

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	<p>The above-mentioned lots of GLDH FS DGKC are withdrawn from the market.</p> <p>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.</p> <p>Previously performed determinations using the a.m. lots GLDH FS DGKC shall be assessed with care and repeated if implausible results occur.</p>



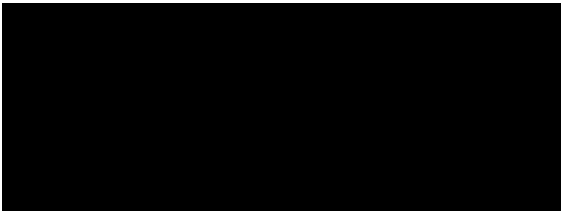
URGENT FIELD SAFETY NOTICE

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 2023-11-24.

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

Best regards,



Strategic Productmanagement Reagents

CONFIRMATION OF RECEIPT

2023-11-13

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

RECALL of GLDH FS DGKC - Falsely high results in patient samples

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 2023-11-30.

Thank you for your cooperation.