

## Urgent Field Safety Notice Recall

### TruCal HbA1c liquid

#### False results due to calibration material

Date	April 11, 2017
Product	<b>TruCal HbA1c liquid</b>
Product Code	1 3320 99 10 043
Lot	<b>23047 – 23050</b>
Expiry date	2017-11
Explanation	DiaSys received a single customer complaint on deviating control results in HbA1c measurement with reagent oneHbA1c FS Cat. No. 1 3329 ... The investigation identified as underlying cause the lot 23047 – 23050 of the calibrator TruCal HbA1c liquid.
Impact on patient results	Patient results determined using this calibrator lot might deviate up to 20%. Controls might not indicate false values.
Measures	For explained reason, the above-mentioned lot of TruCal HbA1c liquid is withdrawn from the market. DiaSys offers replacement for the affected kits. <b>The calibrator lot 23047 – 23050 must not be used anymore. Existing stocks must be disposed of.</b> Please discuss possible concerns about results achieved with a. m. lot with your laboratory manager in order to decide on appropriate measures. <b>Please inform all users of the affected products immediately.</b>

DiaSys has announced the urgent field safety notice to the relevant authorities of the European Union. We ask customers outside the EU 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, sign the attached confirmation, and communicate this information to all concerned customers. Please send it back to us by fax or as scan until **April 26, 2017**.

# CUSTOMER INFORMATION

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

Best regards,

Sabine Befard  
Strategic Product Manager

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