

URGENT FIELD SAFETY NOTICE

Microbiological contamination in NEFA FS

Date	August 05, 2022
Product / Lot	NEFA FS Lot: 31731 Kit lot: 50278298, 50278299, 60150478, 60150514, 60150605, 60150780, 60151016, 60151079, 60151191, 60151219, 60151351, 60151427, 60151762, 60151801, 60152049, 60152177, 60152390
Product code:	1 5781...
Explanation	Based on a customer complaint the above mentioned (a.m.) kit lots of NEFA FS were reviewed. The internal inspection revealed that the a.m. kit lots are potentially affected by microbiological contamination resulting in significantly reduced calibration signal. The potential root cause of the contamination could be identified and corrective actions are already being established.
Impact on patient results	Using the a.m. kit lots of NEFA FS either calibration cannot be performed or measurements of controls and patient samples will result in deviating results.
Measures	As a safety measure, the a.m. kit lots of NEFA FS are withdrawn from the market. Please ensure the replacement of the reagent and immediately stop further measurements. Existing stock must be disposed of. DiaSys offers a replacement for the affected kits. Determinations, which were performed using a.m. kit lots, should be assessed with care and repeated if implausible results occur.

Please inform all users of the affected products immediately.

DiaSys has announced this 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 by fax or as scan until August 20, 2022.

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

Best Regards,

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CONFIRMATION OF RECEIPT

August 05, 2022

Please confirm that the customer information mentioned below and attached to this mail, has been noted by the responsible person in your company:

**Urgent Field Safety Notice – NEFA FS,
Microbiological contamination in NEFA FS
(component R2)**

I confirm having forwarded the above-mentioned information to all customers using the mentioned DiaSys product.

Customer/Distributor name: _____

Contact:
(see signature) _____

Date and signature: _____

Please return this confirmation via fax +49-6432-9146 410 or via e-mail to qm@diasys.de until August 20, 2022.

Thank you for your cooperation.