

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

Recall

UIBC FS Cat. No. 1 1921 99 10 921

Recall due to mistake during the filling process

Date August 25, 2017

Product **UIBC FS Cat. No. 1 1921 99 10 921**

Lot 23602, expiry date 2018-03

Kit Lot 60117536

Explanation Due to a filling process mistake the compartment of reagent R2 of the twin-container was filled with reagent R1. Therefore, both compartments of the twin-container contain reagent R1.

Impact on patient results The essential chemical reaction process will not take place when using only reagent R1 for the measurement. The control samples will show false high results; approx. 80%. Thus, there is no patient risk if a control recovery is performed according to good laboratory practice.

Measures For explained reason, the above mentioned kit lot of UIBC FS is withdrawn from the market. DiaSys offers replacement for the affected kits.

The above mentioned kit lot must not be used any more. Existing stock must be disposed of.

Please discuss with the head of laboratory if patient values determined with the above mentioned lot should be repeated by using a different lot.

Please inform all users 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 8th, 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,

Dr. Sebastian Runkel
Strategic Product Management