



Transforming transfusion diagnostics.

This is to inform you of a product notification involving:

Anti-Le^b ALBAclone®
Lot No. V158461, Item No. Z217, Expiry Date: 27th March 2017

Quotient is contacting you because our records indicate that your organization purchased one or more vials from lot V158461. This notice should be forwarded to the appropriate personnel in your organization affected by this notice.

This communication has been initiated as a precautionary measure following a recently completed technical investigation on lot V158461. The investigation was prompted following performance issues noted during internal use of the reagent, and it has been determined that there is a potential for weak positive or false negative results with lot V158461 with some Le^b positive red blood cells. All positive results which have been observed with use of this reagent lot remain valid.

Quotient have taken the decision to recall this lot from the market based on potential patient risk. Quotient are progressing the replacement manufacture and once this has been tested and cleared for release we will send you replacement vials free of charge within a few days of that time.

A thorough root cause analysis investigation and appropriate corrective and preventative actions will be put in place.

We request that you help us meet our compliance requirements per applicable regulatory guidance, and complete and sign the attached form and return to us at your earliest opportunity.

We apologize for any inconvenience caused by this issue. If you require any further information about this field notice please do not hesitate to contact us on our Customer Service line +44 (0) 131 445 6159.

Sincerely

Derek Robson
Vice President, Quality
07th September 2015

CONFIRMATION OF RECEIPT OF FIELD SAFETY NOTICE

Anti- Le^b ALBAclone®

Lot No. V158461, Item No. Z217, Expiry Date: 27th March 2017

I/WE confirm receipt of the above communication and that all stock of the above lot retained at our facility has now been discarded.

Facility Name _____

Name (please print) _____

Position _____

Signature _____

Date _____

Can you please return this form by fax (+44 (0)131 672 3026) or alternatively email a scanned copy of the form to iain.mcintosh@quotientbd.com