



FIELD SAFETY NOTICE

ALBAcyte® A2 Cells REAGENT RED CELLS

Lot No. V173631, Item No. Z406, Expiry Date: 3rd October 2016

Quotient is contacting you because our records indicate that your organization recently received one or more vials of ALBAcyte® A2 Cells lot V173631. This notice should be forwarded to appropriate personnel who have received this product, and may be affected by this notice.

This Field Safety Corrective Action has been initiated as a precautionary measure. The red blood cells contained in lot V173631 are of the phenotype A2. When tested in parallel with other red blood cells of A2 phenotype, they have been shown to have a slightly higher level of A antigen expression. As you are aware, the lectin *Dolichos biflorus* is commonly used to differentiate between A1 and A2 phenotypes. Because the Anti-A1 lectin has Anti-A specificity rather than Anti-A1 specificity, differentiation between phenotypes is achieved by appropriate dilution of the reagent. In our technical investigation, the A2 cells of lot V173632 demonstrated weakly positive reactions when tested with some manufacturers/lots of Anti-A1 lectin. This appears to be due to the potency of the reagent in combination with the slightly higher expression of A antigen on these red blood cells as compared to other red blood cells of A2 phenotype.

Quotient has manufactured a replacement lot of ALBAcyte® A2 Cells. Once tested and cleared for release, we will send you replacement vial(s) free of charge. Our aim is ship replacement product to you during the week of September 5-9.

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. Please 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 our customer services team on ++44 (0) 131 292 0422

Sincerely

Derek Robson
Vice President, Quality
31st August 2016

CONFIRMATION OF RECEIPT OF FIELD SAFETY NOTICE

ALBAcyte® A2 Cells REAGENT RED CELLS
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I/WE confirm receipt of the above communication and confirm that all stock of the above lot, 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