

External Quality Assessment Scheme

C-reactive protein (CRP), for analyzers Round 1, 2023

Specimens

Please find enclosed 2 liquid commercial human plasma samples S001 and S002, each approximately 1mL.

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

CRP

Storage and use

Analyze the samples as soon as possible. The samples are stored at +2..8 °C after arrival. They are ready for use and should be analyzed as patient samples. Let them reach room temperature before analysis.

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. However, < and > results cannot be processed among the numerical results, they will be processed separately if needed. The traceability of your calibrator (ERM-DA474/IFCC, ERM-DA472/IFCC or ERM-DA470) is not anymore a mandatory field in the LabScala. However, if you wish, you can still report it. The traceability can be found in the reagent insert sheet.

S001



S002



2023-02-13

INSTRUCTIONS

Product no. 2020
LQ723723011-12/FI

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 9, 2023.

Inquiries

EQA Coordinator
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Labquality Oy

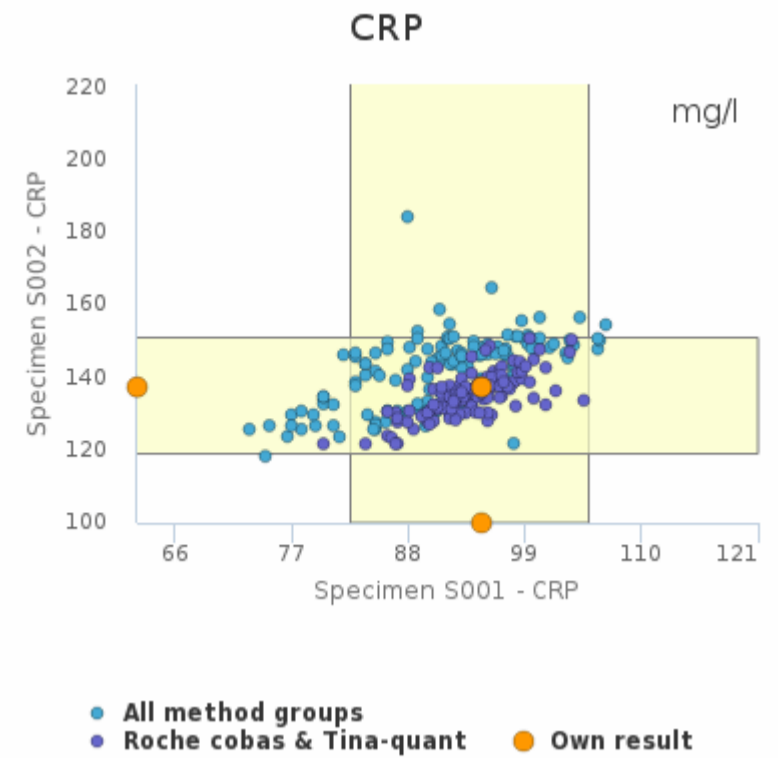
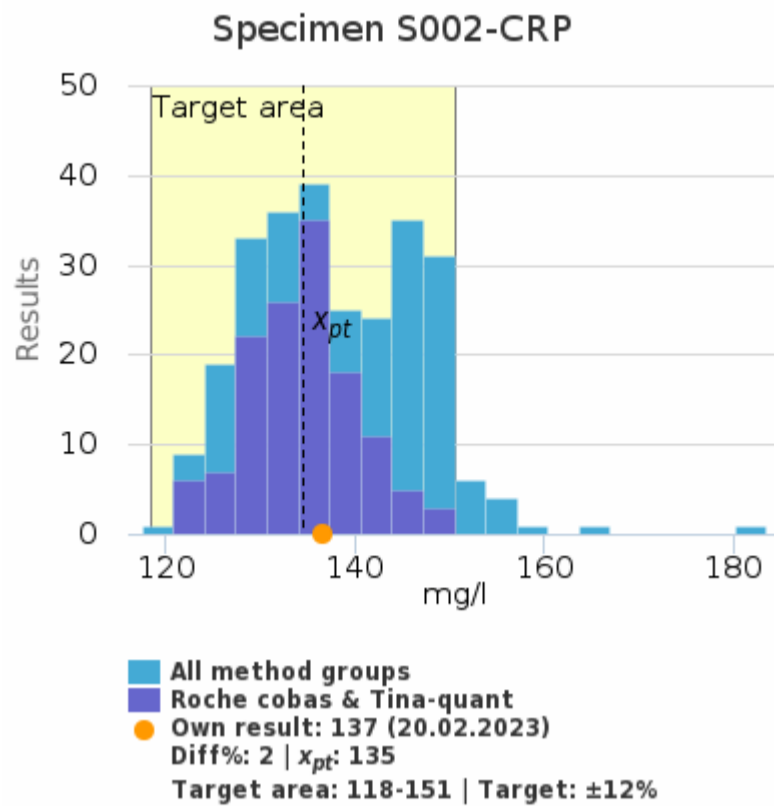
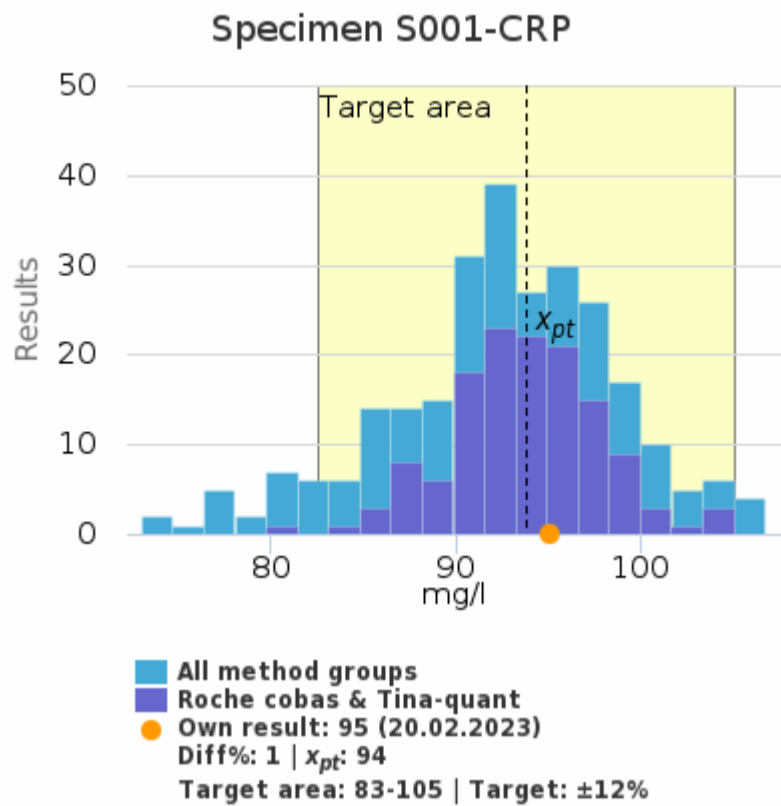
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CRP |cobas 6000

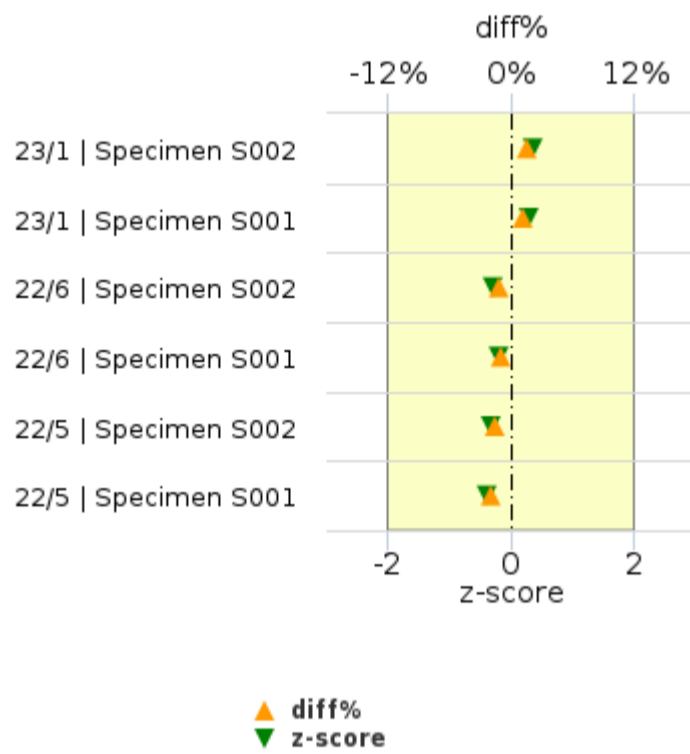


	x_{pt}	sd	SEM	CV%	n
Roche cobas & Tina-quant	94 mg/l	4	<1	4.2	134
All methods	93 mg/l	6	<1	6.6	267

	x_{pt}	sd	SEM	CV%	n
Roche cobas & Tina-quant	135 mg/l	6	<1	4.3	133
All methods	138 mg/l	8	<1	6.1	265

	Inside	Below limit	Over limit
Specimen S001	133	1	0
Specimen S002	133	0	0

History



Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Specimen S002	135	137	2%	0.36
23/1	Specimen S001	94	95	1%	0.30
22/6	Specimen S002	93	92	-1%	-0.28
22/6	Specimen S001	23	23	-1%	-0.20
22/5	Specimen S002	134	132	-2%	-0.34
22/5	Specimen S001	93	91	-2%	-0.39

Report info

Participants

225 participants from 19 countries.

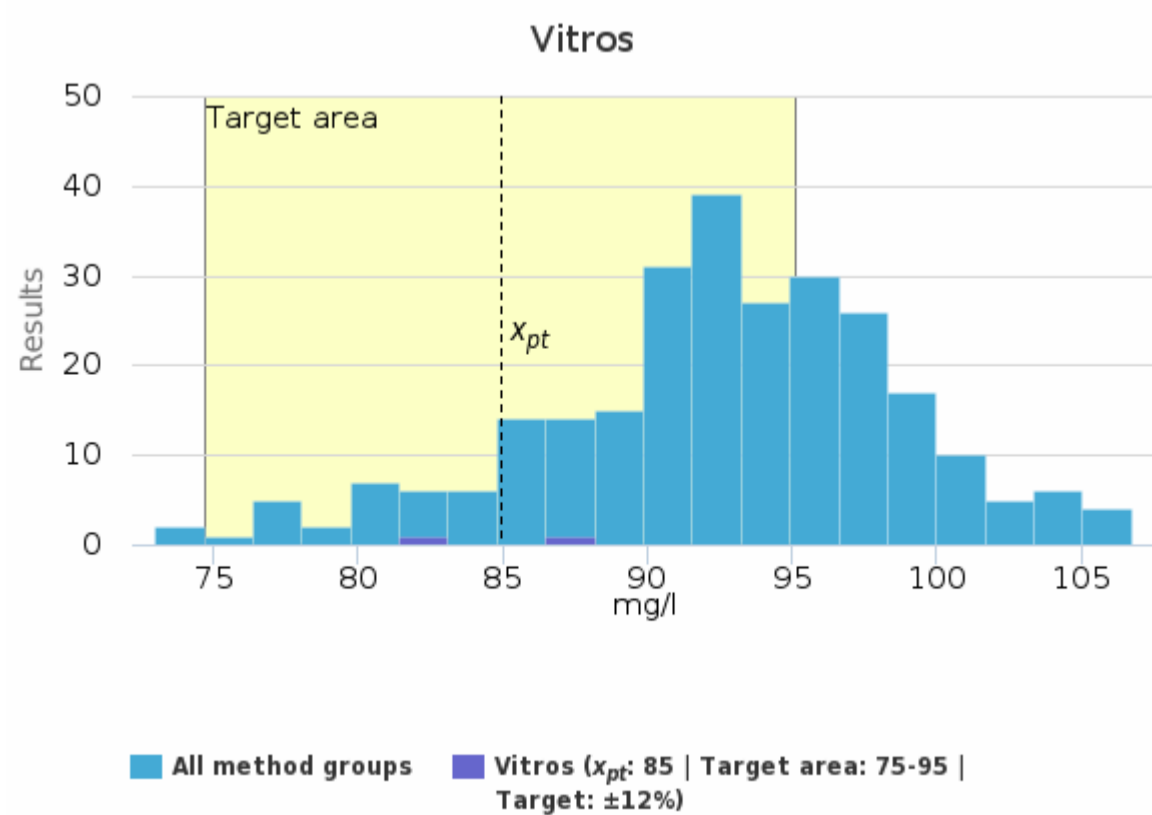
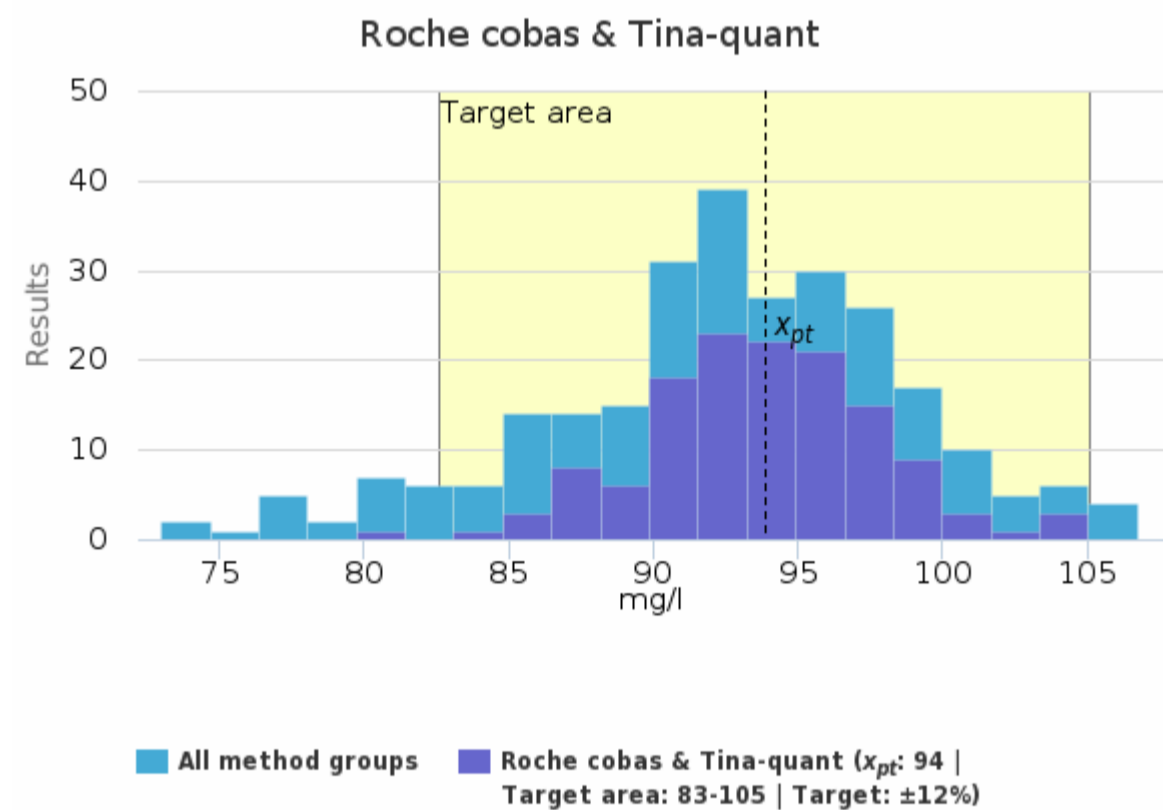
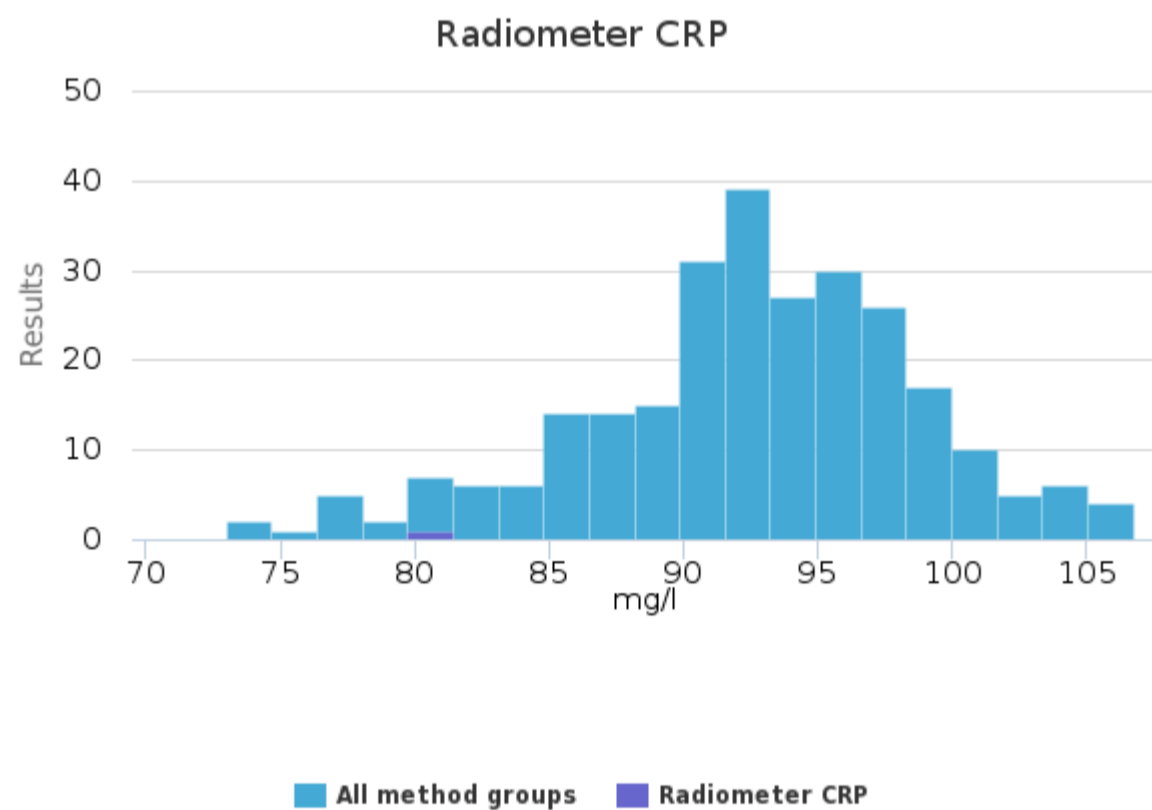
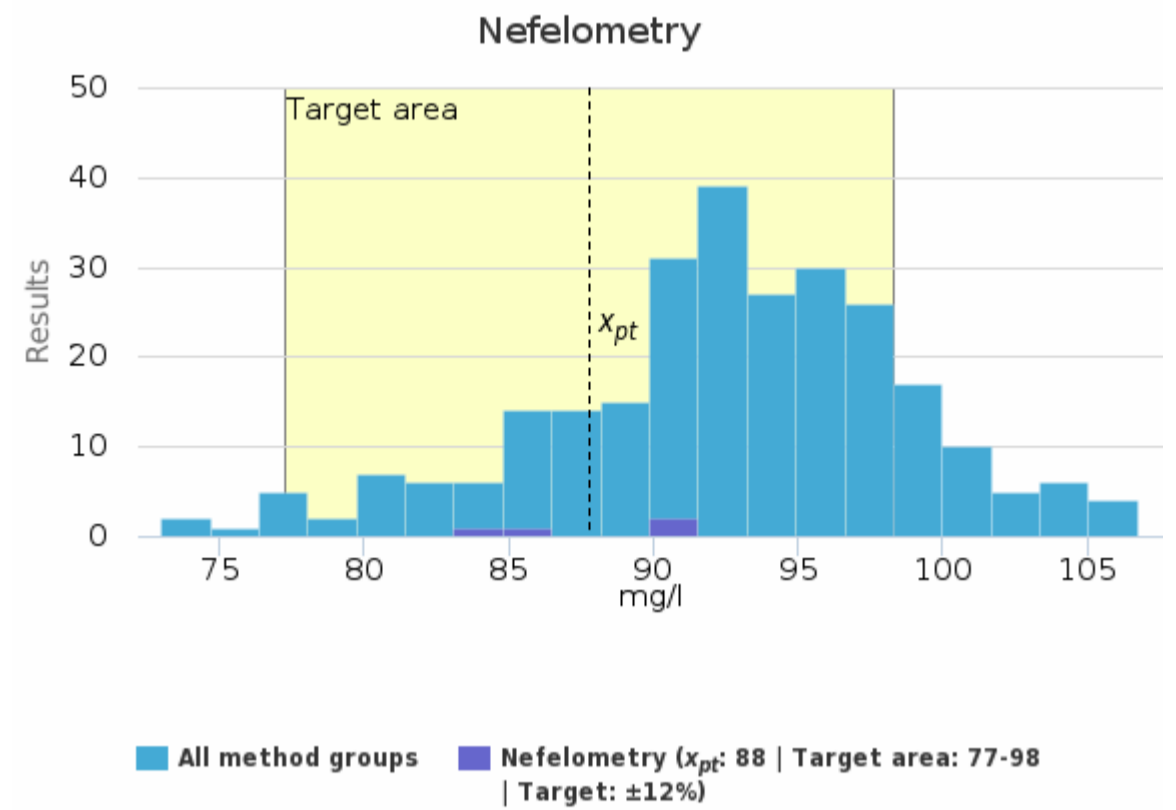
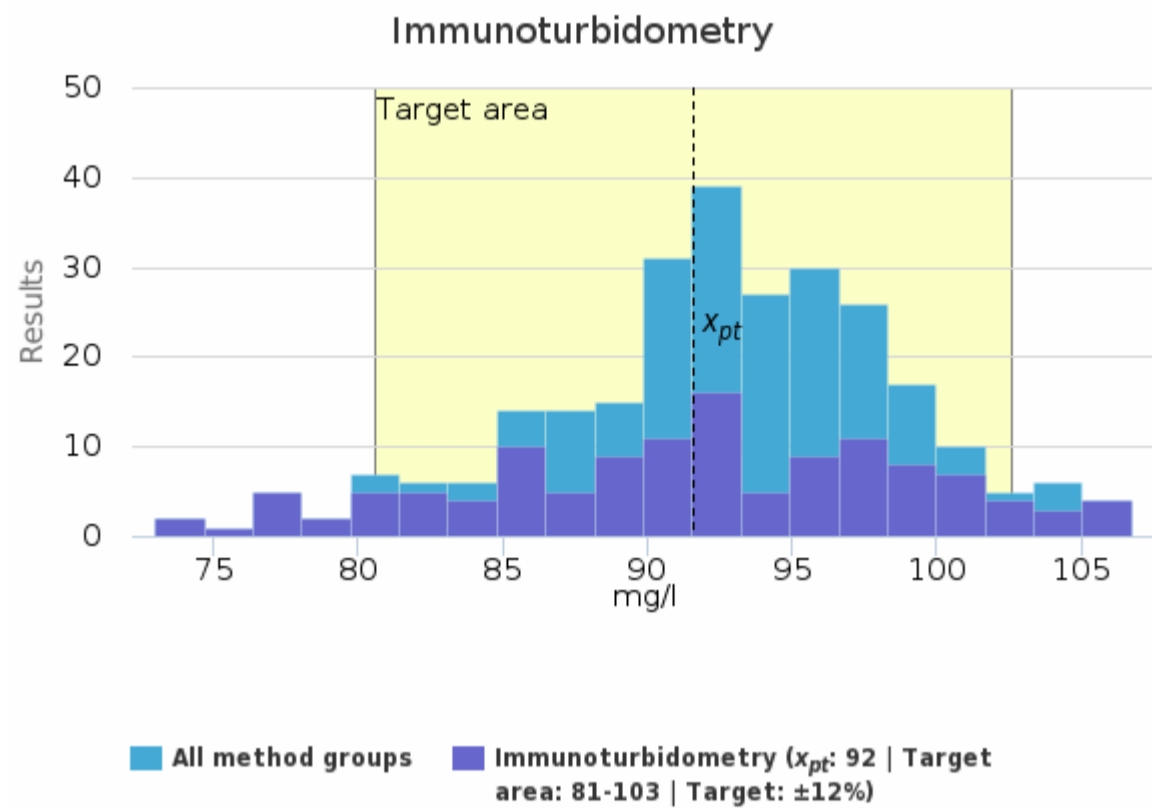
Report info

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).

Specimen S001 | CRP, mg/l

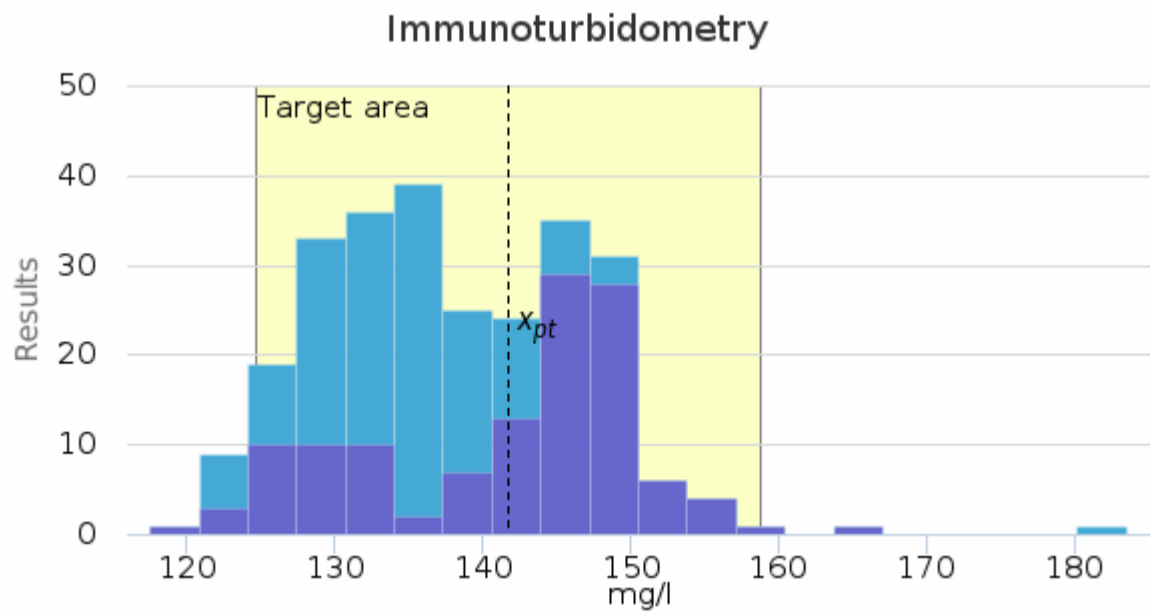
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Immunoturbidometry	92	92	8	8.5	<1	73	107	-	126
Nefelometry	88	88	3	3.7	2	84	91	-	4
Radiometer CRP	-	-	-	-	-	81	81	-	1
Roche cobas & Tina-quant	94	94	4	4.2	<1	84	105	1	134
Vitros	85	85	4	4.9	3	82	88	-	2
All	93	93	6	6.6	<1	74	107	1	267



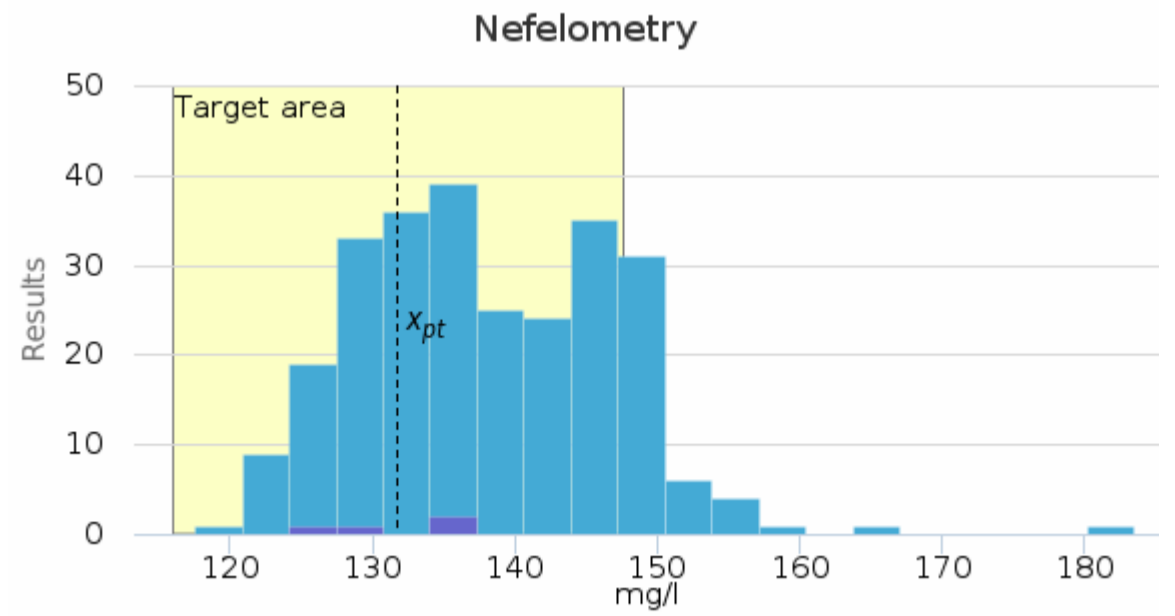
Methodics	Instrument	x_{pt}	sd	CV%	n
Immunoturbidometry		92	8	8.5	126
	ABX Pentra 400	95	9	9.7	5
	Advia Chemistry XPT	99	2	1.7	5
	Alinity c	96	2	2.2	14
	Architect c8000	92	5	5.9	3
	Architect ci4100	91	3	3.2	4
	Architect ci8200	98	2	2.3	3
	Architect c4000	93	2	2.4	2
	Atellica CH 930	92	1	1.3	12
	AU 480	103	3	3.2	9
	AU 680	101	2	2.4	9
	Biosystems BA-400	-	-	-	1
	cobas c501	-	-	-	1
	Dimension EXL	94	4	4.5	3
	Dimension EXL 200	-	-	-	1
	Dimension Vista 1500	87	3	3.8	5
	Dimension Vista 500	-	-	-	1
	DxC 700 AU	-	-	-	1
	Ilab Aries	-	-	-	1
	ILab Taurus	-	-	-	1
	Indiko	-	-	-	1
	Indiko Plus	84	6	7.0	16
	Integra 400 Plus	92	2	2.0	2
	Konelab Prime 30	78	4	4.6	2
	Konelab PRIME 60i	83	5	5.7	8
	Konelab 20	-	-	-	1
Konelab 20i	88	5	5.9	7	
Konelab 20XTi	-	-	-	1	
Konelab 30i	81	7	8.1	4	
Konelab 60i	88	4	4.7	3	
Nefelometry		88	3	3.7	4
	Atellica NEPH 630 System	-	-	-	1
	BN ProSpec	87	3	3.4	3
Radiometer CRP		-	-	-	1
	AQT 90 FLEX	-	-	-	1
Roche cobas & Tina-quant		94	4	4.2	134
	cobas c111	96	4	4.7	22
	cobas c303	93	5	5.1	3
	cobas c311	93	2	2.2	6
	cobas c501	94	3	3.7	53
	cobas c502	92	4	4.4	2
	cobas c503	94	3	2.9	10
	cobas c702	91	5	5.9	13
	Integra 400	90	3	3.7	3
	Integra 400 Plus	94	4	4.5	22
	Vitros		85	4	4.9
Vitros 250		-	-	-	1
Vitros 5600		-	-	-	1

Specimen S002 | CRP, mg/l

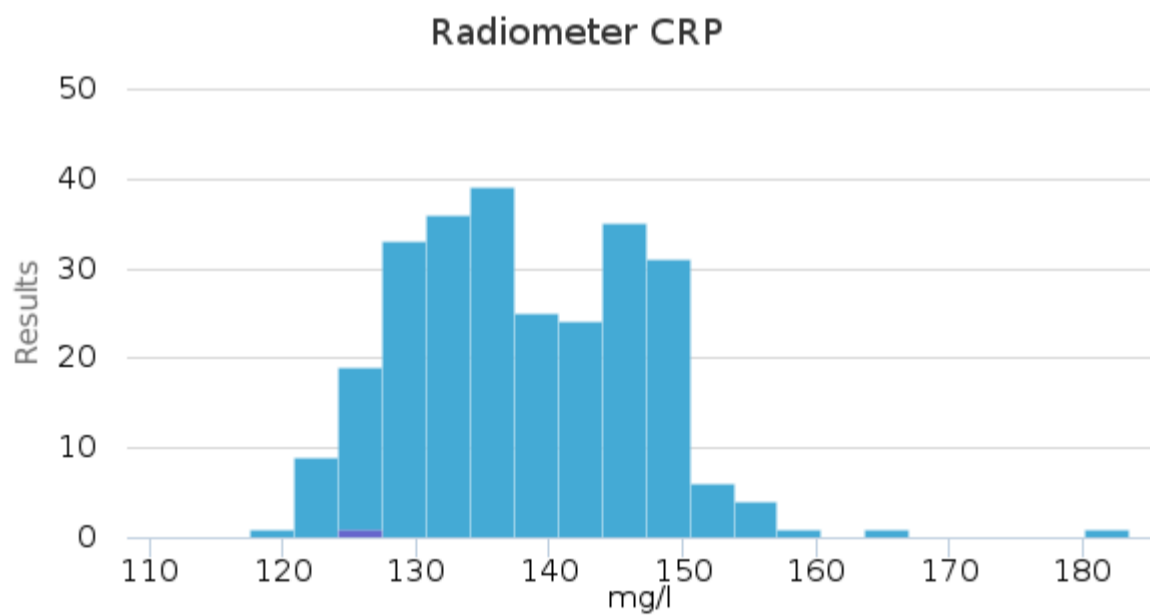
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Immunoturbidometry	142	145	9	6.6	<1	118	164	-	125
Nefelometry	132	132	4	3.4	2	127	136	-	4
Radiometer CRP	-	-	-	-	-	126	126	-	1
Roche cobas & Tina-quant	135	135	6	4.3	<1	121	150	-	133
Vitros	165	165	27	16.3	19	146	184	-	2
All	138	137	8	6.1	<1	118	158	2	265



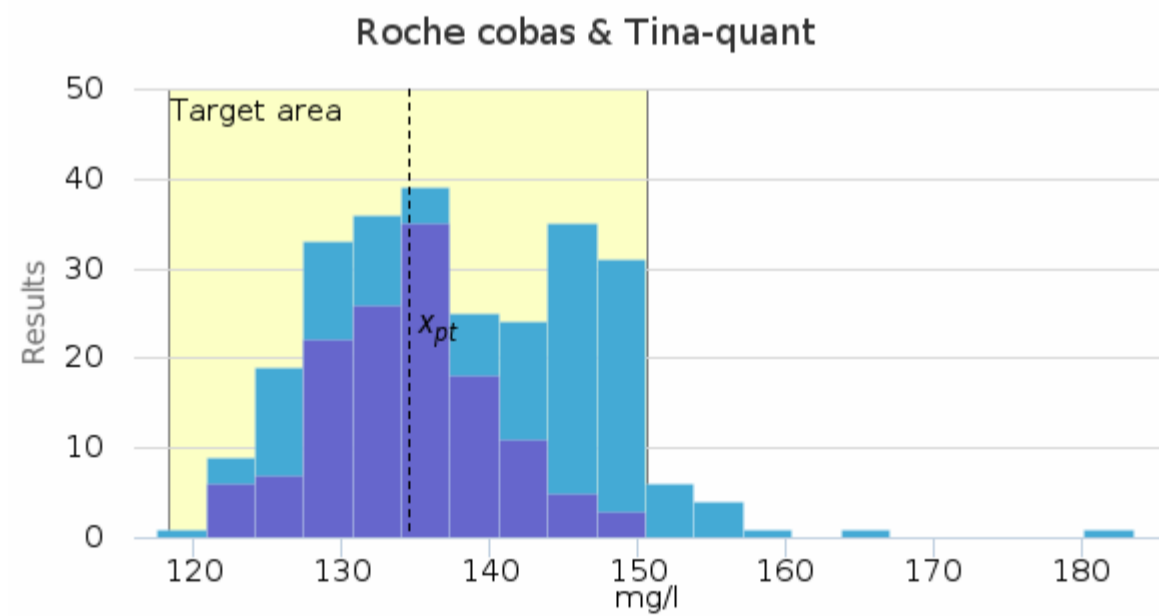
■ All method groups ■ Immunoturbidometry (x_{pt} : 142 | Target area: 125-159 | Target: $\pm 12\%$)



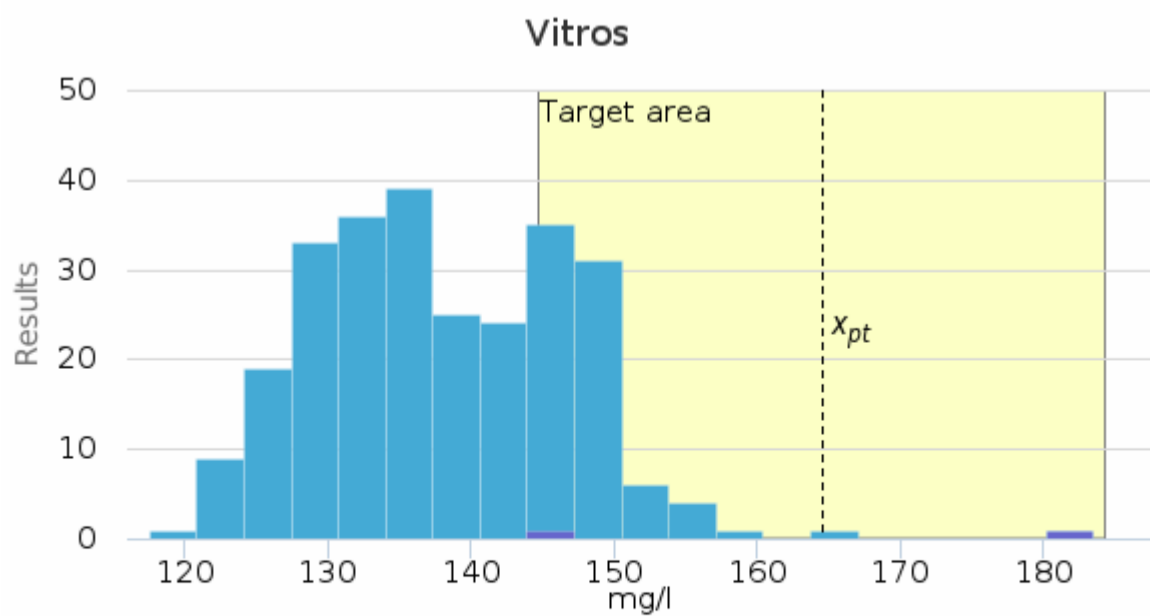
■ All method groups ■ Nefelometry (x_{pt} : 132 | Target area: 116-148 | Target: $\pm 12\%$)



■ All method groups ■ Radiometer CRP



■ All method groups ■ Roche cobas & Tina-quant (x_{pt} : 135 | Target area: 118-151 | Target: $\pm 12\%$)



■ All method groups ■ Vitros (x_{pt} : 165 | Target area: 145-184 | Target: $\pm 12\%$)

Methodics	Instrument	x_{pt}	sd	CV%	n
Immunoturbidometry		142	9	6.6	125
	ABX Pentra 400	146	15	10.0	5
	Advia Chemistry XPT	149	2	1.2	5
	Alinity c	147	3	1.8	14
	Architect c8000	143	3	2.1	3
	Architect ci4100	146	4	2.8	4
	Architect ci8200	147	2	1.3	3
	Architect c4000	147	1	0.8	2
	Atellica CH 930	146	2	1.6	12
	AU 480	148	3	2.2	9
	AU 680	147	3	1.9	9
	Biosystems BA-400	-	-	-	1
	cobas c501	-	-	-	1
	Dimension EXL	148	4	2.7	3
	Dimension EXL 200	-	-	-	1
	Dimension Vista 1500	128	2	1.9	5
	Dimension Vista 500	-	-	-	1
	DxC 700 AU	-	-	-	1
	Ilab Aries	-	-	-	1
	ILab Taurus	-	-	-	1
	Indiko	-	-	-	1
	Indiko Plus	136	11	7.8	16
	Integra 400 Plus	137	11	7.9	2
	Konelab Prime 30	130	6	4.4	2
	Konelab PRIME 60i	132	6	4.4	8
	Konelab 20	-	-	-	1
	Konelab 20i	147	11	7.2	6
Konelab 20XTi	-	-	-	1	
Konelab 30i	130	4	3.2	4	
Konelab 60i	141	10	7.3	3	
Nefelometry		132	4	3.4	4
	Atellica NEPH 630 System	-	-	-	1
	BN ProSpec	131	5	3.6	3
Radiometer CRP		-	-	-	1
	AQT 90 FLEX	-	-	-	1
Roche cobas & Tina-quant		135	6	4.3	133
	cobas c111	138	7	4.9	22
	cobas c303	132	5	4.1	4
	cobas c311	133	4	3.2	6
	cobas c501	134	5	3.5	53
	cobas c502	132	5	3.9	2
	cobas c503	135	3	1.9	9
	cobas c702	131	8	6.1	12
	Integra 400	134	7	5.4	3
	Integra 400 Plus	136	6	4.3	22
	Vitros		165	27	16.3
Vitros 250		-	-	-	1
Vitros 5600		-	-	-	1

Report info**Participants**

225 participants from 19 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.

If a reference value (x_{ref}), is used as an assigned value, uncertainty of the assigned value and metrological traceability will be reported in the Final report letter.

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).

External Quality Assessment Scheme

C-reactive protein (CRP) for analyzers Round 1, 2023

Specimens

Sample S001 (LQ723723011) and sample S002 (LQ723723012) were liquid commercial human plasma samples containing < 0.1% Na-azide.

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

The values given by the manufacturer :

Sample S001: about 90 mg/L

Sample S002: about 140 mg/L

The target values of the samples are traced to ERM® - DA474/IFCC. The values of the samples given by the sample manufacturer are only indicative. Laboratories should compare their results primarily to the calculated assigned value of their method group i.e to the corrected method mean (marked as X_{pt} in the reports).

Comments – Expert

In this round, the concentrations of both samples were high. Reasonably consistent results were obtained from both samples. Most of the results fit in the target range in all groups.

In the immunoturbidimetry group the result levels vary by manufacturer. The average values of the device groups vary from sample S001 between 78 and 103 mg/L and from sample S002 between 128 and 149 mg/L. This means a deviation of up to 16% from the target value given by the sample manufacturer. The output levels of manufacturers' reagents, equipment and even equipment models differ significantly from each other. Only one result is out from the target range in Roche group.

Both the average and median concentrations of both samples correspond quite well to the target concentrations given by the manufacturer.

End of report

2023-03-29

FINAL REPORT

Product no. 2020

Samples sent	2023-02-13
Round closed	2023-03-09
Final report	2023-03-29

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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