



December 29, 2017

FOLLOW-UP URGENT FIELD SAFETY NOTICE – FSN 28317-B
DxH 500, PN B40601

Dear Beckman Coulter Customer,

Beckman Coulter is pleased to announce the release of DxH 500 system software version 1.1.1. This software update addresses specimen misidentification on the DxH 500 when a specific sequence of events occurs as discussed in the Urgent Field Safety Notice dated July 27, 2016 (FSN-28317) and Important Product Information (B96702AA) dated July 2016.

1. Beckman Coulter has investigated the issue and is providing the resolution in the form of a software update to address this issue. The software update will be available beginning March 2018.
2. Your Beckman Coulter service representative will contact you to schedule a date for installing the new software.
3. Software version 1.1.1 will not allow specimen processing until the active software prompt on the screen is acknowledged.

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

Please 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.

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

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,

John Winter
Senior Manager, Commercial Quality & Regulatory Affairs, Europe
Tel +44 (0) 1494 429184/+44 (0)1494 429126
Fax +44 (0) 1494 429182

Enclosed: Vigilance Response Form



Beckman Coulter Diagnostics Limited
Lismeehan
O'Callaghans Mills
Co. Clare
Ireland

Telephone +353 65 6831100
Fax +353 65 6831122
e-mail infoie@beckman.com
Website www.beckman.com

Directors: P Devereux, P Della Puca
Registered in Ireland no 485929 Registered Office: 70 Sir John Rogerson's Quay, Dublin 2, Ireland