

July 17 2015

URGENT FIELD SAFETY NOTICE

BD CD56 PE-CyTM7 (CE-IVD)
Catalog Number: 335826
Lot Number 4300715 (expires 2015-10-31)
Lot Number 4353883 (expires 2015-10-31)

Dear Valued Customer:

Recently you purchased CD56 PE-CyTM7, Catalog Number 335826, lot number 4300715 and/or 4353883. Becton, Dickinson and Company (BD) has determined that the CD56 PE-Cy7 reagent contains a low amount of HLA-DR PE antibody. BD has confirmed that the concentration of the CD56 <antibody in the PE-Cy7 conjugate is sufficient to detect CD56 antigen on the targeted cells. The presence of HLA-DR PE could result in the possibility of an unexpected staining pattern. Therefore, we recommend that you examine your data files obtained using reagents from the affected lot for the possibility of additional staining due to the presence of HLA-DR PE, which might or might not appear based upon the analysis method.

Problem Description and Health Risk

HLA-DR PE cells will be expressed along the PE axis. Any marker that is stained for on the PE axis will contain this incorrectly stained HLA-DR population. This could result in a false positive in the PE channel.

The health hazard associated with this problem is moderate.

Figure 1: Dot plots representing contamination in the PE channel.

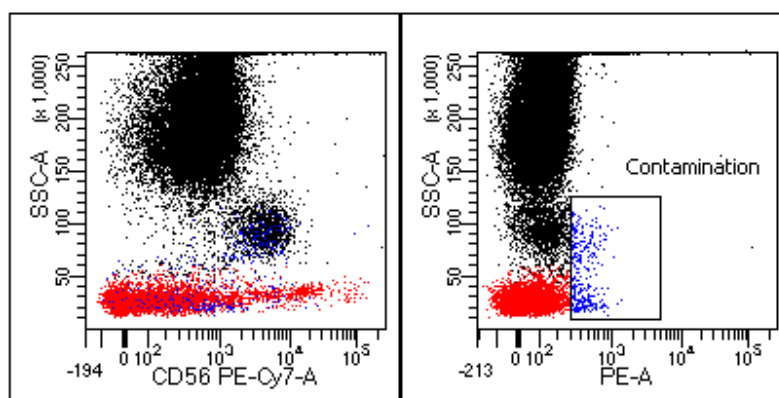
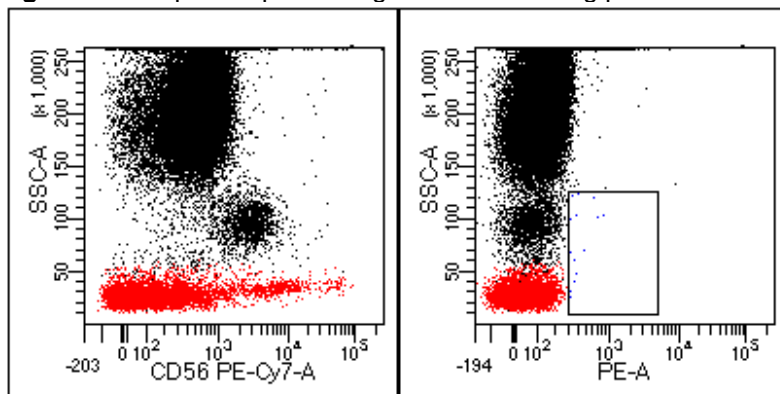


Figure 2: Dot plots representing a normal staining pattern.



Customer Actions

If you have CD56 PE-Cy7, Catalog Number 335826, lot number 4300715 and/or 4353883, evaluate the impact of a false positive in the PE channel on the results.

Discard all remaining stock of CD56 PE-Cy7, Catalog Number 335826, lot number 4300715 and/or 4353883, and request replacement product. BD will replace product at no cost.

As a requirement of our Regulatory Tracking Process, we request that you complete the enclosed Tracking/Verification form, even if you no longer have the affected reagents listed in your inventory. Please return the Tracking/ Verification form to BD Biosciences, per the instructions (mail, fax, or email).

We apologize for any inconvenience that this may have caused and are working toward a long-term solution to this issue. If you require further assistance, please contact your local BD Biosciences Representative.

Sincerely,


RA Manager Post-Market
BD Biosciences & BD Diagnostic Systems

Erembodegem-Dorp 86
B-9320 Erembodegem
Belgium
Tel. : +32 53 720 211
Fax : +32 53 720 200
www.bd.com



Helping all people
live healthy lives

BD Biosciences

Verification Form/Effectiveness Check

PLEASE FILL OUT AND RETURN

FAX number: Please include local Fax number

We do not have any of the following stock on hand.

We have the following units and request replacements:

CD56 PE-Cy7, Catalog No. 335826,

Lot No. 4300715 - Quantity: _____

Lot No. 4353883 - Quantity: _____

I have read and understood the attached notice.

Name: _____

Title: _____

Signature/Date: _____

COMPANY NAME: _____

ADDRESS: _____

CITY: _____ STATE: __ ZIP CODE: _____

PHONE NO. _____