

Ängelholm, November 03, 2014

To users of
HemoCue® Glucose 201 Microcuvette
single packed and vials

Urgent Field Safety Notice

Affected products: HemoCue® Glucose 201 Microcuvettes single packed and vials
Article number: 110705, 110706, 110715, 110716, 110717, 110718, 110719, 110720
Affected lot numbers: see next page

Identifier: 2014-11-03_GL

Dear Customer

HemoCue has become aware that the referenced HemoCue Glucose 201 Microcuvette lot numbers may, at the end of their shelf-life, yield measurements higher than expected. The higher glucose values may have led to unnecessary insulin treatment or lack of glucose treatment.

The microcuvettes of these specific lots have now passed their expiry date and should have been used, or be discarded.

Please note that no adverse event has been reported related to this matter.

Transmission of the Field Safety Notice

Our records indicate you have received one or more of the affected lots. This notice needs to be passed on to all that need to be aware within your organisation. HemoCue kindly requests your cooperation in completing and returning the enclosed Field Safety Notice Verification Form in order to confirm you receipt of this letter, regardless of whether you have product in your inventory.

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



Maria Fagerberg
Regulatory Affairs Manager



Identifier: 2014-11-03_GL

Affected lots of HemoCue® Glucose 201 Microcuvettes:

110705				
1310500	1310501	1310502	1310503	1310518
1310519	1310520	1310521	1310767	1310768
1310769	1310770	1310771	1310772	1310779
1310780	1310781	1310788	1310789	1310790
1310799	1311524	1311525	1311526	1311527
1311528	1311529	1311530	1311531	1311532
1311533	1311534	1311535	1311536	1311537
1311538	1311539	1311541	1311542	
110706				
1310207	1310208	1310209	1310210	1310211
1310212	1310213	1310214	1310215	1310216
1310228	1310231	1310232	1310234	1310235
1310238	1310239	1310247	1310249	1310250
1310256	1310257	1310258	1310259	1310260
1311270	1311271	1311272	1311273	1311274
1311279	1311280	1311281	1311282	1311283
1311284	1311291	1311296	1311297	1311314
1311315	1311316	1311317	1311318	
110715				
1310217	1310218	1310219	1310221	1310222
1310229	1310230	1310237	1310240	1310241
1310242	1310251	1310252	1311267	1311268
1311269	1311298	1311301	1311302	1311303
1311304	1311321	1311322	1311323	1311324

110716				
1310202	1310203	1310204	1310223	1310224
1310225	1310227	1310243	1310244	1310245
1310246	1310261	1311263	1311264	1311265
1311266	1311277	1311278	1311305	1311306
1311307	1311308	1311309	1311310	1311311
1311312	1311313	1311325		
110717				
1310504	1310505	1310506	1310507	1310508
1310509	1310510	1310514	1310515	1310516
1310517	1310773	1310774	1310775	1310776
1310783	1310784	1310785	1310791	1310792
1310794	1310795	1310796	1311540	1311543
1311544	1311545			
110718				
1310511	1310512	1310513	1310777	1310778
1310786	1310787	1310797	1310798	
110719				
1310236	1310237	1310248	1311285	1311286
1311287	1311288	1311289	1311290	1311292
1311293	1311294	1311295	1311299	1311300
110720				
1310205	1310206	1310226	1310253	1310254
1310255	1311319	1311320		



Field Safety Notice Verification form

Identifier: 2014-11-03_GL

I hereby confirm that I have read and understood the information in this Field Safety Notice concerning measurement deviations and that no more microcuvettes from the concerned lots are available for use.

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