

URGENT FIELD SAFETY NOTICE

RECALL of Urea FS

Possible calibration failure on respons[®]910, Sysmex BX-3010 and Sysmex BX-4000

Date	2023-11-03
Product / Lot	Urea FS Product code: 1 3101
	Lots: 34020, 34094, 34578, 34835
	Kit lots: 60158408, 60159321, 60159481, 60159267, 60159593, 60160345, 60160779, 60161027, 60162067, 60161349, 60161252, 60161623, 60162216

Explanation Based on a customer complaint the above-mentioned (a.m.) kit lots of Urea FS have been reviewed. The internal inspection revealed that a decrease in calibration signal may occur, resulting in a calibration failure specifically on respons[®]910, Sysmex BX-3010 and Sysmex BX-4000. The potential root cause of this possible failure is under investigation and corrective actions will be taken.

Impact on patient results Using the a.m. kit lots of Urea FS on respons[®]910, Sysmex BX-3010 and Sysmex BX-4000, calibration may fail and measurements of controls and patient samples cannot be performed. In case of no calibration failure, neither control nor patient sample determination will be affected.

Measures The a.m. kit lots of Urea FS are withdrawn from the market.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 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 November 17, 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