



URGENT FIELD SAFETY NOTICE

PRELIMINARY

Microbiological contamination in NEFA FS

Date	July 26, 2022		
Product / Lot	NEFA FS	Product code: 1 5781...	Lot: 31731
Explanation	Based on a customer complaint the a.m. lot of NEFA FS has been reviewed. The internal inspection revealed that the a.m. lot is affected by microbiological contamination and calibration signal is significantly reduced. The cause of these occurrences are under investigation and corrective actions will be taken.		
Impact on patient results	Using the a.m. lot 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Measures	As a safety measure, the a.m. lot of NEFA FS are withdrawn from the market.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. lot, 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 9, 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,

Malte Hilsch

Strategic Product Management Reagents