



**PRODUCT NOTIFICATION**  
**BDB-25-5314-FA**  
**BD FACS™ 7-Color Setup Beads**

09 June 2025

Dear Customer,

CC: Chairman Medical Board and relevant head of department

**Type of Field Action:**

Product Advisory (No disposition of Product)

**Affected Product:**

Product Name (Brand Name as per labelling)	Catalog No.	Lot No.	UDI-DI	Expiration Date
BD FACS™ 7-Color Setup Beads, IVD	335775	85612	00382903357758	31-AUG-25
	335775	85613	00382903357758	30-SEP-25
BD FACS™ 7- Color Setup Beads, CE	666289	85637	00382906662897	31-AUG-25
	666289	85638	00382906662897	30-SEP-25

**Description of the Problem:**

Based on 51 customer complaints, BD has identified errors in the spectral overlap factors (SOF) table provided for specific lots of BD FACS™ 7-Color Setup Beads as listed in the table above. This issue may affect the accuracy of flow cytometry data due to incorrect flow cytometry setup compensation values for multicolor reagents for which proper fluorescence compensation is required prior to analyzing samples

**Clinical Risk Statement:**

The impacted lots of the BD FACS™ 7-Color Setup Beads have the potential to create a hazardous situation that compromises the accurate setup of the flow cytometry instrument prior to analyzing samples using multicolor reagents, which can lead to potential erroneous results, may delay results and might impact health care management decisions. This may also result in the subject having to return for additional sample collection.

**Complaint & Adverse Event Statement:**

To date, there have been no adverse events worldwide related to this issue.

**Actions for Clinical Users:**

1. Immediately inspect your inventory for the specific catalog and lot numbers listed. It is recommended the clinical laboratory staff review and segregate the affected lots.
2. Remove and discard prior affected label insert with incorrect spectral overlap factor values included on kit box prior to use.
3. The wrong SOF (Spectral Over Factors) values can be corrected by entering the right SOF values provided in Table 1.



4. Ensure the right SOF values are entered in the flow cytometry instrument prior to sample acquisition. Table 1 below shows the corrected spectral overlap factors for the affected product lot numbers. Please follow the instructions in Attachment 1 for manual entering or to scan the barcodes in Attachment 2 to obtain the correct Spectral Over Factors (SOF) values.
5. Customers who have not used the affected product may proceed to enter the SOF values shown in Table 1.
6. If the affected products have been fully or partially used and subjects' samples have been processed and acquired on an instrument with the incorrect SOF values, please review the results. If the subjects' sample is available, after entering the correct SOF values in the flow cytometry instrument, reacquire the sample(s).
7. If the subject sample(s) is not available anymore, this may require the subject to return to collect an additional sample for testing purposes.

Detector	Fluorophores						
	FITC	PE	PerCP	PerCP – Cy5.5	PE – Cy7	APC	APC – Cy7
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP – Cy5.5	93	96	100	100	150	106	80
PE – Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC – Cy7	100	100	86	30	78	95	100

Table 1 – Correct Spectral Overlap Factors values for the affected products

**Action taken by BD:**

BD is investigating root cause and will implement appropriate corrective and preventative measures to prevent recurrence.

**Please Take the Following Actions:**

1. Ensure the contents of this Product Advisory are read and understood.
2. Share and post this customer letter with the users of this application at your facility and forward to any customers to whom you may have distributed the product to ensure awareness.
3. Complete and return the attached Customer Response Form to the BD contact noted on the form confirming acknowledgement of the notification, whether or not you have any affected product, so that BD may confirm your receipt of this notification and clearly indicating the applicable contact person at your facility to support the software upgrade, when available.



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**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 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.

Yours Sincerely,

Signed by:

*Gaurav Verma*



Signer Name: Gaurav Verma  
Signing Reason: I approve this document  
Signing Time: 09-Jun-2025 | 5:44:33 AM PDT  
AAFA2E5F88004BF59A2BF6F108409CF6

09-Jun-2025

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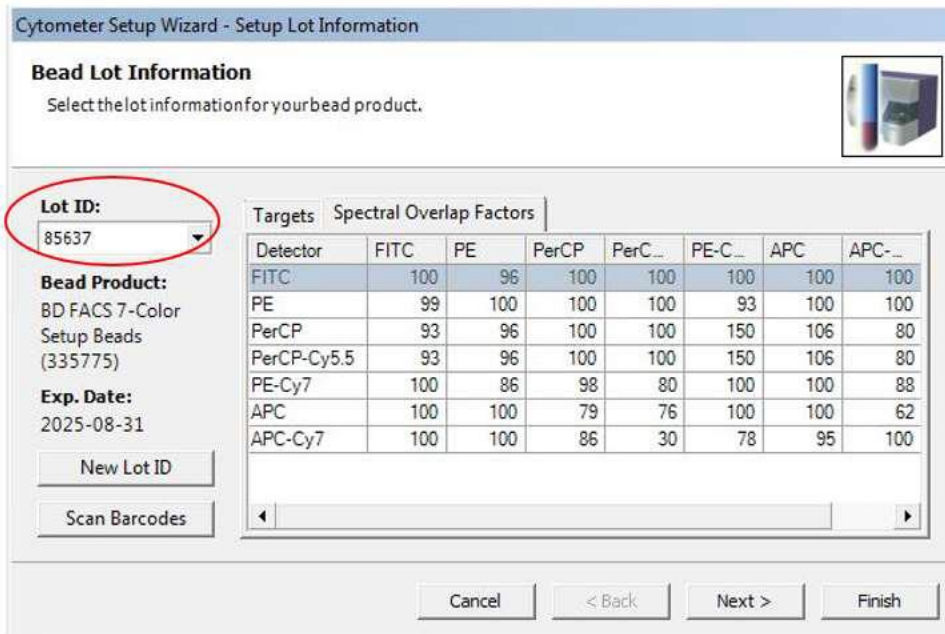
Gaurav Verma  
Director, SEA Quality & Regional RA

## Attachment 1

### Updating Lot Information for Setup Beads Manually

1. Obtain original setup values barcode label provided in the kit. Deface the setup values barcode label and discard.
2. If applicable, remove optimization file that was used to correct the compensation from the initial spectral overlap factor table supplied in the setup values barcode label.
  - **6 Color TBNK.opt** is found in **C:\ProgramData\BD\Shared\Setup Results**
3. Select **Cytometer > Setup > Standard Setup**
4. In Cytometer Setup Wizard – Setup Lot information Window, select the impacted lot of BD FACSTM 7-Color Setup Beads under Lot ID.

*Note: This is applicable to Catalog Numbers 335775 and 666289.*



**Cytometer Setup Wizard - Setup Lot Information**

**Bead Lot Information**  
 Select the lot information for your bead product.

**Lot ID:**  
 85637

**Bead Product:**  
 BD FACS 7-Color  
 Setup Beads  
 (335775)

**Exp. Date:**  
 2025-08-31

New Lot ID  
 Scan Barcodes

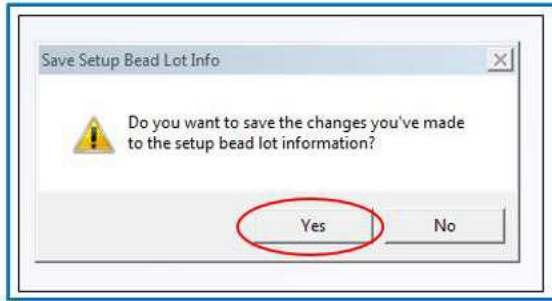
Detector	FITC	PE	PerCP	PerC...	PE-C...	APC	APC-...
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP-Cy5.5	93	96	100	100	150	106	80
PE-Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC-Cy7	100	100	86	30	78	95	100

Cancel < Back Next > Finish

5. Click on **Spectral Overlap Factors** tab
6. Edit the Spectral Overlap Factors to the correct values in Table 1.
7. Click **Next**.
8. Window will pop up **“Do you want to save changes you’ve made to the setup bead lot information?”**  
 “Click **Yes**.”



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9. Proceed to run the tube of BD FACSTM 7-Color Setup Beads.



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## Attachment 2

Catalog Number: 335775

Lot Number: 85612

# BD FACS™ 7-Color Setup Beads

**REF** 335775



2025-08-31

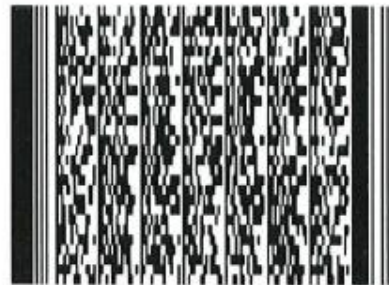
**LOT**

85612

(Exp:)

### Targets

Scatter/ Fluorophore	Target Value
FSC	456
SSC	547
FITC	452
PE	449
PerCP	466
PerCP - Cy5.5	451
PE - Cy7	486
APC	460
APC - Cy7	440



### Spectral Overlap Factors

Detector	Fluorophores						
	FITC	PE	PerCP	PerCP-Cy5.5	PE-Cy7	APC	APC-Cy7
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP-Cy5.5	93	96	100	100	150	106	80
PE-Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC-Cy7	100	100	86	30	78	95	100

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Catalog Number: 335775

Lot Number: 85613

# BD FACS™ 7-Color Setup Beads

**REF** 335775



2025-09-30

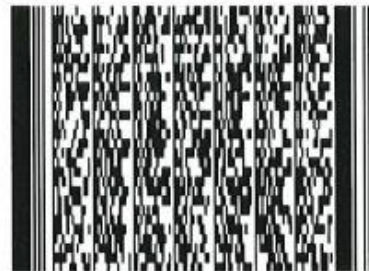
**LOT**

85613

(Exp:)

### Targets

Scatter/ Fluorophore	Target Value
FSC	456
SSC	547
FITC	452
PE	449
PerCP	466
PerCP - Cy5.5	451
PE - Cy7	486
APC	460
APC - Cy7	440



### Spectral Overlap Factors

Detector	Fluorophores						
	FITC	PE	PerCP	PerCP-Cy5.5	PE-Cy7	APC	APC-Cy7
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP-Cy5.5	93	96	100	100	150	106	80
PE - Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC - Cy7	100	100	86	30	78	95	100

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Catalog Number: 666289

Lot Number: 85637

# BD FACS™ 7-Color Setup Beads

**REF** 666289



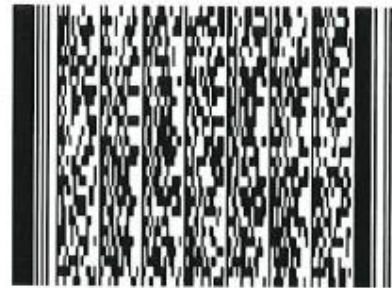
2025-08-31

**LOT**

85637

### Targets

Scatter/ Fluorophore	Target Value
FSC	456
SSC	547
FITC	452
PE	449
PerCP	466
PerCP - Cy5.5	451
PE - Cy7	486
APC	460
APC - Cy7	440



### Spectral Overlap Factors

Detector	Fluorophores						
	FITC	PE	PerCP	PerCP - Cy5.5	PE - Cy7	APC	APC - Cy7
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP - Cy5.5	93	96	100	100	150	106	80
PE - Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC - Cy7	100	100	86	30	78	95	100

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Catalog Number: 666289

Lot Number: 85638

# BD FACS™ 7-Color Setup Beads

**REF** 666289



2025-09-30

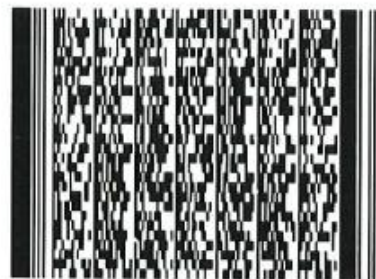
**LOT**

85638

(Exp:)

### Targets

Scatter/ Fluorophore	Target Value
FSC	456
SSC	547
FITC	452
PE	449
PerCP	466
PerCP – Cy5.5	451
PE – Cy7	486
APC	460
APC – Cy7	440



### Spectral Overlap Factors

Detector	Fluorophores						
	FITC	PE	PerCP	PerCP – Cy5.5	PE – Cy7	APC	APC – Cy7
FITC	100	96	100	100	100	100	100
PE	99	100	100	100	93	100	100
PerCP	93	96	100	100	150	106	80
PerCP – Cy5.5	93	96	100	100	150	106	80
PE – Cy7	100	86	98	80	100	100	88
APC	100	100	79	76	100	100	62
APC – Cy7	100	100	86	30	78	95	100

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**CUSTOMER RESPONSE FORM**  
**BDB-25-5314-FA**  
**BD FACS™ 7-Color Setup Beads**

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to **SEA\_Quality** [SEA\\_Quality@bd.com](mailto:SEA_Quality@bd.com) / **local BD representative** by **07 July 2025**

Please tick as appropriate.

I have read and understood the attached notice & will share this Advisory Notice with all users within my facility.

**Completed by:**

<b>Name:</b>	
<b>Signature:</b>	
<b>Date:</b>	
<b>Facility / Address / Telephone Number:</b>	