Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Sectie Algemene Chemie
Gebruikersdag 2025

AKSA Medical

Abbott

DaklaPack europe

BIO-RAD

HUSK MEDICAL

greiner BIO-ONE

Roche

Workshop Total allowable Ergernis & State of the fart

HOE OM TE GAAN MET TEA EN SA IN SKML-RAPPORTEN?

ARMANDO VAN DER HORST – LID SECTIE ALGEMENE CHEMIE SKML

ELSKE KUSTERS – LID SECTIE ALGEMENE CHEMIE SKML

Disclosure belangen Elske Kusters

Geen (potentiële) belangenverstrengeling ✓	
Voor bijeenkomst mogelijk relevante relaties	Geen
Sponsoring of onderzoeksgeld	Geen
Honorarium of andere (financiële) vergoeding	Geen
Aandeelhouder	Geen
Andere relatie, namelijk …	Geen

Programma

10 min	Inleiding
5 min	Uitleg opdracht
15 min	Werken aan opdrachten in 5 groepjes
25 min	Terugkoppeling groepjes (5x5 min)
5 min	Nabespreken/conclusie

Inleiding

Taai onderwerp

Begint bij de terminologie:

- **Sigma-score**
- **TEa – Total Error allowable – Total allowable error**
- **SA – State of the Art**

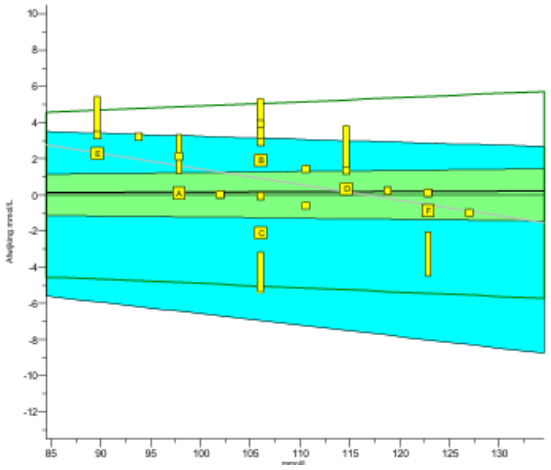
$$Z = \frac{X - \mu}{\sigma}$$

Where

X is the value of interest
μ is the mean
σ is the standard deviation

Terminologie

Chloride — eenheid : mmol/L

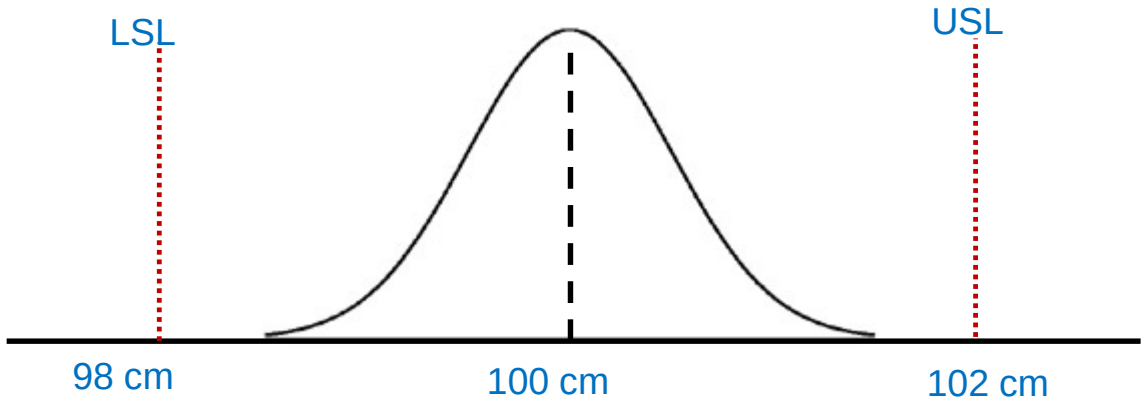


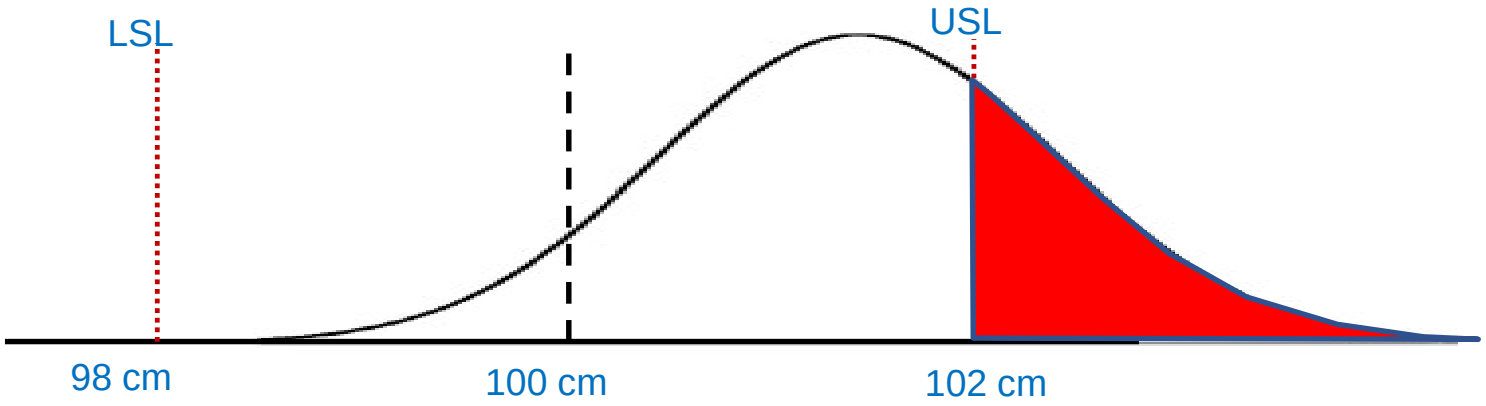
	2025.1	cumulatief
Juistheid	+0.24%	+0.74%
Precisie	1.4%	1.1%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	0.8	0.7
Sigma-SA	4.9 2	4.8 2
Scorepictogram		
Regressielijn	0.0 + 1.002.x	10.0 + 0.914.x
Consensusgroep	ISE	
Methode	Siemens Atellica	
Analyser	Siemens Atellica CH	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 0.999.x	

Sigma-TE	0.8	0.7
Sigma-SA	4.9 2	4.8 2
Scorepictogram		
Regressielijn	0.0 + 1.002.x	10.0 + 0.914.x

Sigma-principe en prestatie score (P-score)

- Hoe goed is goed?





Slide van Joost van de Ven

Sigma-principe – hoe goed is goed?

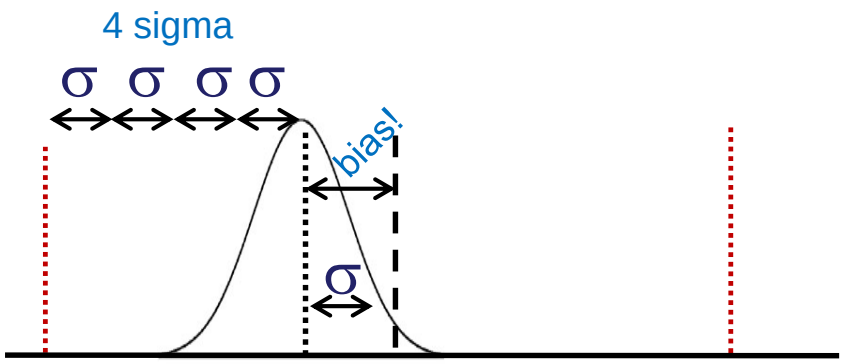
- Six-sigma-norm:
  - Afwijking zo klein dat <1:1.000.000 niet voldoet aan de kwaliteitsnorm
  - Spreiding <1/6 van de norm (= maximaal toegestane fout)

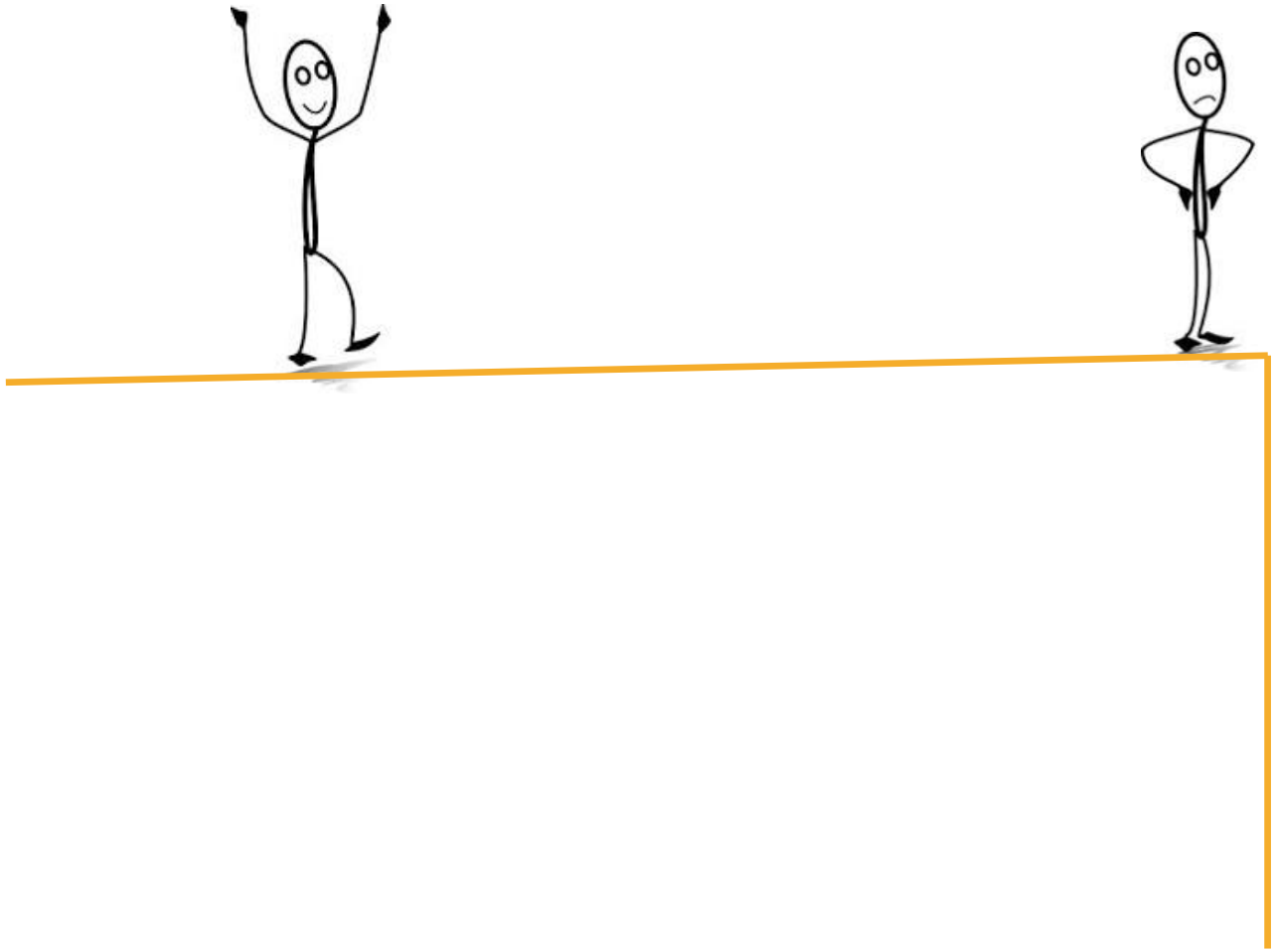
Sigma score	Fouten per miljoen gebeurtenissen (DPMO) (2-zijdig), proces zonder *bias*	DPMO bij systematische fout (*bias*) van 1,5 SD (2-zijdig)
1	317.310	697.700
2	45.500	308.770
3	2.700	66.810
4	63	6.210
5	0,57	233
6	0,002	3,4

Leidraad analytische kwaliteitscontrole mbv six sigma

- Sigma-score
  - Het aantal SD's binnen de kwaliteitsnorm

$$\text{Sigma-score} = \frac{\text{norm} - |\text{bias}|}{\text{CV\%}}$$





Slide van Joost van de Ven

De norm: TE- en SA-gebied

- **Normen SKML**
  - **Total Error** = TE = maximaal toegestane fout o.b.v. biologische variatie (EFLM of Ricos)

    Hoeveel mag de gemeten waarde afwijken van de werkelijke waarde zonder dat het klinisch gevaarlijk/verwarrend wordt?

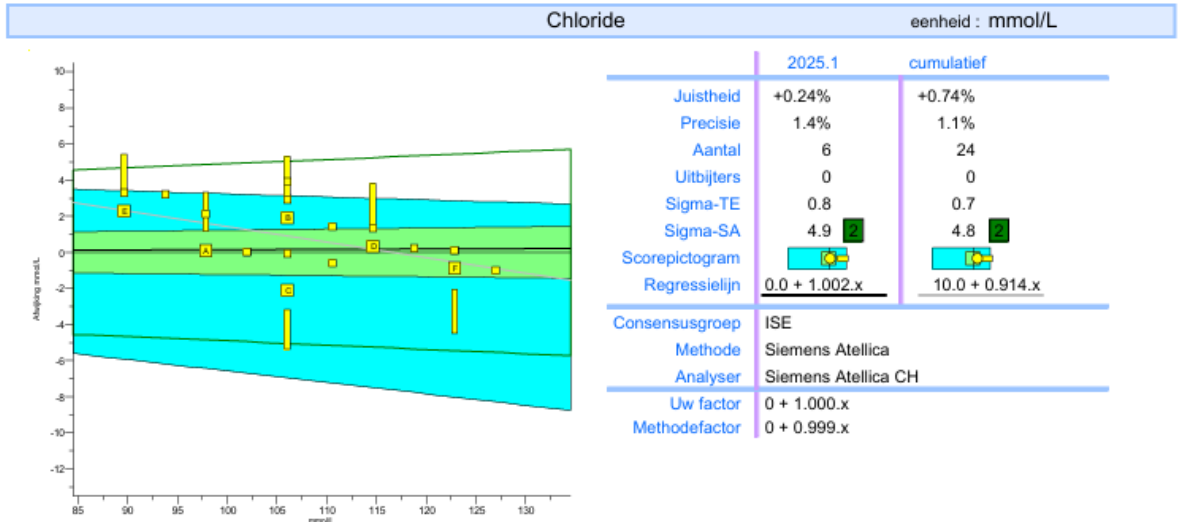
  - **State of the Art** = SA = maximaal toegestane fout o.b.v. 'hoe goed anderen zijn'

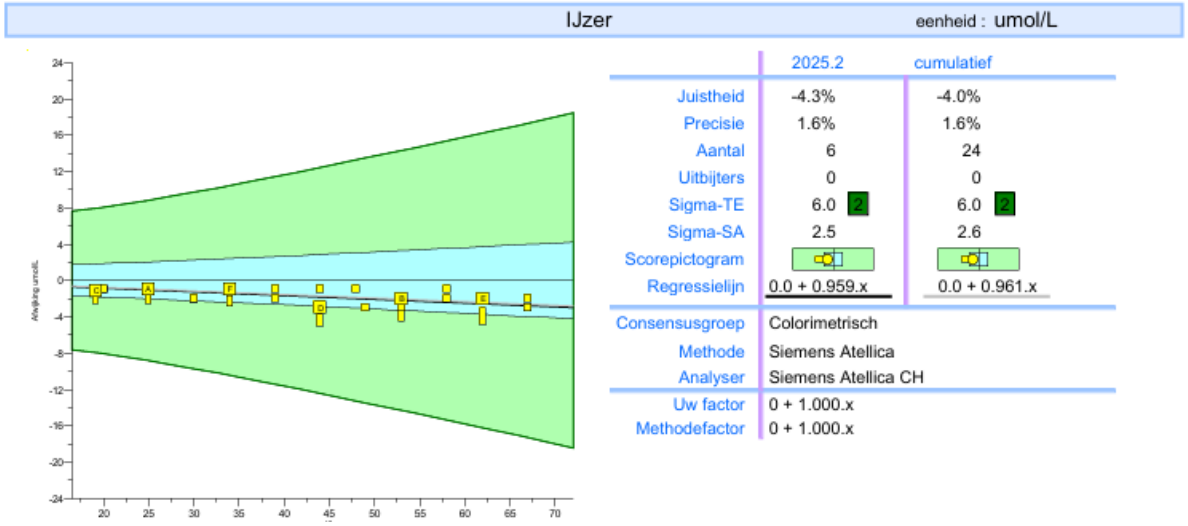
    = 3x CVa van consensusgroep over 3 jaar

    Hoe goed zijn de testen op de markt? Lig je binnen jouw groep?

De norm: TE- en SA-gebied

- Maximaal toelaatbare fout SKML =
  - Total Error (TE) = toegestane fout o.b.v. biologische variatie
  - State of the Art = SA = 3x CVa van consensusgroep over 3 jaar
- Soms SA wijder, soms TE wijder
  - Soms is de test niet zo goed als we klinisch zouden willen
  - Soms kunnen we beter meten dan klinisch nodig

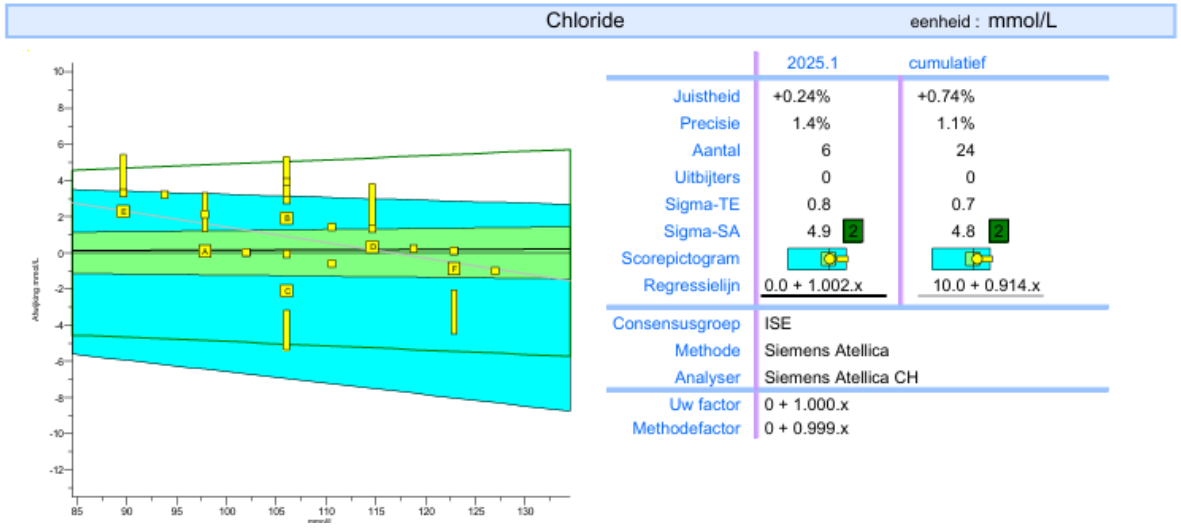


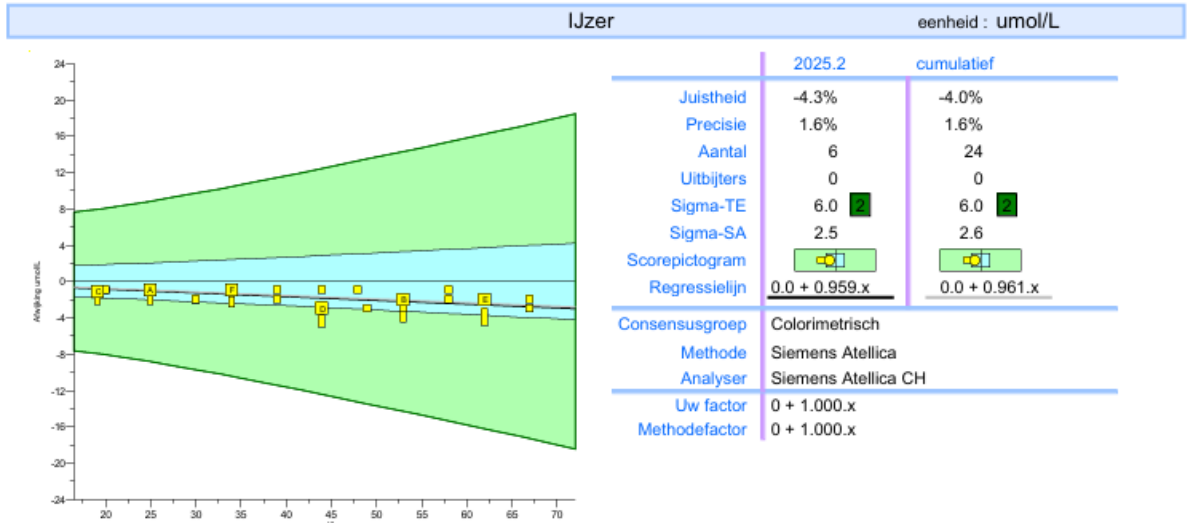


De norm: TE- en SA-gebied

Afwijking van

- Expert- of referentiemethode
  ‘Gouden standaard’
  Harde kleuren
- Andere labs binnen de groep: ALTM
  Geen expert- of referentiemethode
  Zachte kleuren





- SKML: 2 sigma-scores, 1 met TE als norm, 1 met SA als norm

Sigma-scores & SKML Performance-scores

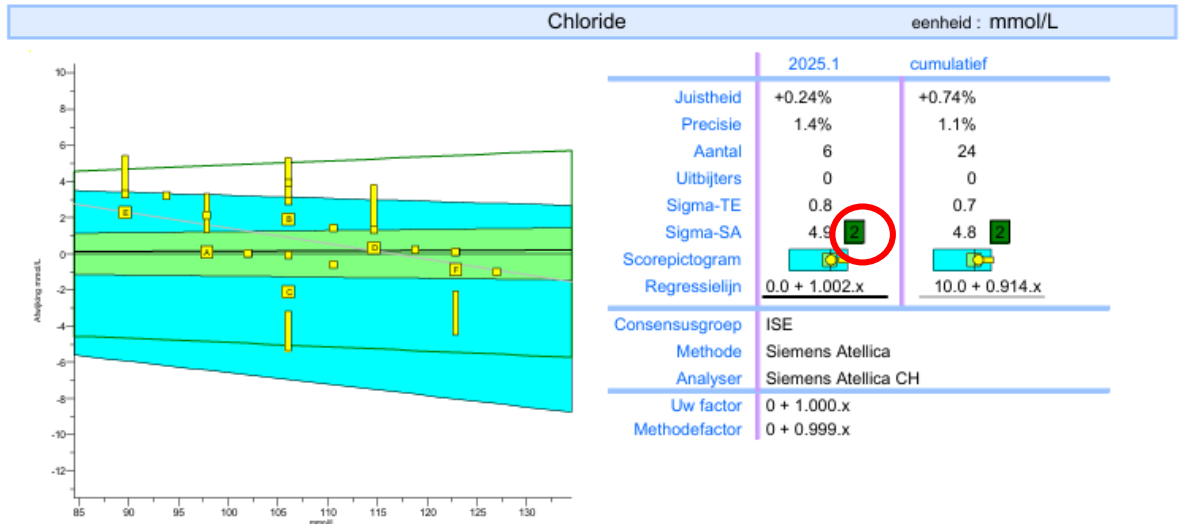
MUSE-handleiding:

SKML: 1:1.000.000 is te streng → 95% (5:100) = sigma van 2 = “voldoende”

Een sigma vanaf 4.5 is daarbij “uitstekend”

Sigma	P-score
≥ 4.5	2
2.0 - 4.5	1
< 2.0	0

P-score bij de <u>hoogste</u> sigma-score



TEa vs SA

Opdracht voor groepjes deelnemers

- Analiet met een voorbeeldplot
- Vragen per analiet
  - Is de beoordeling van deze analiet op SA of TEa?
  - Waarom denk je dat dat zo is?
  - Met wie of wat worden de uitslagen van de deelnemer vergeleken?
  - Welke uitslag is juist?
  - Welke methode is juist bij verschillende tussen methodegroepen?
  - Maakt het uit als de laagste van de twee scores onvoldoende is? Wat zegt dat?

Terugkoppeling per groepje

Analieten:

1. Natrium
2. CK
3. Galzouten
4. CRP
5. Troponine

Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Sectie Algemene Chemie
Gebruikersdag 2025

AKSA Medical

Abbott

DaklaPack europe

BIO-RAD

HUSK MEDICAL

greiner BIO-ONE

Roche

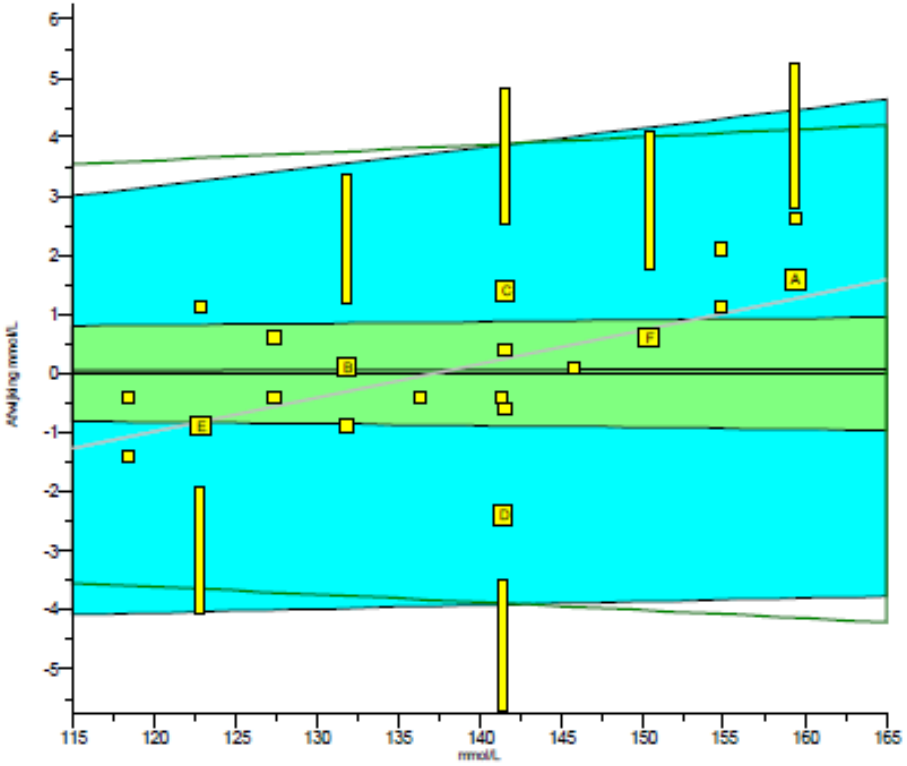
Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

Klinische Chemie, bloed 2025.2

Cobas C15

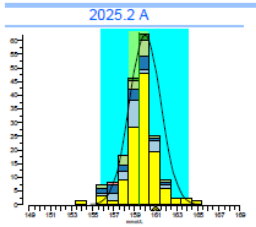
Natrium

eenheid : mmol/L



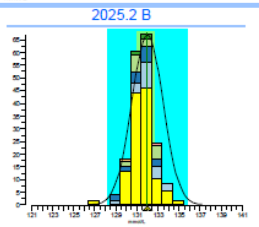
	2025.2	cumulatief
Juistheid	+0.01%	+0.10%
Precisie	0.87%	0.68%
Aantal	6	23
Uitbijters	0	0
Sigma-TE	0.5	0.8
Sigma-SA	3.8 1	4.1 1
Scorepictogram		
Regressielijn	0.0 + 1.000.x	-7.8 + 1.057.x
Consensusgroep	ISE	
Methode	Roche	
Analyser	Roche ISE cobas p	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	

Natrium



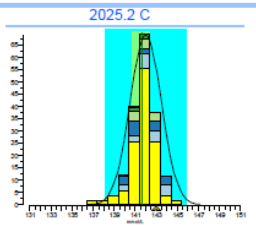
2025.2 A

	cons.	meth.	ref.	lab
gem.	160.0	160.0	159.4	161
SD	1.5	1.5		
n	181	120		
nu	2	2		
rec.	101%	101%	101%	



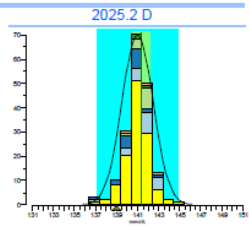
2025.2 B

	cons.	meth.	ref.	lab
gem.	132.0	132.0	131.9	132
SD	1.5	1.5		
n	183	120		
nu	1	1		
rec.	100%	100%	100%	



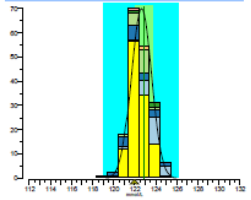
2025.2 C

	cons.	meth.	ref.	lab
gem.	142.0	142.0	141.6	143
SD	1.5	1.5		
n	175	119		
nu	1	1		
rec.	101%	101%	101%	



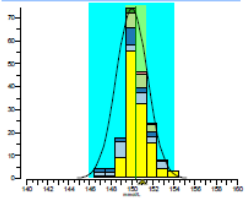
2025.2 D

	cons.	meth.	ref.	lab
gem.	141.0	141.0	141.4	139
SD	1.5	1.5		
n	181	120		
nu	0	0		
rec.	99%	99%	98%	



2025.2 E

	cons.	meth.	ref.	lab
gem.	122.6	122.0	122.9	122
SD	1.0	1.5		
n	182	119		
nu	1	0		
rec.	99%	100%	99%	



2025.2 F

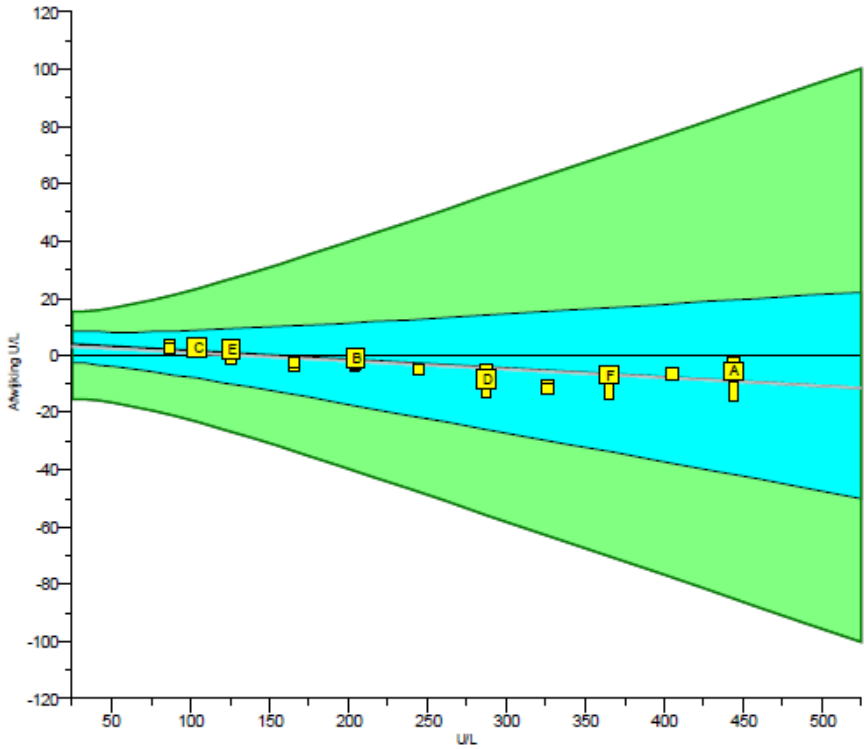
	cons.	meth.	ref.	lab
gem.	150.0	150.0	150.4	151
SD	1.5	1.5		
n	180	120		
nu	0	0		
rec.	101%	101%	100%	

Legenda

Roche | Siemens Atellica | Beckman Coulter AU | Abbott | Siemens Advia | Siemens Dimension | Beckman Coulter DxC

CK

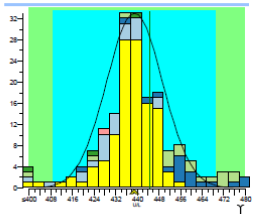
eenheid : U/L



	2025.2	cumulatief
Juistheid	-1.2%	-1.3%
Precisie	0.43%	0.66%
Aantal	6	23
Uitbijters	0	0
Sigma-TE	6.0 2	6.0 2
Sigma-SA	6.0	6.0
Scorepictogram		
Regressielijn	5 + 0.969.x	4 + 0.971.x

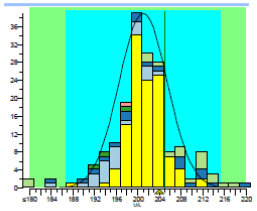
Consensusgroep	IFCC traceerbaar
Methode	Roche IFCC trace
Analyser	Roche cobas c503
Uw factor	0 + 1.000.x
Methodefactor	0 + 0.996.x

2025.2 A



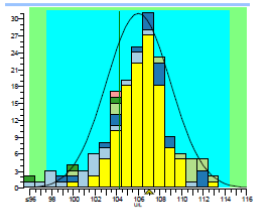
	cons.	meth.	ref.	lab
gem.	439	438	444.8	439
SD	10	6		
n	178	116		
nu	12	6		
rec.	100%	100%	99%	

2025.2 B



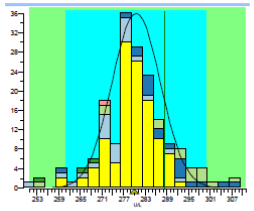
	cons.	meth.	ref.	lab
gem.	201	201	205.1	204
SD	4	3		
n	179	116		
nu	7	3		
rec.	101%	101%	99%	

2025.2 C



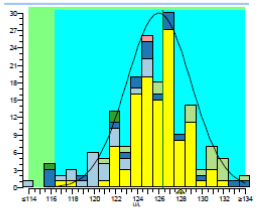
	cons.	meth.	ref.	lab
gem.	106.0	106.5	104.3	107
SD	3.0	2.2		
n	171	116		
nu	3	0		
rec.	101%	100%	103%	

2025.2 D



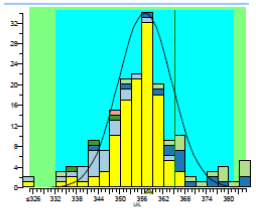
	cons.	meth.	ref.	lab
gem.	280	279	287.4	279
SD	7	4		
n	176	115		
nu	9	4		
rec.	100%	100%	97%	

2025.2 E



	cons.	meth.	ref.	lab
gem.	126.0	126.0	126.4	128
SD	3.0	1.5		
n	177	114		
nu	8	7		
rec.	102%	102%	101%	

2025.2 F



	cons.	meth.	ref.	lab
gem.	358	358	366.1	359
SD	7	5		
n	176	116		
nu	12	5		
rec.	100%	100%	98%	

Legenda

- Roche IFCC traceerbaar
- Siemens Atellica IFCC traceerbaar
- Beckman Coulter AU IFCC traceerbaar
- Abbott IFCC traceerbaar
- Siemens Advia IFCC traceerbaar
- Siemens Dimension IFCC traceerbaar

Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek

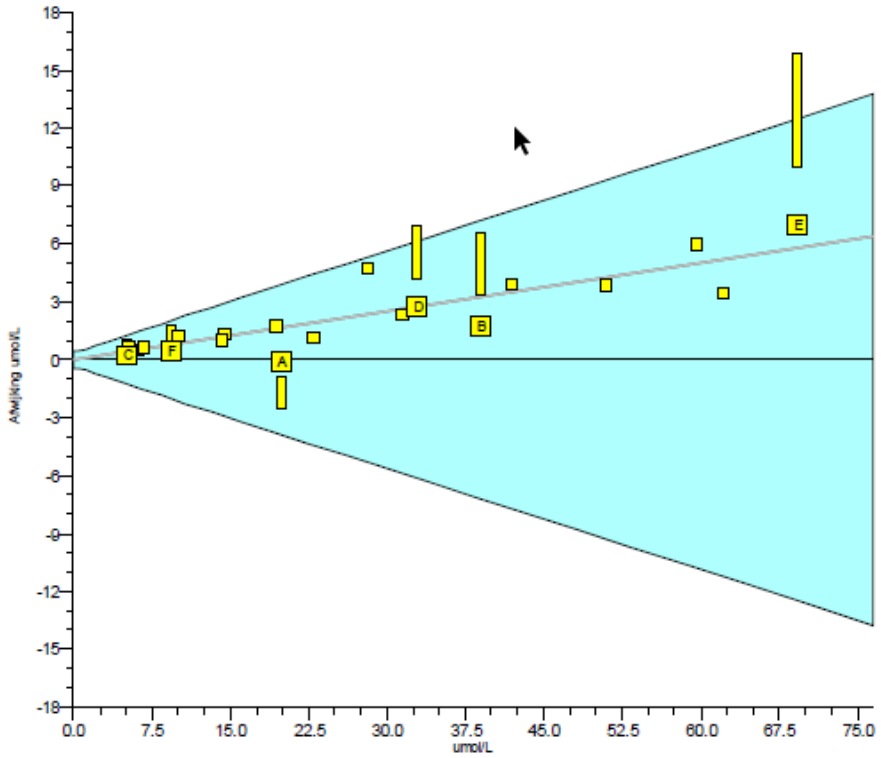
CK

Galzure zouten 2025.2

Galzouten

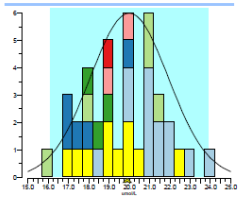
Totaal Galzure zouten

eenheid : umol/L



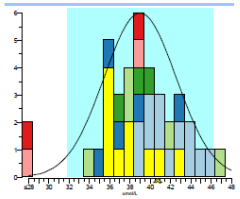
	2025.2	cumulatief
Juistheid	+7.0%	+7.7%
Precisie	3.9%	3.6%
Aantal	6	24
Uitbijters	0	0
Sigma-TE		
Sigma-SA	5.8 2	4.4 1
Scorepictogram		
Regressielijn	0.0 + 1.083.x	0.0 + 1.083.x
Consensusgroep	Overall	
Methode	Dialab	
Analyser	Roche cobas c503, (	
Uw factor	0.0 + 1.000.x	
Methodefactor	0.0 + 0.990.x	

2025.2 A



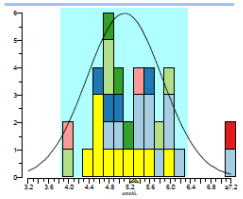
	cons.	meth.	ALTM	lab
gem.	20.0	19.2	20.0	19.9
SD	1.9	1.6	1.9	
n	39	10	39	
nu	0	0	0	
rec.	99%	104%	99%	

2025.2 B



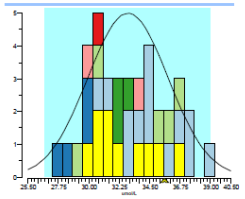
	cons.	meth.	ALTM	lab
gem.	39.0	37.4	39.0	40.7
SD	3.6	2.1	3.6	
n	39	10	39	
nu	2	0	2	
rec.	104%	109%	104%	

2025.2 C



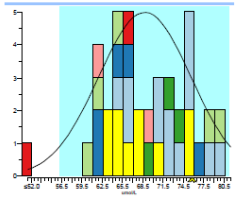
	cons.	meth.	ALTM	lab
gem.	5.10	4.85	5.10	5.3
SD	0.74	0.52	0.74	
n	36	10	36	
nu	1	0	1	
rec.	104%	109%	104%	

2025.2 D



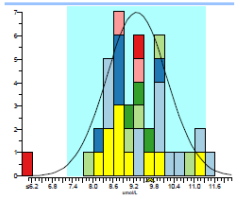
	cons.	meth.	ALTM	lab
gem.	32.9	31.6	32.9	35.6
SD	3.0	1.7	3.0	
n	38	10	38	
nu	0	0	0	
rec.	108%	112%	108%	

2025.2 E



	cons.	meth.	ALTM	lab
gem.	69.3	68.0	69.3	76.3
SD	6.8	4.8	6.8	
n	40	10	40	
nu	1	0	1	
rec.	110%	112%	110%	

2025.2 F



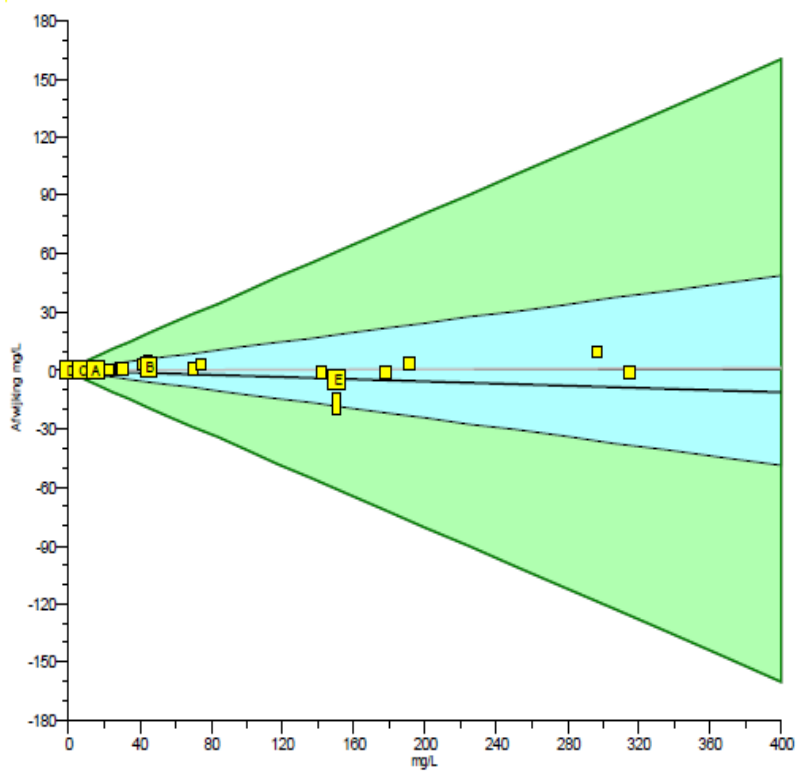
	cons.	meth.	ALTM	lab
gem.	9.4	9.0	9.4	9.8
SD	0.9	0.4	0.9	
n	39	10	39	
nu	1	1	1	
rec.	104%	109%	104%	

Legenda

Dialab	Diazyme	Abbott	Overigen	Sentinel
Beckman Coulter AU	Siemens			

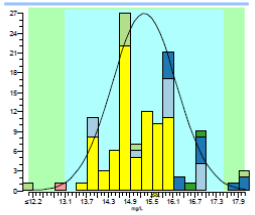
CRP

CRP — eenheid : mg/L



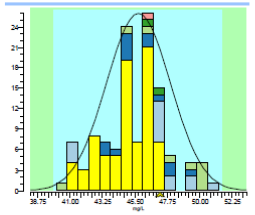
	2025.2	cumulatief
Juistheid	-1.7%	+0.47%
Precisie	3.4%	3.5%
Aantal	6	24
Uitbijters	0	0
Sigma-TE	6.0 2	6.0 2
Sigma-SA	3.7	3.9
Scorepictogram		
Regressielijn	0.0 + 0.972.x	0.0 +
Consensusgroep	Overall	
Methode	Roche	
Analyser	Roche cobas c501, c502	
Uw factor	0.0 + 1.000.x	
Methodefactor	0.0 + 1.000.x	

2025.2 A



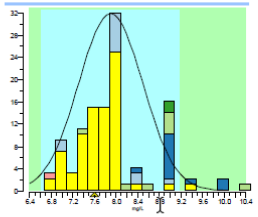
	cons.	meth.	ALTM	lab
gem.	15.4	15.0	15.4	15.7
SD	0.9	0.7	0.9	
n	116	78	116	
nu	4	0	4	
rec.	102%	105%	102%	

2025.2 B



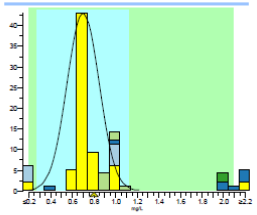
	cons.	meth.	ALTM	lab
gem.	45.5	45.0	45.5	47.0
SD	2.2	1.6	2.2	
n	118	79	118	
nu	0	0	0	
rec.	103%	104%	103%	

2025.2 C



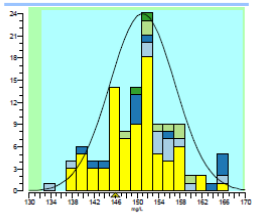
	cons.	meth.	ALTM	lab
gem.	7.90	7.70	7.90	7.6
SD	0.59	0.44	0.59	
n	115	80	115	
nu	3	1	3	
rec.	96%	99%	96%	

2025.2 D



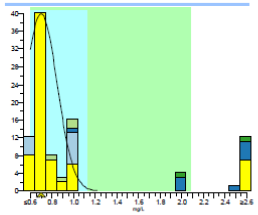
	cons.	meth.	ALTM	lab
gem.	0.70	0.70	0.70	0.8
SD	0.15	0.07	0.15	
n	93	67	93	
nu	16	10	16	
rec.	114%	114%	114%	

2025.2 E



	cons.	meth.	ALTM	lab
gem.	151	150	151	146
SD	6	6	6	
n	116	80	116	
nu	0	0	0	
rec.	97%	97%	97%	

2025.2 F



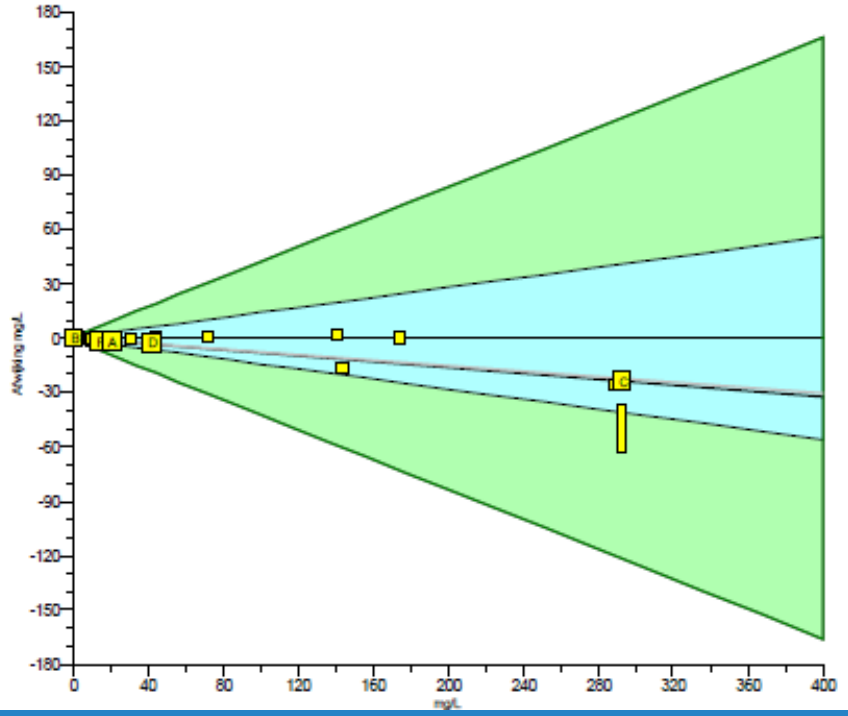
	cons.	meth.	ALTM	lab
gem.	0.70	0.70	0.70	0.7
SD	0.15	0.07	0.15	
n	96	70	96	
nu	21	14	21	
rec.	100%	100%	100%	

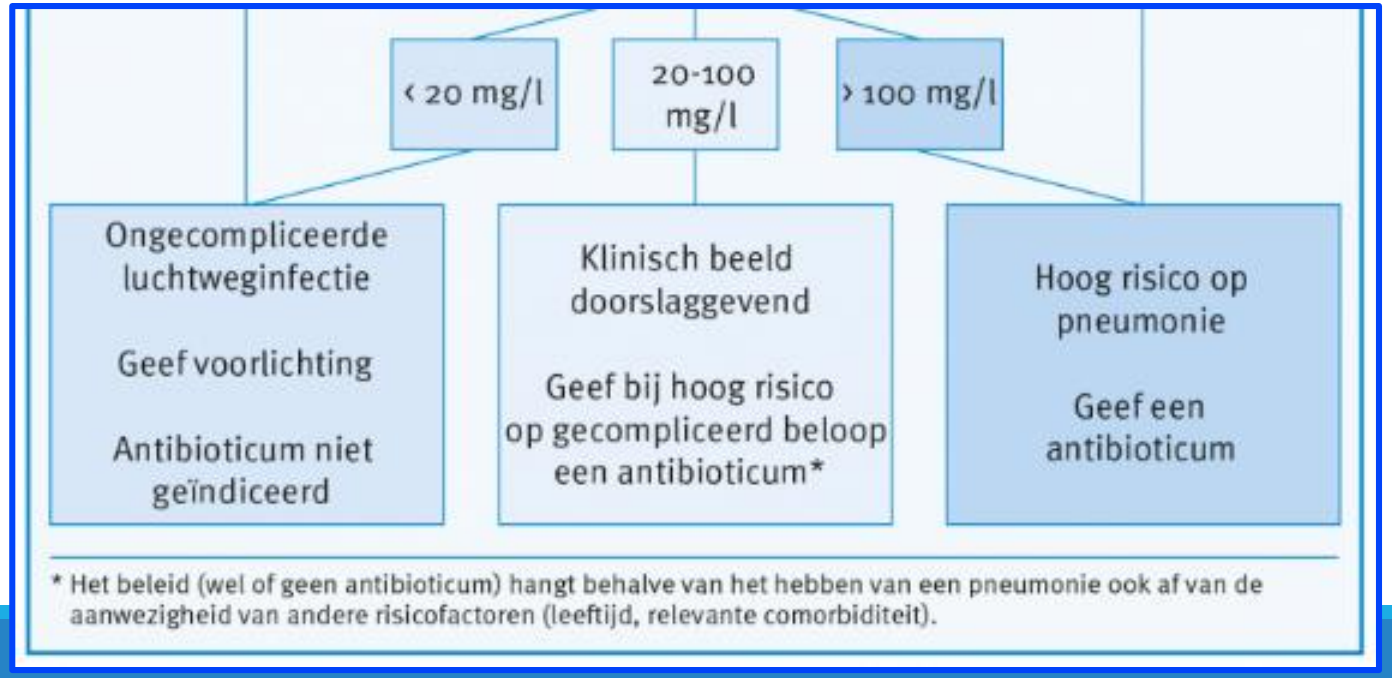
Legenda

Roche | Abbott | Siemens Atellica | Beckman Coulter AU | Siemens ADVIA | Overigen

NHG standaard Acuut Hoesten M78

‘Bepaal CRP (POCT) bij volwassenen zónder risicofactoren en twijfel over pneumonie op basis van klinisch beeld’

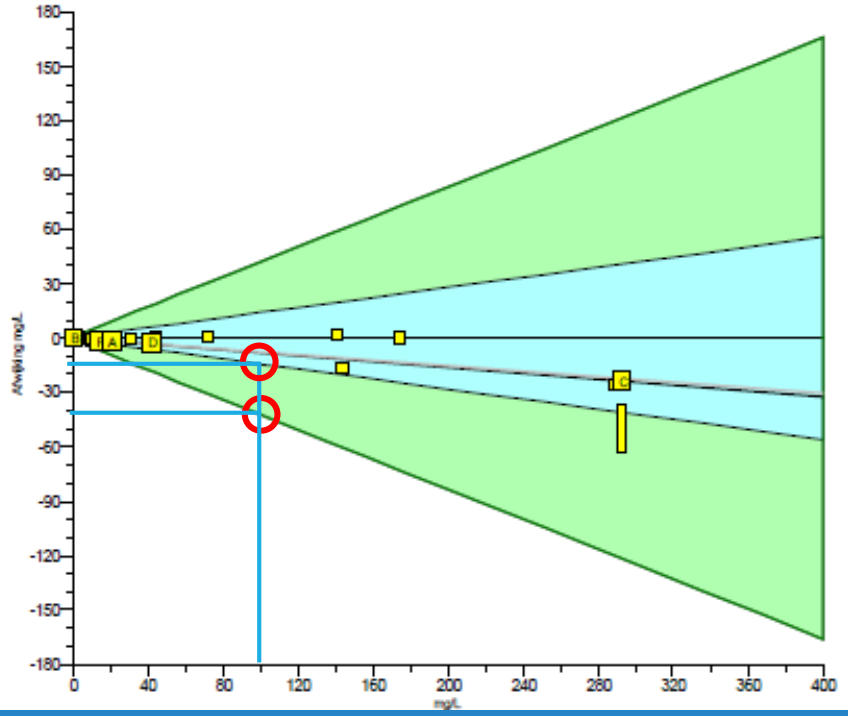


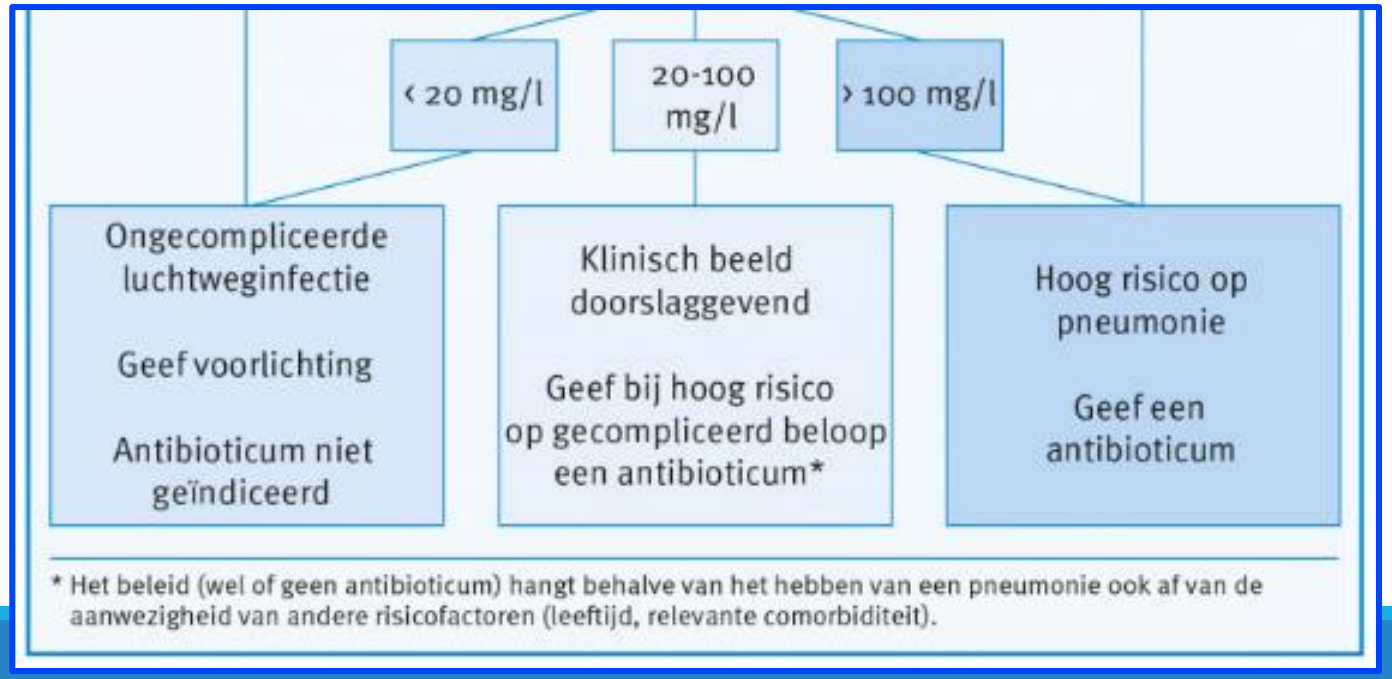


NHG standaard Acuut Hoesten M78

‘Bepaal CRP (POCT) bij volwassenen zónder risicofactoren en twijfel over pneumonie op basis van klinisch beeld’

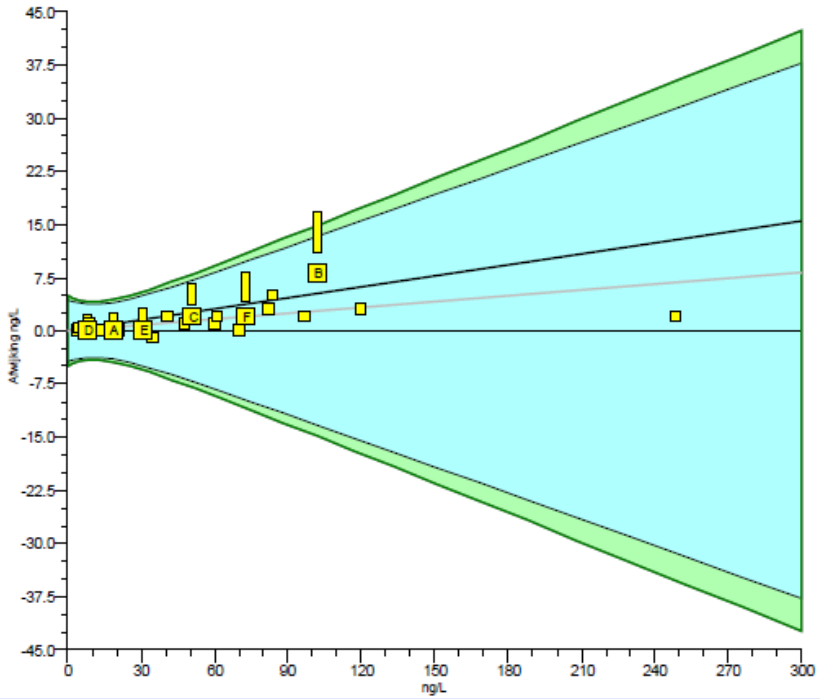
TEa-gebied CRP laat ruimte voor een bias tot 40 mg/L bij 100 mg/L





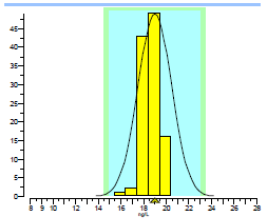
Troponine T : Analyser A van lab X

hs-Troponine T — eenheid : ng/L



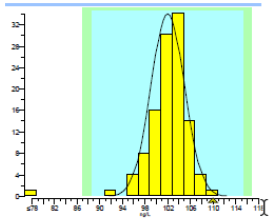
	2025.2	cumulatief
Juistheid	+4.1%	+3.0%
Precisie	3.6%	3.3%
Aantal	6	22
Uitbijters	0	0
Sigma-TE	6.0 2	6.0 2
Sigma-SA	5.7	5.8
Scorepictogram		
Regressielijn	0.0 + 1.052.x	0.0 + 1.027.x
Consensusgroep	Overall	
Methode	Roche	
Analyser	Roche cobas e801	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	

2025.2 A



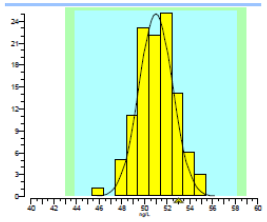
	cons.	meth.	ALTM	lab
gem.	19.0	19.0	19.0	19
SD	1.5	1.5	1.5	
n	111	111	111	
nu	0	0	0	
rec.	100%	100%	100%	

2025.2 B



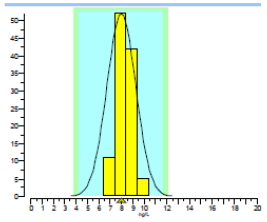
	cons.	meth.	ALTM	lab
gem.	102.0	102.0	102.0	110
SD	3.0	3.0	3.0	
n	113	113	113	
nu	2	2	2	
rec.	108%	108%	108%	

2025.2 C



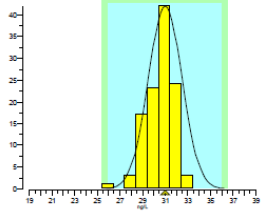
	cons.	meth.	ALTM	lab
gem.	51.0	51.0	51.0	53
SD	1.5	1.5	1.5	
n	110	110	110	
nu	1	1	1	
rec.	104%	104%	104%	

2025.2 D



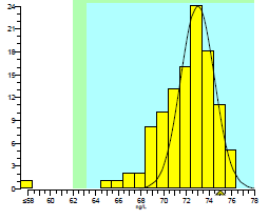
	cons.	meth.	ALTM	lab
gem.	8.0	8.0	8.0	8
SD	1.3	1.3	1.3	
n	110	110	110	
nu	0	0	0	
rec.	100%	100%	100%	

2025.2 E



	cons.	meth.	ALTM	lab
gem.	31.0	31.0	31.0	31
SD	1.5	1.5	1.5	
n	113	113	113	
nu	1	1	1	
rec.	100%	100%	100%	

2025.2 F



	cons.	meth.	ALTM	lab
gem.	73.0	73.0	73.0	75
SD	1.5	1.5	1.5	
n	112	112	112	
nu	7	7	7	
rec.	103%	103%	103%	

Legenda
Roche

Troponine
1-uurs protocol voor beoordeling ACS

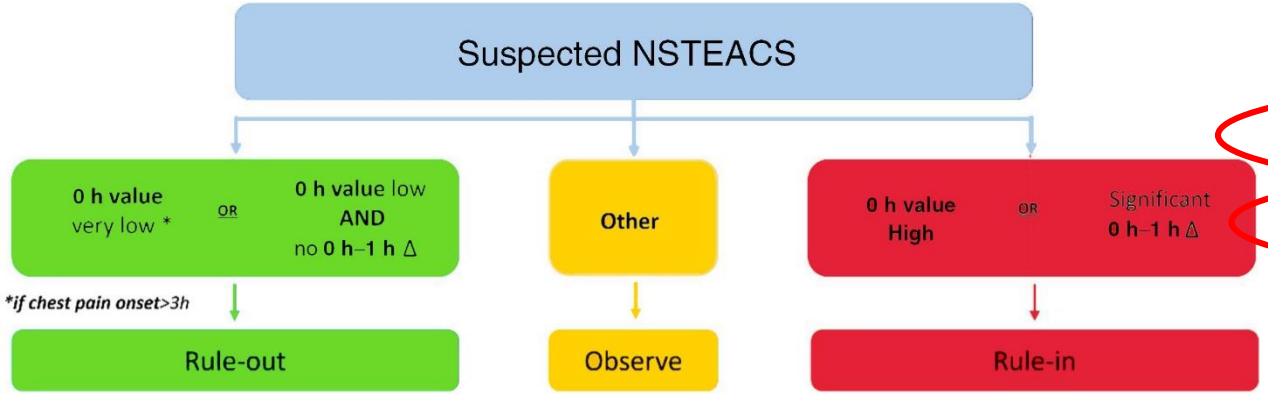


Table 1.
Assay-specific cutoff levels in ng/L within the 0h/1h and 0h/2h algorithm

0 h/1 h algorithm	Very low	Low	No 1 h Δ	High	Very high
hs-cTn T (Elecsys; Roche)[13]	<5	<12	<3	≥ 52	≥ 5
hs-cTn I (Architect; Abbott)[12]	<4	<5	<2	≥ 64	≥ 6
hs-cTn I (Centaur; Siemens)[18]	<3	<6	<3	≥ 120	≥ 12
hs-cTn I (Access; Beckman Coulter)[15]	<4	<5	<4	≥ 50	≥ 15
hs-cTn I (Clarity; Singulex)[19]	<1	<2	<1	≥ 30	≥ 6
hs-cTn I (Vitros; Clinical Diagnostic)[29]	<1	<2	<1	≥ 40	≥ 4
hs-cTn I (Pathfast; LSI Medicine)[34]	<3	<4	<3	≥ 90	≥ 20
hs-cTn I (Triage True; Quidel)[36]	<4	<5	<3	≥ 60	≥ 8
0 h/2 h algorithm	Very low	Low	No 2 h Δ	High	Very high
hs-cTn T (Elecsys; Roche)[35]	<5	<14	<4	≥ 52	≥ 10
hs-cTn I (Architect; Abbott)[17]	<4	<6	<2	≥ 64	≥ 15
hs-cTn I (Centaur; Siemens)[18]	<3	<8	<7	≥ 120	≥ 20
hs-cTn I (Access; Beckman Coulter)[30]	<4	<5	<5	≥ 50	≥ 20
hs-cTn I (Clarity; Sing ulex)[19]	<1	TBD	TBD	≥ 30	TBD
hs-cTn I (Vitros; Clinical Diagnostic)[29]	<1	TBD	TBD	≥ 40	TBD
hs-cTn I (Pathfast; LSI Medicine)[34]	<3	TBD	TBD	≥ 90	TBD
hs-cTn I (Triage True; Quidel)[36]	<4	TBD	TBD	≥ 60	TBD

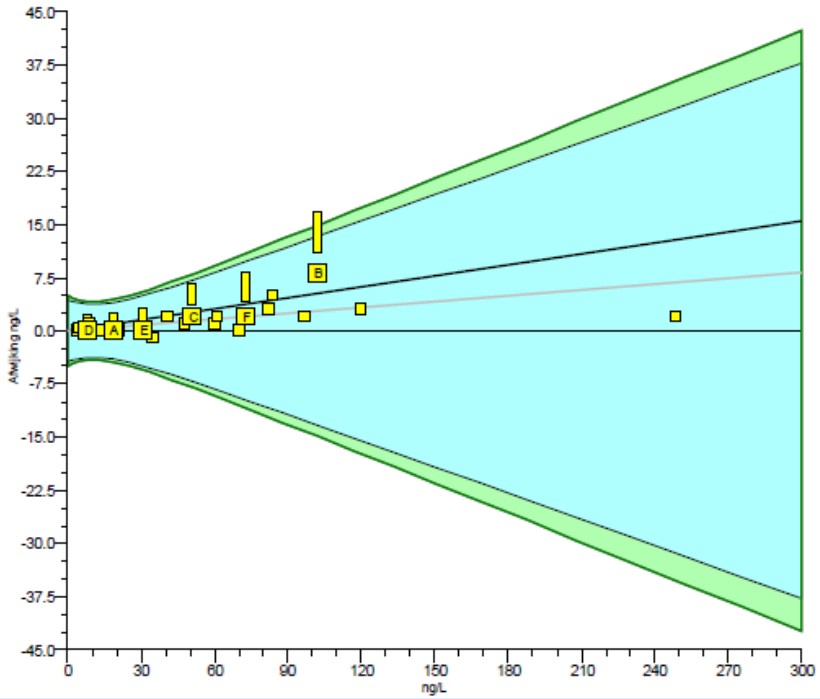
hs-cTn, high-sensitivity cardiac troponin; TBD, to be determined.

Beleid gebaseerd op assay karakteristieken en dus verwachte prestatie van assay.
Voorbeeld troponine T:

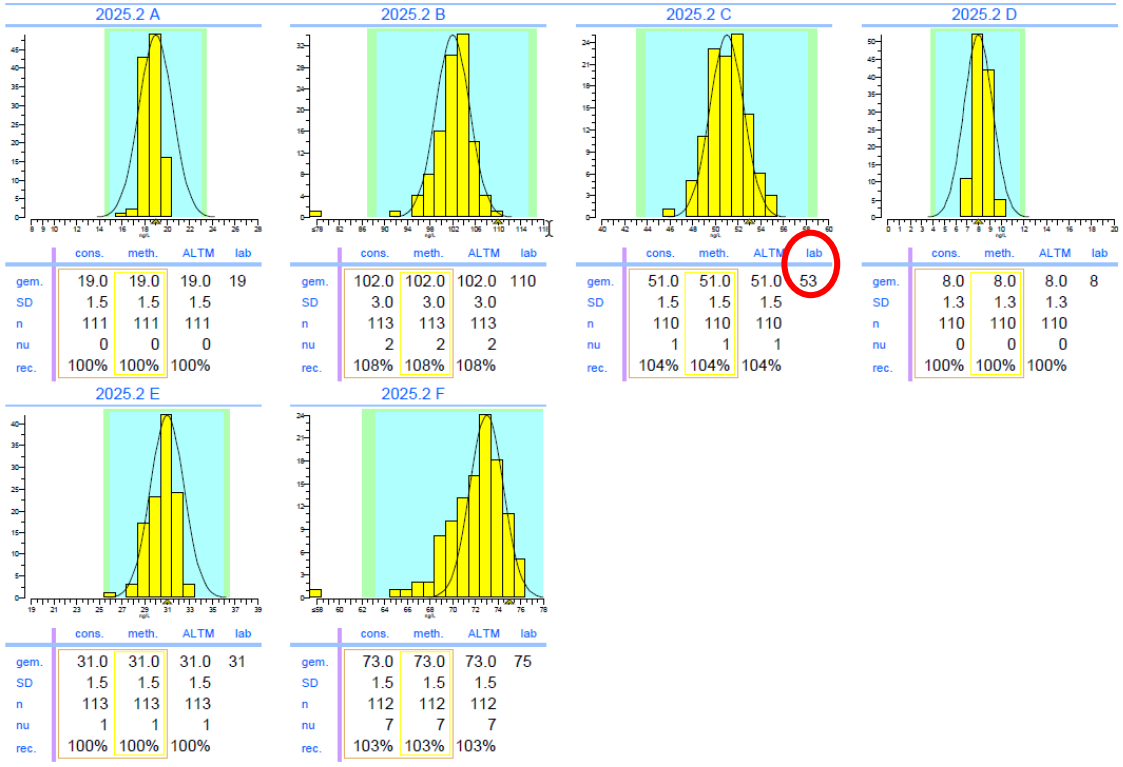
- Naar huis bij <low of <very low: <5 of <12 ng/L
- Δ = 3 ng/L
- ACS bij >high: > 52 ng/L
- Verschillen tussen of afwijkingen van analysers = verschillen in beleid!

Troponine T : Analyser A van lab X

hs-Troponine T — eenheid : ng/L



	2025.2	cumulatief
Juistheid	+4.1%	+3.0%
Precisie	3.6%	3.3%
Aantal	6	22
Uitbijters	0	0
Sigma-TE	6.0 2	6.0 2
Sigma-SA	5.7	5.8
Scorepictogram		
Regressielijn	0.0 + 1.052.x	0.0 + 1.027.x
Consensusgroep	Overall	
Methode	Roche	
Analyser	Roche cobas e801	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	

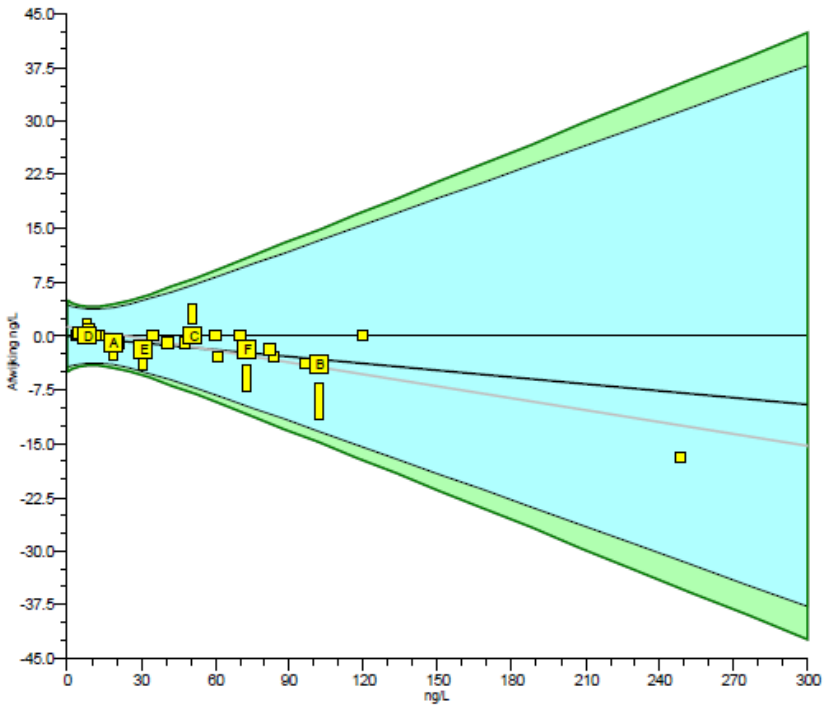


- Naar huis bij <low of <very low: <5 of <12 ng/L
- Δ = 3 ng/L
- ACS bij >high: > 52 ng/L
- Verschillen tussen of afwijkingen van analysers = verschillen in beleid!

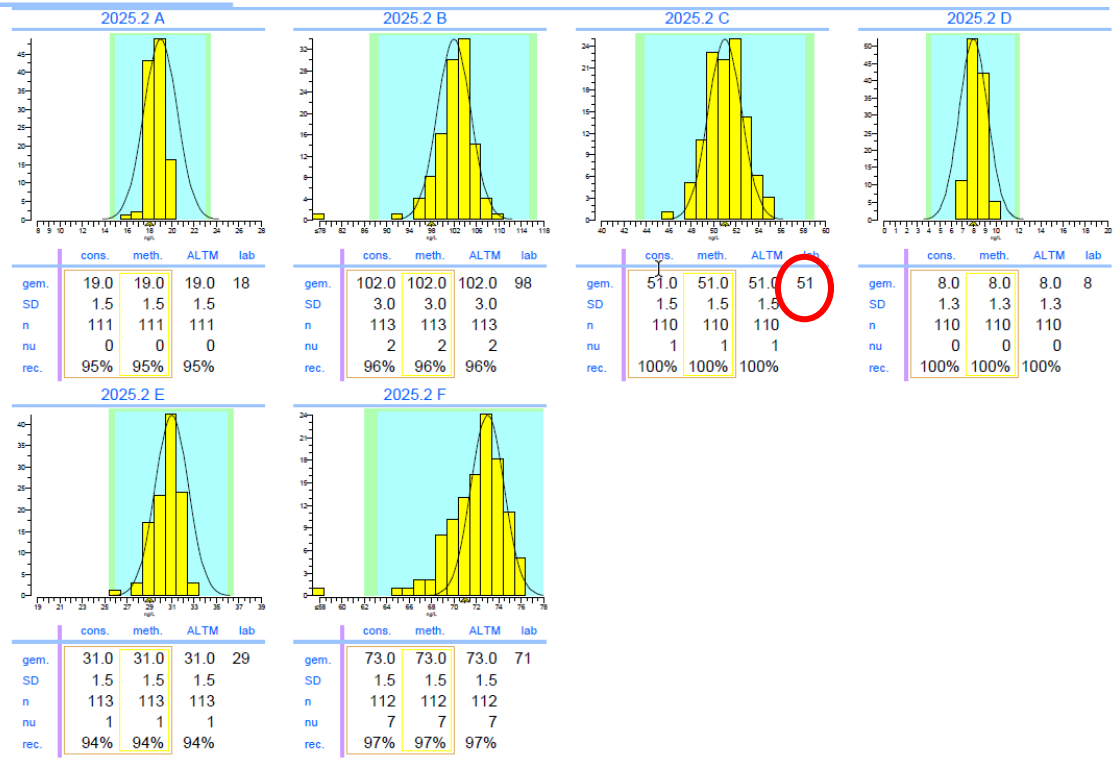
Niet logisch het TEa-gebied te hanteren voor goede prestatie

Troponine T : Analyser B van lab X

hs-Troponine T — eenheid : ng/L



	2025.2	cumulatief
Juistheid	-3.2%	-3.2%
Precisie	2.0%	3.0%
Aantal	6	23
Uitbijters	0	0
Sigma-TE	6.0 2	6.0 2
Sigma-SA	5.6	5.8
Scorepictogram		
Regressielijn	0.0 + 0.968.x	1.2 + 0.945.x
Consensusgroep	Overall	
Methode	Roche	
Analyser	Roche cobas e601, e6	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	



- Naar huis bij <low of <very low: <5 of <12 ng/L
- Δ = 3 ng/L
- ACS bij >high: > 52 ng/L
- Verschillen tussen of afwijkingen van analysers = verschillen in beleid!

Niet logisch het TEa-gebied te hanteren voor goede prestatie

Troponine T : Analyser A van lab Y

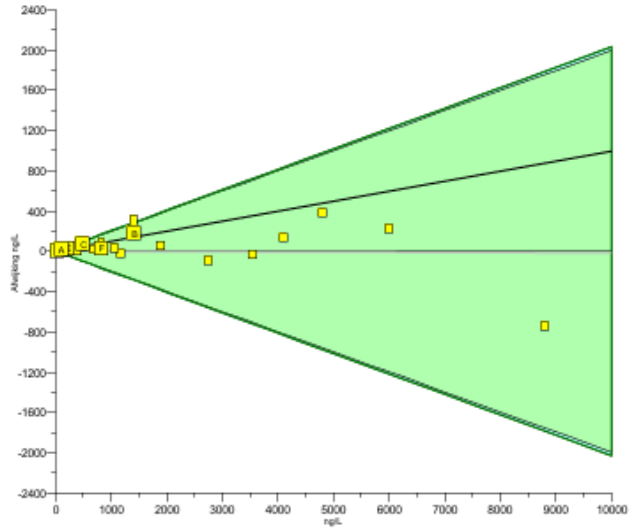
- pagina 4 van 5 -

15 juli 2025 11:14

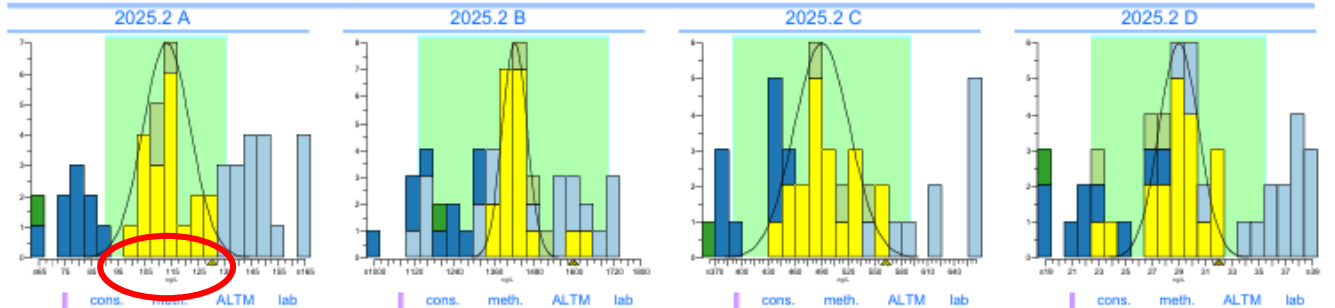
Hartmerkers 2025.2

Atellica-1

hs-Troponine I — eenheid : ng/L



	2025.2	cumulatief
Juistheid	+10%	+2.3%
Precisie	6.5%	12%
Aantal	6	22
Uitbijters	0	0
Sigma-TE	3.8	5.4
Sigma-SA	3.9	5.5
Scorepictogram		
Regressielijn	0 + 1.100.x	0 + 0.998.x
Consensusgroep	Siemens Atellica	
Methode	Siemens Atellica	
Analyser	Siemens Atellica IM	
Uw factor	0 + 1.000.x	
Methodefactor	0 + 1.000.x	



2025.2 A

	cons.	meth.	ALTM	lab
gem.	113	113	115	130
SD	9	9	36	
n	19	19	51	
nu	0	0	0	
rec.	115%	115%	113%	

2025.2 B

	cons.	meth.	ALTM	lab
gem.	1421	1421	1408	1598
SD	37	37	156	
n	19	19	52	
nu	2	2	1	
rec.	112%	112%	114%	

2025.2 C

	cons.	meth.	ALTM	lab
gem.	496	496	498	568
SD	31	31	72	
n	19	19	42	
nu	0	0	1	
rec.	115%	115%	114%	

2025.2 D

	cons.	meth.	ALTM	lab
gem.	29.0	29.0	29.0	32
SD	1.5	1.5	4.4	
n	19	19	49	
nu	2	2	0	
rec.	110%	110%	110%	

2025.2 E

	cons.	meth.	ALTM	lab
gem.	227	227	240	249
SD	21	21	71	
n	19	19	51	
nu	0	0	0	
rec.	110%	110%	104%	

2025.2 F

	cons.	meth.	ALTM	lab
gem.	834	834	842	857
SD	37	37	125	
n	18	18	49	
nu	0	0	0	
rec.	103%	103%	102%	

Legenda: Siemens Atellica, Abbott, Beckman Coulter, Siemens Advia, Biomerieux

Voorbeeld troponine I:

- Naar huis bij <low of <very low: <3 of <6 ng/L
- Δ = 3 ng/L
- ACS bij >high: > 120 ng/L
- Verschillen tussen of afwijkingen van analysers = verschillen in beleid!

Niet logisch het TEa-gebied te hanteren voor goede prestatie

Stichting Kwaliteitsbewaking
Medische Laboratoriumdiagnostiek

Sectie Algemene Chemie
Gebruikersdag 2025

AKSA Medical

Abbott

DaklaPack europe

BIO-RAD

HUSK MEDICAL

greiner BIO-ONE

Roche