

Cressier, 17 June 2021

Follow-up letter Field Safety Notice / FSCA 001-21

Affected products displaying the issue:

Product Name	Id-n°	Catalog No	Lot No	Expiry Date
DiaClon Anti-M/N*	51210	006011	51210 10 01	04.2021
			51210 11 01	06.2021
			51210 12 01	09.2021
			51210 12 02	10.2021
			51210 13 02	10.2021
DiaClon Anti-N	50221	007111	50221 05 01	04.2021
			50221 06 01	06.2021
			50221 07 01	07.2021
			50221 07 02	09.2021

*The only impacted well of the card is the anti-N. There is no issue with anti-M and cti well.

Dear Customer,

We would like to share with you an additional information related to this Field Safety Corrective Action released in February 2021.

In our previous communication, we informed you about non-specific reactions which could be observed in the **anti-N well (MNS2)** of the above-mentioned cards with N negative samples (MNS: -2).

Following the investigations on this issue, we are pleased to announce that the identification of the root cause allows us to provide new batches no longer showing the defect described in the FSN 001-21. New batches will be available as indicated in the table below:



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

Product Name	Id-n°	Catalog No	Lot No	Availability
DiaClon Anti-M/N	51210	006011	51210 14 01 (SAP 6167381401)	Mid-July 2021
DiaClon Anti-N	50221	007111	50221 08 01 (SAP 6120430801)	June 2021

We request you transfer this information to all persons impacted in your institution and/or forward it to all locations where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, in the first instance, please contact your local technical support:

[insert local contact information/e-mail address]

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action.

Yours sincerely,

Quality Assurance Representative

Diane Galéa

Marketing Director Immunohematology

Marc Meyer