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

# URGENT PRODUCT RECALL

**February 2017**

Dear Valued Customer:

BD has observed an increase in the number of complaints of low or no signal, or lot-to-lot variability in signal for single vial reagents with fluorophores. In some cases, users observed vial-to-vial variability in signal within the same lot. Based on internal investigations, BD has identified **specific lots** of the following product formats, shipped between May 16, 2016 and February 10, 2017, that are being recalled:

| Brand | Product Format |
|---|---|
| BD Pharmingen™ | Alexa Fluor® 700 |
| | APC-Cy™7 |
| | APC-H7 |
| | PE-Cy™5 |
| BD Horizon™ | APC-R700 |
| | BUV661 |
| | BV605 |
| | BV650 |
| | BV711 |
| | BV786 |
| | PE-CF594 |
| BD Phosflow™ | Alexa Fluor® 700 |

BD has launched a thorough investigation to identify root cause for the sporadic degradation of the reagents. At this time, all data suggest that a significant change in the lighting conditions at an alternate warehouse location is the primary contributor of the low to no signal in the product. Based on the investigation, the current storage requirement on the product labeling, "*Store undiluted at 4°C and protected from prolonged exposure to light*," is sufficient to protect the product from degradation.

BD recommends that you either discard any remaining inventory and request a replacement or perform quality control using biological cells per your standard protocol on each vial of reagent just prior to use to confirm that the reagent is still performing as intended.

Additionally, please review any data that may have been generated from the affected product list. The potential degradation of product may result in a false identification of cell populations and/or aberrant staining patterns.

Our records indicate that you have been shipped the product lots on the attached list. If you request replacement product, it will be shipped as soon as it becomes available. BD is working diligently to replenish the supply chain with newly manufactured product.

Please complete the attached Customer Response Form so that BD may acknowledge your receipt of this notification and process your product replacement as requested.

If you require 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. Associates will be available to answer your questions and recommend alternative products as needed.

BD is committed to advancing the world of health. Our primary objective is to provide you with the highest quality products. Corrective actions are being initiated to prevent recurrence of this situation in the future.

Thank you for your prompt attention to this important matter.

Sincerely,

Gail Griffiths
Sr. Director Regulatory Compliance
BD Life Sciences

Connor Bates
Head of Research Solutions Global Platform
BD Life Sciences

Please assist BD by promptly returning this form to: **BD Regulatory Compliance**
Email: BDBRC@bd.com
Fax No.: 408-577-1409

**Customer Response Form**

**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 units and request replacement(s):

| Product Name | Catalog No. | Lot No. | No. of Units |
|---|---|---|---|
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