



VL02-000000045

2022年8月30日

お客様各位

株式会社ベリタス
バイオサイエンス本部 技術グループ
マネージャー 横沢 佑弥
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One Lambda 製品 製品ラベル誤記のお詫び

拝啓

時下ますますご清栄のこととお喜び申し上げます。平素はご高配を賜り誠にありがとうございます。

One Lambda 製品の PE Conjugated Goat Anti-Human IgG(製品コード LS-AB2)につきまして、包装ラベルに誤記がありますことをご連絡いたします。製品ラベル及びアルミパックに溶解に必要な精製水の量が「1mL」と記載されておりますが、正しくは 1mL ではなく、ロットにより異なることが判明しました。対象製品及び正しい精製水の量は下記をご覧ください。なお、希釈率が異なることによる MFI への影響はご使用の LABScreen 製品及び LS-AB2 のロットにより異なりますが、約 10-23%です。

この度は皆様に多大なるご迷惑をおかけ致しますことを深くお詫び申し上げます。ご不明な点がございましたら、技術グループまでお問い合わせをお願いいたします。

今後とも弊社及び One Lambda 製品をご愛顧賜りますようお願い申し上げます。

敬具

記

【対象製品】 PE Conjugated Goat Anti-Human IgG

【製品コード】 LS-AB2

【誤記内容】

ロット	バッチ	正	誤
C08	0000683889, C000699224	1.2mL	1mL
C09	0000696027, C000706404	1.4mL	1mL
C10	0000707111, C000721073	1.2mL	1mL
C11	0000708737	1.9mL	1mL
C12	0000722153	2.0mL	1mL

【参考文書】 One Lambda 発行文書:Market Withdrawal (NC# 2022-0314)

問い合わせ先

バイオサイエンス本部技術グループ TEL: 03-5776-0040

以上

A GLOBAL BIOTECHNOLOGY MARKETING COMPANY

株式会社ベリタス Veritas Corporation

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Market Withdrawal

NC# 2022-0314

Commercial name of the affected device: PE-Conjugated Goat Anti-Human IgG, Catalog # LS-AB2
29 AUG 2022

Attention: Distributors and Users

Notice: Lots C08-C12 have incorrect re-suspension volume on the label. The label states a re-suspension volume of 1mL, the correct resuspension volumes are listed below:

Product Catalog	Lot/Batch #	Currently Labeled	Correct Re-suspension volume
LS-AB2	C08/0000683889 C08/C000699224	1 mL	1.2 mL
LS-AB2	C09/0000696027 C09/C000706404	1 mL	1.4 mL
LS-AB2	C10/0000707111 C10/C000721073	1 mL	1.2 mL
LS-AB2	C11/0000708737	1 mL	1.9 mL
LS-AB2	C12/0000722153	1 mL	2.0 mL

Please note that all Quality Control testing passed for LS-AB2 Lot C08-C12 products. The % variation in MFI values between the labeled re-suspension volume and correct volume are listed below:

***The % difference in MFI values when tested on LS12PRA with a Class I Positive control sample using the recommended resuspension volume vs the currently labeled resuspension volume is indicated in the table below**

LS-AB2 LOT	Recommended resuspension volume	Currently labeled resuspension volume	% Difference from labeled vs recommended*
C08	1.2 mL	1 mL	16%
C09	1.4 mL	1 mL	12%
C10	1.2 mL	1 mL	10%
C11	1.9 mL	1 mL	19%
C12	2.0 mL	1 mL	22%

***The % difference in MFI values when tested on LS12PRA with a Class II Positive control sample using the recommended resuspension volume vs the currently labeled resuspension volume is indicated in the table below**

LS-AB2 LOT	Recommended resuspension volume	Currently labeled re-suspension volume	% Difference From labeled vs recommended*
C08	1.2 mL	1 mL	18%
C09	1.4 mL	1 mL	17%
C10	1.2 mL	1 mL	10%
C11	1.9 mL	1 mL	21%
C12	2.0 mL	1 mL	23%

Risk to Health: There is low risk to patients and end users. The variation in MFI values between the labeled vs. correct resuspension volume is minimal and is within normal run to run variation. Resuspension volume is a recommendation based on QC testing. As per standard laboratory guidance each new lot of reagents are required to be validated. A negative control serum should be tested with the same batch of samples to establish the background values for the test run. All test results should be further investigated by the HLA specialist as part of secondary and confirmatory testing as determined by ASHI and EFI guidelines.

Product and Distribution Information:

Product Catalog	Lot/Batch #
LS-AB2	C08/0000683889 C08/C000699224
LS-AB2	C09/0000696027 C09/C000706404
LS-AB2	C10/0000707111 C10/C000721073
LS-AB2	C11/0000708737
LS-AB2	C12/0000722153

Action to be taken by the User: Review results generated by the above-mentioned devices. Reconstitute existing inventory as recommended in the above table as correct resuspension volume.

Action to be taken by Distributors: Please contact your affected customers and provide them with a copy of this letter.

Type of Action by the Manufacturer: Notification to distributors and users.

Transmission of this Field Safety Notice: This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

Contact reference person: If you have additional questions or concerns regarding this matter, you may contact One Lambda's Customer Support team for assistance at Email: 1lambda-TechSupport@thermofisher.com or Phone: +1 747-494-1000 option 2.

We appreciate your immediate attention to this notice. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Angela Estany



Sr. Director, Regulatory Affairs and Quality