

URGENT FIELD SAFETY NOTICE
DxH 500, PN B40601
Software Versions 1.0.0, 1.0.1, and 1.0.2

Dear Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention. There is a possibility of specimen misidentification for the DxH 500 instruments. Patient results may be affected.

ISSUE	<p>A specimen misidentification may occur, despite an active software prompt on the screen, when the following sequence of events occurs:</p> <ul style="list-style-type: none"> • Pending test orders exist on the Worklist. • A new Specimen ID is added using the Next icon on the Sample Analysis – Patient Results screen or by scanning a specimen barcode label. • The user leaves the screen before aspirating the new specimen. • Upon returning to the Sample Analysis – Patient Results screen, the following prompt displays “<i>Worklist contains entries. Confirm next Specimen ID is correct before processing specimen</i>”. • The Next Specimen ID field of the DxH 500 defaults to the first Specimen ID on the Worklist which may not be the newest specimen identified. • The issue occurs when the user fails to verify the Specimen ID. <p>The issue does not occur when the Worklist has no pending test orders.</p>
IMPACT	There is a potential for a set of results being incorrectly associated with another specimen’s ID.
ACTION	Always verify the Specimen ID displayed in the Next Specimen ID field matches the specimen to be processed as directed by the software prompt and the Instructions for Use PN B23922AA.
RESOLUTION	Beckman Coulter is investigating this issue in order to provide a resolution.

The national competent authority has been informed of this field safety corrective action.

Share this information with your laboratory staff and retain this notice 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 a copy of this letter.

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

FSN-28317



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

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Or contact your local Beckman Coulter Representative.

We apologize for the inconvenience to your laboratory.

Sincerely,

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

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form

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