

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE RECALL

CRP FS Cat. No. 1 7002 ...

Precipitations in Reagent CRP FS

| | |
|---------------------------|--|
| Date | March 01, 2019 |
| Product | CRP FS Cat. No.: 1 7002 .. |
| Lot: | 23996, expiry date 2019-06 |
| Kit Lots: | 60117962, 60118033, 60118112, 60118192, 60118364, 60118446, 60118472, 60118665, 60118722 |
| Explanation | Based on the analysis of a customer complaint the a.m. lot CRP FS has been reviewed. The internal inspection confirms that reagent R2 show precipitates of previously unknown cause. |
| Impact on patient results | When using CRP FS reagent lot 23996, problems occur in the measurement process. Measurements of patient samples give incorrect results. |
| Measures | As a safety measure, the above mentioned lot of CRP FS is withdrawn from the market. |

Please ensure the replacement of the reagent and stop immediately further measurements with CRP FS lot 23996. 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 **March 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

Confirmation of receipt

Please confirm that the customer information below is received by your facility:

Urgent Field Safety Notice - Recall CRP FS March 2019

Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: _____

Contact person:
(same as signature) _____

Date / Signature: _____

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-167

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

Dringende Sicherheitsinformation - Rückruf CRP FS März 2016

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: _____

Kontaktperson:
(Name des Unterzeichners) _____

Datum / Unterschrift: _____

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Nummer: +49-6432-9146-167

Vielen Dank für Ihre Bemühungen!