FIELD SAFETY NOTICE

Date: 2022-10-31
FSN Ref: 2022-05
FSCA Ref: 2022-05

Urgent Field Safety Notice
ERY Q® KKD/MNS

Dear Customer,

unfortunately, we have to inform you that in the course of completing the production workflow for the IVDR on 30.09.2022, we discovered that the probe for the detection of the rare allele GYPB*03N.01 is false negative. Due to the rarity of the allele, no corresponding genomic DNA sample was previously available for performance testing. In the past, this probe could only be tested positive with a synthetic DNA. This is also noted accordingly in the instructions for use. All batches on the market are affected.
After a risk assessment and for safety reasons, BAG Diagnostics has decided to also remove the rare, untested alleles JK*01N.06 and JK*02N.06 from the kit.
The kit file for the ERY Q® KKD/MNS kit has been revised accordingly and the three rare, untested alleles GYPB*03N.01, JK*01N.06, JK*02N.06 have been removed from the hittable. Thus, the existing kits can be further used with the new kit file.

Please confirm the implementation of this measure on the attached appendix of this Field Safety Notice and return it to us. We apologise for any inconvenience and thank you for your cooperation.

1. Information on Affected Devices	
1.	1. Commercial name(s)
	ERY Q® KKD/MNS
1.	2. Intended purpose of device(s)
	The ERY Q® kits are in vitro diagnostic medical devices for use by professionals in specialised laboratories.The ERY Q® RH, -Partial D, -Weak D, -ABO, -ABO variant and -KKD/MNS kits are intended for second line determination of blood group characteristics using genomic DNA samples from donors, recipients and pregnant women. The molecular genetic second line determination is carried out using the SSP PCR technique and real-time detection (Realtime PCR) of the amplicons. The ERY Q® RH, -Partial D, -Weak D, -ABO und -ABO variant kits must be used exclusively for the second line determination of the respective characteristics. They are used to complement and confirm previous serological findings in case of discrepant or doubtful typing results. The same applies to the determination of Kell (K), Kidd (K) and Duffy (D) characteristics. The test system for the determination of KKD characteristics must only be used for second line determination.The ERY Q® HPA, -HNA and -Rare kits are intended for typing of blood group, platelet and granulocyte characteristics using genomic DNA samples from donors, recipients and pregnant women. The molecular genetic typing is carried out using the SSP PCR technique and real-time detection (Realtime PCR) of the amplicons. For the determination of MNS characteristics using the ERY Q® KKD/MNS Kit and for genotyping of HNA, HPA and rare blood group characteristics using the ERY Q® HPA, -HNA and -Rare Kits, an initial serological pre-typing is not mandatory.
1.	3. Affected serial or lot number range
	REF: 728407 **Lot: QK2031, QK1021**
1.	4.Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	A performance evaluation revealed that the probe for the rare allele GYPB*03N.01 was negative in a false manner.
2.	2. Hazard giving rise to the FSCA
	False negative results or no result output of the PlexTyper software in the presence of the allele GYPB*03N.01.
2.	3. Predicted risk to patient/users
	When using the ERY Q® KKD/MNS kit, false negative results for the rare allele GYPB*03N.01 may occur. According to the current transfusion guidelines in Germany (Richtlinie Hämotherapie 2017 Update-2021), typing for the antigens of the MNS system before transfusion is not mandatory, but an antibody search and, if this is positive, an antibody differentiation in the serum of the recipient is mandatory. In addition, a serological compatibility test (cross test) with patient serum and donor blood is carried out before transfusion, which must be resolved in the positive case. Thus, the risk of

	transfusion of incompatible blood is minimised by the antibody diagnostics prescribed by the haemotherapy guidelines. In the present case of a false-negative reaction for the allele GYPB*03N.01, there is a very small risk of a haemolytic transfusion reaction for the patient if immunisation has already taken place and antibody diagnostics are incorrect.

3. Type of Action to mitigate the risk		
3.	1. Action To Be Taken by the User ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other: **Use of the newly created kit files** ☐ None - Confirm the implementation of this measure on the attached appendix of this Field Safety Notice and return it to us	
3.	2. By when should the action be completed?	**23.12.2022**

	4. Transmission of this Field Safety Notice
4.	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.