URGENT SAFETY INFORMATION

RECALL

Creatinine PAP FS Cat. No. 1 1759

Incorrect result in patient sample

Date	February 3, 2012
Product	**Creatinine PAP FS Cat. No. 1 1759**
Lot	**15317**
Explanation	Measurement of one patient sample using a.m. reagent lot yielded a highly increased value. The sample was re-tested using other reagent lots as well as other reagents and gave only a slightly high result. Further investigations lead us to assume a deviation on the manufacturing process. In order to prevent any adverse effects, lot 15317 is recalled from the market
Impact on patient results	It is possible that single patient samples give incorrect results.
Measures	Implausible or unexpected results previously measured with a.m. reagent lot should be verified by using a different reagent lot or another method (e.g. creatinine Jaffé). **The a.m. lot must not be used any more. Existing stocks must be disposed of or returned.** The deviating result was only seen with reagent lot 15317. Other lots found correct results. We are working to provide replacement of the affected lot as soon as possible and will inform you promptly.

Please inform all users of the affected lot immediately!

DiaSys has announced the recall to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries; the attached report form may help you.

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 **February 17, 2012**.

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

Best regards,

DiaSys Diagnostic Systems GmbH

[redacted]