

Alba Bioscience Limited, Allan-Robb Campus,
5 James Hamilton Way, Milton Bridge, Penicuik EH26 0BF

Edinburgh, July 10, 2023

QUALITY ADVISORY NOTIFICATION

Dear Customer,

Quotient is contacting you because distribution records indicate that your organisation 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 organisations 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):

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

Notification:

ORTHO™ Sera Anti-Le^a is for the qualitative *in vitro* detection of human Le^a positive red blood cells by the direct agglutination test.

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.

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 attached form and return to us at your earliest opportunity by email:

Vigilance.Notifications@quotientbd.com.



Further information:

Alba Bioscience Limited / Quotient sincerely apologise 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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Confirmation of Actions Performed:

By signing below, I acknowledge that:
<ul style="list-style-type: none"> I have read and understood the communication. I will discontinue use of the product and discard 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