

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE RECALL

CRP FS Cat. No. 1 7002 ...

Microbiological contaminations in CRP FS (component R2)

Date	September 03, 2019
Product	CRP FS Cat. No.: 1 7002 ..
Lot:	24753, expiry date 2020-01 25005, expiry date 2020-02
Kit Lots:	60122696, 60122773, 60122920, 60122932, 60122949, 60123053, 60123054, 60123191, 60123374, 60123375, 60123489, 60123533, 60123586, 60123685, 60123706, 60123774, 60123789, 60123918, 60123941, 60123985.
Explanation	Based on a customer complaint the a.m. lots of CRP FS have been reviewed. The internal inspection confirms that reagent R2 of the o.m. lots is affected by microbiological contaminations. The cause of the microbiological contaminations was investigated and corrective actions were taken.
Impact on patient results	Using CRP FS reagent lots 25005 or 24753, measurements of controls or patient samples may lead to false low results in a concentration range below 20 mg/L CRP.
Measures	As a safety measure, the above mentioned lots of CRP FS are withdrawn from the market. Please ensure the replacement of the reagent and stop immediately further measurements with CRP FS lot 25005 <u>and</u> lot 24753. Existing stock must be disposed of. DiaSys offers a replacement for the affected CRP FS kits. Results measured with a.m. reagent lots must be verified by using a different lot.

Please inform all users of the affected products immediately.

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DiaSys has announced the urgent 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 would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back to us by fax or as scan until **September 18, 2019**.

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

Kind regards,

Irene Delseith-Hermsdorf
Head of Marketing