

20.01.2022

RECALL

Microbiological contamination in NEFA (component R2)

Dear customers,

Article No: LT-FA 0022
Lot: 31011
Expiry: 14.05.2022

Based on a customer complaint the a.m. lot of NEFA has been reviewed. The internal inspection revealed that reagent R2 of the a.m. lot is affected by microbiological contaminations. The cause of the microbiological contaminations is under investigation and corrective actions will be taken.

Impact on patient results:

Using the a.m. lot of NEFA, measurements of controls and patient samples will result in deviating results.

Measures

As a safety measure, the above-mentioned lot of NEFA is withdrawn from the market.

Please ensure the replacement of the reagent and immediately stop further measurements. Existing stock must be disposed of. LABOR + TECHNIK 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.

LABOR + TECHNIK has announced this field safety notice to the relevant authorities of the European Union.

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 February 4, 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



Appendix

Seit über 40 Jahren LABOR + TECHNIK: Qualitäts-Diagnostika preiswert!



Raiffeisenbank Hengersberg-Schöllnach eG
Nr. 181 820 (BLZ 741 616 08)
IBAN: DE75 7416 1608 0000 1818 20
BIC: GENO DEF1 HBW

Österreich:
Raiffeisenbank Großgmain
Nr. 205 955 (BLZ 35 020)
IBAN: AT32 3502 0000 0020 5955
BIC: RVSAAT2S020

Amtsgericht Charlottenburg
HRB 123807 B
Geschäftsführer:
Birgit Lehmann

Sitz: Berlin
UID-Nr. DE268449774

Confirmation of receipt

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

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

Article No: LT-FA 0022
Lot: 31011
Expiry: 14.05.2022

Herewith I confirm that above named customer information reached me and is forwarded to the users of these LABOR + TECHNIK products.

Customer name: _____

Contact person:
(Same as signature) _____

Date / Signature: _____

Please send this document to:

LABOR + TECHNIK
Eberhard Lehmann GmbH
Berlin

Fax-No: 030 / 80 90 26 65
E-Mail: info@lt-sys.de