

08.08.2022

RECALL Microbiological contamination in NEFA

Dear customers,

Article No: LT-FA 0022
Lot: 31731
Expiry: 15.10.2022

Based on a customer complaint the above-mentioned lot of NEFA has been reviewed. The internal inspection revealed that the reagent 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 above-mentioned lot of NEFA, will lead to a significant reduced calibration signal.

Measures

As a safety measure, the above-mentioned lot of NEFA is withdrawn from the market.

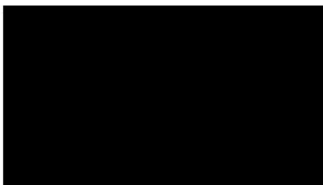
Please ensure the replacement of the reagent and immediately stop further measurements. Existing stock must be disposed of. LABOR + TECHNIK offers a replacement for the affected kits.

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 August 22, 2022.

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



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