The Percentiler

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EMPOWER*IVD*•GLOBE

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ST*T*
Consulting

UNIVERSITEIT
GENT

THE
EMPOWER
PROJECT
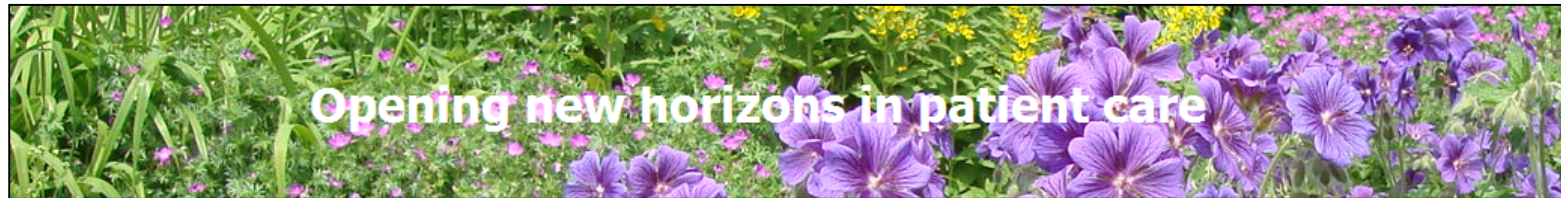
Overview

Status

Concept

Limits

Examples

Summary & Outlook

Participants

Current status (Nov 2014)
(total 124 with ~250 instruments)

- **>75 laboratories/sites in Belgium**
  (Hospitals: ~200 to 2000 beds)

International
Finland, Portugal, Slovakia, Sweden, Czech Republik, Canada, Turkey, US The Netherlands, Germany, Spain, …

Participation confirmed
Laboratories in Northern Ireland, UK, France, Switzerland, Denmark, Germany, Spain, ...

Advia	**7**
Architect	**19**
AU	**13**
Cobas	**152**
Integra	**4**
Modular	**11**
Synchron	**11**
Vista	**5**
Vitros	**26**

Global community

Participants – Geographic spread

IT connectivity

GLIMS (MIPS)

CorLabs (Cegeka)

MOLIS (Vision4Health Belgium S.A)

FONS Openlims (STAPRO Ltd. Czech Healthcare Software House)

Modulab (Systelab, Spain)

LPM, IM Middleware (Data Innovations)

IT connectivity

The Flagger

- **Local IT solutions**

- **Data Innovations**

IT connectivity

E-mail reading into MySQL database#

- **percentile@stt-consulting.com**

- **flagger@stt-consulting.com**

- **[iqcmonitoring@stt-consulting.com]**

#e-mail embeddd table; EXCEL-file; Text-file

Graphical user interface

- **User access since January 2014**

    – **Peer Group Moving Medians**

Real-time monitoring of performance

User Interface

https://www.thepercentiler.be

Login: User = DEMOLAB, password = demo1234

Stratification

Points of care

- **Instrument-specific**

- **Outpatients**

- **No weekends (filtered by our IT)**

Limitations

- **Low volume analytes**

- **Seasonal variation (25OHD)**

Remark

Patient is not measured
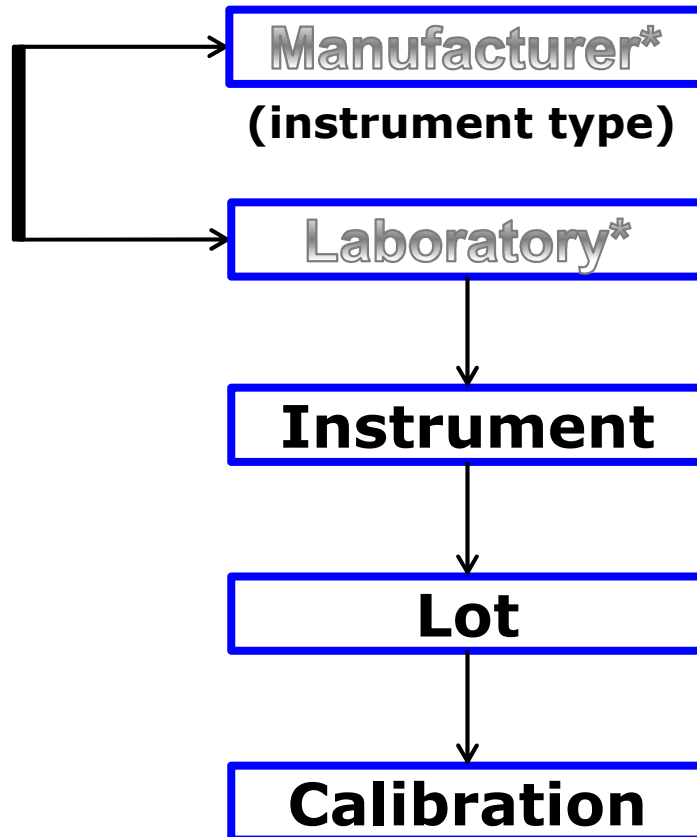
- **By a laboratory**

Patient is measured

- **On *rotor 1* of instrument *x* in laboratory *y* with the assay of manufacturer *z*.**

Only The Percentiler delivers that depth of information!

Application concept
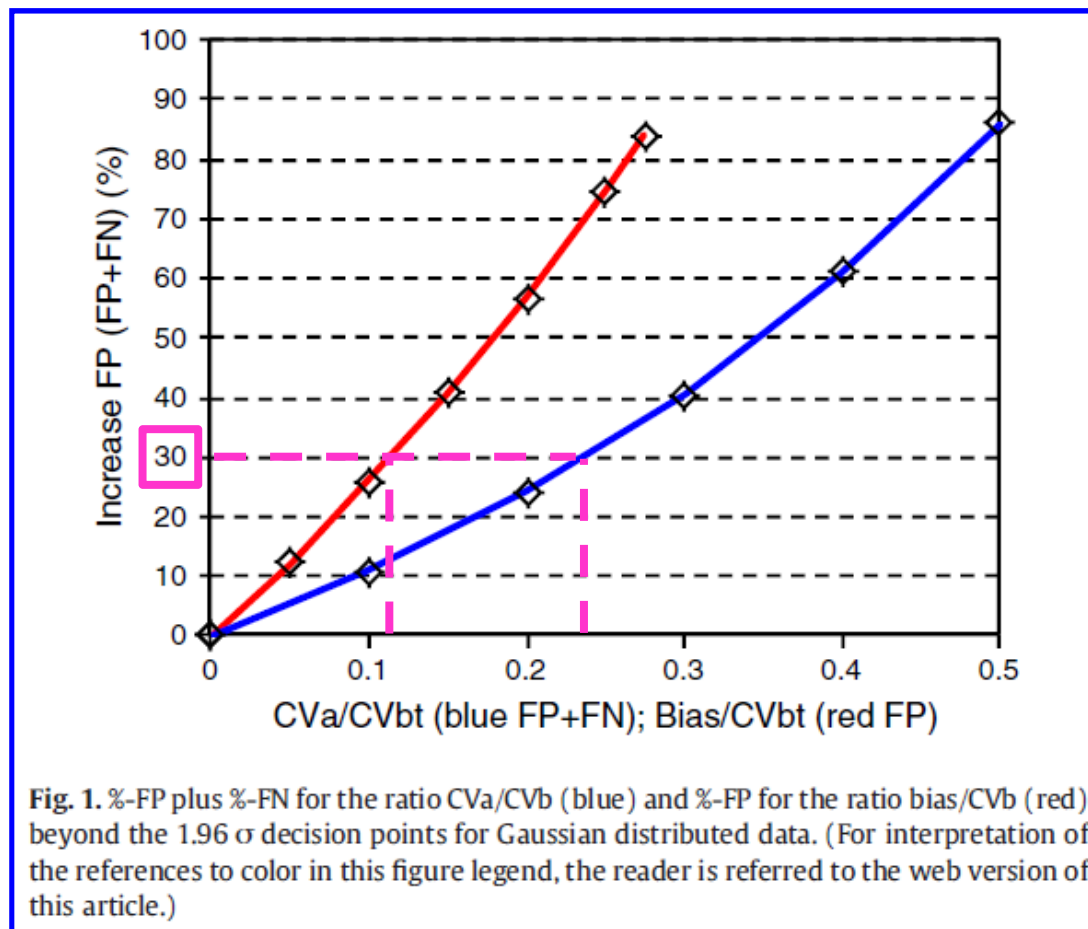
Assessment of bias components

(Percentile monitoring)

Manufacturer*
(instrument type)

Laboratory*

Instrument

Lot

Calibration

Probably*
- **High-volume labs**
- **Outpatients**

Application concept

Theory
**Effect of assay instability on surrogate medical decisions**

Fig. 1. %-FP plus %-FN for the ratio CVa/CVb (blue) and %-FP for the ratio bias/CVb (red) beyond the 1.96 σ decision points for Gaussian distributed data. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

A fresh look at analytical performance specifications from biological variation.
Stepman HC, Stöckl D, Twomey PJ, Thienpont LM. Clin Chim Acta 2013;421:191-2.

Application concept

"Surrogate" medical decision hyponatremia

- **Triplication** "low versus high" period (**±2 mmol/L**)!
- Benchmark stability: 8 years ±1 mmol/L
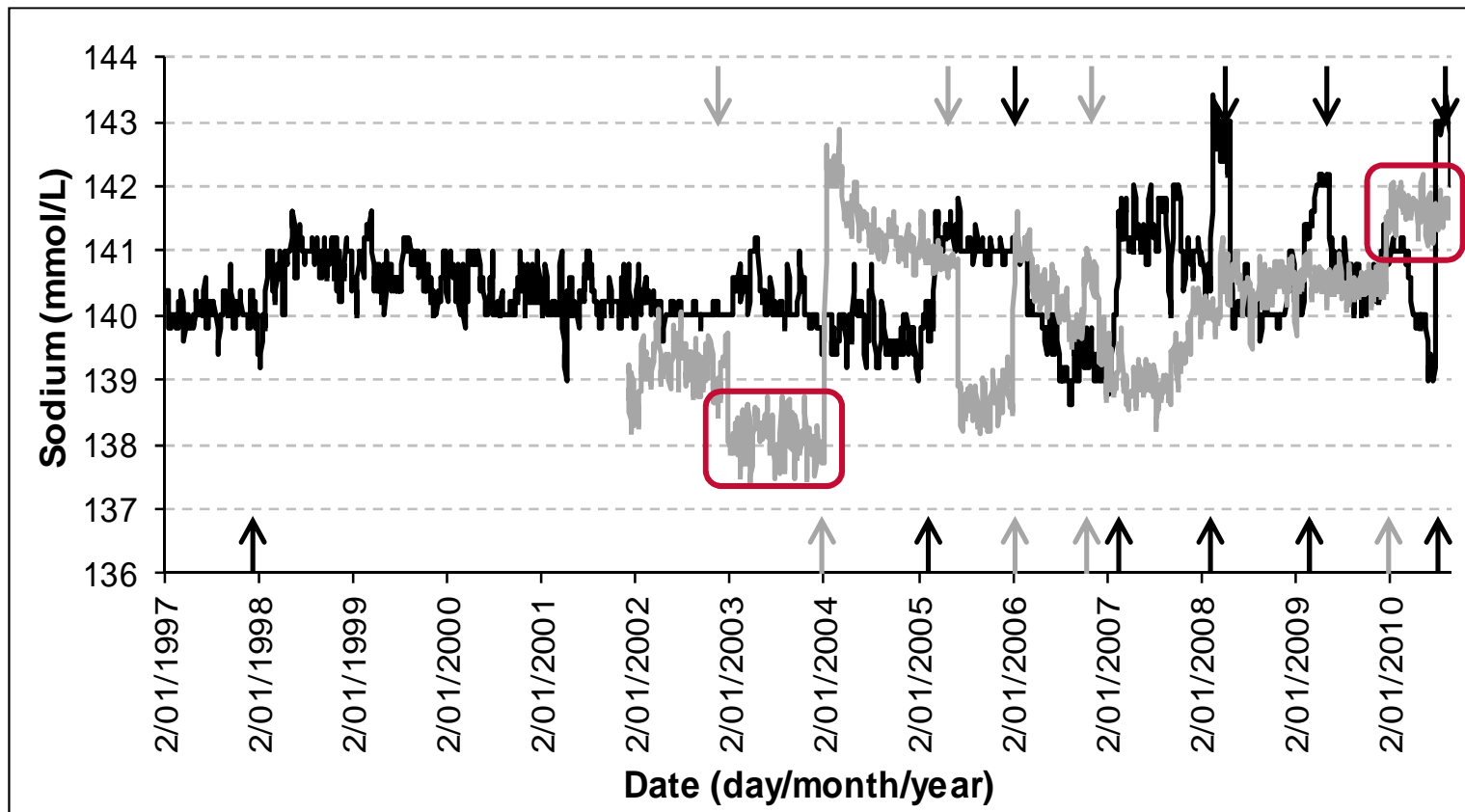
Application concept
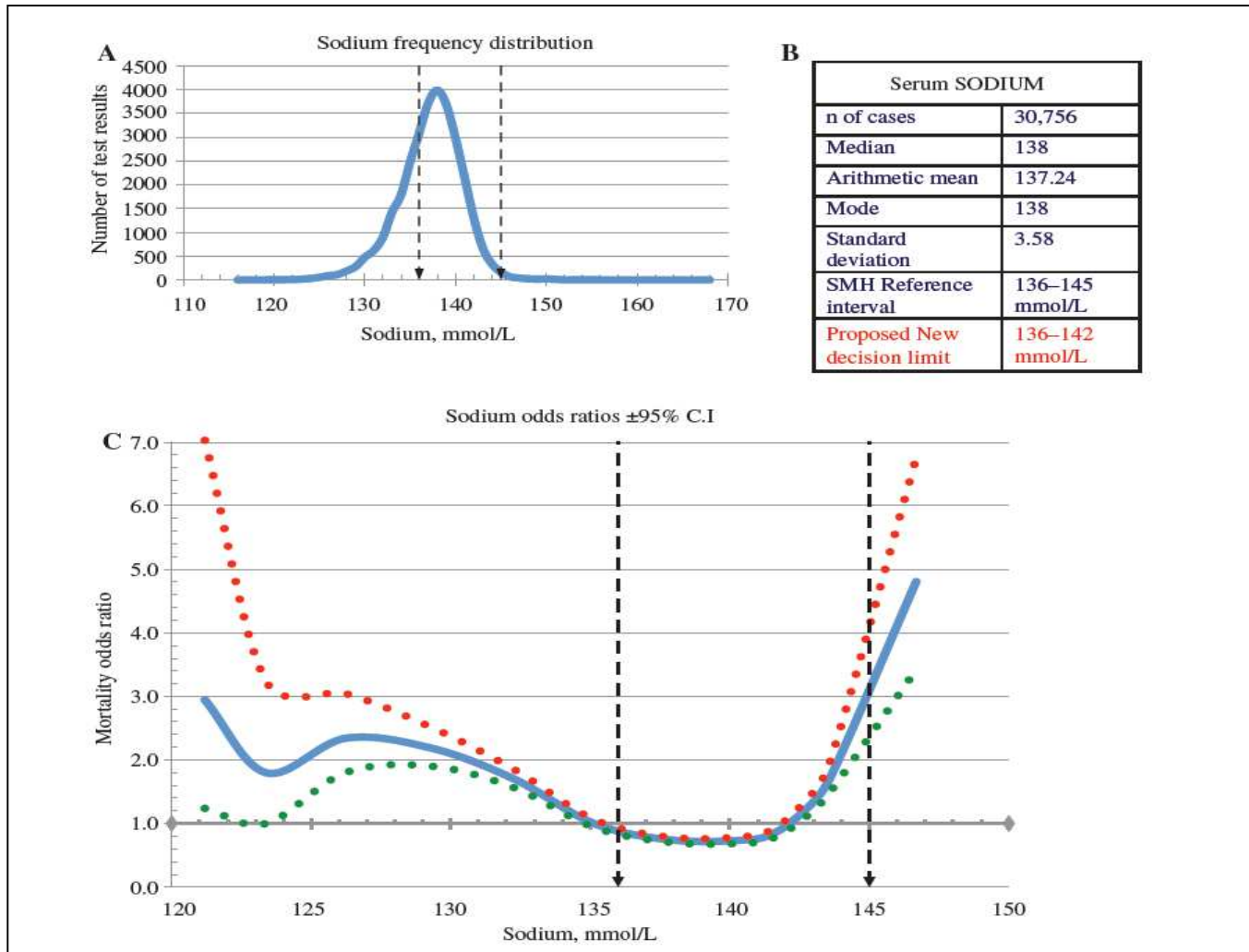
Sodium results & mortality

Risk-based reference intervals:

Narrower than population-based reference intervals

Solinger AB, Rothman SI. 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. Clin Chem Lab Med 2013; 51(9): 1803–1813
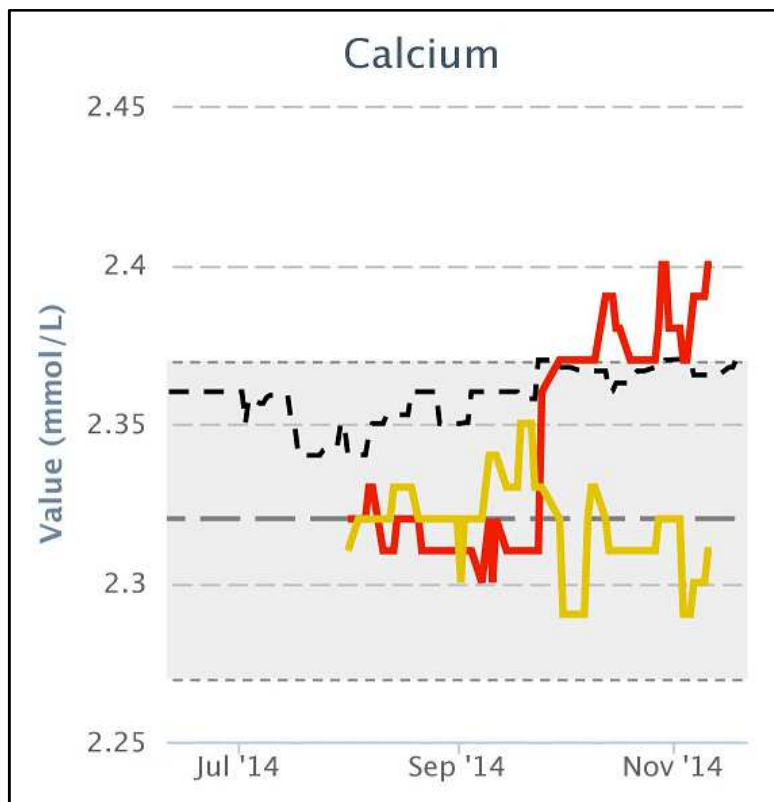
Application concept

Surrogate medical outcome (laboratory population)

	Long-term mean	CV for stable periods (%)	Maximum neg. and pos. bias (%)	Percentage hypo in a biased period	Ratio hypo	Percentage hyper in a biased period	Ratio hyper	Bias specific. (diagnosis) (%)
Calcium								
Lab 1	2.23	1.0	-3.1	40	1.8	5.0	2.4	0.8
			3.7	22		12		
Lab 2	2.29	1.0	-3.5	35	1.8	1.0	5.1	
			3.9	19		5.1		

Application concept

Comparison The Percentiler – The Flagger

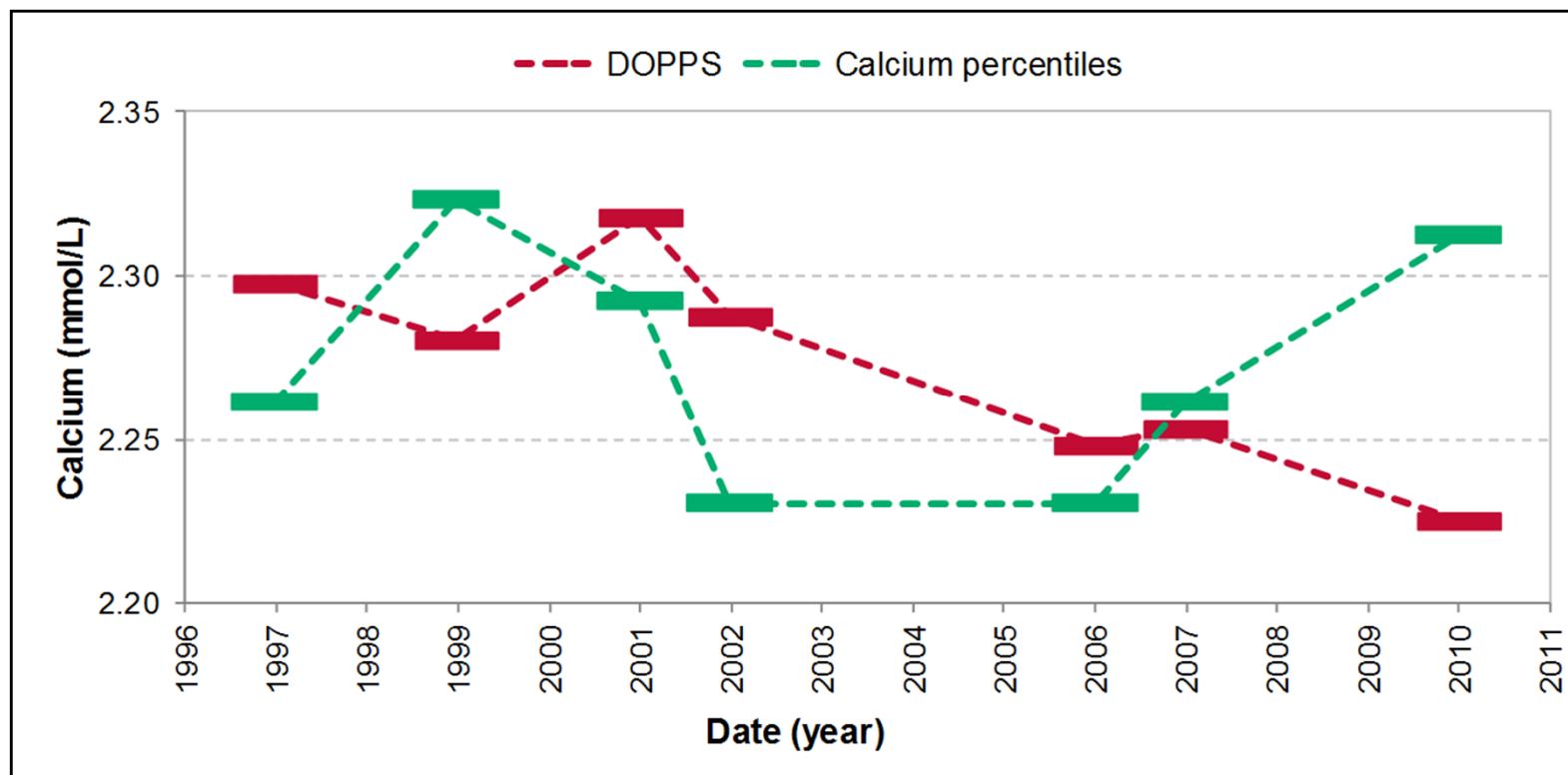- **3-fold hypercalcemia!**
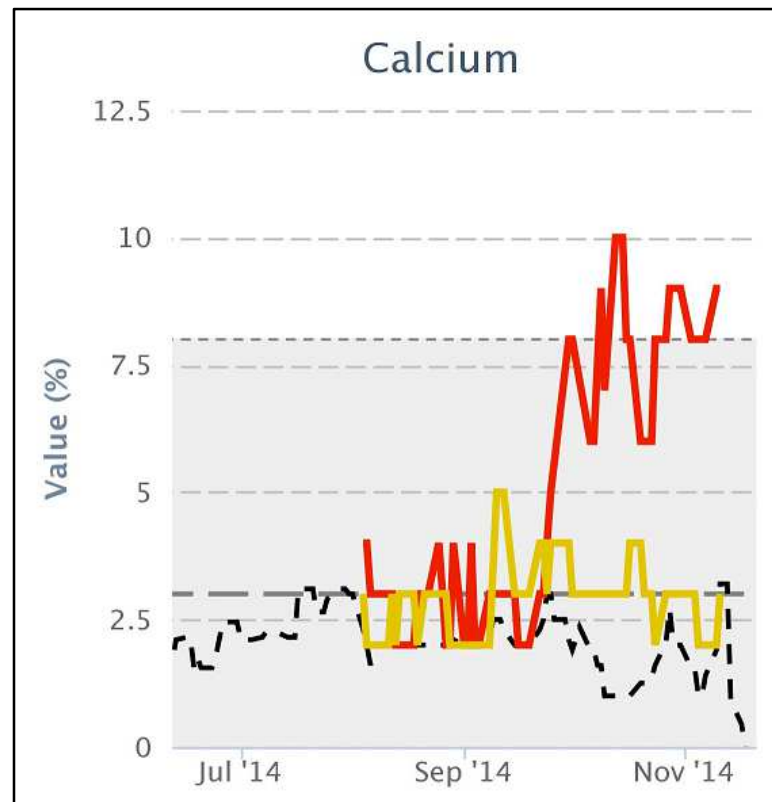
Application concept

DOPPS = Dialysis Outcomes and Practice Pattern Study

Hypothesis: measurable differences in dialysis facility practices influence patient life expectancy, morbidity and health-related quality of life

Practice patterns

- Staff per patient
- Number of patients served
- Dialysis "dose" and other prescriptions
- Methods of delivering dialysis and achieving dose

Outcomes

- Mortality
- Hospitalization
- Infections
- Quality of life
- Development of a new medical conditions
- Normalization of biochemical parameters
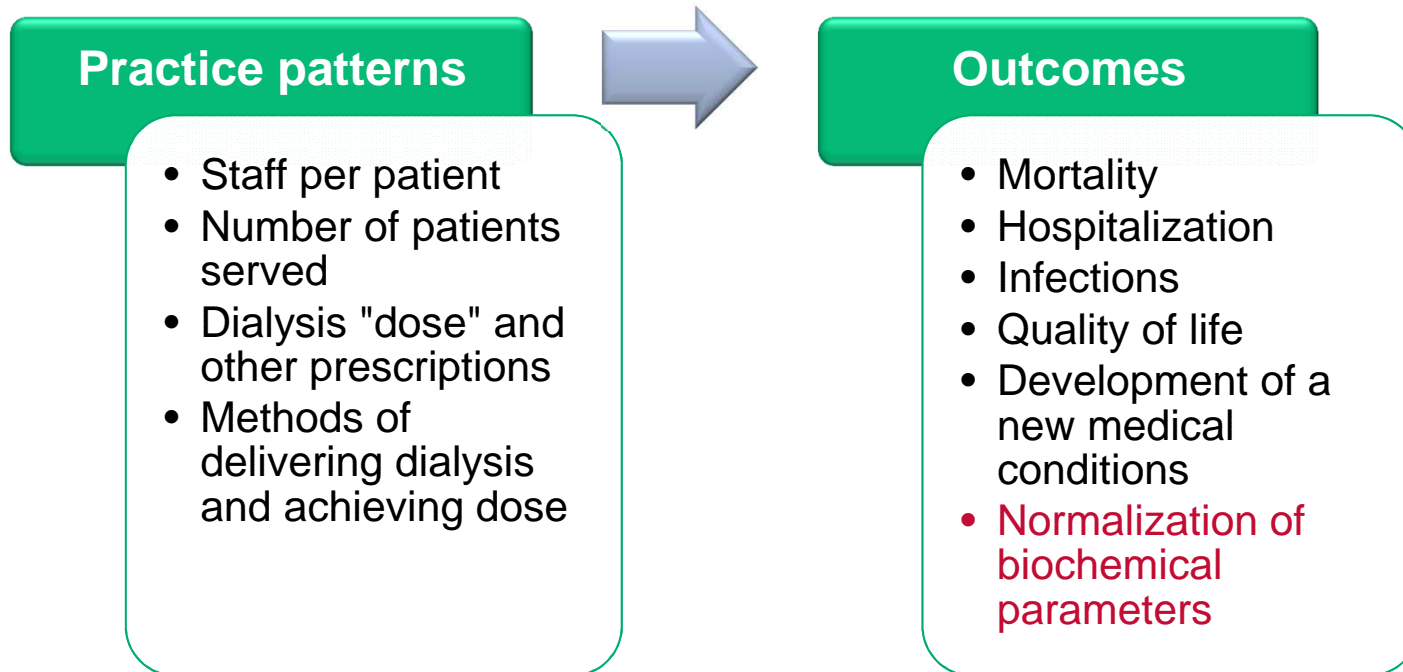
Application concept

Trends by practice patterns or analytical instability?

Performance specifications

	Bias Biology (%)	Bias Empower (%)	Bias Biology (unit)	Bias Empower (unit)	Unit	Median "SI"
ALB	1.3	2.3	0.56	1	g/L	43.0
ALKFOS	6.4	7.0	4.6	5	U/L	71.9
ALT	11.4	11.0	2.1	2	U/L	18.1
AST	5.4	4.9	1.1	1	U/L	20.4
BILTOT	11.4	12.2	0.94	1	µmol/L	8.21
CA	0.8	2.1	0.019	0.05	mmol/L	2.38
CHOL	4	4.1	0.20	0.2	mmol/L	4.91
CL	0.5	1.0	0.51	1	mmol/L	102.0
CRP	21.8	11.0	0.40	0.2	mg/L	1.82
GGT	10.8	9.4	2.3	2	U/L	21.2
GLUC	2.2	3.8	0.12	0.2	mmol/L	5.24
K	1.8	3.4	0.08	0.15	mmol/L	4.44
CREAT	4	4.1	2.9	3	µmol/L	73.0
LDH	4.3	5.4	7.9	10	U/L	183.6
MG	1.8	3.5	0.015	0.03	mmol/L	0.85
NA	0.3	0.7	0.42	1	mmol/L	140.6
P	3.2	3.6	0.036	0.04	mmol/L	1.11
PROT	1.2	1.4	0.83	1	g/L	69.5
UREA	5.5	5.5	0.30	0.3	mmol/L	5.45
URIC ACID	4.9	4.7	15.5	15	µmol/L	317

Examples

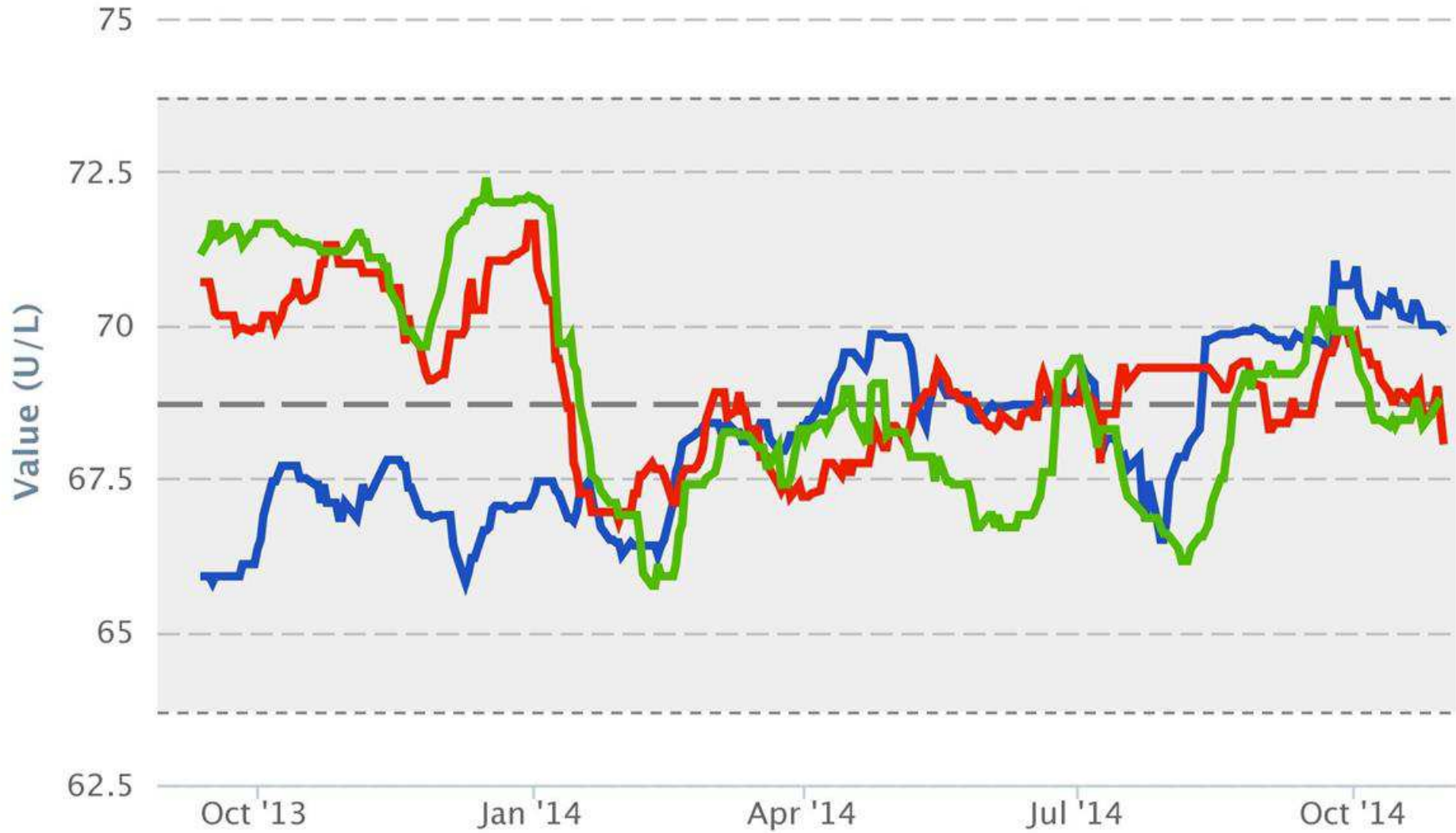

ALT – GPT

Examples

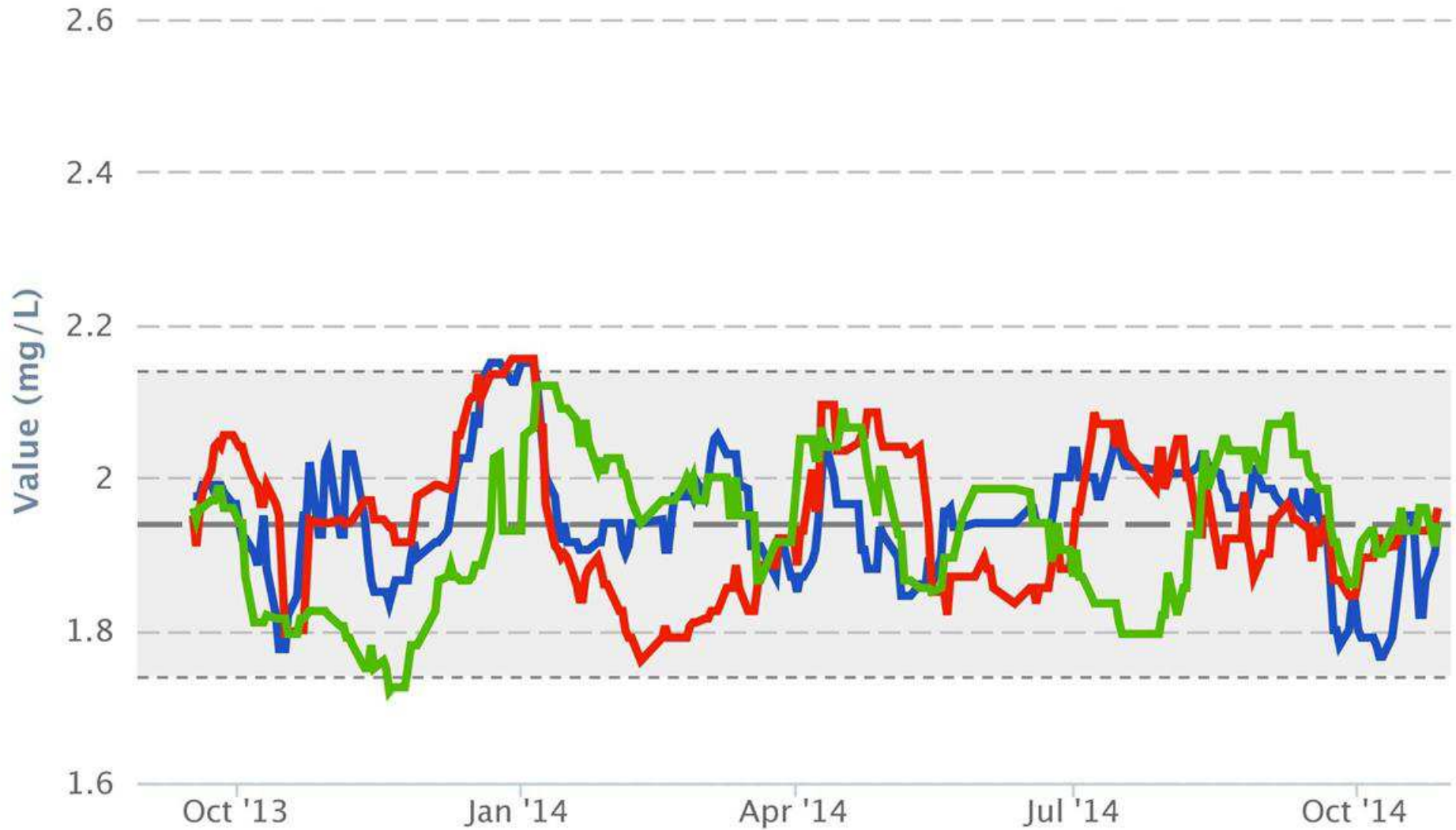AST – GOT
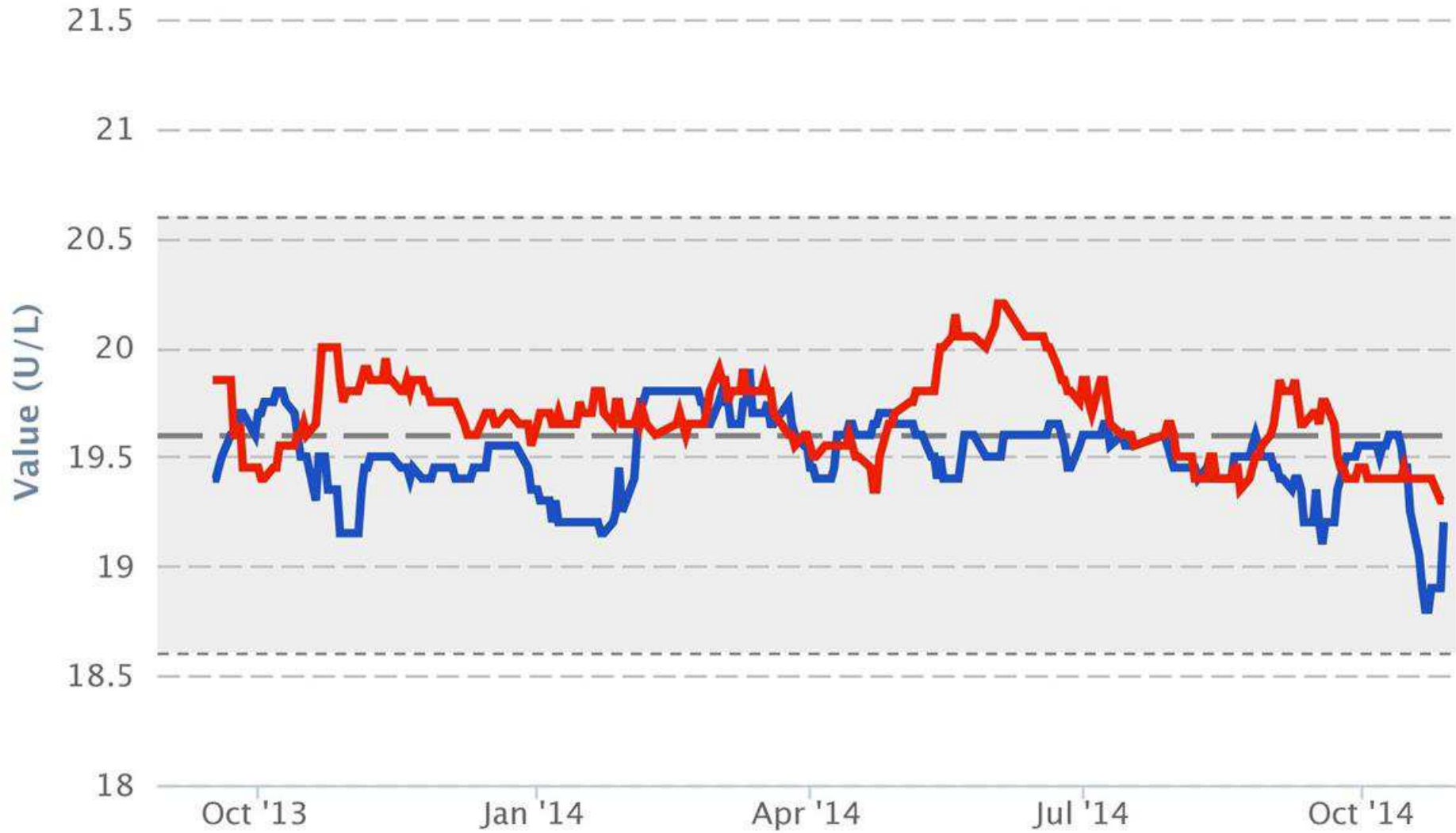
Examples
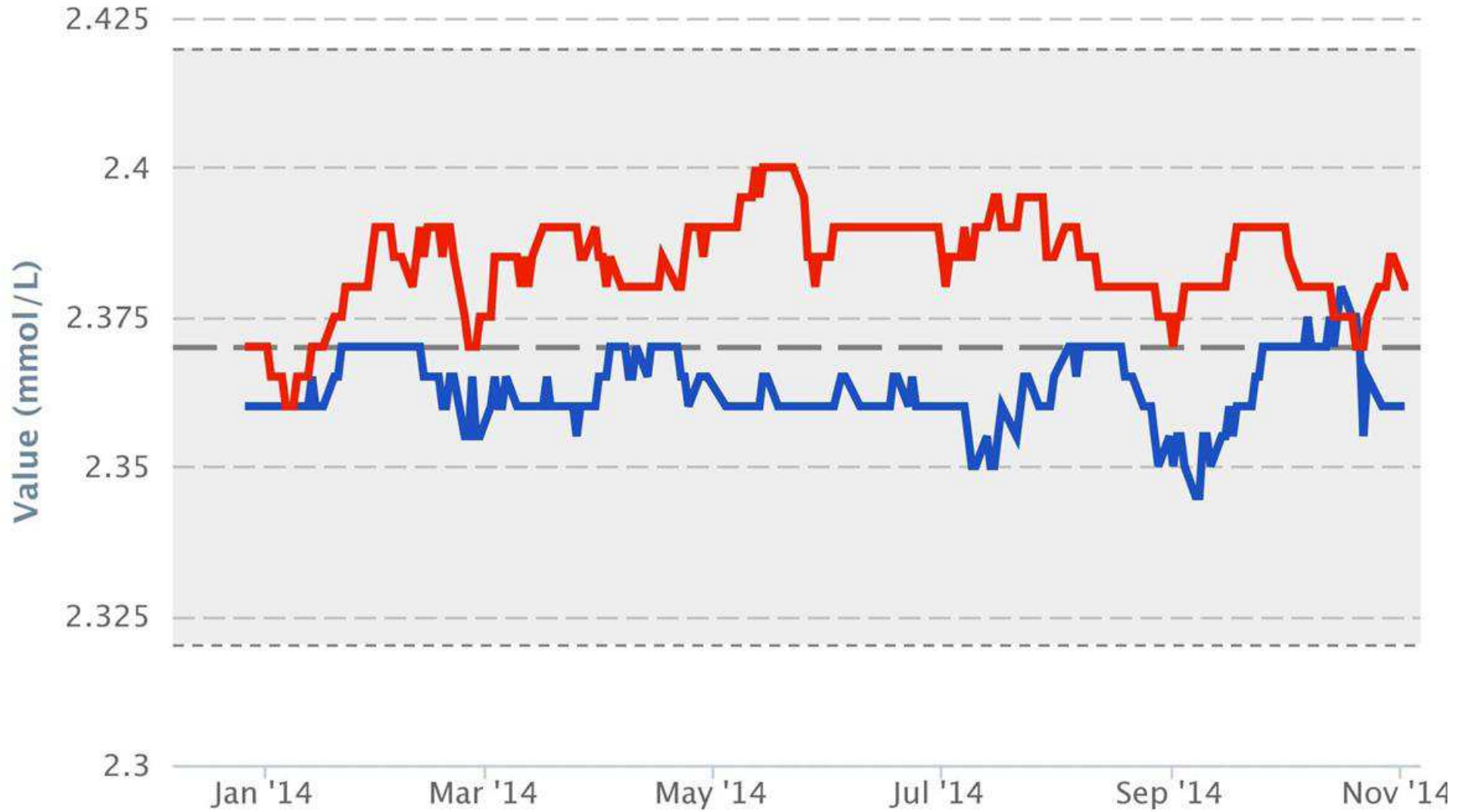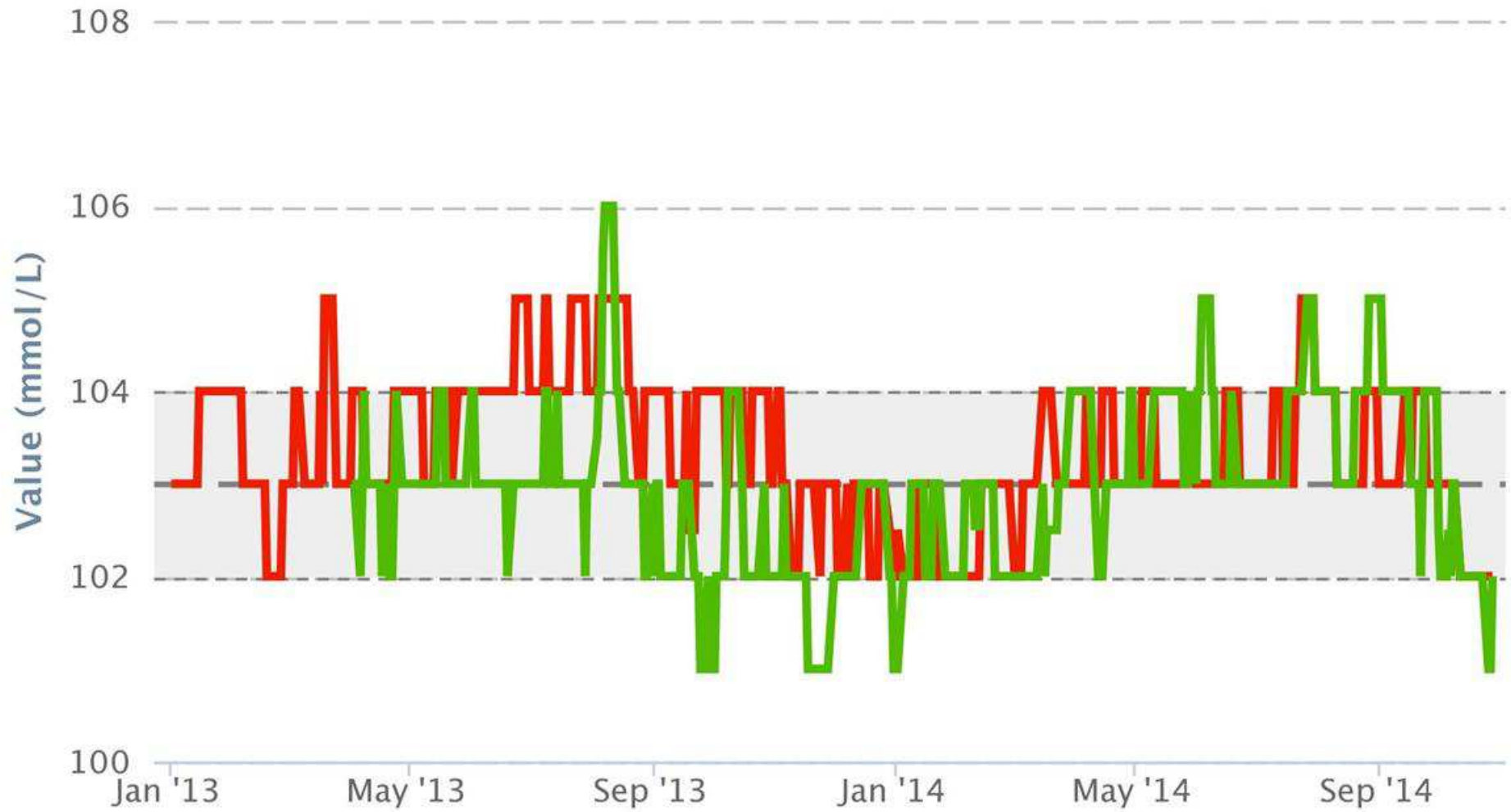

Albumin
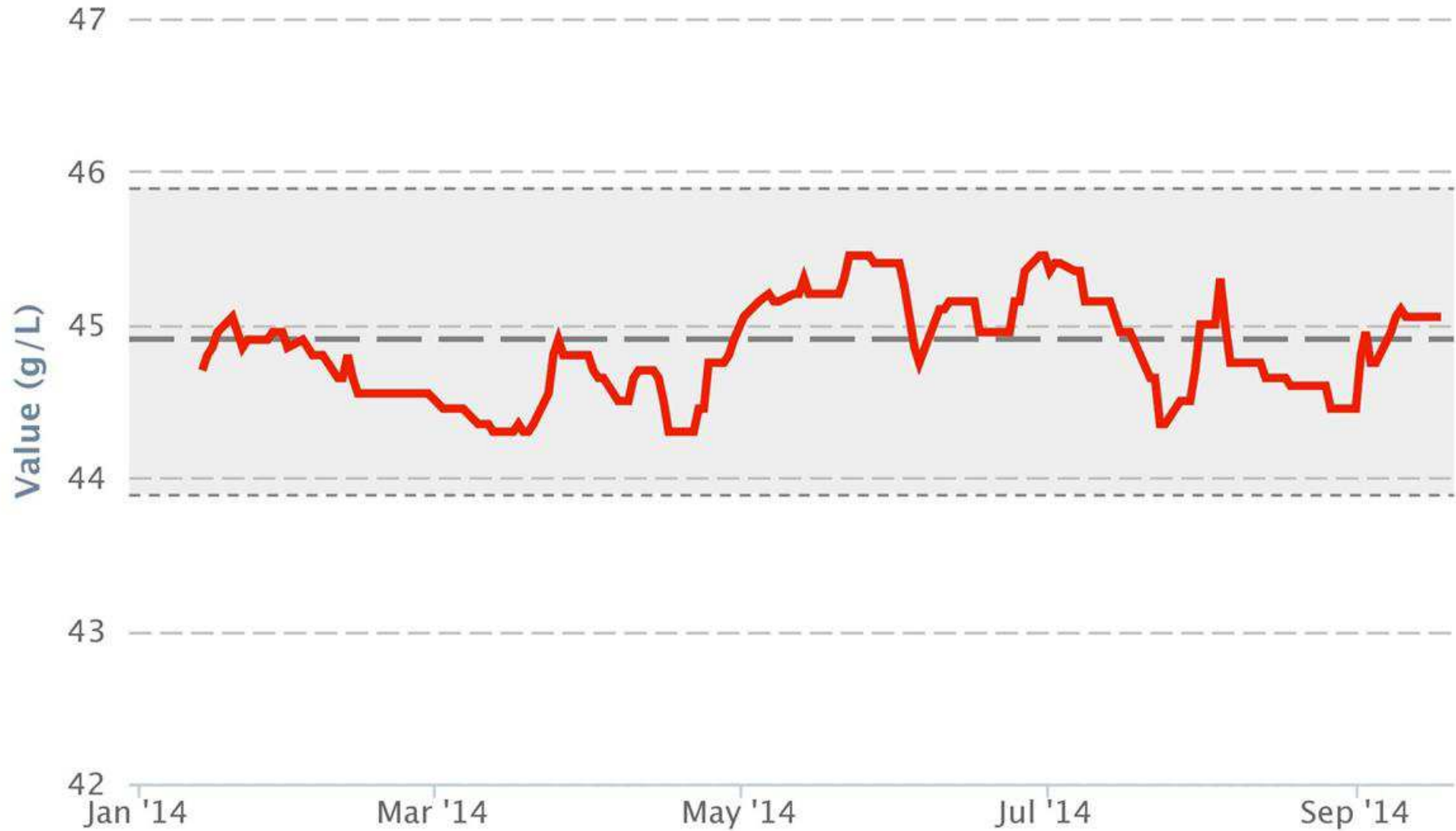
Examples

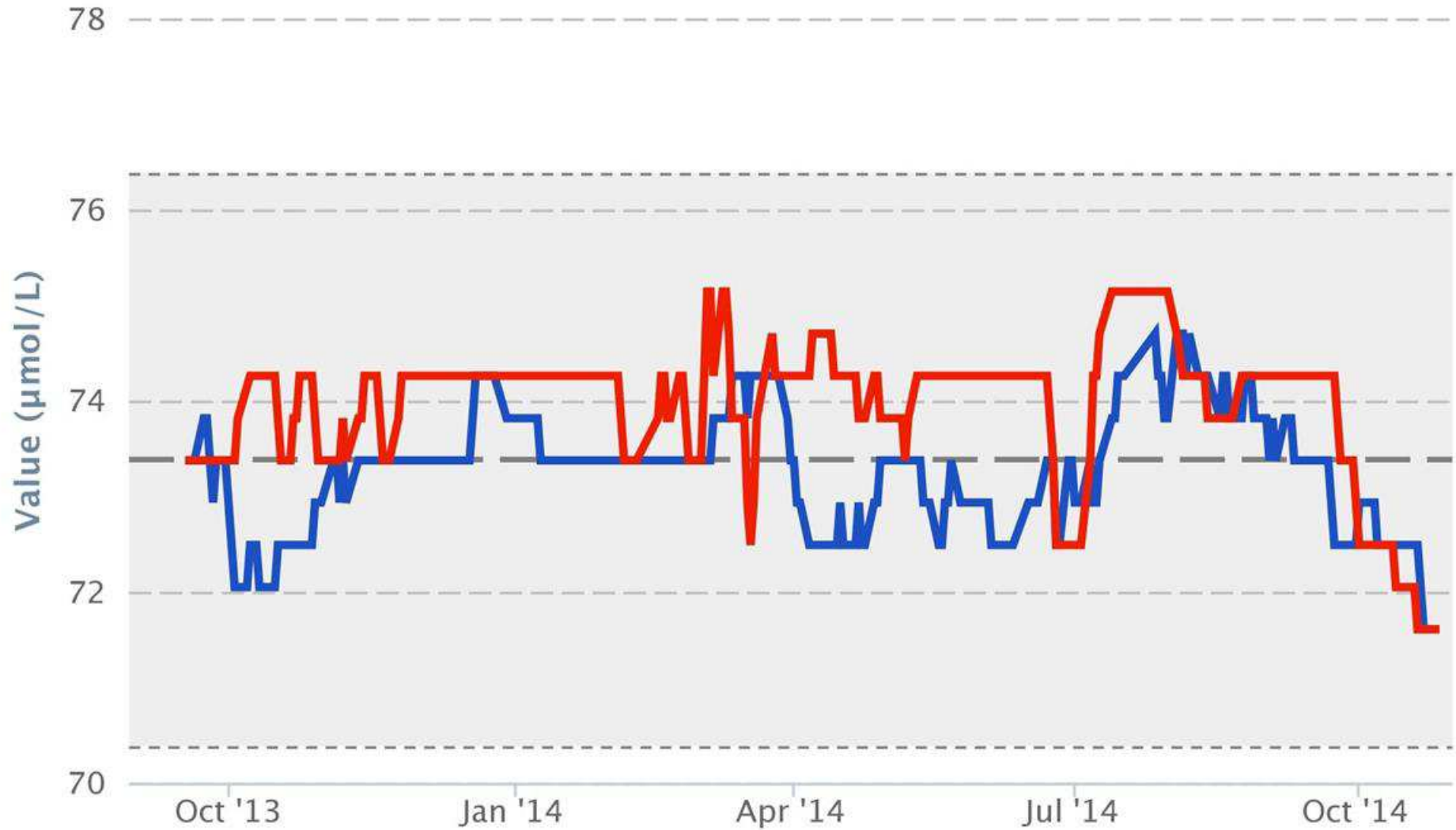Alkaline Phosphatase

Examples
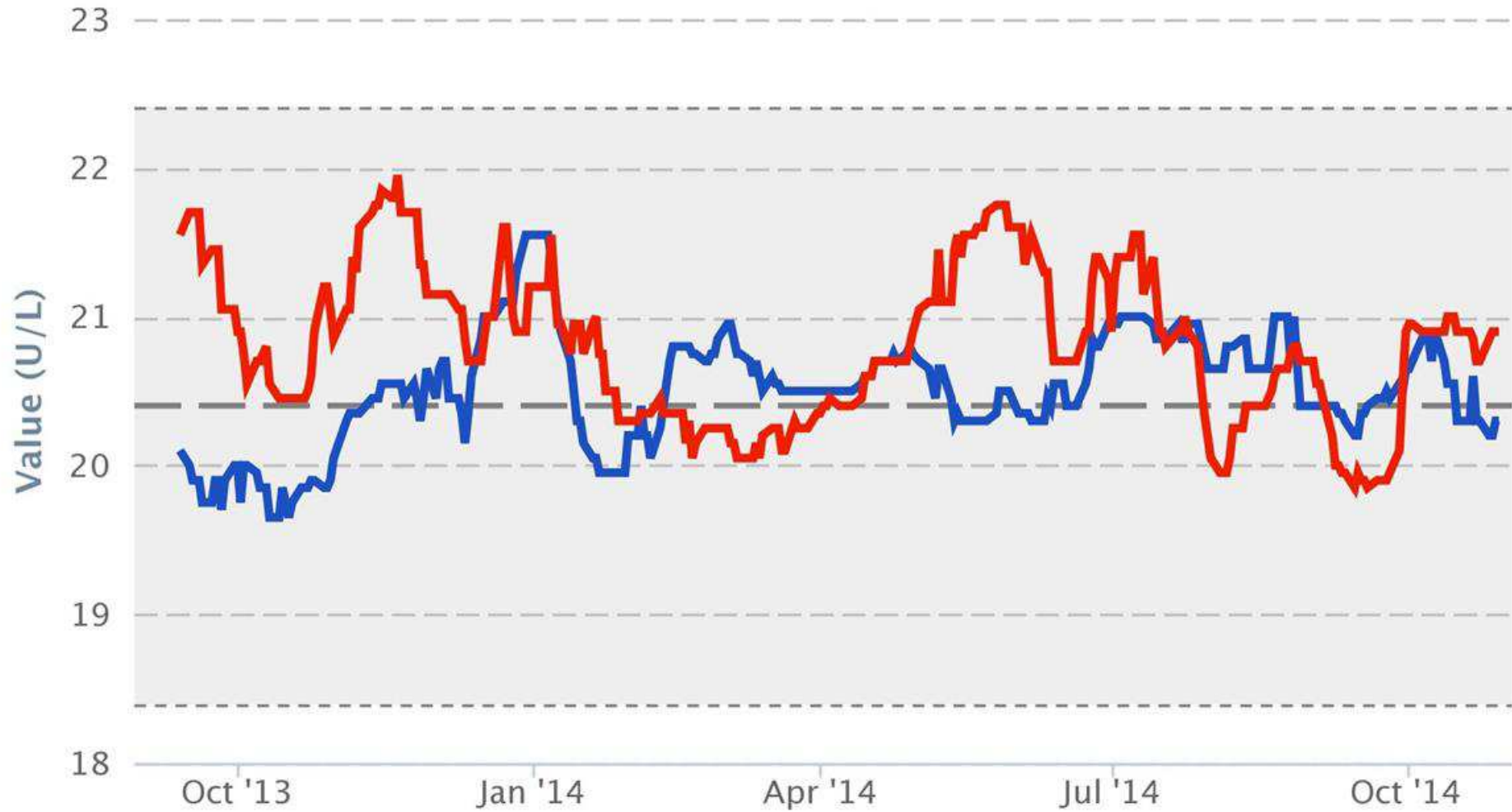

CRP

Examples

Calcium

Examples

Chloride

Examples

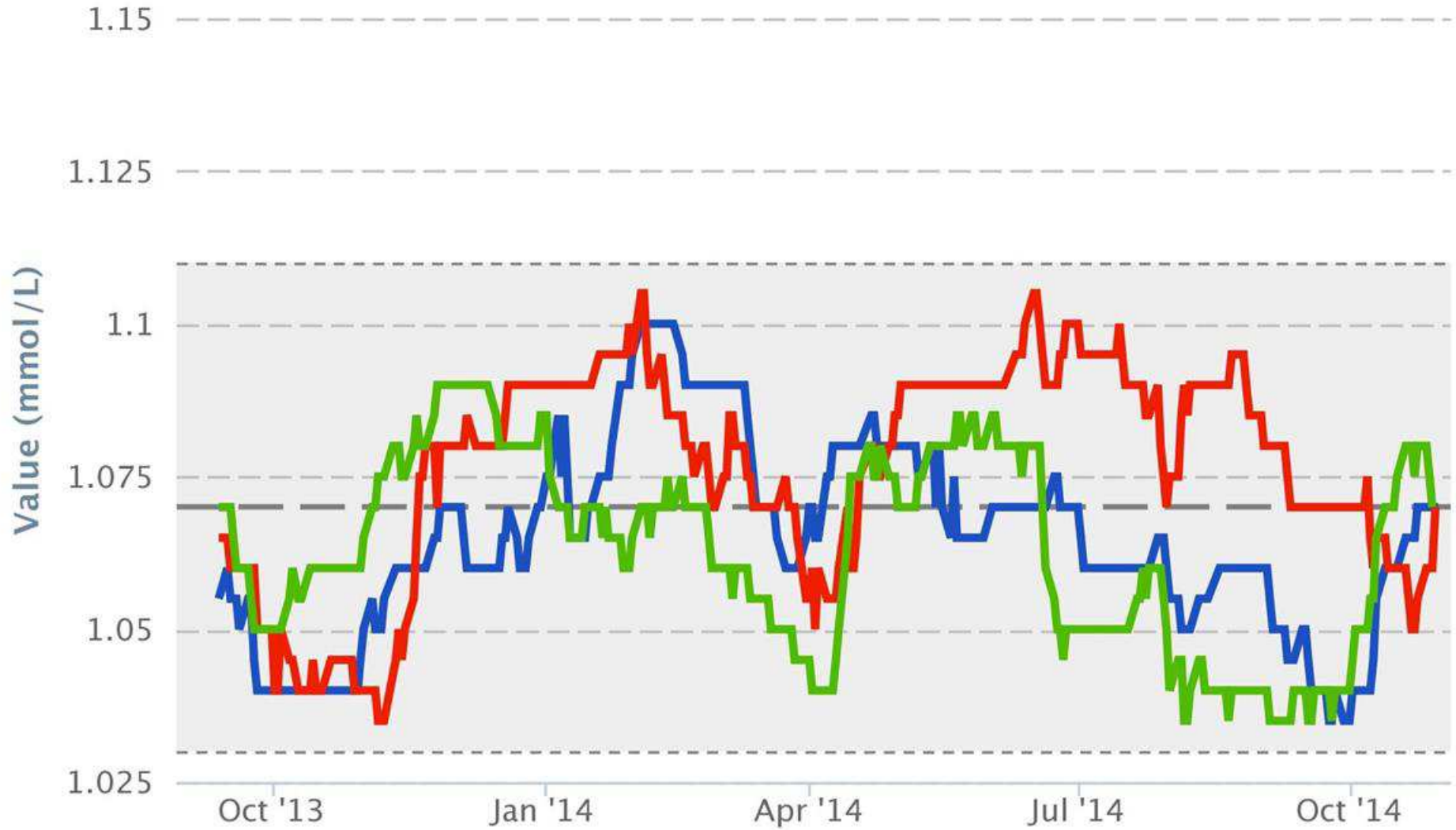Creatinine

Examples

GGT

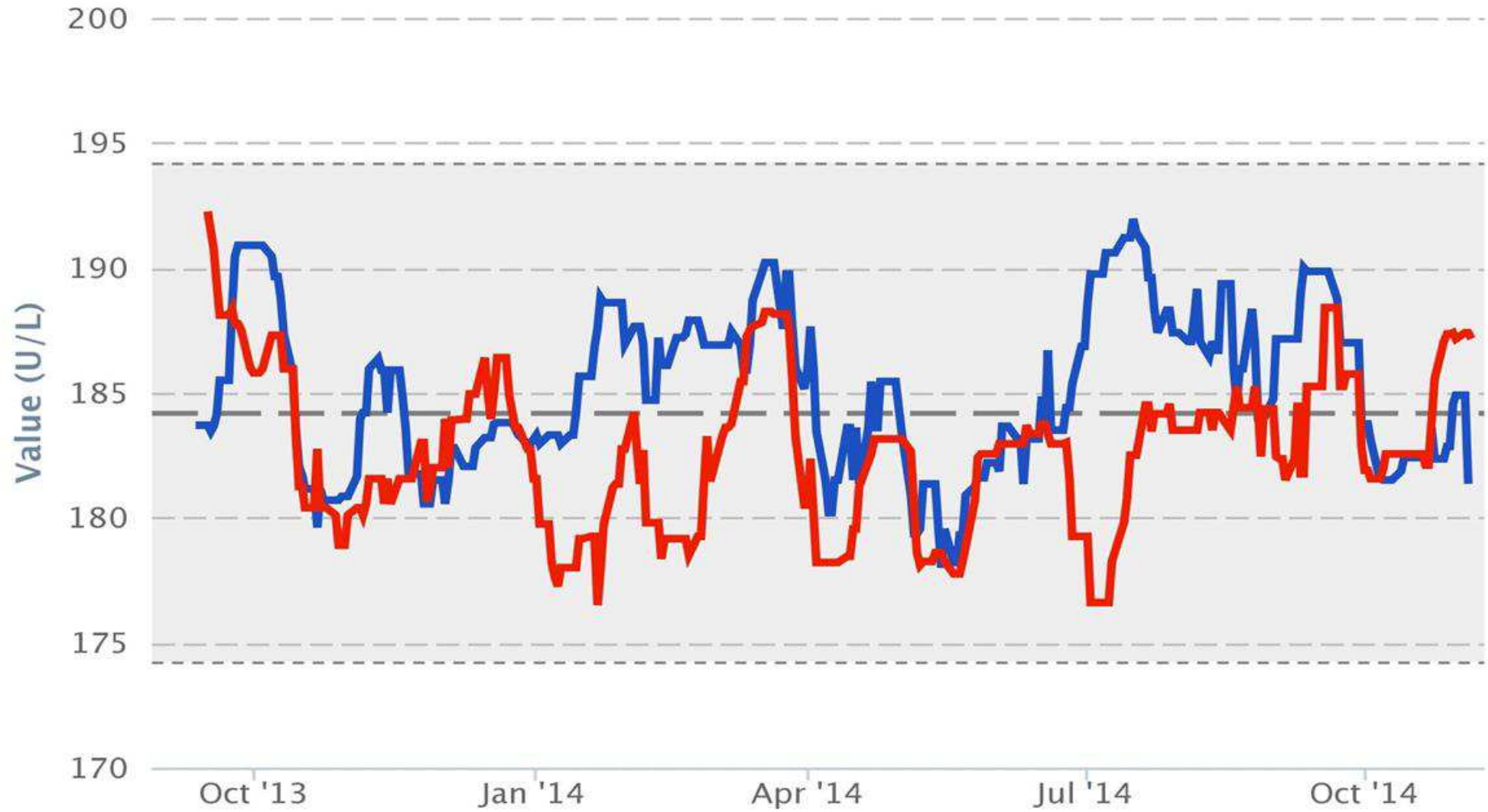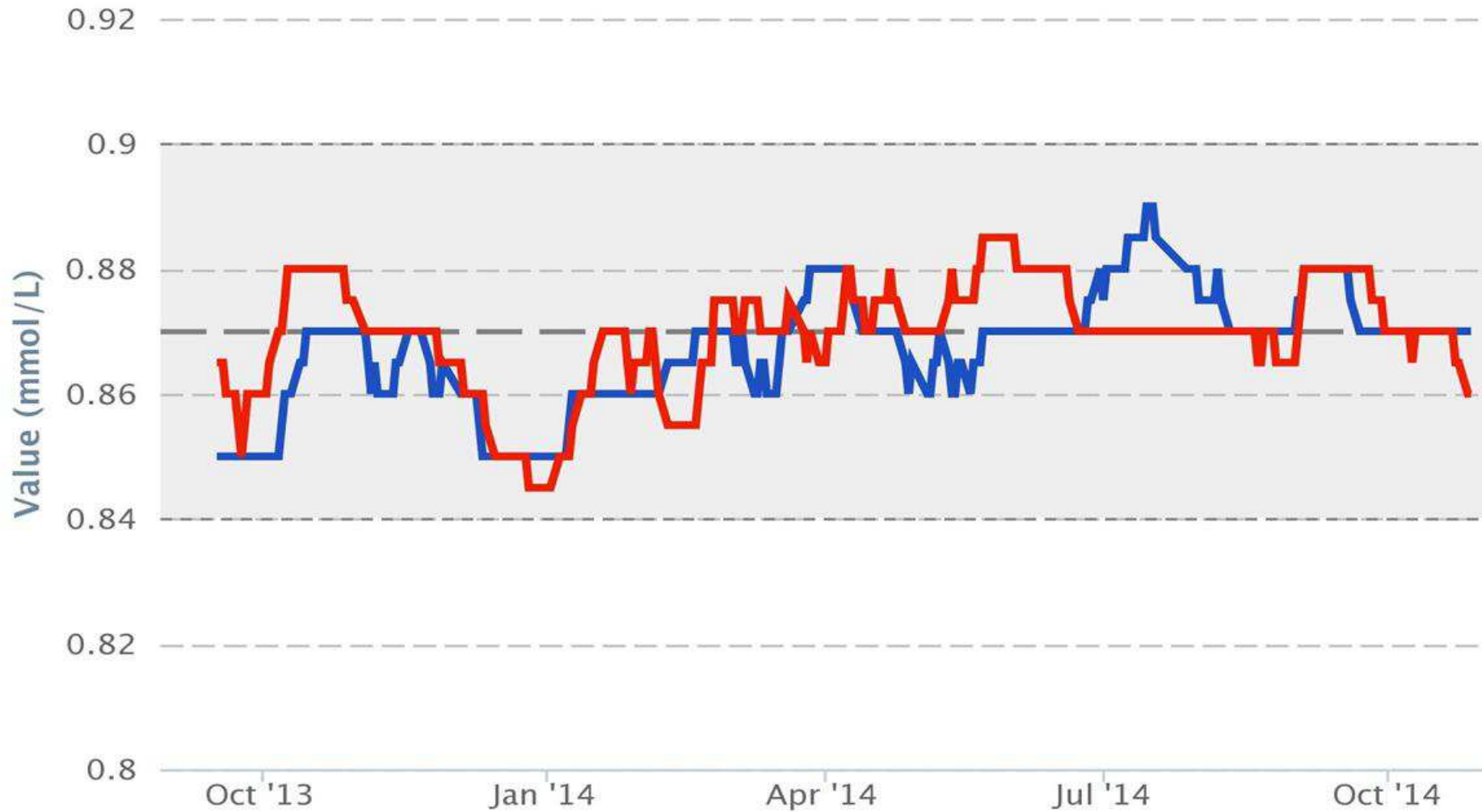# Examples

Glucose

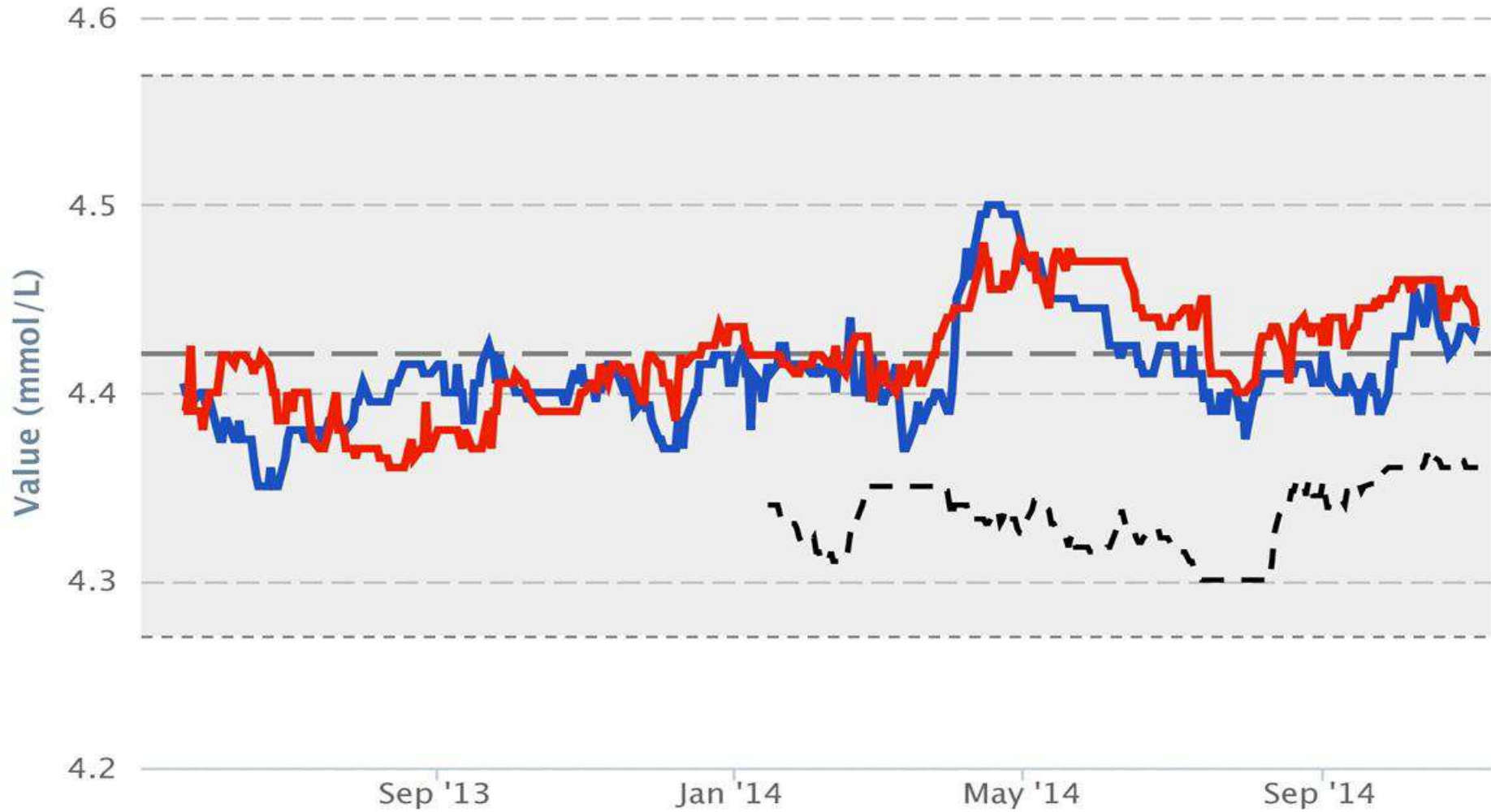# Examples

Inorganic phosphor
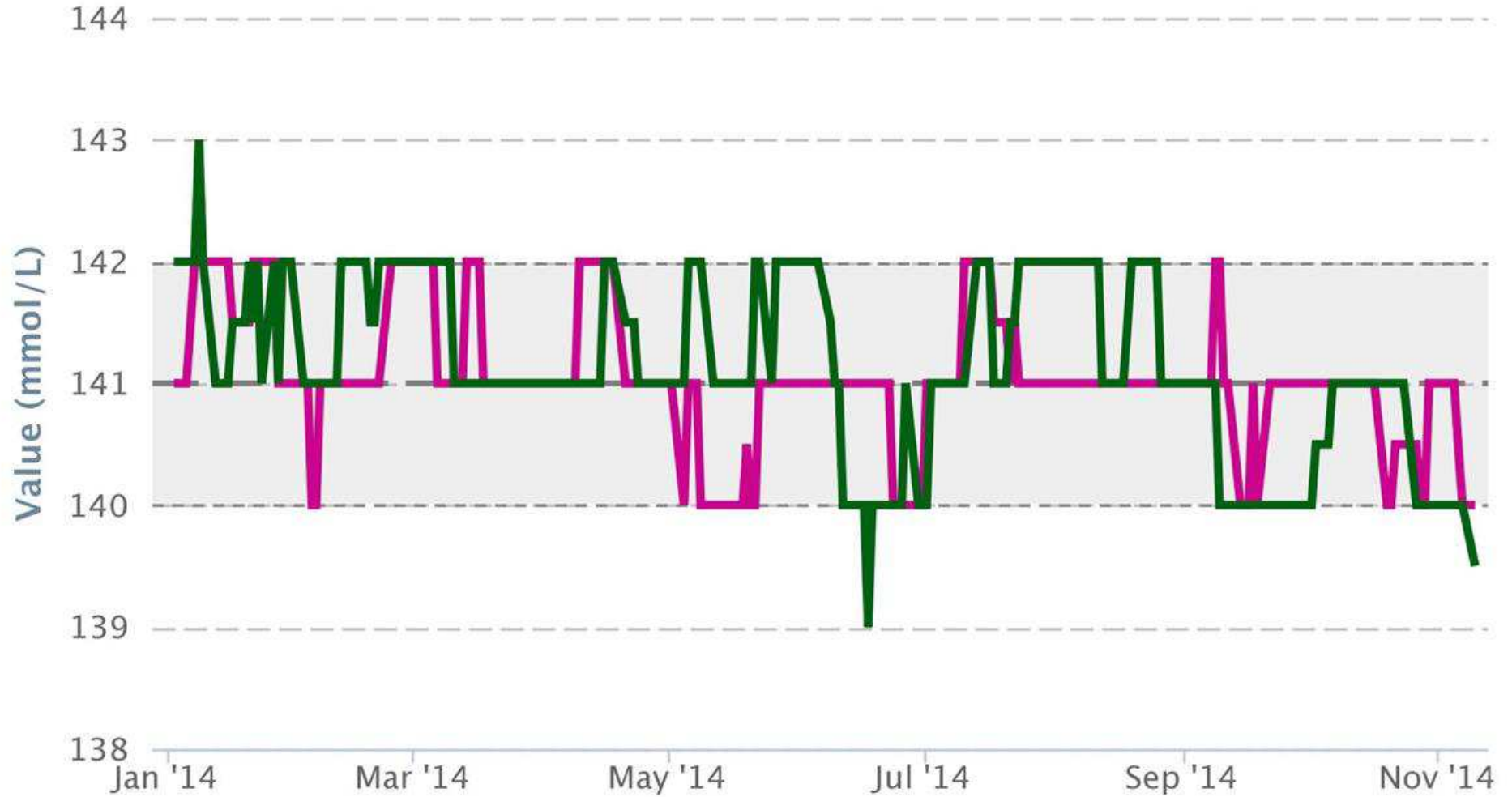
Examples

LDH

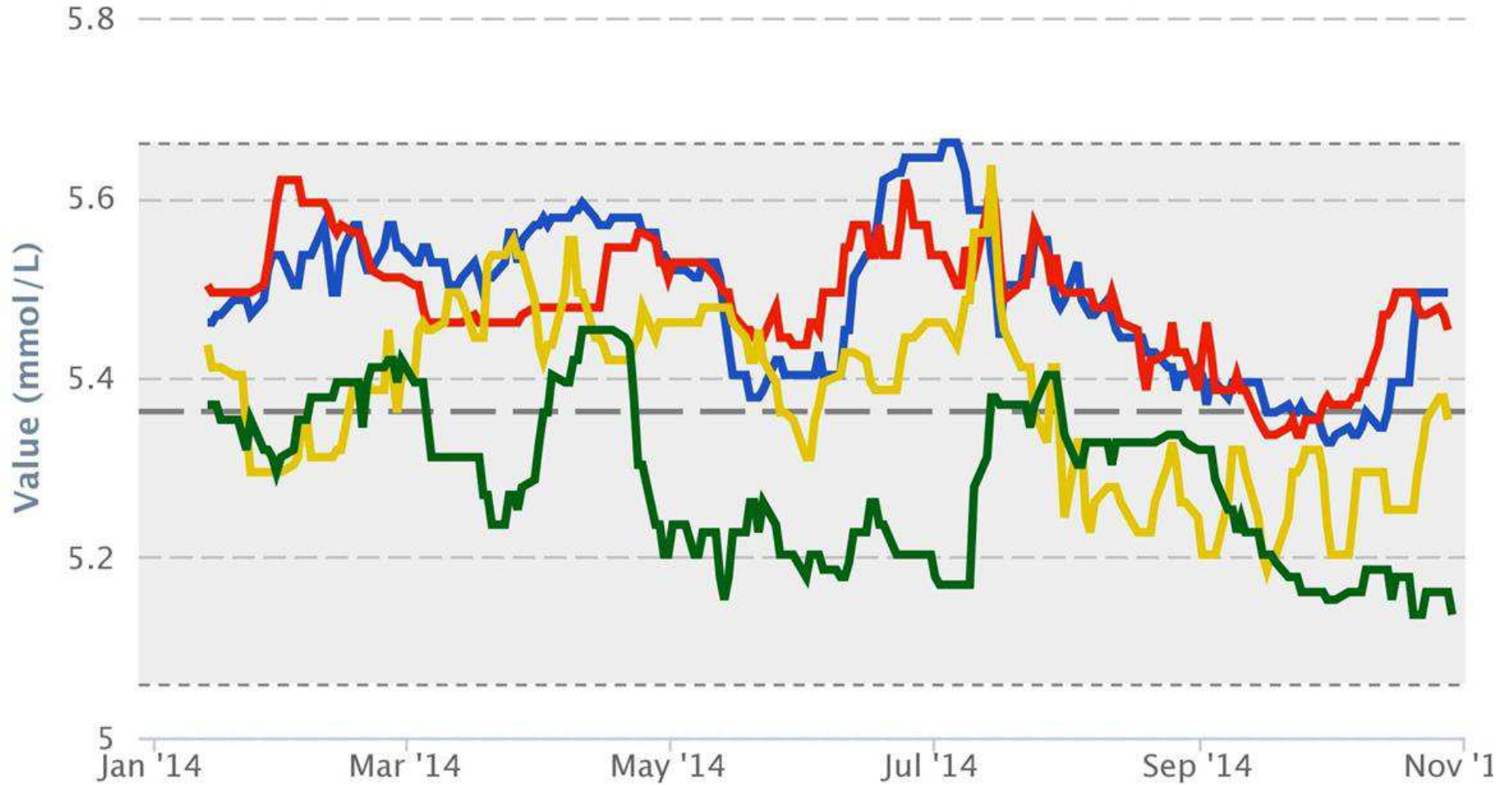# Examples
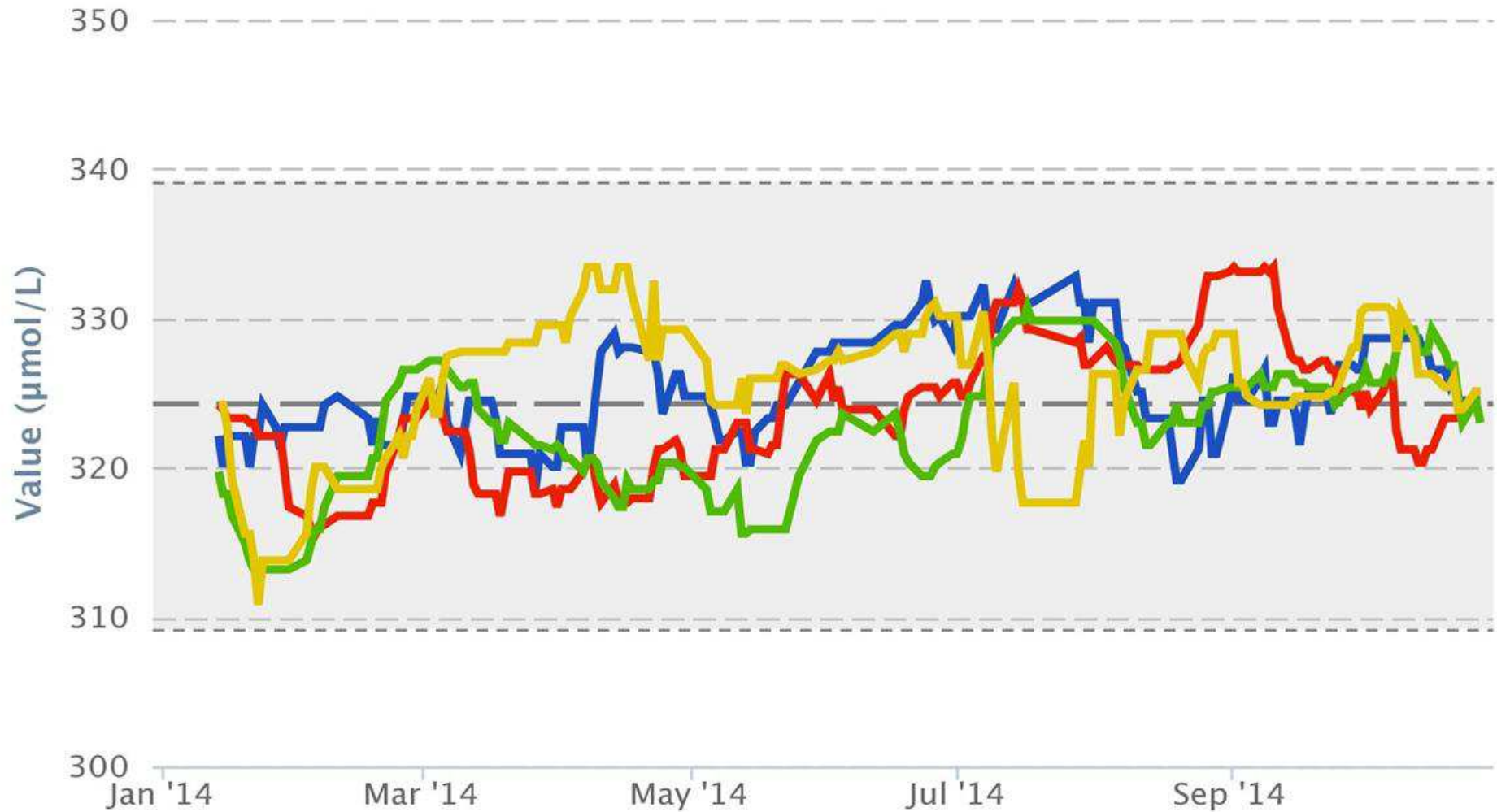

Magnesium

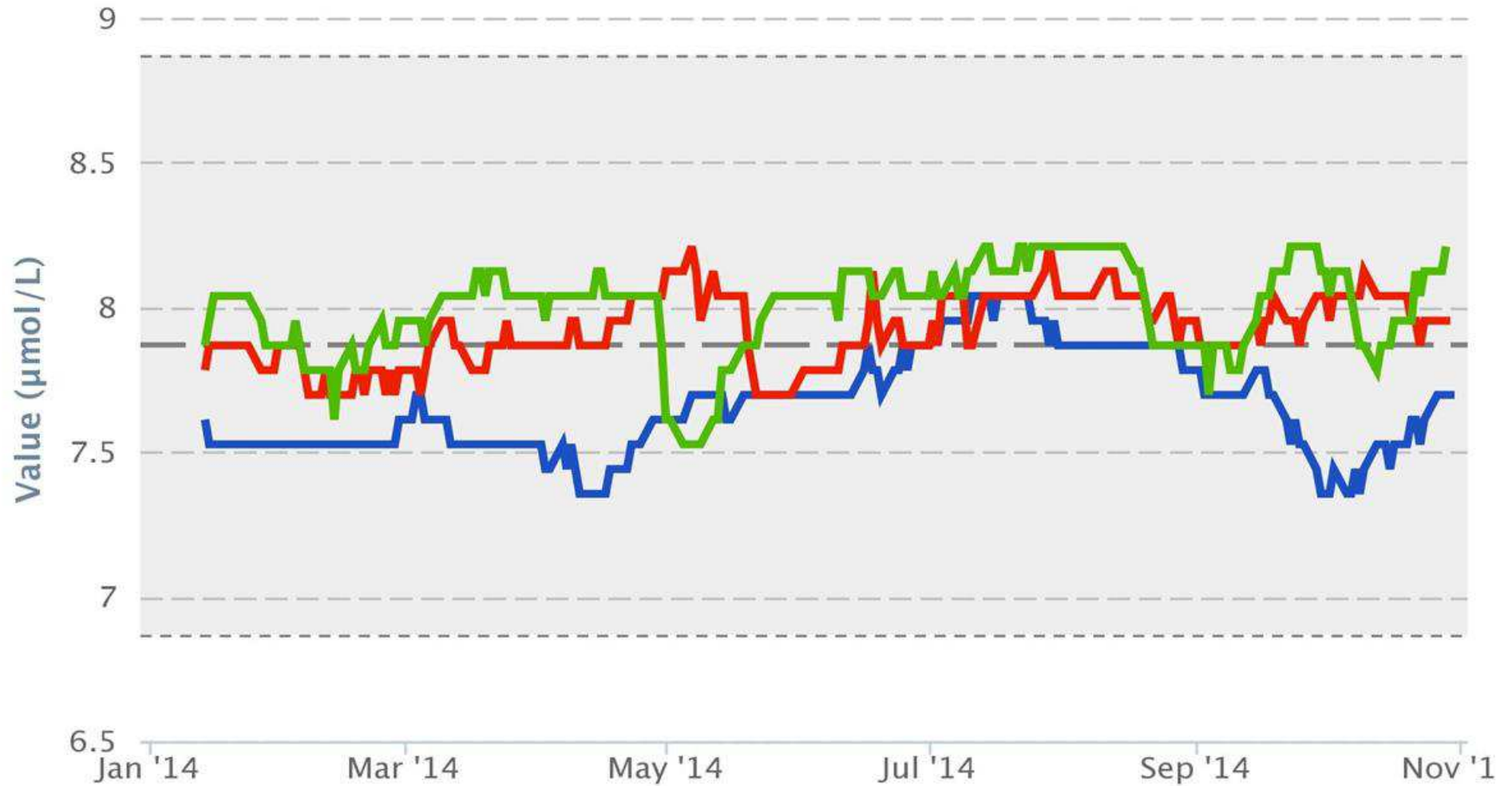# Examples

Potassium

Examples

Sodium

Examples

Urea

Examples

Uric acid
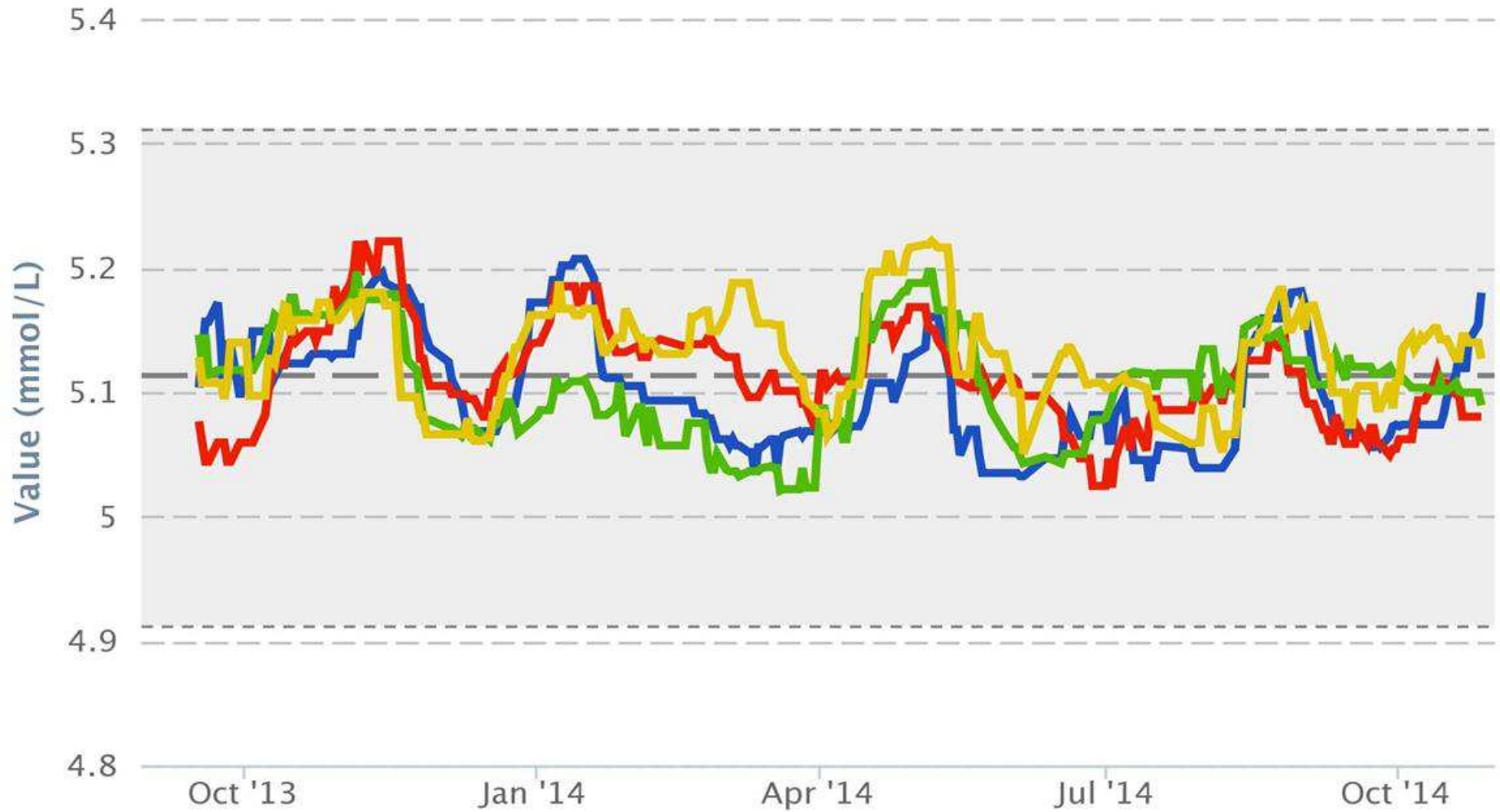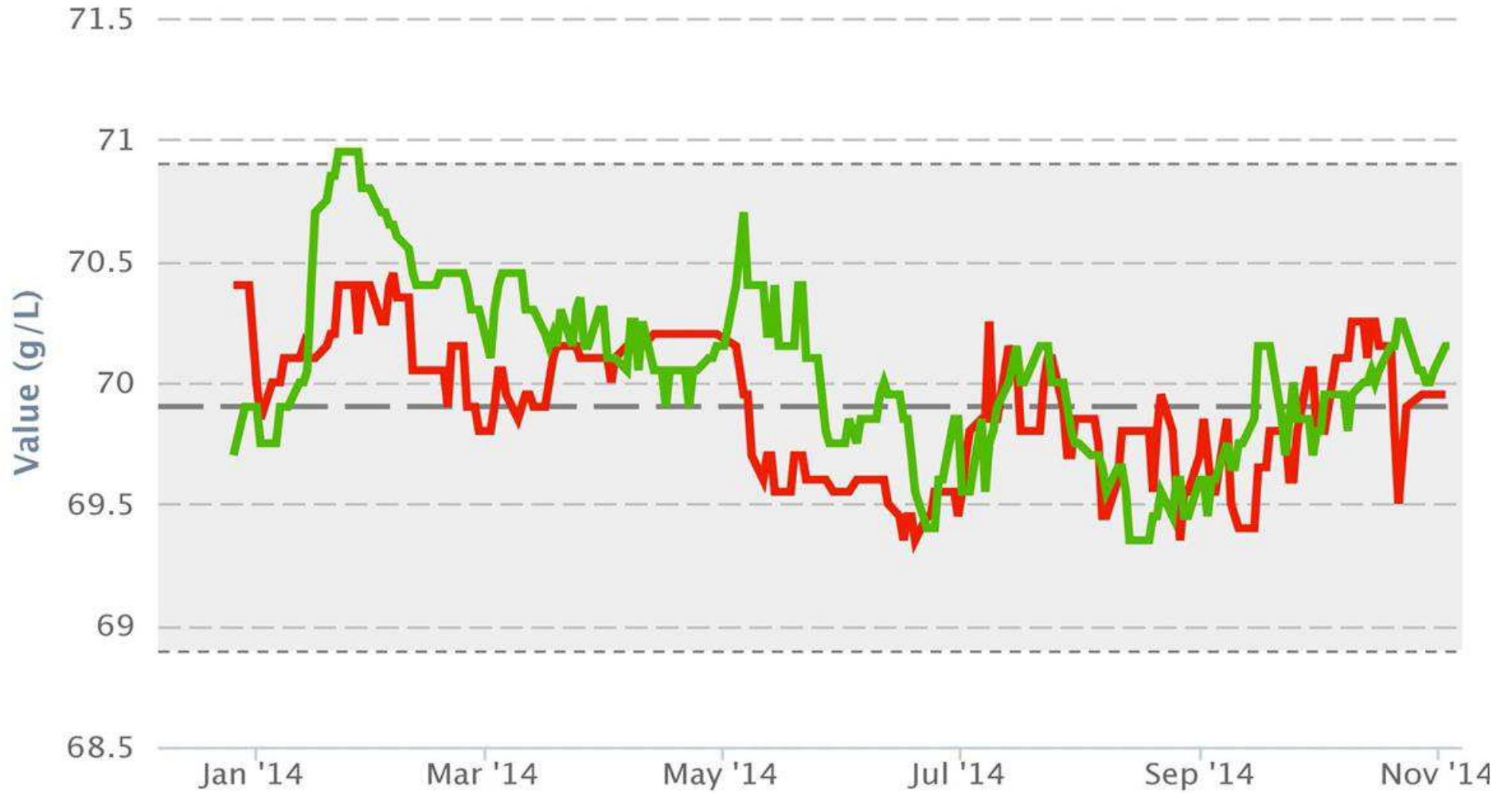
Examples

total-Bilirubin

Examples

total–Cholesterol

Examples

total-Protein

Benefits

Patient percentile (flagging) **monitoring**

- **Gives evidence about stability of performance & the reasons for assay variation (manufacturer, lot-to-lot, calibration, instrument)**

- **Enables monitoring the effect of instability on "surrogate" medical decisions ("flagging" frequency)**

- **Strengthens the laboratory/manufacturer dialogue**

- **Strengthens the physician/laboratory interface by more transparent communication on performance**

- **Helps with establishment of realistic quality goals**

- **Provides basis for comparison across manufacturers**

For the benefit of the patient

Last not least

Promotion of lab-to-lab communication

We promote the exchange of samples between "The Percentiler" laboratories when laboratory biases are suspected.

Promotion of laboratory/peer group-to-manufacturer communication

Peer group observations have been shared with peer group laboratories and the respective manufacturer.

For the benefit of the patient

Project highlights

- Long observation times
- "Deep" information
- Reliable peer groups
- Excellent manufacturer contact
- Experienced, highly responsive "Empower Team"
- Samples are "as commutable as they can be!"
- Realistic, but meaningful limits

Timelines

- **Individual laboratories can join on a continuous basis: free-of-charge**

- **Regular reports: since March 2014 (`www.stt-consulting.com`)**

- **Future structure is open!**

```
In development:
Monitor the "flagging" rate ("The Flagger")
```

Thanks

- **The Percentiler Laboratories**

- **Belgian representatives (& headquarters) of Abbott, Beckman/Analis, Ortho, Roche, Siemens**

- **LIS companies**

- **Belgian Society for Clinical Chemistry**

- **Laboratory of Analytical Chemistry (Gent)**

- **Filip Migom (MIPS) & Tom Fiers (Gent University Hospital)**

- **Bruno Neckebroek (IT)**

- **The "Unknown Soldiers"**