



June 1, 2017

URGENT FIELD SAFETY NOTICE – FSN 29657

COULTER PrepPlus & PrepPlus 2 Part Numbers 286600 & 378600

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:	<ul style="list-style-type: none">As a result of internal investigations, Beckman Coulter has confirmed that when samples are prepared using the PrepPlus or PrepPlus 2 sample preparation systems and then run on a Flow cytometer, there is an imprecision in the absolute counts on only the first tube in a run.The problem is a software issue, where an incorrect volume (aspiration/dispense) of Flow-Count reagent (used to determine lymphocyte population) is dispensed in the first tube position of the PrepPlus/PrepPlus 2 carousel.The issue may generate erroneous results for the reported parameters assayed on the sample in the first tube of the Flow Count worklist.
IMPACT:	<ul style="list-style-type: none">Any sample prepared on the PrepPlus/PrepPlus 2 in the first position of the carousel is subject to potential erroneous absolute count results for the reported parameters assayed on the sample in that tube.The potential magnitude of the error is a positive bias of up to 9.7% on the PrepPlus and 13.4% on the PrepPlus 2.
ACTION:	<ul style="list-style-type: none">Insert an empty daughter tube in place of a patient sample as the first tube in the carousel that is programmed for the addition of Flow-Count Fluorospheres.Refer to the COULTER PrepPlus Operators Guide / PrepPlus 2 Instructions for Use (IFU) for instructions on adding Flow-Count Fluorospheres to daughter tubes.Review all results following the flow cytometer data review instructions referenced in the associated IFU.
RESOLUTION:	<ul style="list-style-type: none"><u>PrepPlus</u>: Based on the current obsolescence of the PrepPlus, this notification will serve as the only labeling update.<u>PrepPlus 2</u>: This issue will be corrected in the next PrepPlus 2 software release.



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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 that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,



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Enclosed: Vigilance Response Form