

Ängelholm, 2013-07-19

To users of the
HemoCue® Urine Albumin
Microcuvettes

Urgent Field Safety Notice

Affected products:

HemoCue® Urine Albumin Microcuvettes
Article number: 110608, 110610, 110611, 110613, 110615, 110616
Within lot number: 1208848 to 1304847

Type of action: Field Safety Corrective Action

Identifier: 2013-07-19_UA

Information regarding defect packaging material for single packed Microcuvettes

HemoCue has recently become aware of a production related problem, which has affected some of the packaging material for Urine Albumin Microcuvettes of the lot numbers mentioned above.

The affected packaging material could potentially lead to Microcuvettes not performing as intended due to exposure to moisture. The root cause of the problem has been identified and the problem has been corrected in the manufacturing process.

Urine Albumin Microcuvettes exposed to moisture will show deviating performance and give high readings.

Microcuvettes from affected lots must not be used and will be replaced with new product. The affected lots are listed in the beginning of this letter. Information on how this will be handled will be provided by your local HemoCue representative.

Transmission of the Field Safety Notice

This notice needs to be passed on to all that need to be aware within your organisation. Please sign the Field Safety Notice Verification form below and return to HemoCue AB.

The HemoCue undersigned confirm that the appropriate Regulatory Agency will be notified.

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

Yours sincerely,
HEMOCUE AB



Magnus Pålsson
Strategic Marketing Manager, Diabetes



Charlotte Bengtsson
Dir Quality & Regulatory Management



Field Safety Notice Verification Form

Identifier: 2013-07-19_UA

I hereby confirm that I have read and understood the information in this Field Safety Notice concerning HemoCue® Urine Albumin Microcuvettes.

I confirm that this notice has been passed on to all that need to be aware within my organisation.

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 12