BD Life Sciences
BD Pharmingen
10975 Torreyana Road
San Diego, CA 92121

URGENT PRODUCT RECALL

April 2017

Dear Valued Customer:

As you may be aware, BD recently initiated a voluntary recall (February 17, 2017) for a subset of Research Use Only (RUO) single vial reagents with fluorophores. This recall was initiated after observing sporadic performance and vial to vial variability during routine internal testing as well as through complaint investigations. (Refer to recalled product formats in Table I)

BD has completed a thorough investigation and evaluation of product inventory, and based on those outcomes, the recall is being expanded to include additional lots of RUO single vial reagents with fluorophores. (Refer to additional product formats in Table II).

Investigation and Root Cause

A comprehensive investigation was initiated to identify root cause and evaluate product inventory and distribution. As a result of this investigation, BD has confirmed that a prolonged exposure to high intensity broad spectrum LED lighting was the root cause that resulted in sporadic performance and vial-to-vial variation attributable to light induced degradation in certain lots of single vial reagents. This exposure occurred after a warehouse relocation in May 2016 where high intensity broad spectrum LED lighting had been installed to enhance employee working conditions. Product degradation from prolonged light exposure has the potential to result in reduced signal intensity that may cause changes in cell staining patterns, lower quantitative values for positive populations or no signal. In the case of tandem dyes, it may also result in changes to the values in the fluorescence spectral overlap matrix for the reagent.

Correction

Upon identification of the impact this lighting had on the RUO single vial reagents, BD promptly took steps to modify the lighting conditions to be equivalent to the previous warehouse. All testing to date has confirmed that our correction has been effective. Additional corrective actions are under evaluation to prevent recurrence of this situation in the future.

Recommended Customer Actions

BD has reviewed your purchases and our records indicate that the only recalled product lots that were shipped to you are those identified on the attached list. We recommend you take the following actions:

A) Discard any remaining inventory from the attached affected product list and request replacement, **or**
B) Inspect your remaining inventory identified on the attached affected product list and, until replacement products are available, conduct QC testing using biological cells per your standard protocol on each vial in order to confirm that the reagent meets your performance expectations, **and**
C) Review any data generated by your research that utilized reagents from the affected product list.

BD is diligently working to replenish the supply chain with newly manufactured product. Therefore, many SKUs are available to ship upon receipt of your replacement order. Other SKUs will ship as soon as they are available.

Acknowledge recall and request replacement:

To acknowledge this recall communication and order replacement product please visit **bdbiosciences.com/productnotice** and follow the instructions on the **My Recall** tab. Utilizing our online process will result in immediate receipt acknowledgement of your request and initiate processing of your replacement order. As an alternative, you may email a completed copy of the Customer Response Form in this letter to BDBRC@bd.com or fax to 408-577-1409.

Information on Other RUO Single Vial Reagents

Other RUO single vial reagents with fluorophores were stored at the same warehouse while the high intensity broad spectrum LED lighting was in use. These product formats are not being recalled because we have conducted extensive testing of these product formats and have determined with a high level of statistical confidence and reliability that they will perform as expected. Additionally, accelerated stability studies on a sampling of these other product formats confirmed that the labeled expiration dates remain valid. These product formats have been released and will continue to be distributed.

For Further Assistance

Please contact BD Support – Research Use Only Recall at 844.858.5650 or email researchapplications@bd.com using "RECALL" in the subject line. Our trained associates will be available to answer your questions and recommend alternative products as needed. Additional information about the matters discussed in this letter can be found at **bdbiosciences.com/productnotice**.

BD is committed to providing all customers with high quality products and any information that will assist you with your research.

Thank you for your prompt attention to this important matter.

Sincerely,



Connor Bates
Head of Research Solutions Global Platform
BD Life Sciences



Gail Griffiths
Sr. Director Regulatory Compliance
BD Life Sciences

Table I – Product Formats recalled in February 2017

Product Format	Brand(s)
Alexa Fluor® 700	BD Pharmingen™ BD Phosflow™
APC-Cy™7	BD Pharmingen™
APC-H7	BD Pharmingen™
APC-R700	BD Horizon™
BUV661	BD Horizon™
BV605	BD Horizon™

Product Format	Brand(s)
BV650	BD Horizon™
BV711	BD Horizon™
BV786	BD Horizon™
PE-CF594	BD Horizon™
PE-Cy™5	BD Pharmingen™

Table II – Product Formats being recalled at this time

Product Format	Brand(s)
Alexa Fluor® 488	BD Pharmingen™ BD Phosflow™
Alexa Fluor® 555	BD Pharmingen™
Alexa Fluor® 647	BD Pharmingen™ BD Phosflow™
APC	BD Pharmingen™ BD Phosflow™
APC-H7	BD Pharmingen™ BD Phosflow™
APC-R700	BD Horizon™
BUV661	BD Horizon™
BV510	BD Horizon™ BD Phosflow™
BV650	BD Horizon™

Product Format	Brand(s)
BV711	BD Horizon™
BV750	BD Horizon™
BV786	BD Horizon™
Cy™5	BD Pharmingen™
Cy™5.5	BD Pharmingen™
PE	BD Pharmingen™ BD Phosflow™ BD Cytometric Bead Array (CBA) BD DimerX
PE-CF594	BD Horizon™ BD Phosflow™
PE-Cy™7	BD Pharmingen™ BD Phosflow™
PerCP-Cy™5.5	BD Pharmingen™ BD Phosflow™

Note: Certain lots from each format were recalled. For your specific information from Table II refer to the attached product table.

Please assist BD by promptly completing and returning this form to BDBRC@bd.com or by visiting **bdbiosciences.com/productnotice**
Fax No.: 408-577-1409

Customer Response Form
Customer No.

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 Urgent Product Recall notice.

Name:	
Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.

☐ We have the following affected product on hand and request replacement(s):