

External Quality Assessment Scheme

## Haemoglobin, 1-level POC analyzers Round 1, 2023

### Specimens

Please find enclosed, according to your order, animal-based sample S001 or sample S002, each 1 mL. Sample S001 is suitable for all other instruments except Hemocue 801 and Hemocue 301. Sample S002 (product 2115) is suitable for the instruments Hemocue 801 and Hemocue 301 only.

### Caution

The quality control sample is bovine based and do not carry any known biohazards for human. However, it should be handled with the same care as a patient sample, i.e. as a potential transmitter of serious diseases.

### Examinations

Hb

### Storage and use

After arrival the samples should be stored at +2...+8 °C. Allow the samples to stand at room temperature for about 20 minutes before analysis. Invert the vial 8-10 times, until the suspension appears homogenous. Do not mix too vigorously. Avoid foam forming in the sample.

Open the vial, turn it upside down and squeeze the vial to get a drop of the sample. Discard the first drop. Analyse as a patient sample. Opened sample should be stored at +2...+8 °C and. It is stable until the round is closed.

### Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S001



S002



2023-02-27

### INSTRUCTIONS

Product no. 2114, 2115  
LQ747123011-012/NL

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi).

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The results should be reported no later than **March 27, 2023.**

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### Inquiries

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### Labquality Oy

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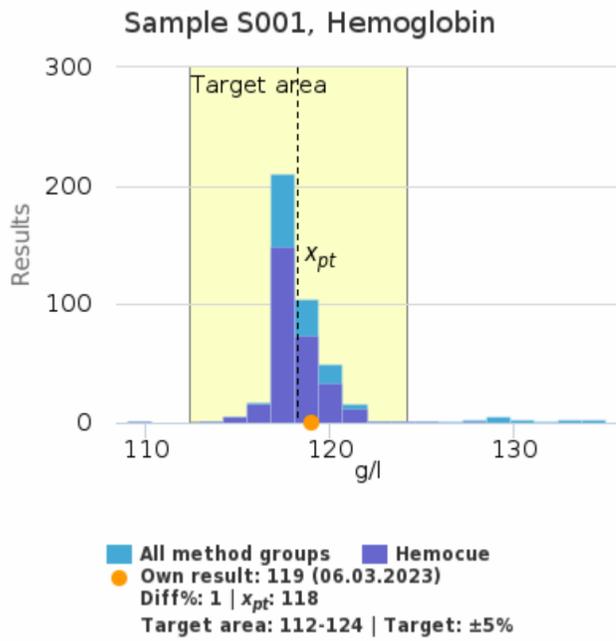
[info@labquality.fi](mailto:info@labquality.fi)  
[www.labquality.com](http://www.labquality.com)



*Only the product 2114 is accredited.*

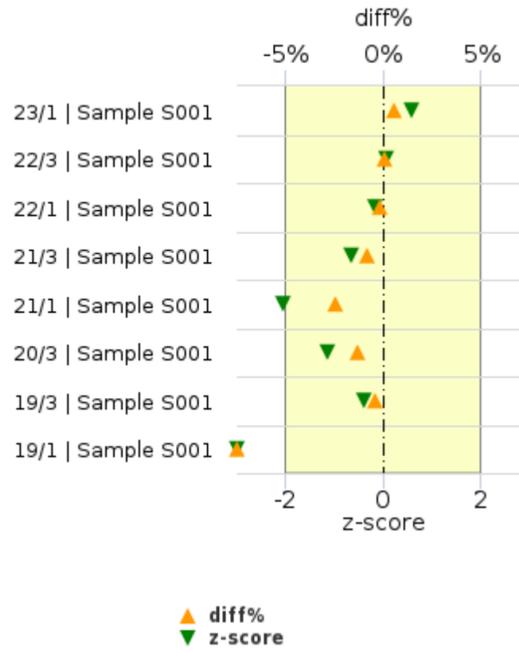


Hemoglobin | Hemocue PNA



	$x_{pt}$	sd	SEM	CV%	n
Hemocue	118 g/l	1	<1	1.1	297
All methods	118 g/l	2	<1	1.3	434

History



Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	118	119	1%	0.57
22/3	Sample S001	159	159	0%	0.06
22/1	Sample S001	78	78	0%	-0.16
21/3	Sample S001	80	79	-1%	-0.64
21/1	Sample S001	120	117	-2%	-2.03
20/3	Sample S001	158	156	-1%	-1.13
19/3	Sample S001	118	117	0%	-0.39
19/1	Sample S001	160	2	-99%	-96.57

**Report info****Participants**

316 participants from 11 countries.

**Report info**

Your own result should be compared to others using the same method.

Assigned values ( $\bar{x}_p$ , target values) are means of the results where results deviating more than  $\pm 3$  standard deviation from the median are removed. The standard uncertainty ( $u$ ) of

the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method.

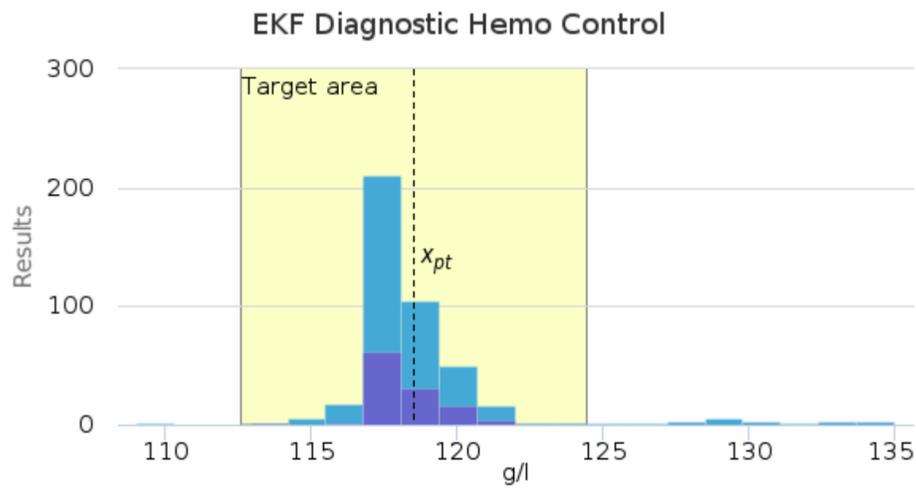
Results reported with  $<$  or  $>$  -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

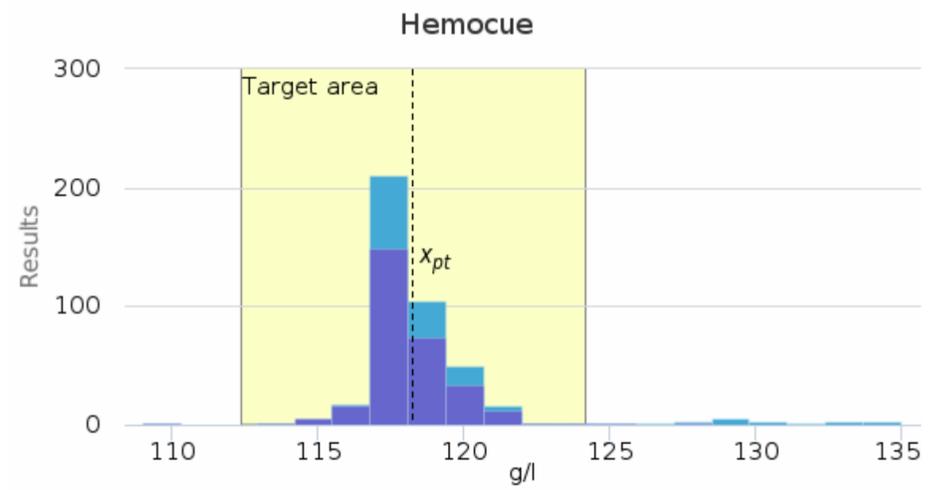
### Sample S001 | Hemoglobin, g/l

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
EKF Diagnostic Hemo Control	119	118	1	0.9	<1	116	121	1	115
Hemocue	118	118	1	1.1	<1	115	122	6	297
QuikRead go	130	130	3	2.1	<1	124	135	-	22
<b>All</b>	<b>118</b>	<b>118</b>	<b>2</b>	<b>1.3</b>	<b>&lt;1</b>	<b>109</b>	<b>127</b>	<b>20</b>	<b>434</b>

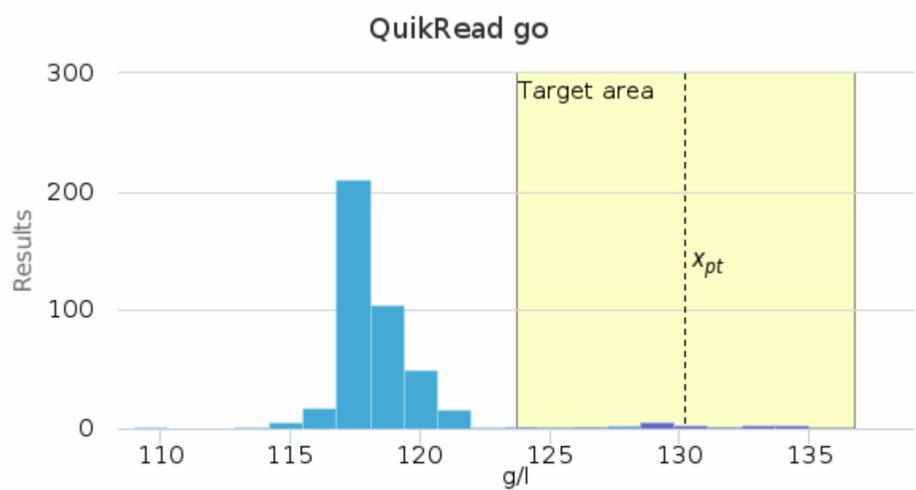
### Sample S001 | Hemoglobin, g/l | histogram summaries in LabScala



■ All method groups ■ EKF Diagnostic Hemo Control ( $x_{pt}$ : 119 | Target area: 113-124 | Target:  $\pm 5\%$ )



■ All method groups ■ Hemocue ( $x_{pt}$ : 118 | Target area: 112-124 | Target:  $\pm 5\%$ )

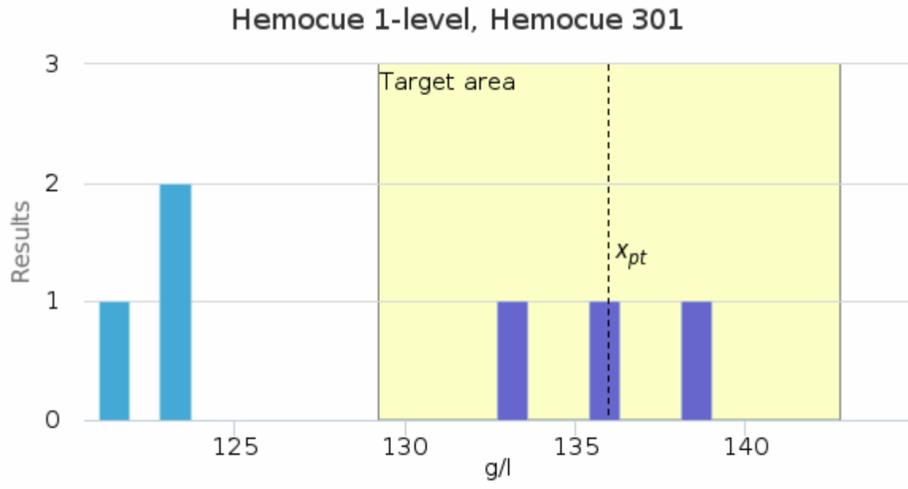


■ All method groups ■ QuikRead go ( $x_{pt}$ : 130 | Target area: 124-137 | Target:  $\pm 5\%$ )

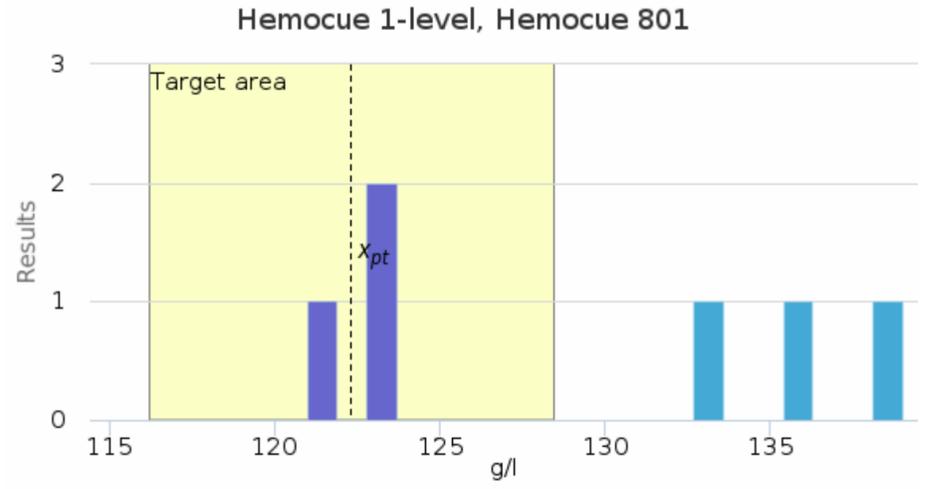
Sample S002, Hemocue 801 & 301 | Hemoglobin, g/l

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Hemocue 1-level, Hemocue 301	136	136	3	2.2	2	133	139	-	3
Hemocue 1-level, Hemocue 801	122	123	1	0.9	<1	121	123	-	3
<b>All</b>	<b>129</b>	<b>128</b>	<b>8</b>	<b>6.0</b>	<b>3</b>	<b>121</b>	<b>139</b>	-	<b>6</b>

Sample S002, Hemocue 801 & 301 | Hemoglobin, g/l | histogram summaries in LabScala



■ All method groups ■ Hemocue 1-level, Hemocue 301 ( $x_{pt}$ : 136 | Target area: 129-143 | Target:  $\pm 5\%$ )



■ All method groups ■ Hemocue 1-level, Hemocue 801 ( $x_{pt}$ : 122 | Target area: 116-128 | Target:  $\pm 5\%$ )

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External Quality Assessment Scheme

## Haemoglobin, 1-level, POCT Round 1, 2023

### Specimens

Samples S001 (LQ747123011) and S002 (LQ747123012) were commercial animal-based hemolyzed samples. Based on the previous tests and the results of this round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

### Report info

Please see the description of the data analysis on the last page of the laboratory-specific histograms and Numerical Summary reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

### Comments – EQA Coordinator

#### Sample S001

The round included 298 Hemocue instruments, 122 EKF Hemocontrol instruments and 22 QuikRead go instruments. Result mean of the sample S001 was 118 g/L. Just like in the previous rounds, the results of QuikRead go (group average,  $X_{pt} = 130$  g/L), were a little higher than those of the Hemocue ( $X_{pt} = 118$  g/L), and EKF Hemocontrol ( $X_{pt} = 119$  g/L) groups. Seven (7) EKF Hemocontrol result and one (1) Hemocue result were rejected before the calculations. These results were probably answered in a wrong unit as the results deviated a lot from other results.

The results of this round were good. Most of the laboratories met the target limits. Within the method groups scattering was small, in all method groups the CV% was less than 5.

#### Sample S002, Hemocue 801 & 301

This round had three (3) Hemocue 801 participants and three (3) Hemocue 301 participants. The sample was different than for the product 2114. As the result levels of Hemocue 801 and Hemocue 301 differ from another, these groups are presented in their own in the calculations and histograms. The group average result ( $X_{pt}$ ) was 122 g/L in the Hemocue 801 group and 136 g/L in the Hemocue 301 group. All the participants met the target limits with ease and the CV% was less than 5 in both methods.

### Annex 1.

Instructions how to proceed if your result is out of the acceptable limits.

### End of report

2023-04-03

### FINAL REPORT

Product no. 2114, 2115

Samples sent	2023-02-27
Round closed	2023-03-27
Final report	2023-04-03

### Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

### Authorized by

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Only product 2114 is accredited.



## Annex 1.

Result outside acceptable limits:

- Please read the meter and strip manual.
- Check that the strips / reagents included in the device are correct and the device is in working order. Check your measurement technique.
- Check and replace strips / reagents that are outdated, wetted, or stored, for example, at the wrong temperature.
- The device's own or unit's internal controls should be used regularly as instructed by the meter manufacturer / laboratory.
- Contact the person in charge at the support laboratory or the device manufacturer.