Becton, Dickinson and Company
BD Biosciences
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bd.com

URGENT MEDICAL DEVICE RECALL
BD FACSLyric™ Flow Cytometer

19 August 2019

For the Attention of: Laboratory Manager

Description of the problem:

BD has identified an issue that affects BD FACSLyric™ instruments. Specifically, BD has confirmed that some BD FACSLyric™ Flow Cytometers experience higher than expected absolute counts when using BD Trucount™ tubes. Excessive electronic abort counts may affect the ratio of cell population events to bead events, potentially resulting in a falsely high absolute count.

BD Multitest™ with or without 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™ reagent for CD4 absolute counts in HIV patients, a falsely high CD4 count may cause a delay in initiation of prophylactic therapy for Opportunistic Infections (OIs). Current clinical guidelines[1] 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 management.

There is also a potential for falsely high absolute cell counts from samples stained with BD Multitest™ 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 the 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 that determine the absolute count of cell populations using BD Trucount™ tubes. This may result in falsely high absolute counts.

When performing a stem cell enumeration test using BD Trucount™ tubes as an LDT, the absolute count of stem cells is used to assess the quality of the transplant product for stem cell transplantation. Falsely high absolute counts may affect the specimen engraftment potency.

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

Our records indicate you have the instrument referenced on the response form.

Please Take the Following Actions:

1. To determine if your instrument is affected, please run the Abort Count Quantification Protocol in Attachment 1.

2. Record the percentage of aborted events on the attached Customer Response Form and submit via fax, email, or online at https://checkyourinstrument.bd.com regardless of the result.

[1] *Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.*

3. For % aborted events < 1.0%: your instrument is performing as expected and no further action is required once the % aborted events has been provided to BD (i.e. once you have submitted the completed Customer Response Form).

4. For % aborted events ≥ 1.0%: BD is instructing that you suspend **all** patient testing. A BD Technical Representative will contact you within 24 hours (Mon-Fri) of receiving the data to schedule a service visit.

5. Please refer to the Frequently Asked Questions in Attachment 2 for more information.

6. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program.

   Web: MedWatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Actions Taken by BD:

1. BD has initiated a Corrective and Preventive Action (CAPA) to further investigate root cause and identify actions to prevent recurrence.

2. BD will schedule an onsite visit by a Field Service Representative to service your BD FACSLyric™ for those instruments with ≥ 1.0% aborted events, following receipt of the aborted event percentage information on the Customer Response Form.

Contact Information

If you require further assistance, please contact BD Customer/Technical Support at 844-918-0554.

BD is committed to advancing the world of health. Our primary objective is providing you with quality products. We apologize 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.

[redacted]
Gail Griffiths
Sr. Director, Regulatory Compliance - US

[redacted]
Tariq Arshad, MD
V.P., Medical and Scientific Affairs

CUSTOMER RESPONSE FORM

BD FACSLyric™

Please assist BD by promptly returning this form to:
BD Regulatory Compliance
Email: BDRC14@bd.com **or FAX: 312-949-0338 or online at https://checkyourinstrument.bd.com**

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No.: _____**Email Address**: _____

Fax No.: _____

☐ I have read and understood the attached notice, and my aborted events percentage is noted in the table below

☐ We no longer have this equipment on hand.

Name:	
Title:	
Signature/Date:	

Catalog No:	Description	Serial Number	Abort Count (events)	÷	Processed Events	X 100	% Aborted Events
				÷		X 100	
				÷		X 100	
				÷		X 100	
				÷		X 100	
				÷		X 100	