



URGENT FIELD SAFETY NOTICE

RECALL of CRP FS

Deviation in recovery in lower concentration range

Date	2023-06-26	
Product / Lot	CRP FS	<p>Cat. No.: 1 7002 ...</p> <p>Lot: 33801/ 50293937, Kit Lot: 60158540, 60158618, 60158731, 60158786, 60158922, 60158937, 60158981, 60159004, 60159088, 60159295</p> <p>Lot: 34108, Kit Lot: 60158891, 60159263, 60159308, 60159309, 60159320, 60159324, 60159498, 60159595, 60159619, 60159634, 60159840, 60159841, 60159892, 60160225</p> <p>Lot: 34574, Kit Lot: 60159445</p>
Explanation	Based on the analysis of a customer complaint the a.m. lots of CRP FS have been reviewed. The internal inspection confirms incorrect recovery of low concentrated samples (<10 mg/L), which leads to false high results. The cause has been traced back to a specific raw material.	
Impact on patient results	CRP FS measurements of patient samples lead to deviating results.	
Measures	<p>The a.m. reagent lots are withdrawn from the market.</p> <p>Please immediately inform all involved users about this recall. Immediately stop further measurements and replace the reagent lots at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits.</p> <p>Determinations performed using a.m. lots of CRP FS shall be assessed with care and repeated if implausible results occur.</p>	

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 2023-07-31.



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

Best regards,



Strategic Product Management Reagents



CONFIRMATION OF RECEIPT

2023-06-27

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

RECALL of CRP FS - Deviation in recovery in lower concentration range

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 e-mail to qm@diasys.de until 2023-07-31.

Thank you for your cooperation.