

# 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	<b>UIBC FS    Cat. No. 1 1921 99 10 921</b>
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Measures	For explained reason, the above mentioned kit lot of UIBC FS is withdrawn from the market.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.**

# CUSTOMER INFORMATION

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 8<sup>th</sup>, 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,

████████████████████  
██

## Confirmation of receipt

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

### **Urgent Field Safety Notice - UIBC FS – Recall due to mistake during the filling process – August 2017**

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 - UIBC FS – Rückruf auf Grund eines Fehlers beim Abfüllprozess – August 2017**

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!