Updated RECALL of Urea FS

Possible calibration failure by using Urea FS of below mentioned kits

Date	2023-12-01		
Product / Lot	Urea FS	Product code:	1 3101
		Lots:	34020, 34094, 34578, 34835, 35065
Explanation	Based on a customer complaint the above-mentioned (a.m.) lots of Urea FS have been reviewed. The first internal inspection revealed that absorption may fall below the absorption limit, resulting in a calibration failure specifically on respons [®] analyzers, Sysmex BX-3010 and Sysmex BX-4000. As a consequence, a Field Safety Notice (FSN) was sent to all affected customers. Investigations have been initiated to identify the possible root cause of this failure and to identify any additional potential influences, e.g. on other analyzer systems. Based on these results, the previous recall has to be expanded as it has been shown that all a.m. lots of Urea FS may show a calibration failure on other devices as well . Corrective actions are already implemented to avoid this failure from now on in the future.		
Impact on patient results	Using the a.m. lots of Urea FS calibration may fail and measurements of controls and patient samples cannot be performed. In case no calibration failure has been observed, we can assure that the determination of control and patient samples is not affected, and there are no deviations in results.		
Measures	The a.m. lots of Urea FS are withdrawn from the market.		
	Please immediately inform all involved users about this recall of Urea FS. Immediately stop further measurements and replace the		

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

DiaSys offers replacement for the affected kits.

reagents at the customer's site. Existing stock must be disposed of.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we ask you to fill in and sign the attached confirmation of receipt as proof that you have received and communicated this information to all concerned customers. Please return it by fax or as scan until December 15, 2023.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Kind regards,

Malte Hilsch Strategic Product Management Reagents





2023-12-01

Please confirm that the customer information mentioned below and attached to this mail, has been noted by the responsible person in your company:

Urgent Field Safety Notice – Possible calibration failure by using Urea FS of below mentioned kits

I confirm having forwarded the above-mentioned information to all customers using the mentioned DiaSys product.

Customer/Distributor name:

Contact: (see signature)

Date and signature:

Please return this confirmation via fax (+49-6432-9146 410) or via email (<u>gm@diasys.de</u>) until December 15, 2023.

Thank you for your cooperation.

