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Measures As a safety measure, the above mentioned lot of CRP FS is withdrawn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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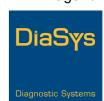
DiaSys has announced the urgent field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

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



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Confirmation of receipt

Vielen Dank für Ihre Bemühungen!

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