LABQUALITY

External Quality Assessment Scheme

Bilirubin, conjugated
Round 1, 2023

Specimens
Sample S001 (LQ750523011) is a liquid human based preparation (à 3 mL).
Sample S002 (LQ750523012) is a liquid human based preparation (à 3 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 HIVAgAb 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
Bilirubin total
Bilirubin conjugated

Storage and use
Sample S001 and sample S002 are ready to use. Remove the controls from the refrigerator and allow them to come to room temperature for 10 to 15 minutes. Gently invert the controls to assure homogeneity of the contents. Avoid foaming the controls.
Bilirubin is sensitive to light and oxygen. Analyze as patient samples.

Result reporting
Please enter the results and methods via LabScala. If you can't find your instrument or reagent from the registry, please contact the EQA Coordinator.

S001:

S002:

2023-02-14

INSTRUCTIONS

Product no. 2109
LQ750523011-012/US

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **March 10, 2023**.

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

Quality Management
ISO 9001:2015

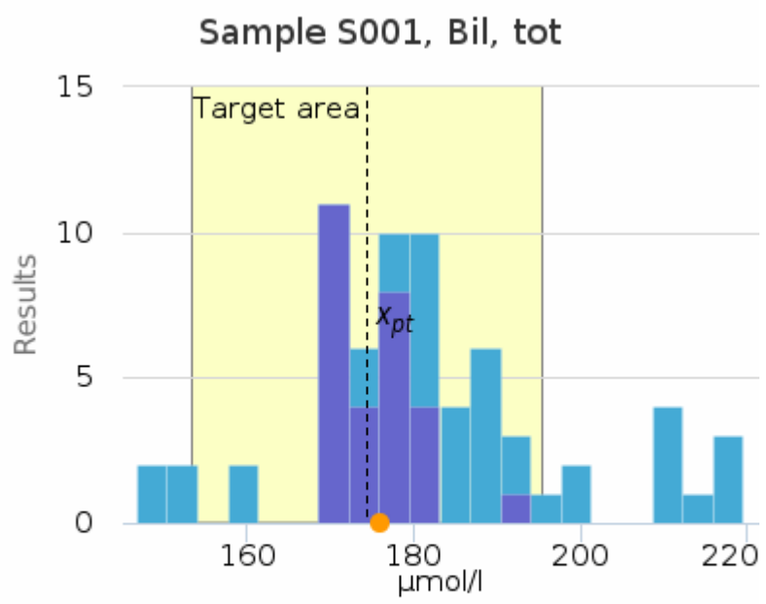
LABQUALITY

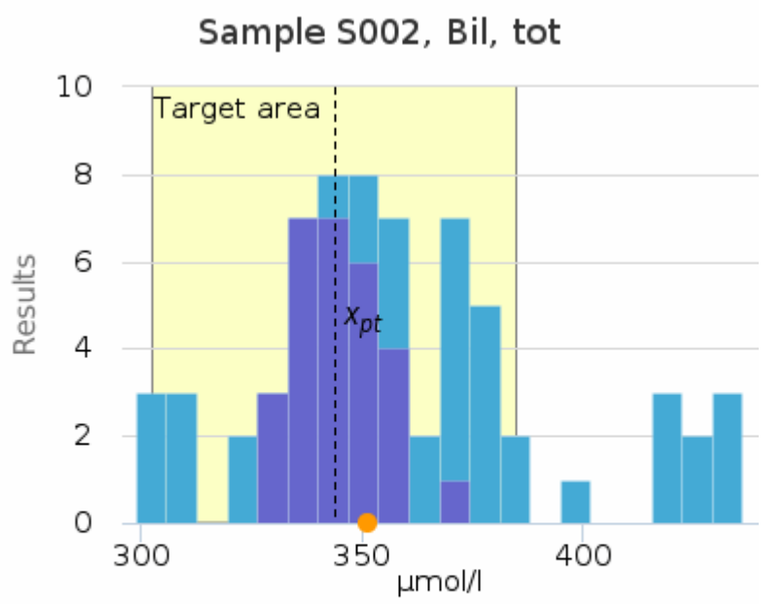
Bilirubin, conjugated, February, 1-2023

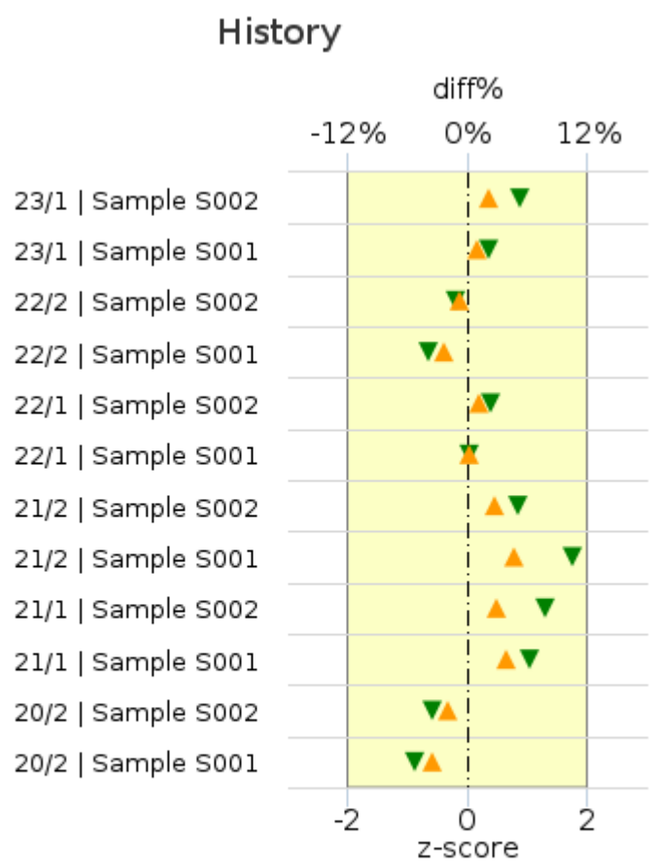
Quantitative report

XXXX

Bil, tot |c501







All method groups Roche cobas Bilirubin
Own result: 176.0 (21.02.2023)
Diff%: 0.9 | x_{pt}: 174.4
Target area: 153.5-195.4 | Target: ±12%

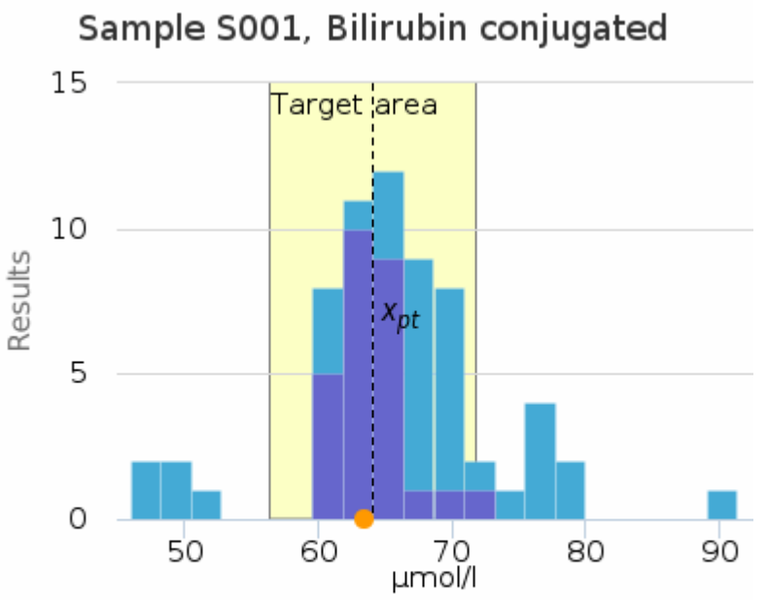
All method groups Roche cobas Bilirubin
Own result: 351.0 (21.02.2023)
Diff%: 2.1 | x_{pt}: 343.8
Target area: 302.5-385.0 | Target: ±12%

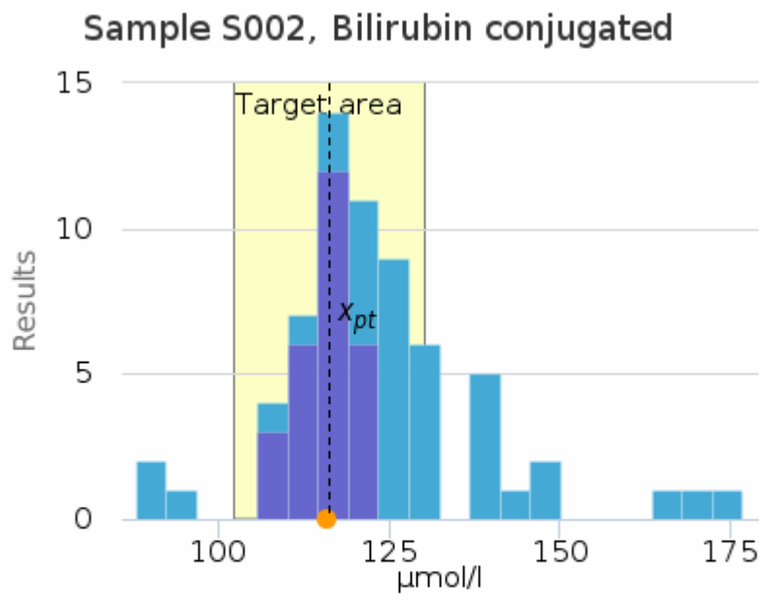
	x_{pt}	sd	SEM	CV%	n
Roche cobas Bilirubin	174.4 µmol/l	4.3	0.8	2.5	28
All methods	181.5 µmol/l	15.9	1.9	8.7	67

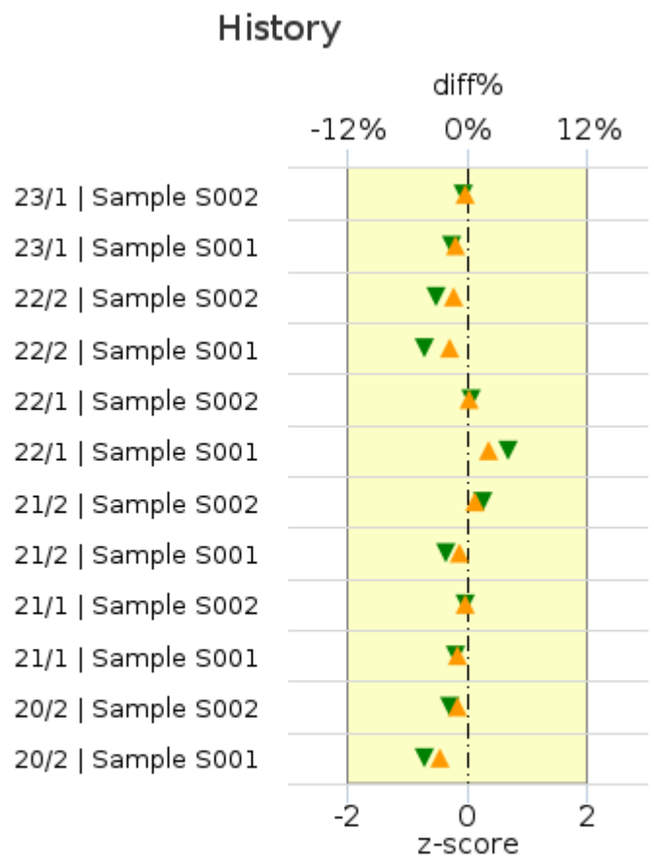
	x_{pt}	sd	SEM	CV%	n
Roche cobas Bilirubin	343.8 µmol/l	8.2	1.6	2.4	28
All methods	358.3 µmol/l	32.7	4.0	9.1	66

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	343.8	351.0	2.1%	0.88
23/1	Sample S001	174.4	176.0	0.9%	0.37
22/2	Sample S002	320.3	318.0	-0.7%	-0.20
22/2	Sample S001	214.0	209.0	-2.3%	-0.65
22/1	Sample S002	124.6	126.0	1.2%	0.38
22/1	Sample S001	246.8	247.0	0.1%	0.02
21/2	Sample S002	321.0	330.0	2.8%	0.84
21/2	Sample S001	217.1	227.0	4.6%	1.76
21/1	Sample S002	249.6	257.0	3.0%	1.30
21/1	Sample S001	128.1	133.0	3.8%	1.03
20/2	Sample S002	350.0	343.0	-2.0%	-0.59
20/2	Sample S001	182.5	176.0	-3.6%	-0.88

Bilirubin conjugated |c501







	x_{pt}	sd	SEM	CV%	n
Roche cobas Bilirubin	64.1 µmol/l	2.8	0.5	4.3	27
All methods	65.4 µmol/l	7.0	0.9	10.7	63

	x_{pt}	sd	SEM	CV%	n
Roche cobas Bilirubin	116.3 µmol/l	3.9	0.8	3.4	27
All methods	121.8 µmol/l	12.8	1.6	10.5	65

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	116.3	116.0	-0.2%	-0.07
23/1	Sample S001	64.1	63.4	-1.1%	-0.26
22/2	Sample S002	178.4	176.0	-1.3%	-0.52
22/2	Sample S001	157.6	155.0	-1.7%	-0.70
22/1	Sample S002	72.7	72.8	0.2%	0.07
22/1	Sample S001	101.8	104.0	2.2%	0.67
21/2	Sample S002	201.7	203.0	0.7%	0.27
21/2	Sample S001	171.1	170.0	-0.7%	-0.37
21/1	Sample S002	102.1	102.0	-0.1%	-0.03
21/1	Sample S001	74.4	73.7	-0.9%	-0.21
20/2	Sample S002	115.0	114.0	-0.9%	-0.29
20/2	Sample S001	64.0	62.3	-2.7%	-0.72

Report info

Participants

60 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).

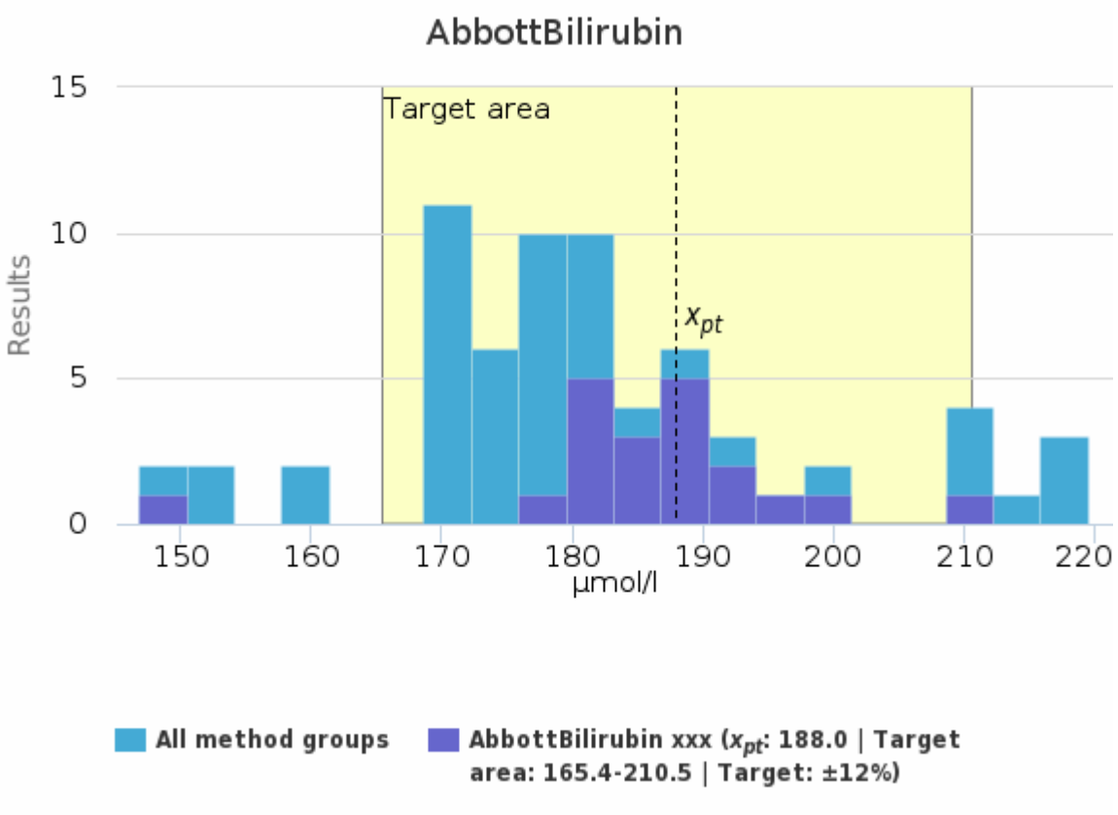
Bilirubin, conjugated, February, 1-2023

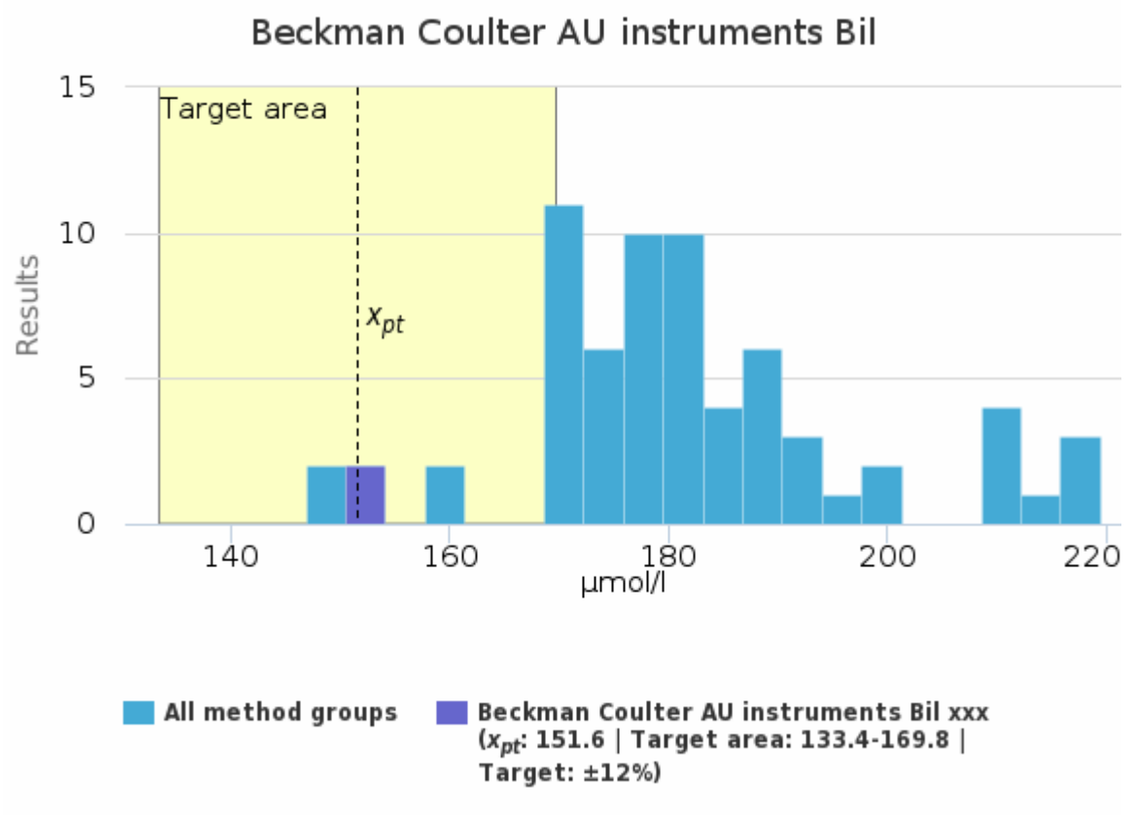
Quantitative report

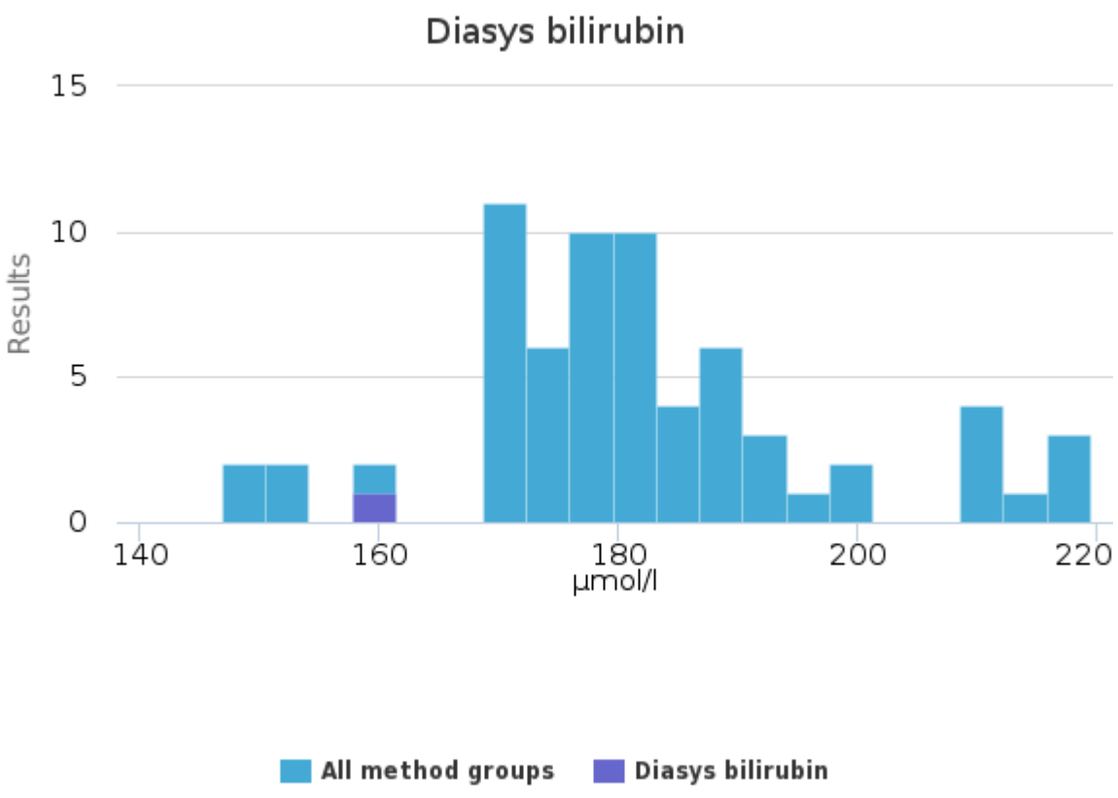
Sample S001 | Bil, tot, µmol/l

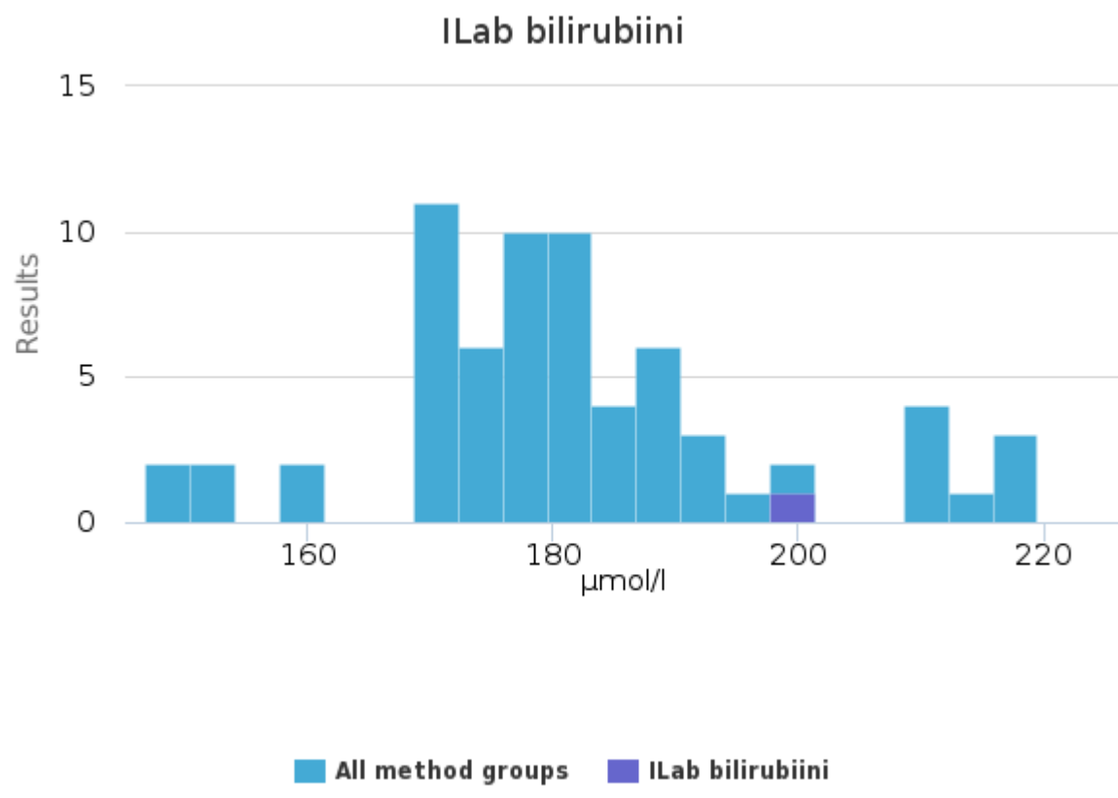
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Bilirubin	188.0	187.2	7.8	4.2	1.8	176.4	209.6	1	20
Beckman Coulter AU instruments Bil	151.6	151.6	1.4	0.9	1.0	150.6	152.6	-	2
Diasys bilirubin	-	-	-	-	-	160.4	160.4	-	1
ILab bilirubiini	-	-	-	-	-	198.4	198.4	-	1
Radiometer bilirubin	-	-	-	-	-	219.5	219.5	-	1
Roche cobas Bilirubin	174.4	174.4	4.3	2.5	0.8	168.9	182.8	1	28
Roche Cobas Integra Bilirubin	183.5	183.5	7.2	3.9	5.1	178.4	188.6	-	2
Siemens Advia Bilirubin	212.7	212.2	3.2	1.5	1.3	209.0	217.0	-	6
Siemens Dimension Vista Bilirubin	-	-	-	-	-	184.0	184.0	-	1
Thermo Fischer Scientific Bili	154.2	154.2	5.9	3.9	4.2	150.0	158.4	-	2
Vitros Bilirubin	175.5	172.7	4.8	2.7	2.8	172.7	181.0	-	3
All	**181.5**	**180.0**	**15.9**	**8.7**	**1.9**	**146.9**	**219.5**	**-**	**67**

Sample S001 | Bil, tot, µmol/l| histogram summaries in LabScala



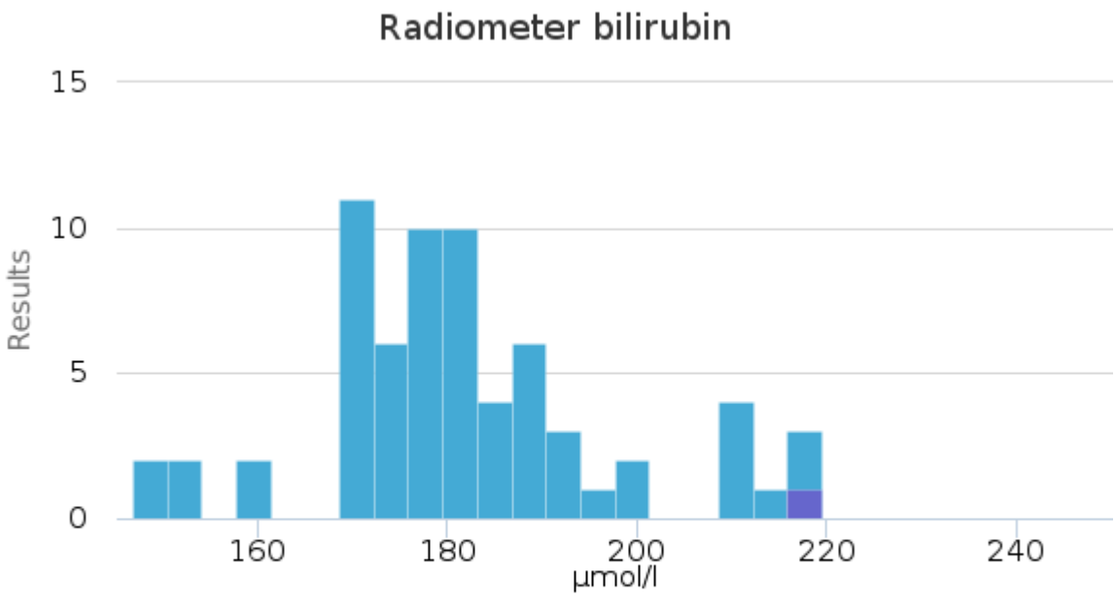


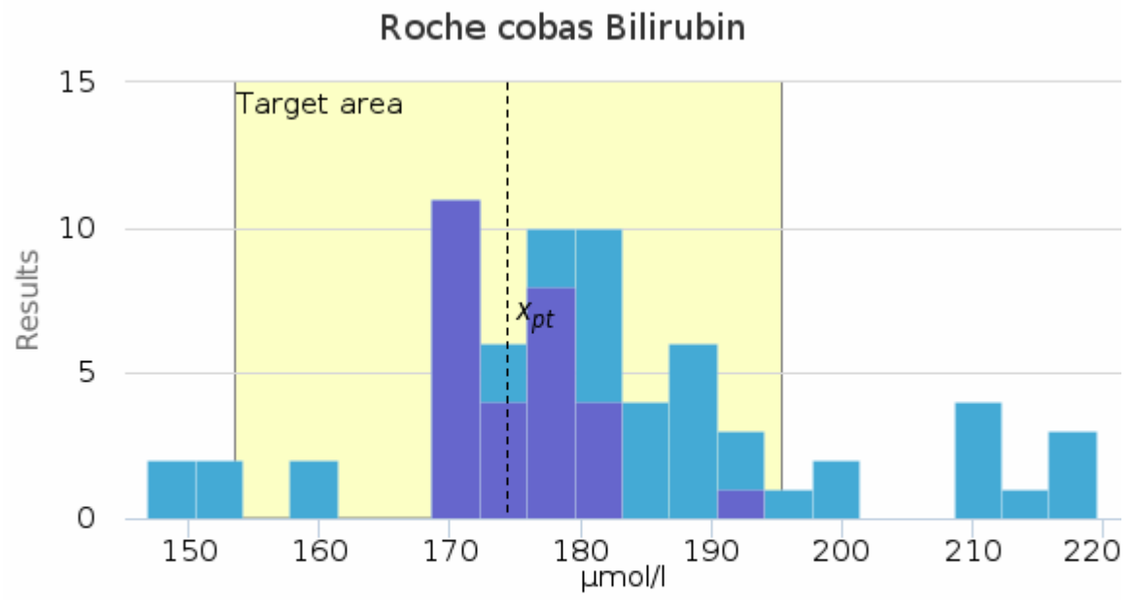


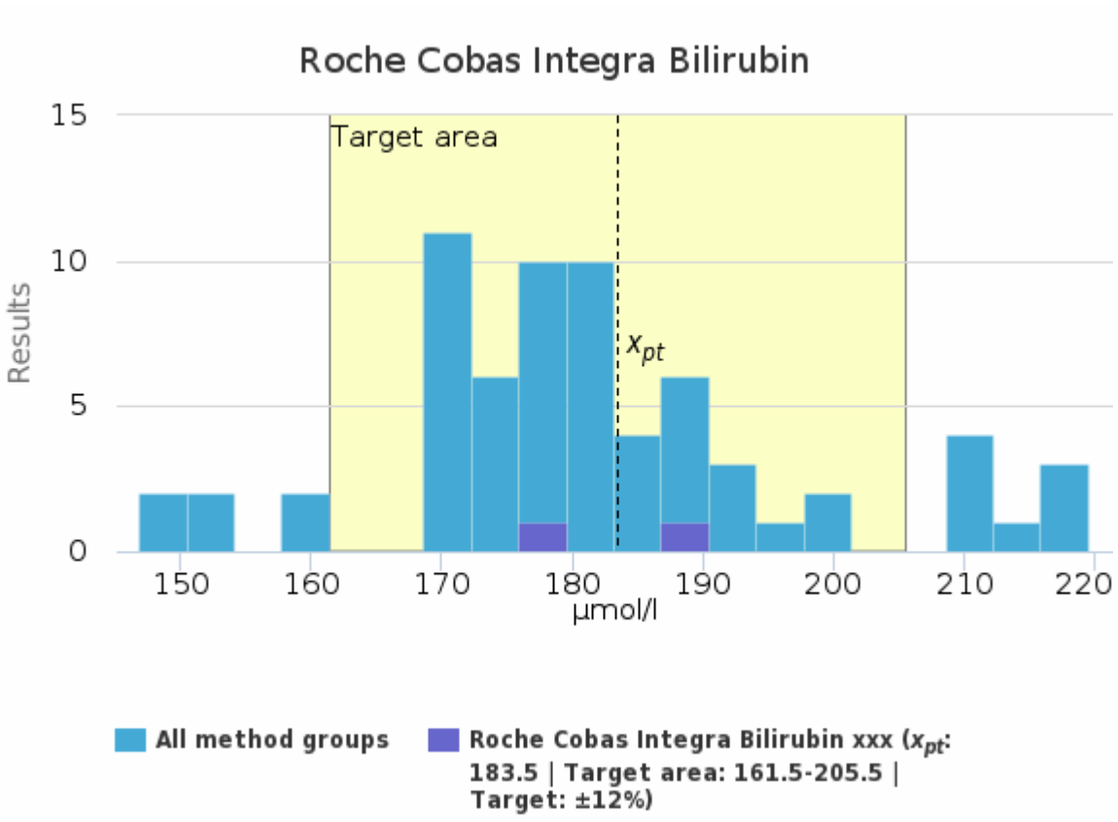


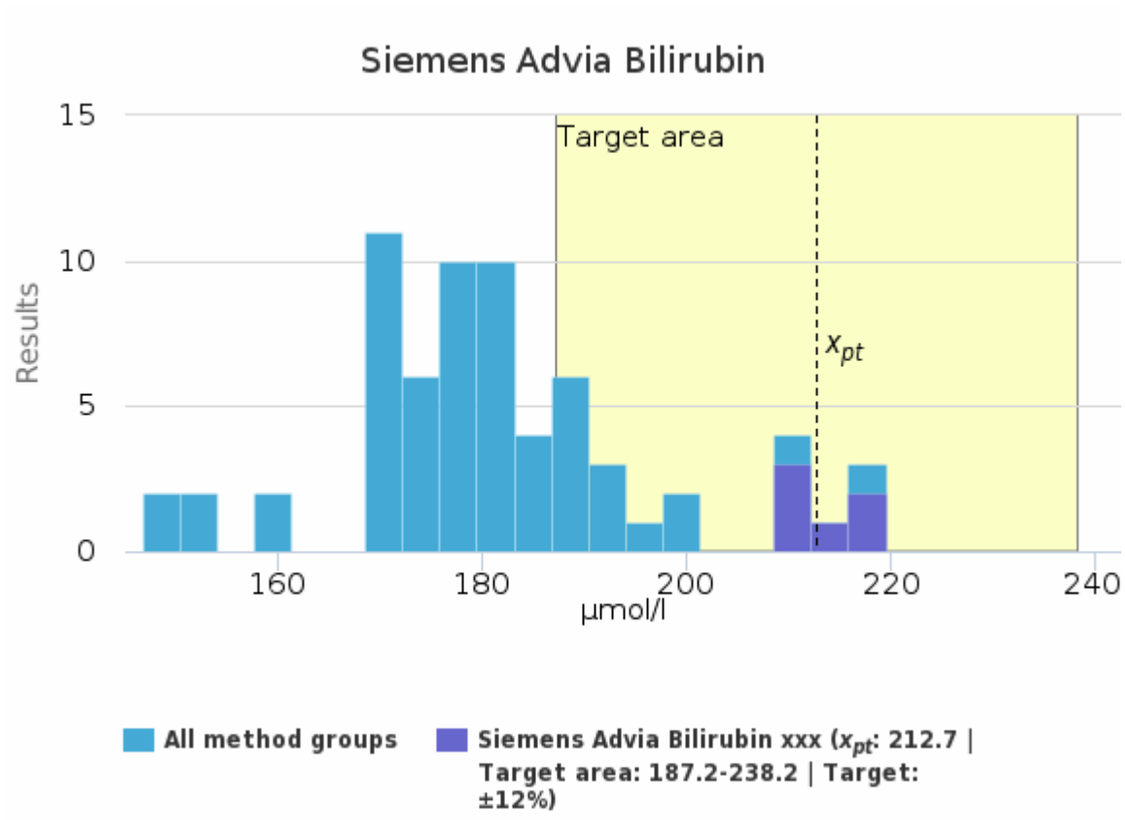
Bilirubin, conjugated, February, 1-2023

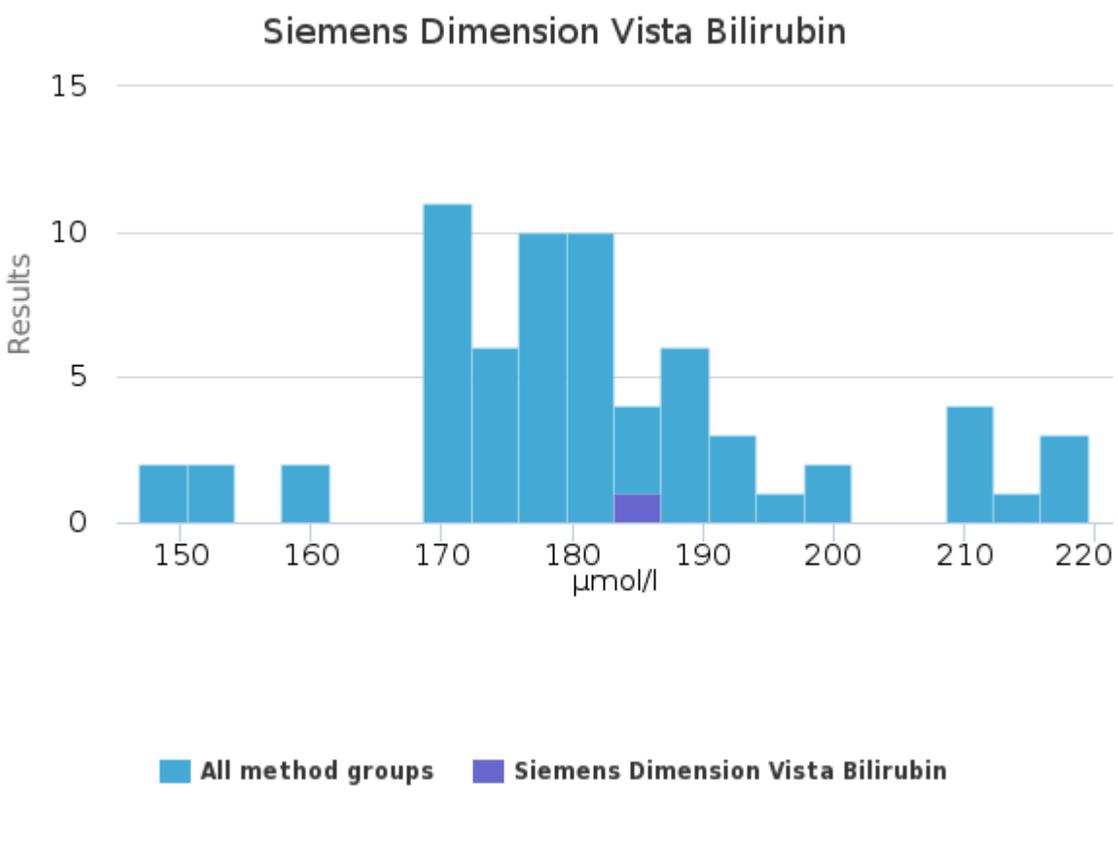
Quantitative report

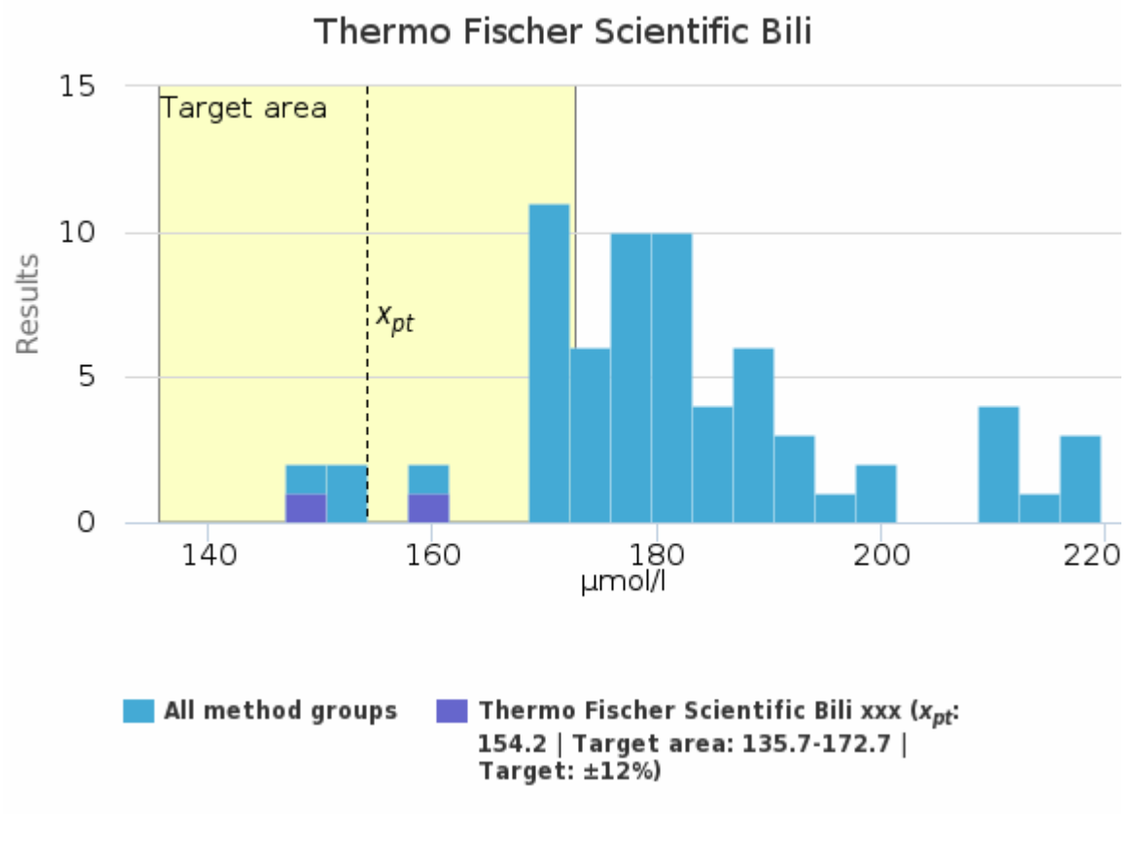






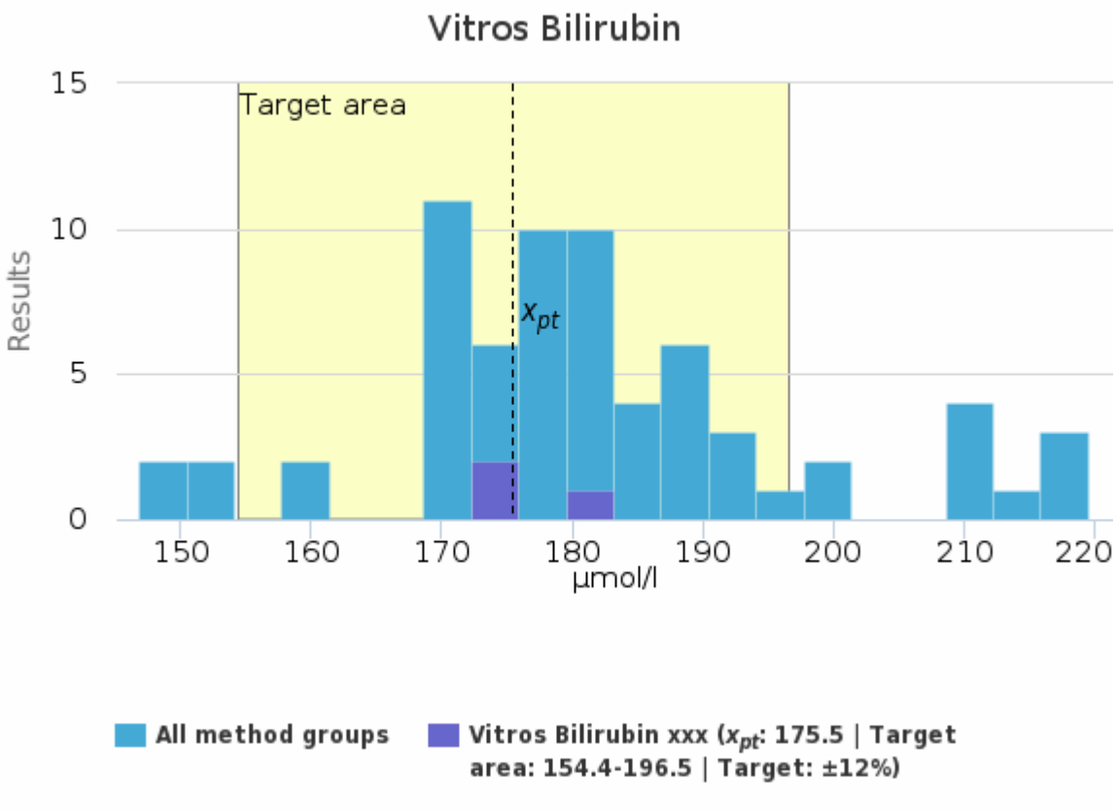






Bilirubin, conjugated, February, 1-2023

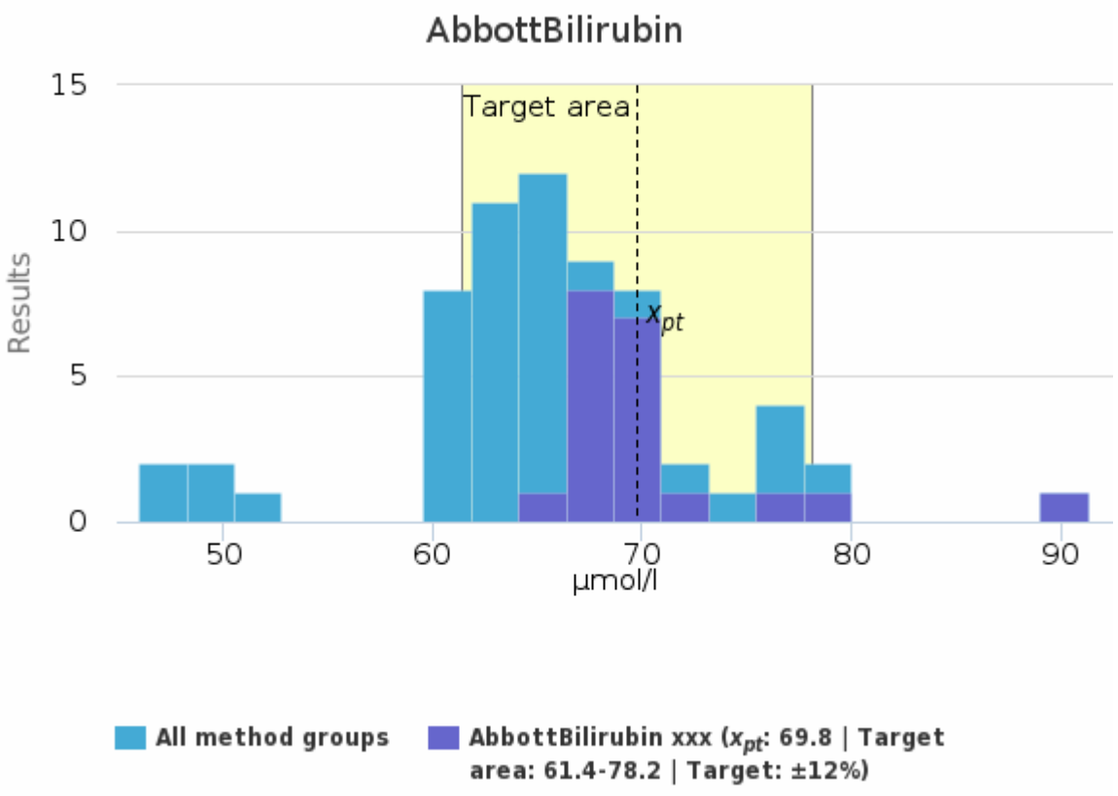
Quantitative report

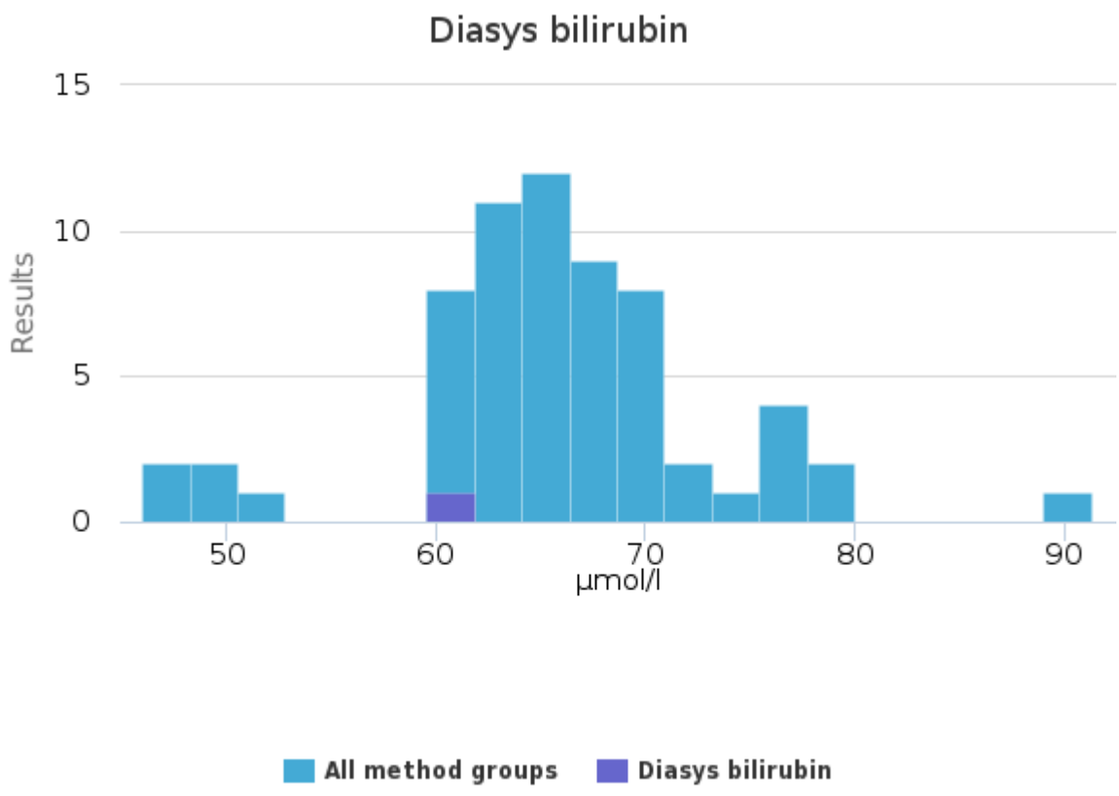


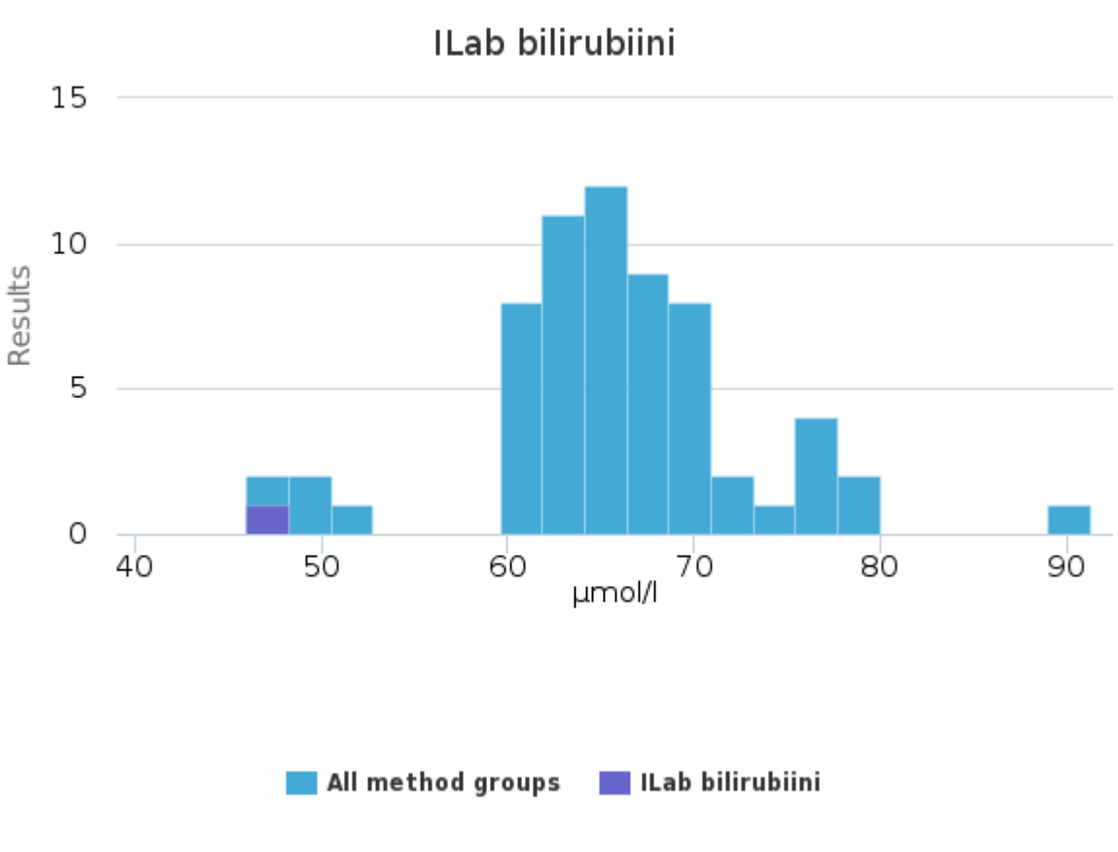
Sample S001 | Bilirubin conjugated, µmol/l

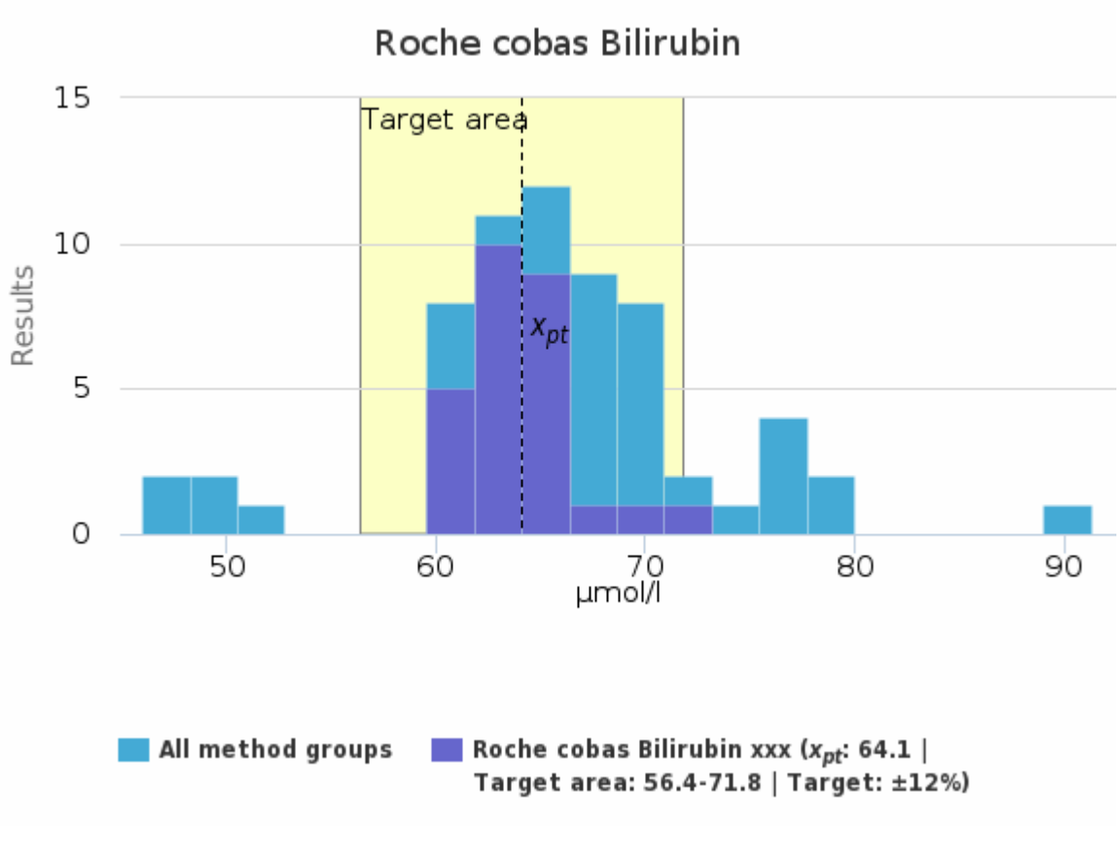
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Bilirubin	69.8	68.7	3.4	4.9	0.8	66.3	79.7	1	20
Diasys bilirubin	-	-	-	-	-	59.6	59.6	-	1
ILab bilirubiini	-	-	-	-	-	46.0	46.0	-	1
Roche cobas Bilirubin	64.1	64.0	2.8	4.3	0.5	60.0	72.0	-	27
Roche Cobas Integra Bilirubin	64.3	65.0	1.4	2.1	0.8	62.8	65.3	-	3
Siemens Advia Bilirubin	76.5	76.0	1.0	1.3	0.5	75.4	78.0	-	5
Siemens Dimension Vista Bilirubin	-	-	-	-	-	46.0	46.0	-	1
Thermo Fischer Scientific Bili	60.7	60.7	1.3	2.1	0.9	59.8	61.6	-	2
Vitros Bilirubin	49.8	49.6	1.4	2.7	0.8	48.6	51.3	-	3
All	**65.4**	**65.3**	**7.0**	**10.7**	**0.9**	**46.0**	**79.7**	**1**	**63**

Sample S001 | Bilirubin conjugated, µmol/l| histogram summaries in LabScala





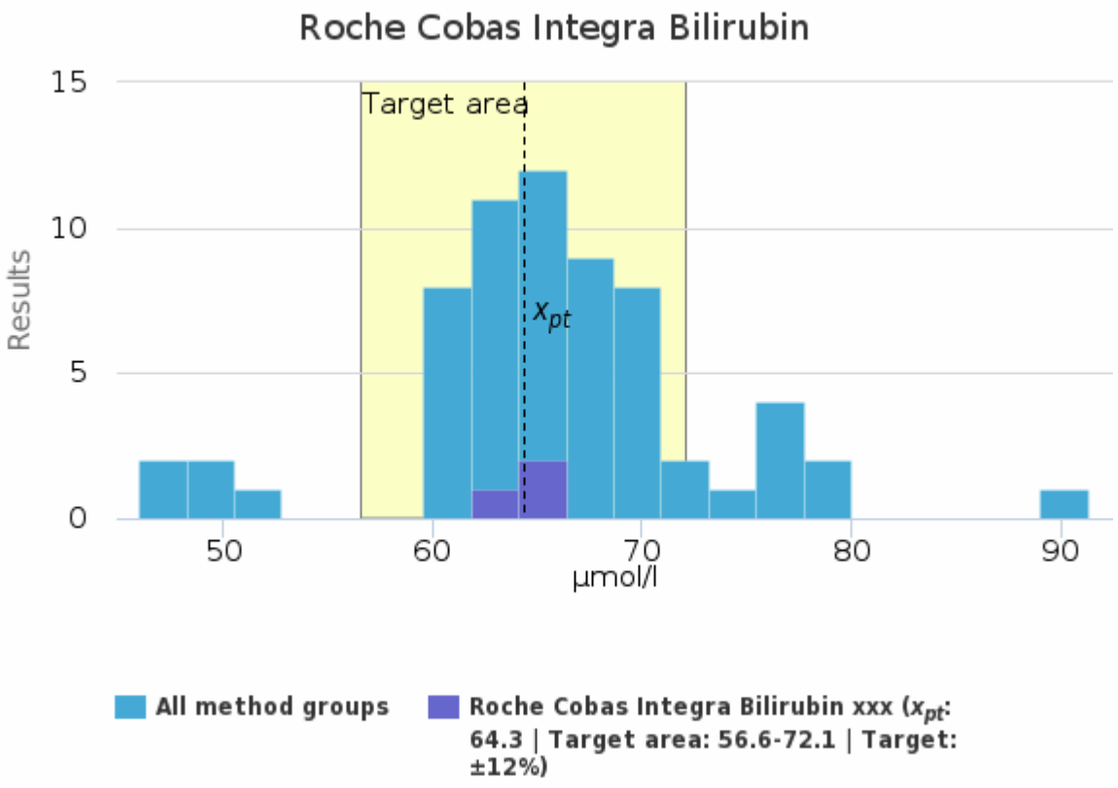


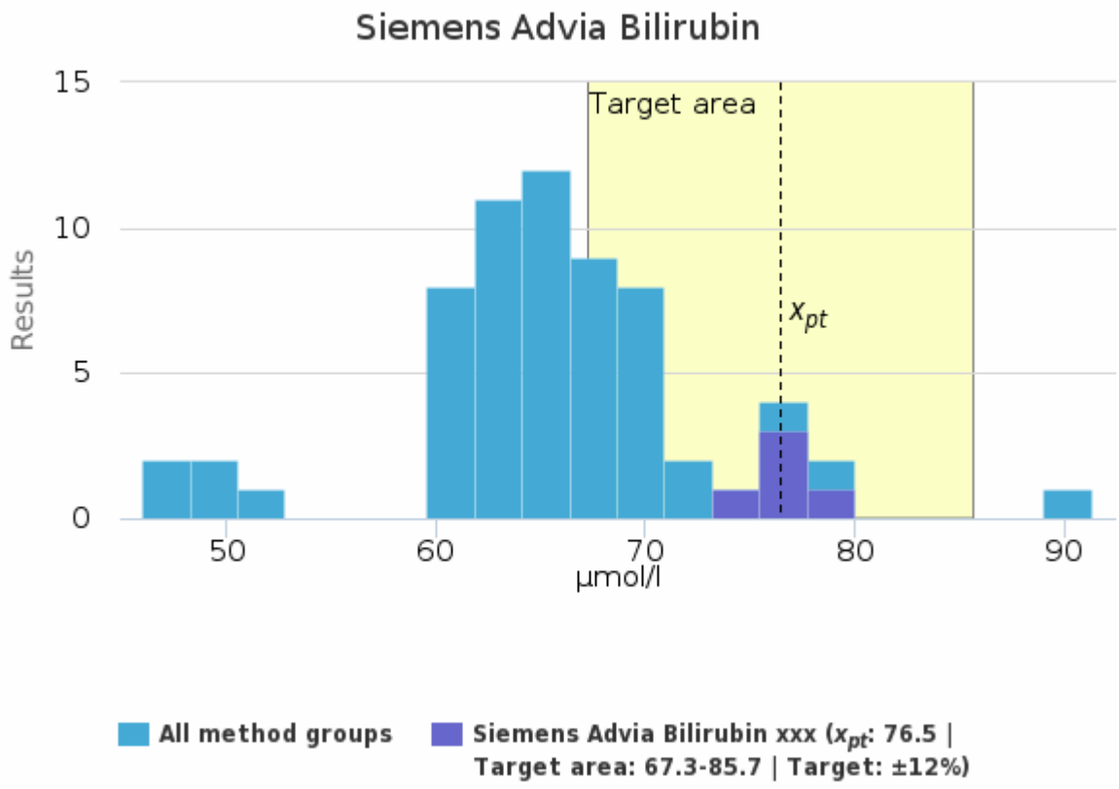


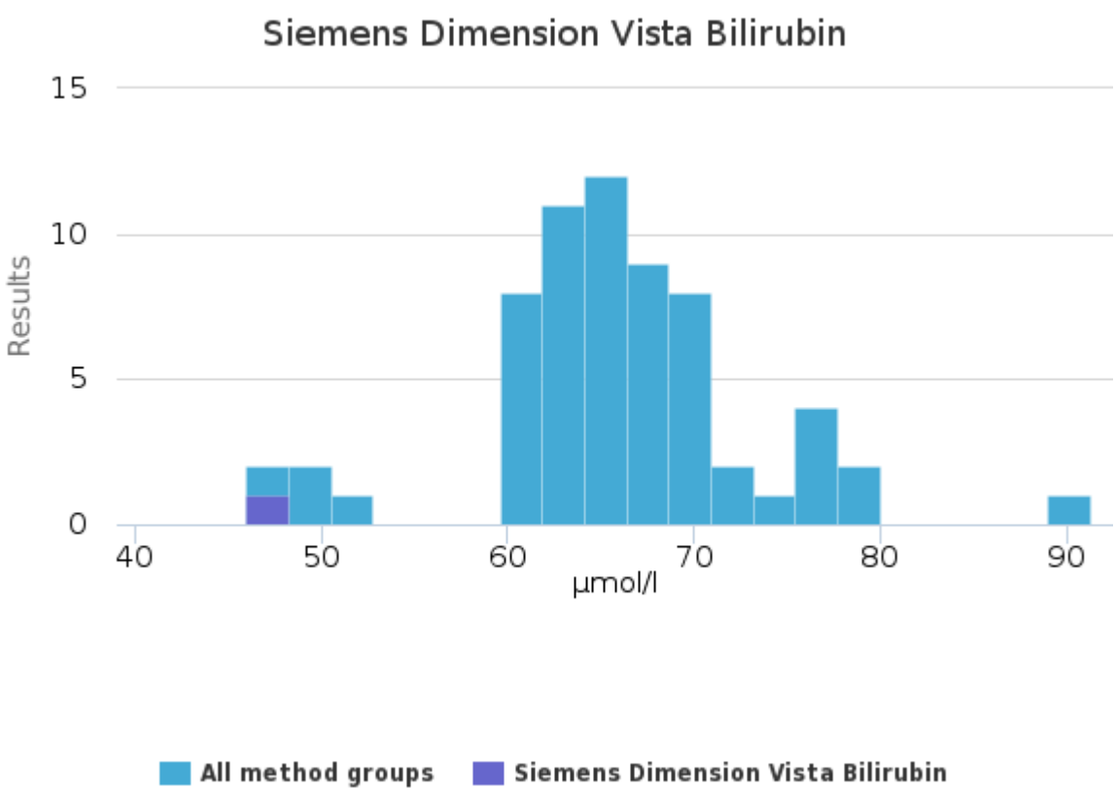
LABQUALITY

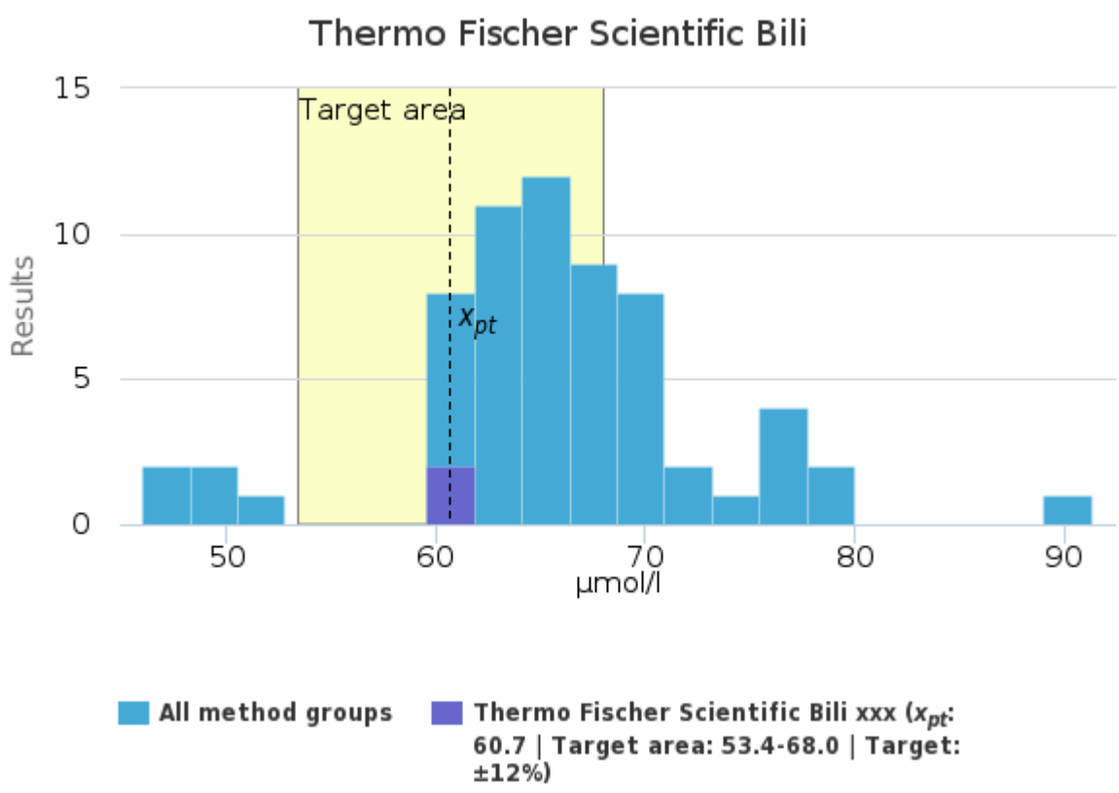
Bilirubin, conjugated, February, 1-2023

Quantitative report









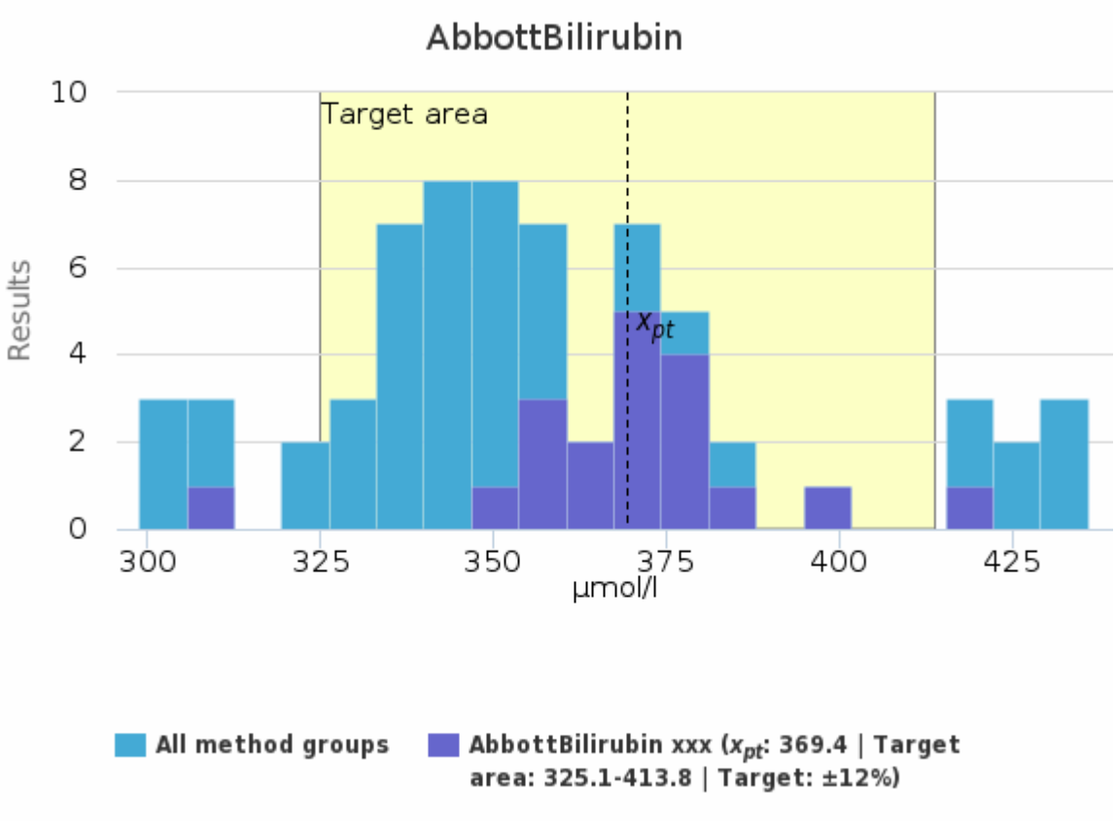
Bilirubin, conjugated, February, 1-2023

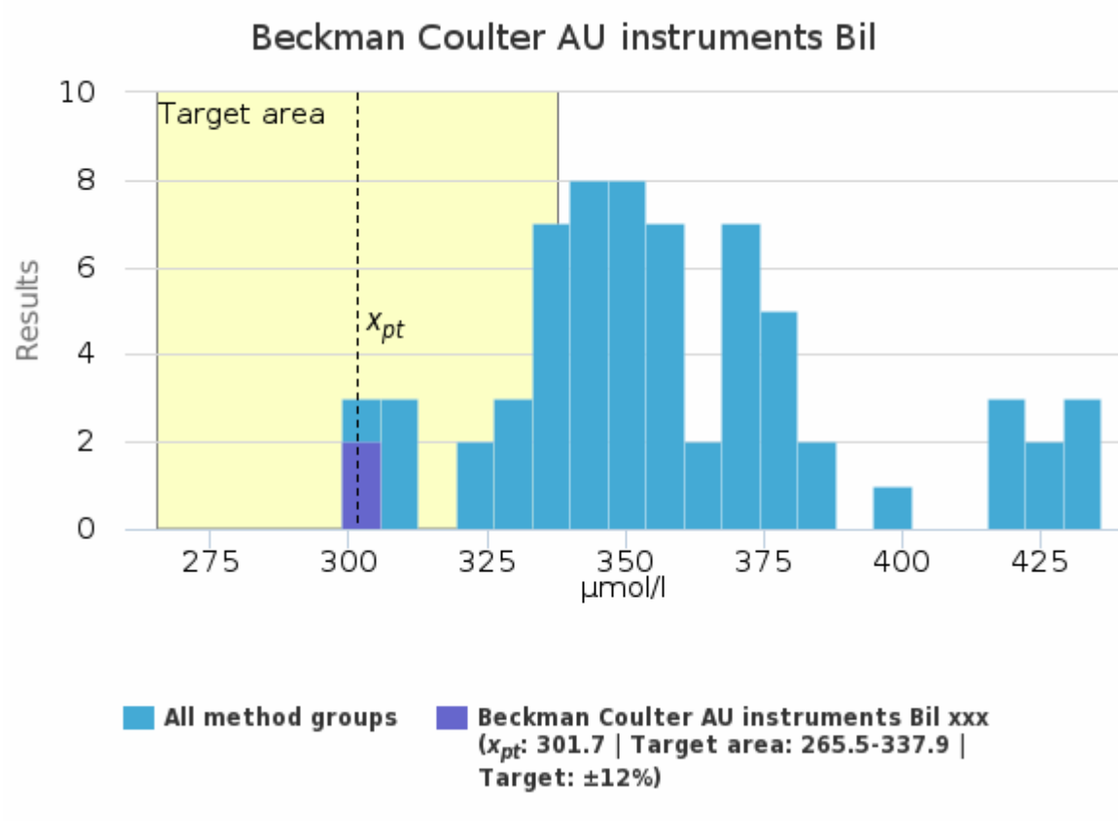
Quantitative report

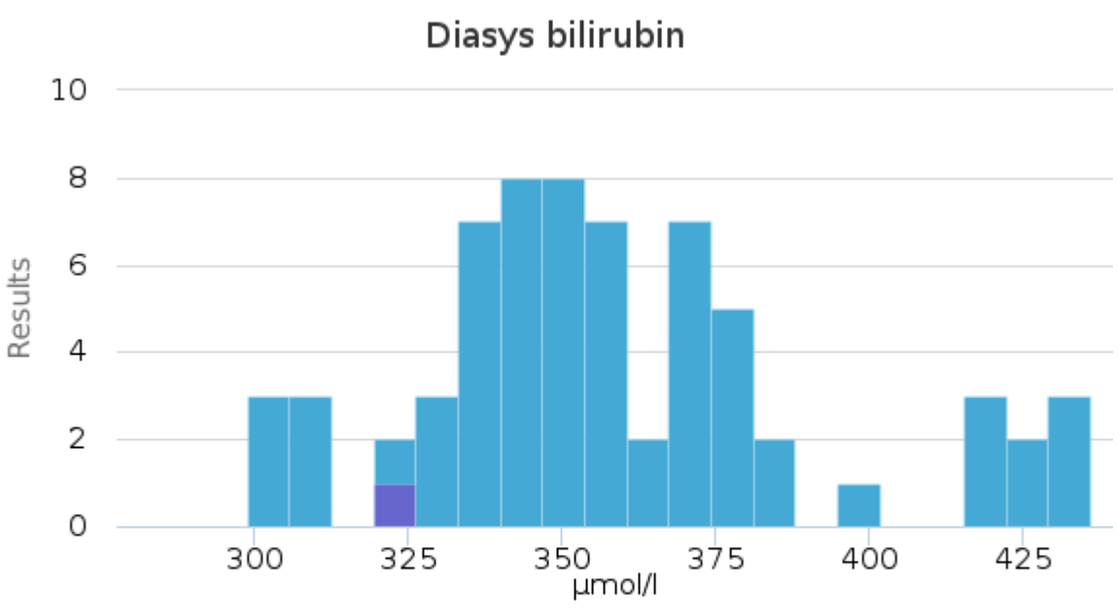
Sample S002 | Bil, tot, µmol/l

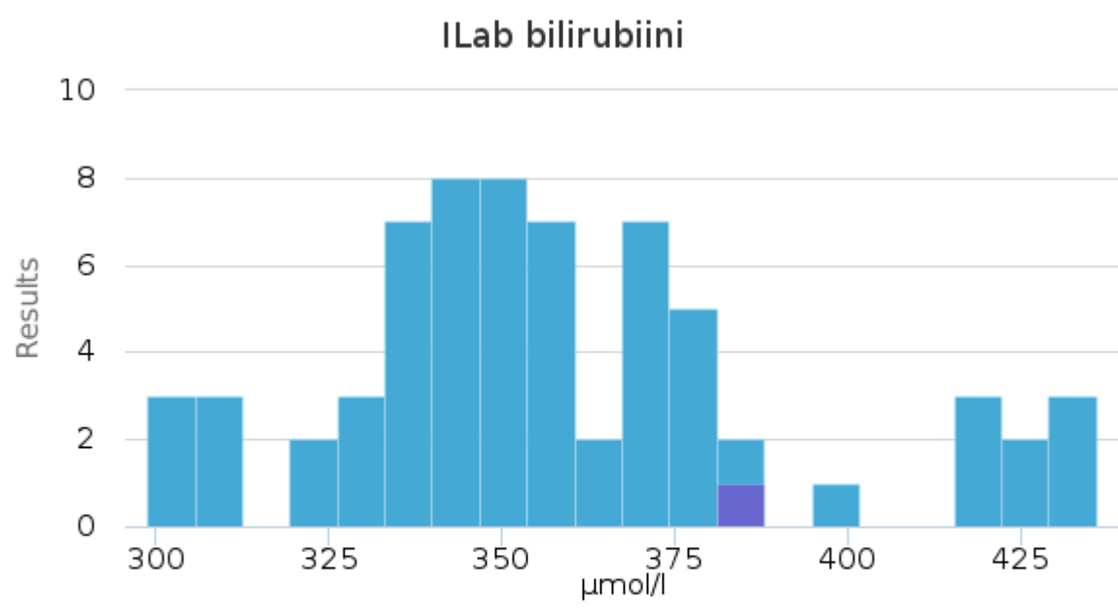
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Bilirubin	369.4	370.0	20.7	5.6	4.7	309.3	416.8	-	19
Beckman Coulter AU instruments Bil	301.7	301.7	4.0	1.3	2.8	298.9	304.5	-	2
Diasys bilirubin	-	-	-	-	-	322.5	322.5	-	1
ILab bilirubiini	-	-	-	-	-	384.8	384.8	-	1
Radiometer bilirubin	-	-	-	-	-	435.1	435.1	-	1
Roche cobas Bilirubin	343.8	343.0	8.2	2.4	1.6	329.0	358.2	1	28
Roche Cobas Integra Bilirubin	358.2	358.2	14.0	3.9	9.9	348.3	368.1	-	2
Siemens Advia Bilirubin	425.3	423.5	7.2	1.7	2.9	418.0	436.0	-	6
Siemens Dimension Vista Bilirubin	-	-	-	-	-	342.0	342.0	-	1
Thermo Fischer Scientific Bili	315.7	315.7	10.8	3.4	7.7	308.0	323.3	-	2
Vitros Bilirubin	329.1	306.1	42.8	13.0	24.7	302.7	378.4	-	3
All	**358.3**	**353.0**	**32.7**	**9.1**	**4.0**	**298.9**	**436.0**	**-**	**66**

Sample S002 | Bil, tot, µmol/l| histogram summaries in LabScala



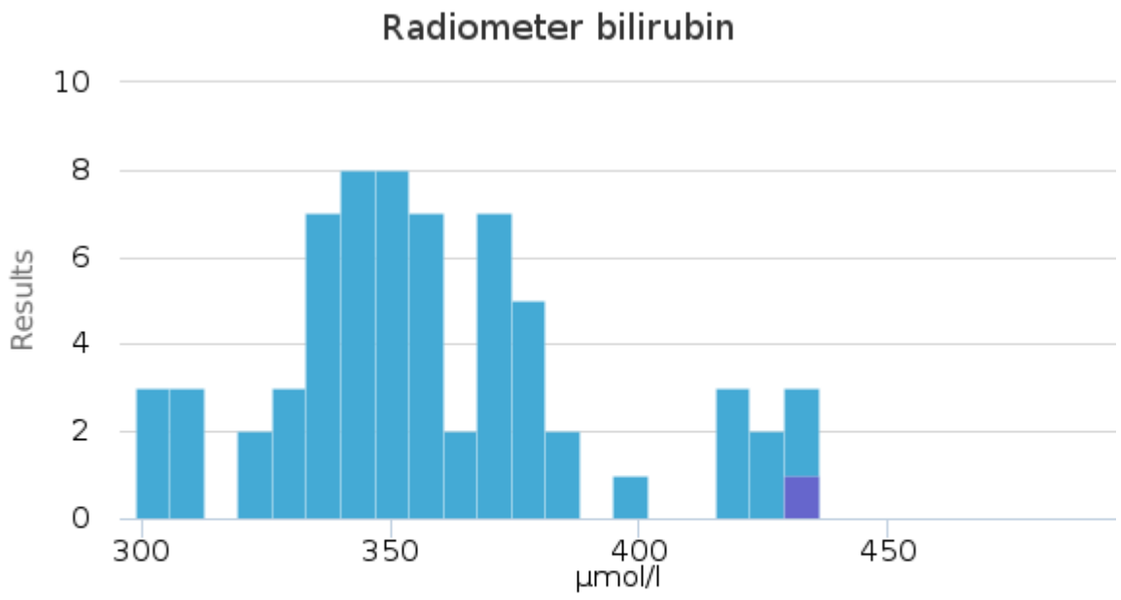


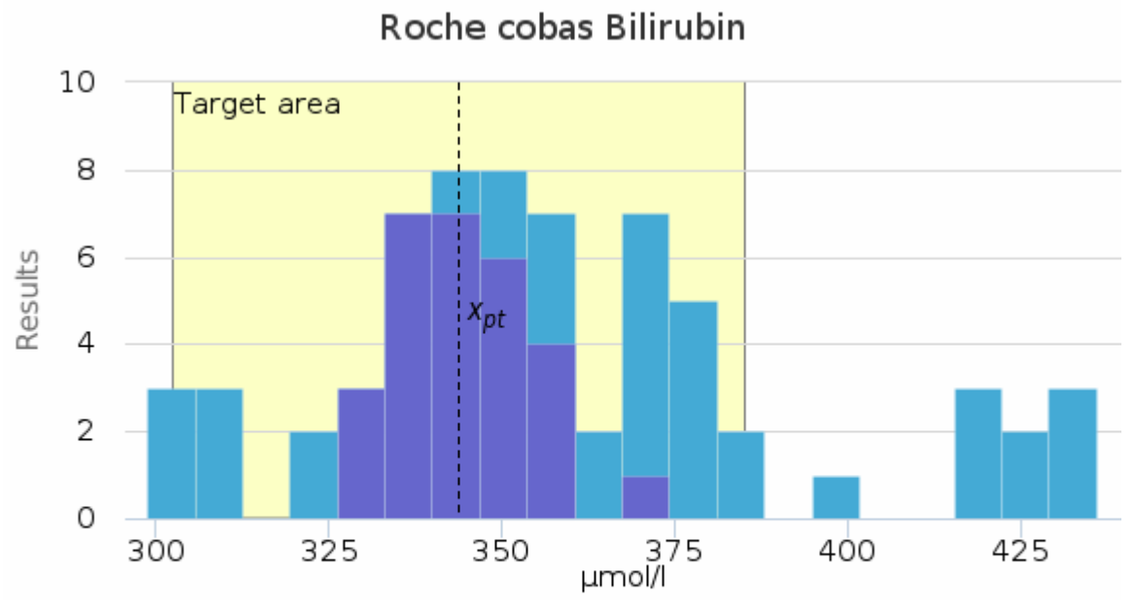


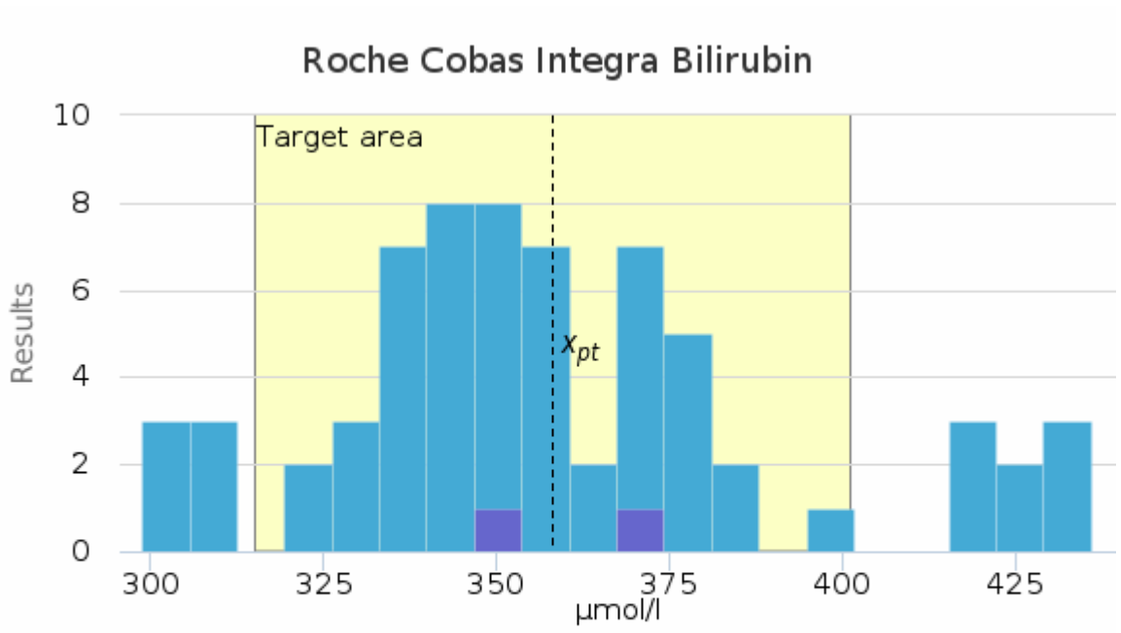


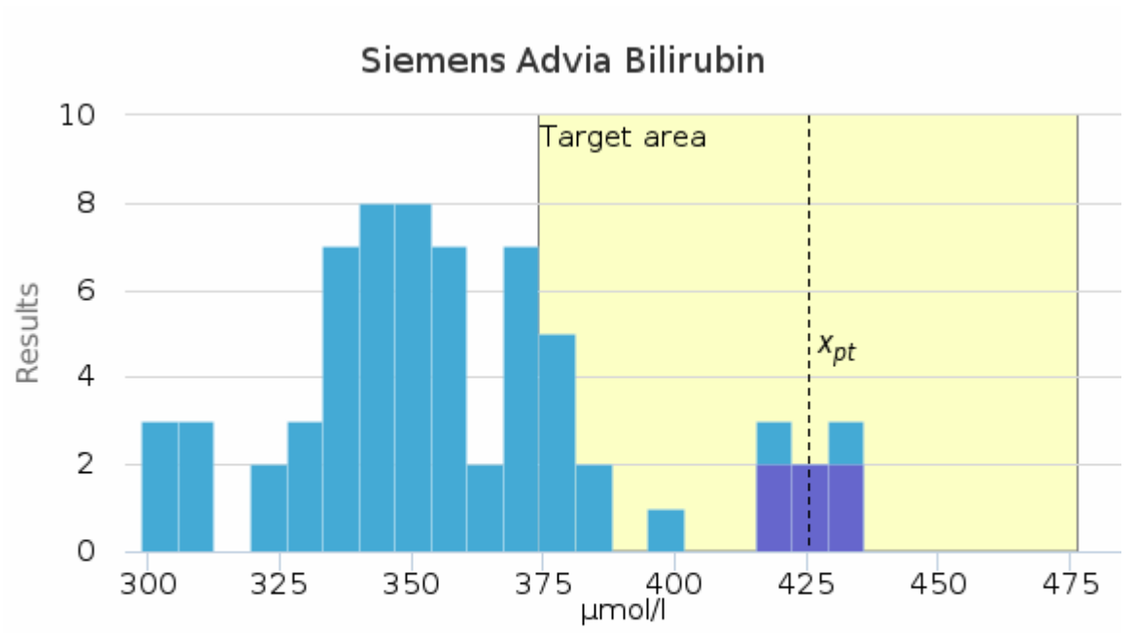
Bilirubin, conjugated, February, 1-2023

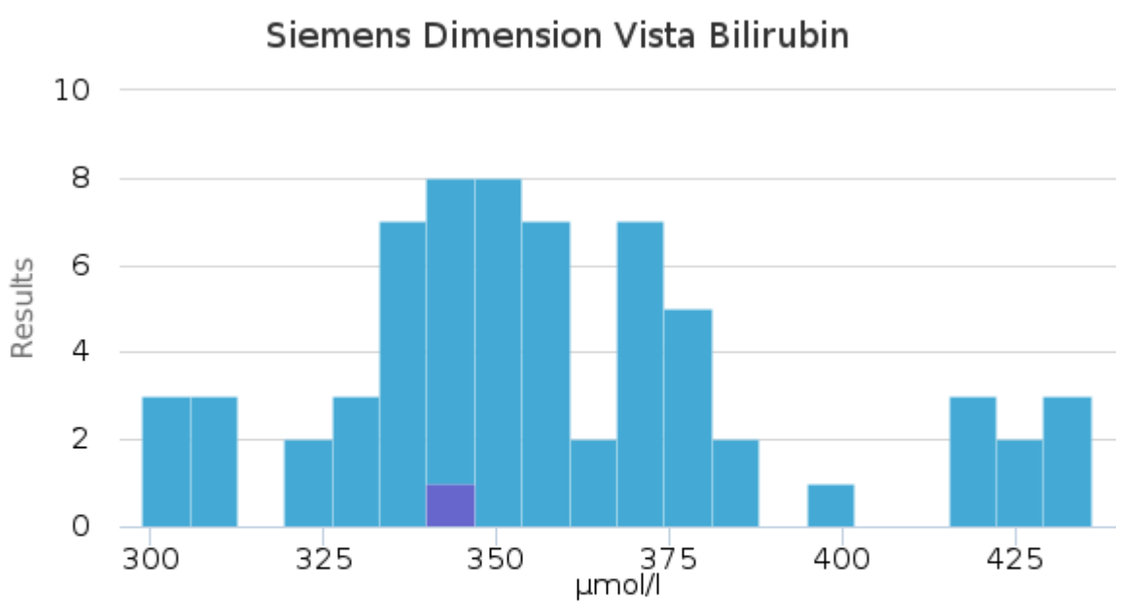
Quantitative report

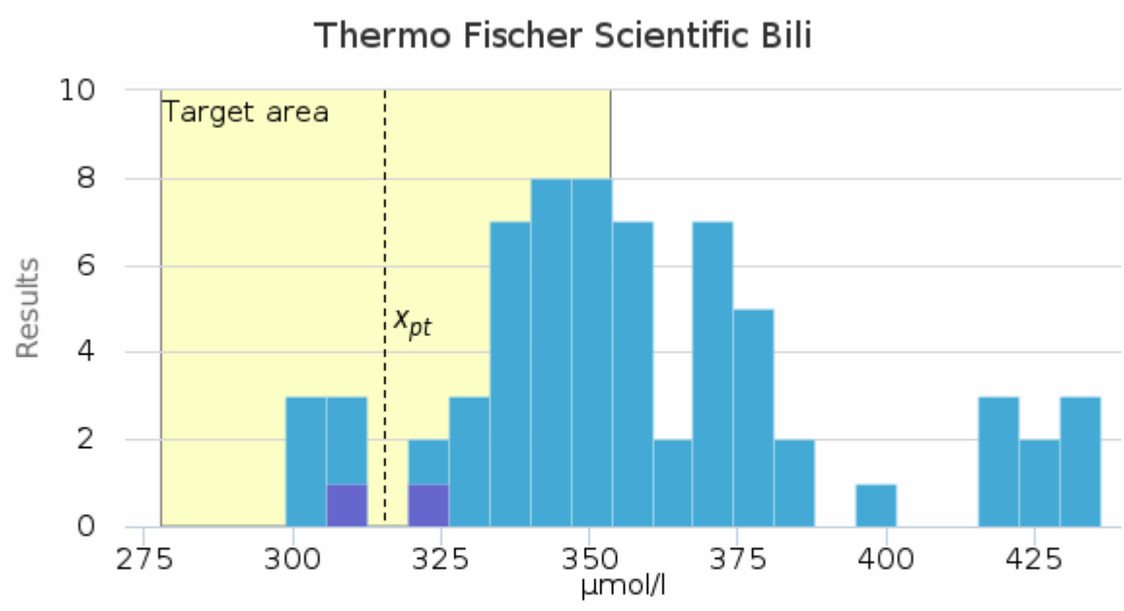






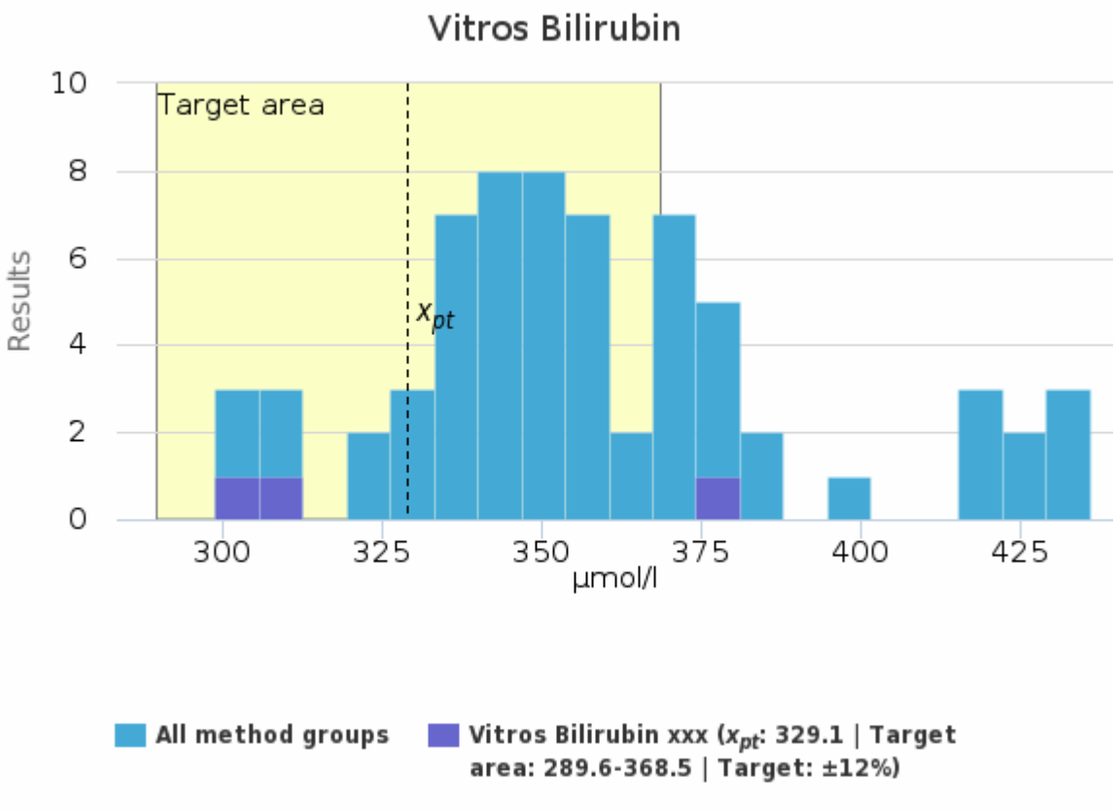






Bilirubin, conjugated, February, 1-2023

Quantitative report



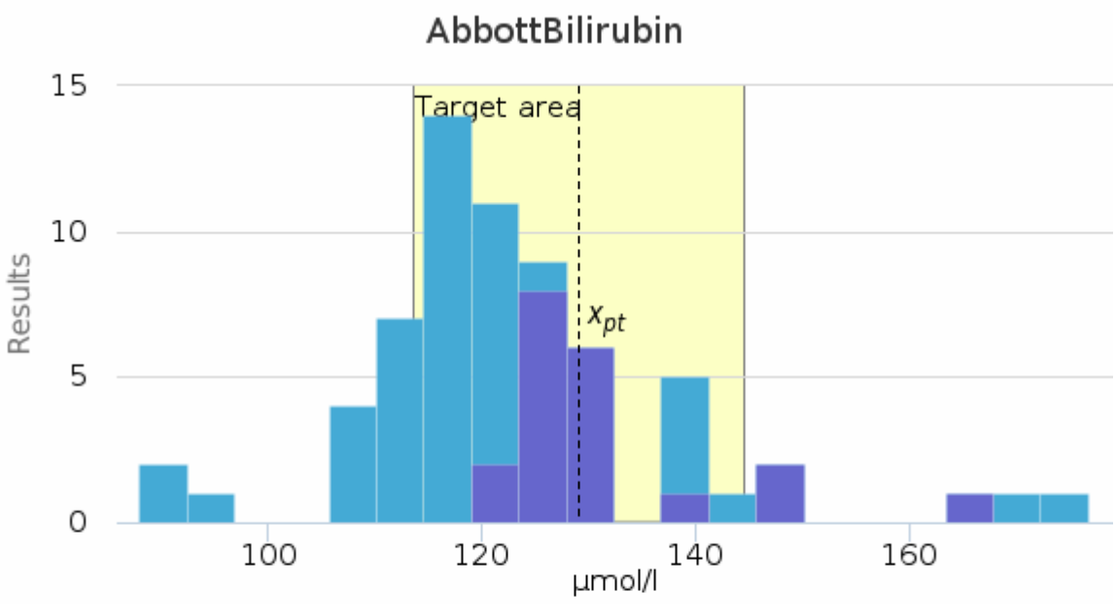
Bilirubin, conjugated, February, 1-2023

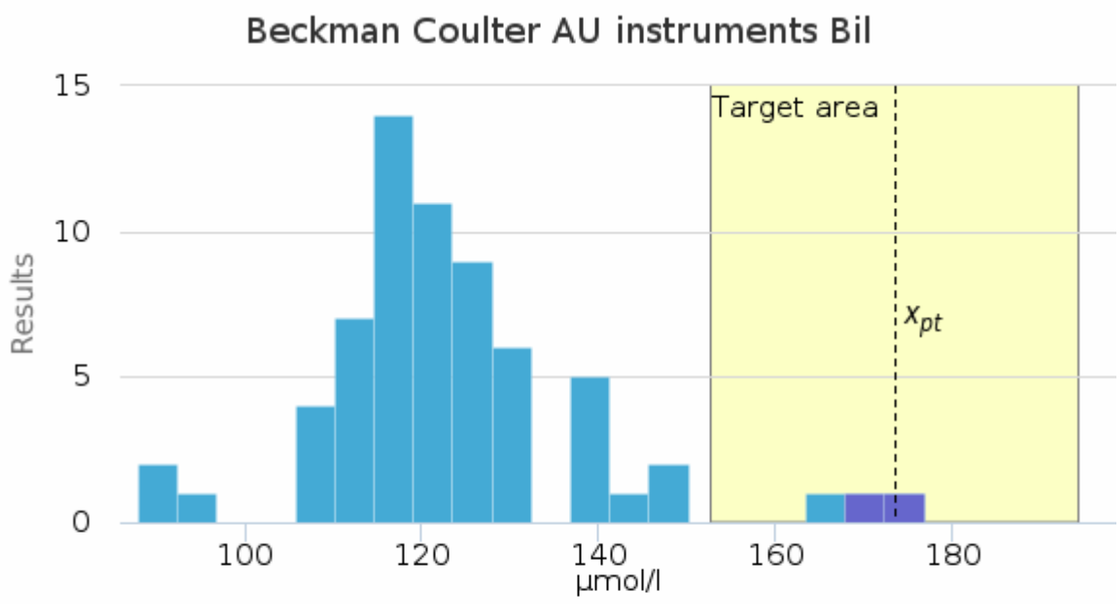
Quantitative report

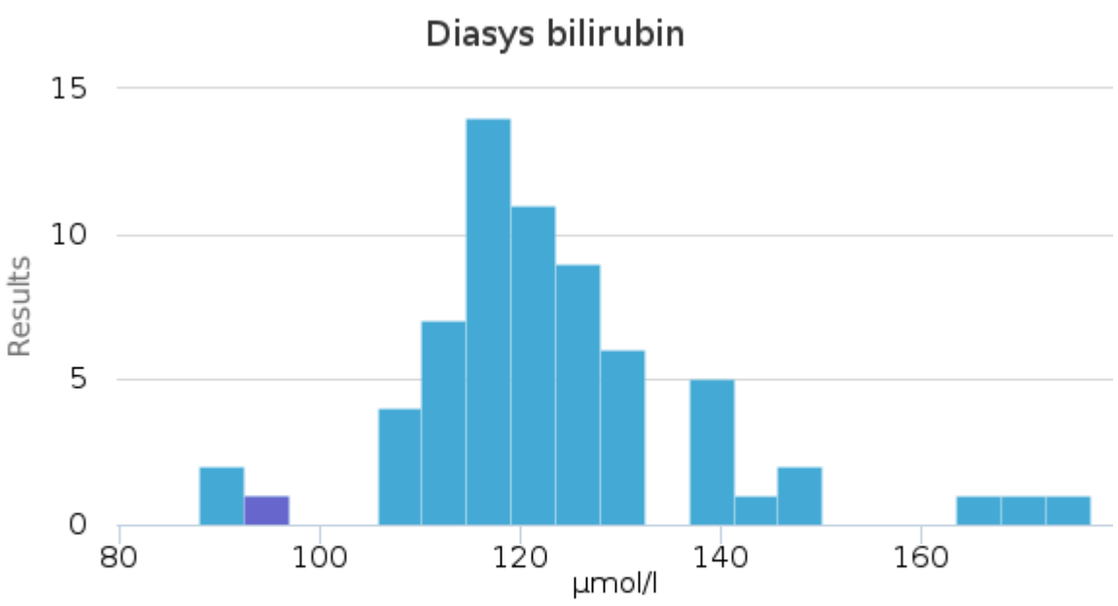
Sample S002 | Bilirubin conjugated, µmol/l

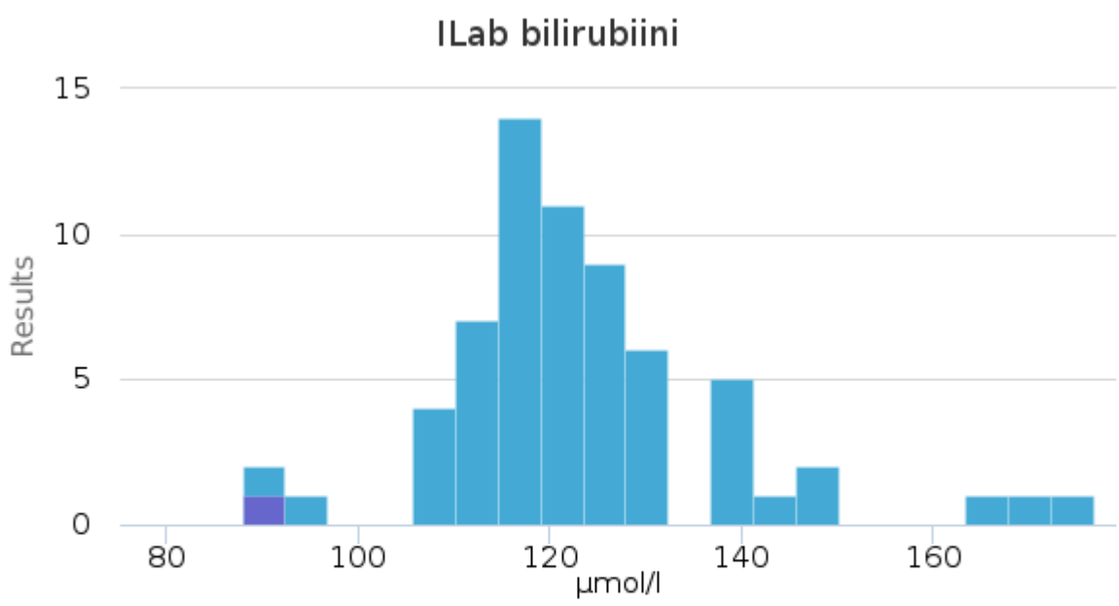
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Bilirubin	129.0	126.8	7.3	5.7	1.7	119.2	146.4	1	20
Beckman Coulter AU instruments Bil	173.5	173.5	4.7	2.7	3.3	170.2	176.8	-	2
Diasys bilirubin	-	-	-	-	-	94.0	94.0	-	1
ILab bilirubiini	-	-	-	-	-	88.7	88.7	-	1
Roche cobas Bilirubin	116.3	118.0	3.9	3.4	0.8	109.0	123.0	-	27
Roche Cobas Integra Bilirubin	119.3	120.1	2.3	2.0	1.4	116.6	121.1	-	3
Siemens Advia Bilirubin	140.2	140.0	1.9	1.4	0.9	138.0	143.0	-	5
Siemens Dimension Vista Bilirubin	-	-	-	-	-	88.0	88.0	-	1
Thermo Fischer Scientific Bili	111.4	111.4	1.9	1.7	1.4	110.0	112.7	-	2
Vitros Bilirubin	121.1	123.1	5.1	4.2	2.9	115.3	124.8	-	3
All	**121.8**	**120.1**	**12.8**	**10.5**	**1.6**	**88.0**	**166.9**	**2**	**65**

Sample S002 | Bilirubin conjugated, µmol/l| histogram summaries in LabScala



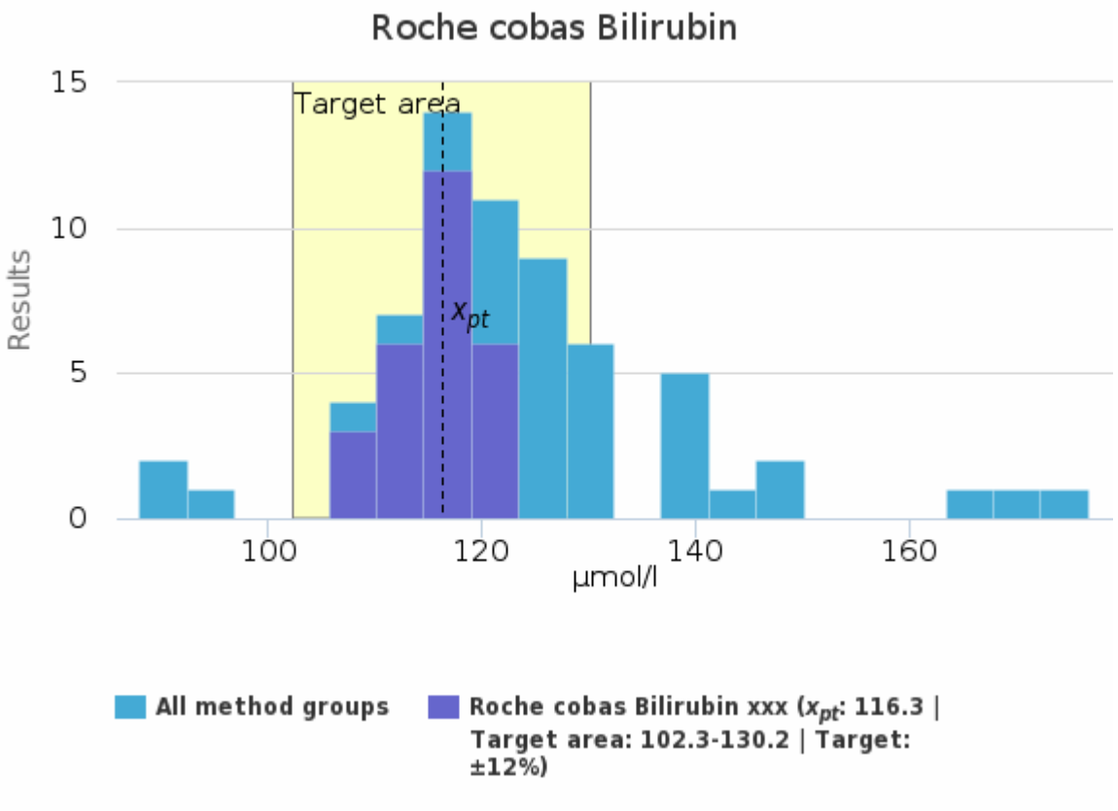


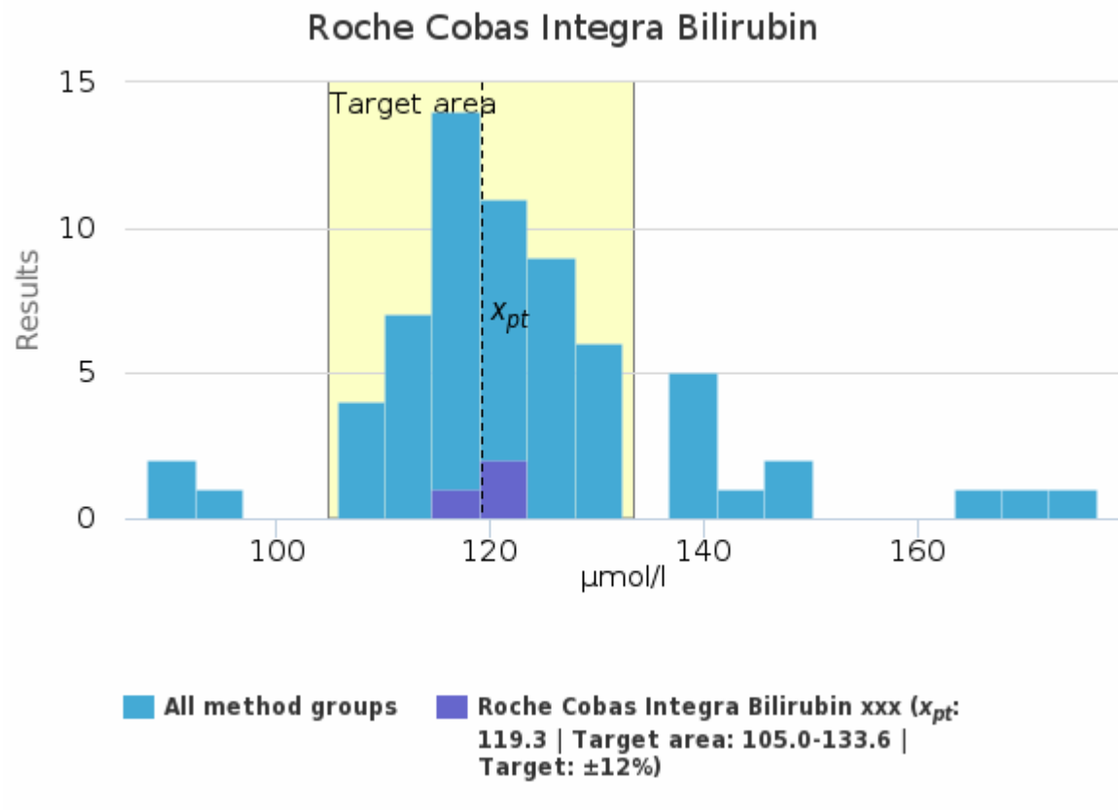


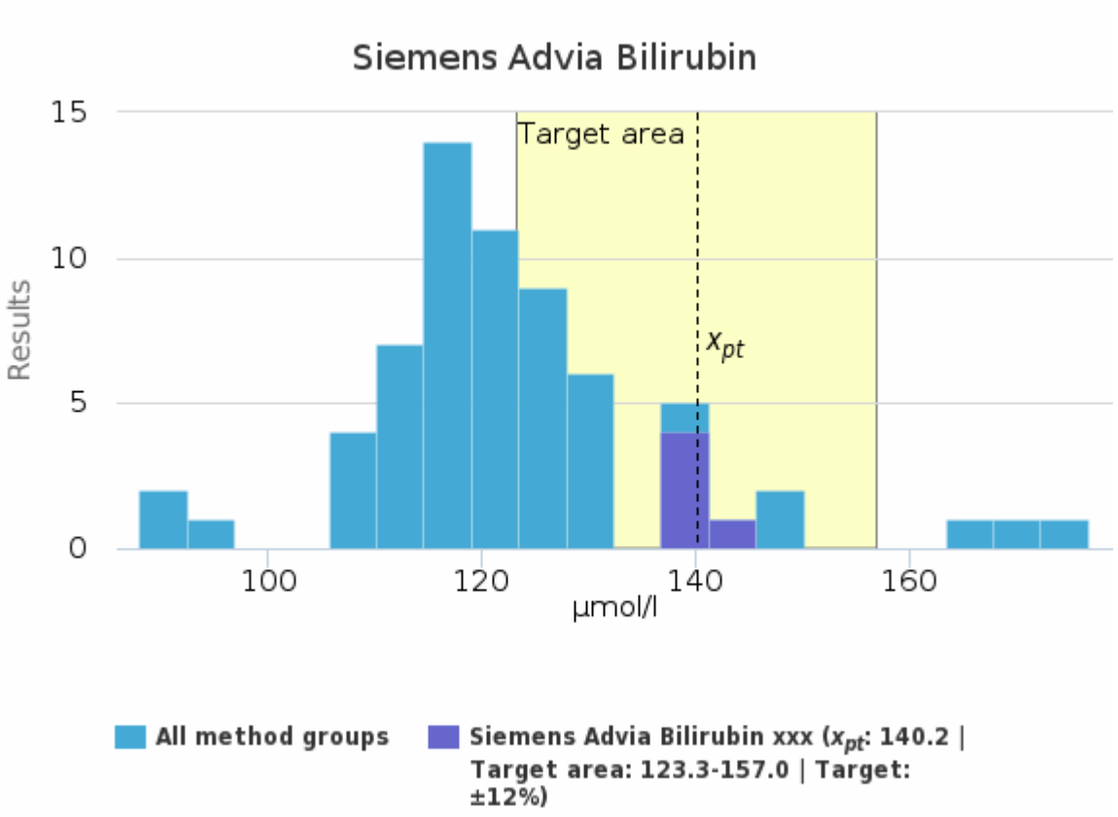


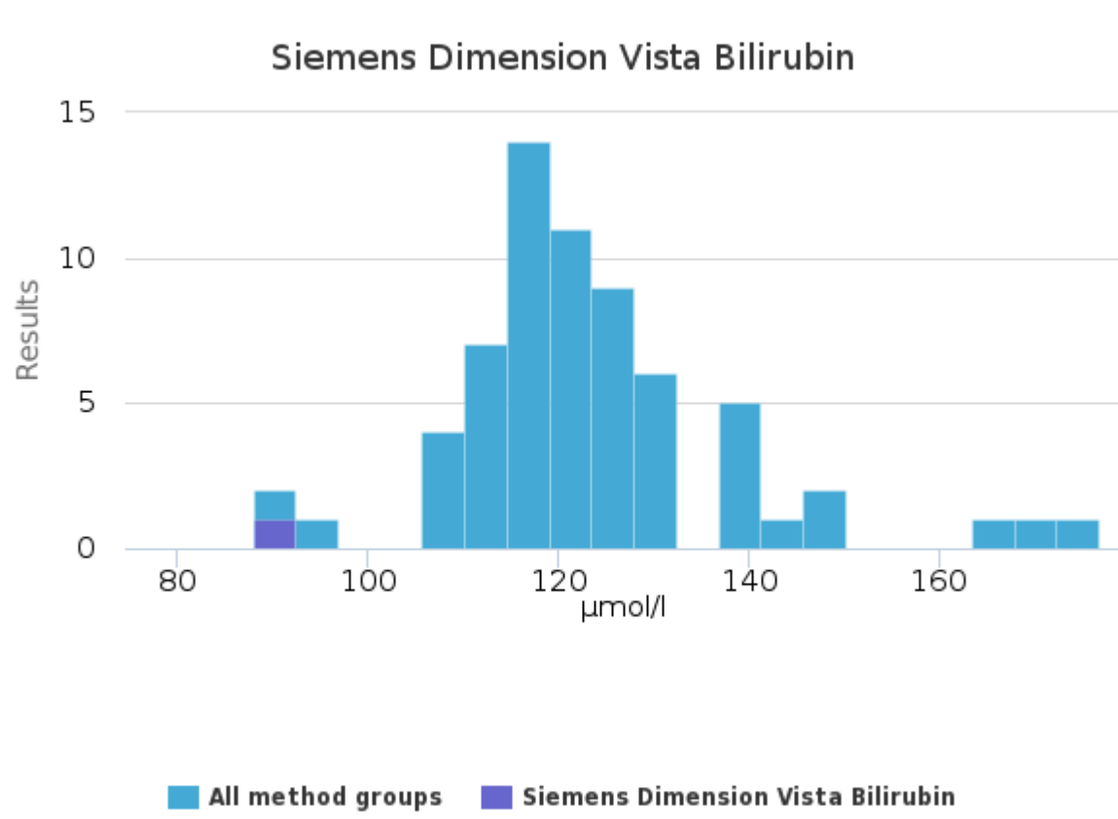
Bilirubin, conjugated, February, 1-2023

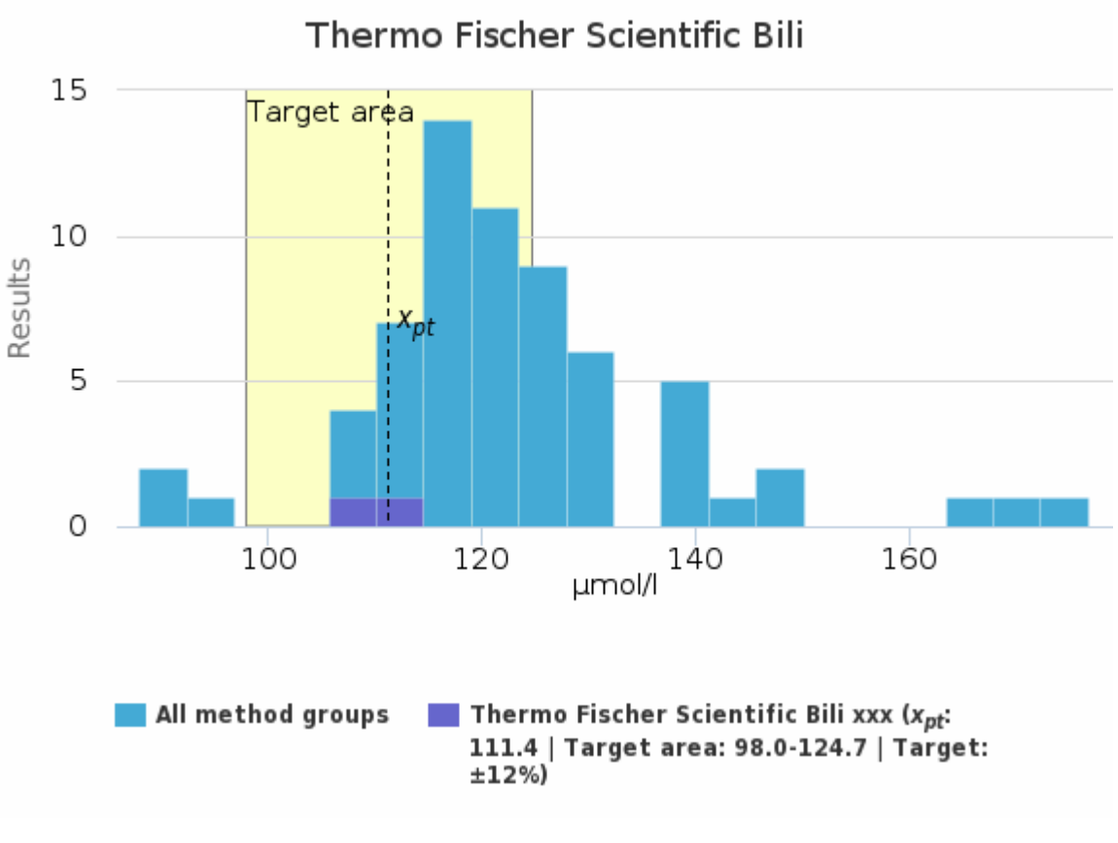
Quantitative report

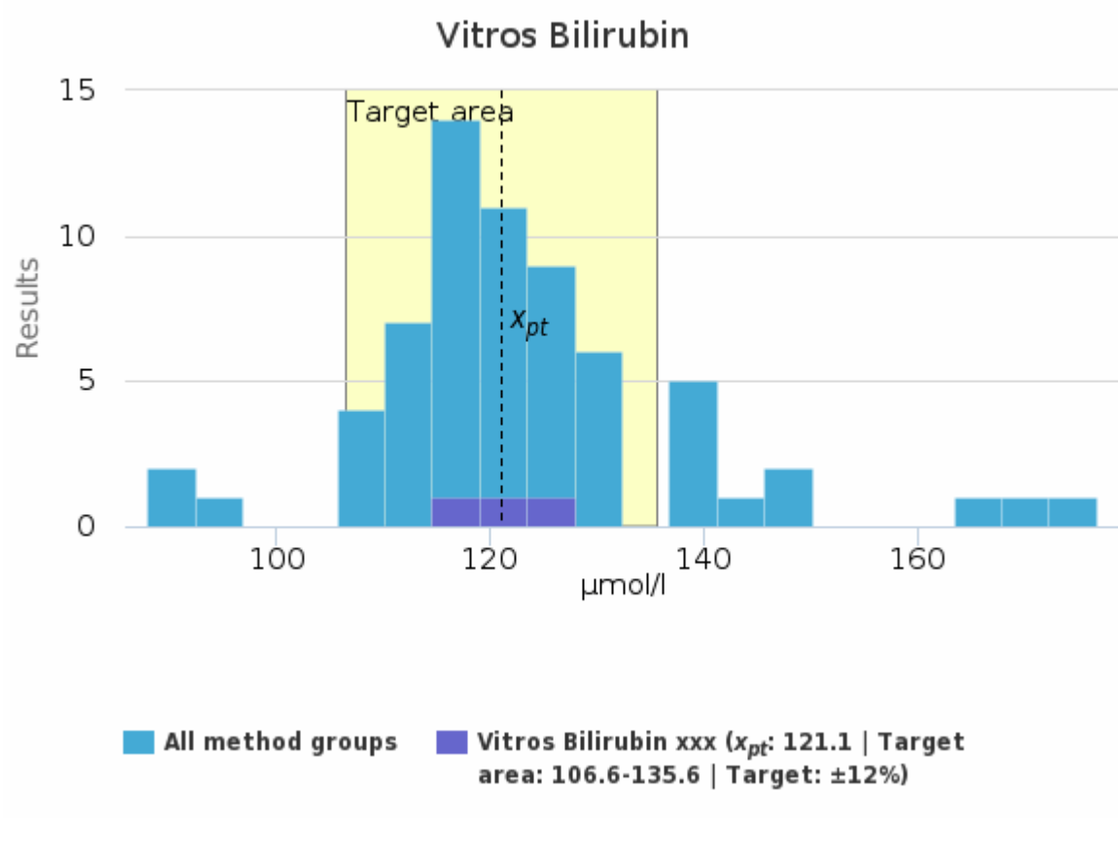












LABQUALITY

Bilirubin, conjugated, February, 1-2023

Quantitative report

Report info

Participants

60 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).

LABQUALITY

External Quality Assessment Scheme

Bilirubin, conjugated
Round 1, 2023

Specimens
Sample S001 (LQ750523011) was human liquid sera
Sample S002 (LQ750523012) was human liquid sera.

Based on the previous tests and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

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

Comments – Expert
The sample S001 represented a sample in a normal range, and the sample S002 was clearly elevated. The same was true for both bilirubin and conjugated bilirubin. About 40% of the respondents were using a method from Roche and about 30% from Abbott. There were around 10 different method groups in this round.

Bilirubin:
The round average in sample S001 was 181.5 µmol/L and the CV% was 8. The average CV% within different method groups was 3, which is good. The range between the results was from 147 µmol/L to 220 µmol/L, there were 67 responders in this round. The round average in sample S002 was 358.3 µmol/L and the CV% 9.1. The average CV% within different method groups was 4, which is good. The range between the results was from 289.9 µmol/L to 436 µmol/L, there were 66 responders. The range reported by the manufacturer for sample S001 was from 102 µmol/L to 229 µmol/L, depending on the method used. The range reported by the manufacturer for sample S002 was from 209 µmol/L to 467 µmol/L. The reported results were well within the limits reported by the manufacturer. The highest results in this round, around 18% above average, were reported with the Siemens Advia Bilirubin method. The lowest results in this round, around 16% lower than average, were reported with the Beckman Coulter AU method.

Conjugated bilirubin:
The round average in sample S001 was 65.4 µmol/L and CV% 10.7. The average CV% within different method groups was 3, which is good. The range between the results was from 46.0 µmol/L to 79.7 µmol/L, there were 63 responders in this round. The round average in sample S002 was 121.8 µmol/L and CV% 10.5. The average CV% within different method groups was 4, which is good. The range between the results was from 88.0 µmol/L to 166.9 µmol/L, there were 65 responders. The range reported by the manufacturer for sample S001 was from 36 µmol/L to 131 µmol/L, depending on the method used. The range reported by the manufacturer for sample S002 was from 69 µmol/L to 198 µmol/L. The reported results were well within the limits reported by the manufacturer. The Siemens Advia Bilirubin method gave 16% higher results compared to the global average. In sample S002, Beckman Coulter gave even higher results (42% higher) compared to the global average. The lowest results in this round of sample S001 were with the Bilirubin method, 24% below the global average.

End of report

2023-03-28

FINAL REPORT

Product no. 2109

Subcontracting: Sample preparation, Sample pretesting

Samples sent	2023-02-14
Round closed	2023-03-10
Final report	2023-03-28

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.

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PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015