August 22th, 2023

Urgent Field Safety Notice from Alba BioScience (Quotient)
FSN 00002-2023

Dear Customer,

On behalf of Quotient, QuidelOrtho™ is contacting you because our distribution records indicate that your organization has received the product(s) detailed below. This notice must be forwarded to the 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:
Monoclonal Anti-Lea and Anti-Leb blood grouping reagents enable red blood cells to be classified as one of four phenotypes: Le(a-b+), Le(a+b-), Le(a-b-), Le(a+b+). The latter phenotype, Le(a+b+), is extremely rare. Agglutination of red cells with either of these reagents indicates the presence of the appropriate antigen on the red cell surface. Lewis antigens are also present in serum and other bodily fluids. Cord cells do not express Lewis antigens in sufficient quantity to be agglutinated by these reagents and therefore will group as Le(a-b-). An infant's true Lewis status does not normally become apparent until the age of two years (approx.).

Commercial Name:
ORTHO™ Sera Anti-Lea

Unique Device Identifier(s) (UDI-DI) :
10758750013234

Device Model/Catalogue/Part number(s):
6904497

Alba Code	Ortho Code	Product Description	Lot Number	Expiry Date
FD212B	6904497	ORTHO™ Sera Anti-Le^a	V239361	01 November 2023
FD212B	6904497	ORTHO™ Sera Anti-Le^a	V243312	27 November 2023
FD212B	6904497	ORTHO™ Sera Anti-Le^a	V255872	05 October 2024

Description of Product Problem
A Customer Complaint investigation has confirmed that the lots of ORTHO™ Sera Anti-Le^a stated above show unexpected negative results with Le^a antigen positive red cells. This phenomenon was noted during testing of these lots against reagent red blood cells and EDTA red cells positively expressing the Le^a antigen. At time of product release, all lots met release criteria, however, during in-house testing we have noted deterioration in performance over shelf life, leading to the potential for failure to detect red cells with reduced expression of the Lea antigen.

Potential Health Consequences of a Defective Device
The risk involved with this defect would be to report Le(a+) individuals (blood recipients and/or donors) as Le(a-). The worst possible scenarios would be:

- Transfusion: To sensitize a Le(a-) patient with blood from a Le(a+) donor (falsely labelled Le(a-)), in case of first transfusion. Hemolytic transfusion reactions (HTRs) caused by Lewis (Le) antibodies in previously sensitized Le(a-) patients with blood from Le(a+) donors, in case of a subsequent transfusion.
- Perinatal setting: Hemolytic disease of the fetus and newborn (HDFN)
- Solid organ transplantation: Antibody-mediated rejection (AbMR) of allograft

Nevertheless, it is relevant to highlight that although the potential scenarios discussed above are not impossible, in general, antibodies against antigens of the Lewis system are not considered clinically relevant as cause of HTRs, HDFN or AbMR.

Action/s required:

- The reagents listed above should be removed from use and discarded. Quotient is recommending that a review of previous donor and patient testing performed with these lots of antisera should be conducted.
- Repeat testing should be conducted using an alternative lot of antisera if previously obtained results appear anomalous.
- All required regulatory notifications are being completed. We request that you help us meet our compliance requirements. Please perform the required actions: complete and sign the form below and return it to Quotient at your earliest opportunity by email: Vigilance.Notifications@quotientbd.com.
- Refer to the enclosed Confirmation of Receipt form from QuidelOrtho for product replacement or credit.

Action must be taken by 01-Sep-23

Further information:

We apologize for any inconvenience caused by this issue. If you require any further information, please do not hesitate to contact our Global Services Organization at *00 800 08 37 25 60 (Denmark, Norway & Iceland), 0201408174 (Sweden), 0800 895 963 (UK, Ireland).*

Ricardo Escolá
Director EMEA Quality,
Regulatory & Compliance

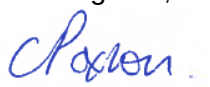
Enclosure:
Letter from Quotient
Confirmation of Receipt Form (Ref. CL2023-180a_CustConfirm)

Action Being Taken By The Manufacturer

Replacement Lot has been manufactured within a x5 concentration, which results in a higher total protein content which gives sufficient buffering capacity for the antibody to remain stable and specific during shelf life.

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,



Department Leader, Complaint Management

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All affected stock can be replaced or credited following your normal ordering channel. Please place your order directly with Ortho Clinical Diagnostics (QuidelOrtho™) or your usual distributor via the Confirmation of Receipt form (Ref.CL2023-180a_CustConfirm).

Affected Product(s) and Action Required:

Ortho Code	Product Description	Lot Number	Expiry Date
6904497	ORTHO™ Sera Anti-Le^a	V239361	01 November 2023
6904497	ORTHO™ Sera Anti-Le^a	V243312	27 November 2023
6904497	ORTHO™ Sera Anti-Le^a	V255872	05 October 2024

Confirmation of Actions Performed:

By signing below, I acknowledge that:

- I have read and understood the communication.
- I will discontinue the use of the product and discard the remaining inventory.
- I will review previous results for tests performed with these lots of antisera and will perform testing for any anomalous results identified with an alternate lot of antisera.

Facility Name _____

Name (please print) _____

Position/Title _____

Signature _____

Date _____

Please complete and return this form to Quotient, by email to
Vigilance.Notifications@quotientbd.com