DiaMed GmbH
Pra Rond 23
1785 Cressier FR / Switzerland
Phone: +41 (0)26 674 51 11
Fax: +41 (0)26 674 54 45

Cressier, 10.02.2017

Urgent: Field Safety Notice / 001-17

Affected device:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Dia (Diego) Positive	004134	All lots currently in date	
ID-DiaCell SF	003640		
ID-DiaCell Pool	003630 / 003631		
ID-DiaCell ABO/I-II *	003610		
ID-DiaCell ABO/I-II-III *	003618		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaCell I-II	003613		
ID-DiaPanel	004114		
ID-DiaCell I-II-III	004310		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaCell I-II-III Asia	003614		
ID-DiaScreen Prophylax	004330		
ID-DiaPanel Plus 6	004414		
ID-DiaCell I-II	003613VJ		
ID-DiaPanel (1-11)	004114VJ		
ID-Dia Positiv	004134VJ		
ID-DiaCell I-II-III	004310VJ		

** Vials ID-DiaCell I, ID-DiaCell II, ID-Diacell III only (ID-DiaCell ABO out of scope)*

Dear **Customer,**

This letter contains important information that requires your immediate attention.

Description of the problem:

We would like to share with you, and your team, information about unexpected reactions primarily on eluates and QC samples but also with some patient samples when using the above mentioned products.
This phenomenon is observed randomly between batches, and also within single batches.

Impact on the patient:

A risk assessment has been done, and the conclusion is that this unexpected result requires further confirmation testing before a final transfusion decision is made and. Negative results can be reliably accepted as negative.

Immediate protective measure:

In case of doubtful reactions, please re-test with a new kit. If the results remain in doubt, we would advise you to send the sample to a reference laboratory and if an urgent transfusion is required, perform a crossmatch.

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A team of internal and external experts has been and continues working to identify the root cause and determine corrective actions.

Further investigations are still ongoing and will continue until we can provide a solution.

Please note that the relevant European Regulatory Agency has been advised of this FSCA.

In case of questions, in the first instance, please contact our Customer Service Laboratory:

slabor_cressier@bio-rad.com

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Director, Clinical Diagnostics Group - Europe	Vice President and General Manager, Immunohematology Division
Agnes Eude Goethals	Ann Madden

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Please fill out and sign this document until 2017-02-17

Urgent: Field Safety Notice / 001-17
Reply Form for Customers

PRODUCT:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Dia (Diego) Positive	004134	All lots currently in date	
ID-DiaCell SF	003640		
ID-DiaCell Pool	003630 / 003631		
ID-DiaCell ABO/I-II *	003610		
ID-DiaCell ABO/I-II-III *	003618		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaCell I-II	003613		
ID-DiaPanel	004114		
ID-DiaCell I-II-III	004310		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaCell I-II-III Asia	003614		
ID-DiaScreen Prophylax	004330		
ID-DiaPanel Plus 6	004414		
ID-DiaCell I-II	003613VJ		
ID-DiaPanel (1-11)	004114VJ		
ID-Dia Positiv	004134VJ		
ID-DiaCell I-II-III	004310VJ		

** Vials ID-DiaCell I, ID-DiaCell II, ID-Diacell III only (ID-DiaCell ABO out of scope)*

CUSTOMER INFORMATION:

Hospital / Laboratory	
Address (Street, Postcode, Country)	
Phone Number	
Undersigning manager name	
Customer Account Number	

STATEMENT:

I have read and understood this Field Safety Notice, and shared the information with laboratory staff.

Date: ..... **Signature:** .....

H006001 07.12

Annex II

DiaMed GmbH
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Cressier, 20.02.2017

Field Safety Notice 001-17_Follow-up letter

Affected devices displaying the issue:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Dia (Diego) Positive	004134 / 004134VJ	All lots currently in date	
ID-DiaCell SF	003640		
ID-DiaCell Pool	003630 / 003631		
ID-DiaCell ABO/I-II	003610		
ID-DiaCell ABO/I-II-III	003618		
ID-DiaScreen I-II-III-IV-VP-VIP	004316		
ID-DiaCell I-II	003613 / 003613VJ		
ID-DiaPanel	004114 / 004114VJ		
ID-DiaCell I-II-III	004310 / 004310VJ		
ID-DiaScreen I-II-III-IV	004311		
ID-DiaCell I-II-III Asia	003614		
ID-DiaScreen Prophylax	004330		
ID-DiaPanel Plus 6	004414		

Other Devices from the same product range not displaying the issue but requiring your attention:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-DiaCell ABO	003619 / 003617 / 003615 / 003624 / 003620 / 003621 / 003622 / 003623 / 003621VJ / 003623VJ / 003624VJ /	All lots currently in date	
ID-DiaCell IP-IIP-IIIP	005310 / 005310VJ		
ID-DiaScreen VP-VIP	005311 / 005311VJ		
ID-DiaPanel-P	004214 / 004214VJ		

Dear **Customer,**

We would like to provide additional information on the FSN 001-17 communicated on February 10th, 2017 and related to unexpected reactions that could be observed when using the above listed products.

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Description of the problem

Applications displaying the issue:

We received complaints regarding indirect antiglobulin test (IAT), especially when eluates and QC samples were tested, less frequently when patient samples were tested.

Applications that were described in the complaints received:

- **Most frequent** applications

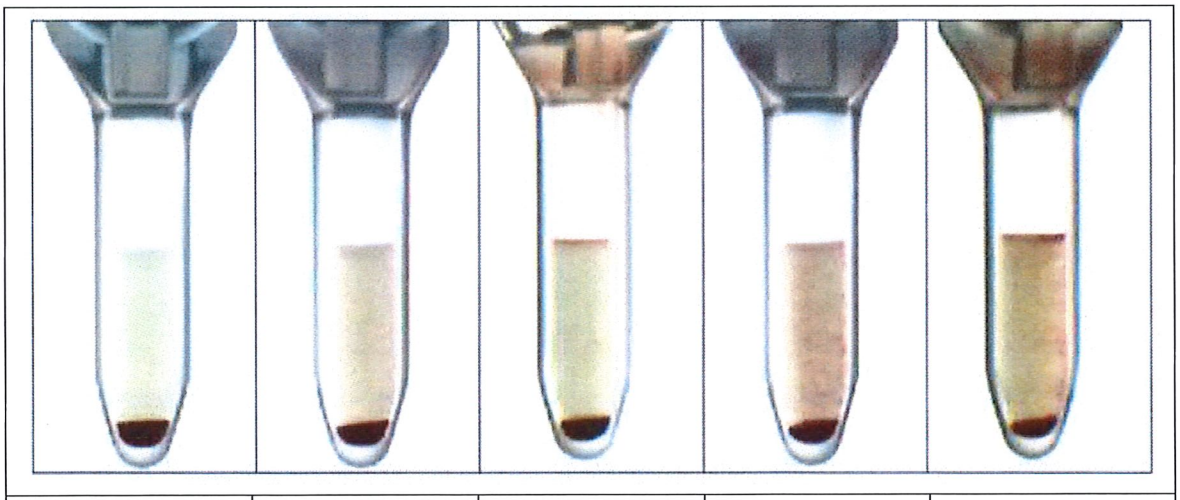
  1. IAT for the testing of eluates subsequent to a Direct Antiglobulin Testing (DAT) positive results.
  2. Routine quality control of above listed ID-DiaCells performed in the laboratory using our internal quality controls, as well as QC samples from third parties.

- **Less frequent** applications

  3. IAT of patient samples for the screening and detection of irregular antibodies
  4. IAT for the identification of irregular antibodies performed subsequent to a positive antibody screening.

The following are examples of the unexpected reactions (the image ① shows a normal negative for comparison)

These images can be observed in both manual and automated methods from doubtful (images ② and ③) to false positive reaction (images ④ and ⑤).



❶	❷	❸	❹	❺
Negative	Doubtful	Doubtful	False positive	False positive

Table 1_Example of unexpected reactions

The instrument may render a "?", wR, wF, (image ② and ③) or any option up to ++ (images ④ and ⑤) , depending on the intensity of the reaction.

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Other applications not displaying the issue so far but requiring your attention:

Today **no cases** were reported on the following applications:

5. Antibody screening using papain treated ID-DiaCells
6. Antibody identification using papain treated ID-DiaPanel
7. ABO Reverse group using ID-DiaCell ABO

If you are facing the described unexpected results with these applications, please contact immediately our Customer Service Laboratory at slabor_cressier@bio-rad.com to report the case and provide any necessary data allowing its proper handling.

Impact on the patient

A risk assessment has concluded that unexpected reactions (from doubtful to false positive as illustrated in table 1) require further confirmation testing before a final decision for transfusion is made.
The impact of the unexpected reaction is described below for each application:

Application		Impact of doubtful to false positive results
1	IAT for the testing of eluates	Impossibility to identify an antibody of a DAT positive patient sample (eluate).
2	Quality Control of above listed ID-DiaCells	Impossibility to validate your QC tests due to unexpected positive results compared to the expected QC sample reactivity pattern.
3	IAT of patient samples for the screening of irregular antibodies	Results requiring further confirmation through antibody identification.
4	IAT for the identification of irregular antibodies	Impossibility to identify an irregular antibody detected during screening test.
5	Enzyme test with papainized cells of patient samples for the screening of irregular antibodies	Results requiring further confirmation through antibody identification.
6	Enzyme test with papainized cells of patient samples for the identification of irregular antibodies	Impossibility to identify an irregular antibody detected during screening test.
7	ABO Reverse group	Discrepant results between reverse grouping and ABO forward grouping which require further investigation.

Immediate protective measure:

Please re-test any unexpected reactions (see table 1) with a new kit.

If the results are not conclusive, we recommend using an alternative method.

We advise the Medical Director to review the previous results of the Laboratory and assess the needs to take further actions.

Important note: Negative results obtained with the concerned ID-DiaCell's are valid.

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Please note that the relevant European Regulatory Agencies have been advised of this FSN follow-up letter.

In case of any questions, in the first instance, please contact our Customer Service Laboratory:

slabor_cressier@bio-rad.com

Our representatives are briefed to help you in managing this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Director, Clinical Diagnostics Group - Europe

Agnes Eude Goethals

Vice President and General Manager, Immunohematology Division

Ann Madden