

Patient Percentile Monitoring Clinical Laboratory AZ Sint-Lucas

10/12/2014
Timothy Ghys
Klinisch Bioloog
AZ Sint-Lucas Gent



Betrouwbare zorg



Overview

1. Introduction

Hospital AZ Sint-Lucas

Clinical Laboratory AZ Sint-Lucas

(I/E)QC Clinical Laboratory

2. Patient Percentile Monitoring data

(ALT; TP; ALP; Ca; LDH; CHOL; CRP; Na, Uric Acid)

3. Conclusions/Remarks



Betrouwbare zorg

Overview

1. Introduction

Hospital AZ Sint-Lucas

Clinical Laboratory AZ Sint-Lucas

(I/E)QC Clinical Laboratory

2. Patient Percentile Monitoring data

(ALT; TP; ALP; Ca; LDH; CHOL; CRP; Na, Uric Acid)

3. Conclusions/Remarks



Betrouwbare zorg

1. AZ Sint-Lucas

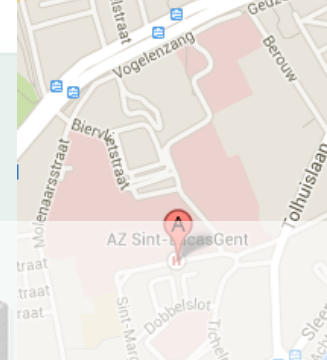
- **General Hospital**

- Campus Sint-Lucas & Campus Volkskliniek (till 2018)

- **Medical activity (2012)**

- 805 beds hospitalisation + 103 daycare hospital
 - +/- 70.000 admissions (40.303 daycare hospital)

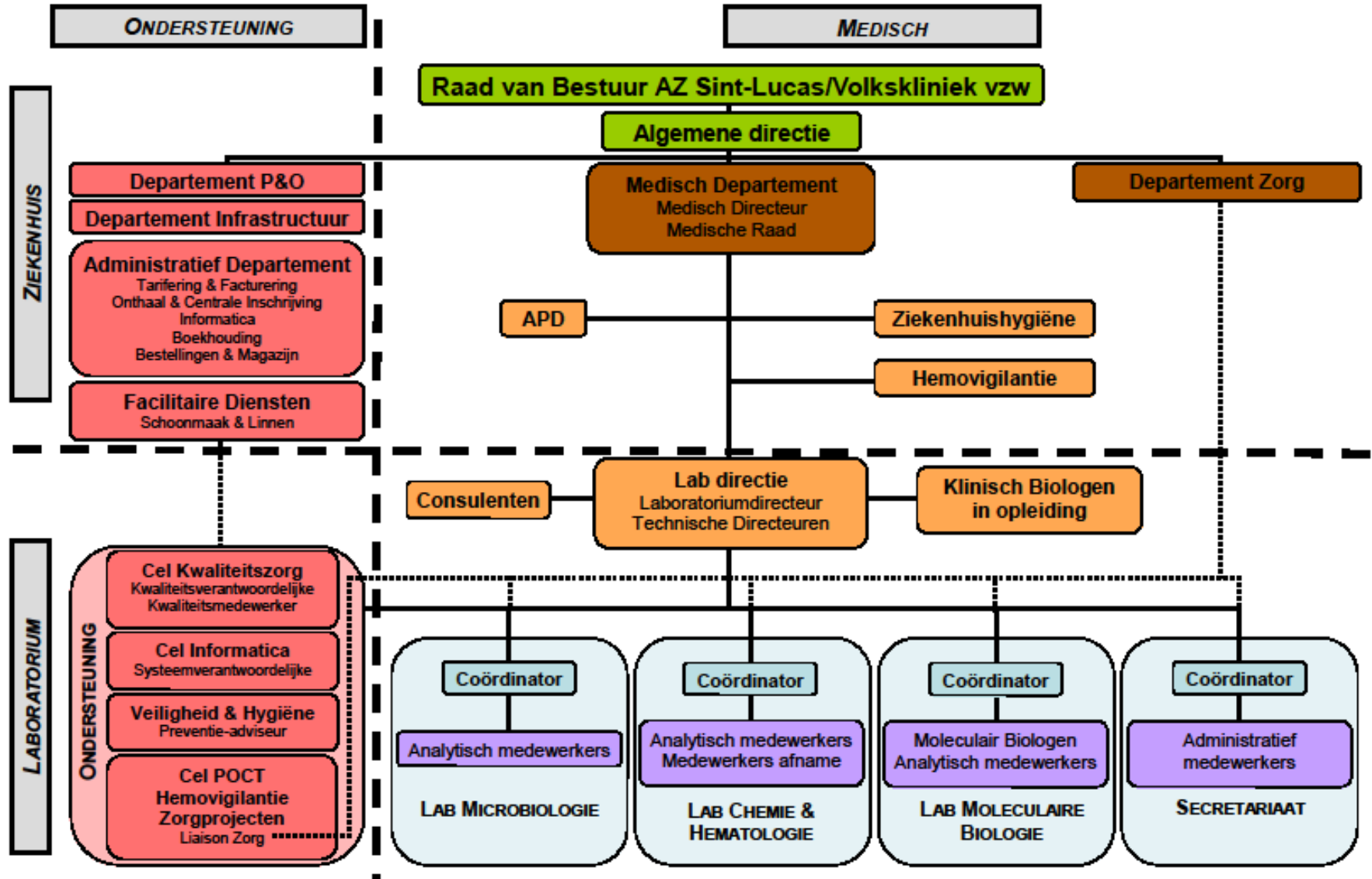
- Largest Emergency Department in East-Flanders
 - Large maternity department (>2500 deliveries/jr)
 - Oncology
 - Neurosurgery



Betrouwbare zorg



1. Clinical Laboratory AZ Sint-Lucas



1. Clinical Laboratory AZ Sint-Lucas

- **Clinical laboratory**

- 68 people (53.7 FTE)
 - Chemistry & Hematology (32.1 fte)
 - Microbiology (9.5 fte)
 - Administration (9.1 fte)
 - Molecular biology (3 fte)

- **Medical activity**

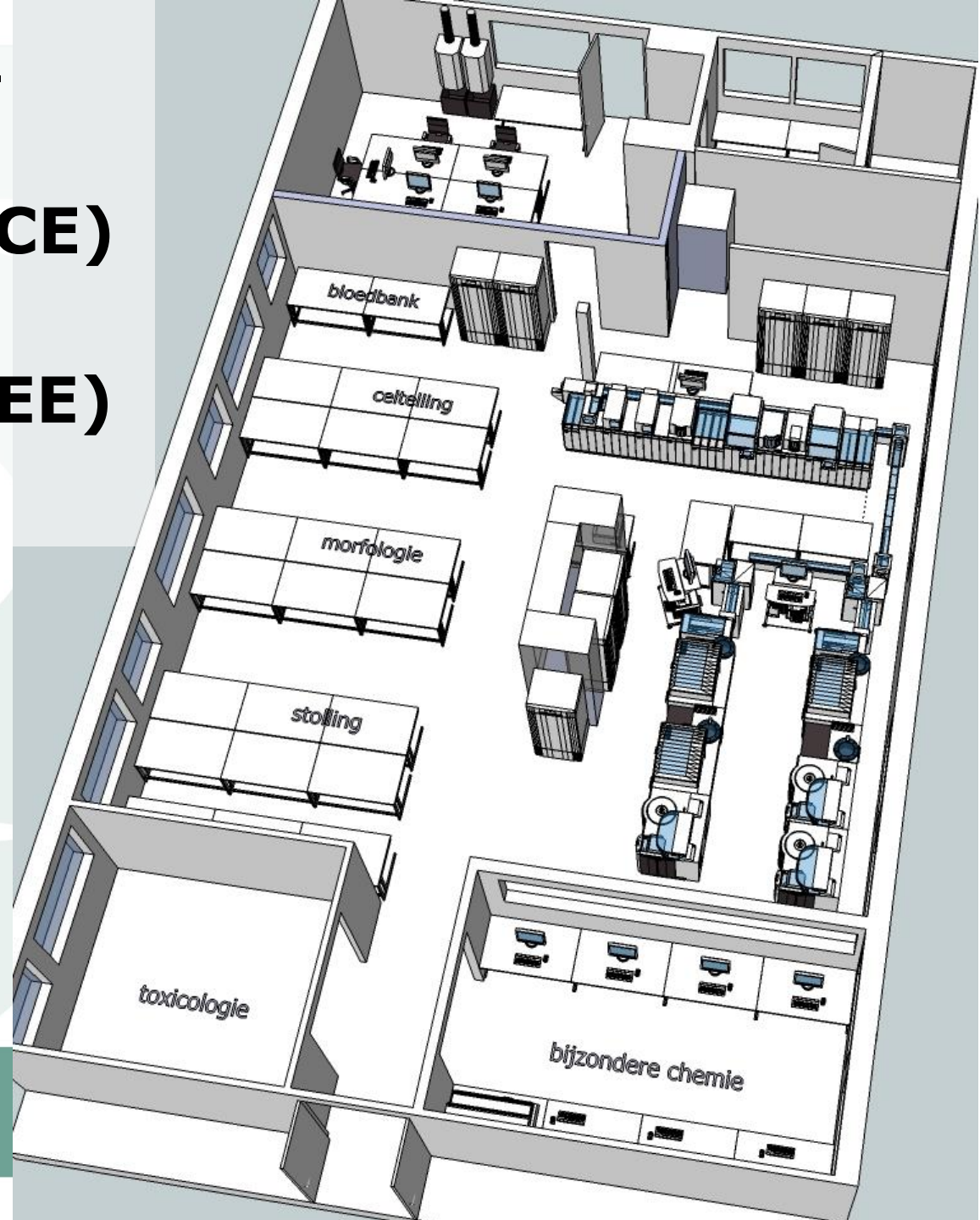
- +/- 22.000 lab requests/month
- +/- 142.000 blood withdrawels (>60% lab; >16000 outpatients)
- 6 clinical biologists (3micro/3chem)
 - 2 specialists in training



Betrouwbare zorg

Clinical chemistry

- MPA
- Cobas6000-1 (CCE)
C501₁ C501₂ E601₁
- Cobas6000-2 (CEE)
C501₃ E601₂ E601₃



1. IQC LAB AZ Sint-Lucas

- **Clinical chemistry**

- **IQC Precision**

- 10 values → mean (target) and SD

MEAN ± xSD (x 2 or 3)



Betrouwbare zorg

1. IQC LAB AZ Sint-Lucas

- **Clinical chemistry**
 - **IQC BIAS**

- **PEER** = Cumulative mean peer group (large # labs)
(>cumulative mean methodgroup > target package insert, assayed qc > own mean)
- **TEA** = Total Error Allowable = bias + 1.65 CV ($BV_{\text{desirable}}$)
(TEA BV_{minimal} > d-value WIV-ISP (NHI) > CLIA > 3xpeerSD > package insert)

PEER \pm TEA



Betrouwbare zorg

1. IQC LAB AZ Sint-Lucas

- **Statistical quality control**

- **IQC FU DAILY**

- **Technicians** 2SD; 3SD; TEA; trendspotting (glims)
- **QC-cel:** 2SD; 3SD; TEA; trendspotting (e-mail)
- **Clinical biologist:** TEA (e-mail)

- **IQC FU WEEKLY**

- **QC-cel and Instrument specialists:**
2SD; 3SD; TEA (e-mail)



Betrouwbare zorg

1. IQC LAB AZ Sint-Lucas

- **Statistical quality control**

- **IQC FU MONTHLY**

- **QC-cel: interinstrument data grid analysis (URT Bio-Rad)**

Lab : 829884, Lot : 16730

Data reference set: Data Set A

Data Set A: Your laboratory, Cumulative

Data Set B1: Your laboratory, Cumulative

Data Set B2: Your laboratory, Cumulative

Data Set B3: Your laboratory, Another Instrument Roche cobas 6000/Routine laboratorium 3[555099], Date range: From: 18/10/2014 To: 18/11/2014

Data Set B4: Consensus group: Peer, Cumulative

Data Set B5: Consensus group: Method, Cumulative

Alert thresholds: SDI: ± 1.00 , CVR: 1.40,

*** QC-cel: Patient Percentile Monitoring??**

Data Set	Analyte	Instrument	Reagent	Level	Mean	SD	CV	Pts	# Labs	SDI	CVR	Bias%	TE p<0.05	TEB%	Sigma	TEa	TEa Selection
A	Albumin	Roche cobas 6000 [829884]	Dedicated Reagent	1	29,10	0,80	2,75									10,00	CLIA
B1				1													
B2		Roche cobas 6000 [831729]		1	29,16	0,58	1,99	60	1		0,73						
B3		Roche cobas 6000 [555099]		1	29,65	0,50	1,70	57	1		0,62						
B4				1	28,71	0,95	3,30	55463	237		1,20						
B5				1	28,26	1,06	3,74	130026	558		1,36						
A	Albumin	Roche cobas 6000 [829884]	Dedicated Reagent	2	44,00	1,01	2,30									10,00	CLIA
B1				2													
B2		Roche cobas 6000 [831729]		2	45,07	0,56	1,24	61	1		0,54						
B3		Roche cobas 6000 [555099]		2	44,88	0,51	1,13	57	1		0,49						
B4				2	44,10	1,07	2,43	51192	236		1,06						
B5				2	43,21	1,40	3,24	125401	554		1,41						
A	Alkaline Phosphatase	Roche cobas 6000 [829884]	Dedicated Reagent	1	87,50	2,50	2,86	252	1							12,00	BV Des bias/ Des imprecision
B1				1	86,53	1,11	1,29	58	1	-0,39	0,45	-1,11	3,23	26,96	8,46		
B2		Roche cobas 6000		1													
B3		Roche cobas 6000 [555099]		1	86,80	1,56	1,79	57	1	-0,28	0,63	-0,80	3,76	31,30	6,25		
B4				1	87,69	3,80	4,34	38469	229	0,08	1,52	0,22	7,37	61,44	2,72		
B5				1	94,14	9,65	10,25	222302	1094	2,66	3,59	7,59	24,49	204,10	0,43		

1. EQC LAB AZ Sint-Lucas

- **Clinical laboratory**
 - 78 EQC schedules

UK NEQAS - Urinary Antigens: Legionella

UK NEQAS - Viruses in CSF (molecular)

WIV - Alcohol

WIV - Allergie

WIV - Beenmergonderzoek

WIV - Cardiale Merkers

WIV - CD34 + stem cell enumeration

WIV - Chemie/Immunoassays/TDM

WIV - Flowcytometrie

WIV - HbA1c

WIV - HbA1c volbloed

WIV - Hemato

WIV - Hemoglobinopathieën

WIV - Immuno/coagulation/D-dimeren/AT

WIV - Microbiologie/serologie/parasitologie

WIV - Niet-infectieuze serologie

WIV - POCT glucose

WIV - Sperma

QCMD - MRSA

QCMD - MTB

QCMD - NG

QCMD - Parasitic gastroenteritis

QCMD - VZV

Ringtest Beenmerg

Ringtest BILULU

Ringtest BILULU Molecular

Ringtest Helicobacter pylori

Ringtest Master Comparisons

SKML - Antifungal drugs

SKML - PNH

UK NEQAS - Anaerobe survey

UK NEQAS - Antimicrobial susceptibility

UK NEQAS - BCR-ABL

UK NEQAS - Blood parasitology

UK NEQAS - C. trachomatis & N. gonorrhoeae

UK NEQAS - Clostridium difficile

UK NEQAS - Faecal parasitology

UK NEQAS - General bacteriology

UK NEQAS - JAK2

UK NEQAS - Malaria rapid

UK NEQAS - Molecular detection of HPV

UK NEQAS - Molecular Pathology

UK NEQAS - Monoclonal Protein Identification

UK NEQAS - MRSA screening

UK NEQAS - MSS First Trimester

UK NEQAS - MSS Second Trimester

UK NEQAS - Mycobacterium culture

UK NEQAS - Mycology

CAP - ISH

CAP - KRAS

ECAT - D-Dimer

ECAT - FII/FV Leiden/MTHFR

ECAT - HIT

ECAT - HLA B27

ECAT - Thrombophilia

EliA Autoimmunity

ESP Colon EQA

EUROIMMUN - ANA

EUROIMMUN - ANCA

EUROIMMUN - CCP

EUROIMMUN - Coeliac disease

EUROIMMUN - Liver

EUROIMMUN - Phospholipids

EUROIMMUN - Thyroid gland

INSTAND - Bordetella pertussis

INSTAND - Chlamydia pneumoniae

INSTAND - Legionella pneumophila

INSTAND - MRSA

INSTAND - Norovirus

NordiQC HER-2 ISH

QCMD - Coronavirus RNA

QCMD - CT

QCMD - EV

QCMD - HBV

QCMD - HCV

QCMD - HCV gt

QCMD - HPV

QCMD - HSV



Betrouwbare zorg

Overview

1. Introduction

Hospital AZ Sint-Lucas

Clinical Laboratory AZ Sint-Lucas

(I/E)QC Clinical Laboratory

2. Patient Percentile Monitoring data

(ALT; TP; ALP; Ca; LDH; CHOL; CRP; Na, Uric Acid)

3. Conclusions/Remarks



Betrouwbare zorg

2. Patient Percentile Monitoring

The Percentiler

Quality

Samples

• ALT

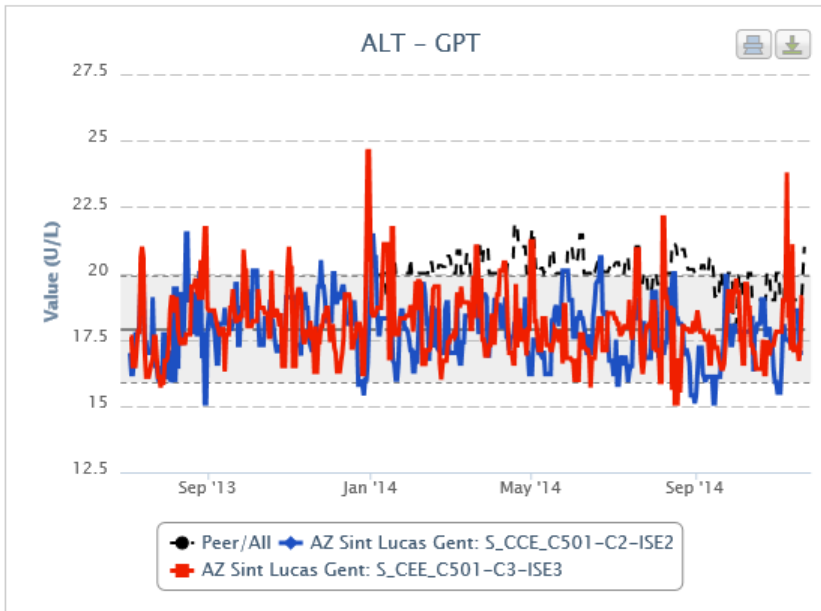
ALT
regulated **good**
over different
systems

Lab: Device model: Device:

Start date: Stop date: Include weekend data:

Range: 3M 6M 1Y All Moving median: 5 8 16

-
-
-
-
-
-
-
-
-
-



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	17.90	-5.8	11.6
Peer/All	19.00	-9.5	7.8
Target	21.00	9.5	NA
Range: period			
Your	17.90	-5.8	11.6
Peer/All	19.00	-9.5	7.8
Target	21.00	9.5	NA



Betrouwbare zorg



2. Patient Percentile Monitoring

The Percentiler

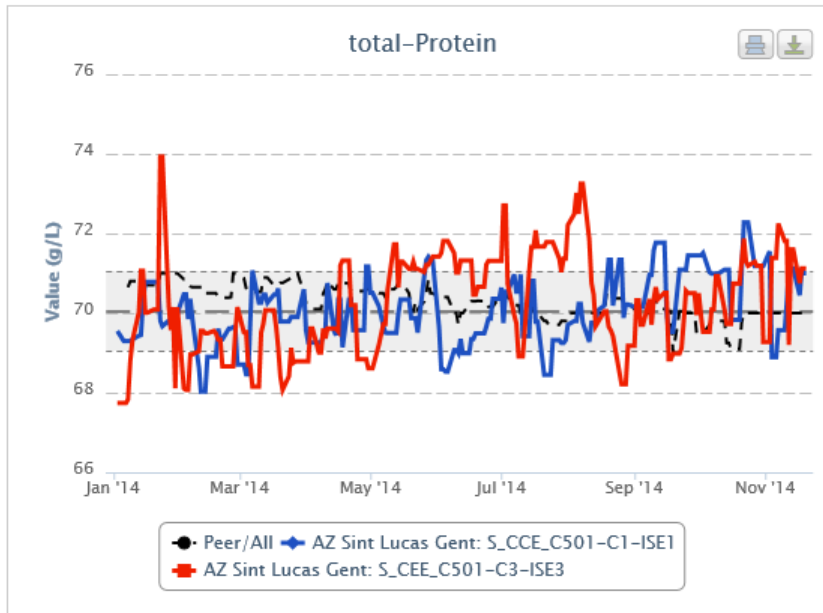
• TP

Lab:
 Device model:
 Device:

Start date:
 Stop date:
 Include weekend data:

Range:
 Moving median:

- ALT
- AST
- ALB
- ALP
- CRP
- Ca
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH
- Mg
- K
- Na
- UREA
- UAC
- BIL
- CHOL
- PROT**



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	70.04	0.6	2.4
Peer/All	69.65	-3.3	2.0
Target	72.00	1.4	NA
Range: period			
Your	70.07	0.6	2.3
Peer/All	69.65	-3.3	2.0
Target	72.00	1.4	NA

TP
regulated **good**

!be ware for
patient mix!



Betrouwbare zorg



2. Patient Percentile Monitoring

ALP Targets



Can any method hit the Alkaline Phosphatase (ALP) target?

ALP
Hard to handle

!be ware for
patient mix
&
number of results!

!Systematically
Under the PEER!
Bio-Rad PEER±TEA
65 – 83 U/L

The Percentiler

Quality
Samples

- **ALP**

Lab:

Start date: 17

Range: 3M 6M 1Y All

Device model:

Stop date: 17

Moving median: 5 8 16

Device:

Include weekend data:

ALT

AST

ALB

ALP

CRP

Ca

CI

CRE

GGT

GLU

PHOS

LDH

Mg

K

Na

UREA

UAC

BIL

CHOL

PROT

Alkaline Phosphatase

	Value	Bias (%)	Robust CV(%)
Range: all			
Your	73.60	-0.5	8.3
Peer/All	74.00	1.4	4.0
Target	73.00	6.8	NA
Range: period			
Your	72.35	-3.5	7.1
Peer/All	75.00	2.7	5.9
Target	73.00	6.8	NA



Betrouwbare zorg



2. Patient Percentile Monitoring

• ALP (criteria?)

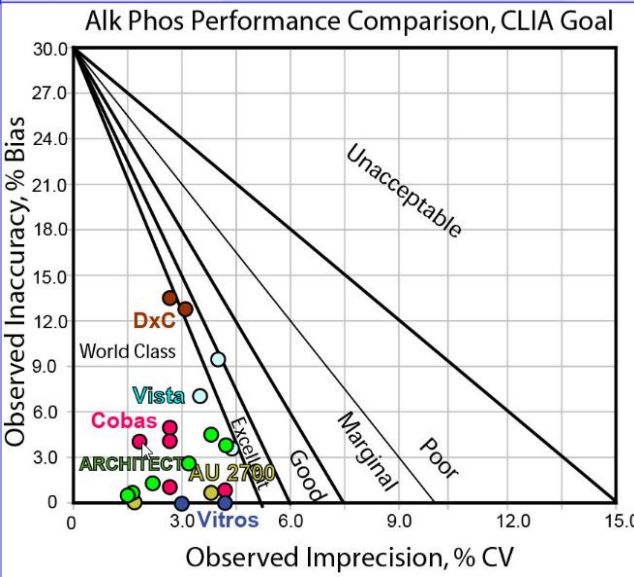
ALP Targets



Can any method hit the Alkaline Phosphatase (ALP) target?

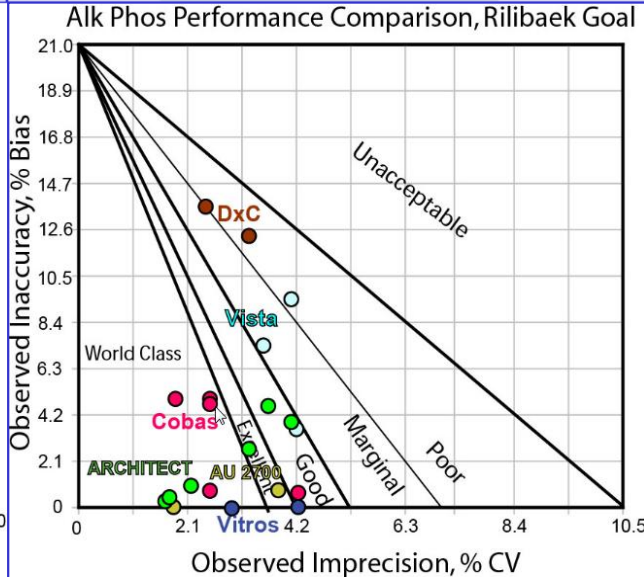
CLIA & Spanish minimum consensus

$\pm 30\%$



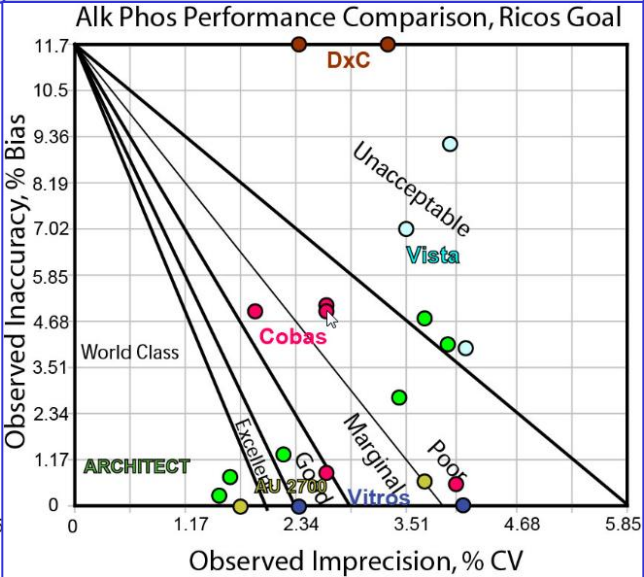
Rilibäk

$\pm 21\%$



Desirable BV RCPA

$\pm 12\%$



Betrouwbare zorg



azsint-lucas

<http://www.westgard.com/alp-goalshtm.htm>

2. Patient Percentile Monitoring

The Percentiler

Quality

Samples

• Ca

Lab: All labs

Device model: All device models

Device: All devices

Start date: 2014/03/01

Stop date: 2014/12/31

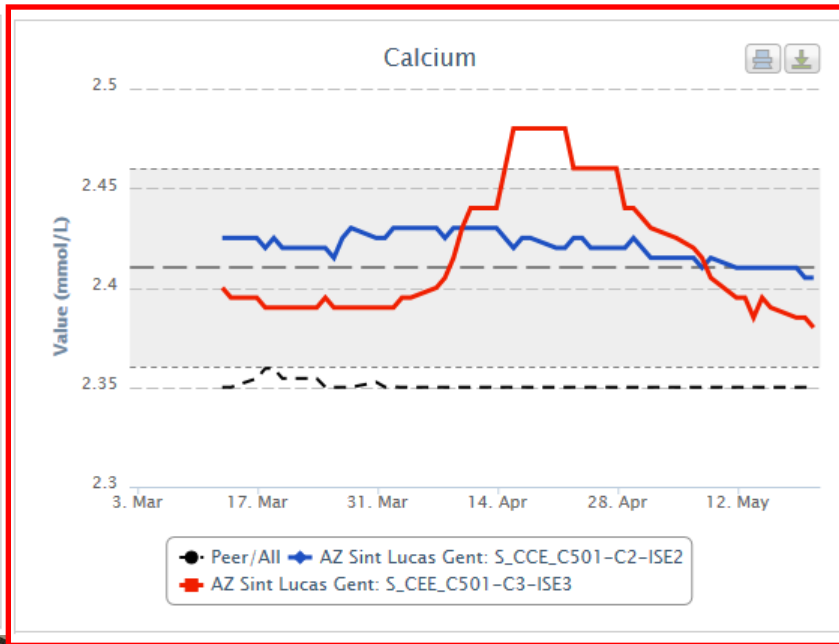
Include weekend data: No

Range: 3M 6M 1Y All

Moving median: 5 8 16

Filter

- ALT
- AST
- ALB
- ALP
- CRP
- Ca**
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH
- Mg
- K
- Na
- UREA
- UAC
- BIL
- CHOL
- PROT



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	2.41	2.1	1.8
Peer/All	2.36	0.4	0.6
Target	2.35	2.1	NA
Range: period			
Your	2.41	2.1	1.2
Peer/All	2.36	0.4	0.6
Target	2.35	2.1	NA

Ca
regulated **good**
over different
systems

April 2014
Contamination
water tank C3

PEER?



Betrouwbare zorg

2. Patient Percentile Monitoring

The Percentiler

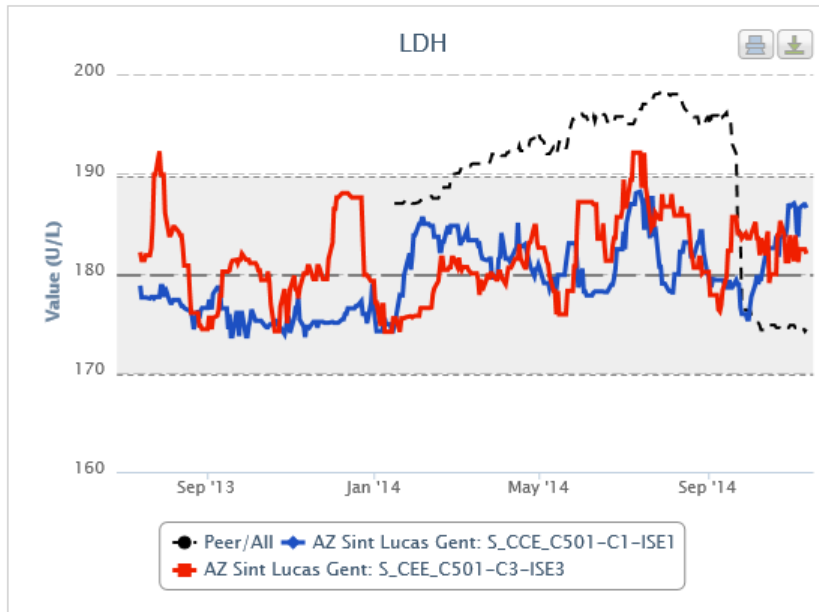
Quality

Samples

• LDH

Lab: All labs
Device model: All device models
Device: All devices
Start date:
Stop date:
Include weekend data: No
Range: 3M 6M 1Y **All**
Moving median: 5 8 **16**

- ALT
- AST
- ALB
- ALP
- CRP
- Ca
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH**
- Mg
- K
- Na
- UREA
- UAC
- BIL
- CHOL
- PROT



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	179.80	2.7	5.7
Peer/All	175.00	0.0	5.9
Target	175.00	5.7	NA
Range: period			
Your	179.80	2.7	5.7
Peer/All	175.00	0.0	5.9
Target	175.00	5.7	NA

LDH regulated good over different systems

PEER? pre-analytics? drop?



Betrouwbare zorg



2. Patient Percentile Monitoring

The Percentiler

• CHOL

Quality

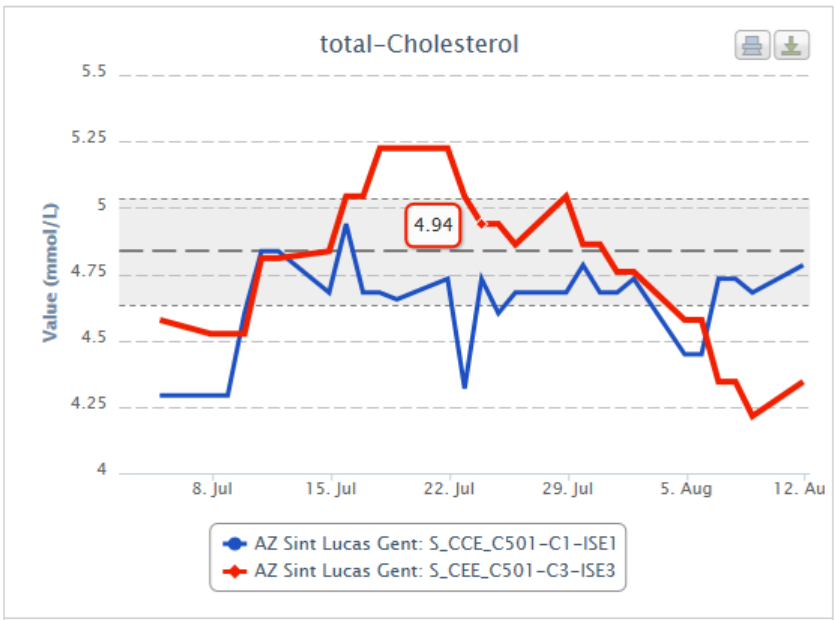
Samples

Lab: Device model: Device:

Start date: Stop date: Include weekend data:

Range: Moving median:

- ALT
- AST
- ALB
- ALP
- CRP
- Ca
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH
- Mg
- K
- Na
- UREA
- UAC
- BIL
- CHOL**
- PROT



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	4.84	1.1	7.1
Peer/All	4.78	-8.0	2.6
Target	5.20	3.8	NA
Range: period			
Your	4.73	□	8.9
Peer/All	□	□	□
Target	5.20	3.8	NA

CHOL
Lot 6809770,
04/06/2013
C1 L1↓

2013
No peer yet
(PPM)



Betrouwbare zorg



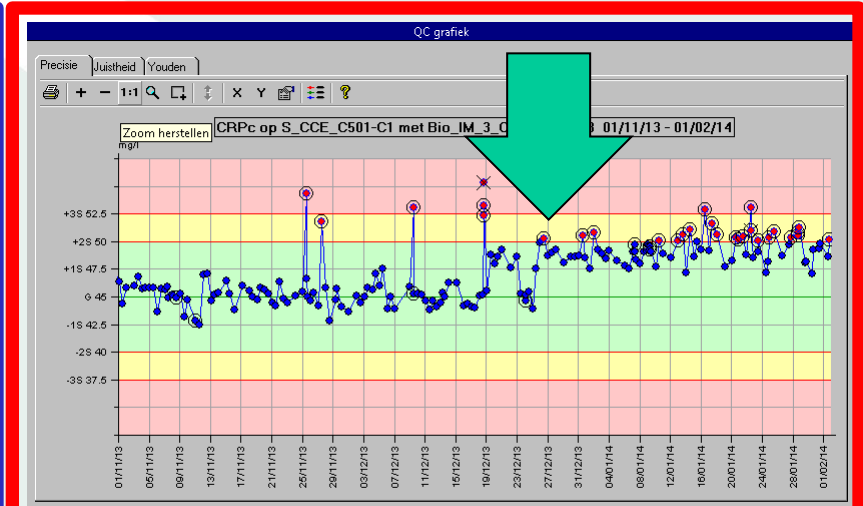
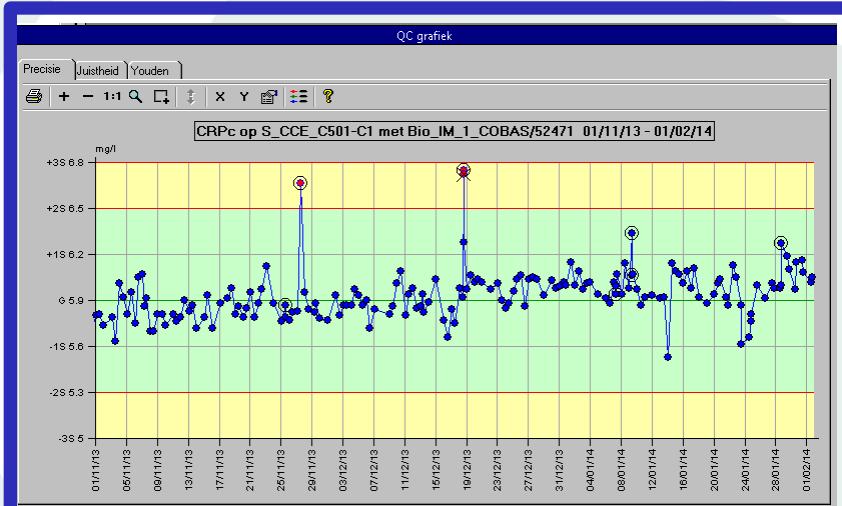
2. Patient Percentile Monitoring

• CRP

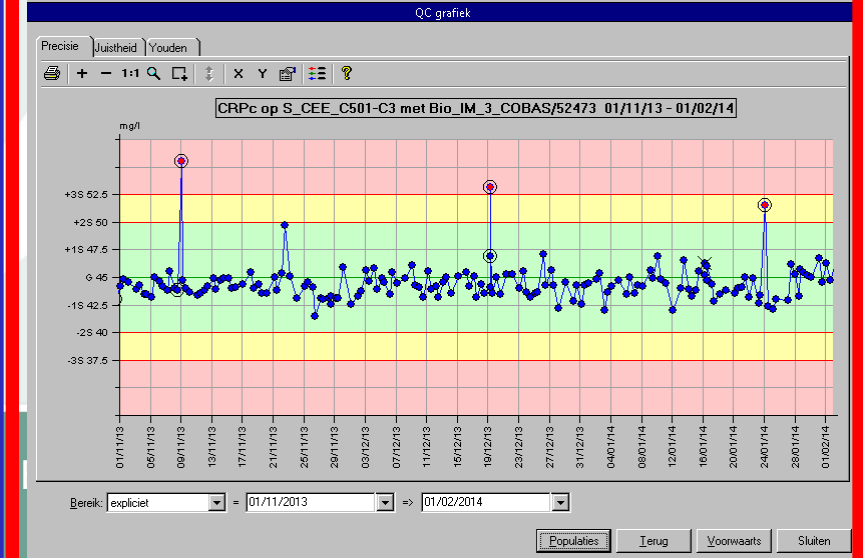
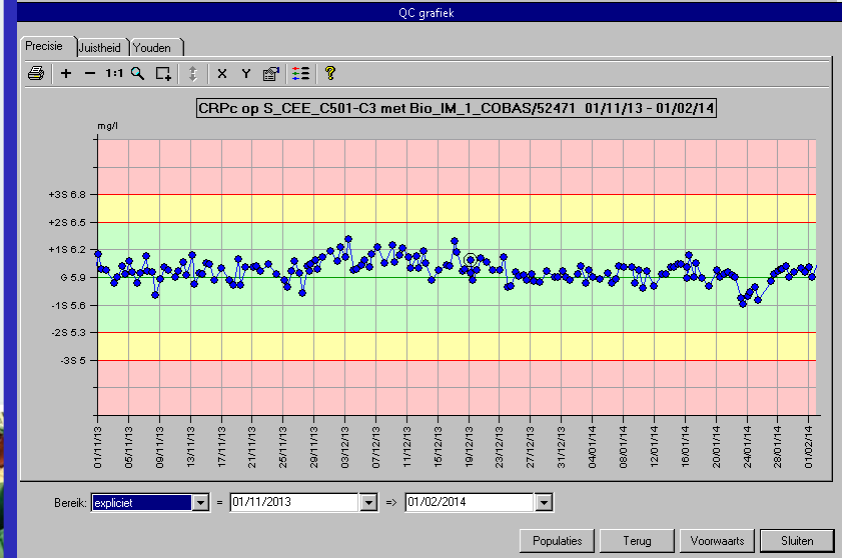
L1

L3

C1



C3



2. Patient Percentile Monitoring

The Percentiler

Quality Samples

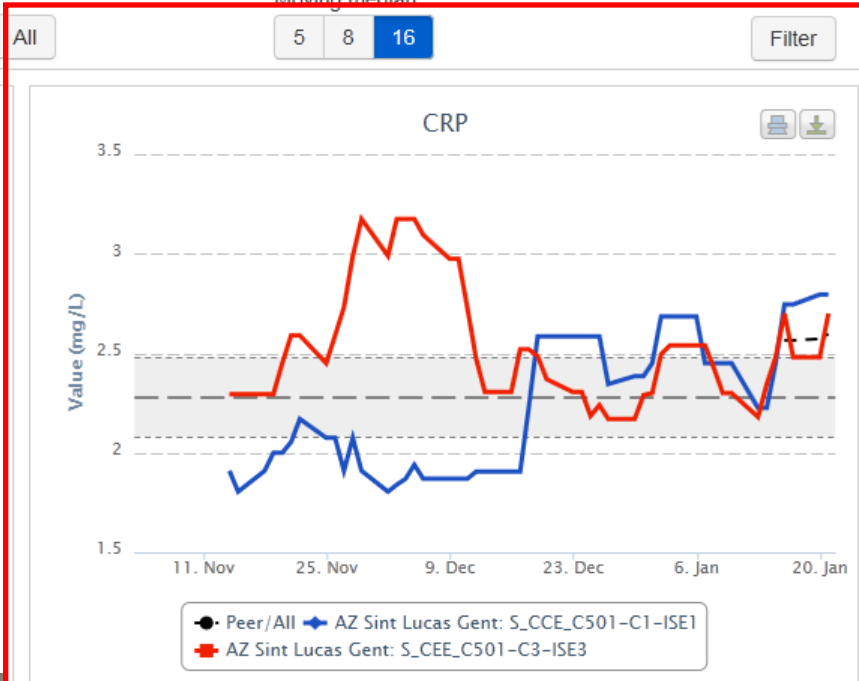
• CRP

Lab: All labs | Device model: All device models | Device: All devices

Start date: 2013/11/01 | Stop date: 2014/01/31 | Include weekend data: No

Range: 3M 6M 1Y All | Moving median: 5 8 16 | Filter

- ALT
- AST
- ALB
- ALP
- CRP**
- Ca
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH
- Mg
- K
- Na
- UREA
- UAC
- BIL
- CHOL
- PROT



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	2.28	-23.2	35.1
Peer/All	2.97	14.1	47.5
Target	2.60	7.7	NA
Range: period			
Your	2.28	-17.6	39.1
Peer/All	2.76	6.2	42.8
Target	2.60	7.7	NA

CRP
 IQC C1 L3↑
 PPM C3↑

VS C3 (PPM)

!be aware concentration PPM!!



Betrouwbare zorg



2. Patient Percentile Monitoring

The Percentiler

Quality

Samples

• Na

Lab:

Device model:

Device:

Start date:

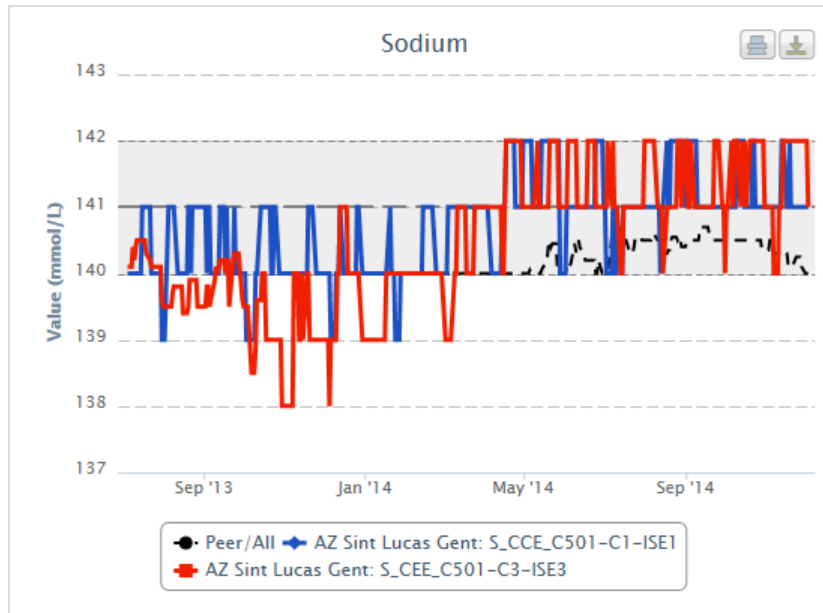
Stop date:

Include weekend data:

Range:

Moving median:

-
-
-
-
-
-
-
-
-
-
-
-
-
-
-
-
-
-
-
-



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	141.0	0.5	1.1
Peer/All	140.4	-0.1	0.7
Target	140.5	0.7	NA
Range: period			
Your	141.0	0.5	1.1
Peer/All	140.4	-0.1	0.7
Target	140.5	0.7	NA

Na
regulated **good**
over different
systems

Calibrated
every 12h

1-2 meq/L above
PEER

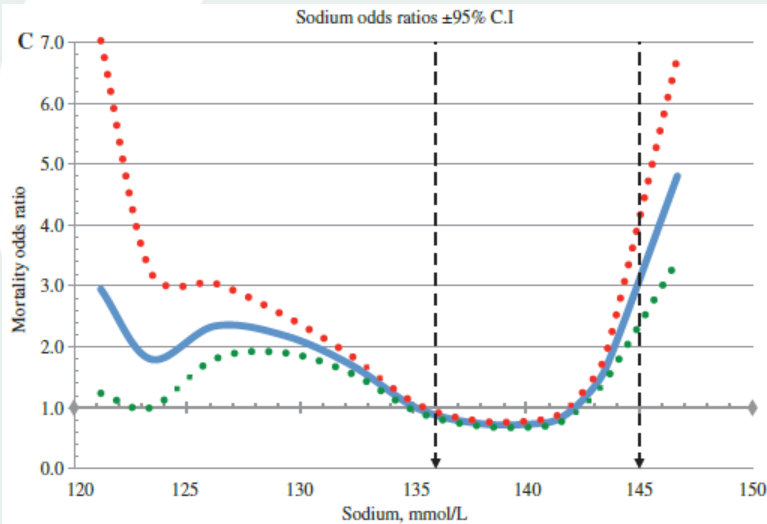


Betrouwbare zorg



Alan B. Solinger and Steven I. Rothman*

Risks of mortality associated with common laboratory tests: a novel, simple and meaningful way to set decision limits from data available in the Electronic Medical Record



We note that our upper DL for sodium at 142 mmol/L is lower than the usual RI upper limit of 145 mmol/L, where the OR has risen to 4.1 (95% CI).

Milan 2014 quality consensus

Model 1:
performance goals should be defined regarding to the **effect** they have on **clinical outcomes**



Betrouwbare zorg

2. Patient Percentile Monitoring

• Uric Acid (spring & summertime!)

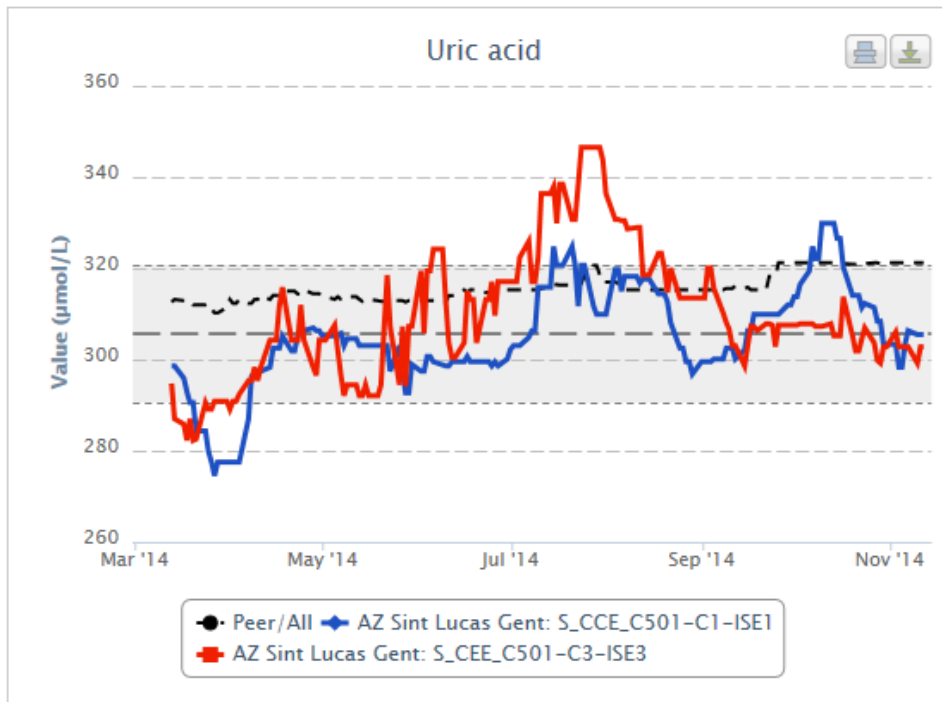
Uric Acid Seasonal

Lab: Device model: Device:

Start date: Stop date: Include weekend data:

Range: Moving median:

- ALT
- AST
- ALB
- ALP
- CRP
- Ca
- CI
- CRE
- GGT
- GLU
- PHOS
- LDH
- Mg
- K
- Na
- UREA
- UAC**
- BIL
- CHOL
- PROT



	Value	Bias (%)	Robust CV(%)
Range: all			
Your	305.75	-4.8	10.1
Peer/All	321.22	3.6	5.5
Target	310.00	4.8	NA
Range: period			
Your	304.56	-5.2	9.6
Peer/All	321.22	3.6	5.5
Target	310.00	4.8	NA

[Gallerani et al. Seasonal variation in the onset of microcrystalline arthritis. Rheumatology 1999;38:1003-6](#)
[Schlesinger et al. Acute gouty arthritis is seasonal. J Rheumatol 1998;25:342-4](#)
[Williamson CS. Gout: a clinical study of 116 cases. J Am Med Assoc 1920;74:1625-9](#)

Overview

1. Introduction

Hospital AZ Sint-Lucas

Clinical Laboratory AZ Sint-Lucas

(I/E)QC Clinical Laboratory

2. Patient Percentile Monitoring data

(ALT; TP; ALP; Ca; LDH; CHOL; CRP; Na, Uric Acid)

3. Conclusions/Remarks



Betrouwbare zorg

3. Conclusions/Remarks (+)

- + includes pre- and post-analytics
- + matrix & stability
- + shifts
- + cost
- + motivated communication manufacturers

BUT

- Need good PEER GROUPS

- Groups? (C501 Cobas6000 \pm C7/501 Cobas8000)
- Participants (number?), Limits (calculation)?



Betrouwbare zorg

3. Conclusions/Remarks (-)



Betrouwbare zorg

3. Conclusions/Remarks (-)

- **Size matters** (n)



- **Concentrations** (CRP; clinical importance)

- **Mid to long term control** (Bias > Precision)

- **Patient mix** (weekends, dialysis, oncology)



Betrouwbare zorg

Thank you for your attention!

Timothy.ghys@azstlucas.be

