

# CUSTOMER INFORMATION

## URGENT FIELD SAFETY NOTICE

### Recall of oneHbA1c IS

Date:	March 09, 2018
Product:	oneHbA1c IS, Cat. No. 1 3329...
Kit lots:	60119089 03 006 97, 60119264 03 007 97, 60119656 03 004 98, 60119936 03 004 99, 60120997 03 009 99, 60120999 03 101 02, 60121001 03 102 02, 60121002 03 103 02, 60121004 03 102 01, 60121005 03 105 02
Explanation:	Further investigation concerning the customer information of 04. December 2017 showed, that caused by specific temperature effects, above mentioned kit lots might lead to deviating patient results caused by instabilities of the reagent.
Impact on patient results:	Specific temperature effects might result in falsely decreased patient results in the above mentioned kit lots.
Measures:	<ul style="list-style-type: none"><li>• Please inform all users about the recall of above mentioned oneHbA1c IS kit lots immediately.</li><li>• Exchange and immediately stop further measurements with above mentioned oneHbA1c IS kits lots. Existing stock must be discarded. DiaSys offers replacement for the affected number of kits.</li><li>• Please discuss with the head of laboratory if patient values determined with above mentioned oneHbA1c IS kit lots should be repeated with a new kit lot.</li></ul>

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 **23.03.2018**.

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

Kind regards

Sabine Befard  
Product Management Reagents

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**DiaSys**

Diagnostic Systems

## Confirmation of receipt

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

### Urgent Field Safety Notice - Recall oneHbA1c IS Lots:

60119089 03 006 97, 60119264 03 007 97, 60119656 03 004 98, 60119936 03 004 99,  
60120997 03 009 99, 60120999 03 101 02, 60121001 03 102 02, 60121002 03 103 02,  
60121004 03 102 01, 60121005 03 105 02

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 - Rückruf oneHbA1c IS Lots:

60119089 03 006 97, 60119264 03 007 97, 60119656 03 004 98, 60119936 03 004 99,  
60120997 03 009 99, 60120999 03 101 02, 60121001 03 102 02, 60121002 03 103 02,  
60121004 03 102 01, 60121005 03 105 02

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!