SKML Congres **De Waarde van de expert**
Ede, 9 juni 2015

Humorale Immunologie

Harmonisatie
Dr. C.W. Weykamp, Chemicus, SKB, Winterswijk

Gebruik van ALTM en referentie waarden in de Combi Immunochemie rondzending
Dr. I.A. Haagen, Klinisch Chemicus/Medisch Immunoloog, OLVG, Amsterdam
Dr. C.W. Weykamp, Chemicus, SKB, Winterswijk

Expertwaarde versus consensus voor ENA testing
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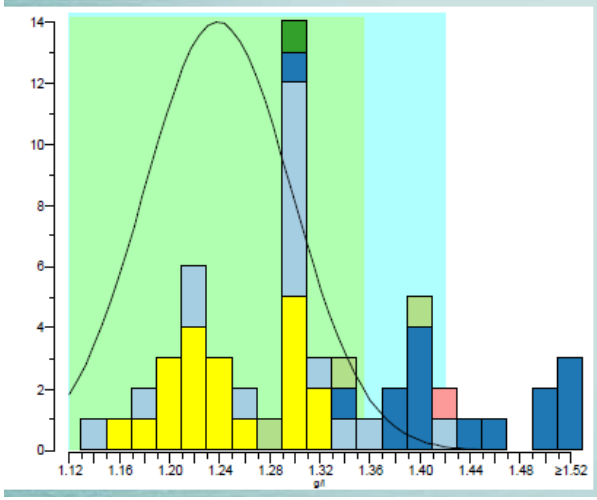
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Doelen

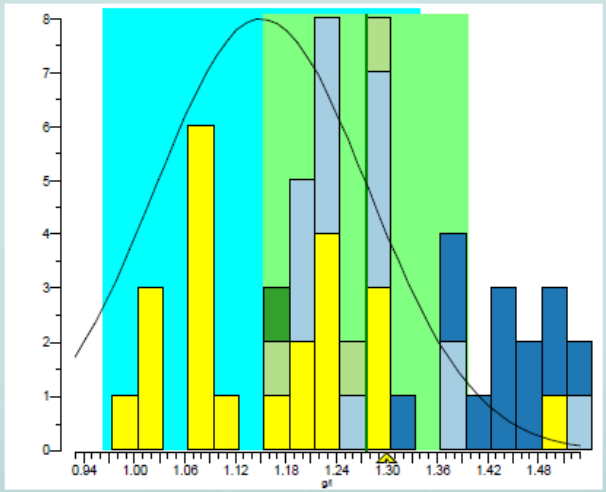
- Is mijn methode geschikt om juist te meten?

Combi Immunochemie α1 Antitrypsine

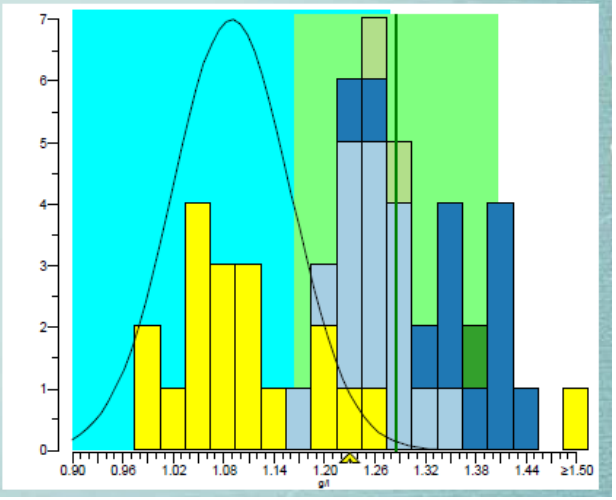
2012.1B



2013.1B



2014.1D



Herman Steigstra
Gebruikersdag 30 oktober 2014

Harmonisation Proteins

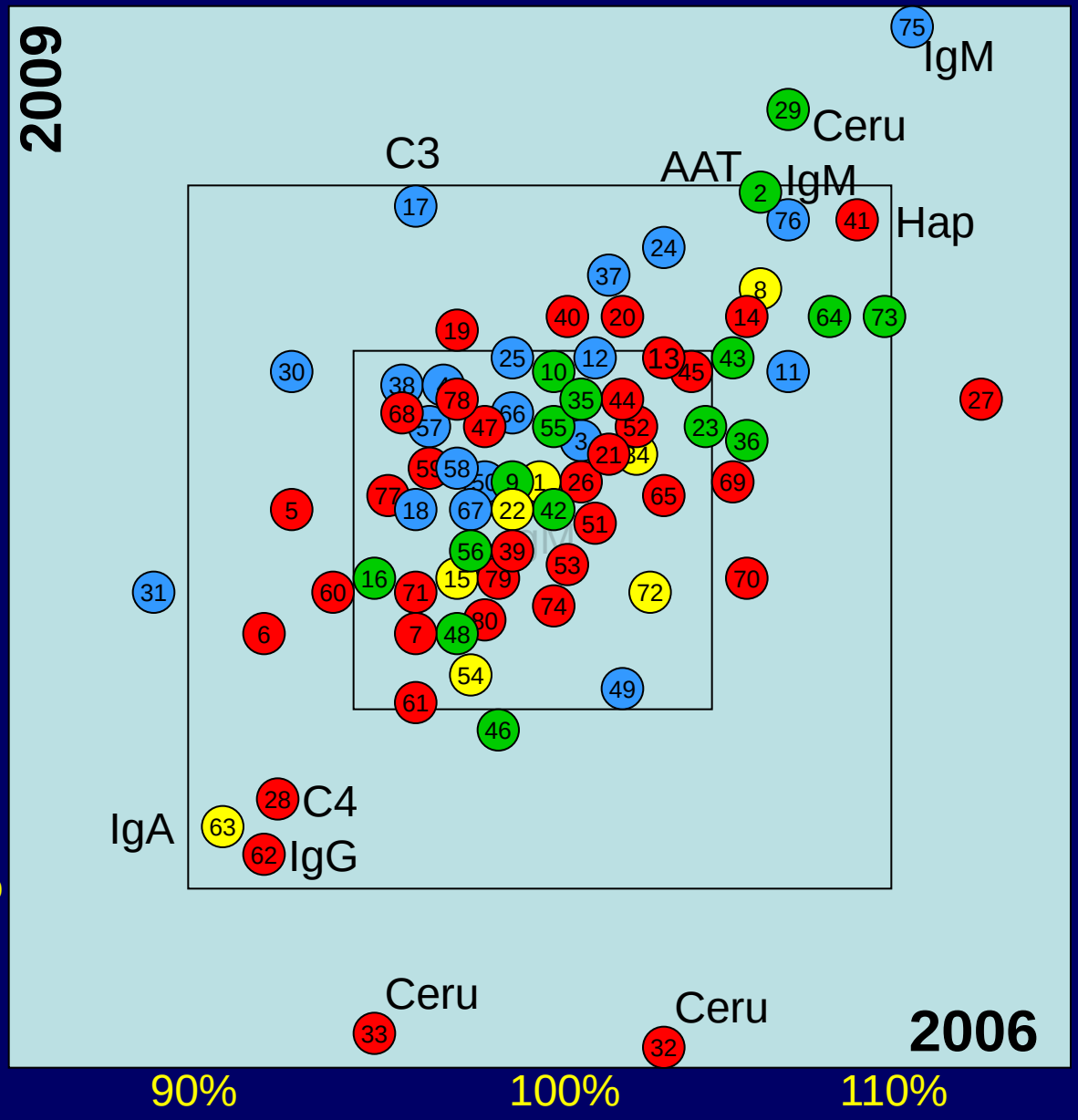
SKML Approach and Results 2003 - 2009

Inez-Anne Haagen, OLVG, Amsterdam
Cas Weykamp, SKB, Winterswijk
SKML Workshop, June 15 2011

Method	n	Recovery		Interlab CV	
		2006	2009	2006	2009
A1AT	50	101	104	8%	7%
Albumine	49	101	104	5%	6%
C3c	43	97	101	5%	6%
C4	43	104	101	5%	8%
Cerulopl.	23	100	101	9%	13%
Hapto	79	101	104	5%	5%
Prealb	12	101	103	6%	4%
Transferr	84	100	100	4%	5%
IgG	92	98	98	4%	6%
IgA	89	103	101	7%	6%
IgM	89	104	103	6%	7%
Overall		101	102	6%	7%

11 Proteins – Alle Methods

- 27 Abbott
- 27 Beckman
- 27 Siemens
- 27 Roche



Meyers: From Chaos to Order, 2011

Traceability of Laboratory Results

The standard includes 5 categories of reference systems. There are well established procedures to address standardization of measurands in categories 1, 2 and 3. Category 4 includes measurands for which reference materials are available for calibration, but there is no RMP. Category 5 includes measurands for which neither RMPs nor reference materials for calibration are available.

Standardization

Category	Reference measurement procedure	Primary reference material (pure substance)	Secondary reference material (value assigned)	Examples
1	Yes	Yes	Possible	Electrolytes, glucose, cortisol
2	Yes	No	Possible	Enzymes
3	Yes	No	No	Hemostatic factors
4	No	No	Yes	Proteins, tumor markers, HIV[a]
5	No	No	No	EBV[b], VZV[c]

Harmonization

[a] Human Immunodeficiency virus
[b] Epstein Barr virus
[c] Varicella zoster virus

Clinical Chemistry 56:12
1880–1888 (2010)

Characterization of the New Serum Protein Reference Material ERM-DA470k/IFCC: Value Assignment by Immunoassay

Ingrid Zegers,[1*] Thomas Keller,[2] Wiebke Schreiber,[3] Joanna Sheldon,[4] Riccardo Albertini,[5] Søren Blirup-Jensen,[6] Myron Johnson,[7] Stefanie Trapmann,[1] Hendrik Emons,[1] Giampaolo Merlini,[5] and Heinz Schimmel[1]

RESULTS: For 12 proteins [α_2 macroglobulin (A2M), α_1 acid glycoprotein (orosomucoid, AAG), α_1 antitrypsin (α_1-protease inhibitor, AAT), albumin (ALB), complement 3c (C3c), complement 4 (C4), haptoglobin (HPT), IgA, IgG, IgM, transferrin (TRF), and transthyretin (TTR)], the results allowed assignment of certified values in ERM-DA470k/IFCC. For CRP, we observed a bias between the lyophilized and liquid frozen materials, and for CER, the distribution of values was too broad. Therefore, these 2 proteins were not certified in the ERM-DA470k/IFCC. Different value transfer procedures were tested (open and closed procedures) and found to provide equivalent results.

We used methods that are validated and well-established routine methods based on turbidimetry, nephelometry, and occasionally visible spectrometry (in the case of ALB). The concentrations of calibrant and reference material dilutions were optimized for each platform/reagent combination.

Certified values for:
α2macroglobuline
α1 acid glycoprotein
α1 anti-trypsin
Albumin
Complement C3
Complement C4
Haptoglobin
IgA
IgG
IgM
Transferrine
Transthyretin

Not Certified for:
CRP
Ceruloplasmin
β2 microglobulin

HIM
Combi immunochemie

skml
Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

CRM 470=ERM-DA470(k)

Certified Reference Material Proteins

IRMM = Institute Reference Materials Methods

European Union

Worldwide accepted by Abbott – Beckman – Roche – Siemens

Dus resultaat alle labs zelfde?

Zou het?

α1 Macroglobuline	Haptoglobine
α1 Acid Glycoprotein	IgG
α1 Antitrypsine	IgM
Albumine	IgA
Complement 3C	Transferrine
Complement 4	Transthyretine

Sectie HIM van de SKML:
…….Dat gaan we testen

- 120 ampullen ERM470 gekocht
- Combi Immuno Chemie 2012.1A

Als alles klopt: Recovery 100%

ERM470 ingezet als Rondzendmonster

Eiwit	n	Target in g/L Bijsluiter ERM470	Overall Gemiddelde Rondzending 2012.1A (Interlab CV%)	Recovery
Albumine	69	37.2	37.3 (5%)	100%
Haptoglobine	99	0.889	0.916 (5%)	103%
IgA	97	1.80	1.79 (4%)	99%
IgG	111	9.17	8.84 (6%)	96%
IgM	99	0.723	0.736 (5%)	102%
Transferrine	110	2.36	2.42 (5%)	103%
AAT	56	1.12	1.15 (8%)	103%
Overall				101%

Recovery ERM470 per Eiwit per Methode

Methode	Albumine	Haptoglo	IgA	IgG	IgM	Transferr	A1AT	Overall
Overall	100	103	99	96	102	103	103	101
Abbott Architect	103	98	95	98	105	98	105	100
Beckman Immage	100	98	100	99	100	103	111	102
Beckman UniCel	99	102	99	96	108	104	111	103
Siemens Behring	96	99	102	100	103	98	102	100
Siemens ProSpec	102	100	103	102	101	94	101	101
Siemens VISTA	100	100	93	94	93	96	-	96
Olympus	102	90	91	99	98	106	107	99
Roche Cobas 6000	98	108	100	92	102	104	97	100
Roche Integra	106	104	104	94	103	101	91	100
Roche Modular	103	103	100	97	101	104	101	101

Wens: Elk jaar herhalen
…….Actueel Beeld Harmonisatie

Te duur (€120/ampul)

<u>Alternatief:</u>

- **Grote batch monsters gemaakt**
- **Afgeijkt op ERM470**
- **Combi ImmunoChemie**
  2013 – 2014 – 2015 – 2016 - 2017
  “Doorloper”

Recovery in ERM470 en Rondzendmonster

Methode	Albumine		Haptoglob		IgA		IgG		IgM		transferrine		AAT		Overall	
	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.	ERM 470	DL.
Overall	100	100	103	103	99	99	96	96	102	102	103	103	103	103	101	101
AbbArch	103	105	98	99	95	95	98	101	105	105	98	99	105	104	100	101
Beck Imm	100	98	98	98	100	101	99	101	100	103	103	107	111	113	102	103
Beck Uni	99	99	102	101	99	98	96	97	108	101	104	103	111	110	103	101
Sie Behr	96	105	99	107	102	102	100	99	103	106	98	101	102	102	100	102
Sie ProS	102	99	100	101	103	104	102	100	101	102	94	98	101	99	101	100
Sie VIST	100	102	100	102	93	92	94	88	93	100	96	98	-	-	96	97
Olympus	102	102	90	93	91	92	99	94	98	95	106	102	107	101	99	97
Roc6000	98	97	108	106	100	99	92	91	102	100	104	102	97	96	100	99
RocInteg	106	108	104	101	104	103	94	95	103	102	101	98	91	93	100	100
Roc Mod	103	102	103	104	100	100	97	95	101	103	104	105	101	100	101	101

Beklaagdenbankje

Categorie	n	Eiwit/Methode
Zalm Zalm (4+)	2	(A1AT Beckman Immage) (A1AT Beckman UniCel)
Zalm Geel (3+)	0	-
Geel Geel (2+)	2	(Albumine Roche Integra) (Haptoglobine Roche Cobas 6000)
Geel Groen (1+)	6	-
Groen Groen (0)	67	-
LBlauw Groen (1-)	4	-
LBlauw LBla (2-)	4	(IgA Siemens VISTA) (IgA Olympus) (IgG Roche C6000) (A1AT Roche Integr)
DBlauw LBla (3-)	2	(Haptoglobine Olympus) (IgG Siemens VISTA)
DBlauw DBLa (4-)	0	-

Er is nog wel wat te doen: Ceruloplasmine

Methode	n	ERM470		Doorloper	
		Gemidd	SD	Gemidd	SD
Overall	29	0.169	0.017	0.274	0.036
Beckman Immage	9	0.187	0.015	0.316	0.024
Siemens Behring	5	0.164	0.009	0.266	0.009
Siemens Pro Spec	7	0.163	0.010	0.258	0.015
Olympus	1	0.170	-	0.260	-
Roche Cobas 6000	2	0.160	0.007	0.240	0.007
Roche Integra	1	0.140	-	0.260	-
Roche Modular	4	0.160	0.018	0.252	0.025

Indien u contact heeft met uw firma betreffende het bepalen van eiwitten uit de combi immunochemie rondzending…..
Graag willen wij dit weten!

Adres:

Mw.dr.IA. Haagen,
coördinator Combi Immunochemie
Medisch Immunoloog/Klinisch Chemicus
OLVG, Amsterdam

i.a.haagen@olvg.nl

Roche: Herstandaardisatie van speciale eiwitten

5 oktober 2012

Graag willen wij u informeren over de herstandaardisatie van vijf speciale eiwitbepalingen namelijk de Tina-quant® Albumine, α-1 Antitrypsine, Haptoglobine, IgG gen. 2 en Prealbumine op alle Klinisch Chemische systemen. Het nieuwe ERM DA470k/IFCC is als referentiemateriaal hiervoor gebruikt.

Intern onderzoek, afwijkingen in de externe kwaliteitsbewakingssystemen en onderlinge vergelijkbaarheid tussen Roche-systemen hebben geleid tot een nieuwe masterlot-kalibratie van Tina-quant® Albumine, α-1 Antitrypsine, Haptoglobine, IgG gen. 2 en Prealbumine bepalingen. Door een nieuw masterlot-kalibratie zijn de gebruikte C.f.a.s. calibratoren traceerbaar naar het referentiemateriaal ERM DA470k/IFCC.

De volgende aanpassing van de C.f.a.s. PUC, Protein en PAC zijn (klik op het betreffende percentage naar de link voor de benodigde documenten):

Bepaling	INTEGRA	MODULAR P	c501/c502	c702	C.f.a.s calibrator
Albumine*	+4.5%	+4.5%	+4.5%	+4.5%	C.f.a.s PUC (03121291122)
α-1 Antitrypsine	-12.4%	-5.1%	-12.7%	-12.7%	C.f.a.s Protein (11355279216)
Haptoglobine	-3.8%	-6.9%	-7.6%	-7.6%	C.f.a.s Protein (11355279216)
IgG Gen.2	None	+4.1%	+11.5%	+4.1%	C.f.a.s Protein (11355279216)
Prealbumine	-9.6%	None	-6.4%	-6.4%	C.f.a.s PAC (03555941190)

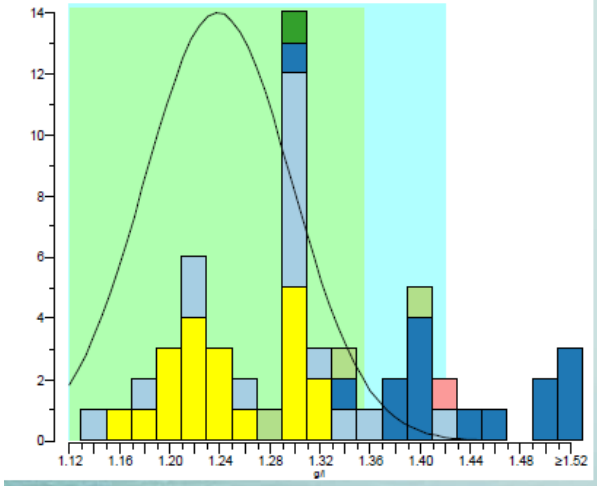
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Doelen

- Is mijn methode geschikt om juist

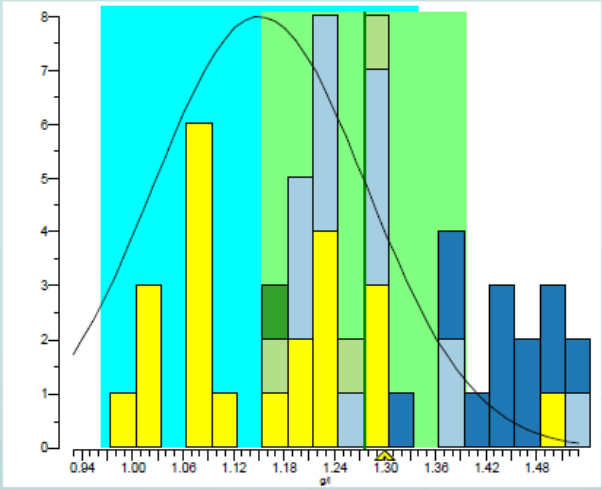
Combi Immunochemie α1 Antitrypsine

2012.1B



Roche 1.24
Referentie 1.286

2013.1B



Roche 1.16
Referentie 1.286

Albumine									
Sample	Target	Cobas 6000				Modular			
		n	mean	SD	Recovery	n	mean	SD	Recovery
ERM 2012	37.2	16	36.6	1.8	98%	10	38.4	1.9	103%
EQA 2012	35.4	16	34.6	2.0	97%	10	36.3	1.1	102%
EQA 2013		17	35.3	1.8	100%	7	34.6	1.6	98%
EQA 2014		15	33.8	2.1	95%	7	35.0	1.7	99%

Bepaling	*INTEGRA*	*MODULAR P*	*c501/c502*	*c702*	*C.f.a.s calibrator*
Albumine*	+4,5%	+4,5%	+4,5%	+4,5%	C.f.a.s PUC (03121305122)
α-1 Antitrypsine	-12,4%	-5,1%	-12,7%	-12,7%	C.f.a.s Protein (11355279216)
Haptoglobine	-3,8%	-6,9%	-7,6%	-7,6%	C.f.a.s Protein (11355279216)
IgG Gen.2	None	+4,1%	+11,5%	+4,1%	C.f.a.s Protein (11355279216)
Prealbumine	-9,6%	None	-6,4%	-6,4%	C.f.a.s PAC (03555941190)

* Geldt alleen voor de Tina Quant Albumine. De BCG/BCP Albumine wordt gekalibreerd met C.f.a.s. (10759350190) en is niet aangepast.

IgG									
Sample	Target	Cobas 6000				Modular			
		n	mean	SD	Recovery	n	mean	SD	Recovery
ERM 2012	9.17	36	8.43	0.38	92%	10	8.86	0.15	97%
EQA 2012	8.91	36	8.11	0.37	91%	10	8.45	0.20	95%
EQA 2013		39	8.40	0.56	94%	10	8.45	0.37	95%
EQA 2014		36	8.47	0.17	95%	8	8.58	0.15	96%

Bepaling	*INTEGRA*	*MODULAR P*	*c501/c502*	*c702*	*C.f.a.s calibrator*
Albumine*	+4,5%	+4,5%	+4,5%	+4,5%	C.f.a.s PUC (03121305122)
α-1 Antitrypsine	-12,4%	-5,1%	-12,7%	-12,7%	C.f.a.s Protein (11355279216)
Haptoglobine	-3,8%	-6,9%	-7,6%	-7,6%	C.f.a.s Protein (11355279216)
IgG Gen.2	None	+4,1%	+11,5%	+4,1%	C.f.a.s Protein (11355279216)
Prealbumine	-9,6%	None	-6,4%	-6,4%	C.f.a.s PAC (03555941190)

* Geldt alleen voor de Tina Quant Albumine. De BCG/BCP Albumine wordt gekalibreerd met C.f.a.s. (10759350190) en is niet aangepast.

IgM									
Sample	Target	Cobas 6000				Modular			
		n	mean	SD	Recovery	n	mean	SD	Recovery
ERM 2012	0.723	35	0.736	0.025	102%	10	0.727	0.044	101%
EQA 2012	0.809	35	0.811	0.026	100%	10	0.833	0.028	103%
EQA 2013		37	0.806	0.035	100%	10	0.810	0.028	100%
EQA 2014		35	0.807	0.020	100%	6	0.850	0.040	105%

Bepaling	*INTEGRA*	*MODULAR P*	*c501/c502*	*c702*	*C.f.a.s calibrator*
Albumine*	+4,5%	+4,5%	+4,5%	+4,5%	C.f.a.s PUC (03121305122)
α-1 Antitrypsine	-12.4%	-6.1%	-12.7%	-12.7%	C.f.a.s Protein (11355279216)
Haptoglobine	-3,8%	-6,9%	-7,6%	-7,6%	C.f.a.s Protein (11355279216)
IgG Gen.2	None	+4.1%	+11.5%	+4.1%	C.f.a.s Protein (11355279216)
Prealbumine	-9,6%	None	-6,4%	-6,4%	C.f.a.s PAC (03555941190)

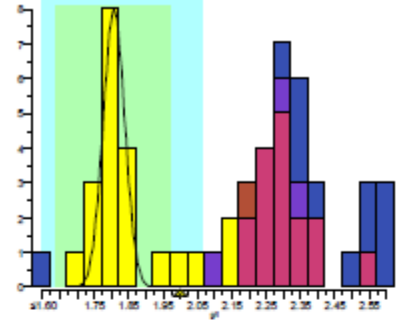
* Geldt alleen voor de Tina Quant Albumine. De BCG/BCP Albumine wordt gekalibreerd met C.f.a.s. (10759350190) en is niet aangepast.

A1AT									
Sample	Target	Cobas 6000				Modular			
		n	mean	SD	Recovery	n	mean	SD	Recovery
ERM 2012	1.12	14	1.09	0.04	97%	4	1.13	0.04	101%
EQA 2012	1.286	14	1.24	0.04	96%	4	1.29	0.04	100%
EQA 2013		17	1.17	0.13	91%	4	1.17	0.10	91%
EQA 2014		17	1.14	0.14	89%	2	1.10	0.07	86%

Bepaling	*INTEGRA*	*MODULAR P*	*c501/c502*	*c702*	*C.f.a.s calibrator*
Albumine*	+4,5%	+4,5%	+4,5%	+4,5%	C.f.a.s PUC (03121305122)
α-1 Antitrypsine	-12.4%	-6.1%	-12.7%	-12.7%	C.f.a.s Protein (11355279216)
Haptoglobine	-3,8%	-6,9%	-7,6%	-7,6%	C.f.a.s Protein (11355279216)
IgG Gen.2	None	+4.1%	+11.5%	+4.1%	C.f.a.s Protein (11355279216)
Prealbumine	-9,6%	None	-6,4%	-6,4%	C.f.a.s PAC (03555941190)

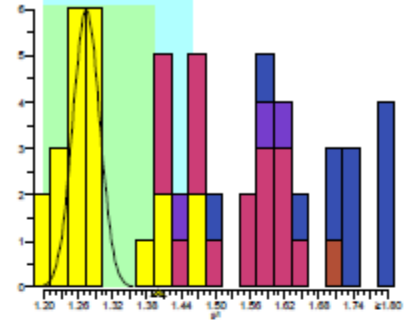
* Geldt alleen voor de Tina Quant Albumine. De BCG/BCP Albumine wordt gekalibreerd met C.f.a.s. (10759350190) en is niet aangepast.

2013.4 A



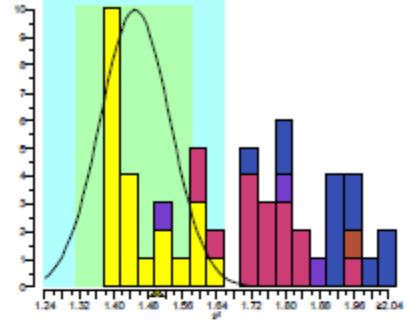
	cons.	meth.	ALTM	lab
gem.	1.81	1.81	2.16	2.0
SD	0.03	0.03	0.34	
n	21	21	53	
nu	6	6	0	

2013.4 B



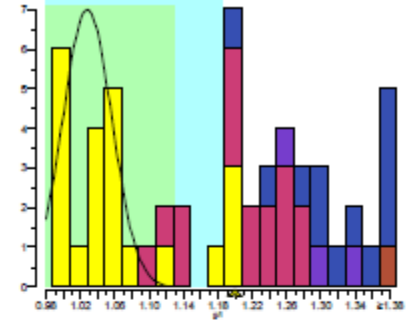
	cons.	meth.	ALTM	lab
gem.	1.27	1.27	1.48	1.4
SD	0.02	0.02	0.22	
n	22	22	55	
nu	7	7	0	

2013.4 C



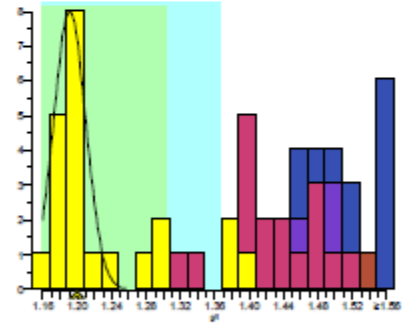
	cons.	meth.	ALTM	lab
gem.	1.45	1.45	1.67	1.5
SD	0.08	0.08	0.24	
n	22	22	54	
nu	0	0	0	

2013.4 D



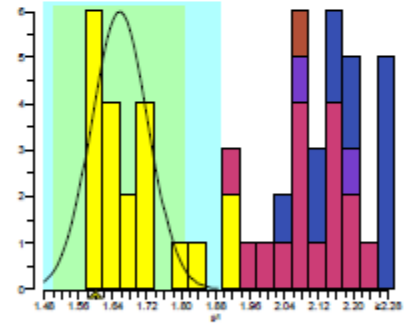
	cons.	meth.	ALTM	lab
gem.	1.03	1.03	1.18	1.2
SD	0.03	0.03	0.15	
n	22	22	54	
nu	5	5	0	

2013.4 E



	cons.	meth.	ALTM	lab
gem.	1.19	1.19	1.39	1.2
SD	0.02	0.02	0.17	
n	22	22	54	
nu	6	6	0	

2013.4 F



	cons.	meth.	ALTM	lab
gem.	1.66	1.65	1.98	1.6
SD	0.07	0.06	0.30	
n	20	20	51	
nu	2	3	0	

α1-Antitrypsine

Legenda

- Roche (turb)
- Beckman (turb/lum)
- Siemens (nefel)
- Abbott (turb)
- Olympus (turb)
- Siemens (turb/lum)
- Overig
- Ortho Diagnostics (turb)
- Beckman (nefel)

Almere, 3 juni 2014

Betreft: FINALE VERSIE

Herstandaardisatie van de bepalingen voor Tina-quant Albumine, α-1 Antitrypsine, Haptoglobine, IgG gen. 2, Prealbumine en Complement C4 voor de COBAS INTEGRA, MODULAR <P> en cobas systemen c501/c502 en c701/c702.

De volgende aanpassing van de C.f.a.s. PUC (Proteins in Urine/CSF) met productnummer 03121305 122, C.f.a.s. Protein met productnummer 11355279 216 en C.f.a.s. PAC (Pre-Albumine, ASLO en Ceruloplasmine) met productnummer 03555941 190 zijn doorgevoerd, waarbij de tabel de range weergeeft van aanpassingen voor alle lot nummers, die op dit moment verkrijgbaar zijn in de markt:

Bepaling	*INTEGRA*	*MODULAR <P>*	*c501/c502*	*c701/c702*	*C.f.a.s calibrator*
Tina-quant Albumine in serum	+5.6/+10.3%	+4.2%	+6.7/+11.9%	+1.9/+6.9%	C.f.a.s PUC
Tina-quant Albumine in Urine	+5.6/+10.3%	+4.2%	+1.6/-3.9%	-3.2/-9.1%	C.f.a.s PUC
Tina-quant Albumine in CSF	-5.2/-8.6%	+4.2%	+0.6/+5.5%	+0.4/-4.4%	C.f.a.s PUC
Tina-quant α-1 Antitrypsine	+21.1/+26.1%	None	+14.9/+20.8%	+14.9/+20.8%	C.f.a.s Protein
Tina-quant Haptoglobine	None	-5.2/-7.4%	-5.9/-7.0%	-5.9/-7.0%	C.f.a.s Protein
Tina-quant IgG Gen.2	None	+4.1%	+11.5%	+4.1%	C.f.a.s Protein
Tina-quant Pre-albumine	-8.7/-10.4%	None	-6.5/-8.0%	-6.5/-8.0%	C.f.a.s PAC
Tina-quant Complement C4	-5.8/-8.3%	+1.9/+2.5%	+3.4/+5.3%	+7.1/+8.2%	C.f.a.s Protein

Van ALTM naar Referentie Waarde **2014.3**

Geachte deelnemer,

Voor alle parameters werd de score tot nu toe toegekend op basis van uw eigen consensusgroep.

Met ingang van de huidige rondzending wordt de score voor een aantal parameters te weten Albumine, Albumine BCG, IgG, IgA, IgM, AAG, A1AT, haptoglobine, A2-macroglobuline, C3c en C4, toegekend op basis van een referentie waarde die traceerbaar is naar ERM-DA470.

Met vriendelijke groet,

Inez-Anne Haagen

Coördinator Combi Immunochemie

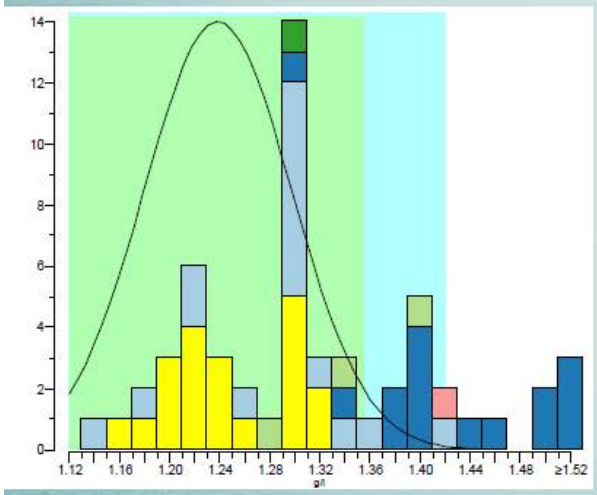
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Doelen

- Is mijn methode geschikt om juist te meten?

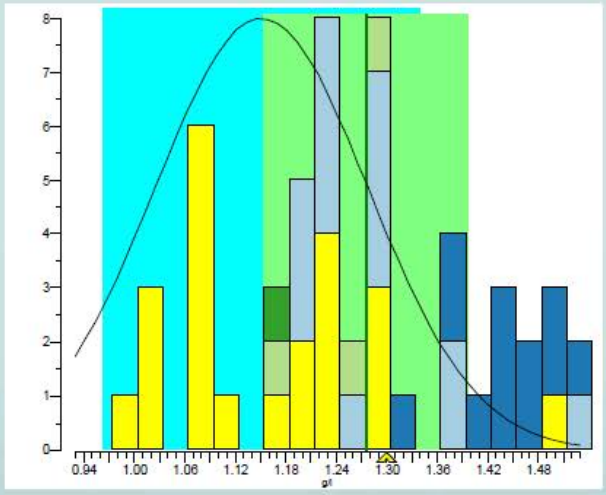
Combi Immunochemie α1 Antitrypsine

2012.1B



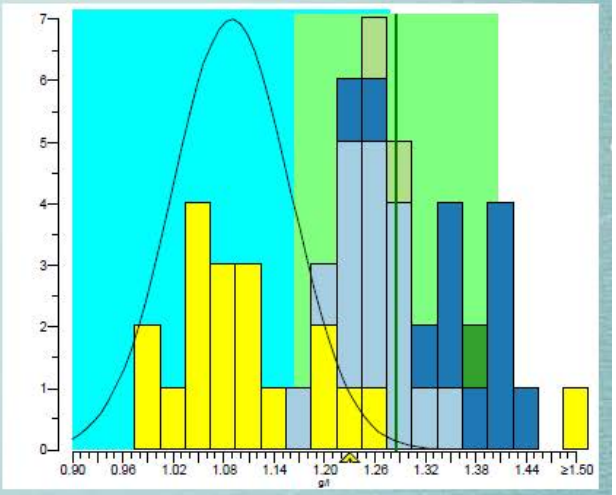
Roche 1.24
Referentie 1.286

2013.1B



Roche 1.16
Referentie 1.286

2014.1D

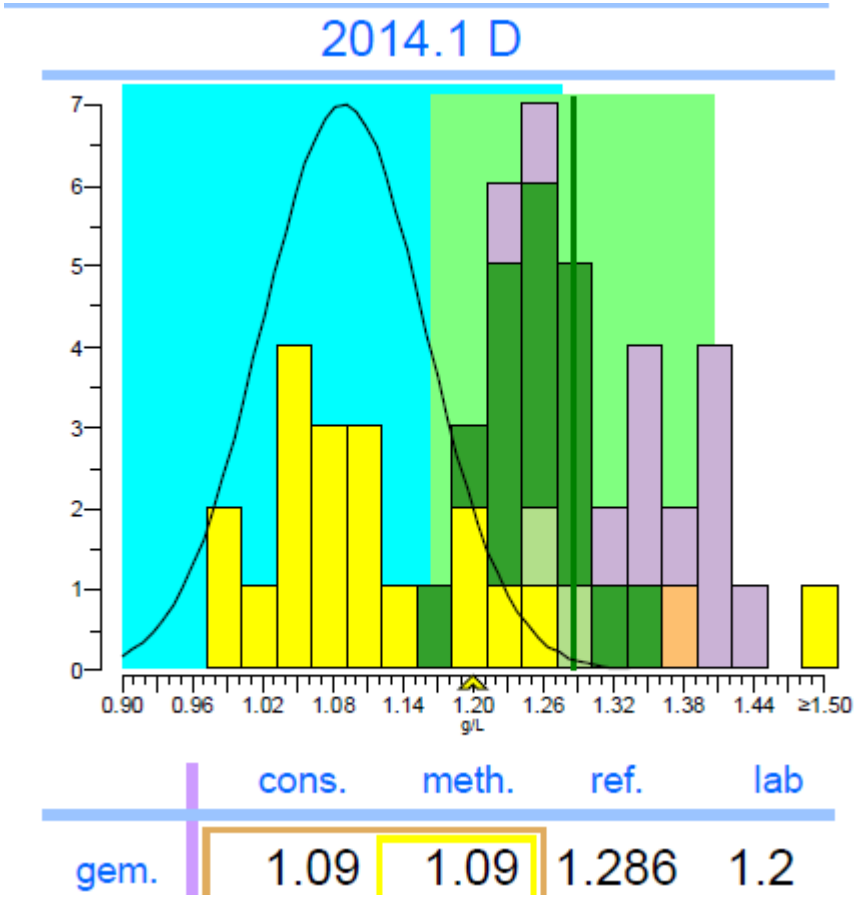


Roche 1.09
Referentie 1.286

A1AT

Target: 1.286 g/L

EQA February 2014



Mean Roche (n=14)
Overall 1.07
Suggests Factor 20%

Abbott (2):	1.29
Beckman (12):	1.36
Siemens (16):	1.26

Legenda

Roche (turb) | Beckman (turb/lum) | Abbott (turb) | Siemens (nefel) | Siemens (turb/lum)
Olympus (turb) | Overig | Ortho Diagnostics (turb) | Beckman (nefel)

Almere, 3 juni 2014

Betreft: FINALE VERSIE

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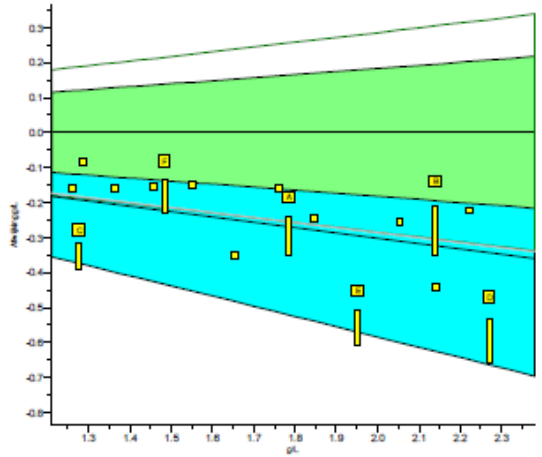
Tina-quant Albumine in Urine	+5.6/+10.3%	+4.2%	+1.6/-3.9%	-3.2/-9.1%	C.f.a.s PUC
Tina-quant Albumine in CSF	-5.2/-8.6%	+4.2%	+0.6/+5.5%	+0.4/-4.4%	C.f.a.s PUC
Tina-quant α-1 Antitrypsine	+21.1/+26.1%	None	+14.9/+20.8%	+14.9/+20.8%	C.f.a.s Protein
Tina-quant Haptoglobine	None	-5.2/-7.4%	-5.9/-7.0%	-5.9/-7.0%	C.f.a.s Protein
Tina-quant IgG Gen.2	None	+4.1%	+11.5%	+4.1%	C.f.a.s Protein
Tina-quant Pre-albumine	-8.7/-10.4%	None	-6.5/-8.0%	-6.5/-8.0%	C.f.a.s PAC
Tina-quant Complement C4	-5.8/-8.3%	+1.9/+2.5%	+3.4/+5.3%	+7.1/+8.2%	C.f.a.s Protein

α1-Antitrypsine

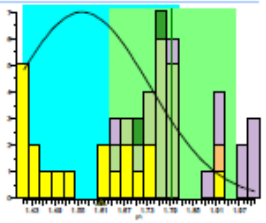
eenheid : g/L



	2014.3	cumulatief
Juistheid	-15%	-14%
Precisie	9.1%	7.6%
Aantal	6	18
Uitbijters	0	0
Sigma-TE	-0.8	-0.6
Sigma-SA	0.7	0.9
Score pictogram		
Regressielijn	0.00 + 0.848.x	0.00 + 0.857.x

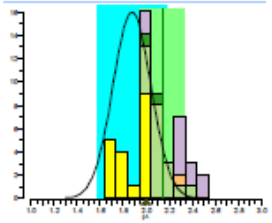
Consensusgroep	Roche
Methode	Roche (turb)

2014.3 A



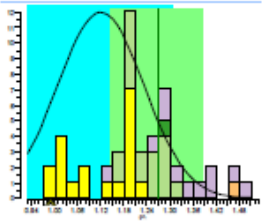
	cons.	meth.	ref.	lab
gem.	1.55	1.55	1.786	1.6
SD	0.18	0.18		
n	19	19		
nu	0	0		

2014.3 B



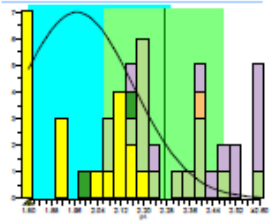
	cons.	meth.	ref.	lab
gem.	1.88	1.88	2.140	2.0
SD	0.16	0.16		
n	19	19		
nu	0	0		

2014.3 C



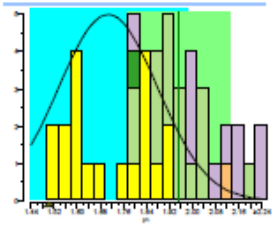
	cons.	meth.	ref.	lab
gem.	1.13	1.13	1.278	1.0
SD	0.11	0.11		
n	19	19		
nu	0	0		

2014.3 D



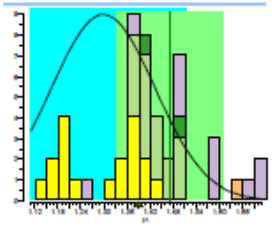
	cons.	meth.	ref.	lab
gem.	1.97	1.97	2.271	1.8
SD	0.20	0.20		
n	19	19		
nu	0	0		

2014.3 E



	cons.	meth.	ref.	lab
gem.	1.71	1.71	1.952	1.5
SD	0.17	0.17		
n	19	19		
nu	0	0		

2014.3 F



	cons.	meth.	ref.	lab
gem.	1.31	1.31	1.484	1.4
SD	0.13	0.13		
n	18	18		
nu	0	0		

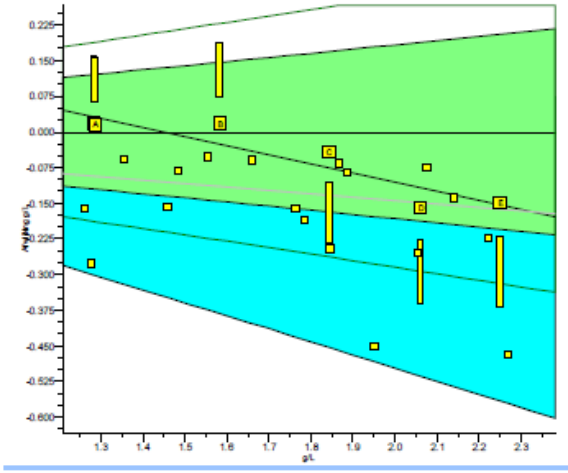
Legenda

Roche (turb) | Beckman (turb/turn) | Siemens (nefel) | Abbott (turb) | Siemens (turb/turn)

Olympus (turb) | Overig | Ortho Diagnostics (turb) | Beckman (nefel)

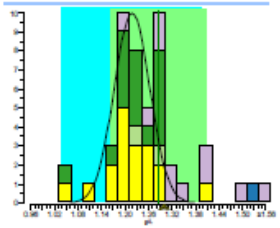
α1-Antitrypsine

eenheid : g/L



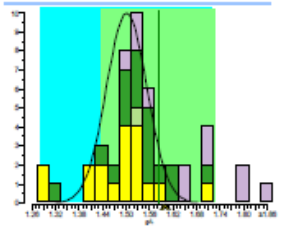
	2015.1	cumulatief
Juistheid	-3.1%	-6.8%
Precisie	1.4%	5.0%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	2.8	1.2
Sigma-SA	4.6 (2)	2.9 (1)
Score pictogram		
Regressielijn	0.28 + 0.808.x	0.00 + 0.928.x
Consensusgroep	Roche	
Methode	Roche (turb)	
Analyser	Roche Cobas 8000	
Uw factor	0.00 + 1.000.x	
Methode factor	0.00 + 1.000.x	

2015.1 A



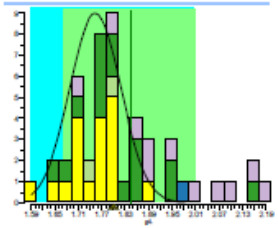
	cons.	meth.	ref.	lab
gem.	1.22	1.22	1.286	1.3
SD	0.05	0.05		
n	18	18		
nu	2	2		

2015.1 B



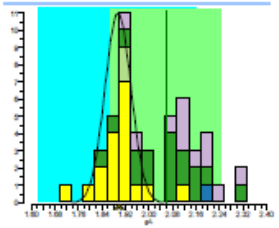
	cons.	meth.	ref.	lab
gem.	1.50	1.50	1.583	1.6
SD	0.05	0.05		
n	18	18		
nu	3	3		

2015.1 C



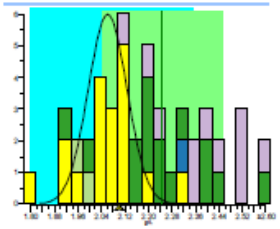
	cons.	meth.	ref.	lab
gem.	1.75	1.75	1.843	1.8
SD	0.07	0.07		
n	18	18		
nu	0	0		

2015.1 D



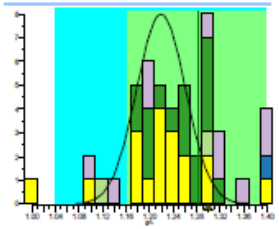
	cons.	meth.	ref.	lab
gem.	1.90	1.90	2.061	1.9
SD	0.04	0.04		
n	18	18		
nu	2	2		

2015.1 E



	cons.	meth.	ref.	lab
gem.	2.06	2.06	2.249	2.1
SD	0.07	0.07		
n	18	18		
nu	2	2		

2015.1 F



	cons.	meth.	ref.	lab
gem.	1.22	1.22	1.283	1.3
SD	0.04	0.04		
n	18	18		
nu	2	2		

Legenda

Roche (turb) | Beckman (turb/turn) | Abbott (turb) | Siemens (nefel) | Siemens (turb/turn)

Olympus (turb) | Overig | Ortho Diagnostics (turb) | Beckman (nefel)

Klaar?

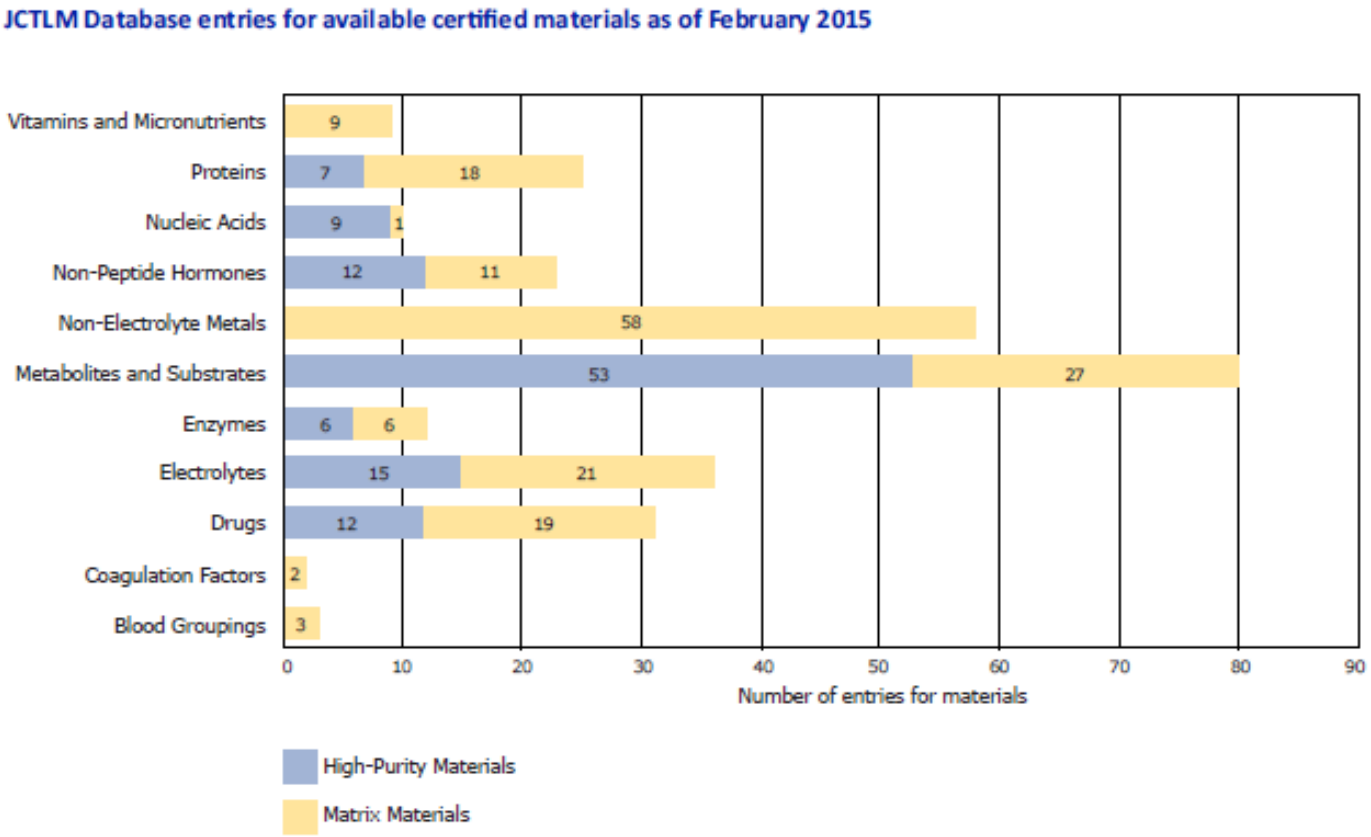
NEE

- CRP
- ß2 Microglobuline
- IgG subklassen
- Serum Vrij Lichte Ketens
- Ceruloplasmine
- ….

Certified values for:
α2macroglobuline
α1 acid glycoprotein
α1 anti-trypsin
Albumin
Complement C3
Complement C4
Haptoglobin
IgA
IgG
IgM
Transferrine
Transthyretin

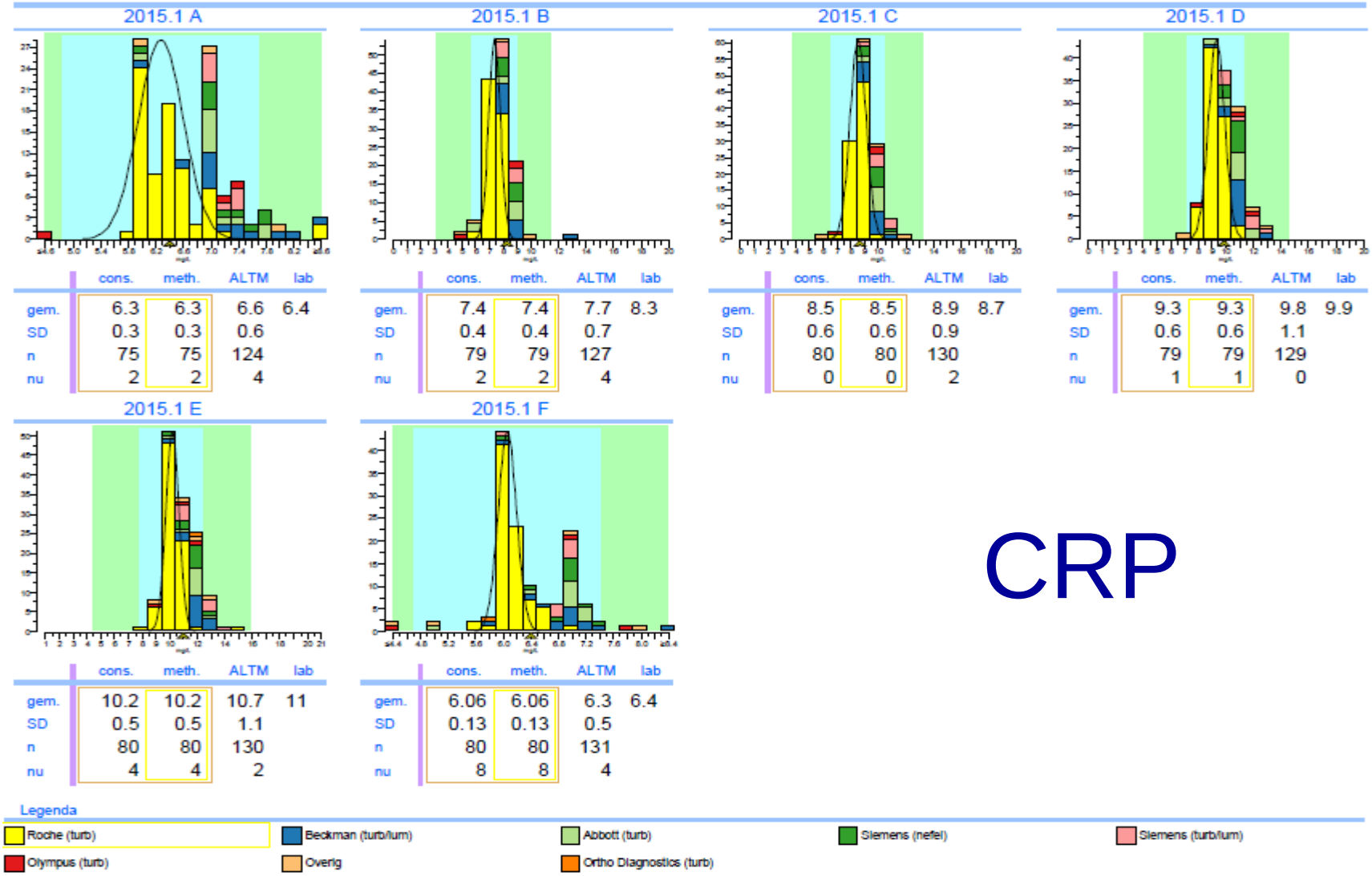
Not Certified for:
CRP
Ceruloplasmin
β2 microglobulin

JCTLM Newsletter mrt 2015



Are your in vitro diagnostic measurement results traceable to Higher Order Reference Materials, or Reference Methods?

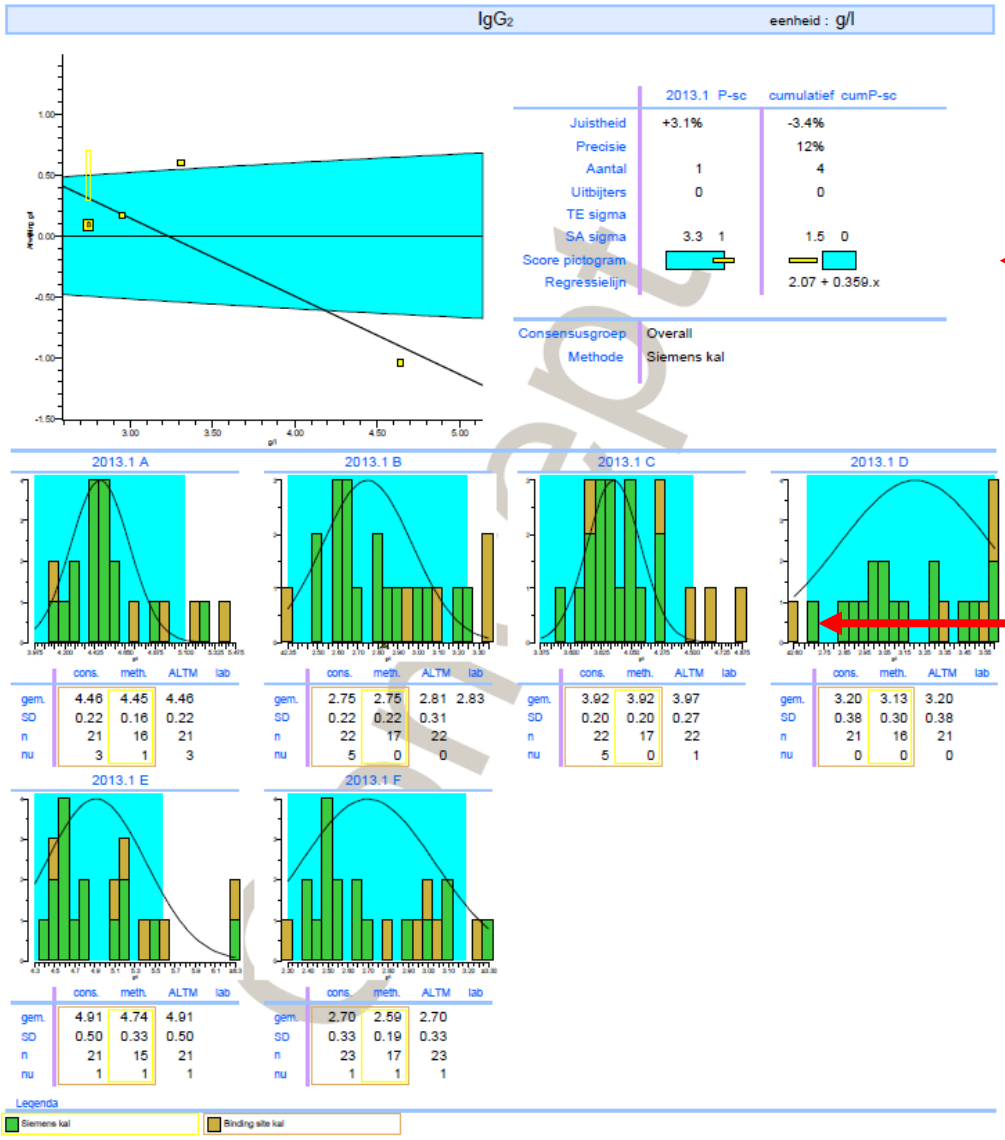
Institute for Reference Materials and Measurements (IRMM), European Union	
Phone: +32 (0)14 571 705 **Fax: +32 (0)14 590 406**	Email: jrc-irmm-rm-sales@ec.europa.eu Web: http://www.irmm.jrc.be/
Name of the reference material	**ERM-DA474/IFCC, Human serum**
Quantity	Mass concentration
Analyte certified/assigned value	41.2 mg/L
Expanded uncertainty (level of confidence 95 %)	2.5 mg/L
Reference(s) on commutability	Certification Report for ERM-DA474
Comment(s)	Each sample consists of at least 1 mL processed human serum spiked with CRP. It contains the following additives: (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium azide, bezamidine chloride and aprotinin). The material is kept under argon gas in Duran glass ampoules.
Traceability	1) Traceable to SI 2) Protein standardization IV: Value transfer procedure for the assignment of serum protein values from a reference preparation to a target material, Clin. Chem. Lab. Med., 2001, 39, 1110-1122 3) Traceable to ERM-DA470
CRM listing	List I



CRP

HIM

Combi immunochemie

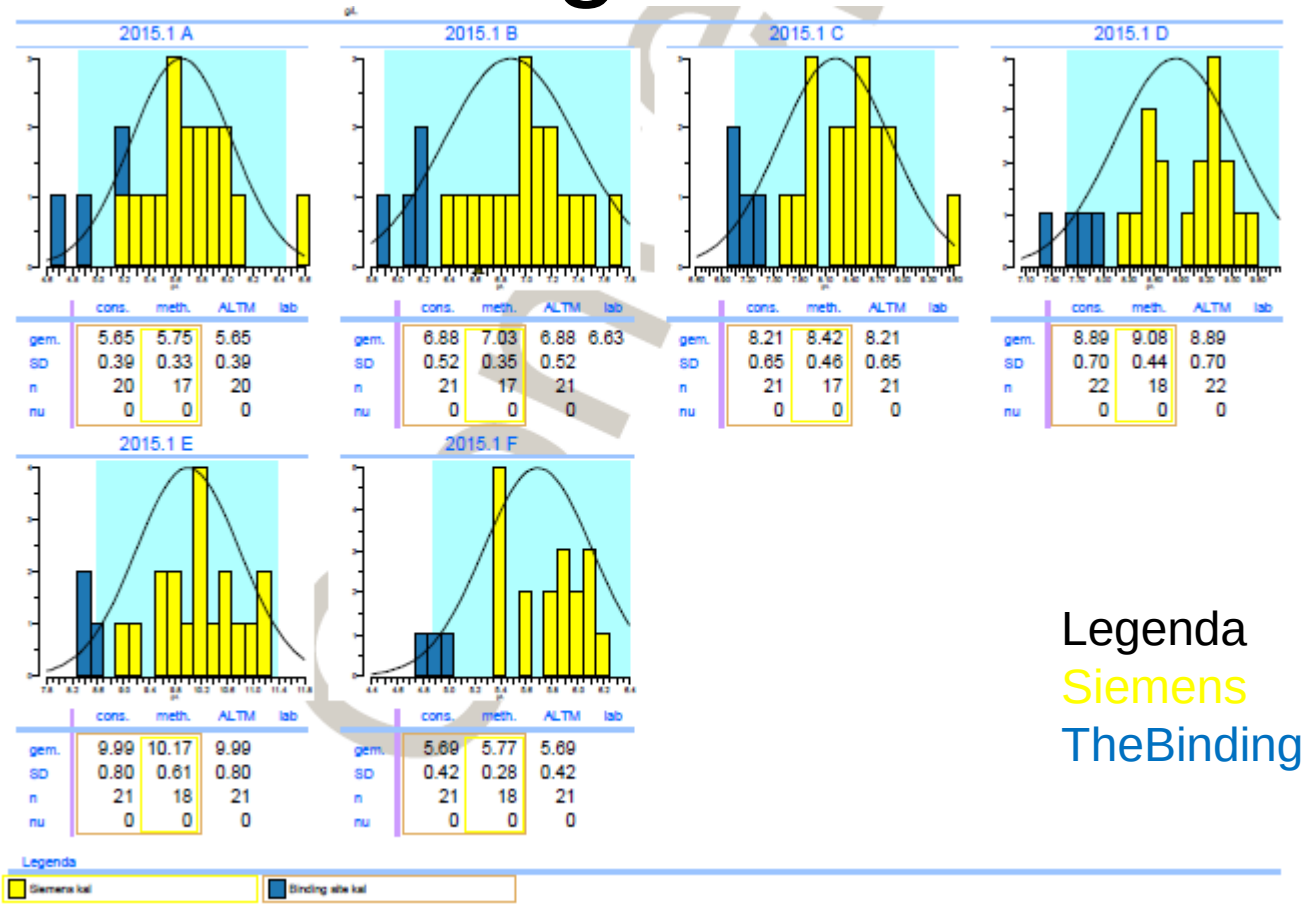


Calibratie?

Factor?

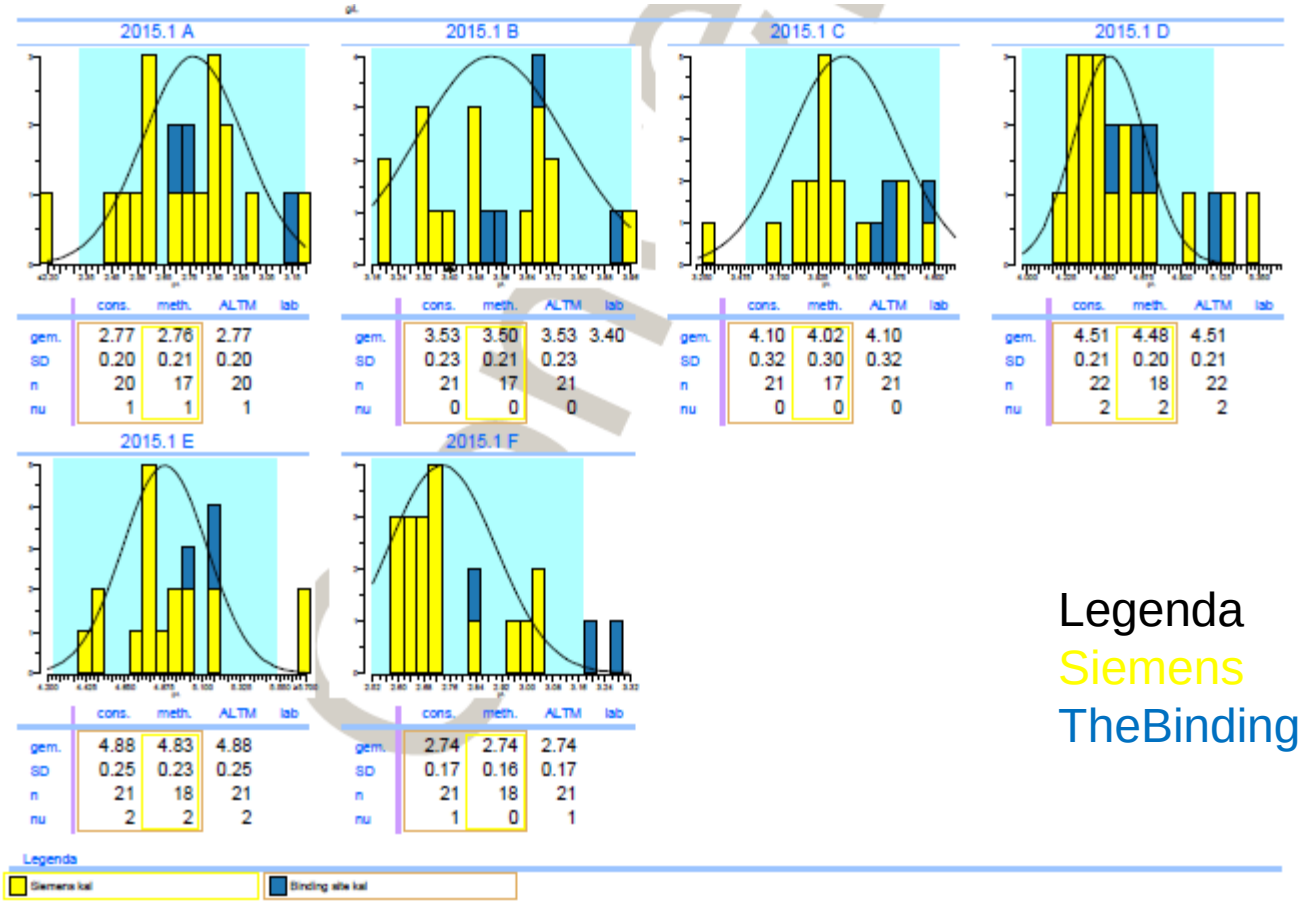
Legenda
Siemens kal
TheBindingSite kal

IgG1



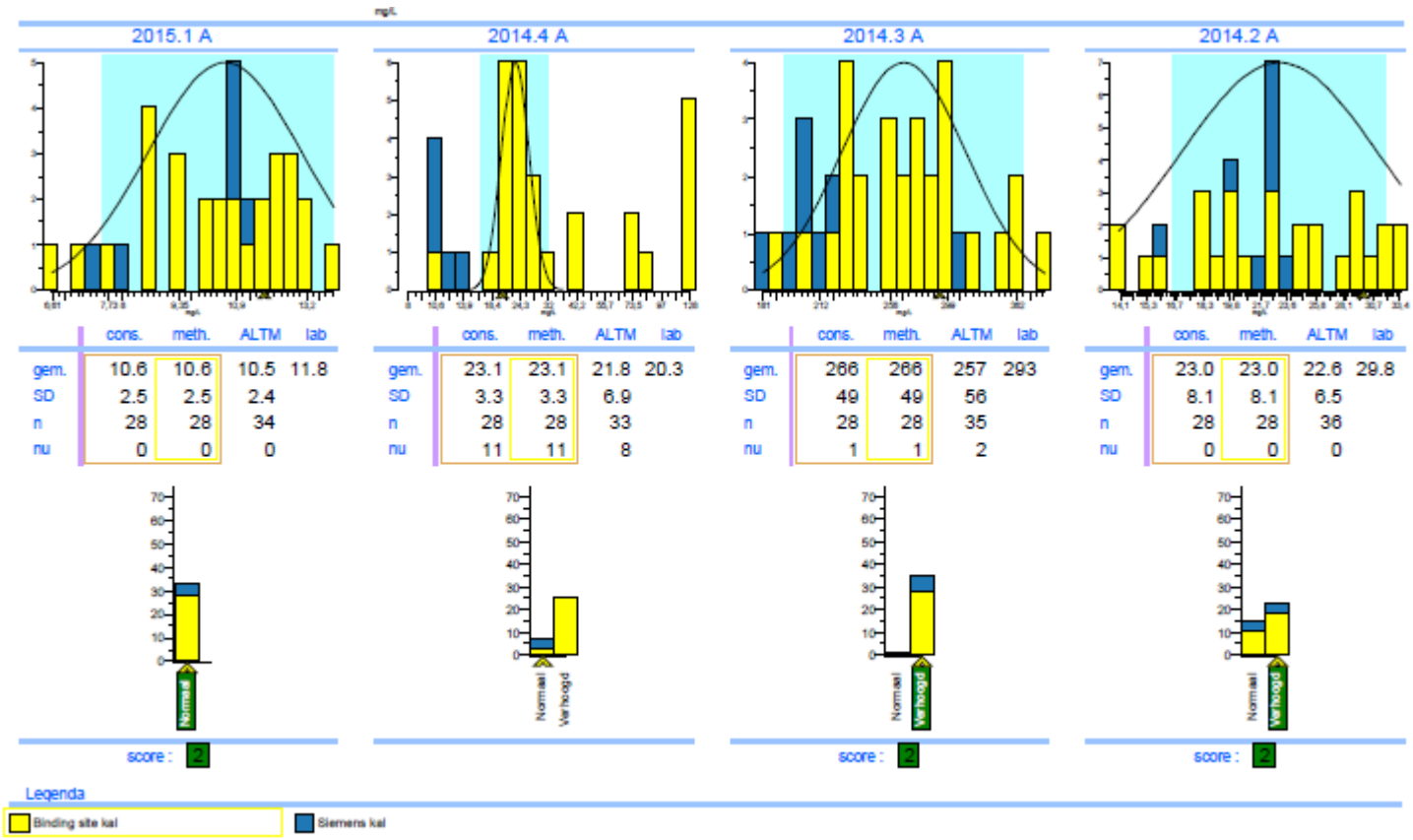
Legenda
Siemens
TheBindingSite kal

IgG2



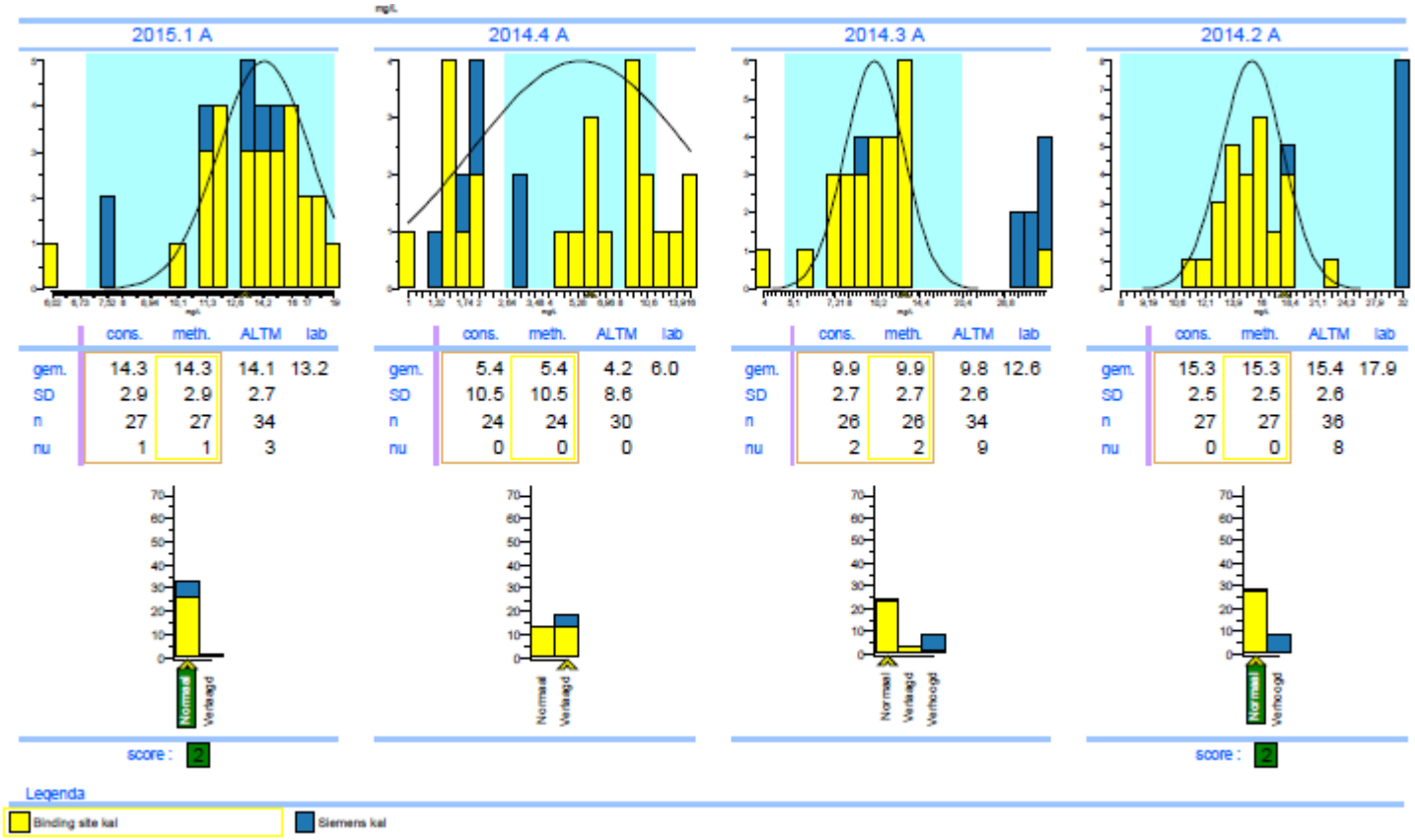
Legenda
Siemens
TheBindingSite kal

sVLK kappa 2015.1



Legenda
Siemens
TheBindingSite kal

sVLK Lambda 2015.1



Legenda
Siemens
TheBindingSite kal

Indien u contact heeft met uw firma betreffende het bepalen van eiwitten uit de combi immunochemie rondzending…..
Graag willen wij dit weten!

Adres:

Mw.dr.IA. Haagen,
coördinator Combi Immunochemie
Medisch Immunoloog/Klinisch Chemicus
OLVG, Amsterdam

i.a.haagen@olvg.nl

Met dank aan Cas Weykamp!

Dank voor uw aandacht!