

May 3, 2016

**IMPORTANT PRODUCT NOTICE**

<b>PRODUCT</b>	<b>REF</b>	<b>SOFTWARE VERSION</b>
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802, B68304	2.0.0.0 and greater
UniCel DxH 600 Coulter Cellular Analysis System	B23858	1.0.0.0 and greater

Dear Beckman Coulter Customer,

Beckman Coulter is sending you this letter relating to possible background failures for the DxH 800 and DxH 600 instruments. Please note that Red Blood Cell (RBC) and Platelet (PLT) Counts may be affected.

<b>ISSUE</b>	Beckman Coulter has identified an issue where the RBC aperture baths can contain residue in the sweep flow fittings. This residue may potentially create increased background failures, flagged results and vote outs for RBC and PLT parameters.
<b>IMPACT</b>	You may experience: <ul style="list-style-type: none"><li>• Daily Checks Background failures for RBC and/or PLT.</li><li>• Non-numeric codes for complete vote outs (-----) or flagged partial vote outs for the RBC and/or PLT parameter results.</li></ul> No other parameters are impacted.
<b>ACTION</b>	<ul style="list-style-type: none"><li>• Address any Daily Checks system alarms and background failures as indicated in the Online Help or Instructions for Use (part number B26647AC and B16421AD).</li><li>• Monitor flags on patient and control results according to your laboratory protocols.</li></ul>
<b>RESOLUTION</b>	Beckman Coulter Support will contact you to schedule a service visit for the replacement of the RBC aperture bath.

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.

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

IPN-27816



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 to your laboratory.

Sincerely,



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

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