



URGENT FIELD SAFETY NOTICE – CORRECTION

8th August 2017

Dear Valued Customer:

BD has recently confirmed that the Instructions for Use (IFU) part number 23-5351-03, dated 6/2016, for the reagent lots listed in the Product Tables below, contains errors in Table 2: Representative reference intervals for BD Multitest™ CD3/CD8/CD45/CD4 listed on page 22. Product performance is not impacted. Table 1 below illustrates the values currently listed in the IFU and the correct values.

Table 1: Comparison of current values listed in the IFU (Table 2 p22) and the correct values

Lymphocyte Subset	N	Unit	As Listed in IFU		Correct Values	
			Mean	95% Range	Mean	95% Range
Helper/inducer T lymphocytes	164	%	45	33–58	45	33–58
		cells/μL	511	220–1,129	941	404–1,612
Suppressor/cytotoxic T lymphocytes	164	%	941	404–1,622	24	13–39
		cells/μL	72	56–86	511	220–1,129
T lymphocytes	164	%	24	13–39	72	56–86
		cells/μL	1,513	723–2,737	1,513	773–2,737

Our records indicate that you may have been shipped the below referenced lot(s) of product. Please retain this letter for your records. No further action is required at this time.

If you require further assistance, please contact your local BD Biosciences representative or distributor.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products. Thank you for your prompt attention to this important matter.

Sincerely,

Mieke Vleugels
Manager RA Post-market & Industry
BD Life Sciences



Product Table: 342417

Product Name	Catalog No.	Lot No.	Expiration Date
BD Multitest™ CD3/CD8/CD45/CD4	342417	13532	2018-11-30
		18636	2017-12-31
		29783	2019-03-31
		33552	2018-10-30
		40550	2019-01-31
		70946	2019-03-31
		09831	2017-10-31
		20936	2018-02-28
		25555	2018-06-30
		31761	2018-03-31
		31864	2017-07-31
		51629	2017-08-31
		51897	2018-05-31
		84976	2018-07-31
94769	2017-09-30		



Product Table: 342447

Product Name	Catalog No.	Lot No.	Expiration Date
BD Multitest™ CD3/CD8/CD45/CD4 with BD Trucount™ Tubes	342447	11816	2019-03-31
		11819	2019-03-31
		35773	2019-04-30
		35775	2019-04-30
		63687	2019-05-31
		70875	2019-02-28
		03951	2017-08-31
		09823	2017-09-30
		20649	2018-07-31
		23539	2018-11-30
		25563	2018-05-31
		26584	2018-06-30
		27802	2017-10-31
		29704	2017-12-31
		29705	2017-12-31
		33569	2018-09-30
		34537	2017-12-31
		38857	2017-07-31
		38858	2017-07-31
		38864	2017-07-31
		42504	2017-07-31
		42517	2018-09-30
		43620	2018-07-31
		45543	2018-02-28
		50963	2018-07-31
		53847	2017-12-31
		53862	2017-12-31
		55701	2018-02-28
		57694	2018-07-31
		60147	2017-10-31
		60974	2017-10-31
		61386	2018-03-31
71855	2017-08-31		
81744	2018-03-31		
81755	2018-03-31		
81769	2017-12-31		
87604	2018-07-31		
87798	2017-08-31		
90737	2017-12-31		
93727	2018-03-31		



Please assist BD by promptly returning this form to: Mr Ian Gerrard, Strategic Market Manager at the below email

Email: BDBUKI_Marketing@bd.com

Customer Response Form

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

Postal Code or Zip: _____ **City:** _____

Country: _____

Contact Person: _____

Telephone No.: _____ **Email Address:** _____

Fax No.: _____

I have read and understood the attached Urgent Product Notice.

Name:	
Title:	
Signature and Date:	