen misidentification for the stand-alone DxH 800 and DxH 600 where the Primary Identifier is configured to Tube Position ID. This issue does not occur if the primary identifier is configured as Specimen ID.

ISSUE :	Results from a patient control sample could be misidentified by being associated with a pending test order for a patient sample already on the Worklist when the following sequence of events occurs: <ul style="list-style-type: none">• The Primary Identifier is Tube Position ID.• A patient control file is setup for ID XXXXX, and a pending test order for a patient sample ID XXXXX is subsequently added to the Worklist.• The patient control sample is analyzed using cassette presentation, but that tube does not contain a barcode-labeled Specimen ID or the label cannot be read.
IMPACT:	Upon analysis, the results from the analyzed patient control tube will be associated with the patient sample that was pending on the Worklist and not the patient control file.
ACTION:	Ensure that there are no pending or active patient test orders in the worklist before analyzing a patient control with a Tube Position ID.
RESOLUTION:	Beckman Coulter is investigating this issue in order to provide a resolution.

Share this information with your laboratory staff and retain this notice 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 that we are assured you have received this important communication.

FA 28316



If you have any questions regarding this notice, 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

We apologize for any inconvenience to your laboratory.

Sincerely,



Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Encl: Response Form

FA-28316

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