

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

PRETERM RECALIBRATION OF oneHbA1c IS FOR INNOVASTAR

Falsely low results in patient samples for HbA1c determinations on InnovaStar

Date	December 5, 2016
Product and Lots	oneHbA1c IS, Cat. No. 1 3329..., lots 89 and 90 Kit lots: 60111036 60111037 60111038 60111039 60111473 60111674 60112212 60113019 60113028
Explanation	Internal measurements for quality assurance have shown that a preterm recalibration of oneHbA1c IS lots 89 and 90 is mandatory to ensure the high quality of analysis. Initial calibrations for lots 89 and 90 stored on "ParamCard" included into the oneHbA1c IS reagent kits show falsely low results for patient samples but an acceptable recovery of controls.
Impact on patient results	Falsely low results (up to -10%) for patient samples are observed whereas recovery of dedicated controls is found within acceptance range.
Measures	Please inform all users about the preterm recalibration of oneHbA1c IS lots 89 and 90 immediately. <i>For customer <u>already using</u> oneHbA1c IS lots 89 and 90 on InnovaStar:</i> Immediately recalibrate your InnovaStar by typing in the recalibration codes (see next page) into the InnovaStar. Do not use the previously stored calibration anymore. <i>For customers going to use oneHbA1c IS lots 89 and 90 <u>in future</u> on InnovaStar:</i> Read in the ParamCard provided together with the reagent kit and immediately type in the recalibration codes from the next page. Instructions for entering the recalibration codes can be found in the manual or in the attached document "Instruction for entering the recalibration codes for oneHbA1c IS".

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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.

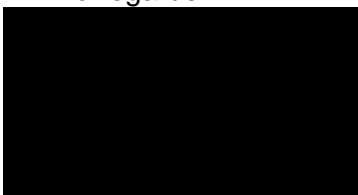
Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until **18.12.2016**.

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

Recalibration codes oneHbA1c IS lot 89 and 90

Parameter	Lot	Expiry Reagent	Recalibration-codes	Security-code	Expiry recalibration
HbA1c	89	2017-07	No change	088	2017-07
			20527444		
			No change		
			41008440		
No change					
HbA1c	90	2017-07	10366364	242	2017-07
			20518328		
			30651308		
			40990317		
			No change		

Kind regards



Confirmation of receipt

Please confirm that the customer information below is received by your facility:

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Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: _____

Contact person: _____
(same as signature)

Date / Signature: _____

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-167

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

DRINGENDE SICHERHEITSINFORMATION

VORZEITIGE REKALIBRATION DES oneHbA1c IS TESTES FÜR INNOVASTAR

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: _____

Kontaktperson: _____
(Name des Unterzeichners)

Datum / Unterschrift: _____

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Nummer: +49-6432-9146-167
Vielen Dank für Ihre Bemühungen!