

External Quality Assessment Scheme

## Bilirubin, neonatal Round 1, 2023

### Specimens

Please find enclosed lyophilized samples S001 and S002, each 1 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, neo

### Storage and use

Both samples, S001 and S002, are lyophilized samples. Open the vial carefully to prevent any loss of the material. Add 1.0 mL of high-grade room temperature laboratory water to the sample. Close immediately the vial and let stand, protected from light, for about half an hour until all the material is completely dissolved. Invert the vial several times to dissolve any material adhering to the stopper. The specimen should be stored at +2...8 °C and analyzed as a patient sample. The reconstituted controls are stable for 4 hours at room temperature and for 8 hours when stored at +2...8 °C.

Analyse the samples as soon as possible after arrival. Let them reach room temperature before analysis. Bilirubin is sensitive to light and oxygen.

### 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



2023-01-30

### INSTRUCTIONS

Product no. 2040  
LQ747623011-012/FI

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

The results should be reported no later than **March 2, 2023**.

### Inquiries

EQA Coordinator  
Liisa Ylitepsa  
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### Labquality Oy

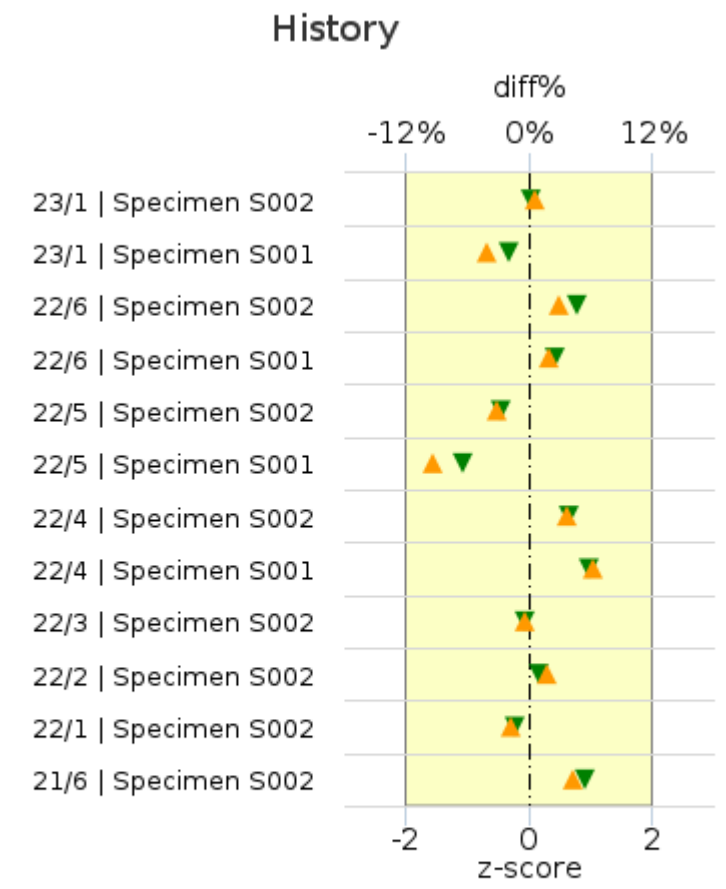
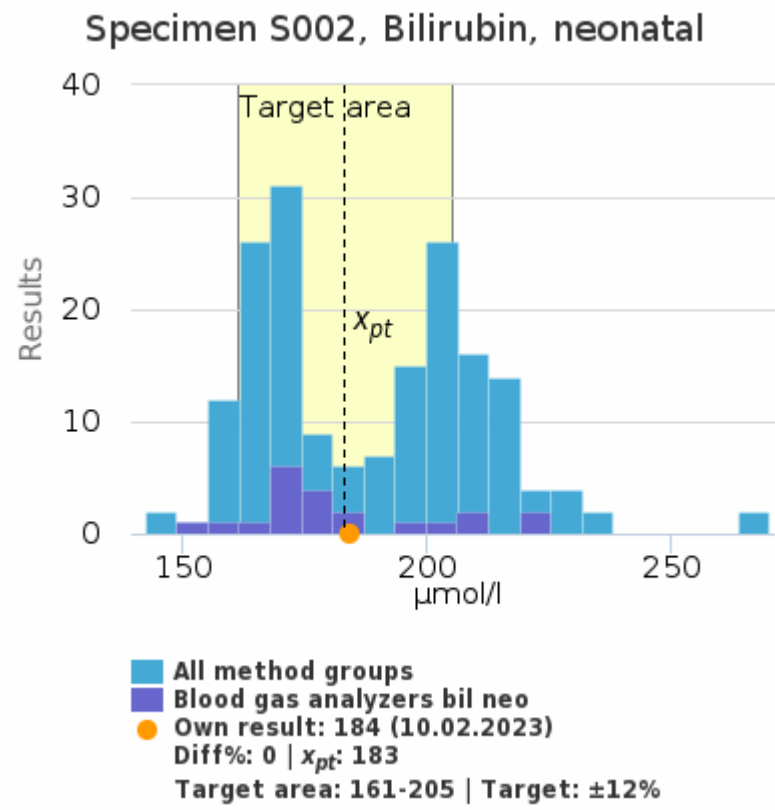
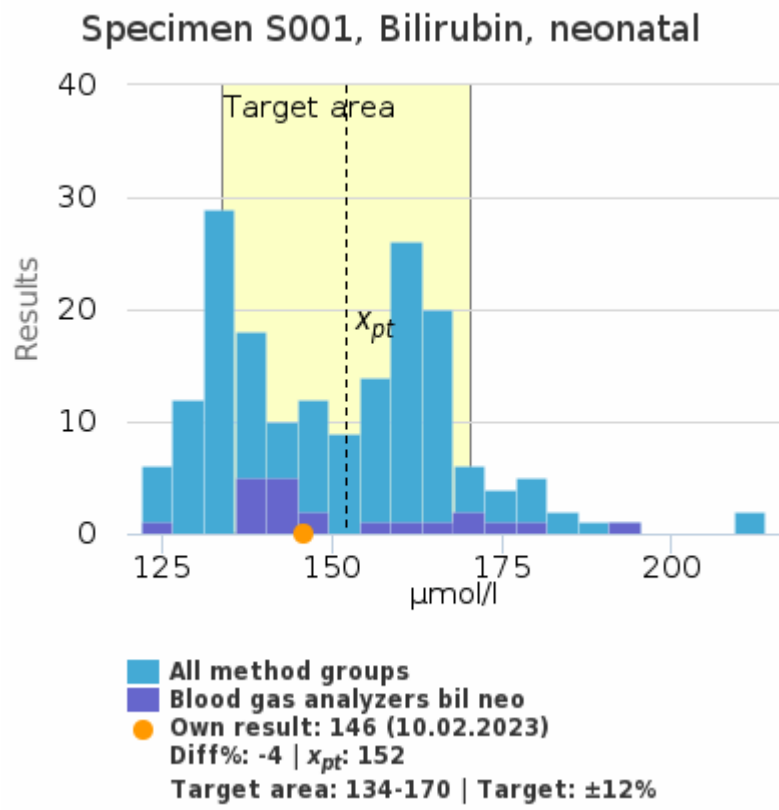
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Bilirubin, neonatal | KBA 1 (ABL)



	$x_{pt}$	sd	SEM	CV%	n
Blood gas analyzers bil neo	152 $\mu\text{mol/l}$	18	4	11.8	21
All methods	150 $\mu\text{mol/l}$	16	1	10.7	177

	$x_{pt}$	sd	SEM	CV%	n
Blood gas analyzers bil neo	183 $\mu\text{mol/l}$	20	4	10.8	21
All methods	188 $\mu\text{mol/l}$	21	2	11.5	177

Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Specimen S002	183	184	0%	0.04
23/1	Specimen S001	152	146	-4%	-0.34
22/6	Specimen S002	263	271	3%	0.79
22/6	Specimen S001	141	144	2%	0.41
22/5	Specimen S002	272	263	-3%	-0.44
22/5	Specimen S001	182	165	-9%	-1.06
22/4	Specimen S002	176	182	4%	0.66
22/4	Specimen S001	141	150	6%	0.98
22/3	Specimen S002	315	314	0%	-0.08
22/2	Specimen S002	267	272	2%	0.16
22/1	Specimen S002	151	148	-2%	-0.22
21/6	Specimen S002	314	327	4%	0.92

**Report info****Participants**

108 participants from 13 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.

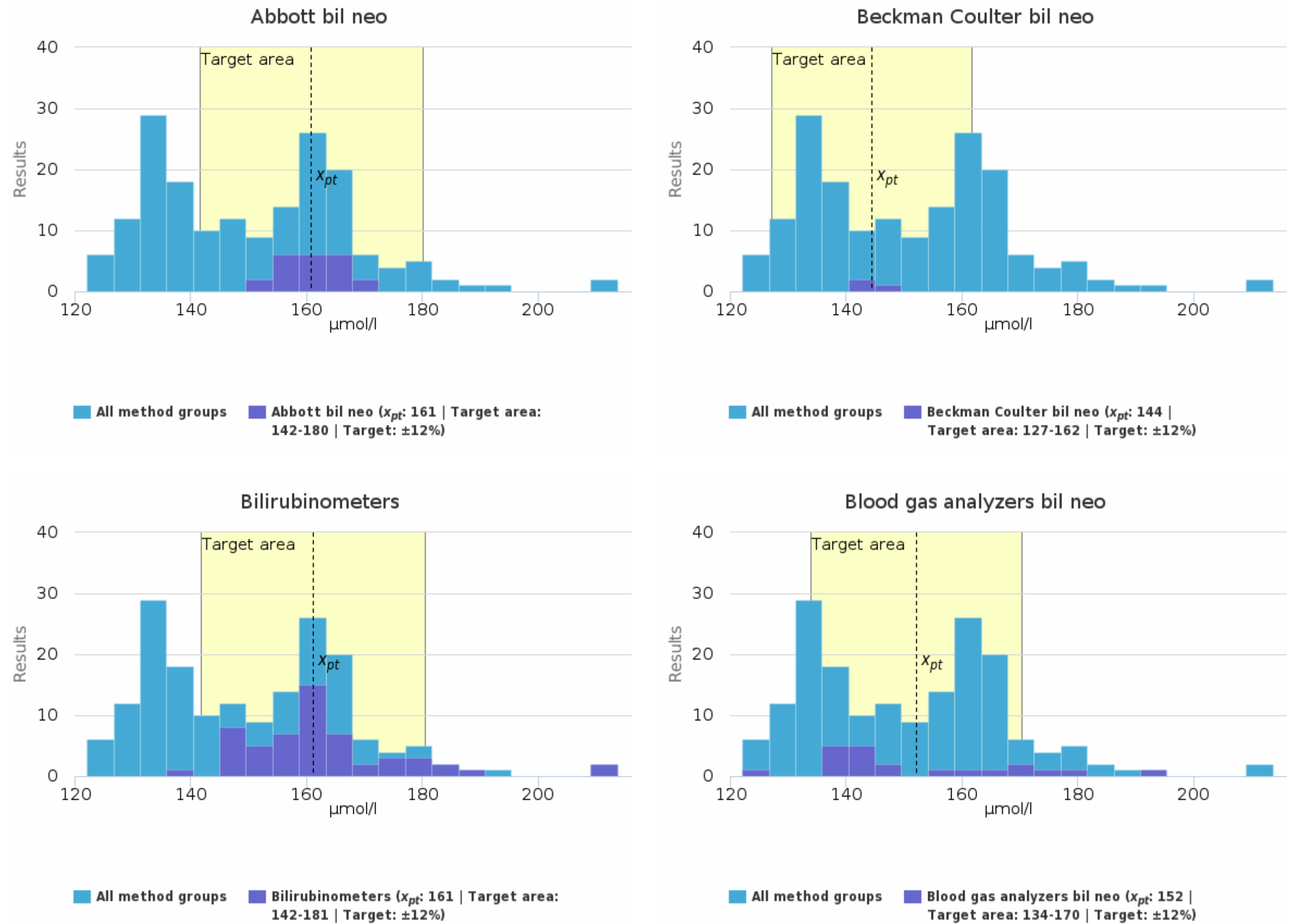
Results reported with  $<$  or  $>$  -signs cannot be included in the statistics.

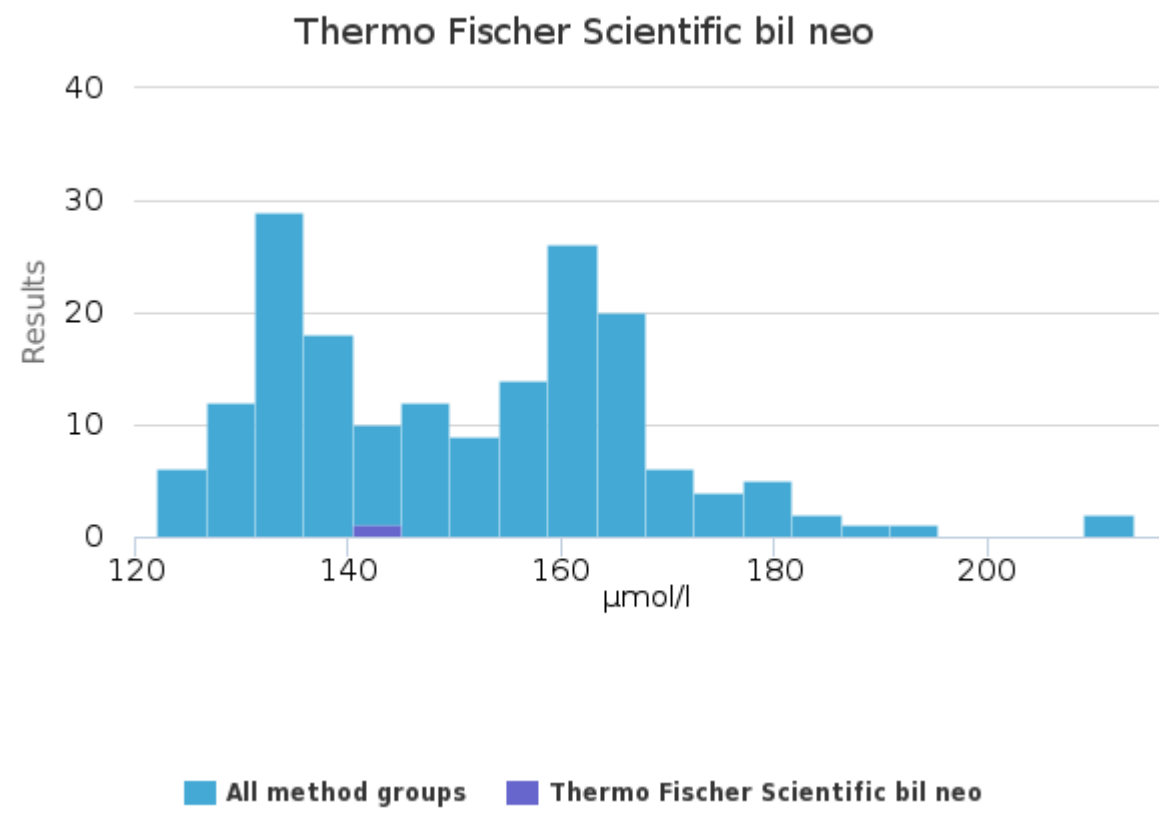
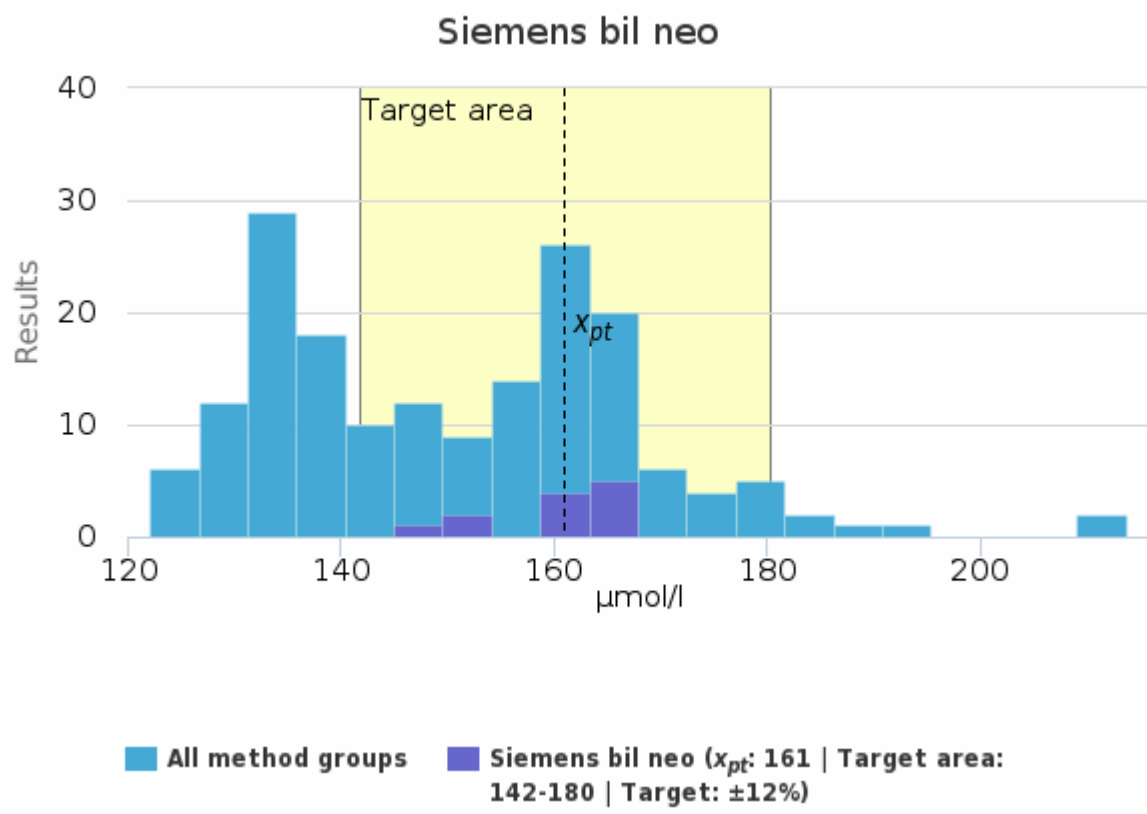
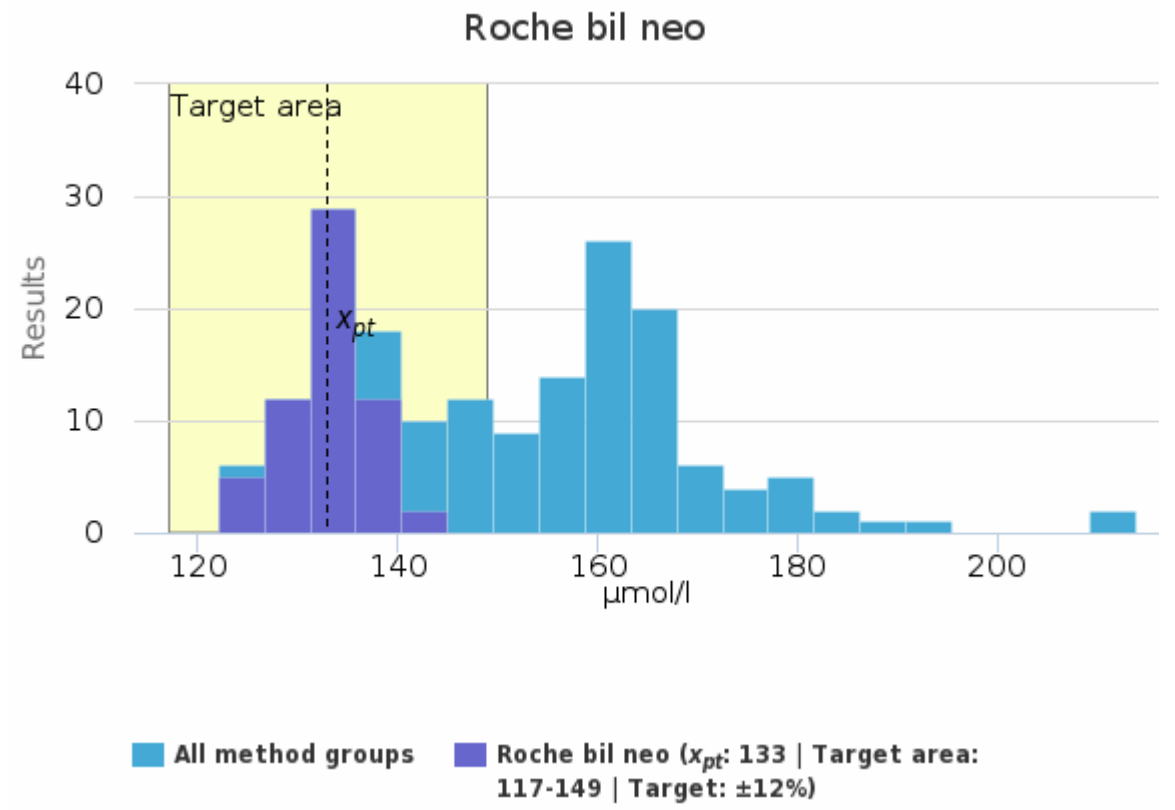
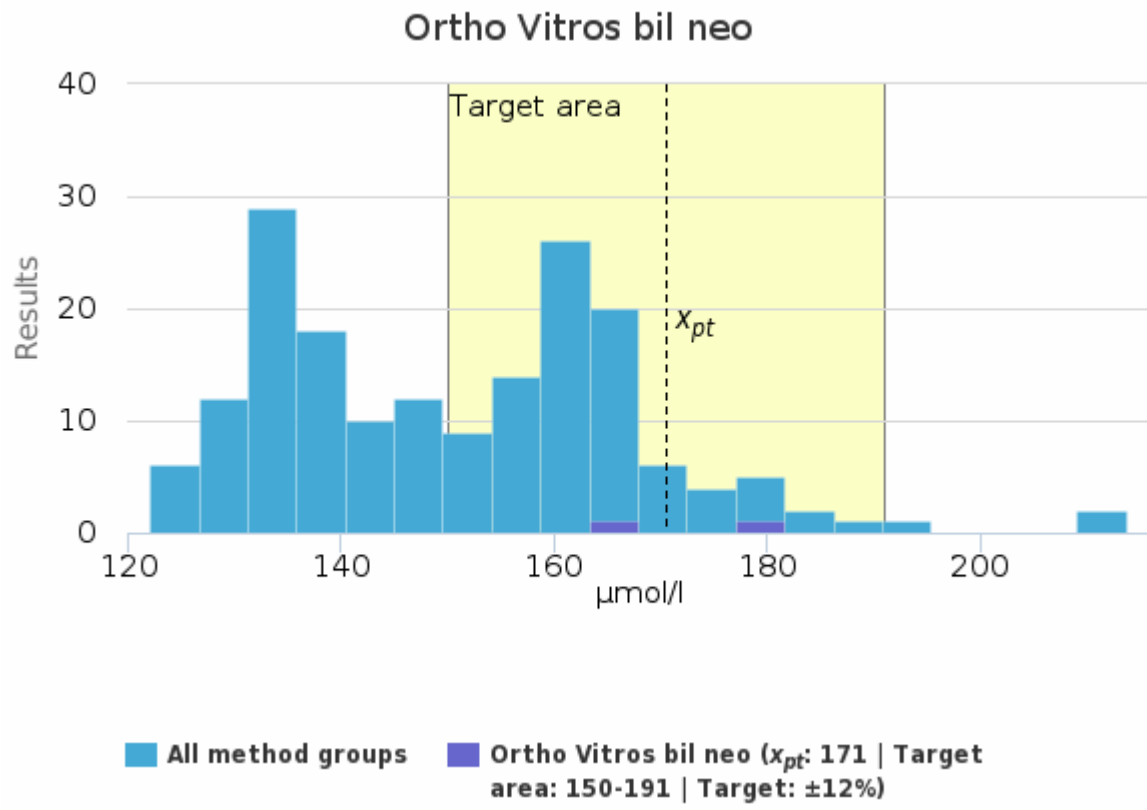
For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

### Specimen S001 | Bilirubin, neonatal, $\mu\text{mol/l}$

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott bil neo	161	161	6	3.6	1	150	171	-	22
Beckman Coulter bil neo	144	144	3	1.9	2	142	147	-	3
Bilirubinometers	161	161	11	6.9	2	140	188	2	56
Blood gas analyzers bil neo	152	143	18	11.8	4	123	194	-	21
Ortho Vitros bil neo	171	171	10	5.8	7	164	178	-	2
Roche bil neo	133	133	4	3.1	<1	122	143	-	60
Siemens bil neo	161	163	6	4.0	2	149	168	-	12
Thermo Fischer Scientific bil neo	-	-	-	-	-	142	142	-	1
<b>All</b>	<b>150</b>	<b>150</b>	<b>16</b>	<b>10.7</b>	<b>1</b>	<b>122</b>	<b>194</b>	<b>2</b>	<b>177</b>

### Specimen S001 | Bilirubin, neonatal, $\mu\text{mol/l}$ | histogram summaries in LabScala

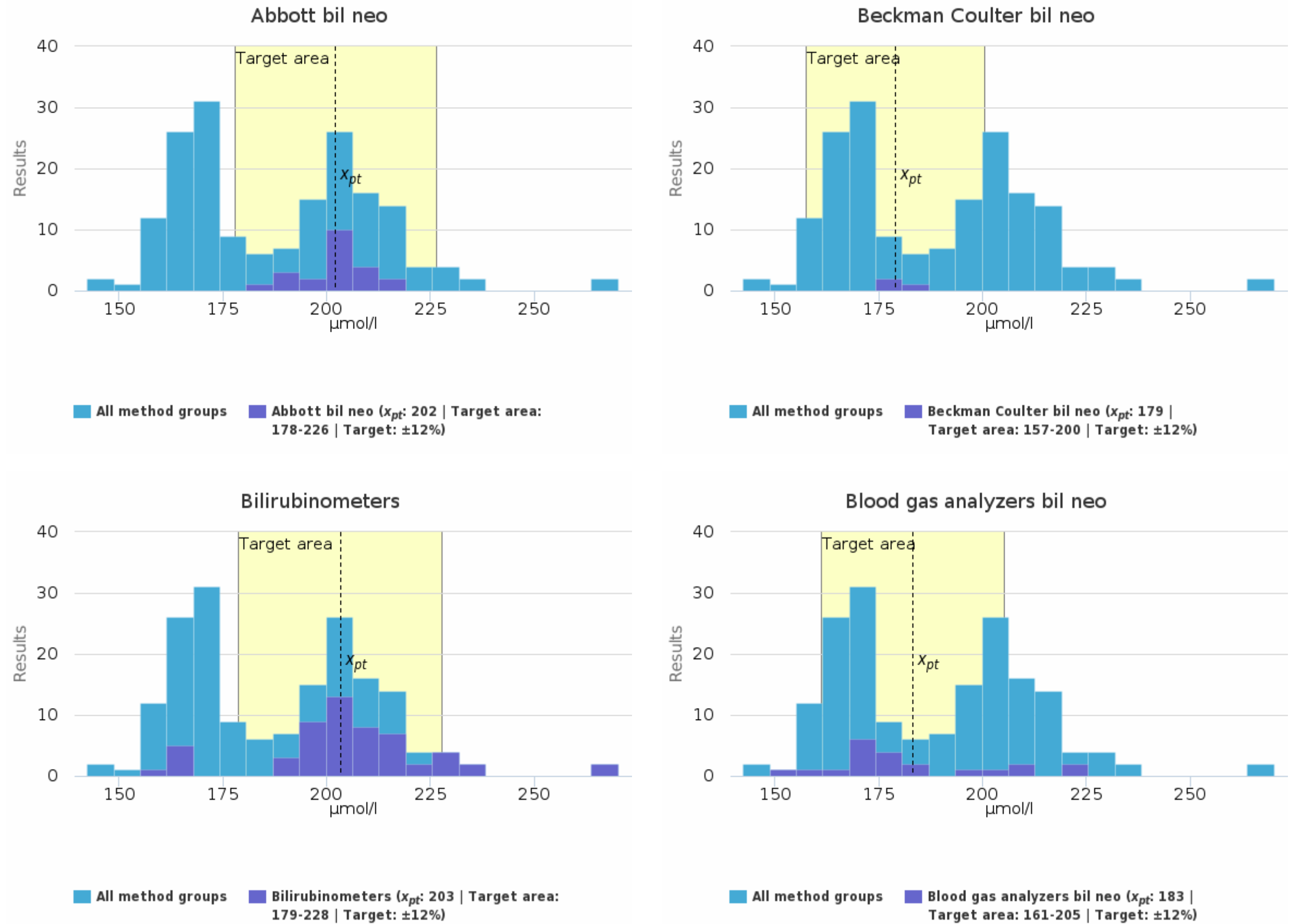


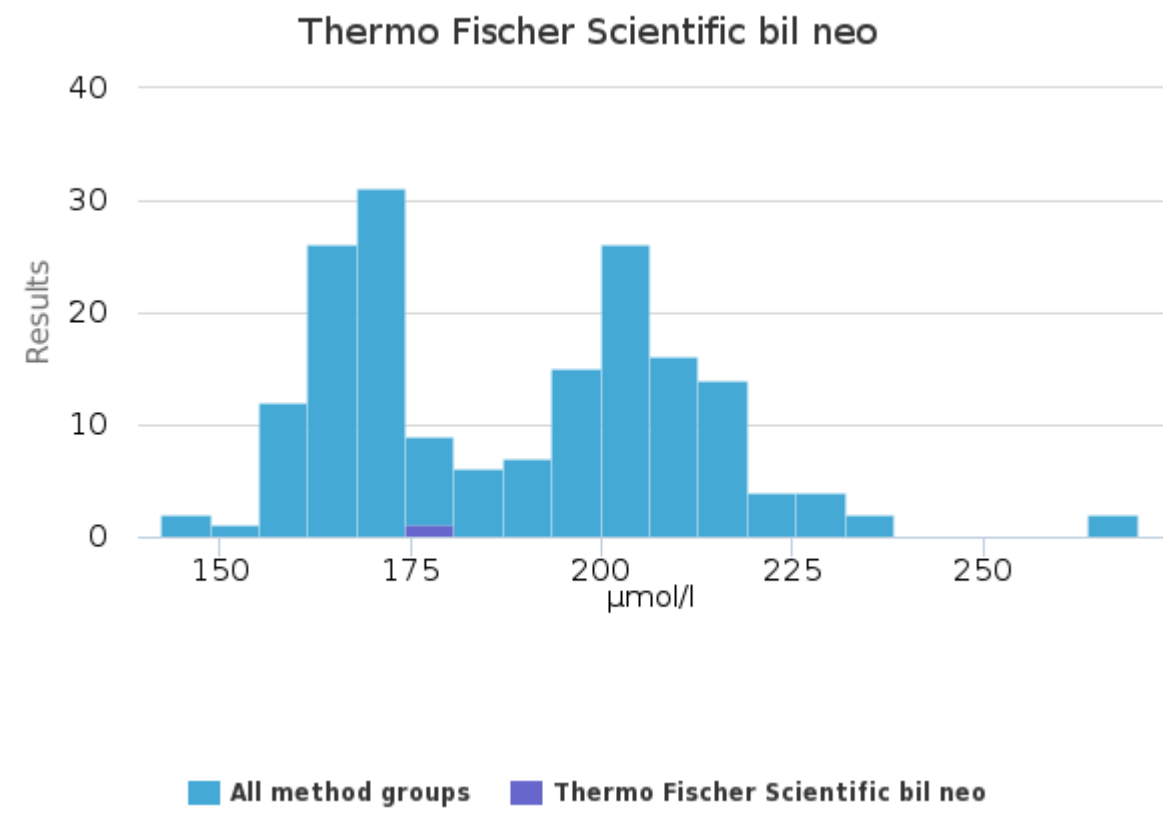
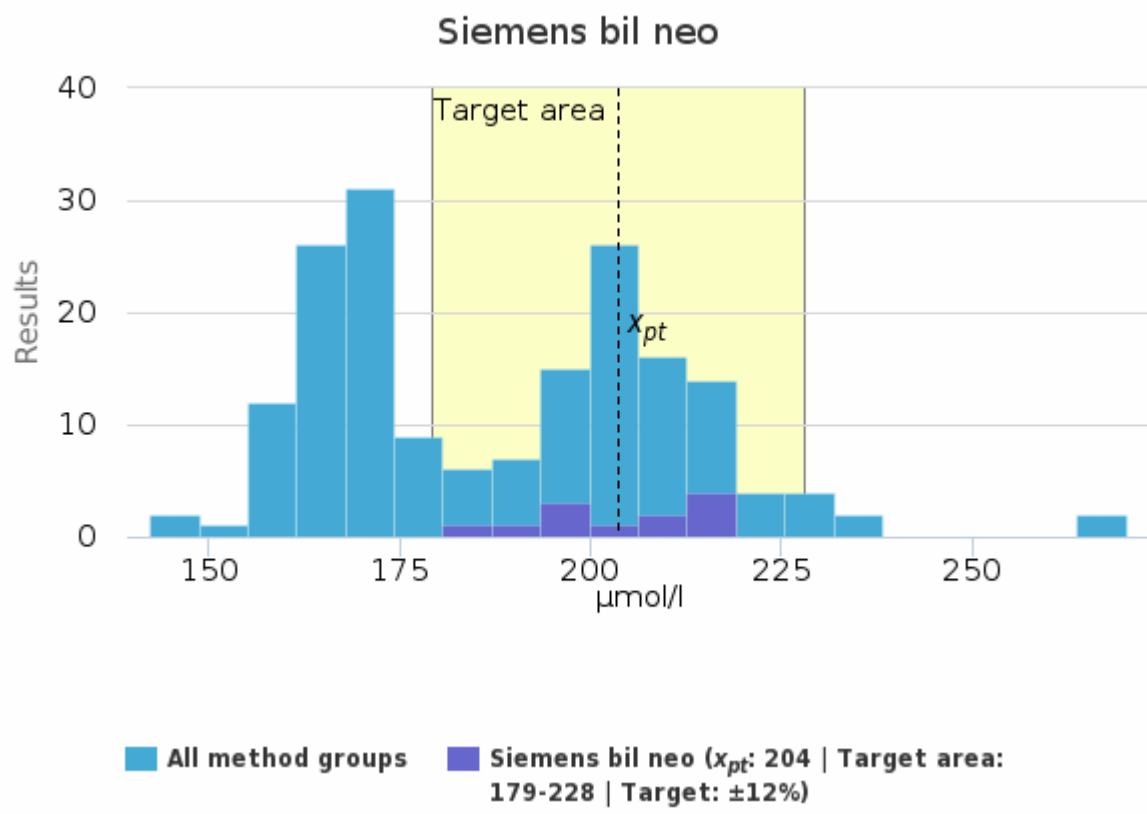
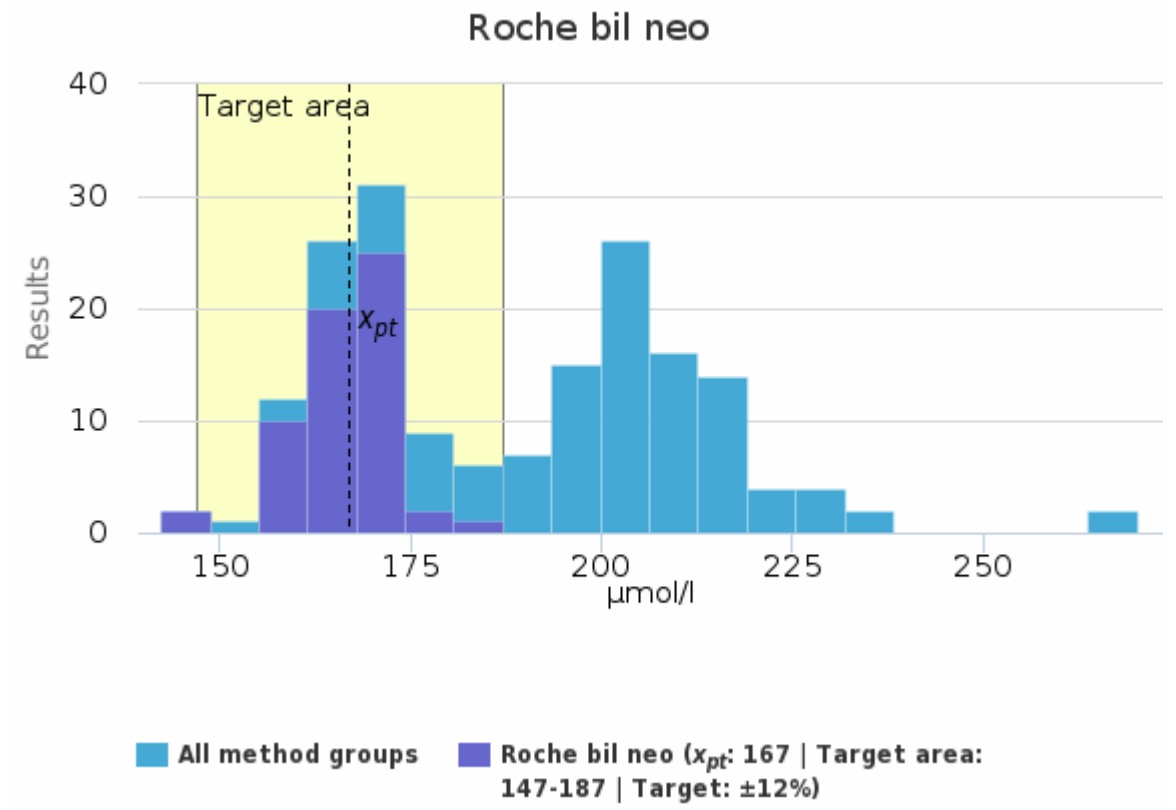
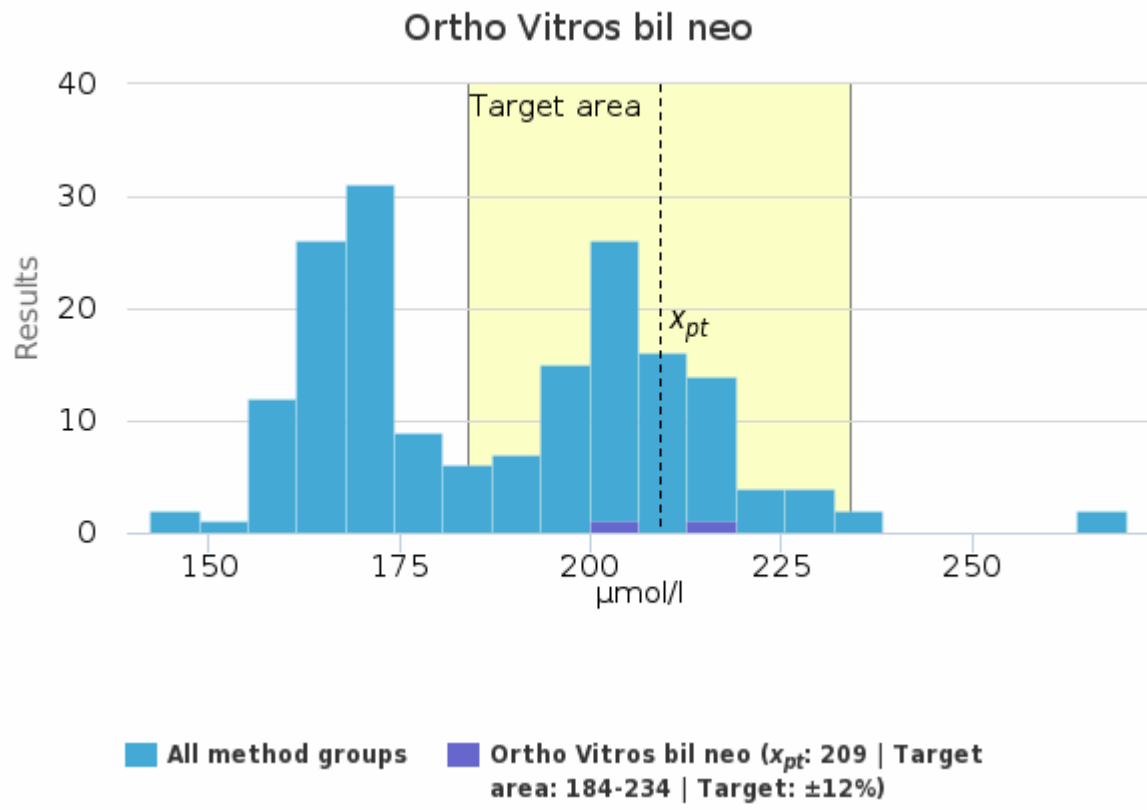


### Specimen S002 | Bilirubin, neonatal, $\mu\text{mol/l}$

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott bil neo	202	204	8	4.0	2	187	218	-	22
Beckman Coulter bil neo	179	177	3	1.9	2	177	183	-	3
Bilirubinometers	203	203	18	8.7	2	161	236	2	56
Blood gas analyzers bil neo	183	178	20	10.8	4	155	225	-	21
Ortho Vitros bil neo	209	209	8	3.8	6	203	215	-	2
Roche bil neo	167	167	6	3.3	<1	155	182	2	60
Siemens bil neo	204	206	11	5.6	3	183	217	-	12
Thermo Fischer Scientific bil neo	-	-	-	-	-	177	177	-	1
<b>All</b>	<b>188</b>	<b>189</b>	<b>21</b>	<b>11.5</b>	<b>2</b>	<b>142</b>	<b>236</b>	<b>2</b>	<b>177</b>

### Specimen S002 | Bilirubin, neonatal, $\mu\text{mol/l}$ | histogram summaries in LabScala





**Report info****Participants**

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**Report info**

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External Quality Assessment Scheme

## Bilirubin, neonatal Round 1, 2023

### Specimens

Sample S001 (LQ747623011) and sample S002 (LQ747623012) were lyophilized samples of human origin.

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

In this round, results were reported in eight (8) different method groups. Total variation (CV%) was 10.7% in S001 and in S002 11.5%. Mean of all results,  $X_{pt}$ , for S001 was 150  $\mu\text{mol/L}$  and for S002 188  $\mu\text{mol/L}$ .

### S001

The highest mean result values were in the Ortho Vitros-method group (method group mean,  $X_{pt} = 171 \mu\text{mol/L}$ ,  $n=2$ ) and in the Bilirubinometers- ( $X_{pt} = 161 \mu\text{mol/L}$ ,  $n=56$ ), the Abbott- ( $X_{pt} = 161 \mu\text{mol/L}$ ,  $n=22$ ), and in the Siemens-method group ( $X_{pt} = 161 \mu\text{mol/L}$ ,  $n=12$ ), where the number of participants was higher compared to the Ortho Vitros-method group. The lowest result mean was in the Roche-method group ( $X_{pt} = 133 \mu\text{mol/L}$ ,  $n=60$ ).

The highest intra-method variation could be found in the Blood Gas Analyzers-method group (CV = 11.8%,  $n=21$ ). The lowest intra-method variations were in the Beckman Coulter- (CV = 1.9%,  $n=3$ ) and in the Roche-method group (CV = 3.1%,  $n=60$ ).

### S002

Ortho Vitros -method group ( $X_{pt} = 209 \mu\text{mol/L}$ ,  $n=2$ ) and Siemens-method group ( $X_{pt} = 204 \mu\text{mol/L}$ ,  $n=12$ ) had the highest result means. The lowest result mean was in the Roche -method group ( $X_{pt} = 167 \mu\text{mol/L}$ ,  $n=60$ ).

The highest intra-method variation could be found in the Blood Gas Analyzers-method group (CV = 10.8%,  $n=21$ ). The lowest intra-method variation was in the Beckman Coulter- (CV = 1.9 %,  $n=3$ ) and Roche-method group (CV = 3.3%,  $n=60$ ).

### End of report

2023-03-10

### FINAL REPORT

Product no. 2040

Samples sent	2023-01-31
Round closed	2023-03-02
Final report	2023-03-10

### 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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### Expert

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