The Problem of the Use of different Units for the same Analyte

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Comparability of results

- Measurement traceability to the reference material or procedures
- Measurement traceability to International System of units - SI units
- Interchange of information between laboratories

Comparability of results

- Of the seven base SI-units the mass unit **kilogram** and unit for substance amount **mole** are the ones are mostly used in clinical chemistry
- Several non-SI but internationally accepted units : litre, IU
- Traceability to international coventional standards

Unit used in EQA schemes

- Aim to follow international agreements
- Specific instructions on the recording and reporting the test results are supplied to laboratories (e.g. units and significant figures).
- Regardless of detailed instructions the data an EQA-coordinator receives contains results with various units

Challenges in units

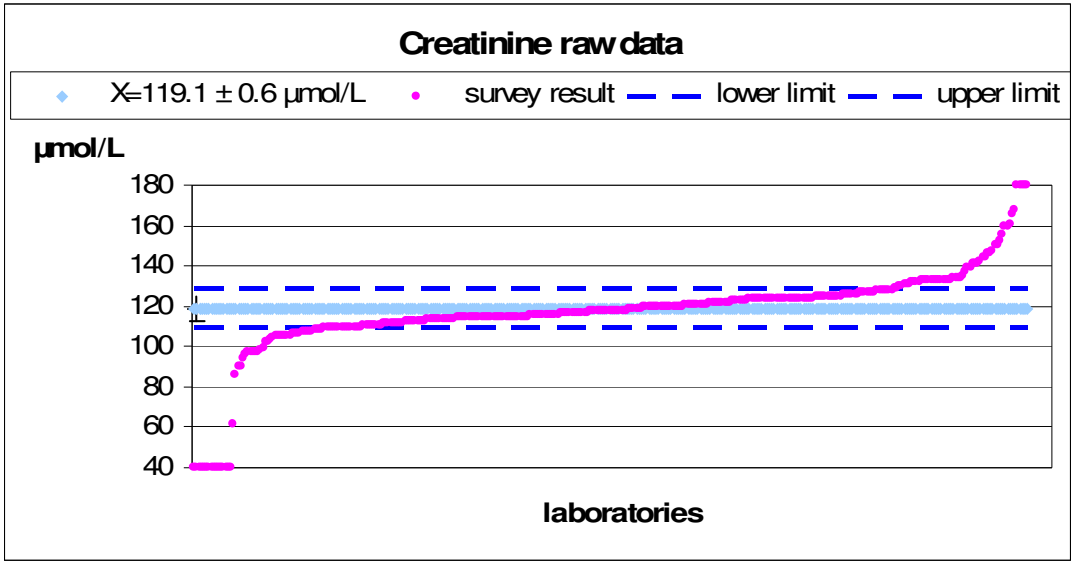
- easy to handle conversion (creatinine)
- units close to each other (alpha-fetoprotein)
- same standards but different conversion factors from different reagent producers (prolactin)
- manufacturer has assays with the different standardisations for the same analyte (growth hormone)

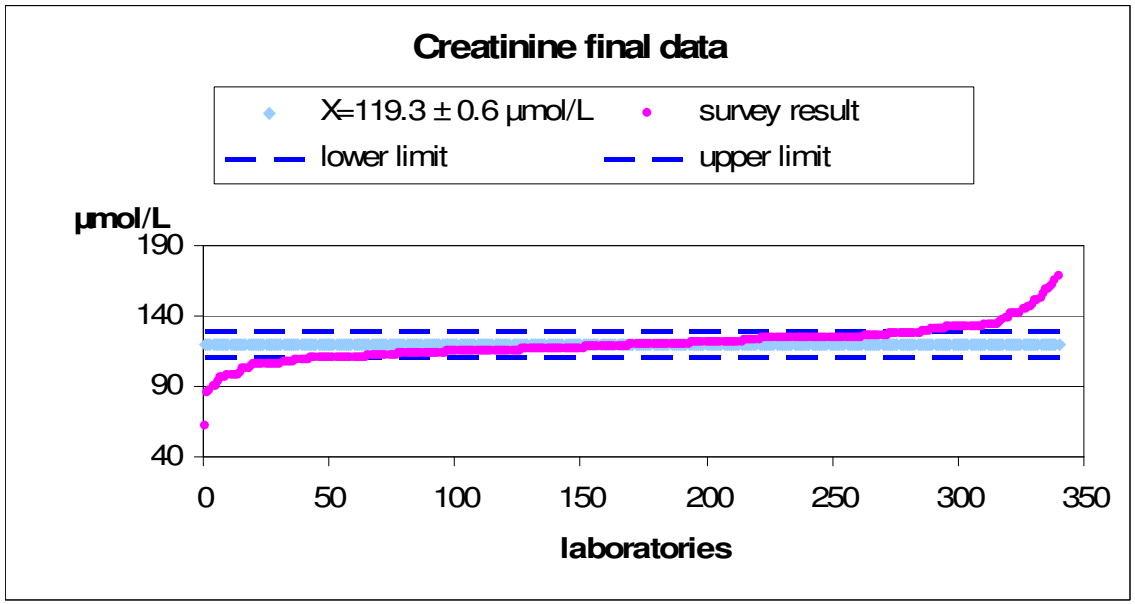
Creatinine

- Traceable to IDMS refererence method
- SI unit µmol/L, unit conversion factor from mg/dL 88.4
- 25% of laboratories reported creatinine results in mg/dL
- 41 (6%) of laboratories reported in “wrong” units
  - not reported the that they use mass units
  - mistakenly reported in SI-units (µmol/L) although in their method specifications they have reported mg/dL units

S-Krea , Fotometria, Jaffe

Näyte	Määritys	Tryhmä	Alaryhmä	Laite	Men.	Tulos	Kspiiri	Rec. nro
001	0005	008	0	1		1.1	123	**001662**
001	0005	008	0	1		1.2	123	**001663**
001	0005	008	0	1		1.2	123	**001664**
001	0005	008	0	1		1.2	123	**001665**
001	0005	008	0	1		1.3	123	**001666**
001	0005	008	0	1		1.3	123	**001667**
001	0005	008	0	1		1.3	123	**001668**
001	0005	008	0	1		115.0	000	**001784**
001	0005	008	0	1		115.0	012	**001785**
001	0005	008	0	1		115.0	011	**001786**
001	0005	008	0	1		115.0	017	**001787**
001	0005	008	0	1		115.0	000	**001788**
001	0005	008	0	1		115.0	101	**001789**
001	0005	008	0	1		115.0	101	**001790**
001	0005	008	0	1	**1.800 /**	159.1	123	**001992**
001	0005	008	0	1	**1.820 /**	160.8	123	**001993**
001	0005	008	0	1	**1.870 /**	165.3	123	**001994**
001	0005	008	0	1	**1.900 /**	167.9	123	**001995**
001	0005	008	0	1	**117.000** /	10342.8	000	**001996**
001	0005	008	0	1	**119.000** /	10519.6	000	**001997**
001	0005	008	0	1	**121.992** /	10784.0	101	**001998**
001	0005	008	0	1	**120.000** /	11403.6	101	**001999**

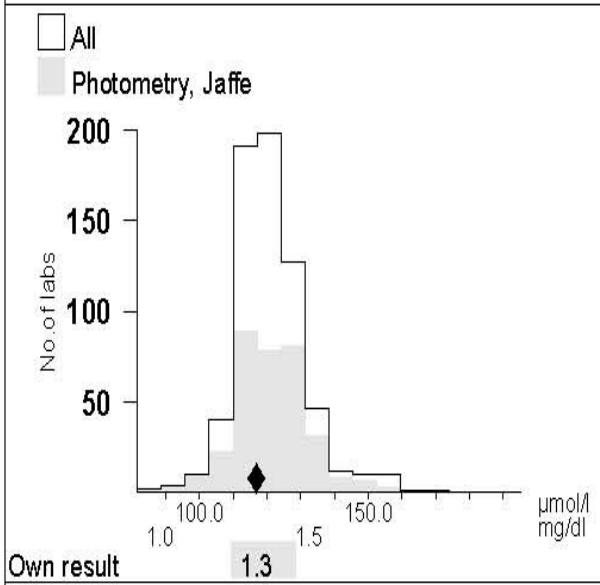

Creatinine raw data
X=119.1 ± 0.6 µmol/L
survey result
lower limit
upper limit
µmol/L
180
160
140
120
100
80
60
40
laboratories


Creatinine final data
X=119.3 ± 0.6 µmol/L
survey result
lower limit
upper limit
µmol/L
190
140
90
40
0
50
100
150
200
250
300
350
laboratories

Creatinine

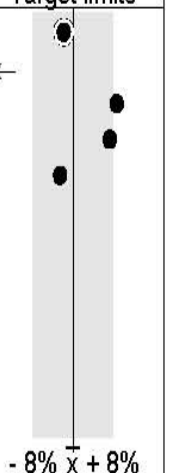
Apparatus name: ROCHE, Modular P/D
Reagent: Roche

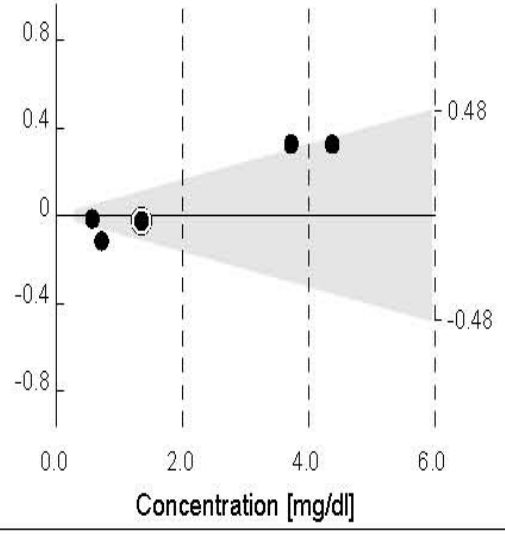
Result distribution



Result and target relation in the method group of the month concerned.

Month	S	$\bar{x}$	Result	Diff%	Target limits
5/09	**Af**	**1.3**	**1.3**	**-1.8**	
4/09	Zl	0.7	0.6	-16.3	←
3/09	Yf	3.7	4.0	8.8	
2/09	Xl	4.4	4.7	7.4	
1/09	Of	0.6	0.6	-2.6	
12/08		-	-	-	
11/08		-	-	-	
10/08		-	-	-	
9/08		-	-	-	
8/08		-	-	-	
7/08		-	-	-	
6/08		-	-	-	





Results	$\bar{x}$ (mean)	SD (std deviation)	CV%	n (number of results)	x ± 8% (target limits)
Own group	1.3	0.1	8.8	340	1.2 - 1.5
All output groups	1.3	0.1	8.3	664	

Analytical performance

60 % of laboratory´s results have been within the total error limits (target limits) in the current method group.

Alpha-fetoprotein

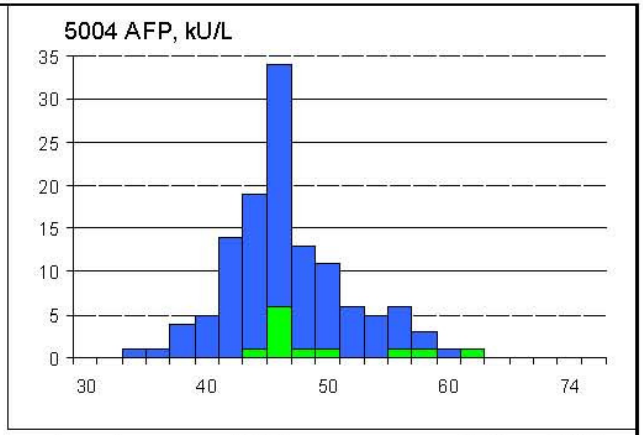
- Default unit kU/L
- 15 /128 laboratories use ng/mL or µg/L
- WHO 1st IS of AFP 1975
- Conversion factor is 0.83 from mass units to IU (1 IU = 1.21 ng of AFP)

Alpha-fetoprotein

Labquality Oy

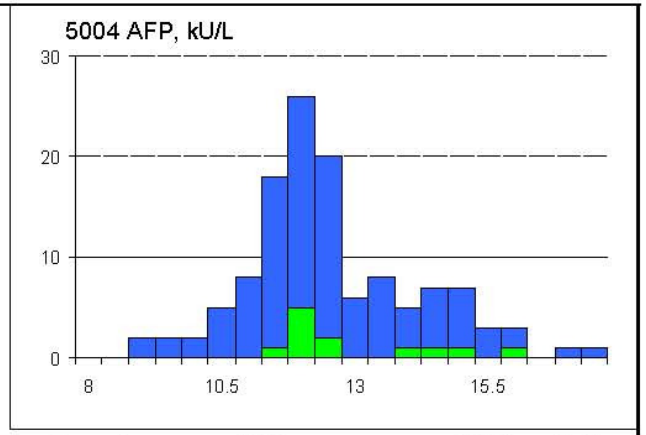
HISTOGRAMS: Tumour markers 2009/01

Sample 001
Group 344
Abbott Architect

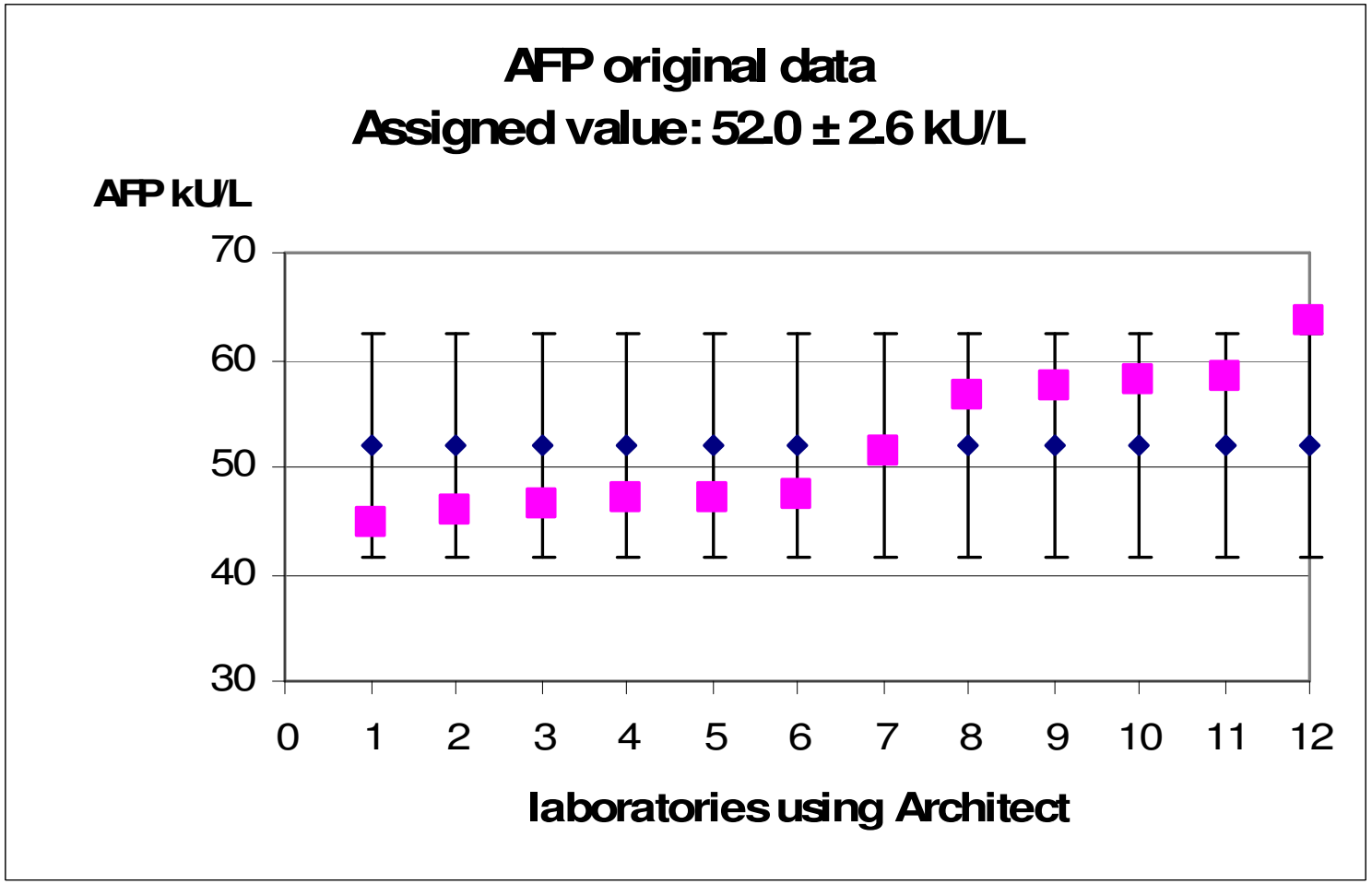


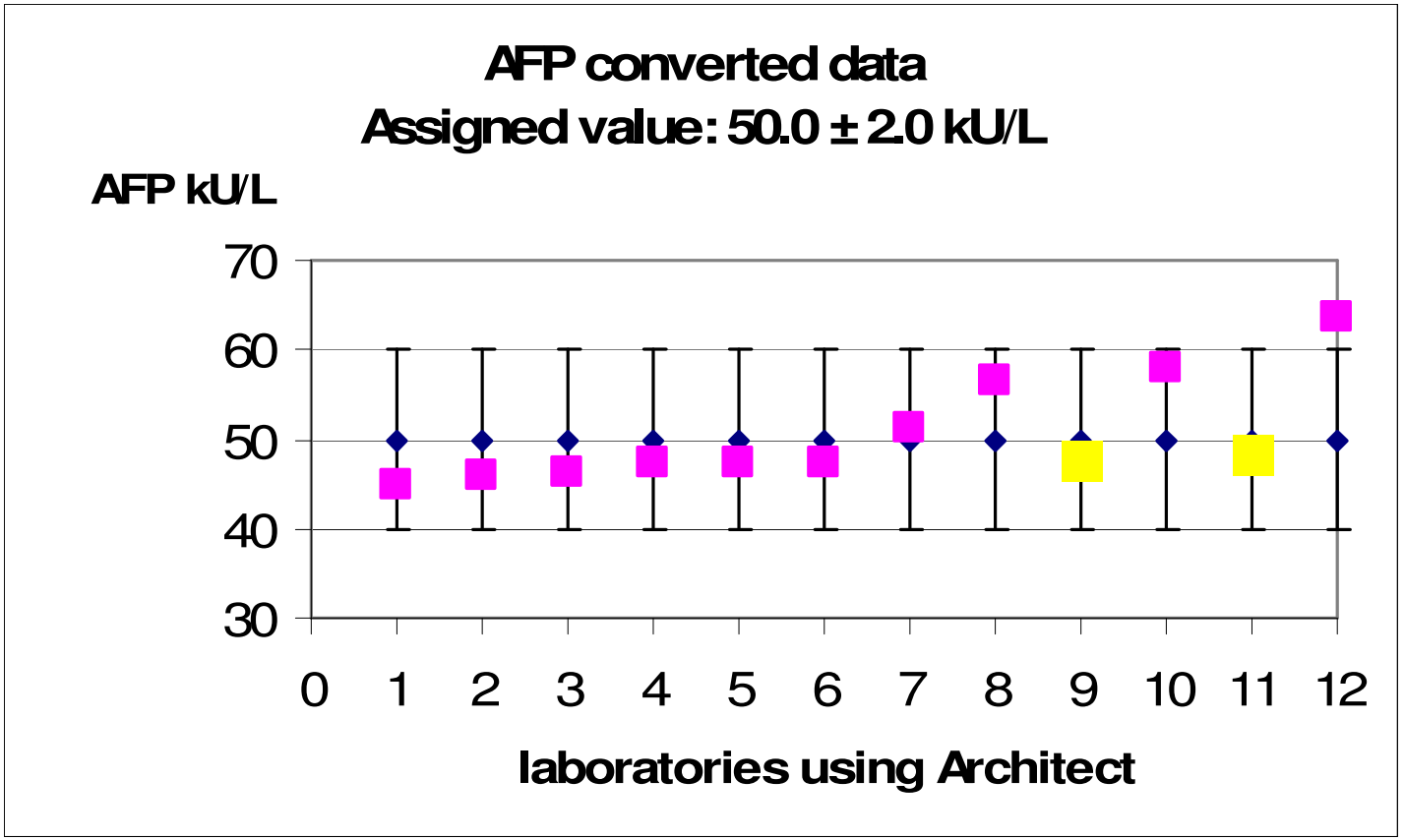
Results	x (mean)	n	x ± 20 %	s	CV%	SEM
Own group	50.41	12	40.33 - 60.49	5.87	11.6	1.69
All output groups	47.54	123	38.03 - 57.05	4.82	10.1	0.43

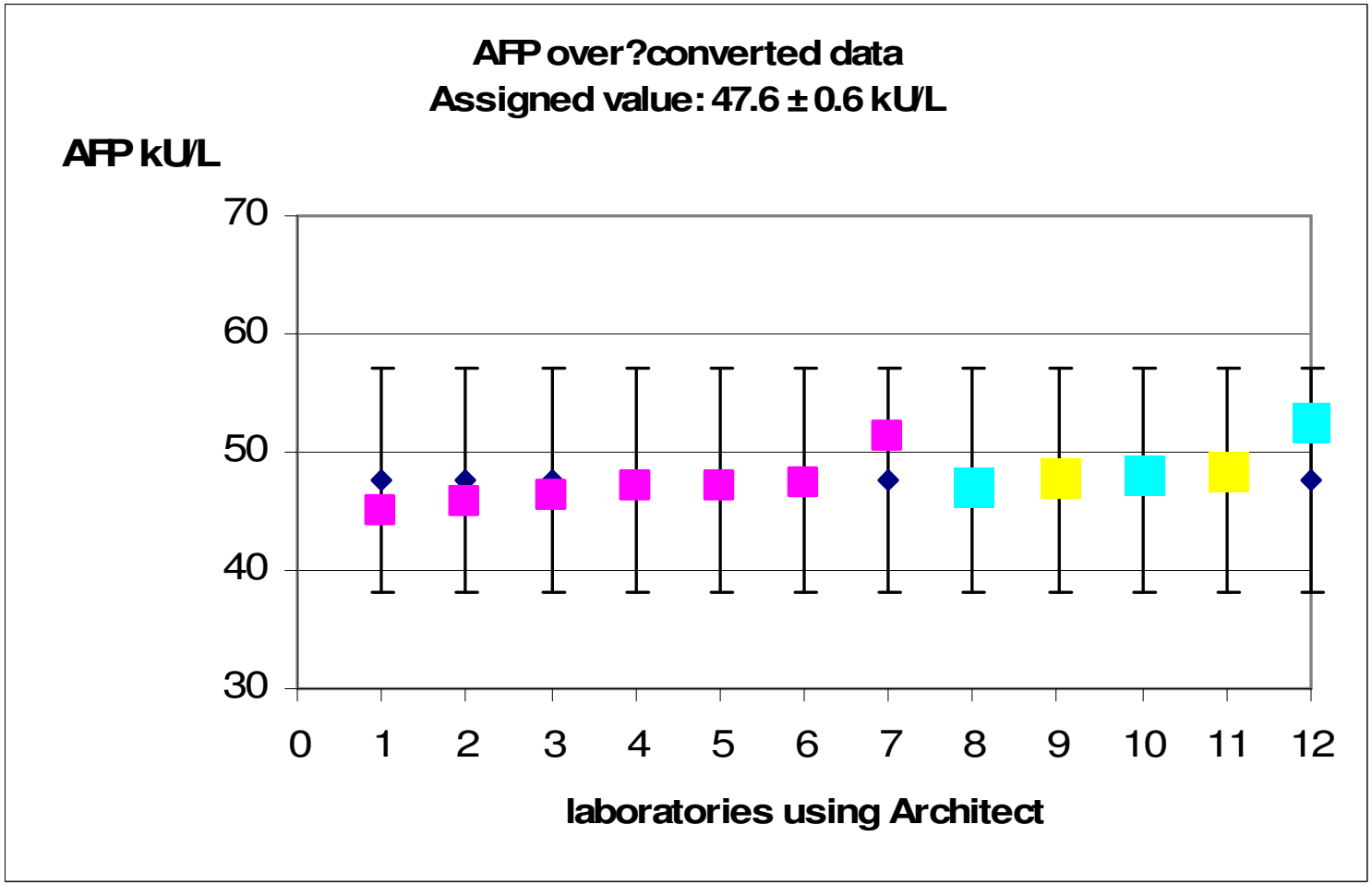
Sample 002
Group 344
Abbott Architect



Results	x (mean)	n	x ± 20 %	s	CV%	SEM
Own group	13.21	12	10.57 - 15.85	1.39	10.5	0.40
All output groups	12.74	124	10.19 - 15.28	1.59	12.5	0.14

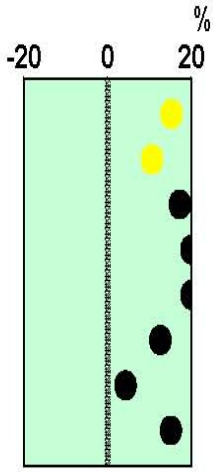

AFP original data
Assigned value: 52.0 ± 2.6 kU/L
AFP kU/L
70
60
50
40
30
0
1
2
3
4
5
6
7
8
9
10
11
12
laboratories using Architect


AFP converted data
Assigned value: 50.0 ± 2.0 kU/L
AFP kU/L
70
60
50
40
30
0
1
2
3
4
5
6
7
8
9
10
11
12
laboratories using Architect

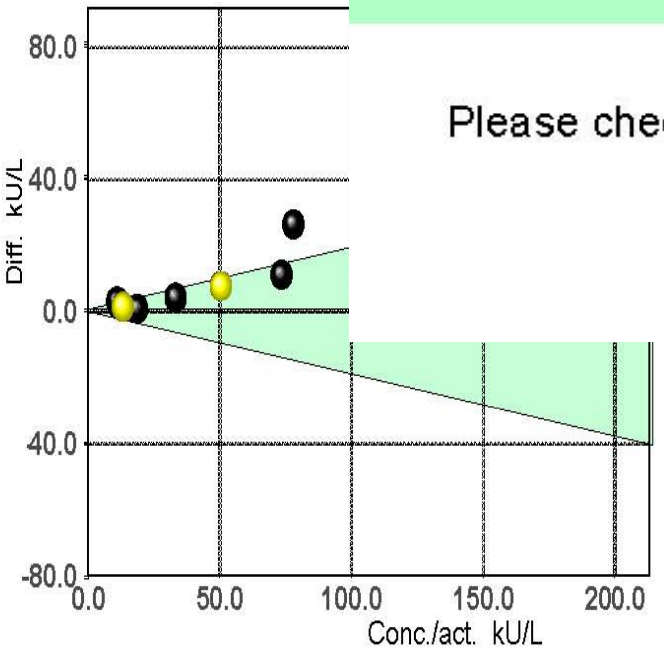

AFP over?converted data
Assigned value: 47.6 ± 0.6 kU/L
AFP kU/L
70
60
50
40
30
0
1
2
3
4
5
6
7
8
9
10
11
12
laboratories using Architect

Previous survey data

Survey	X	Sample	No	Own	Diff%
09/01	50.4	Sak 344	001	58.1	15.3
09/01	13.2	Sal 344	002	14.6	10.6
08/04	11.6	Sai 344	001	13.6	17.2
08/04	11.0	Saj 344	002	14.0	**27.3**
08/03	78.0	Sag 344	001	104.3	**33.7**
08/03	33.3	Sah 344	002	37.5	12.6
08/02	18.6	Sae 344	001	19.4	4.3
08/02	73.5	Saf 344	002	84.6	15.1



Conc./act. dependent performance



Comments

Comments

Please check your unit.

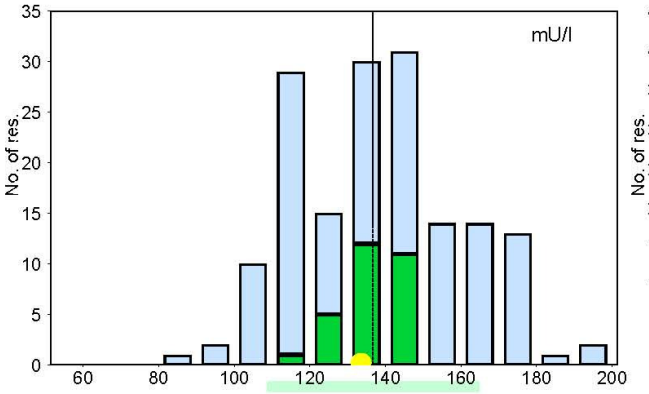
Prolactin

- Two international standards are used:
  - 3rd IS 84/500 (1 ng=21.2 µIU)
  - 1st IRP 75/504 (1 ng=32 µIU)
- Default unit mU/L
- 34 / 168 (20%) laboratories use unit ng/mL
- Several unit conversion factors of different manufacturers

Assay	Factor	Primary standard
Abbott Architect	**21**	3rd IS 84/500
Abbott Axym	**24**	3rd IS 84/500
Adaltis EIAgen	**21.2**	3rd IS 84/500
Beckman Coulter UniCel	**21.2**	
Beckman Coulter Immunotech	**30.3**	3rd IS 84/500
bioMerieux Vidas	**22**	
Diasorin Liaison	**21.2**	3rd IS 84/500
DRG Diagnostics ELISA	**21.2**	3rd IS 84/500
DRG Prolactin IRMA		1st IRP 75/504
Perkin Elmer AutoDefia	**36**	3rd IS 84/500
Roche Elecsys&Modular E&cobas	**21.2**	3rd IS 84/500
Siemens Advia Centaur	**21.2**	3rd IS 84/500
Siemens Immulite	**21.2**	3rd IS 84/500
TOSOH AIA	**27**	

lab	org_result	lab_ unit	factor	final_result	peer group
1	6.27	ng/ml	21.2	132.9	Roche Elecsys & cobas e 411
2	6.3	ng/ml	21.2	133.6	Roche Modular E & cobas e 601
3	6.6	ng/ml	21.2	139.9	Monobind AccuBind ELISA
4	6.74	ng/ml	21.2	142.9	Beckman Coulter Unicel
5	6.81	abb ng/ml	24	163.4	Abbott AxSym & IMx
5	6.81	ng/ml	21.2	144.4	Beckman Coulter Unicel
7	6.88	ng/ml	21.2	145.9	Siemens Immulite, 2000, 2500
8	7.1	ng/ml	21.2	150.5	DRG Diagnostics EIA
9	7.37	bio ng/ml	22	162.1	bioMerieux Vidas
10	7.41	abb ng/ml	24	177.8	Abbott AxSym & IMx
11	7.41	abb ng/ml	24	177.8	Abbott AxSym & IMx
12	7.5	ng/ml	21.2	159.0	Siemens Immulite, 2000, 2500
13	7.63	arc ng/ml	21	183.1	Abbott Architect
14	7.72	arc ng/ml	21	162.1	Abbott Architect
15	7.83	ng/ml	21.2	166.0	Adaltis EIA
16	7.9	bio ng/ml	22	173.8	bioMerieux Vidas
18	8.09	bio ng/ml	22	178.0	bioMerieux Vidas

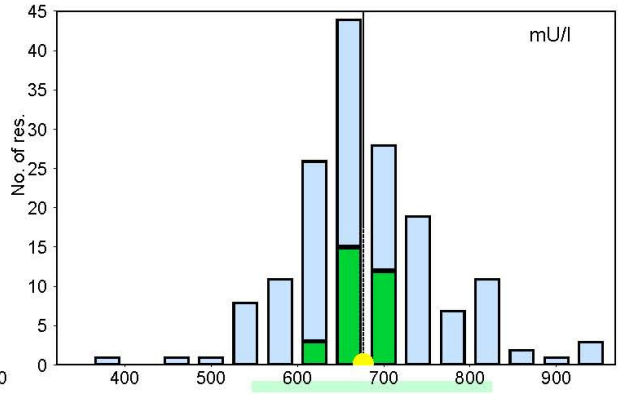
Prolactin (0663)	-	001	Roche Modular E & cobas e 601 360	Roche Modular E 560



Sample B1
Own result 134 mU/l
Diff% -2.3

Assigned value (X): 137 mU/l
Target limits (X ± 20.0%): 109-164 mU/l

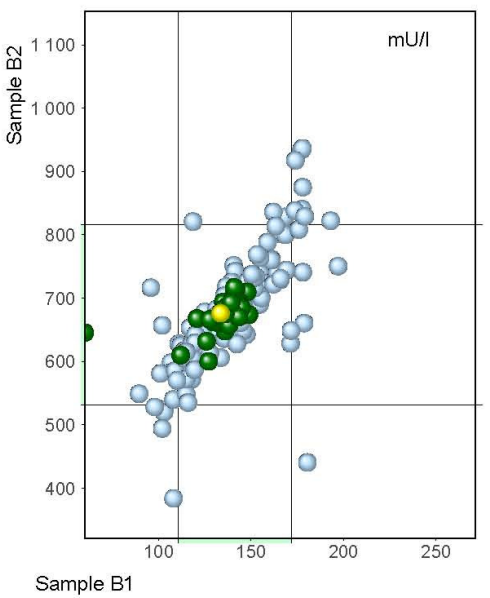
	x	sd	SEM	CV%	n
Own group	136.7	7.5	1.4	5.5	29
All	138.6	23.9	1.9	17.3	165



Sample B2
Own result 676 mU/l
Diff% 0.0

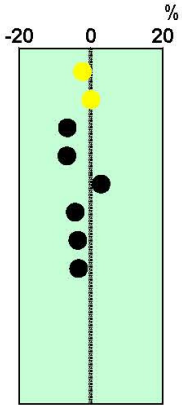
Assigned value (X): 676 mU/l
Target limits (X ± 20.0%): 541-811 mU/l

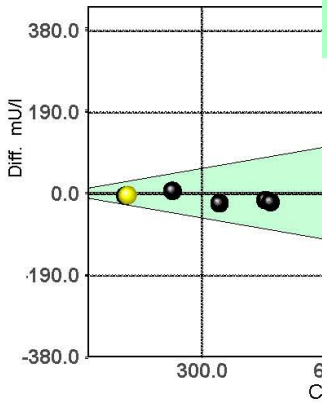
	x	sd	SEM	CV%	n
Own group	676.2	25.9	4.7	3.8	30
All	675.0	75.2	5.9	11.1	163



Previous survey data | Conc./act. dependent performance | Comments

Survey	X	Sample	No	Own	Diff%
09/02	137	Hbd 360	001	134	-2.3
09/02	676	Hbc 360	002	676	0.0
08/05	338	Hbb 360	001	316	-6.5
08/05	686	Hbc 360	002	640	-6.7
08/02	235	Hal 400	001	242	2.8
08/02	450	Har 400	002	430	-4.4
07/05	132	Hap 400	001	127	-3.6
07/05	439	Har 400	002	424	-3.4
07/02	-	Hal 400	001	233	-
07/02	-	Har 400	002	445	-
06/05	-	Hap 400	001	127	-
06/05	-	Har 400	002	424	-





Comments

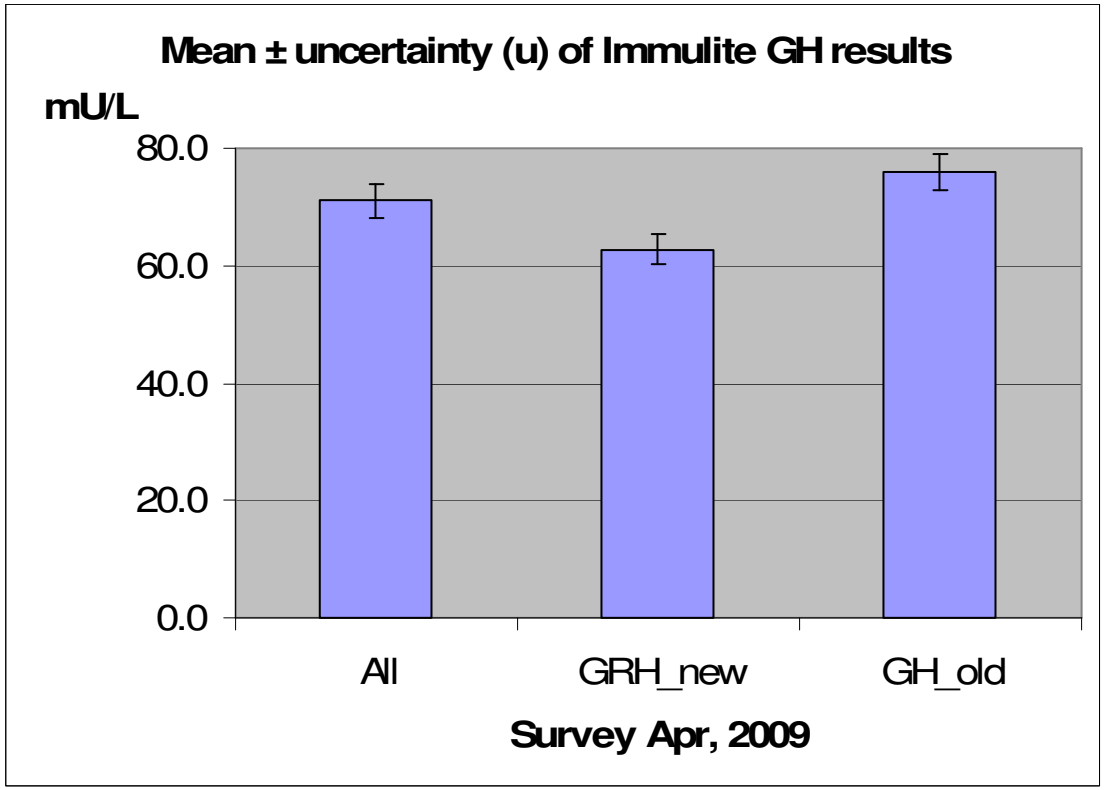
Factor 21.2 was used when converting ng/mL results into mU/L.

Growth Hormone

- Change of GH assay standardisation of Siemens Immulite analysers
- 2 international standards
  - recombinant 2nd IS 98/574
  - pituary derived WHO 1st 80/505
  - 3 unit conversion factors: 3.0, 2.4. and 2.6
- change in calibration and conversion factors influences on results and assigned values

laboratory	GH_OLD	GRH_NEW	starting date
1	x		
2	x		
3	x		
4	x		
5	x		
6	x		
7	x		
8		x	5.6.2009
9		x	1.6.2009
10		x	30.3.2009
11		x	5.1.2009
12		x	29.12.2008
13		x	11.11.2008
14		x	11.11.2008
15		x	15.9.2008
16		x	5.8.2008
17		x	20.6.2008
18		x	22.5.2008
19		x	21.4.2008
20		x?	1.1.2005

Apr, 2009				
	mean (mU/L)	u	CV%	n
All	71.0	2.9	17.2	27
GRH_new	62.8	2.7	10.9	10
GH_old	76.0	3.0	12.8	17



- EQA data should also be unit wise correct since the assigned values are often determined by participant consensus.
- All the uncertainty in units has influence on the assigned values, their uncertainties and to a laboratory's performance statistics.
- Guidance of laboratories to use internationally agreed units traceable to the SI units is one of our tasks.