

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE RECALL

NEFA FS Cat. No. 1 5781 ..

Falsely low results in the high measuring range

Date August 06, 2015

Product **NEFA FS Cat. No. 1 5781 ..**

Lot: **20025, expiry date 2015-08**

20110, expiry date 2015-09

20211, expiry date 2015-10

20337, expiry date 2016-02

Explanation Controls and patient samples at concentrations above 2 mmol/L show falsely low results when using the above mentioned reagents lots. To avoid a possible impairment, above mentioned lots are being recalled from the market.

Impact on patient results Investigations showed falsely low patient results in the pathological range above 2 mmol/L. Values in the decision range are not affected.

Measures As a safety measure, the above mentioned lots of NEFA FS are withdrawn from the market. DiaSys offers a replacement for the affected kits NEFA FS.

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

Results measured with a.m. lots should be verified by using a different lot.

Please inform all users of the affected products immediately.

CUSTOMER INFORMATION

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.

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 **August 19, 2015**.

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

Kind regards,

██████████

Strategic Product Management



Confirmation of receipt

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

Recall NEFA FS – Falsely low results in the high measuring range

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: +49-6432-9146-32

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

Rückruf NEFA FS – Falsch niedrige Ergebnisse im hohen Messbereich

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: +49-6432-9146-32

Vielen Dank für Ihre Bemühungen!