Zoektocht naar de Heilige Graal & de ideale rapportage

Christa Cobbaert
Namens de sectie algemene chemie
3 juni 2010

SKML sectie algemene chemie

Dr. P.F.H. (Paul) Franck

HAGA Ziekenhuis

DEN HAAG

Dr. ir. A.W.H.M. (Aldy) Kuypers

Panteinziekenhuis

BOXMEER

Dr. R. (Robert) de Jonge

Erasmus MC
ROTTERDAM

Dr. Ch.M. (Christa) Boersma-Cobbaert

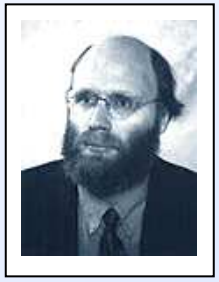
LUMC

LEIDEN

Dr. C.W. (Cas) Weykamp

Streekziekenhuis
Kon. Beatrix

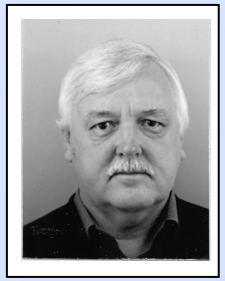
WINTERSWIJK



Adviseurs:

H. Steigstra

W. de Jonge

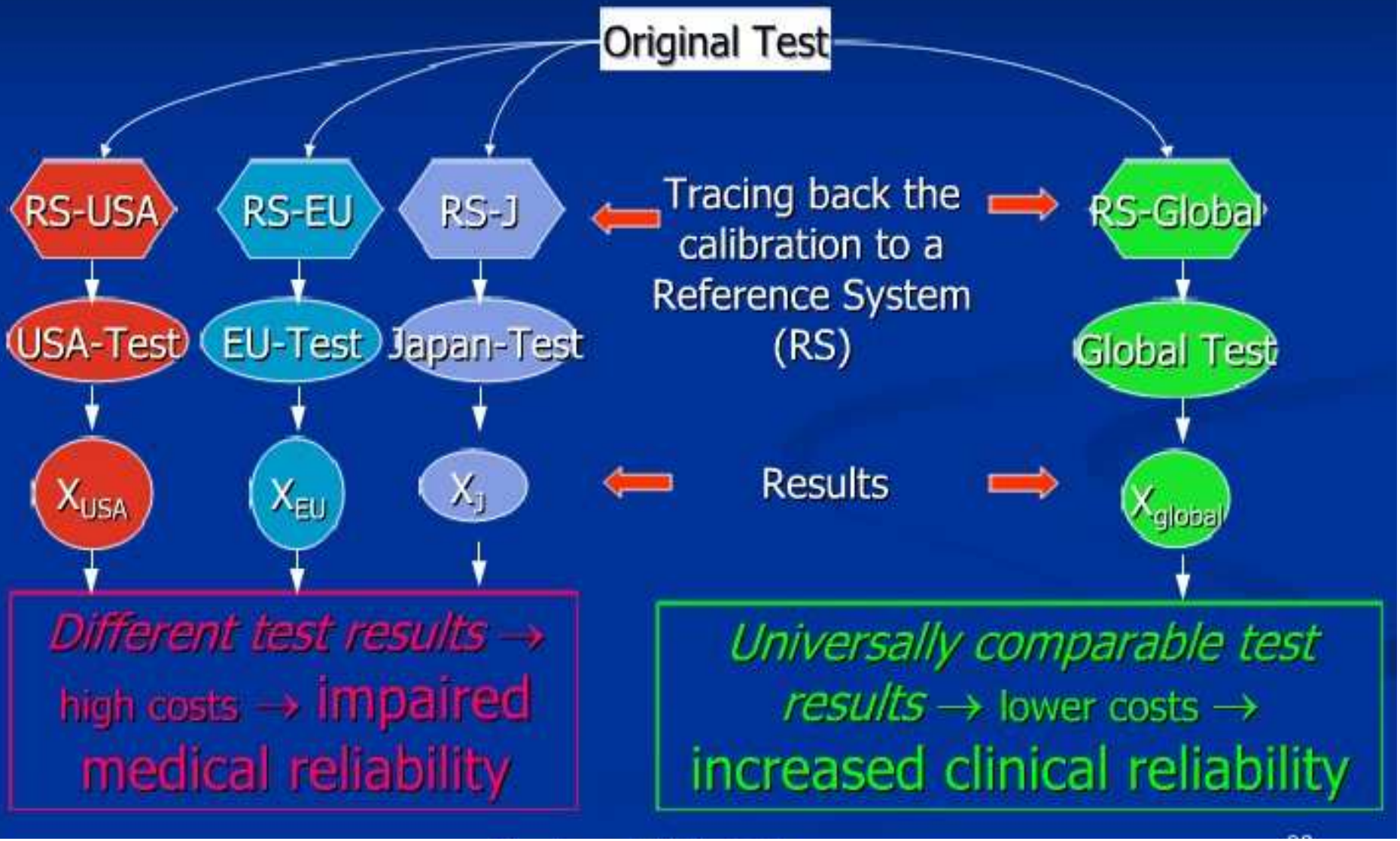


Content

- *Changing times*
- *Lessons learned & starting points*
- *Adaptability SKML section AC*
- *Output: the information pyramid*
  - *Day report and annual review report on top of the regular quarter report*
- *Conclusions*

I. Changing times ...

Need for Internationally Recognized Reference Measurement Systems



Joint Committee on Traceability in Laboratory Medicine

Other key stakeholders:
- Producers of Reference Materials
- Regulatory Bodies
- IVD Industry
- EQAS Organizations

Objectives and Purpose

To support comparability and equivalence of measurement results in Laboratory Medicine for the purpose of improving healthcare, through worldwide accepted traceability effort following the principles of metrology

To support IVD manufacturers in registration and licensing the CE label conforming with the EU directive

Traceability & type A analytes

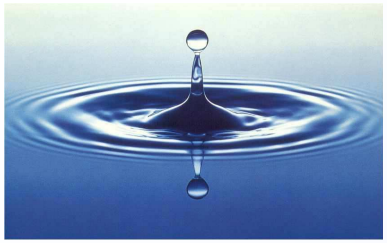
- Well defined "measurand"
- Concentrations expressed in SI-units
- Results are universal and not method-dependent
- About 65 analytes
  - e.g. glucose, elektrolytes, ureum, cholesterol, steroid hormones
- Complete traceability chain

skml

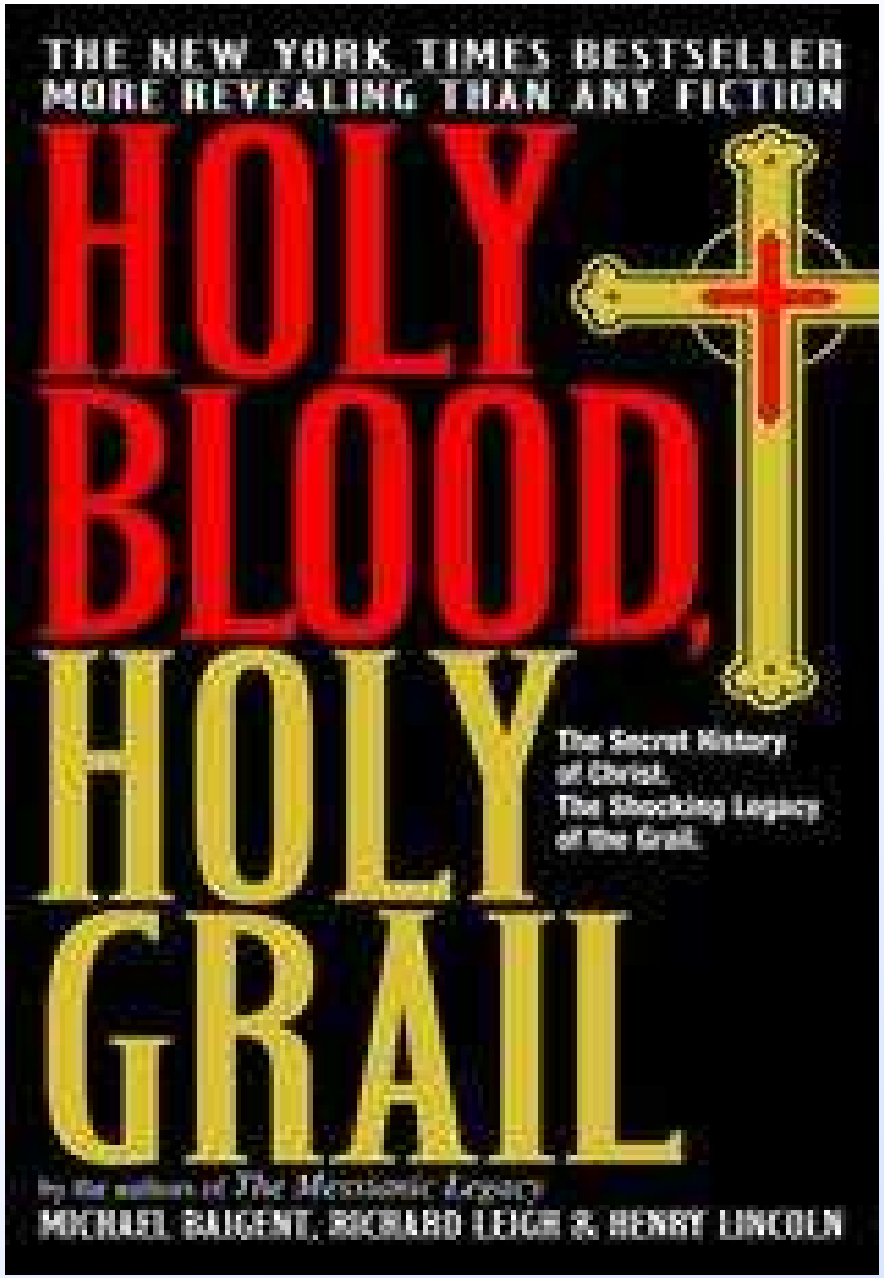
Standardization in laboratory medicine – primary goal

Measurement results should contribute to GMP for optimal patient care and patient safety:

- **for risk classification**
- **for diagnosis**
- **for monitoring treatment**



II. Calibration 2000 achievements



Taking lessons from Calibration 2000

1. Commutable EQA materials
2. Value assigned for trueness verification / temporary recalibration
3. Scoring system based on biological variation and clinical relevance

→ COMBI NEW STYLE based on 3 pillars

Introduced in the Netherlands since 2005.

Fresh frozen EQA-materials for general clinical chemistry analytes

1. Unequivocally characterized measurand
2. Human serum matrix
3. Liquid frozen
4. Not/minimally processed
5. Stable at - 70 ^{o}C (enzymes!)
6. Commutable (wet/dry chemistry)
7. No matrix effects
8. Value assigned and suitable for bias assessment

Holy Grail
San Greal
Sang Real

III. Adaptability…

Modernized EQA-design for clin. chemistry

1. 24 interdependent samples per year (12 pairs; linear relation!)
2. Volume 1 mL; liquid frozen
3. CLSI C37A material (lipids)!
4. Human Recombinant Enzymes
5. Yearly distribution on dry ice
6. Systematic concentration range (donor selection/spiking)
7. Systematic value assignment with JCTLM-endorsed RMs (18/25)

Systematic concentration range

Spiking by accurate weighing

Na - K -Cl - Ca - Mg - Li - P -ureum - creatinine
uric acid - glucose - bilirubin

Spiking by arbitrary weighing

ALP - ASAT -ALAT - LD -GGT -CK -amylase
Fe – Fe-binding - osmolality

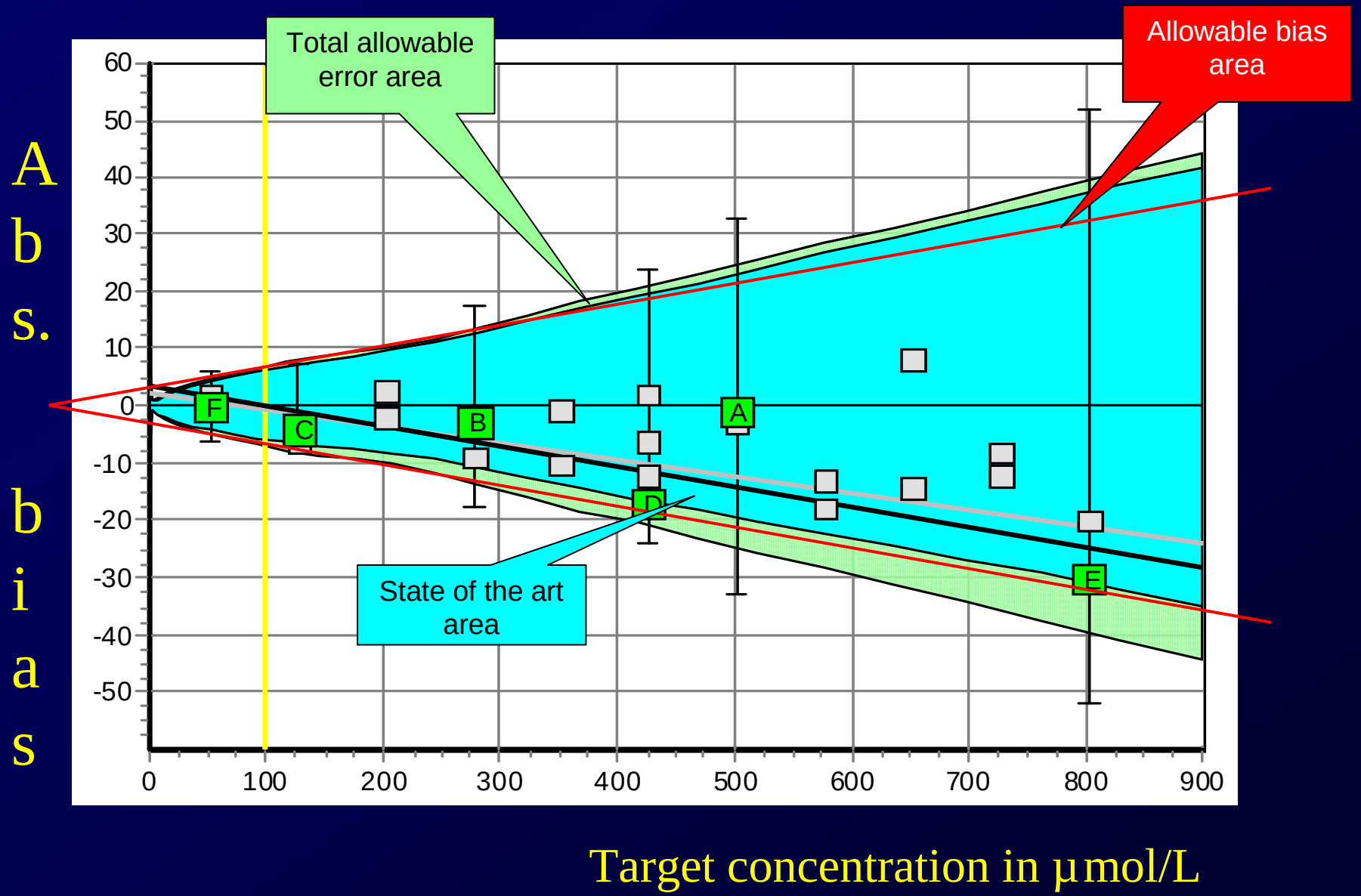
Adequate concentration range through donor selection

Cholesterol – HDLc - Triglycerides - LDLc
Apo A1 - Apo B - Lp(a)
Total protein and albumin

Low levels through dialysis

Same category as spiking by accurate weighing

Scoring system based on biological variation



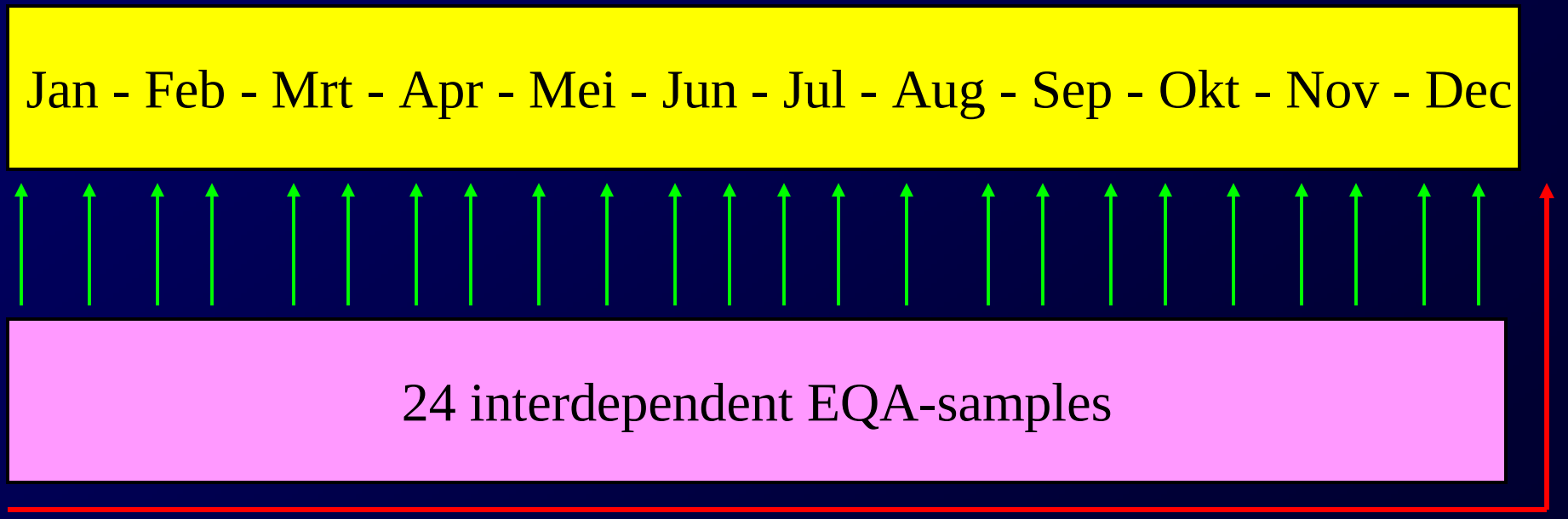
IV.OUTPUT: the information piramid

Informatiepiramide

NEW EQA-reports to participants

Simple real-time DAY REPORT: only bias, trend in time, concentration can be examined

ANNUAL REVIEW REPORT with method bias, recovery, linearity, precision, interlab CVs and interpretations, conclusions, recommendations



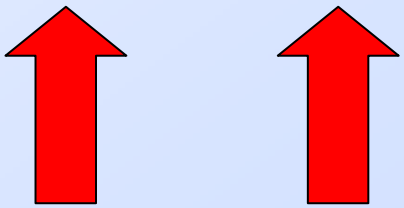
I. Tussenrapport

Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Deelnemer :16 15 april 2010 10:28 Pagina 1

Neonatale Bilirubine 2010.1

Bepaling		Uw resultaten Gem.	V.C.	Landelijk Gem.	V.C.	Referentie	SA-Score 2010.1	Cum.	TE-Score 2010.1	Cum.
Albumine	g/l	21,8	1,9%	21,1	3,1%		40	40	40	40
Kreatinine	µmol/l	13	28%	15	16%		12	12	12	12
Bilirubine	µmol/l	347	4,7%	355	2,3%		43	43	43	43



II. Kwartaalrapport

skml
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Combi Algemene Chemie

ALG. CHEMIE

Bepaling		Uw resultaten		Landelijk			SA-Score		TE-Score	
		Gem.	V.C.	Gem.	V.C.	Referentie	2005.1	Cum.	2005.1	Cum.
Natrium	mmol/l	134,3	0,31%	137,0	0,8%		100	98	0	38
Kalium	mmol/l	5,32	0,7%	5,42	1,0%		84	95	100	100
Chloride	mmol/l	97,5	0,23%	98,1	1,0%		100	100	100	63
Glucose	mmol/l	21,7	0,5%	22,0	1,8%		92	90	97	97
Magnesium	mmol/l	1,40	0,6%	1,45	2,0%		85	92	74	80
Calcium	mmol/l	2,78	1,8%	2,79	1,9%		99	95	81	68
Anorg. Fosfaat	mmol/l	1,82	1,0%	1,78	1,5%		83	94	89	97
Uraat	mmol/l	0,422	0,8%	0,419	1,7%	0,425	100	100	100	100
Ureum	mmol/l	23,4	1,0%	24,0	2,0%		95	83	100	100
Kreatinine	µmol/l	386	1,8%	384	1,1%	375,0	98	97	95	96
Bilirubine	µmol/l	47,9	0,9%	46,8	2,6%		83	97	96	99
Alk. Fosfatase	U/l	189	0,9%	189	2,4%		100	66	100	82
Gamma-GT	U/l	107	0,8%	97	2,1%	102,8	0	30	100	86
LD	U/l	465	3,2%	739	5,3%	465		7	100	15
ASAT	U/l	186	1,3%	189	1,7%	190,6	83	63	38	88
ALAT	U/l	51,0	2,2%	50,4	3,3%	49,9	100	89	100	100

skml
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

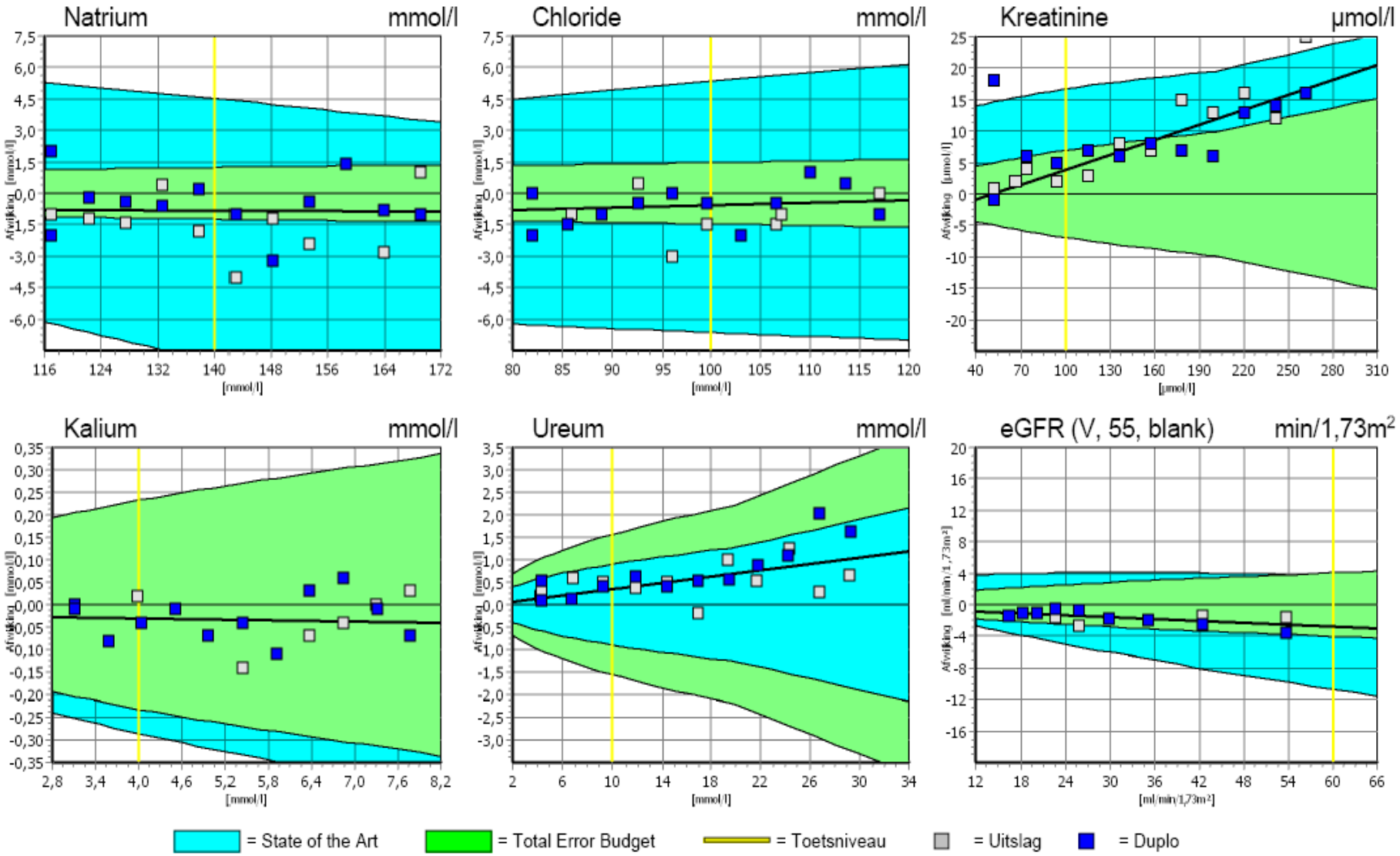
IIIa. Jaarrapport

Jaarrapport Combi Algemene Chemie 2009

Analyte		Juistheid				Regressie statistiek							Overall Score		
		Uw gem.	Toetsniveau Cons.	Toetsniveau Ref.	Rank	Uw VC	VC all	Intercept	Slope	n	Uitb.	Rank	SDsa score	Total Error score	Rank TE
Natrium	mmol/l	139,2	138,1	140,0	81	1,0%	0,9%		0,994	24	0	36	100	53	85
Kalium	mmol/l	3,98	3,96	4,00	75	0,9%	1,1%		0,994	24	0	72	100	100	91
Chloride	mmol/l	99,3	99,2	100,0	63	0,9%	1,0%		0,993	24	0	68	100	76	70
Ureum	mmol/l	10,4	10,0		31	1,5%	2,2%		1,037	24	4	82	95	99	49
Kreatinine	µmol/l	105	109	100	39	1,9%	2,2%		1,055	24	2	64	94	66	44
eGFR (V, 55, blank)	l/min/1,73m²	57	56	60	50	2,3%	2,7%		0,947	18	0	61	100	91	74
Uraat	mmol/l	0,484	0,488	0,500	52	2,1%	1,7%	-0,012	0,993	24	0	30	100	100	100
Osmolaliteit	mOsm./kg	291	300		4	0,6%	1,1%		0,970	24	2	88	100	9	4
Calcium	mmol/l	2,50	2,52	2,50	100	1,2%	1,6%	-0,19	1,075	24	0	72	100	94	95
Magnesium	mmol/l	1,09	1,04	1,00	2	2,0%	2,4%		1,094	24	2	63	81	9	5
Anorg. Fosfaat	mmol/l	0,99	1,00		66	1,6%	1,8%		0,991	24	2	57	93	94	17
IJzer	µmol/l	30,6	30,0		27	2,4%	1,5%		1,019	24	1	10	98	100	34
Totaal ijzerb. cap.	µmol/l	41,8	45,0		29	4,0%	2,8%	-31,9	1,636	24	2	28	77	22	40
Bilirubine	µmol/l	22,0	20,0		30	4,4%	3,5%		1,102	24	1	32	61	98	44
Albumine	g/l	41,0	40,0		27	1,5%	1,7%		1,025	24	0	60	100	78	43
Totaal Eiwit	g/l	73,3	70,5	70,0	5	1,5%	1,7%		1,047	24	1	58	99	22	7
Alk. Fosfatase	U/l	154	150		55	1,5%	2,5%		1,029	24	4	81	98	98	52
Gamma-GT	U/l	47	49	50	26	2,5%	2,0%	-2	0,993	24	0	33	95	100	65
ASAT	U/l	44	48	50	8	5,1%	2,2%		0,887	24	1	8	67	70	11
ALAT	U/l	44	48	50	15	1,9%	2,5%		0,888	24	1	74	90	95	33
LD	U/l	473	697	500	40	7,1%	2,4%		0,945	24	0	8	0	92	49
CK	U/l	152	147	150	83	1,8%	1,8%		1,011	24	0	52	99	100	100
Amylase	U/l	260	316	250	51	1,2%	1,6%	4	1,025	24	1	72	0	100	48
Lipase	U/l	26,9	25,0		39	4,6%	4,3%		1,074	24	1	39	93	97	36
Glucose	mmol/l	10,3	10,0	10,0	17	1,6%	1,6%	0,4	0,992	24	0	47	99	85	26
Cholesterol	mmol/l	5,16	5,09	5,00	26	4,0%	1,9%		1,032	24	0	3	96	91	16
Triglyceriden	mmol/l	2,03	2,00		74	1,7%	2,8%		1,016	24	3	88	94	98	17
HDL-Cholesterol	mmol/l	1,02	1,00	1,00	62	1,9%	3,1%		1,019	24	1	88	96	96	61
LDL-Cholesterol	mmol/l	3,09	3,00		48	2,6%	3,3%		1,030	24	1	65	96	96	38
Pseudo Cholinesterase	kU/l	5,86	6,00		26	3,3%	2,0%		0,976	24	0	13	100	95	32
hs-CRP	mg/l	-1,468	25,000		58	14%	16%	1,207	-0,107	6	0	75	0	0	92
Apo A1 lipoproteïne	g/l	1,49	1,40		15	2,9%	3,7%	-0,27	1,260	24	1	79	98	75	18

Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

Jaarrapport Combi Algemene Chemie 2009



IIIa. Jaarrapport cont'd

skml
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

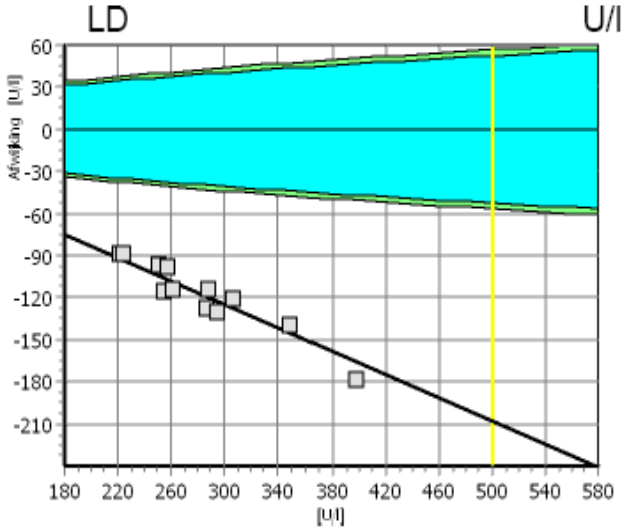
Jaarrapport Hartmerkers 2009

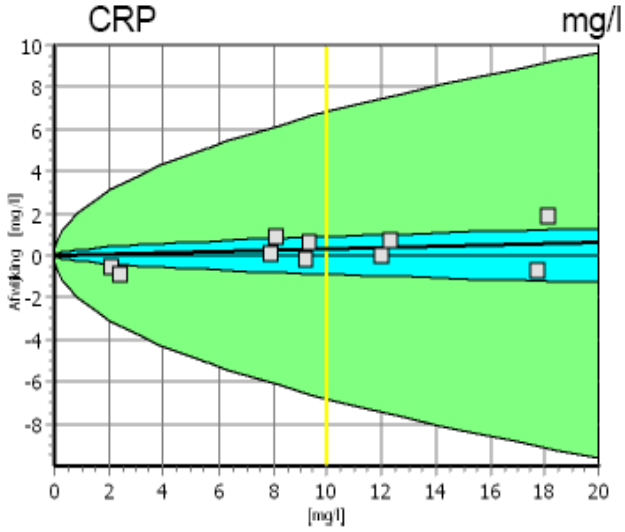
Analyte		Juistheid				Regressie statistiek							Overall Score		
		Uw gem.	Toetsniveau Cons.	Toetsniveau Ref.	Rank	Uw VC	VC all	Intercept	Slope	n	Uitb.	Rank	SDsa score	Total Error score	Rank TE
LD	U/l	292	500		9	4,8%	2,1%		0,583	12	0	20	0	0	12
CK	U/l	158	150		20	2,1%	1,5%		1,056	12	0	27	98	100	100
CRP	mg/l	10,3	10,0		60	8,0%	4,5%		1,031	10	0	17	70	100	100
Troponine T	µg/l	0,106	0,100		33	4,8%	6,1%		1,057	12	1	70	99	99	85
NT-proBNP	ng/l	1658	1695		57	2,0%	2,0%		0,978	12	3	50	100	96	47

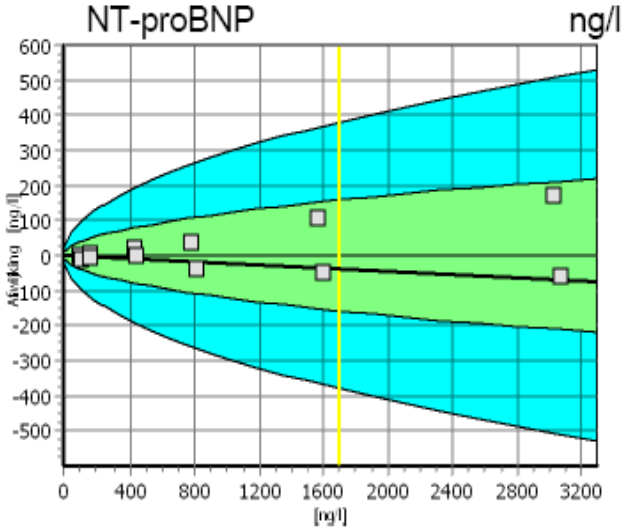
skml

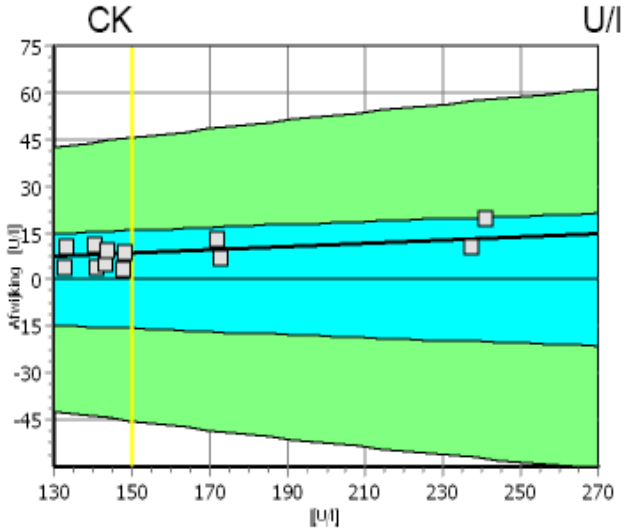
skml
Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

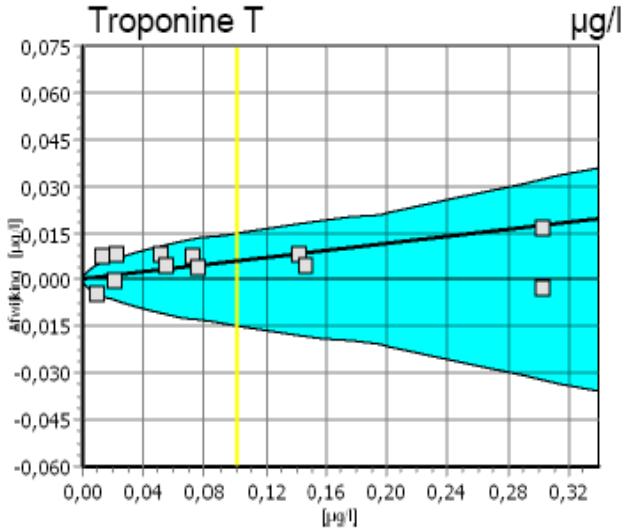
Jaarrapport Hartmerkers 2009











= State of the Art = Total Error Budget = Toetsniveau = Uitslag = Duplo

IIIb. Jaarbrief 2009

1. Inleiding
2. Gebruikte Instrumenten: op weg naar Vierstromenland
3. Commuteerbaarheid: zelfreflectie van de SKML
4. Kreatinine en e-GFR: hoe worden aanbevelingen opgevolgd?
5. LD: chaos in de rapportage
6. Hartmerkers: een veld in beweging
7. Bilirubine: de gevolgen van de herstandaardisatie
8. APOA1 en APOB: beter dan HDL-c en LDL-c?
9. HbA1c: steeds betere reproduceerbaarheid en juistheid
10. hs-CRP: kwaliteit van de meting in het lage meetgebied
11. Osmolaliteit: vergelijk van instrumenten
12. Woord van Dank
13. Enquête

Doel jaarrapport en jaarbrief

Jaarrapport:

Review van een heel jaar

Voor hoofden laboratoria

Van belang bij formuleren nieuw beleid

Jaarbrief:

Identificeren van probleemgebieden

Identificeren van veranderingsgebieden

Jaarbrief identificeert problemen

	Method A	*Method B*	*Method C*
Lab 1			
Lab 2			
Lab 3			
Lab 4			
Lab 5			

PPP: bad performing method

	Method A	*Method B*	*Method C*
Lab 1			
Lab 2			
Lab 3			
Lab 4			
Lab 5			

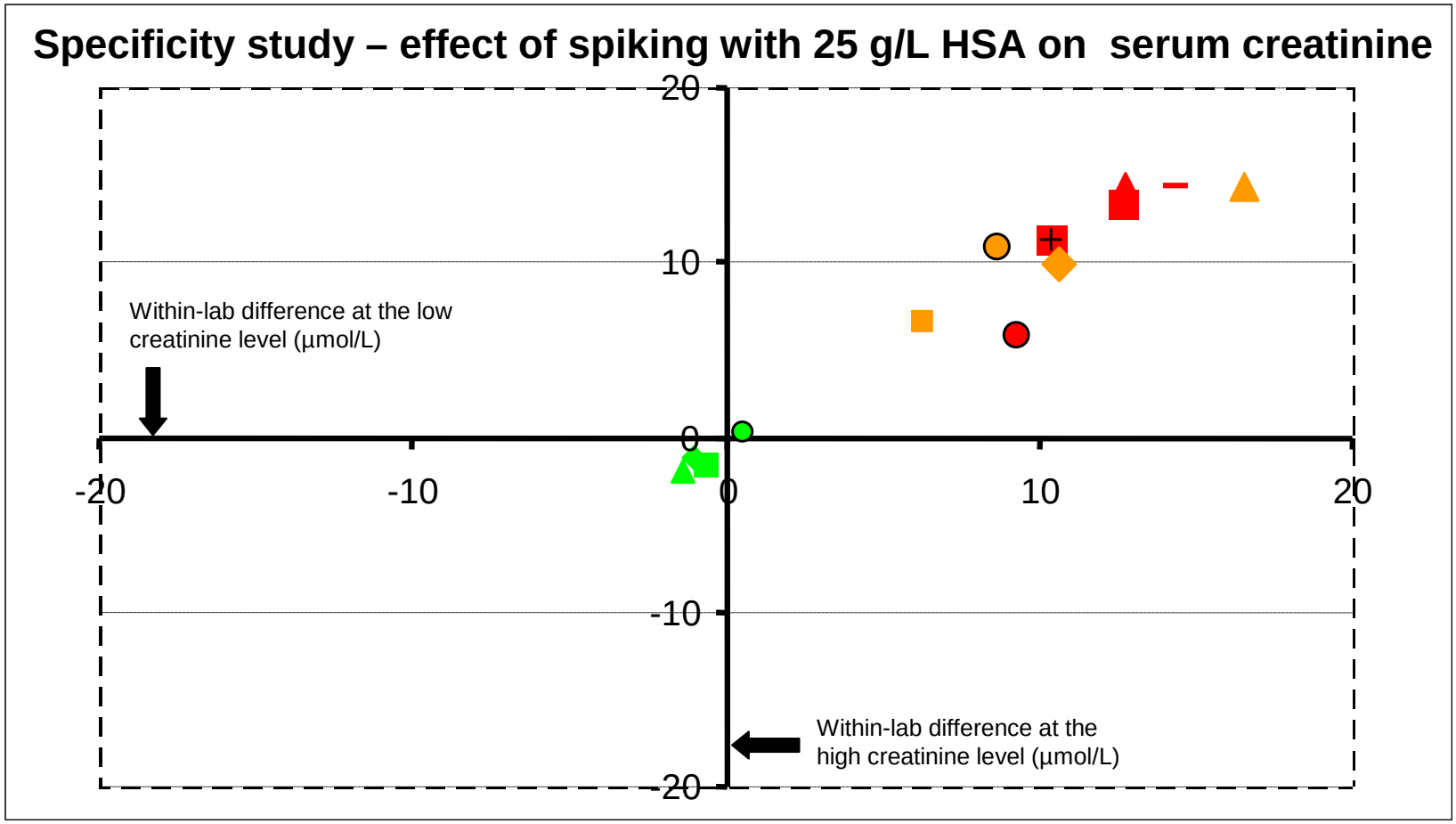
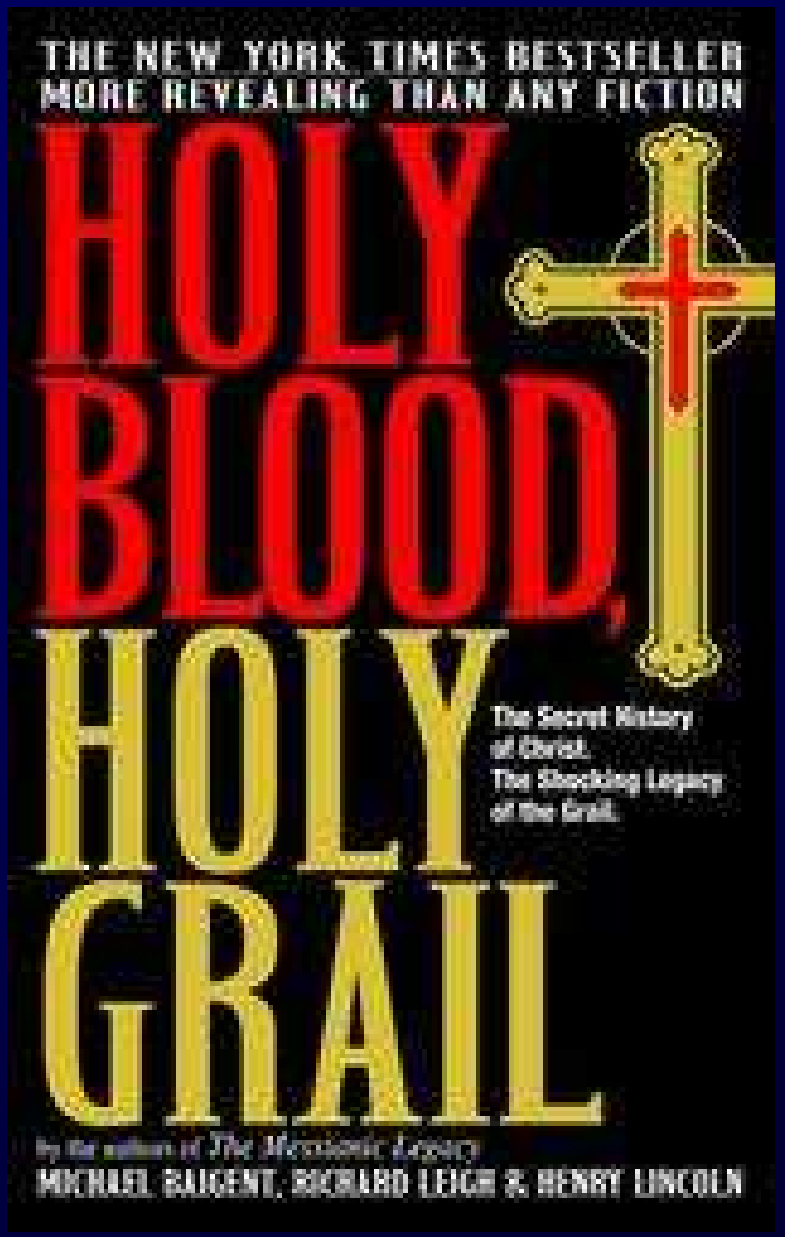


Figure 1. Scattergram presenting the within-lab serum creatinine differences (in µmol/L) found between HSA-spiked and unspiked specimens at the low (X-axis) and the high (Y-axis) creatinine level. Within-lab differences between HSA-spiked and unspiked specimens are aggregated per method-analyzer combination. To this end, average differences were calculated from the individual lab data. Specific method and analyzer combinations are described in the Materials and Methods section.

- Enzymatic Mean Abbott Architect
- Enzymatic Mean OCD Vitros
- Enzymatic Mean Roche Cobas
- Enzymatic Mean Roche Modular
- Jaffe kin with comp. Mean Roche Cobas
- Jaffe kin with comp. Mean Roche Integra
- Jaffe kin with comp. Mean Roche Modular
- Jaffe kin with comp. Mean Siemens Advia
- Jaffe kin with comp. Siemens Dimension RxL
- Jaffe kinetic Mean Abbott Architect
- Jaffe kinetic Mean Beckman Coulter LX20
- Jaffe kinetic Siemens Advia 1650
- Jaffe kinetic Siemens Dimension RxL

Cobbaert et al., Clin Chem 2009

V. Conclusion:



Procession of the Precious Blood of Jesus Christ, Bruges, Belgium.

Informatiepiramide