QUOTIENT

[redacted]

[redacted]

Edinburgh, August 24, 2023

URGENT FIELD SAFETY NOTICE

FSN 00003-2023

(New FSN, Follow-up FSN not expected)

Dear Customer,

Quotient is contacting you because our distribution records indicate that your organization has received the product(s) detailed below. This notice must be forwarded to appropriate personnel affected by this notice. If this material has been transferred to organizations other than your own, we request you pass on this notification or forward their details to Alba Bioscience Limited so that we may contact them directly.

AFFECTED PRODUCT(S)

Device Type:
ALBAcyte® A1 Cells are for ABO reverse grouping of patient or donor serum/plasma. These reagent red blood cells are presented as a 2-3% suspension of washed red blood cells in Modified Alsever's Solution. ALBAcyte® A1 Cells are prepared as a pool, i.e. more than one donation.

ABO blood grouping is generally performed by testing red blood cells with Anti-A, Anti-B and, optionally, Anti-A,B. Confirmation of the red blood cell group can be provided by simultaneously performing a reverse or serum group, i.e. testing the donor or patient's serum/plasma with group A1 and group B reagent red blood cells to detect Anti-A and Anti-B.

[redacted]

Device(s) and serial or lot number range affected:

Catalogue number	Commercial name	UDI	Lot Number	Expiry Date
Z401	ALBAcyte® A1 Cells	1 vial: 05060242470646 3 vials: 05060242477812 10 vials: 05060242477805	V263528	25-Sep-2023

DESCRIPTION OF THE PRODUCT PROBLEM

During routine internal testing, the products demonstrated unexpected performance, which was subsequently confirmed by further testing. Investigations have identified that the product is mis-labeled in that one of the three units used to manufacture this reagent red blood cell product was derived from a non-group A1 donor and represents a subgroup of A.

POTENTIAL HEALTH CONSEQUENCES OF A DEFECTIVE DEVICE

Due to the nature of the defect and the results of the investigation, the main risk considered would involve a delay in determination of blood group, since additional testing may be required in the event of a discrepant reverse typing result. Nevertheless, the probability of occurrence of this scenario is limited as no discordant results were detected in internal investigative testing compared to the previous lot of ALBAcyte® A1 Cells.

ACTION/S REQUIRED by 01-OCT-2023

- Impacted lots of ALBAcyte® A1 Cells can be used for reverse grouping and as controls in the absence of an alternative product.
- The reagent lots listed above should be removed from use and discarded when an alternative reagent is available or the replacement lot of ALBAcyte® A1 Cells is received.
- If the impacted lots are used to investigate cold agglutinin activity, be aware that due to increased H antigen expression compared to typical A1 cells, reaction strength may not be as expected.
- Repeat testing should be conducted using the replacement lot of ALBAcyte® A1 Cells, or an alternative source, if results obtained with the impacted lots appear anomalous.
- All required regulatory notifications are being completed. We request that you help us meet our compliance requirements. Please complete and sign the attached form and return to us at your earliest opportunity by email: vigilance.notifications@quotientbd.com.

ACTION BEING TAKEN BY THE MANUFACTURER

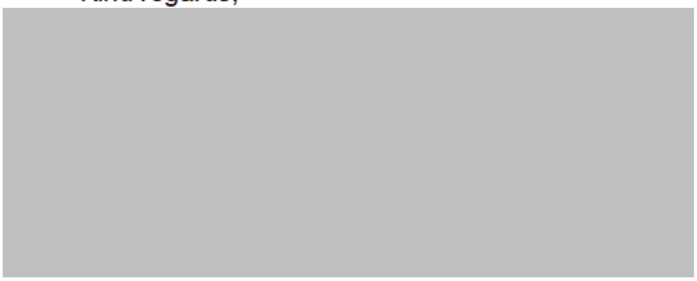
A replacement lot has been manufactured according to the product design and tests performed during manufacture and at batch release confirmed the composition exclusively of A1 red blood cells.

The replacement products will be shipped automatically to the location which received the impacted products. Delivery is expected by 01-Sep-2023.

Further information:

Alba Bioscience Limited / Quotient sincerely apologize for any inconvenience caused by this issue. If you require any further information, please do not hesitate to contact Quotient at: vigilance.notifications@quotientbd.com.

Kind regards,



QUOTIENT

URGENT FIELD SAFETY NOTICE
FSN 00003-2023

Affected Product(s) and Action Required:

Product Ref	Product Description	Lot Number	Expiry Date
Z401	ALBAcyte® A1 Cells	V263528	25-Sep-2023

Confirmation of Actions Performed:

By signing below, I acknowledge that:

- I have read and understood the communication.
- I will discontinue use of the product and discard remaining inventory when an alternative and/or replacement A1 reagent red blood cell product is available.
- I will review previous results for tests performed with these lots and will investigate any anomalous results identified.

Facility Name _____

Name (please print) _____

Position/Title _____

Signature _____

Date _____

Please complete and return this form to Quotient, by email to
vigilance.notifications@quotientbd.com