LABQUALITY

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.

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

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**Inquiries**
EQA Coordinator
Liisa Ylitepsa
liisa.ylitepsa@labquality.fi

**Labquality Oy**
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

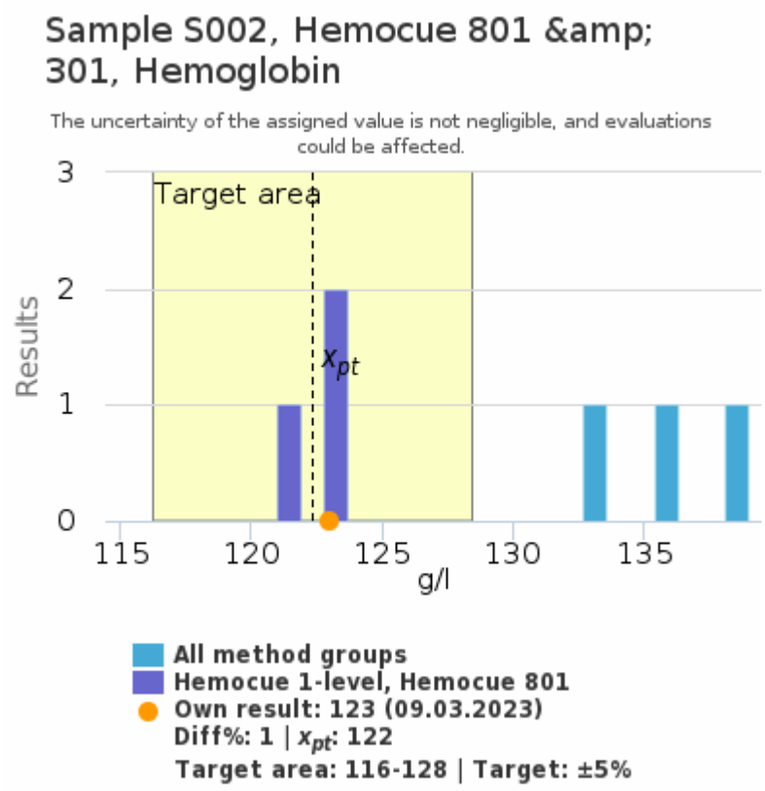
info@labquality.fi
www.labquality.com

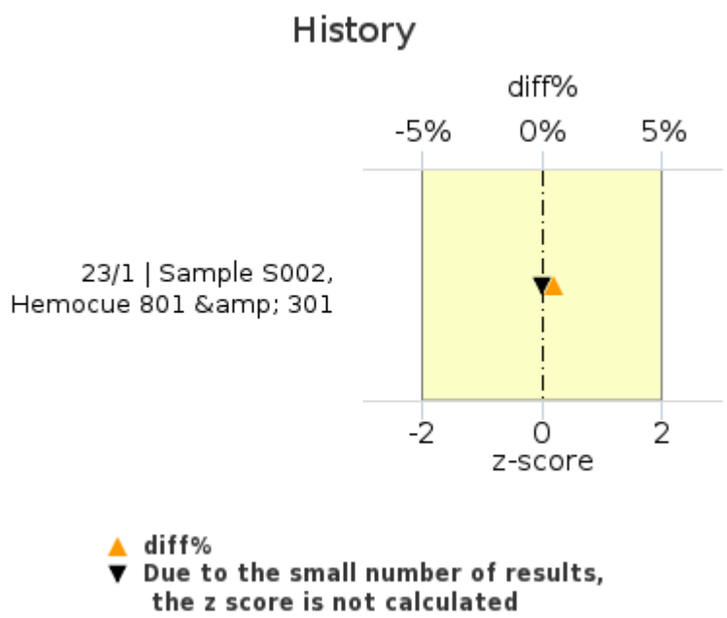
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

*Only the product 2114 is accredited.*

Quality Management
ISO 9001:2015

**Hemoglobin |1131**




| Round | Sample | $x_{pt}$ | Result | diff% | z-score |
|---|---|---|---|---|---|
| 23/1 | Sample S002, Hemocue 801 & 301 | 122 | 123 | 1% | - |

| | $x_{pt}$ | sd | SEM | CV% | n |
|---|---|---|---|---|---|
| Hemocue 1-level, Hemocue 801 | 122 g/l | 1 | <1 | 0.9 | 3 |
| All methods | 129 g/l | 8 | 3 | 6.0 | 6 |

## Report info

### Participants

316 participants from 11 countries.

### Report info

Your own result should be compared to others using the same method.
Assigned values ($x_{pt}$, target values) are means of the results where results deviating more than +/- 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 " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

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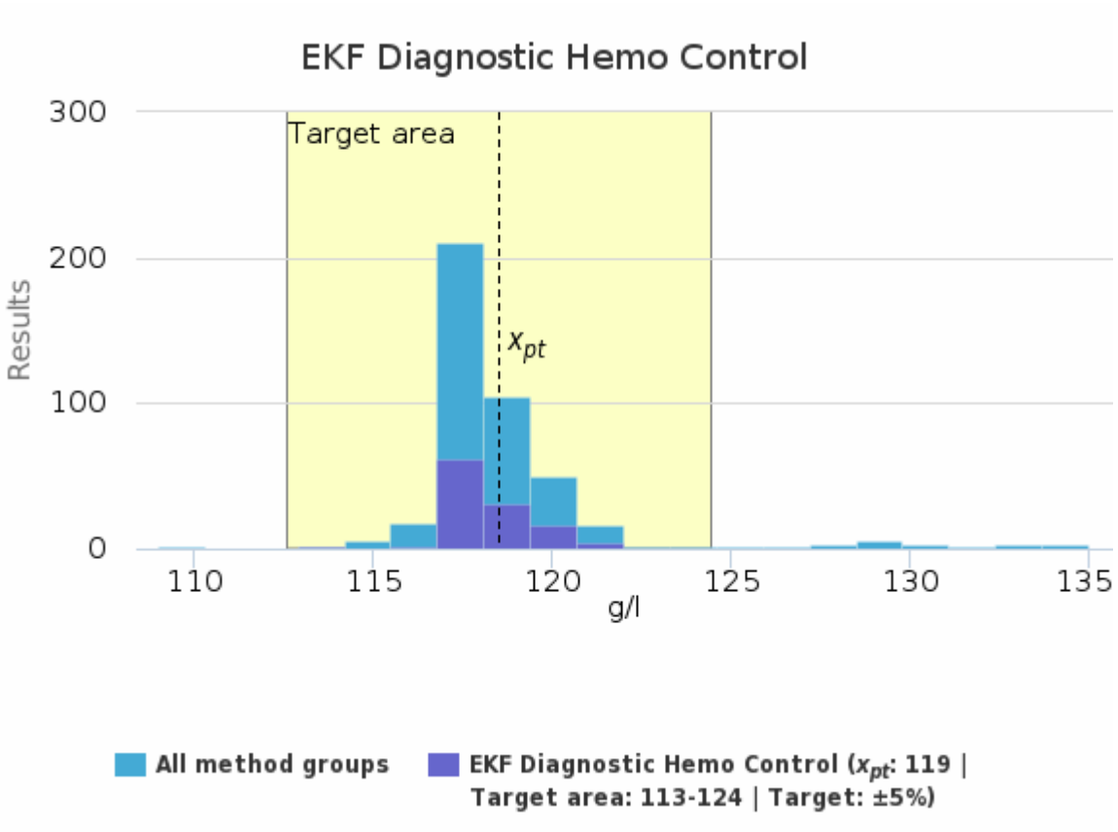
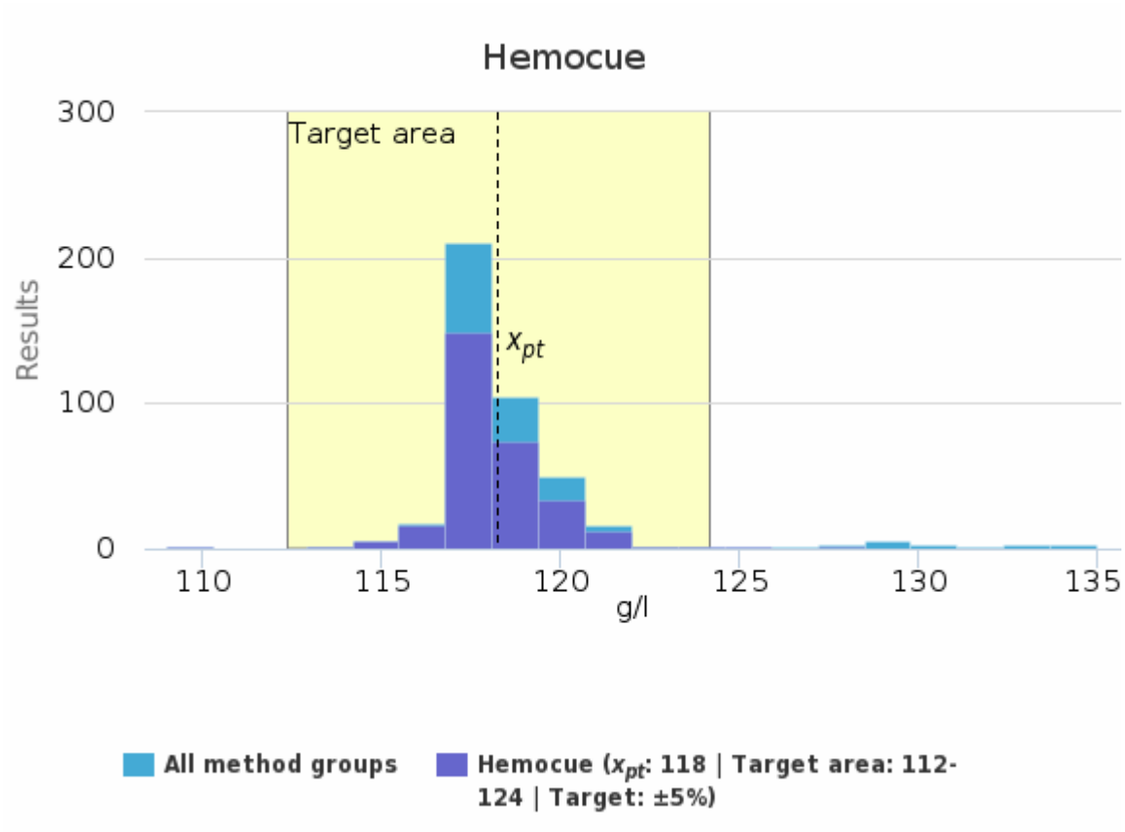
# Haemoglobin, POC, March, 1-2023

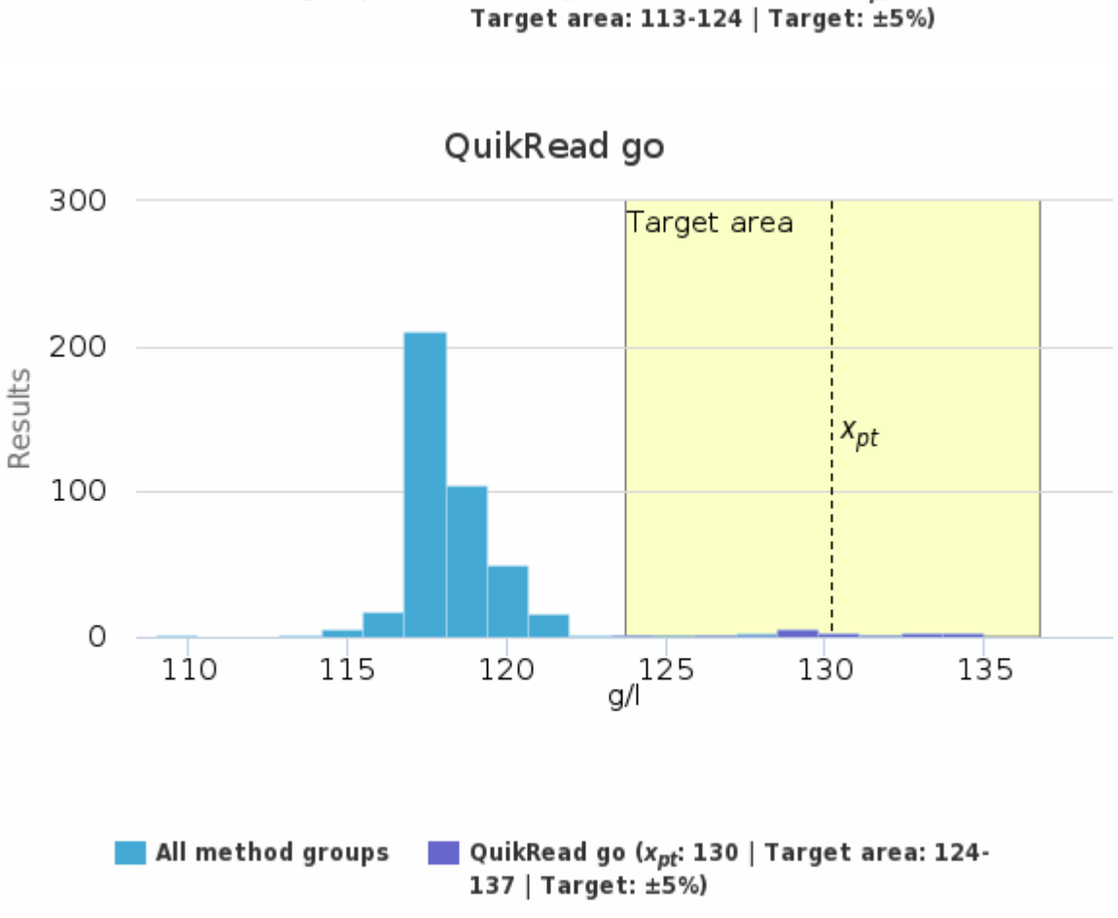
## Sample S001 | Hemoglobin, g/l

| 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 |
| **All** | **118** | **118** | **2** | **1.3** | **<1** | **109** | **127** | **20** | **434** |

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



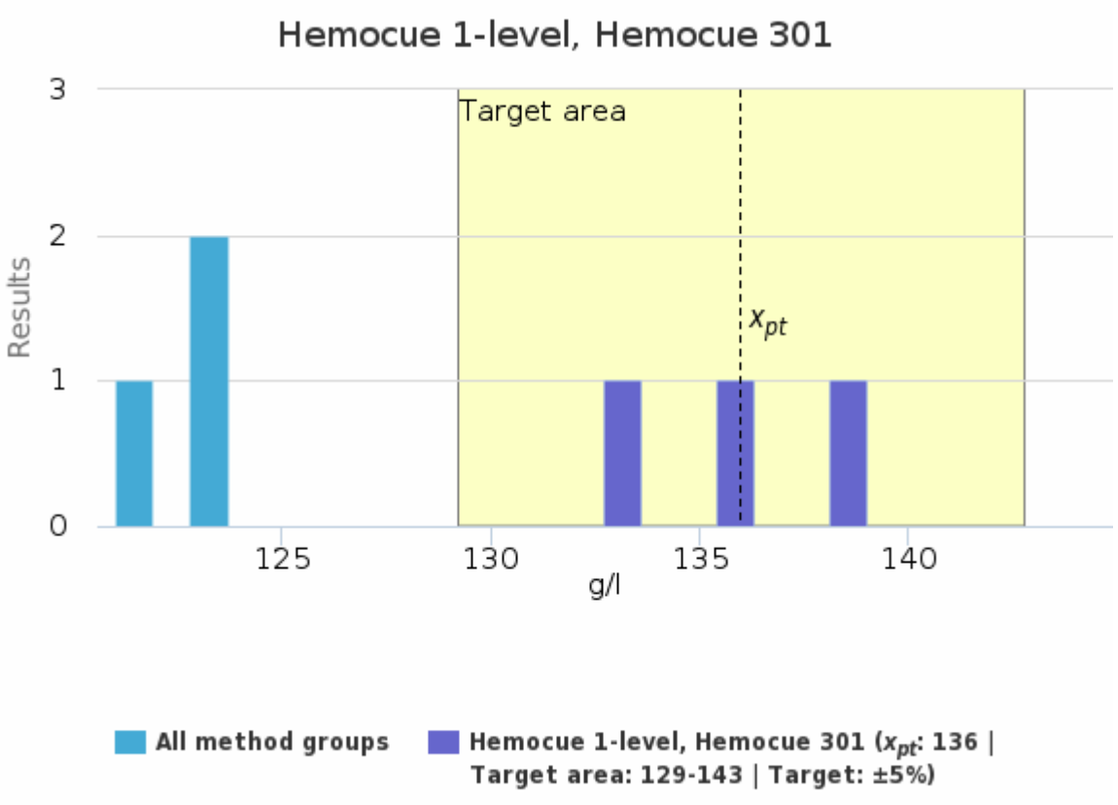



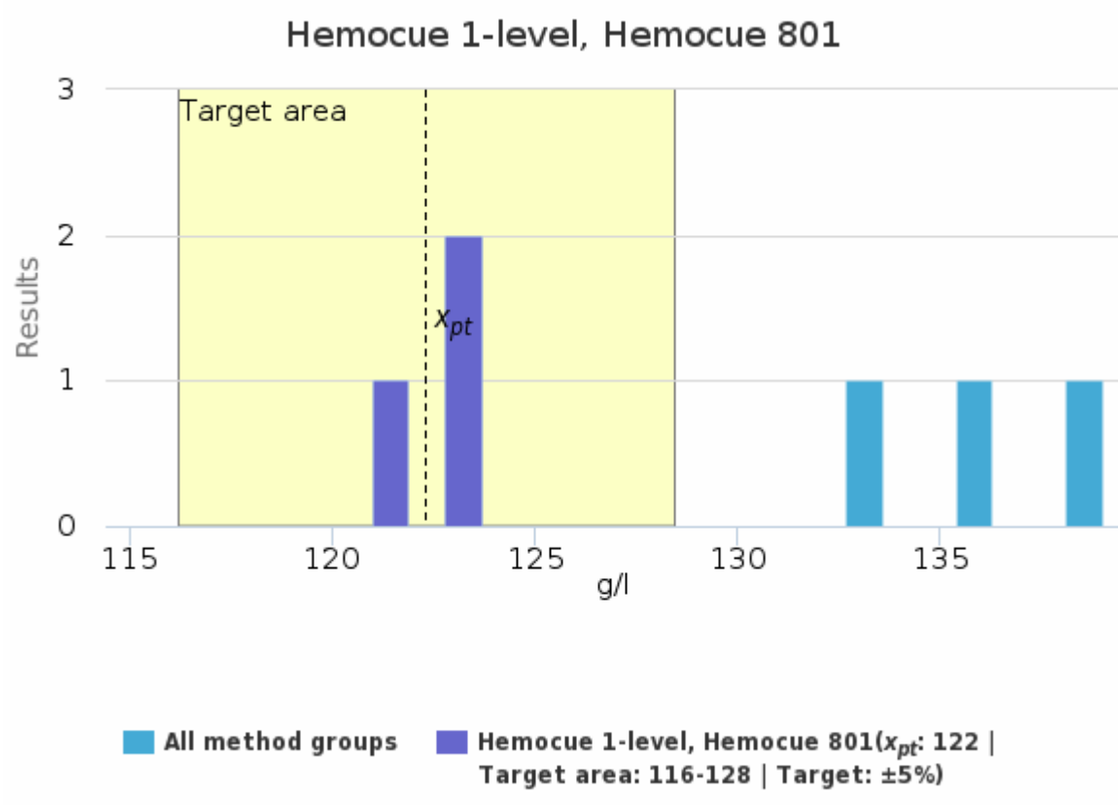



## Sample S002, Hemocue 801 & 301 | Hemoglobin, g/l

| 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 |
| **All** | **129** | **128** | **8** | **6.0** | **3** | **121** | **139** | **-** | **6** |

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



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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, Xpt = 130 g/L), were a little higher than those of the Hemocue (Xpt = 118 g/L), and EKF Hemocontrol (Xpt = 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 (Xpt) 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**
EQA Coordinator
Liisa Ylitepsa
liisa.ylitepsa@labquality.fi

**Labquality Oy**
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

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**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.