

URGENT FIELD SAFETY NOTICE

RECALL of TruCal G6PDH, lot DY003T and DY008T

Deviation of patient results by using TruCal G6PDH, lot DY003T and DY008T

Date	2023-10-27
Product / Lot	TruCal G6PDH Cat. No.: 1 7900 99 10 040, 2 levels Lot: DY003T Lot: DY008T
Explanation	Based on the analysis of a customer complaint the a.m. lots of TruCal G6PDH have been reviewed. The internal inspection confirms falsely high patient results by using the mentioned lots of the calibrator. Control recoveries show no corresponding deviations when using the above mentioned calibrator lots.
Impact on patient results	G6PDH measurements on patient samples lead to falsely high values.
Measures	The a.m. calibrator lots are withdrawn from the market. Please immediately inform all involved users about this recall. Immediately stop further measurements and replace the calibrator lots at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits. Determinations performed using a.m. lots of TruCal G6PDH shall be repeated.

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 2023-12-31.

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

Best regards,

████████████████████
Head of Global Marketing

CONFIRMATION OF RECEIPT

2023-10-27

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

Urgent Field Safety Notice – RECALL of TruCal G6PDH, lot DY003T and DY008T

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 email (qm@diasys.de) until December 31, 2023.

Thank you for your cooperation.