LABQUALITY

External Quality Assessment Scheme

Ketones (beta-hydroxibutyrate), Round 1, 2023

Specimens
Please find enclosed 2 liquid human-based samples S001 and S002, each 0.4 mL.

Caution
Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations
beta-hydroxibutyrate

Storage and use
Store unopened vials in a refrigerator (+2…8 °C). Unopened samples are stable until the round is closed. Allow samples to stand for at least 15 minutes at room temperature before use. Roll the tube gently back and forth for 20-30 seconds, occasionally inverting. Do not shake. Avoid foam formation. Open the vial, turn it upside down and squeeze the vial to get a drop of the sample. Discard the first drop. Analyze as a patient sample. Once opened samples are analyzable for 2 days when stored at +2 ... 8 °C.

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. Please insert expire date and lot-number of used strip or reagent to LabScala. If you are answering results from a clinical chemistry analyzer (i.e. other than POC devices) please select in the Strip manufacturer column OTHER and in Strip-column No strip.

S001

S002

2023-05-15

INSTRUCTIONS

Product no. 2526
LQ735023011-012 /UK

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 **June 15, 2023.**

Inquiries
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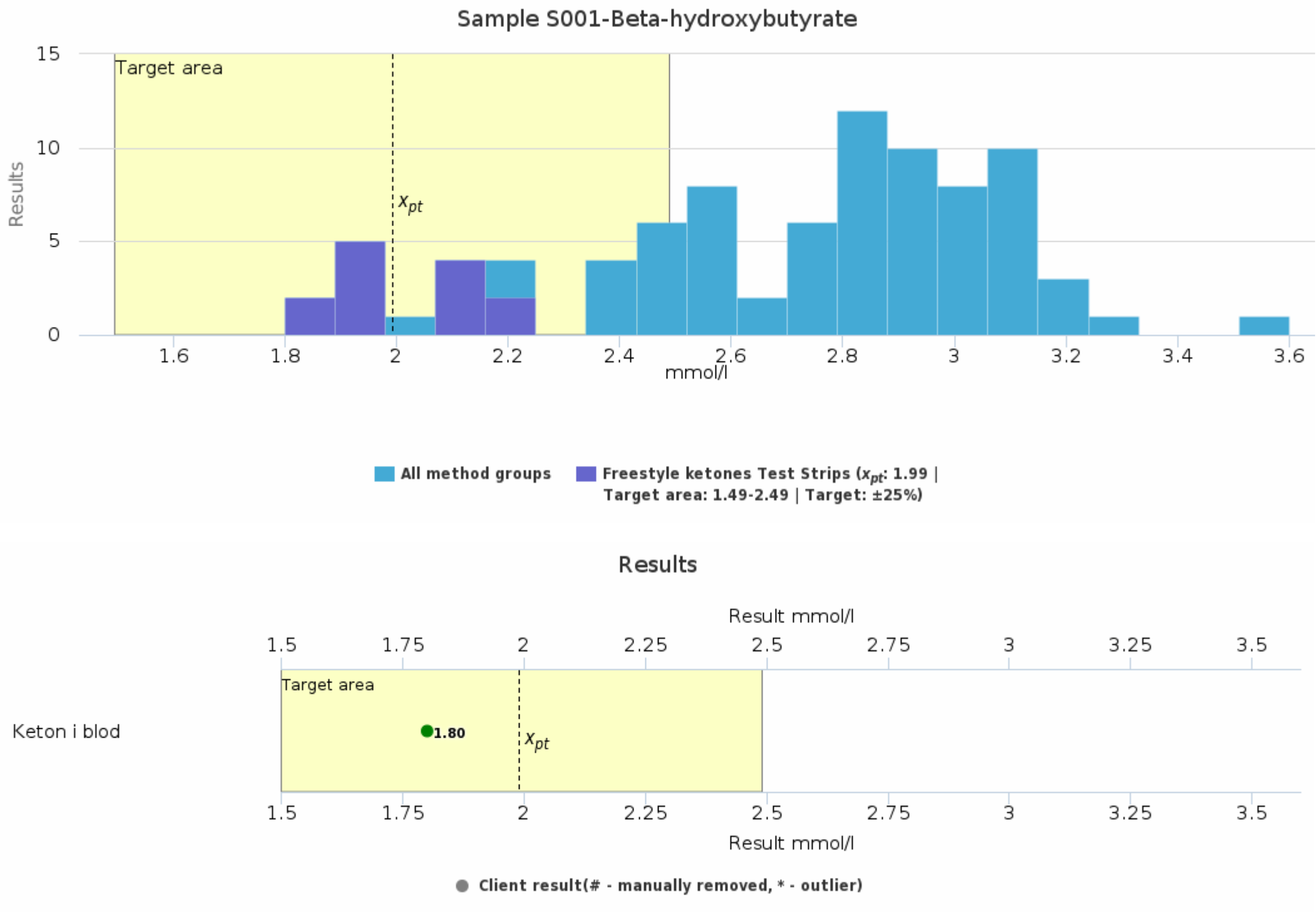
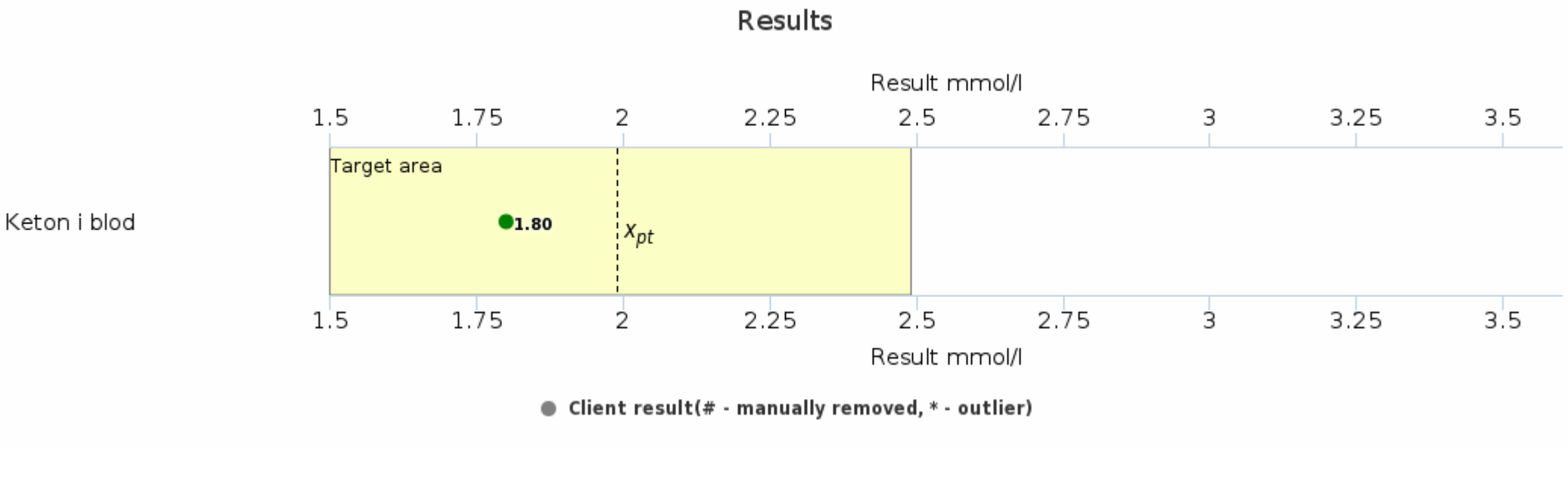
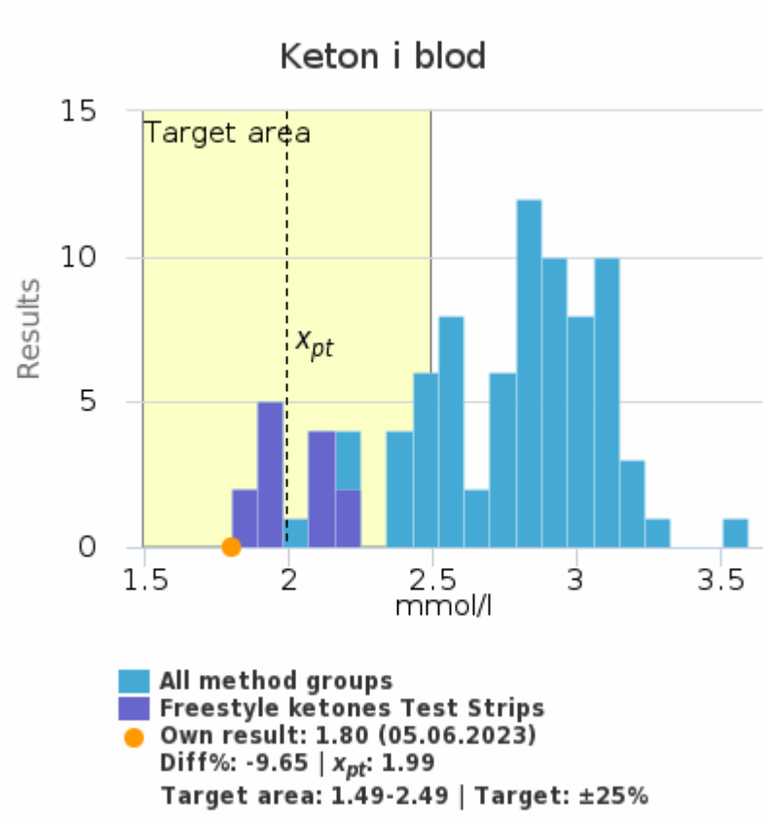
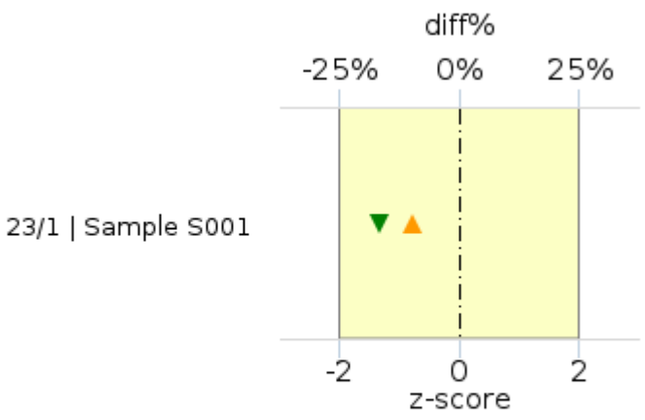
Sample S001|Beta-hydroxybutyrate |Freestyle ketones Test Strips





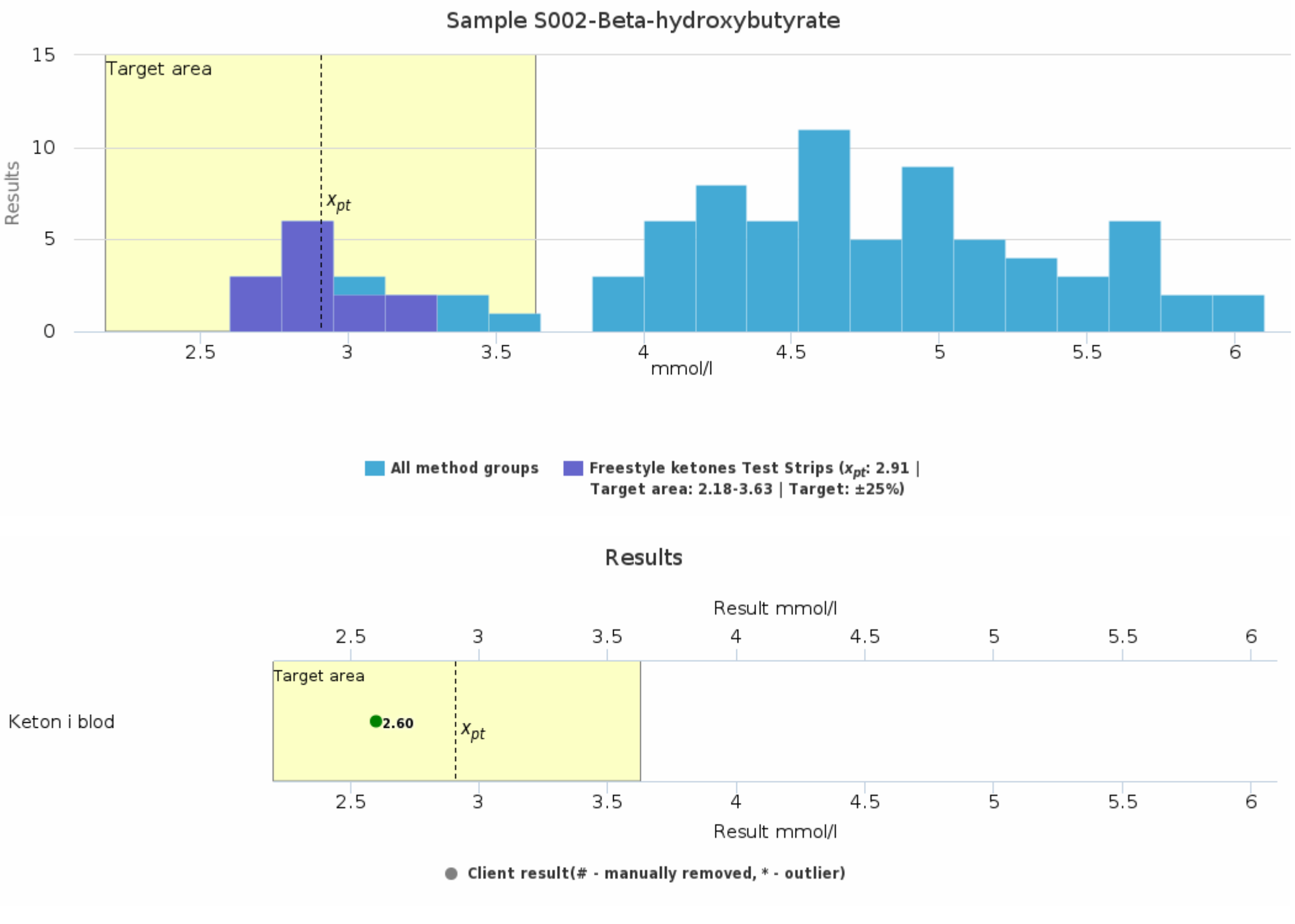
Sample S001|Beta-hydroxybutyrate |Device specific histograms in LabScala



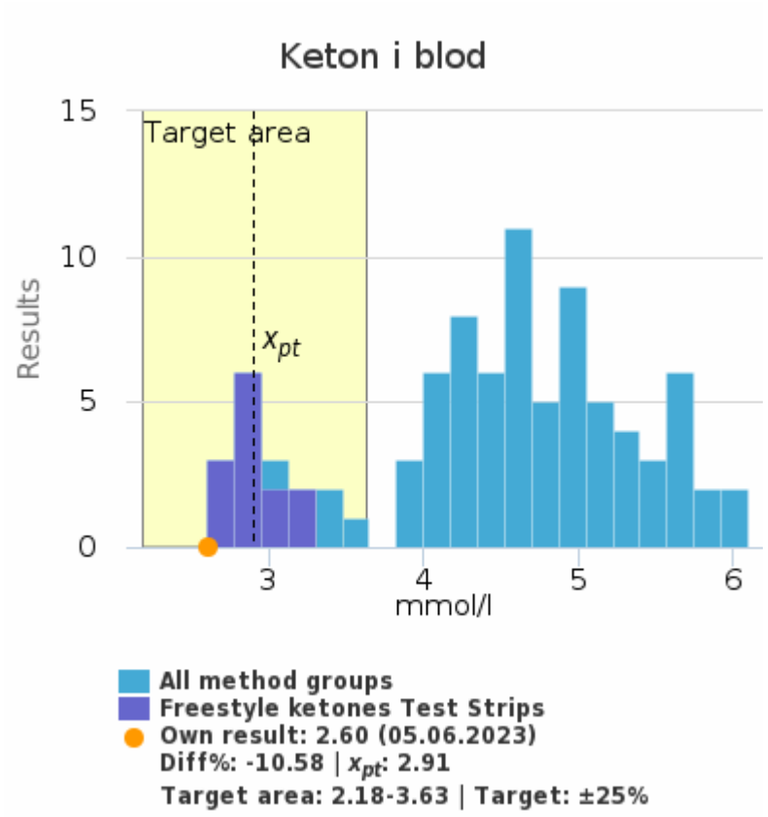


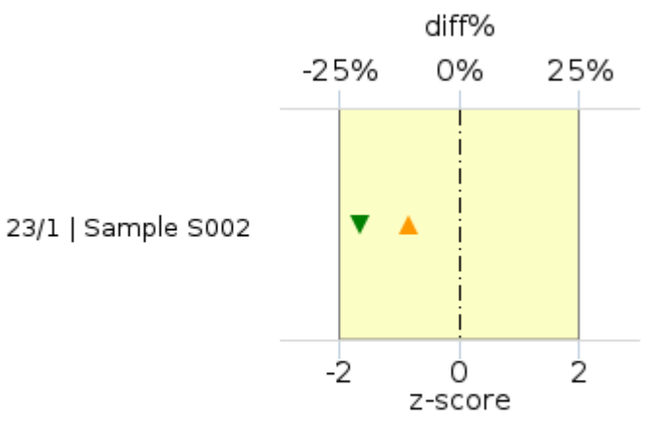
Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S001	1.99	1.80	-9.65%	-1.33

Sample S002|Beta-hydroxybutyrate |Freestyle ketones Test Strips



Sample S002|Beta-hydroxybutyrate |Device specific histograms in LabScala





Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	2.91	2.60	-10.58%	-1.67

Report info

Participants

72 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" in LabScala User instructions

If your quality control result falls outside the acceptable range or below the measuring range, attention should be paid to the technique of analysis:

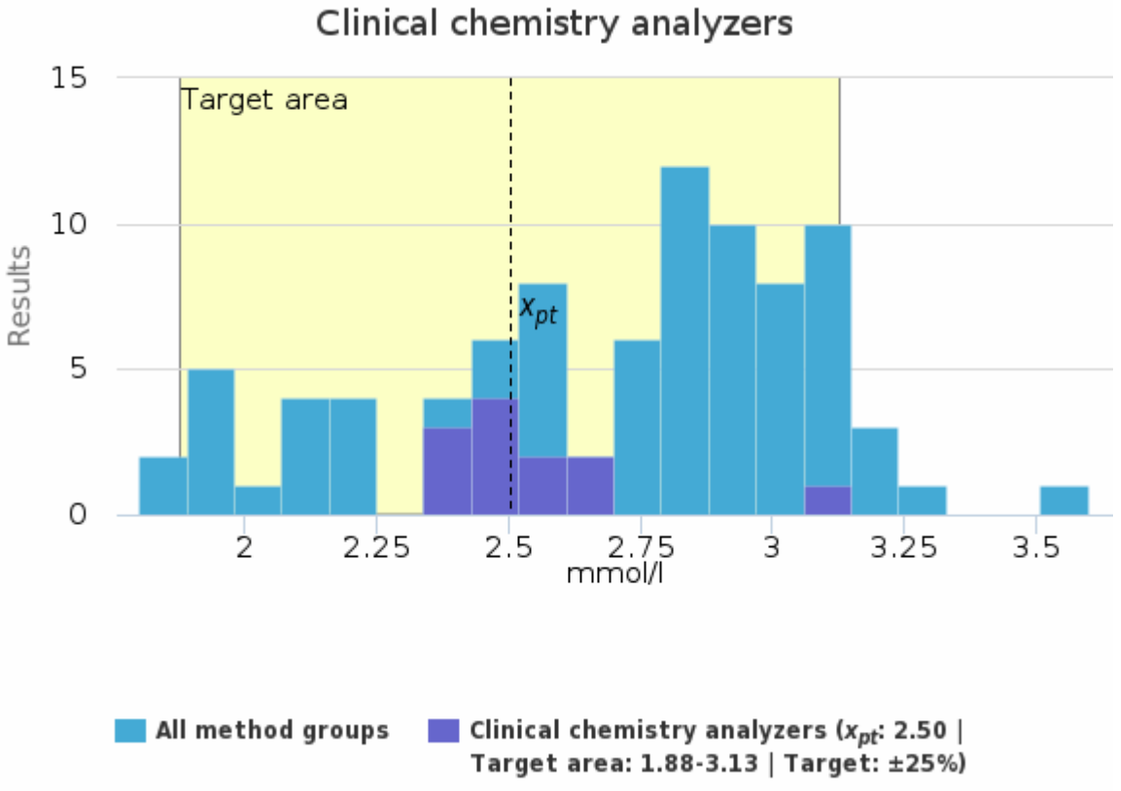
Read the operating manual and check the technique
Check the compatibility of the strips and the meters
Clean the meter according to the manufacturer instructions
If a strip batch-specific coefficient is used for the meter, check that the coefficient is correct or that the meter has been calibrated for the strip batch it is intended to use
Change the strip batch if it is spoilt (e.g. due to moisture, wrong storage or it’s expiration date is over)
Control solutions should be used regularly
If your result is below the measurement range, check the lowest detection limit of the meter.

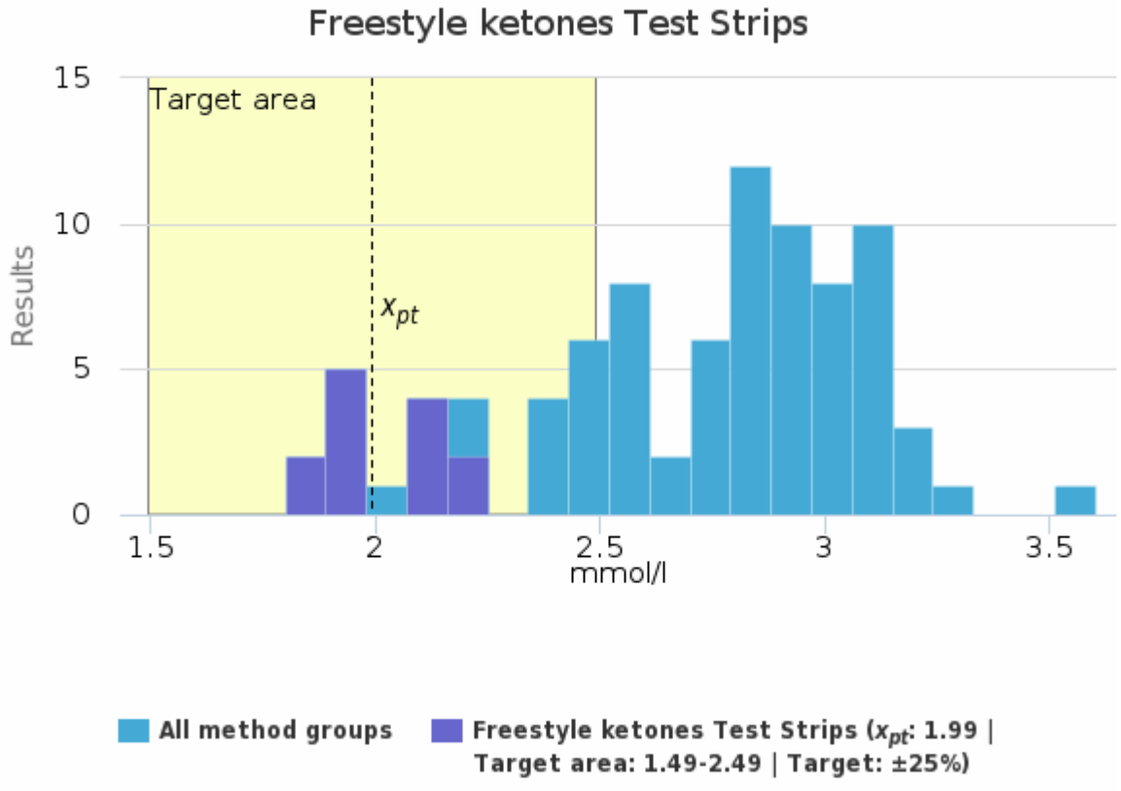
Ketones (beta-hydroxybutyrate), March, 1-2023

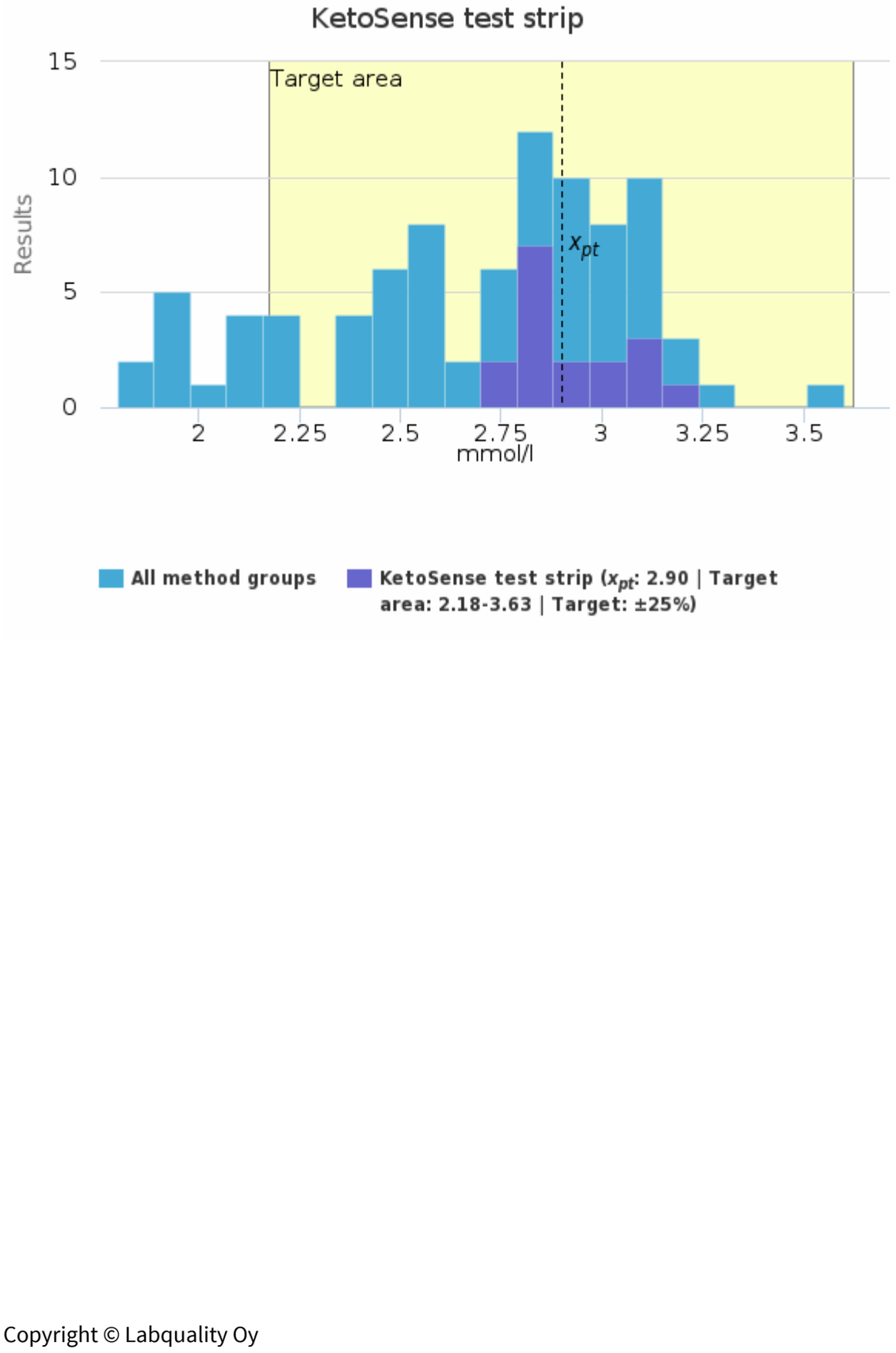
Sample S001 | Beta-hydroxybutyrate, mmol/l

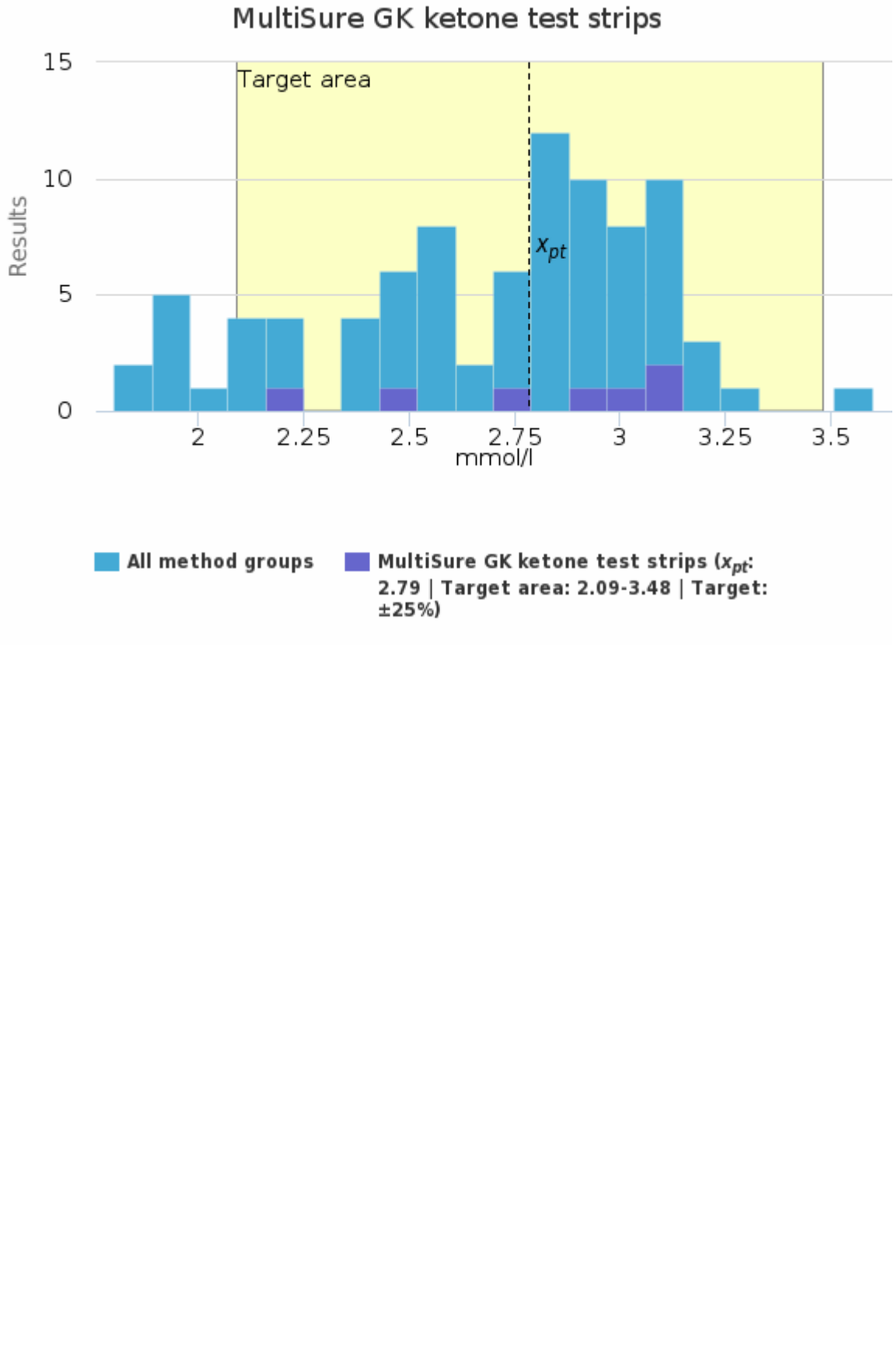
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Clinical chemistry analyzers	2.50	2.50	0.10	3.8	0.03	2.39	2.67	1	12
Freestyle ketones Test Strips	1.99	1.90	0.14	7.2	0.04	1.80	2.20	-	13
KetoSense test strip	2.90	2.80	0.15	5.3	0.04	2.70	3.20	-	17
MultiSure GK ketone test strips	2.79	2.90	0.34	12.2	0.13	2.20	3.10	-	7
StatStrip ketone test strip	2.95	2.90	0.26	8.8	0.05	2.40	3.60	-	23
Wellion LEONARDO KET test strips	2.66	2.70	0.27	10.2	0.07	2.00	3.00	-	15
All	**2.68**	**2.80**	**0.39**	**14.6**	**0.04**	**1.80**	**3.60**	**-**	**87**

Sample S001 | Beta-hydroxybutyrate, mmol/l| histogram summaries in LabScala

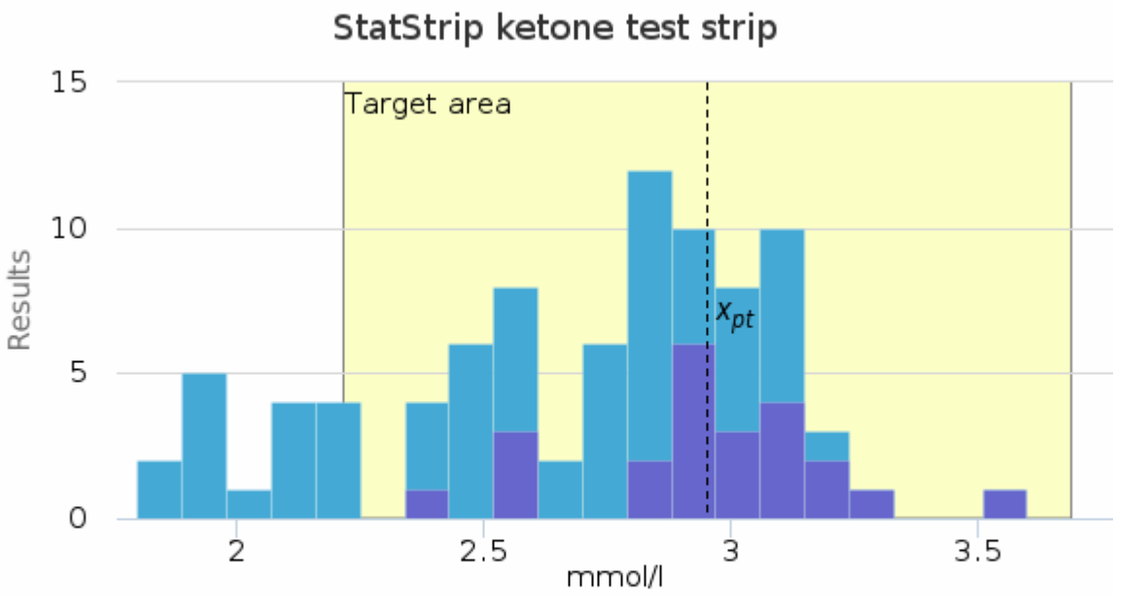


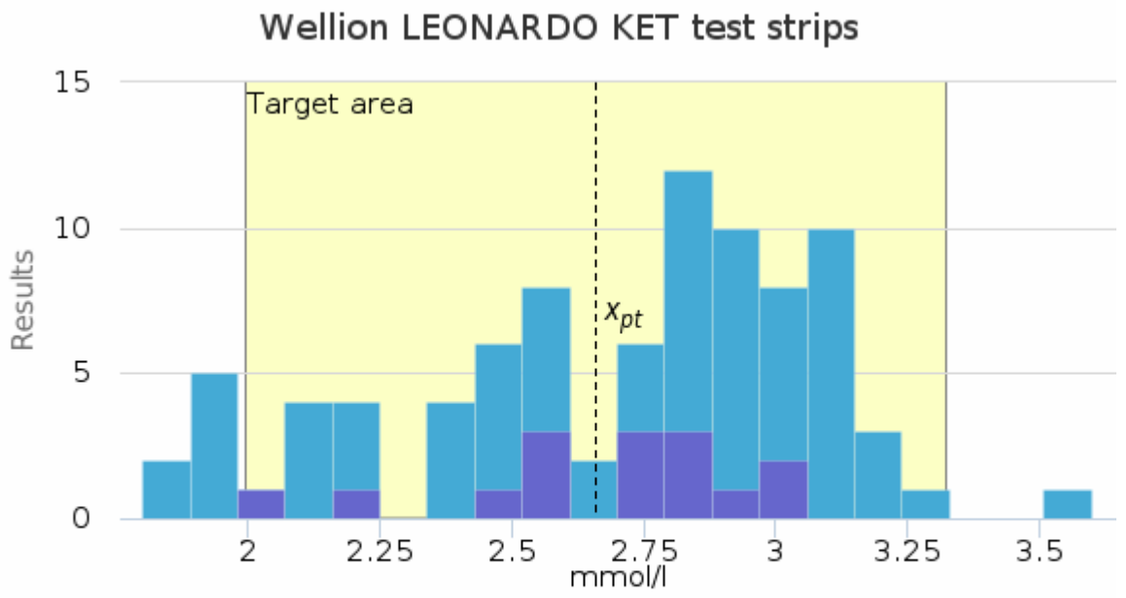






Ketones (beta-hydroxybutyrate), March, 1-2023

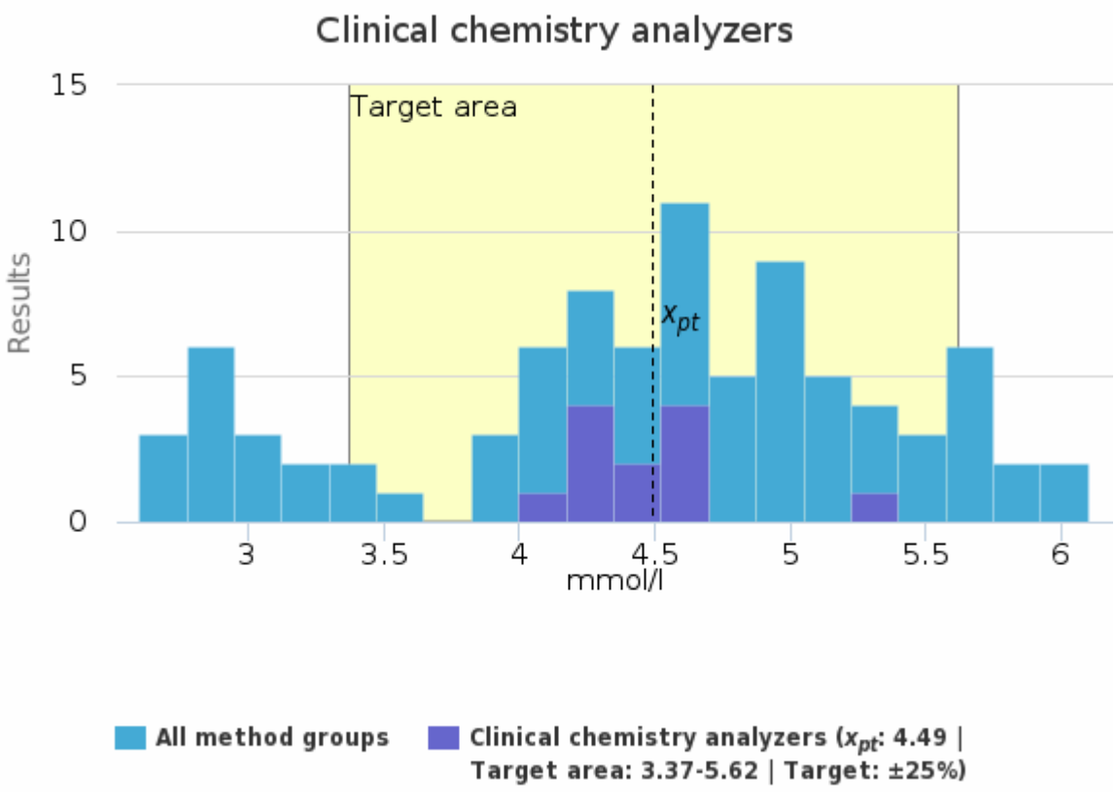


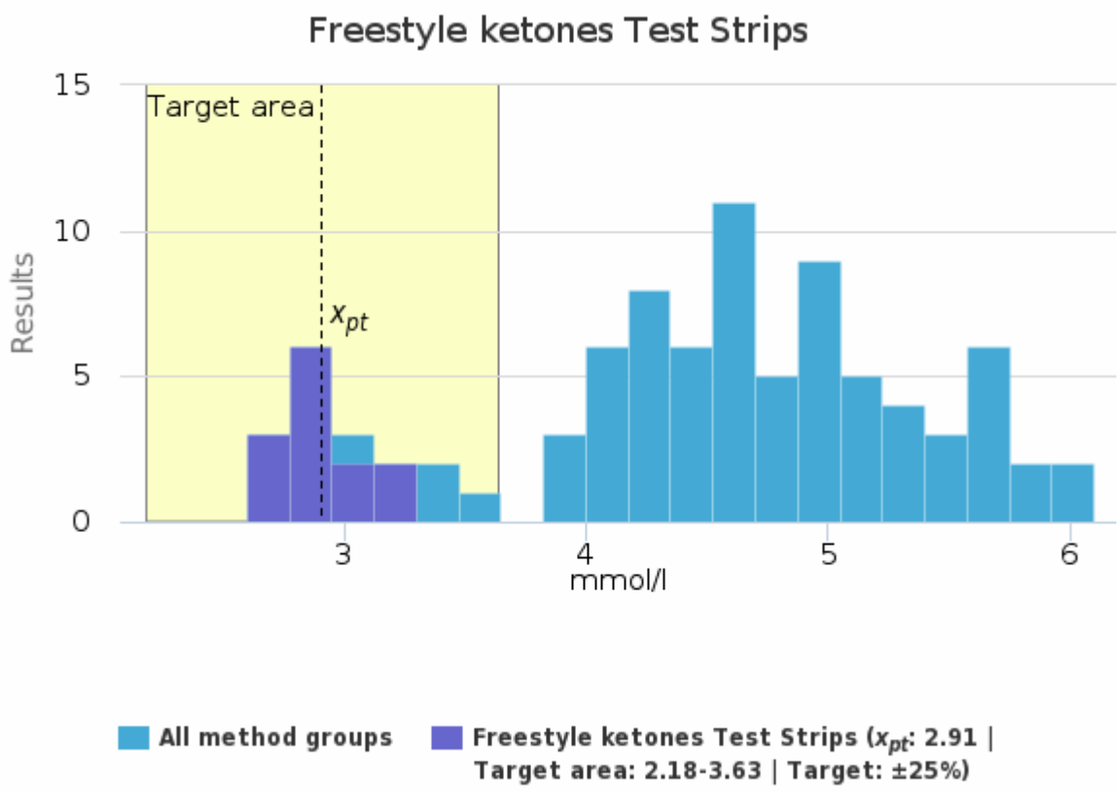


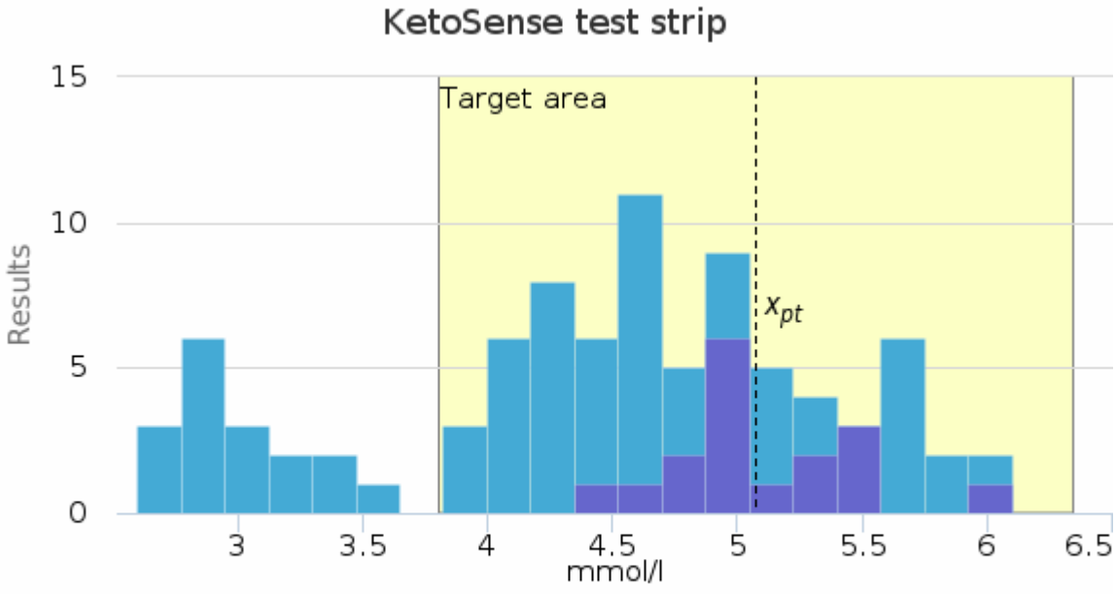
Sample S002 | Beta-hydroxybutyrate, mmol/l

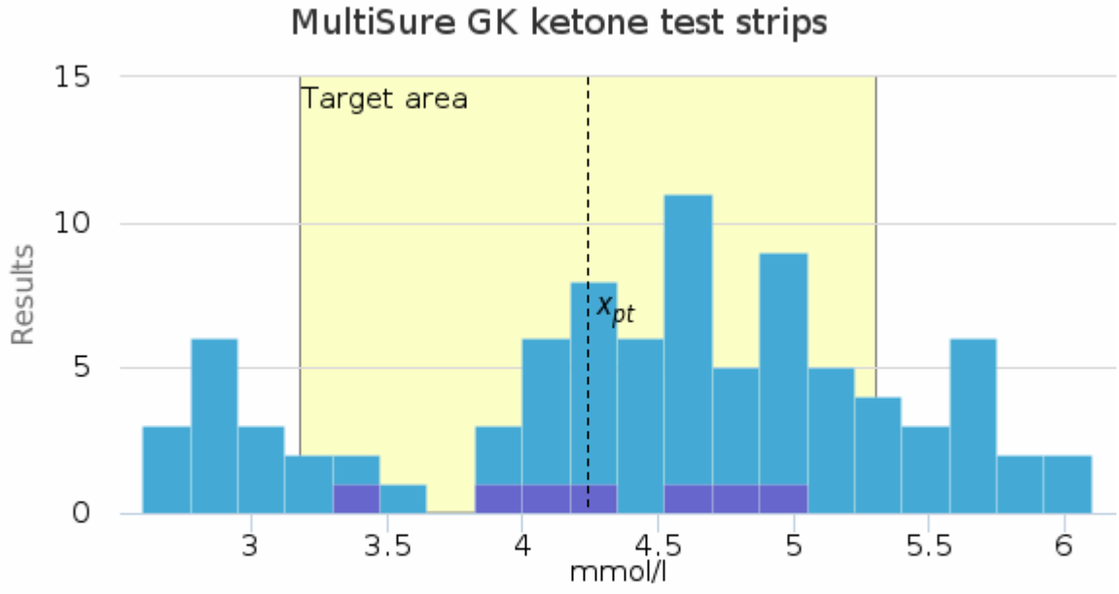
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Clinical chemistry analyzers	4.49	4.50	0.34	7.6	0.10	4.05	5.36	-	12
Freestyle ketones Test Strips	2.91	2.90	0.18	6.4	0.05	2.60	3.20	-	13
KetoSense test strip	5.08	5.00	0.36	7.2	0.09	4.50	6.00	-	17
MultiSure GK ketone test strips	4.24	4.20	0.53	12.4	0.20	3.40	4.90	-	7
StatStrip ketone test strip	5.12	5.10	0.63	12.3	0.13	3.90	6.10	-	23
Wellion LEONARDO KET test strips	4.13	4.30	0.49	11.9	0.13	3.00	4.70	-	15
All	**4.45**	**4.60**	**0.88**	**19.9**	**0.09**	**2.60**	**6.10**	**-**	**87**

Sample S002 | Beta-hydroxybutyrate, mmol/l| histogram summaries in LabScala

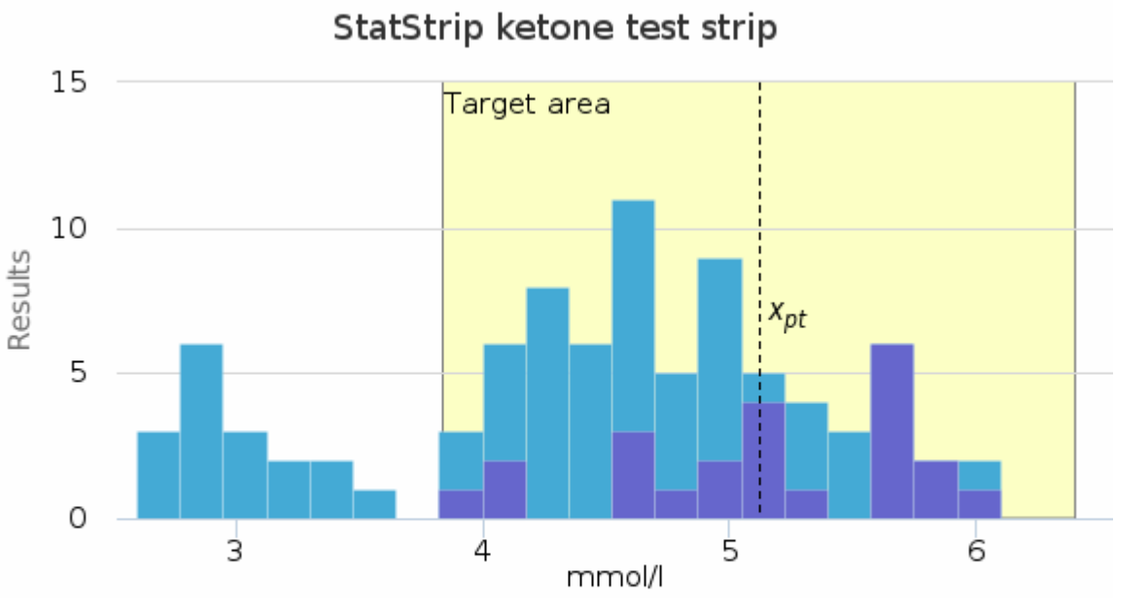


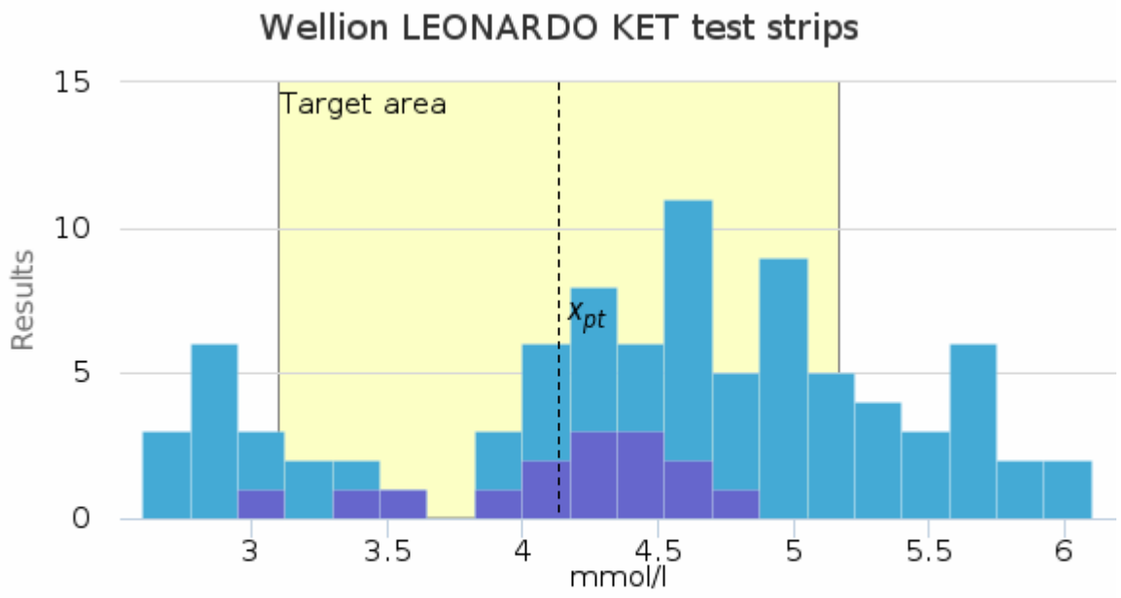






Ketones (beta-hydroxybutyrate), March, 1-2023





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LABQUALITY

External Quality Assessment Scheme

Ketones (beta-hydroxybutyrate), POCT Round 1, 2023

Specimens
Sample S001 (LQ735023011) and Sample S002 (LQ735023012) were liquid products of human origin.

Based on the pretesting and the results of this round, the samples were 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 – Expert
87 laboratories participated from several different countries in this round. Both concentrations of the samples were not at a normal level and if samples had been samples of a patient, it would have been necessary to alert the medical staff on all the results obtained. Abbott FreeStyle strips gave clearly lower results than the other method groups in both samples. The CV% within the method groups were good, although in two method groups there were some deviating results.

Annex 1.
Instructions how to proceed if your result is out of the acceptable limits.

End of report

2023-07-03

FINAL REPORT

Product no. 2526

Samples sent	2023-05-15
Round closed	2023-06-15
Final report	2023-07-03

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
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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.