
URGENT FIELD SAFETY NOTICE
ID-DiaCell I-II-III

Product UDI	Catalog Number	Product Name	Batch Number/ Lot Number	IHD Display Batch	Expiration Date (MM/DD/YYYY)
07611969000968	004310	ID-DiaCell I-II-III	133842941	45184.94.1	09/28/2026

The "ID-DiaCell I-II-III" are Reagent Red Blood Cells intended to be used for screening of irregular red blood cell antibodies in human donor and patient serum or plasma for immunohematology testing. The qualitative determination can be carried out manually or using instruments intended for the ID-System. For in vitro diagnostic use by trained laboratory personnel.

This letter contains important safety information. Please ensure all impacted users in your facility are made aware of this letter and the recommended actions.

**For the attention of professional users in a laboratory
Please retain this letter for your records**

Date: 2026-09-09

Bio-Rad Field Action Reference: FA-CDG-26019

Legal Manufacturer: DiaMed GmbH, SRN: CH-MF000020826 GLN: 7601001392533

Dear Valued Customer / Channel Partner,

The purpose of this letter is to advise you that Bio-Rad is initiating a field action for the product identified above. This letter contains important information that requires your immediate attention.

Description of the issue:

Bio-Rad identified unexpected weak or borderline positive reactivity with Screening Cell III of ID-DiaCell I-II-III, Batch 133842941/45184.94.1.

The issue was initially identified during pre-acceptance testing. At some sites, the observed reactivity resulted in pre-acceptance testing failures, preventing the affected batch from being

released for routine use. At other sites, the product passed laboratory QC; however, weak false positive reactivity of Screening Cell III was subsequently observed during routine use.

Risk to Health:

False positive antibody screening results may lead to unnecessary follow-up testing, delays in result availability or blood unit release, and potential discard of donor blood units.

Action(s) to be taken by the Customer:

Bio-Rad is requesting that customers affected by this notice take the following action(s):

- If a suspected nonspecific reaction is identified during result validation, please discard the unused impacted products and use a different lot from your standing orders.
- If you do not have any other lot of ID-DiaCell I-II-III available, please contact Bio-Rad to request a replacement for the affected products.

Resolution by Bio-Rad:

Bio-Rad is committed to ensuring the highest standards of product quality and patient safety. An internal investigation is currently underway to determine the root cause of this issue and to identify opportunities to further strengthen our quality control processes. These actions are intended to prevent recurrence and ensure continued compliance with applicable regulatory and quality requirements.

Please ensure that this notice is shared with all relevant individuals within your organization and that a copy is retained for your records. If you have distributed or transferred the affected product listed above to another organization, kindly provide them with a copy of this letter.

To confirm receipt of this important communication, please complete and return the enclosed Response Form within 10 days.

If you have any questions regarding this communication, please contact our Technical Support or your Bio-Rad local representative. Contact information is available on our website at: [Contact Information | Bio-Rad](https://www.bio-rad.com/help-center/contact-information), <https://www.bio-rad.com/help-center/contact-information>.

The National Competent (Regulatory) Authority has been informed of this field safety corrective action. Bio-Rad would like to assure you that maintaining the highest level of safety and quality is our top priority. We apologize for any inconvenience this issue may have caused.

Sincerely,

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