Head Office: 132, Anyangcheondong-ro, Dongan-Gu, Anyang-si, Gyeonggi-do, 431-836, Korea
Tel.: +82-31-460-0300, Fax: +82-31-460-0401
Web site: www.infopia21.com E-mail: jhseo@infopia21.com

Urgent Field Safety Notice

Information regarding defective Test Cartridges

Commercial name of the affected product: HemoCue® HbA1c 501 System
FSCA-identifier: IP-H-150311-01
Type of action: Device recall

Date: 05.11.2015

Attention: Users of HemoCue® HbA1c 501 System.

One lot of test cartridges manufactured in November 2014 has been found, in some cases, to give elevated results. We have decided to proceed with a recall of the defective devices.

Please read carefully the following information.

Details on affected devices:
Model Name: HemoCue® HbA1c 501 Test Cartridges
Model#.: 405110
Lot#.: F14K12K21DL

The HemoCue® HbA1c 501 System is used for the quantitative measurement of percent concentration of hemoglobin A1c (HbA1c %) in whole blood (capillary and venous). The measurement of hemoglobin A1c concentration is recommended for monitoring the average blood glucose levels, for long-term care of people with diabetes. The HemoCue® HbA1c 501 System is intended to be used in laboratories, clinics and hospitals. *(www.infopia21.com).*

Description of the problem:
In some cases the HemoCue® HbA1c 501 Test Cartridge **lot# F14K12K21DL** gives elevated results. An elevated HbA1c result has in general low immediate impact for the patient and thus the risk for patient injury is marginal.

The root cause has been identified and corrective and preventive actions have been taken.

Advise on action to be taken by the user:
The test cartridge lot# F14K12K21DL, manufactured by Infopia Co. Ltd and distributed by HemoCue AB will be withdrawn and replaced.

Test cartridges still in stock from this lot must not be used and are to be discarded locally by the user. Discarded test cartridges will be replaced by the local distributor.

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Please confirm by **December 11, 2015**, by signing the Product Information Verification form below, that you have read and understood the information in this letter. This confirmation also serves as an information to your local distributor regarding the number of test cartridges to be replaced.

We apologize for any inconvenience this may cause you. If you have any questions regarding this recall, please send an e-mail to local representative or to cuvettes@hemocue.se.

Distributor:

HemoCue AB
Address: Kuvettgatan 1, SE-262 71 Ängelholm, Sweden
Phone: +46 431 48 12 00, Fax: +46 431 48 12 25
E-mail: cuvettes@hemocue.se

[redacted]

Manufacturer:

Infopia. Co.,Ltd
Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea

[redacted]

[redacted]

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Product information Verification form
Identifier: **IP-H-150311-01**

I hereby confirm that I have read and understood the information in this letter concerning HemoCue® HbA1c 501 Test Cartridge lot#. F14K12K21DL.

I confirm that:

- This notice has been passed on to all that need to be aware within my organization.
- I have discarded all remaining test cartridges of lot#. F14K12K21DL.

No. of discarded test cartridges of lot#. F14K12K21DL: .....

Date:.....

Signature:.....

Name in block letters:.....

Institution:.....

Full address:

.....

.....

.....

.....

Please sign and return to:
e-mail: to local representative or cuvettes@hemocue.se
or
fax: +46 77 570 02 13