

# URGENT FIELD SAFETY NOTICE

## RECALL of TruCal PCT

### Incorrect absorbance of calibrator

Date	2023-05-25
Product / Lot	TruCal PCT      Cat. No.: 1 7310 99 10 082 Lot: 33713-33718, Kit Lot: 60158521
Explanation	Based on the analysis of a customer complaint the a.m. lot TruCal PCT has been reviewed. The internal inspection confirms incorrect absorbance of the calibrator, which leads to incorrect calibration of the reagent Procalcitonin FS. The root cause is still under investigation.
Impact on patient results	Procalcitonin measurements of controls and patient samples leads to deviating results.
Measures	The a.m. calibrator lot is withdrawn from the market.  <b>Please immediately inform all involved users about this recall. Immediately stop further measurements and replace the calibrator set at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits.</b>  Determinations performed using a.m. lot TruCal PCT shall be assessed with care and repeated if implausible results occur.

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 2023-06-06.

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

Best regards,

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Strategic Product Management Reagents



# CONFIRMATION OF RECEIPT

2023-05-25

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 TruCal PCT - Incorrect absorbance of calibrator

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](mailto:qm@diasys.de) until 2023-06-06.

Thank you for your cooperation.