November 17, 2022

URGENT FIELD SAFETY NOTICE

LeukoSure Enumeration Kit

REF	LOT	
175621	5621089K 5621090K	08-NOV-2022 22-FEB-2023

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	The above-mentioned lots of LeukoSure Enumeration Kit may not be able to acquire 10,000 LeukoSure Fluorosphere events within 300 seconds as outlined in the Statement of Warnings in the product instructions for use (IFU) PN 175624 Revision EE. The issue is due to inadequate lysing of red blood cells.
IMPACT:	In the worst-case scenario, the following outcomes may occur: • Erroneously high leukocyte count in blood component reported exceeding the allowable imprecisions limits of the assay. • Delay of release of blood products that meet standard for labeling as “Leukocytes Reduced”. There is no impact to results if your kit of LeukoSure Fluorosphere is achieving the 10,000 LeukoSure Fluorospheres events within 300 seconds per the IFU.
ACTION:	• If the 10,000 LeukoSure Fluorosphere events are not achieved within 300 seconds as outlined in *Statement of Warnings* in the product instructions for use (IFU) PN 175624 Revision EE, stop using the products immediately and safely discard any remaining inventory as per local regulations. Please contact your local Beckman Coulter representative for replacement product. • Retrospective review of results is not required if results have been generated and reported after achieving the acquisition of 10,000 LeukoSure Fluorospheres events within 300 seconds in line with the labeling requirements.

	• Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous test results that may have been generated and reported without achieving the acquisition of 10,000 LeukoSure Fluorospheres events within 300 seconds in line with the labeling requirements.
RESOLUTION:	Beckman Coulter is conducting further investigation to implement control measures to prevent recurrence of the reported issue.

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

Please share this information with your laboratory staff and retain this notification 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 we are assured you have received this important communication.

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

- From our website: http://www.beckman.com
- You may request replacement product by contacting your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Sudharsan Sathyamurthy
Signer Name: Sudharsan Sathyamurthy
Signing Reason: I approve this document
Signing Time: 18-Nov-2022 | 5:28:25 AM PST
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Sudharsan Sathyamurthy
Director, Flow Cytometry Business Unit Quality and Regulatory Affairs

Enclosure: Response Form