



**Becton Dickinson Benelux NV**

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RPR Gent (Afdeling Dendermonde)

[bd.com](http://bd.com)

## **URGENT - FIELD SAFETY NOTICE**

Date: 23 February 2018

Product Name	Catalog (Ref) No.	Lot No.	Expiration Date (YYYYMMDD)	Product Package Size
BD OneFlow™ B-CLPD T1	659293	7038969	20181231	20 Tests
		7243868	20190531	
		7248685	20190531	
		7317597	20190531	

**For the Attention of:** Lab Manager

### **Description of the Problem and Health Hazard(s):**

BD has recently confirmed that the Instructions for Use (IFU) part number 23-17184-00, dated 12/2016, for the reagent lots listed in the Product Table above, contains an error in Table 1: BD OneFlow B-CLPD T1 antibody panel listed on page 7. The table below illustrates the values currently listed in the IFU and the correct values.

Antibody	Fluorochrome	Clone		Isotype
		As Listed	Correct Description	
CD10	PE	MEM-78	HI10a	IgG <sub>1</sub> , κ

BD has confirmed that product performance is not impacted.

Our records indicate that you may have been shipped the above referenced lot(s) of product. BD is not requesting that customers discard, return or discontinue use of the product.

### **Please Take the Following Actions:**

1. Please retain this letter for your records.
2. Share this Field Safety Notification with all users of the product to ensure they are also aware of this Field Safety Corrective Action.
3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification.

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**bd.com****Contact Information**

If you require further assistance, please contact:

BD Contact	Contact Information
<b>BD Customer/Technical Support</b>	Please contact your local BD representative

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.

Sincerely,



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

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**CUSTOMER RESPONSE FORM  
BD OneFlow™ B-CLPD T1**

**Please assist BD by promptly returning this form to:**

**Name:**

**Email:**

**Facility:** \_\_\_\_\_

Please use full, current facility name. Do not use initials.

**Street Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Contact Person:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_ **Email Address:** \_\_\_\_\_

**Fax No.:** \_\_\_\_\_

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

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