August 19, 2019

URGENT FIELD SAFETY NOTICE – STATUS UPDATE

Products	Part Number	Software Versions
UniCel DxH 800 Coulter Cellular Analysis System UniCel DxH 600 Coulter Cellular Analysis System UniCel DxH 900 Coulter Cellular Analysis System	All	All

Dear Beckman Coulter Customer,

This notification supplements and provides an important status update on the resolution of the issue outlined in our previous **urgent Field Safety Notice Letter FSN 33718-2 (dated June 2019, issued to existing customers) and Letter PN C46850 (dated May 2019, issued to new customers)** concerning confirmation of sporadic erroneously elevated platelet results without displaying flags or system messages.

ISSUE:	As reported in our urgent Field Safety Notice Letter FSN 33718-2 (dated June 2019, issued to existing customers) and Letter PN C46850 (dated May 2019, provided with new instrument installations), 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. Preliminary root cause investigation indicates that sweep flow disruption may occur following the Clear RBC Apertures procedure. 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. There have been no reports of this issue on the DxH 900. Beckman Coulter has confirmed the root cause of the issue and will be releasing a software update as a corrective action to eliminate the root cause and resolve the issue (expected in August 2019). In the meantime, please continue to follow the instructions included in the ACTION section below.
ACTION:	**It is important for you to continue following the actions described in urgent Field Safety Notice 33718-2 (dated June 2019, issued to existing customers) and Letter PN C46850 (dated May 2019, issued to new customers) until the software update has been installed.**

RESOLUTION:	Beckman Coulter has confirmed that the root cause of the unflagged elevated platelet results was a software-controlled cycle introduced in 2015 (the "Clear RBC Apertures" procedure), which uses a pressurized back-flushing sequence through the sweep flow to dislodge trapped debris in RBC/PLT apertures. In rare instances, the system did not fully remove the air pockets created by the Clear RBC Apertures process, disrupting the normal function of the sweep flow and leading to the increase in customer complaints due to unflagged erroneously elevated platelet counts. • Beckman Coulter will release a mandatory customer-installable software update as a resolution of this issue (currently expected to be available in August 2019). The software update will disable the Clear RBC Apertures procedure through the Diagnostics Menu and prevent the procedure from occurring automatically upon shutdown. • A software update kit will begin being available by end of August/September 2019, it will contain a DVD with installation instructions for this update and a response form. As noted above, your facility's installation of this software is mandatory. • Please note that upon installation of the updated software, your laboratory will no longer be required to follow the actions stated in the previous urgent Field Safety Notice Letter (dated June 2019) and Letter PN: C46850 (dated May 2019). This software update will disable the Clear RBC Apertures procedure and eliminate the cause of the problem.

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

Please share this information with your laboratory and retain this notification as part of your laboratory Quality System documentation.

If you have any questions or comments regarding this follow-up field action, please contact Beckman Coulter Customer Support Center through our website: http://www.beckmancoulter.com

We appreciate your patience and support through resolution of this recall.

Sincerely,

Roger Janczak
Vice President, Quality and Regulatory Affairs