



Bio-Rad
Medical Diagnostics GmbH

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December 12, 2023

Urgent Field Safety Notice

Anti-Di^a (DI1), Catalog Number 808270
UDI 07611969951956; SRN DE-MF-000019864

Dear Valued Customer:

Bio-Rad Laboratories would like to inform you that our polyclonal blood grouping reagent Anti-Di^a (DI1) contains additional antibodies against low-incidence antigens of the MNS blood group system. This may result in unexpected false positive test results.

Impacted lots:

Product	Catalog Number	Lot	Expiration date	UDI
Anti-Di ^a (DI1)	808270	3125010-00	06-Jun-2024	(01)07611969951956(17) 20240606(10)3125010-00
Anti-Di ^a (DI1)	808270	3149050-00	03-Jan-2025	(01)07611969951956(17) 20250103(10)3149050-00
Anti-Di ^a (DI1)	808270	3215020-00	26-Mar-2025	(01)07611969951956(17) 20250326(10)3215020-00
Anti-Di ^a (DI1)	808270	3248070-00	15-Nov-2025	(01)07611969951956(17) 20251115(10)3248070-00
Anti-Di ^a (DI1)	808270	3332050-00	24-Jul-2026	(01)07611969951956(17) 20260724(10)3332050-00

Impact on blood donor testing:

False positive results, if blood donors are Mut pos, Di^a neg, will lead to an incorrect record in the blood bank database.

Blood donors may also be screened if Di^a neg blood is required (patient presenting with an anti-Di^a). Depending on local guidelines and regional specificities, crossmatch compatible blood by IAT at 37°C can be used. The recommendations and practices may vary in different geographies. The higher the prevalence of Dia, the higher the risks as anti-Di^a may lead to severe transfusion reactions.

Impact on patient testing:

Patients who have already developed an anti-Di^a may be typed falsely positive if they are Mut positive, questioning the antibody specificity. This may delay the result and the proper risk evaluation in the patient context and possibly the blood selection, depending on local guidelines,



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ref. the donor selection. If the transfusion is urgent, crossmatch compatible blood in IAT at 37°C may be used.

Anti-Dia may also be used to prepare local screening/identification RBC panels. Therefore, a Mut pos, Di^a neg RBC may be labelled as Di^a pos. In such a case, an anti-Mut (quite rare and little is known about its clinical significance) may be concluded as an anti-Dia and, depending on local policies, Dia neg blood may be selected instead of GP.Mur neg (or GP.Hut, GP.Hop all carrying Mut antigen).

Impact on the patient:

The Di^a antigen has an occurrence of 0.01% in most populations but of 12% in Asian populations. In consequence of a false positive reaction the patient may be transfused with a Dia pos unit, depending on availability of Dia antigen selectable blood units. If the requested crossmatch is not properly assessed, a potentially mismatched positive unit may lead to alloimmunization of the patient. If the patient is already alloimmunized and the patient anti-Dia is below the detection limit of antibody screening methods, the antibody may be boosted and transfusion reactions potentially leading to patient harm may be caused.

Customer Actions

Bio-Rad's recommendation for management of Anti-Di^a (DI1), Lots: 3125010-00, 3149050-00, 3215020-00, 3248070-00, and 3332050-00 is to verify positive test results by additional testing with Papain/Ficin treated red blood cells to exclude a reaction with an additional antibody against a low-incidence antigen of the MNS blood group system.

Necessity of sample retesting:

Previously obtained negative test results are valid. Previously obtained positive test results may be confirmed by additional testing with Papain/Ficin treated red blood cells.

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
Assoc. Dir, Product Quality Assurance

Barbara Becker
International Product Manager Reagents