# URGENT FIELD SAFETY NOTICE

**Updated RECALL of Urea FS**

**Possible calibration failure by using Urea FS of below mentioned kits**

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| 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.<br>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| Measures | The a.m. lots of Urea FS are withdrawn from the market.<br>**Please immediately inform all involved users about this recall of Urea FS. Immediately stop further measurements and replace the reagents at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits**. | | |

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.

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

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