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April 21st, 2020

Urgent Field Safety Notice

Reverse-Cyte 0.8% Lot 630x20007, Exp. 2020-05-16
FSCA 01-20

Dear valued Customer,

Our records indicate that you have received one of the below mentioned products. Please find herewith and attached guidance and documents regarding a Field Safety Corrective Action with the reference FSCA 01-20 on the below mentioned products.

Products affected:

Product Cat. No.	Product Name	Lot number	Expiry Date
213588	Reverse - Cyte 0.8% A_1,A_2,B,0	630020007	2020-05-16
213591	Reverse - Cyte 0.8% A_1	630120007	2020-05-16
213592	Reverse - Cyte 0.8% A_2	630220007	2020-05-16
213593	Reverse - Cyte 0.8% B	630320007	2020-05-16
213594	Reverse - Cyte 0.8% 0	630420007	2020-05-16
213598	Reverse - Cyte 0.8% A_1,B	630520007	2020-05-16

Description of the problem:

Through our routine vigilance process, we have received feedback for unexpected (false-positive) reactivity with different cells of the products Reverse-Cyte 0.8% A_1,A_2,B,0, ref. 213588, lot 630020007, Exp. 2020-05-16 and Reverse-Cyte 0.8% A_1,B, ref. 213598, lot 630520007, Exp. 2020-05-16.

Until now, cells A_1, B, or 0 were reported to provide false-positive results. Not all kits and not every cell in each of these kits are affected. The rate of false positive reactions in affected kits is variable.

The cause of these unexpected reactions is known and was corrected.

We would like to emphasize that our risk analysis has shown that there is no danger for the patient. The remaining risk is exclusively reduced to an ABO discrepancy with subsequent need for investigation and delay in transfusion. In no case a wrong blood grouping and transfusion of an incompatible blood bag may result due to the test interpretation given that ABO forward typing is a mandatory IH practice.

However, in case of experiencing the above-mentioned ABO discrepancies, we recommend to you **to switch to the use of the new lots 630x20009, Exp. 2020-06-13 for above listed products**.

Please forward this information to your laboratory, to all persons who are working with this product and keep a copy of this letter in your file. We would also ask you to return the attached customer response form by email.

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Course of Action:

- Please forward this information to your laboratory, to all persons who are working with this product.
- Each customer should confirm receipt of this important information by returning the Customer Response Form to our attention.
- Due date for completion: May 8th, 2020.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred to.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We thank you for your comprehension and apologize for any inconvenience this may cause to you.

Yours sincerely,

Sascha Feuerhahn
Technical Director
Medion Grifols Diagnostics AG