



URGENT FIELD SAFETY NOTICE

RECALL of GLDH FS DGKC

Falsely high results in patient samples

Date 2023-11-13

Product / Lot GLDH FS DGKC

Cat. No.: 1 2411

Lot: 34345; Kit Lot: 60159495,
60159796, 60158717, 60158718,
60160610, 60160273, 60158995,
60159539, 60160689, 60159336,
60160288, 60159105, 60159440,
60159806

Lot: 34346; Kit Lot: 60160708,
60161688, 60161574, 60162124,
60162696, 60161156, 60161855,
60161671, 60162523, 60160756,
60162280, 60161274

Lot: 34347; Kit Lot: 60160162, 60160165

Explanation DiaSys Diagnostic Systems GmbH informs about the recall of the above-mentioned (a.m.) lots of GLDH FS DGKC. Based on the analysis of a customer complaint the a.m. lots of GLDH FS DGKC have been reviewed. The internal inspection confirms the incorrect recovery of the quality controls and patient samples. The potential root cause of this possible failure is under investigation and corrective actions will be taken.

Impact on patient results Using the a.m. lots of GLDH FS DGKC cause falsely high results when measured in quality controls or patient samples.

Measures The above-mentioned lots of GLDH FS DGKC are withdrawn from the market.

Please immediately inform all involved users about this recall. Immediately stop further measurements and replace the reagents at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits.

Previously performed determinations using the a.m. lots GLDH FS DGKC shall be assessed with care and repeated if implausible results occur.



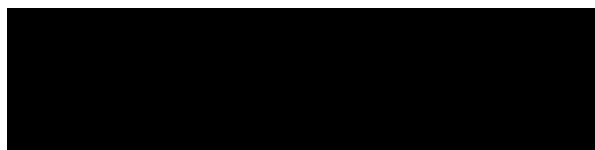
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DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we ask you to fill in and sign the attached confirmation of receipt as proof that you have received and communicated this information to all concerned customers. Please return it by fax or as scan until 2023-11-30.

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

Best regards,



Michel Cardoso da Fonseca

Strategic Productmanagement Reagents