

November 5, 2015

URGENT FIELD SAFETY NOTICE

CD22 (S-HCL-1) APC (CE-IVD)
Catalog Number: 333145
Lot Number: 4335641 (expires 11-30-2016)
Lot Number: 4352613 (expires 11-30-2016)
Lot Number: 5061915 (expires 02-28-2017)
Lot Number: 5139958 (expires 02-28-2017)

Dear Valued Customer:

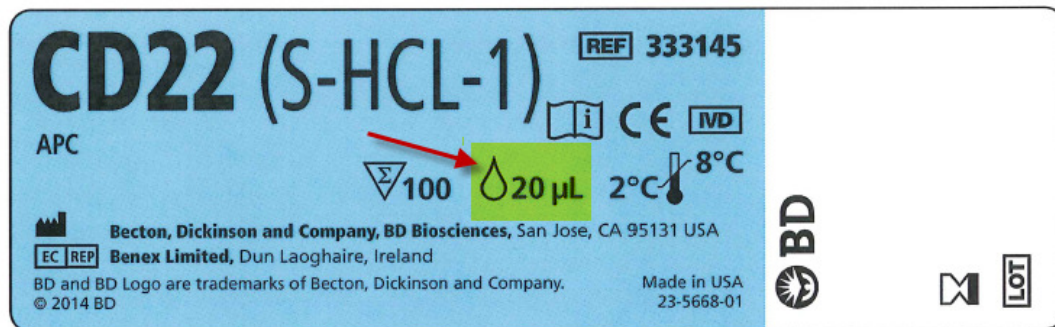
Recently you purchased CD22 (S-HCL-1) APC (CE-IVD), catalog number 333145, lot number 4335641, 4352613, 5061915 or 5139958.

Becton, Dickinson and Company (BD) has determined that the CD22 (S-HCL-1) APC (CE-IVD) vial label contains an error. Discard all remaining stock of CD22 (S-HCL-1) APC (CE-IVD), catalog number 333145, lot number 4335641, 4352613, 5061915 or 5139958 and request replacement product. BD will replace product at no cost.

Problem Description and Health Risk

The CD22 (S-HCL-1) APC (CE-IVD), catalog number 333145, lot number 4335641, 4352613, 5061915 or 5139958 vial label incorrectly indicates that 20 μ L/test is appropriate (See Figure 1). The correct volume is 5 μ L/test. There is no risk to patient safety or results.

Figure 1: Example Label



Customer Actions

1. Discard all remaining stock of CD22 (S-HCL-1) APC (CE-IVD), catalog number 333145, lot number 4335641, 4352613, 5061915 or 5139958 and request replacement product. BD will replace product at no cost.
2. As a requirement of our Regulatory Tracking Process, we request that you complete the enclosed Tracking/Verification form, even if you no longer have the affected reagents listed in your inventory. Please return the Tracking/ Verification form to BD Biosciences, per the instructions (mail, fax, or email).

Erembodegem-Dorp 86
9320 Erembodegem-Belgium
tel: +32 53 720 211
fax: +32 53 720 200
www.bd.com



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live healthy lives

We apologize for any inconvenience that this may have caused and are working toward a long-term solution to this issue. If you require further assistance, please contact BD Customer Support at +32.2.400.98.95 or contact your local BD representative.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Ann Vanlandschoot', written over a light blue horizontal line.

Ann Vanlandschoot, Ph.D.
RA Manager Post-Market
BD Biosciences Europe/EMA



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live healthy lives

BD Biosciences

Verification Form/Effectiveness Check

PLEASE FILL OUT AND RETURN

FAX number: Please include local Fax number

<p><input type="checkbox"/> We do not have any of the following stock on hand.</p> <p><input type="checkbox"/> We have the following units and request replacements:</p> <p>CD22 (S-HCL-1) APC (CE-IVD), Catalog Number 333145:</p> <p>Lot No. 4335641 - Quantity: _____</p> <p>Lot No. 4352613 - Quantity: _____</p> <p>Lot No. 5061915 - Quantity: _____</p> <p>Lot No. 5139958 - Quantity: _____</p>
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<p><input type="checkbox"/> I have read and understood the attached notice.</p>
Name: _____
Title: _____
Signature/Date: _____

COMPANY NAME: _____
ADDRESS: _____
CITY: _____ STATE: _____ ZIP CODE: _____
PHONE NO. _____