

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

Recall of oneHbA1c FS

Date:	March 09, 2018
Product:	oneHbA1c FS, Cat. No. 1 3329...
Kit lots:	60117738, 60118964, 60119664, 60120059, 60120060, 60120181, 60120481, 60120549, 60120732, 60121284, 60121334, 60122018, 60122403, 60122826
Explanation:	Further investigation concerning the customer information of 04. December 2017 showed, that caused by specific temperature effects, the 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">• Please inform all users about the recall of above mentioned oneHbA1c FS kit lots immediately.• Exchange and immediately stop further measurements with above mentioned oneHbA1c FS kit lots. Existing stock must be discarded. DiaSys offers replacement for the affected number of kits.• Please discuss with the head of laboratory if patient values determined with above mentioned oneHbA1c FS kit lots should be repeated with a new kit lot.

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

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">• Please inform all users about the recall of above mentioned oneHbA1c IS kit lots immediately.• 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.• 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.

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.

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Kind regards

Sabine Befard
Product Management Reagents

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DiaSys

Diagnostic Systems