



URGENT FIELD SAFETY NOTICE

ALBAclone Anti-Le^b

Product Code: Z217

Lot No. V192485

1st October 2018

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 V192485. This notice should be forwarded to appropriate personnel who have received this product and may be affected by this notice.

Affected Product Lot(s)

Product Code	Product Description	Lot Number	Expiry Date
Z217	ALBAclone Anti-Le ^b	V192485	18 JAN 2020

Notification:

Performance data on lot V192485 has indicated potential for weak or negative reactions with some cells which positively express the Le^b antigen. Use of this reagent to type blood samples would yield, in a small number of those tested, an erroneous negative reaction. Quotient is therefore taking the following action / making the following recommendations,

1. Immediately stop use of this lot and destroy / dispose of all remaining inventory. Disposal methods are described fully within the Instructions for Use document.
2. Review all test results generated using the impacted lot.
3. Furthermore, if any third party organisation has received test results associated with this lot we request that you forward this notification onto them and appropriate personnel within their organisation.



Transforming transfusion diagnostics.

Action/s required:

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

Following due diligence Quotient will perform follow up to this communication to ensure that this is done. To avoid unnecessary inconvenience, 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 organisations other than your own we request you pass on this notification.

Further information:

Quotient sincerely apologise for any inconvenience caused by this issue. Quotient will advise as soon as possible on the availability of an alternate lot following determination of root cause of this incident.

Quotient have completed regulatory reporting of this and relevant Competent Authorities advised on this field safety correction action. If you require any further information about this Field Safety 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 FIELD SAFETY NOTICE

Product Name	Product Code	Lot Number	Expiration Date
<i>ALBAclone Anti-Le^b</i>	Z217	V192485	18 JAN 2020

I/We acknowledge receipt of the above communication.

Please check when completed	
	I have read and understood the communication.
	I have no remaining stock of Lot V192485

Please indicate quantities below	
	Total number of kits received which are affected by this notification.
	Number of kits that have been used and are no longer in use/in stock at the time of receiving this notice.
	Number of kits that have been distributed to other parties. If different from zero please forward notification to them and ask for their acknowledgement. Advise of locations / countries to which impacted lot has been distributed.
	Number of kits that have been discarded as requested in this notice.

Facility Name _____

Name (please print) _____

Position/Title _____

Signature _____

Date _____

Please complete and return this form to Quotient, by fax (+44 (0)131 672 3026) or alternately, email a scanned copy to Product.Notifications@quotientbd.com