URGENT FIELD SAFETY NOTICE

FSN 00003-2025

ALBAsera® Anti-Wr^a

(New FSN, Follow-up FSN not expected)

Edinburgh, September 01, 2025

Dear Customer,

Alba Bioscience Limited (''Alba'') is contacting you because distribution records indicate that your organisation has received the product detailed below.

This notice is being issued in accordance with regulatory requirements. Please ensure that this information is forwarded immediately to all relevant personnel within your organisation. If the affected material has been supplied to other facilities, please forward this notification to them or provide their details to Alba so we may contact them directly.

AFFECTED PRODUCT

Device Type:

ALBAsera® Anti-Wr^a Blood Grouping Reagent is for the *in vitro* detection and identification of human Wr^a positive red blood cells by indirect agglutination.

Commercial Name:

ALBAsera® Anti-Wr^a

Unique Device Identifier (UDI-DI):

05060242470301

Device Model/Catalogue/Part Number:

Z231

Affected Serial or Lot Number Range:

Code	Product Description	Lot Number	Expiry Date
Z231	ALBAsera® Anti-Wr^a Blood Grouping Reagent	V279519	09 December 2026

DESCRIPTION OF THE PRODUCT PROBLEM

Internal studies have confirmed that Lot V279519 of ALBAsera® Anti-Wr^a demonstrates reduced reactivity. This may result in weaker-than-expected positive reactions, or false negative reactions, when testing Wr(a+) reagent red cells.

- Reactivity with EDTA red cells is unaffected.
- The issue is limited to this lot only. All previously distributed lots are unaffected.

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POTENTIAL HEALTH CONSEQUENCES OF A DEFECTIVE DEVICE

Immediate Consequences:

- Operational impact: Possible delays in issuing compatible blood due to repeat testing, result clarification, or escalation.
- Clinical impact (rare): If a patient with clinically significant anti-Wr^a receives Wr(a+) red cells, an acute haemolytic transfusion reaction (HTR) may occur. Acute HTRs are uncommon; severity ranges from mild to severe and, rarely, fatal.

Long-term Consequences:

- Delayed HTR: Reduced detection sensitivity may contribute to delayed haemolytic transfusion reactions (more commonly reported than acute events); severity ranges from mild to severe and, rarely, fatal.
- Alloimmunisation: Potential for alloimmunisation to Wr(a+) red cells, with implications for future transfusions or pregnancies.
- HDFN: Maternal IgG anti-Wr^a has been reported to cause haemolytic disease of the foetus and newborn (HDFN), typically mild, though severe cases have been reported.

Mitigating factors:

- Reactivity with EDTA red cells is unaffected for this lot, which reduces - but does not eliminate - the likelihood of clinical impact.

ACTIONS REQUIRED

- Immediately discontinue use of ALBAsera® Anti-Wr^a Lot V279519. Remove from inventory and discard all remaining stock of this lot.
- A review of testing previously performed with ALBAsera® Anti-Wr^a Lot V279519 should be performed to confirm that results obtained were consistent with expected outcomes.
- Help us meet compliance requirements by completing the attached acknowledgement form, detailing:
  - Disposition of affected product (e.g., discarded / none remaining / redistributed)
  - Quantity discarded (number of vials/units)
- Return the completed form at your earliest opportunity and no later than **26 September 2025**, by email to: Vigilance.Notifications@alivedx.com
- If the material has been supplied to other facilities, please forward this notice to them or provide their contact details to Alba so that we may contact them directly.
- Retain this notice and records of the actions taken for your documentation.

ACTION BEING TAKEN BY THE MANUFACTURER

Alba is working with inter-departmental teams to complete a thorough root cause investigation and will implement robust Corrective Actions. Alba has ceased the distribution of Lot V279519 and a new lot of ALBAsera® Anti-Wr^a is available and can be provided to replace the implicated product. A member of our Customer Services team will contact you to coordinate replacement or credit.

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Further Information:

Alba sincerely apologises for any inconvenience caused by this issue. If you require any further information, please do not hesitate to contact us by email at vigilance.notifications@alivedx.com

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Affected Product and Action Required:

Code	Product Description	Lot Number	Expiry	Action	Quantity Discarded
Z231	ALBAsera® Anti-Wr^a Blood Grouping Reagent	V279519	09 December 2026	Discard	

Confirmation of Actions Performed:

By signing below, I acknowledge that:

- I have read and understood the communication.
- I have discontinued use of the product and have discarded remaining inventory.
- I have confirmed the quantity discarded.

Facility Name _____

Facility Address _____

Facility Country _____

Facility ZIP code _____

Name (please print) _____

Position/Title _____

Signature _____

Date _____

Please complete and return this form to Alba by email to: Vigilance.Notifications@alivedx.com

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