



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

Cressier, September 11th, 2014

Urgent: Field Safety Notice / 002-14

Affected device

Product name: NaCl, Enzyme Test and Cold Agglutinins
Product Id. _REF 50520_005014 / 005015 / 005016
LOT Number: 50520.93.09 exp. 2016.01

Dear Customer,

This letter contains important information that requires your immediate attention.

BioRad/DiaMed GmbH is voluntarily recalling the product identified above. This recall is being conducted as a precautionary measure due to a product contamination.

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

Description of the problem:

In the context of an internal investigation, we were able to demonstrate that the well number 3 of some of the ID cards **NaCl, Enzyme Test and Cold Agglutinins** of the above lot may contain, on a random basis, a very small amount of monoclonal anti-E (anti-RH3).

Impact on the patient:

This issue might have led to unexpected results for tests carried out where the cell used in position 3 was E+ (RH:3):

- Reverse group with the group O cell
- Antibody screening with ID-Diacell if carried out in saline or enzyme with the following cells: I-II-III Asia, ID-DiaScreen Prophylax, ID-Diacell I-II-Dia+, ID-Dia+, ID-SF.
- Identification Panel, ID-Panel Plus 6 tested in enzyme or in saline
- Enzyme crossmatch.

Considering the usual practices in the laboratories, the residual patient risk is extremely low as these results should have led to additional tests.

Immediate protective measure:

In light of this information, we advise the users of this lot of ID cards to use another lot if available in the laboratory and destroy the remaining stock of lot 50520.93.09. This lot will be replaced free of charge.

* The replacement lots **50520.95.02** and **50520.95.03** will be sent the week 38.

Note: If no other lot is immediately available and if you need to perform a test using these ID cards, considering the low associated risk, it might be possible to use the lot 50520.93.09 but with a particular attention to the interpretation of positive results:

- By manual method, don't use the well 3 of the card.
- On the automates, if a positive result is obtained in the well 3, use the manual method following the instructions above.

Any negative result obtained with this lot would be perfectly valid.

Please fill out and sign the Field Safety Notice reply form (Annex I) and return the completed form to DiaMed GmbH until the 17th of September 2014.

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

+41 (0) 26 674 54 21
slabor_cressier@bio-rad.com

Our collaborators are briefed to help you manage this situation.

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

Yours sincerely,

DiaMed GmbH
RA/QA Manager

Agnes Eude Goethals

Clinical Diagnostics Operations, Europe
Senior Vice President

Patrick Bugeon



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Urgent: Field Safety Notice / 002-14 Reply Form for Customers

Product name: NaCl, Enzyme Test and Cold Agglutinins
Product Id. _REF 50520_005014 / 005015 / 005016
LOT Number: 50520.93.09 exp. 2016.01

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

- Use if possible another lot than the one indicated above of ID Cards NaCl, Enzyme Test and Cold Agglutinins.
- As soon as a replacement lot is available, destroy the remaining stock ID-cards with the lot number **50520.93.09**
- Complete the attached **Certificate of Destruction** and send the required information back to the distributor.

Hospital / Laboratory

Address

Phone Number

Completed by: Name / Signature / Title / Date



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Please fill out and sign this document until the end of the week 38.

Certificate of Destruction

ID-Card NaCl, Enzyme Test and Cold Agglutinins LOT 50520.93.09

LABORATORY	
COUNTRY	
CONTACT PERSON	

REF. Number	Total Number of boxes received	Boxes Still on stock	
		Number	Date of destruction
005014			
005015			
005016			

I,.....,do hereby certify that, due to the problem reported on the **NaCl, Enzyme Test and Cold Agglutinins (lot number 50520.93.09)** and according to the instructions issued by BioRad/DiaMed GmbH, I have destroyed the above mentioned products.

Date:

Signature:

Name:

Position: