



Bio-Rad
Medical Diagnostics GmbH

Industriestr. 1, D-63303 Dreieich,
Germany
Phone : +49 (0) 6103 3130-0
Fax :+49 (0) 6103 3130-989

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Urgent Product Notification

Anti-Lu^a (LU1), Catalog Number 808216, Lot 3113160-00, UDI 07611969951864

Dear Valued Customer:

Bio-Rad Laboratories would like to inform you that our polyclonal blood grouping reagent Anti-Lu^a (LU1) (Catalog Number 808216, Lot 3113160-00, UDI 07611969951864) shows a decrease in reactivity with erythrocytes with low antigenicity. This may result in unexpected false negative results.

Impact on the patient:

Alloanti-Lu^a is not considered as a clinically relevant antibody and no transfusion reactions are reported. However, false negative results may lead to a transfusion mismatch leading to an immunization of the patient, or - if already immunized - to a transfusion reaction in patients with serious preconditions.

Customer Actions

Bio-Rad's recommendation for management of Anti-Lu^a (LU1) Lot: 3113160-00 is to stop using the product. Please sign and return the attached confirmation form indicating that the affected lot has been discarded and insert the number of vials that require replacement. The impacted products will be replaced free of charge by another lot.

If you have distributed this product to any other facility, you are required to provide a copy of this notification to them and/or notify Bio-Rad.

Customers who have any questions regarding this notification should contact their Bio-Rad representative.

We apologize for any inconvenience this may have caused and appreciate your support of Bio-Rad products.

Sincerely,

Bio-Rad Medical Diagnostics GmbH

Dr. Marc Gorzellik
QA Manager

Barbara Becker
International Product Manager Reagents