30 Tuas Avenue 2
Singapore 639461
Registration No. 201114149N

bd.com

URGENT PRODUCT NOTIFICATION – CORRECTION

26 July 2017

Dear Customer,
Copy: Chairman Medical Board and Head of Departments

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 and the correct values

			As Listed in IFU		Correct Values	
Lymphocyte Subset	**N**	**Unit**	**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.

Advancing the world of health

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YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Please fill in the attached form whether or not you have any inventory remaining so that we may acknowledge your receipt of this notification. Simply complete the attached form, sign and fax the completed form to your local BD contact.

2. We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant.

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 the highest quality products. We apologize for any inconvenience you may have experienced and thank you in advance for your prompt attention to this important matter.

Sincerely,

[redacted]

Rose Kwong
Senior Regulatory Affairs & Compliance Executive

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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
		41792	2018-10-31
		50593	2018-07-31
		51629	2017-08-31
		51897	2018-05-31
		54563	2018-03-31
		60395	2017-12-31
		84976	2018-07-31
		94769	2017-09-30

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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

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URGENT PRODUCT NOTIFICATION – CORRECTION

(CUSTOMER ACKNOWLEDGEMENT)

BD Multitest™ CD3/CD8/CD45/CD4

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

Please tick as appropriate.

- ❑ I confirmed that I have read and understood the Product Notification dated 26 July 2017, regarding the above BD products.
- ❑ Other comments:

_____

_____

Completed by:

Name: _____ **Signature/Date:** _____

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

Street Address: _____

Telephone No.: _____ **Fax No.**: _____

Company stamp:

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