10 Eskadale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

August 23rd, 2019

URGENT FIELD SAFETY NOTICE: BDB-19-1585-1

BD FACSLyric™ Flow Cytometer
(**REF**: 651164; 651165; 654587; 659180; 663029)

Type of Action: Advisory

Dear Customer,

BD has become aware, through customer feedback, that specific serial numbers of **BD FACSLyric™ Flow Cytometers,** belonging to one or more of the configurations listed in the table below, have the potential to read high absolute counts when using the BD Trucount™ beads. Excessive abort counts affect the ratio of cell population events to bead events, resulting in erroneously high cell count.

Instrument Name	REF
FACSLyric 2L4C Instrument	651164
FACSLyric 2L6C Instrument	651165
FACSLyric 3L8C Instrument	654587
FACSLyric 3L10C Instrument	659180
FACSLyric 3L12C Instrument	663029

As a result, BD is issuing this Field Safety Notice to provide customers with an **Abort Count Quantification Protocol** (Appendix 1) which will enable them to identify if their BD FACSLyric™ Flow Cytometer is underperforming and requires follow-up activity.

BD Multitest™ and BD TriTest™ with BD Trucount™ tubes are intended for use with FACSLyric™ for the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency. These reagents determine the percentages and absolute counts of mature human lymphocyte subsets: T, B, and NK cells.

When using the BD Multitest™ and BD TriTest™ reagent with BD Trucount tubes for the determination of CD4 absolute counts in HIV patients, a falsely high CD4 count can be generated as a consequence of an high Trucount abort count. This in turn may cause a delay in the initiation of a prophylactic therapy for Opportunistic Infections (OIs). Current clinical guidelines use a combination of HIV viral load, CD4 absolute counts, and other disease sequelae for the overall evaluation of a patient's disease burden and subsequent clinical decisions.

There is also a potential for falsely high absolute cell counts from samples stained with BD Multitest™ or BD Tritest™ reagent which may result in an erroneous assessment of the immune function for Primary Immune Deficiency (PID) initial screening, or immune suppressive therapy management. For PID and immune suppressed patients (post-organ or stem cell transplantation), the assessment of T-, B- and NK subpopulation as part of the initial screening or ongoing monitoring has the potential to affect decisions regarding care and management.

Excessive abort counts may also affect laboratory developed tests (LDT) or experiments in which the absolute count of cell populations is determined using BD Trucount™ tubes. Falsely high absolute counts may be generated.

The absolute count of stem cells is used to assess the quality of the transplant product for stem cell transplantation. When stem cell enumeration is determined using BD Trucount™ tubes on BD FACSlyric as an LDT, a high abort count may cause a false high absolute count affecting the specimen engraftment potency.

For leucoreduced blood product testing using BD Trucount™ tubes to identify residual nucleated cells, with propidium iodide a an LDT, a falsely high number of residual cell counts may prevent the use of the leucoreduced blood products for transfusion.

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Advice on actions to be taken by the Customer:

1. Share this product notification with all users of the designated **BD FACSLyric™ Flow Cytometer** instruments within your facility to ensure awareness.

2. If you have further distributed the instruments, please identify those users and notify them at once of this product notification.

3. Perform **Abort Count Quantification Protocol** per Appendix 1 provided here below to identify if your BD FACSLyric™ Flow Cytometer performs as per manufacturing specifications or requires follow-up activities.

4. On completion of the Abort Count Quantification Protocol, if the **percentage aborted events are less than 1.0%**, your instrument(s) performs as per manufacturing specifications and no follow-up activities are required for your instrument(s)
   a. Email the completed Customer Reply Form to techsupport@bd.com providing your device serial number (located on the model plate on the back of the instrument) and percent abort events,

5. Differently, if on completion of the Abort Count Quantification Protocol, the **percentage of aborted events is greater than or equal to 1.0%**, follow-up activities are required for your instrument
   a. Suspend all clinical testing until your instrument is evaluated by your field service engineer and the abort count issue is resolved
   b. Email the completed Customer Reply Form to techsupport@bd.com providing your device serial number (located on the model plate on the back of the instrument) and percent abort events, and call 0800 917 8776, select option 1 then 3.
   c. If your instrument is aborting a percentage of BD Trucount™ beads equal to or higher than 1.0%, it is likely that the absolute counts of your clinical testing may be falsely high. BD recommends that you review both the results obtained when using your process controls (i.e. BD™ Multi-Check and BD™ Multi-Check CD4 Low Controls) and your instrument validation data. The impact to patient data is likely minimal when your process controls fall within your laboratory defined ranges and are reviewed daily. Additional recommended checks to verify the correctness of the patient data generated until now can include: 1.) Calculations of absolute counts using a dual platform method where absolute counts were determined by a hematology analyzer; and 2.) A review of historical patient data acquired on an alternative platform.

In all cases, it is important that we receive the Customer Reply Form from your facility for reconciliation purposes. The relevant regulatory authorities have been notified of the field safety corrective action.

If you have additional questions, please contact your local BD Biosciences Application Specialist on +44 (0) 7825919023 or e-mail david.sowter@bd.com.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products.

We apologise for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible. We remain at your disposal for any question you might further have

Yours Sincerely,

William David
Senior Director, EMEA Quality Compliance
BD Switzerland Sarl

Appendix 1 - Abort Count Quantification Protocol

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FIELD SAFETY NOTICE: BDB-19-1585-1
Customer Response Form

BD FACSLyric™ Flow Cytometer
(REF: 651164; 651165; 654587; 659180; 663029)

Please read in conjunction with Field Safety Notice BDB-19-1585-1 and return completed form as soon as possible or **no later than September 27th, 2019.**

- I have read and understood the contents of this Field Safety Notice and performed the Abort Count Quantification Protocol on each of my instruments
- I have noted the Percentage Aborted Events per the Abort Count Quantification Protocol for each of my instruments and the results are listed in the Table below for each instrument serial number

$$\frac{\text{Abort Count}}{\text{Processed Events}} \times 100\%$$

Serial Number	Abort Count (events) (per the Abort Count Quantification Protocol)	÷	Processed Events (per the Abort Count Quantification Protocol)	X 100	% Aborted Events
		÷		X 100	
		÷		X 100	
		÷		X 100	
		÷		X 100	
		÷		X 100	

Email the Customer Reply Form to techsupport@bd.com or telephone 0800 917 8776, select option 1 then 3.

Name of Trust	
Name of Hospital / Facility	
Hospital / Facility Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	