Bio-Rad
Medical Diagnostics GmbH

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May 18, 2022

Urgent Field Safety Notice

Anti-Lu^a (LU1), Catalog Number 808216, Lot 3131020-00 & Lot 3131030-00 UDI 07611969951864

Dear Valued Customer:

Bio-Rad Laboratories would like to inform you that our polyclonal blood grouping reagent Anti-Lu^a (Lu1):

Product	Catalog Number	Lot	Expiration date	UDI
Anti-Lu^a (LU1)	808216	3131020-00	26-Jul-2023	07611969951864
Anti-Lu^a (LU1)	808216	3131030-00	26-Jul-2023	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), Lots: 3131020-00 and 3131030-00 is to stop using the product. Please sign and return the attached confirmation form indicating that the affected lots have been discarded and insert the number of vials that require replacement.

The impacted products will be replaced free of charge by another lot. This is a newly produced lot with a reduced shelf life of nine months. All our data support that the product will be stable for at least nine months. The reduced shelf life will prevent any inconveniences caused by a decrease in reactivity.

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Necessity of sample retesting:
As per the product's Instruction For Use (IFU), a positive and a negative control should be performed parallel. If these controls reacted correctly positive and negative, previously obtained test results are valid.

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