CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action

Creatinine PAP FS Cat. No. 1 1759…

Possible deviating results due to coloration of reagent R2

Date	July 12, 2017
Product	**Creatinine PAP FS Cat. No. 1 1759…**
Lot:	The following lots are affected. 23842, expiry date 2018-04 24197, expiry date 2018-06
Explanation	Individual bottles of reagent R2 might have an unusual coloration that can lead to deviating results. The deviation results from a higher reagent blank. Deviating result can only arise if an unaffected R2 bottle is replaced by an affected bottle, or vice versa, without previous recalibration.Thus, the risk is associated only with a change in R2 bottles. The performance of the reagent is not affected.
Impact on patient results	Case 1: An unaffected R2 bottle is used for initial calibration before switching to a miscolored R2 bottle without recalibration. This will result in false high patient values. Case 2: A miscolored R2 bottle is used for initial calibration before switching to an unaffected R2 bottle without recalibration. This will result in false low patient values.
Measures	For above explained reasons please make sure to always perform a control recovery when switching to a new reagent R2 bottle.If the control recovery shows a deviation of more than +/- 15% a recalibration is necessary. Please discuss with the head of laboratory if patient values determined with above mentioned lots should be repeated. **This is a temporary measure, which has to be conducted from lot 23842 onwards until the main cause is fully clarified. We will keep you informed.** **Please inform all users immediately.**

DiaSys Diagnostic Systems GmbH · Alte Strasse 9 · 65558 Holzheim · Germany
www.diasys-diagnostics.com · reagents@diasys.de

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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 **July 26, 2017.**

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

Kind regards,

[redacted]

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