

April 13, 2015

URGENT MEDICAL DEVICE RECALL

COULTER DxH Diluent  **628017**

Lot Numbers 3099980 - 3512190

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the lot numbers of COULTER DxH Diluent listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<p>Beckman Coulter has received an increased number of complaints related to Hemoglobin (HGB) on UniCel DxH 800 and DxH 600 Coulter Cellular Analysis Systems, including</p> <ul style="list-style-type: none">➤ HGB background failures➤ HGB Shift error messages➤ HGB incomplete computations (.....)➤ Failures in delta check, H&H check, XB, XM, and low recovery or downward trending of HGB on Coulter 6C Cell Controls➤ Some customers observed false low HGB values. <p>The investigation has revealed that the issues may be related to variability in components of the COULTER DxH Diluent.</p>
IMPACT:	<p>The use of the DxH Diluent lots listed in this notice may eventually result in a compromised HGB chamber, indicated by the occurrence of events listed in the Issue section. The HGB chambers are being replaced on an as needed basis.</p> <p>Sporadic incorrect HGB results may be observed if your system's HGB chamber is compromised.</p> <p>The issue is not observed with all DxH 800 and DxH 600 systems.</p>
ACTION:	<p>If your system is experiencing the symptoms noted in the Impact section, call Beckman Coulter. New inventory of DxH Diluent is being built for general distribution. Beckman Coulter Service will take actions to address HGB issues until the new lot(s) can be provided to your account.</p> <p>Consult with your laboratory management to determine whether a retrospective review of results is necessary.</p>
RESOLUTION:	<p>All new lots of DxH Diluent are being manufactured with materials that will reduce the variability in performance. Your laboratory will automatically receive these new lots as soon as they become available.</p>

FA-22392

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.

If you have any questions regarding this notice, please 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.

e to your laboratory.



Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form