

FIELD SAFETY NOTICE - 14th Oct 2016

**ALBAclone® Advanced Partial RhD Typing Kit**

Lot No. V163020 & V157640, Item No. Z293

Quotient is contacting you because our records indicate that your organization recently received one or more kits of ALBAclone® Advanced Partial RhD Typing Kit lot V163020 and/or V157640 Product Code Z293. This notice should be forwarded to appropriate personnel who have received this product, and may be affected by this notice.

Following a review of the stability data for Component L (Anti-D Cell Line LHM57/17) of the ALBAclone® Advanced Partial RhD Typing Kit we have implemented a change, effective immediately, whereby the shelf life for this component of the kit will be reduced from 24 months to 12 months. This change also impacts the kit format in which the product is sold. The expiry of the overall kit is that of the shortest component expiry, therefore the Z293 kit shelf life will reduce to 12 months. This change took effect in September, with the release of the newest lot: V174693, (expiry 13 JUL 17), containing the revised 12 month shelf life expiry date.

The reduction in shelf life therefore directly impacts lots V163020, (expiry prior to shelf life reduction 11 AUG 17, expiry post shelf life reduction 11 AUG 16), and V157640, (expiry prior to shelf life reduction 09 MAR 17, expiry post shelf life reduction 09 MAR 16), which are currently in the field and are now considered to be expired as a result of the change described above. Both lots have been subject of previous notifications, the most recent, of which was sent on the 3<sup>rd</sup> October 2016, highlighting the reduction in shelf life from 24 months to 12 months. We have taken the decision to recommend that use of these lots is stopped and users revert to using lot V174693, (expiry 13 JUL 17).

Quotient has provided replacements where requested and will continue to do so as required. We request that you discard any existing stock of Lot No. V163020 & V157640.

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 change. We apologise for any inconvenience caused by this issue. Quotient are currently performing further investigative work to determine actions that will allow us to restore the shelf life to 24 months to this product.

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

We apologise 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

Sincerely,



Derek Robson  
Vice President, Quality  
14th October 2016

## CONFIRMATION OF RECEIPT OF FIELD SAFETY NOTICE

**ALBAclone® Advanced Partial RhD Typing Kit**

Lot No. V163020 &amp; V157640, Item No. Z293

I/WE confirm receipt of the above communication and confirm that all stock of the above lot(s), received at our facility or transferred to another organization, has now been discarded.

Facility Name \_\_\_\_\_

Name (please print) \_\_\_\_\_

Position \_\_\_\_\_

Quantity received \_\_\_\_\_

Quantity discarded \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

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