May 20, 2019

# URGENT MEDICAL DEVICE RECALL -- UPDATE

| PRODUCT | REF | SOFTWARE VERSIONS |
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| UniCel DxH 800 Coulter Cellular Analysis System | 629029, B24465, B24802, B68304, B66445, B63322 | All |
| UniCel DxH 600 Coulter Cellular Analysis System | B23858 | All |
| UniCel DxH 900 Coulter Cellular Analysis System | C11478 | All |

Attention Beckman Coulter Customer,

This notification replaces our previous Urgent Medical Device Letter dated July 30, 2018 concerning sporadic erroneously elevated platelet results. This letter contains important information that needs your immediate attention. Patient results may be affected. No injury has been reported in association with this issue. Please note that Beckman Coulter has expanded the scope of the recall to include the DxH 900 system, as indicated in the table above.

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| **ISSUE:** | As reported in our Urgent Medical Device Letter dated July 30, 2018, Beckman Coulter has confirmed complaints of sporadic erroneously elevated platelet results without flags or system messages. The underlying issue is temporary disturbance of the sweep flow. While we have not received additional complaints, these erroneous results may be difficult to detect absent other information. The issue may affect one or multiple samples tested in sequence. Beckman Coulter has not received complaints of this issue impacting the other reported parameters: HGB, WBC Count, WBC Differential, or RBC results. |
| **IMPACT:** | • Thrombocytopenia may go unrecognized.<br>• Patients at high risk include those with malignancies (including those with iatrogenic thrombocytopenia), heparin-induced thrombocytopenia, thrombotic microangiopathic anemia, immune thrombocytopenic purpura and thrombocytopenia associated with pre-eclampsia.<br>• The reported magnitude of error ranges from 33 x $10^3$ cells/µL to 990 x $10^3$ cells/µL based on reported complaints. |
| **ACTION:** | • Run samples on an instrument not subject to this recall to confirm the platelet results.<br>• If an alternative instrument is not available, use the following quality control measures to aid in identification of discrepant platelet results:<br>  ○ Perform manual scanning/estimate of platelets on a peripheral smear and compare with instrument results. Note that this method will identify samples with marked to moderate thrombocytopenia but may not identify smaller discrepancies.<br>  ○ Repeat testing of samples in a workflow configuration may facilitate the identification of discrepancies. If an erroneous result is detected, review results from adjacent samples, i.e., those tested on the instrument both before and after the erroneous result.<br>  ○ Additional instrument and/or LIS features including reference ranges, XM (exponentially-weighted moving average) and delta checks may be informative.<br>  ○ Follow your laboratory's standard operating procedure to confirm unexpected results.<br>• Ongoing investigation indicates that the probable root cause is the sweep flow disruption that may occur following the "Clear RBC Apertures" procedure. This potential root cause is currently under further investigation. Customers should discontinue using this procedure. If you suspect that your instrument has a clogged aperture that will not clear, discontinue use of the analyzer, contact Beckman Coulter Customer Support Center and request service.<br>• Communicate to the ordering physicians the need to avoid patient treatment based solely on any single test result, and to interpret all results in the context of other clinical and laboratory features. Physicians should be vigilant when reviewing platelet count results, particularly in patients at risk for thrombocytopenia, such as those with leukemia, certain types of anemia, infection, alcohol abuse, autoimmune diseases, thrombotic microangiopathy, hypersplenism, pregnant patients, patients on chemotherapy, receiving heparin treatment or taking certain medication including quinine, anticonvulsants and sulfonamide antibiotics.<br>• Consult with your Medical Director to determine if a retrospective review of results is warranted.<br>• Report any unflagged erroneously elevated platelet counts experienced in your laboratory to Beckman Coulter (contact information is at the end of this letter) and you may also report to the |

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| | United States Food and Drug Administration (Visit www.fda.gov/medwatch, or call 1-800-FDA-1088). |
| **RESOLUTION:** | • To detect and flag erroneously elevated platelets due to temporary disturbance of the sweep flow, Beckman Coulter implemented an algorithm improvement. This algorithm improvement was implemented by way of one of the following:<br>1. Software upgrades, DxH 800 version 3.2.1 and above and DxH 600 version 1.3.1 and above.<br>2. Customer-installable software patch made available in October 2018<br>3. Software version 1.0.0 and above for DxH 900<br>• If your DxH 800 / DxH 600 system has not yet been upgraded with the improved algorithm, please contact your local Beckman Coulter representative. All fielded DxH 900 analyzers have the improved algorithm incorporated into their original software.<br>Beckman Coulter continues to investigate the unflagged elevated platelets issue and assess the "Clear RBC Apertures procedure" as well as other potential root and/or contributing causes. **The algorithm improvement is currently being evaluated. Please continue to follow the instructions in this notification letter. This includes customers whose systems already have the updated algorithm.** |

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have transferred any of the affected product(s) listed above to other laboratories, please provide them with a copy of this letter.

So that we are assured you have received this important communication, respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact Beckman Coulter Customer Support Center:

- From our website: http://www.beckmancoulter.com
- By phone call 800-526-7694 in United States and Canada.

We apologize for any inconvenience to your laboratory.

Sincerely,

Roger Janczak
Vice President, Quality and Regulatory Affairs