


IMPORTANT PRODUCT NOTICE
UniCel® DxH Slidemaker Stainer COULTER® Cellular Analysis Systems
Part Number 775222

Dear Beckman Coulter Customer,

Beckman Coulter is sending you this letter concerning possible mislabeling of your DxH Slidemaker Stainer. Results are not affected by this issue.

ISSUE:	Beckman Coulter has confirmed a possible mislabeling of the product name on the front panel of the Sample Transport Module (STM) on some DxH Slidemaker Stainer Coulter Cellular Analysis Systems.
IMPACT:	Some DxH Slidemaker Stainer systems are incorrectly labeled as “UniCel DxH 800 Coulter Cellular Analysis System”.
ACTION:	<ul style="list-style-type: none"> • Inspect the label on your DxH Slidemaker Stainer system as shown below. • If the system is mislabeled, contact Beckman Coulter for the label to be corrected. <div style="text-align: center;">  <p>Correct Incorrect</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; background-color: #e0e0e0;"> <i>UniCel DxH Slidemaker Stainer</i> <small>Coulter® Cellular Analysis System</small> </div> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; background-color: #e0e0e0;"> <i>UniCel DxH 800</i> <small>Coulter® Cellular Analysis System</small> </div> </div> </div>
RESOLUTION:	Beckman Coulter Service will install the correct label for your system. The issue has been corrected for all new products.

Please share this information with your laboratory staff and retain this notification as part of your laboratory’s Quality System documentation. If you have forwarded any of the affected product(s) 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.

IPN-25596

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 this has created for your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read "Marwan Fathallah". The signature is fluid and cursive, with a horizontal line underneath the name.

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs

Enclosures: Response Form

IPN-25596