

URGENT FIELD SAFETY NOTICE

INCORRECT CALIBRATION VALUE FOR TRUCAL G6PDH AND FALSE TARGET VALUE FOR TRULAB G6PDH

Date	June 22, 2021
Product / Lot	TruCal G6PDH lot DY002N, art. no. 1 7900 99 10 040 TruLab G6PDH lot DY003N, art. no. 1 7900 99 10 045
Explanation	<p>TruCal G6PDH is a calibrator set consisting of two levels. For level 2 of lot DY002N, an incorrect calibration value was assigned and indicated in the corresponding value sheet. Since the correct calibration value is outside the linearity range of the reagent, reassignment is not advisable.</p> <p>TruLab G6PDH is a control set consisting of three levels. For level 3 of lot DY003N, an incorrect target value was assigned and indicated in the corresponding value sheet. Since the correct target value is outside the linearity range of the reagent, reassignment is not advisable.</p>
Impact on patient results	Patient results based on calibration with TruCal G6PDH lot DY002N are found falsely low. This cannot be detected by recovery of control lot DY003N, since the incorrect calibration value does not allow the detection of the wrong control value.
Measures	<p>For this reason, the above mentioned lots of TruCal G6PDH and TruLab G6PDH are withdrawn from the market. DiaSys offers replacements for the affected lots.</p> <p>Immediately inform all affected users about the issue described above.</p> <p>Stop any further measurement with affected lots of calibrator and control.</p> <p>Discard above mentioned lots.</p> <p>Recalculation of already obtained results is not possible. Repeat measurements performed with calibrator set TruCal G6PDH lot DY002N.</p>

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 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 02.07.2021.

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



CONFIRMATION OF RECEIPT

June 22, 2021

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

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I hereby confirm having forwarded the above-mentioned information to all customers using the mentioned DiaSys products.

Customer name: _____

Contact person:
(same as signature) _____

Date / Signature: _____

Please return this confirmation via fax +49-6432-9146-167 or return via e-mail to qm@diasys.de.

Thank you for your cooperation.