



URGENT FIELD SAFETY NOTICE

22 NOV 17

ALBAclone Anti-Le^b
Product Code: Z217
Lot No. V185008

Dear Customer

Quotient is contacting you because our records indicate that your organisation recently received one or more vials of ALBAclone Anti-Le^b, Z217, Lot number V185008. This notice should be forwarded to appropriate personnel who have received this product, and may be affected by this notice.

Affected Product(s)

Product Code	Product Description	Lot Number	Expiry Date
Z217	ALBAclone Anti-Le ^b	V185008	29 MAY 19

Notification:

Performance data on lot V185008 has indicated that there is a potential for weak or negative reactions with some cells which express the Le^b antigen. There is therefore a potential that should this reagent be used to type blood samples a small number of those tested would yield an erroneous negative reaction.

Quotient recommends that end users consider reviewing test results obtained using the impacted lot. Furthermore, if any third party organisation has received test results associated with this lot we request that you forward this notification onto the appropriate personnel.

Quotient will advise as soon as possible on the availability of an alternate lot. If you have stock remaining, we advise that use of this is stopped and the inventory is destroyed / disposed of following instructions in the Instructions for Use document.



Action/s required:

We request that you help us meet our compliance requirements by completing the attached form and returning to us. This can be via email of a scanned copy of the form to vigilance.notifications@quotientbd.com or alternatively via fax to (+44 (0)131 672 3026). We also kindly request that the attached form is returned to us as soon as possible.

If you are not the appropriate person to receive this notice, we ask for your support in forwarding this to the appropriate personnel in your organisation affected by this notice. Furthermore, if this material has been passed to other organisations other than your own we request you pass on this notification. If you require any further information about this notice, please do not hesitate to contact us.

Further information:

Quotient sincerely apologise for any inconvenience caused by this issue. The relevant Competent Authorities have been advised on this field safety correction action. If you require any further information about this field notice please do not hesitate to contact our customer services team on +44 (0) 131 292 0422 (customer.serviceEU@quotientbd.com)

Kindest regards,

Iain McIntosh
Quality Manager



CONFIRMATION OF RECEIPT OF THE NOTIFICATION

ALBAClone Anti-Le^b

Product Code: Z217, Lot No. V185008, Expiry Date 29th MAY 2019

Notification Delivered 22nd November 2017

I/WE confirm receipt of the above communication and that the above lot has been used/discarded.

Organization name	
Address	
Number Received	
Number Used	
Number Onward Distributed (Contracted Distributors only)	
Number Destroyed	
Name (please print)	
Position	
Signature	
Date	

Please complete and return this form by fax (+44 (0)131 672 3026) or alternatively email a scanned copy of the form to vigilance.notifications@quotientbd.com