



URGENT PRODUCT ADVISORY
BDB-21-4224
 BD OneFlow™ Setup Beads

16 August 2021

Product Description	Cat. No.	Lot No.	Expiry Date
BD OneFlow™ Setup Beads	658620	1074178	28-Feb-2022
		1130959	28-Feb-2022

Dear Customer,

The purpose of this letter is to advise you that BD is initiating a field correction of the product as identified in the table above. This product contains the Bead Lot 1040836.

Description of the problem:

BD has recently confirmed that the incorrect MFI target ranges for APC-H7 are listed on the Monthly and Daily Target Range Cards for the specific lots of BD OneFlow™ Setup Beads listed in the table above (refer to Image 1). The target ranges are for use with BD FACSCanto II only. If the incorrect values are used there is a risk of reporting erroneous patient results. BD has not received any reports of related adverse events.

Fluorophore	-2%	TMFI	+2%
FITC	9640	9837	10034
PE	10892	11114	11336
PERCP-CY5.5	38174	38953	39732
PE-CY7	17772	18135	18498
APC	51375	52423	53471
APC-H7	18398	18773	19148
V450	10825	11046	11267
V500-C	28201	28777	29353

Fluorophore	TMFI RANGES (+/- 15%)	
FITC	8361	11313
PE	9447	12781
PERCP-CY5.5	33110	44798
PE-CY7	15415	20855
APC	44560	60285
APC-H7	15957	21589
V450	9389	12703
V500-C	24460	33094

Image 1: Monthly and Daily Target Range Cards with incorrect target ranges for APC-H7

BD has corrected the ranges for APC-H7 (refer to Image 2) in the images below. **Please refer to the Appendix for a reference copy of the updated Monthly and Daily Target Range Cards for future use with the affected lots.**



BD OneFlow™ Setup Beads (Monthly)

REF 658620 LOT 1040836

Fluorophore	-2%	TMFI	+2%
FITC	9640	9837	10034
PE	10892	11114	11336
PERCP-CY5.5	38174	38953	39732
PE-CY7	17772	18135	18498
APC	51375	52423	53471
APC-H7	104942	107084	109226
U450	10825	11046	11267
U500-C	28201	28777	29353

Monthly Target Ranges 23-16178-00

BD OneFlow™ Setup Beads (Daily)

REF 658620 LOT 1040836

Fluorophore	TMFI RANGES (+/- 15%)	
FITC	8361	11313
PE	9447	12781
PERCP-CY5.5	33110	44796
PE-CY7	15415	20855
APC	44560	60286
APC-H7	91021	123147
U450	9389	12703
U500-C	24460	33094

Daily Performance Ranges (optional) 23-16356-00

Image 2: Monthly and Daily Target Range Cards with correct target ranges for APC-H7

Our records indicate you have been shipped the affected product which was distributed beginning May 11, 2021.

Risk to Health:

Erroneous patient results can lead to a false positive resulting in a misdiagnosis or a false negative resulting in a missed diagnosis. Misdiagnosis could cause the patient to undergo unnecessary treatment and potentially suffer adverse health consequences. Missed diagnosis could result in disease progression until the patient can be correctly diagnosed.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalog and lot numbers listed above.
2. Share this notification with all users of the product within your facility to ensure that they are also aware of this advisory.
3. If you have remaining inventory of affected product, replace the original Monthly and Daily Target Range Cards with the new Monthly and Daily Target Range Cards with the corrected target range for APC-H7 (refer to Appendix).
4. Complete the attached Customer Response Form and return to the contact noted on the form.

Actions Taken by BD:

- An investigation has been initiated to identify root cause and corrective actions will be implemented to prevent recurrence.



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Singapore 609930
Registration No. 201114149N
bd.com

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

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,

A handwritten signature in black ink, appearing to read 'EY', written over a horizontal line.

Erwin Yap
Quality Senior Manager
Southeast Asia



CUSTOMER RESPONSE FORM
BDB-21-4224
 BD OneFlow™ 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 / **local BD representative** by **30 August 2021**.

Please tick as appropriate.

- I have read and understood the attached notice. I will share this notification with all users of the product within your facility to ensure that they are also aware of this advisory. I shall clarify with the appointed distributor/BD representative for clarification(s) to this notification.
- We do not have affected product(s) in our inventory.
- We have identified the affected product(s) in our inventory. **We will destroy the original Monthly and Daily Target range cards and replace with new cards that has the corrected target range for APC-H7 referenced in the Appendix.**

Product Description	Cat. No.	Lot No.	Expiry Date	Qty. in Eaches
BD OneFlow™ Setup Beads	658620	1074178	28-Feb-2022	
		1130959	28-Feb-2022	

Completed by:

Name:	
Signature:	
Date:	
Facility / Address / Telephone Number:	



APPENDIX

Updated Monthly and Daily Target Range Cards with correct target ranges for APC-H7

BD OneFlow™ Setup Beads (Monthly)			
REF	658620	LOT	1040836
Fluorophore	-2%	TMFI	+2%
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Monthly Target Ranges 23-16178-00

BD OneFlow™ Setup Beads (Daily)			
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Daily Performance Ranges (optional) 23-16356-00