

QUOTIENT

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URGENT FIELD SAFETY NOTICE

05 MAY 2017

ALBAclone® Advanced Partial RhD Typing Kit

Product Code Z293.

Lot No. V174693

Dear Customer

Quotient is contacting you because our records indicate that your organisation recently purchased one or more kits of ALBAclone® Advanced Partial RhD Typing Kit V174693 Product Code Z293. This product is intended for the in-vitro classification of human partial RhD and weak D types 1 and 2 by indirect agglutination. The product is not suitable for routine RhD typing.

This notice should be forwarded to appropriate personnel who are using this product and may be affected.

Affected Product(s)

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

Notification for the following:

Performance data for component L (Anti-D LHM57/17) of the lot listed above has indicated deterioration in potency.

Part of Lot No V174693 when tested with some weak RhD samples is generating reactions of reduced strength/grading. A previous notification was distributed on 23rd November 2016 pertaining to weak or negative reactions with weak RhD samples when using part H.

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Quotient are requesting that customers immediately stop use of lot V174693. Reduced reactivity of parts H and Lis considered to make interpretation of the RhD variant sample type more difficult given results are available from ten monoclonal Anti-D cell lines instead of the twelve representing the design intent of the product.

Quotient's stability data indicates that component L was performing satisfactorily up to and including 27th January 2017. We therefore recommend that users consider completing a review of all results obtained from use of this lot from 27th January 2017 onwards. It should be noted that false negative results with the affected components would not produce a specific pattern for an alternative Rh D variant that would result in a difference in determination of sample type. At time of review, Quotient request that where an organisation has received test results associated with this lot that you forward this notification onto the appropriate personnel.

Quotient are advising that an alternate lot (Lot number V178660, Expiry 9th 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).

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.

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 (O) 131 292 0422 (customer.serviceEU@quotientbd.com)

Kindest regards,

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CONFIRMATION OF RECEIPT OF NOTIFICATION

ALBAclone® Advanced Partial RhD Typing Kit

Lot No. V174693, Item No. 2293, 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.

Organisation name
Address
Number Received
Number Used
Number Discarded
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 vigilance.notifications@quotientbd.com