Ängelholm November 17, 2014

To users of
HemoCue® Glucose 201 Microcuvettes

Urgent Field Safety Notice

Affected products: HemoCue® Glucose 201 Microcuvettes vials
Article number: 110716
Affected lot numbers: 1407345

Identifier: 2014-11-17_GL

Dear Customer

HemoCue has recently become aware of that parts of lot 1407345 of the HemoCue® Glucose 201 Microcuvette have been produced without enzymes in the reagent. Due to lack of enzymes, no reaction will take place in the microcuvette when filled with whole blood. A result of zero mg/dL (or mmol/L) or very close to zero will be shown on the display of the HemoCue® Glucose 201/201^{+} Analyzer upon measurement.

Please note that if you have used any microcuvettes from lot 1407345 and received results within the range expected for the patient, the microcuvette and the performed measurement is not affected by the above problem.

HemoCue AB has taken immediate actions to prevent that this or similar problems can happen again.

Transmission of the Field Safety Notice
Our records indicate you have received the affected lot. This notice should be communicated to all that need to be aware within your organisation. HemoCue kindly request your cooperation in completing the actions below.

What you should do:

1. Please check your inventory and quarantine any remaining vials of the HemoCue® Glucose 201 Microcuvettes from lot 1407345.
2. If you have remaining vials:
    1. Contact your HemoCue local representative to arrange for return of the remaining vials and replacement.
    2. Upon receipt of replacement and return of vials from the affected lot, please complete page 3 of this letter and return to your HemoCue local representative.
3. If you do not have any remaining vials, please complete page 3 of this letter and return to your HemoCue local representative.

HemoCue AB
Visit: Kuvettgatan 1
SE-262 71 Ängelholm
Sweden
hemocue.com

Post: HemoCue AB
P. O. Box 1204
SE-262 23 Ängelholm
Sweden

Phone: +46 431 48 12 00
Fax: +46 431 48 12 25
E-mail: info@hemocue.se
Org no: 556342-9272

Applicable Competent Health Authorities have been notified of this Field Safety Corrective Action.

We apologize for any inconvenience this may cause. If you have any questions regarding this Field Safety Notice, please send an e-mail to cuvettes@hemocue.se.

Yours sincerely,
HEMOCUE AB

Agneta Tufvesson Alm
Global Product Manager Glucose

Ann Jönsson
VP RA/QA

Field Safety Notice Verification form
Identifier: 2014-11-17_GL

I hereby confirm that I have read and understood the information in this Field Safety Notice and that this notice has been passed on to all that need to be aware within my organisation.

Number of remaining vials of HemoCue®
Glucose 201 Microcuvettes Lot 1407345
in stock: .....

All remaining vials returned to
HemoCue local representative (date): .....

Replacement received: .....

Date:.....

Signature:.....

Name in block letters:.....

Institution:.....

Full address:

Please sign and return, no later than Dec 14, 2014, to:
e-mail: << addtion of e-mail adress of local representative>>
or
fax:<<addition of fax number of local representative>>