

**Field Safety Notice****Distributor Notice**

05 MAY 2017

Dear Customer

Quotient is contacting you because you are a contracted distributor of Quotient products and our records indicate that your organisation recently received one or more kits of ALBAclone® Advanced Partial RhD Typing Kit V174693 Product Code Z293. This notice should be forwarded to appropriate organisations who have received this product, and may be affected by this notice.

**Affected Product(s)**

Product Code	Product Description	Lot Number	Expiry Date
Z293	ALBAclone® Advanced Partial RhD Typing Kit	V174693	13 JUL 17

**Nature of Notification:**

Performance data for component L (Anti-D LHM57/17) of the lot listed above has indicated deterioration in potency. Our records show that the above referenced lot was purchased by your organisation.

Part L of Lot No V174693 when tested with some weak RhD samples is generating reactions of reduced strength/grading. You may be aware that a previous notification was distributed on 23<sup>rd</sup> November 2016 pertaining to weak or negative reactions with weak RhD samples when using part H. As a result of the combined impact of potency reduction of these two components, we are requesting that customers discontinue use of any remaining stock of lot V174693 immediately.

Quotient's stability data indicates that component L was performing satisfactorily up to and including 27<sup>th</sup> January 2017. We therefore recommend that users consider completing a review of all results obtained from use of this lot from 27<sup>th</sup> January 2017 onwards.

Quotient are advising that an alternate lot (Lot number V178660, Expiry 9<sup>th</sup> December 2017) is available to replace any existing stock you may have. If you have stock remaining, we request that you please contact our customer services team on +44 (0) 131 292 0422 (customer.serviceEU@quotientbd.com).

**Actions required by Distributors:**

Please forward the attached field safety notice to all recipients of this lot.

To help us meet our compliance requirements, we respectfully ask for your support in completing and signing the attached form and returning to us at your earliest opportunity. The relevant Competent Authorities have been advised on this field safety correction action. We also request that you provide a list of all countries that this lot has been distributed. This will allow us fulfil our regulatory obligations.

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. If you require any further information about this notice, please do not hesitate to contact us

Quotient sincerely apologies for any inconvenience caused by this issue. 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 NOTIFICATION****ALBAclone® Advanced Partial RhD Typing Kit****Lot No. V174693, Item No. Z293, Expiry Date: July 17th 2017**

Notification Delivered 05 May 2017

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

Organization name	
Address	
Number Received	
Number Distributed	
Number Discarded	
Number confirmed as discarded by customers	
Name (please print)	
Position	
Signature	
Date	

Please list countries that this lot has been distributed:

Can you please return this form by fax (+44 (0)131 672 3026) or alternatively email a scanned copy of the form to [vigilance.notifications@quotientbd.com](mailto:vigilance.notifications@quotientbd.com)