



July 18, 2014

**UPDATE FOR URGENT FIELD SAFETY NOTICE**  
**UniCel DxH 800 Coulter Cellular Analysis System, PNs 629029, B24465, and B24802**  
**UniCel DxH 600 Coulter Cellular Analysis System, PN B23858**  
**DxH Cleaner 10L Lots 3071440 and 3071450**  
**DxH Cleaner 5L Lot 3071360**

Dear Beckman Coulter DxH Series Customer,

Beckman Coulter is pleased to provide this update to the communications that you previously received concerning optical degradation on the DxH 800 and DxH 600 Coulter Cellular Analysis Systems (previous communications listed below). The additional flush flow cell and extended cleaning actions outlined in the previous letters, FSN-PCA 20894 and B43100AA, are *no longer required*.

Letter Identifier	Date
FSN 20894	November 2013
B43100AA	November 2013 ( instruments installed after 08 Nov 2013)
FSN 20894-2	February 2014

**Update:**

- The results of our investigation have shown that the DxH Cleaners that were identified in the prior letter, FSN-20894-2, were the main contributors to the optical degradation issue.
- All lots identified in the prior letter have been removed from Beckman Coulter inventory.
- Beckman Coulter has received a decreased number of optical degradation complaints since the identified lots were removed from Beckman Coulter inventory.

**Actions:**

- Discard the existing DxH Cleaner lots from your inventory as listed in Table 1.
- Your laboratory can discontinue performing the additional flush flow cell and extended cleaning actions as outlined in the previous letters.
- Please follow the existing directions in the Instructions for Use (IFU):
  - If a flow cell clog error occurs, perform troubleshooting as directed in the IFU.
  - Perform routine Shutdown as recommended in the IFU.
  - Only perform cleaning procedures as described in the current IFU.

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

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products listed above to another laboratory, 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.

FSN 20894-3

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If you have any questions or concerns regarding this product announcement please contact your local Beckman Coulter Customer Support Center. We apologize for the inconvenience that this has caused your laboratory.


Sincerely,



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

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**Table 1**  
**Affected Lot Numbers of DxH Cleaner**

DESCRIPTION	REF	LOT	
DxH Cleaner 10L	628023	3071440	16 Aug 2014
DxH Cleaner 10L	628023	3071450	16 Aug 2014
DxH Cleaner 5L	628022	3071360	15 Aug 2014