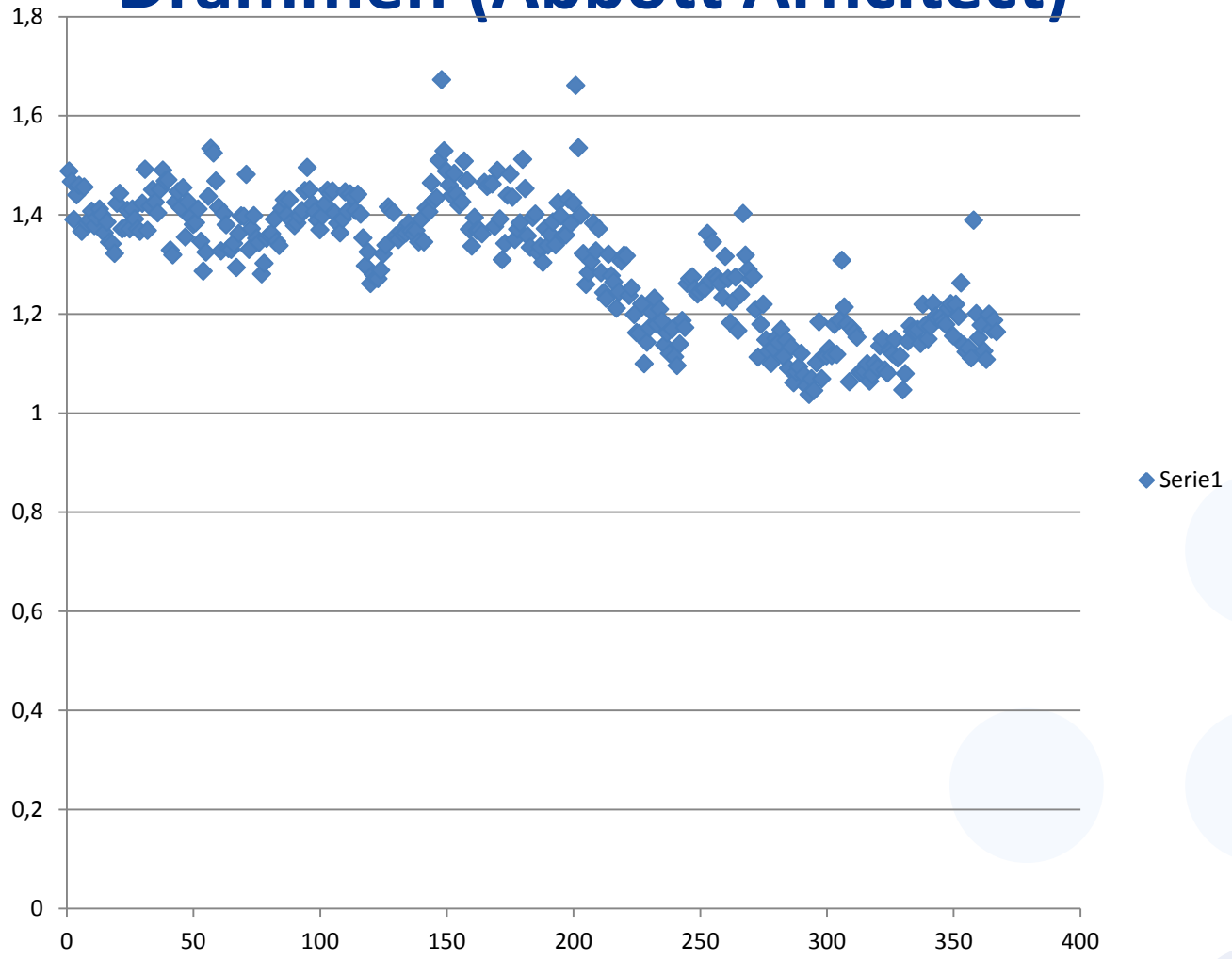
VESTRE VIKEN

Fall i TSH

Trine Lauritzen, overlege MBK VVHF
/Øyvind Skadberg, Avdoverlege SUS

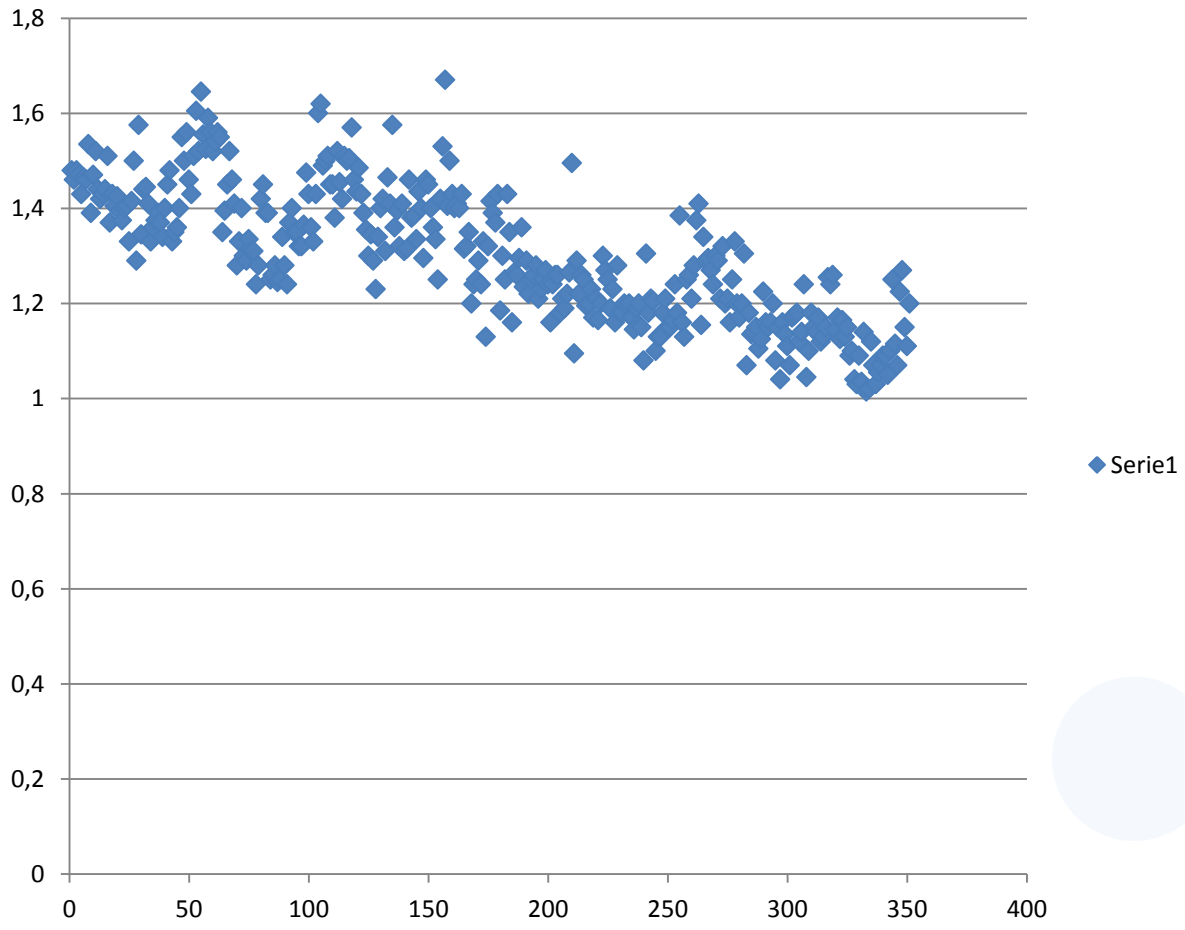
VESTRE VIKEN

Median (pasient) pr uke fra 1/1-2011 til dd – Drammen (Abbott Arhcitect)



VESTRE VIKEN

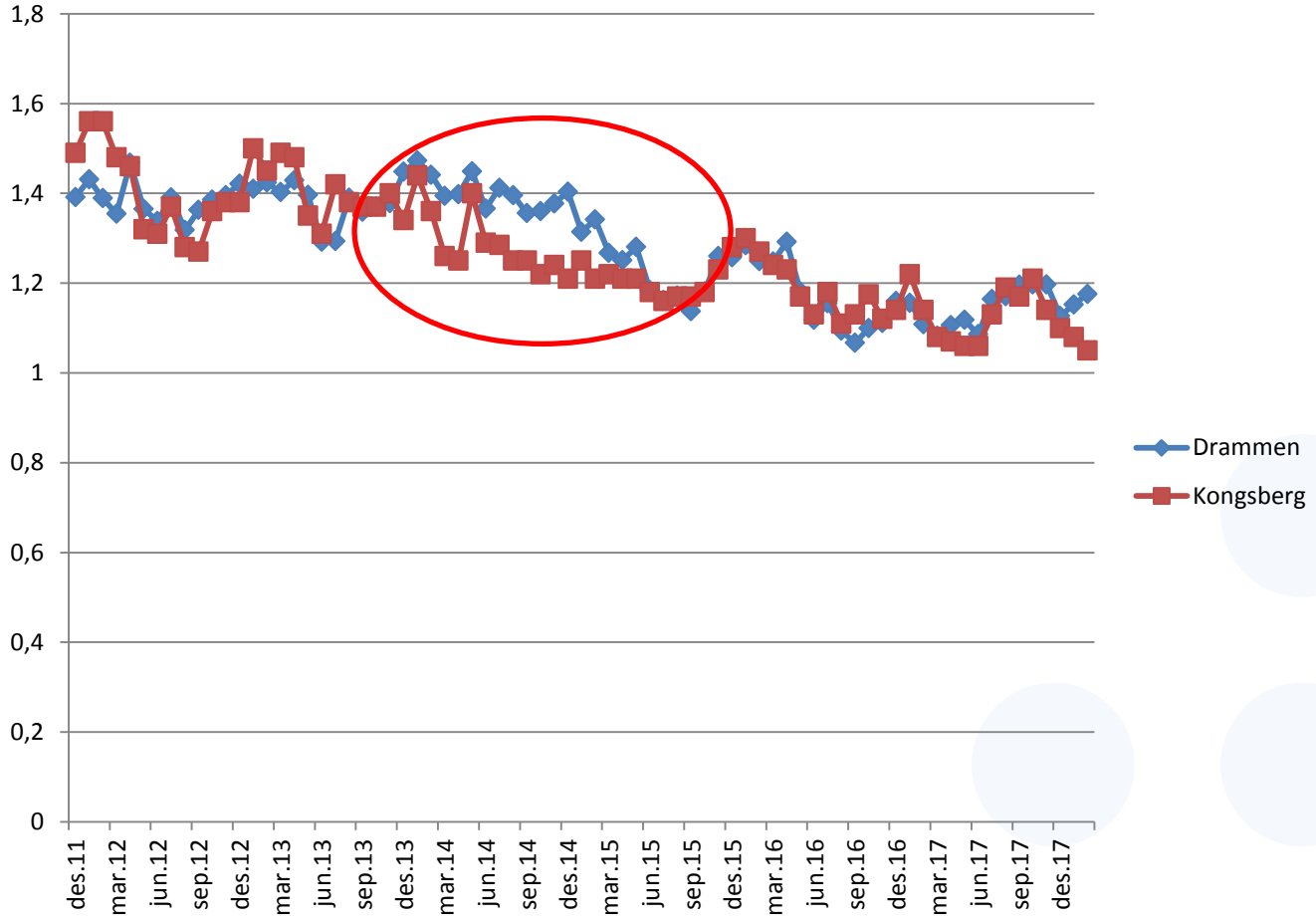
Median pr uke fra 1/1-2011 til dd -Kongsberg



- Abbott Architect
- 1/3 så mange resultater som Drammen

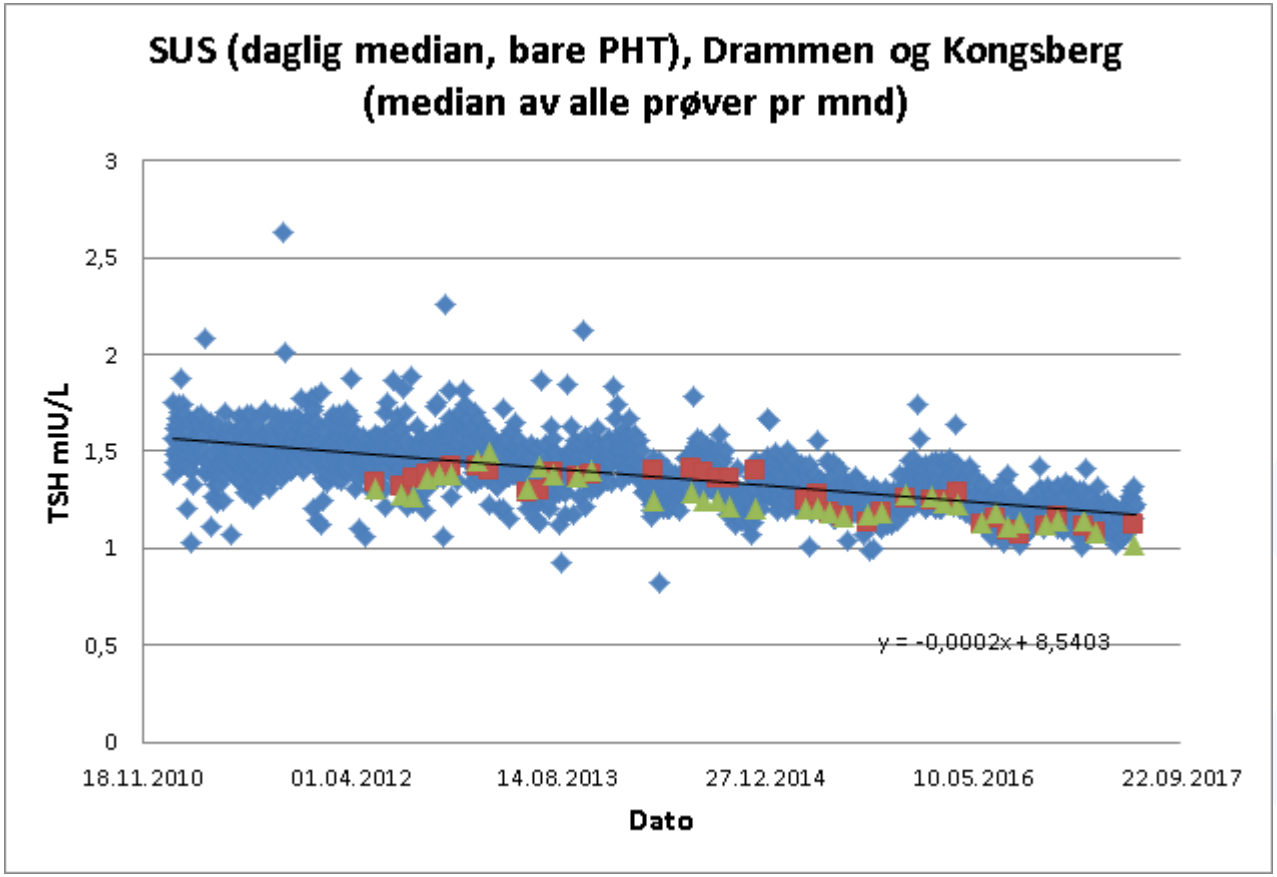
VESTRE VIKEN

Median pr mnd



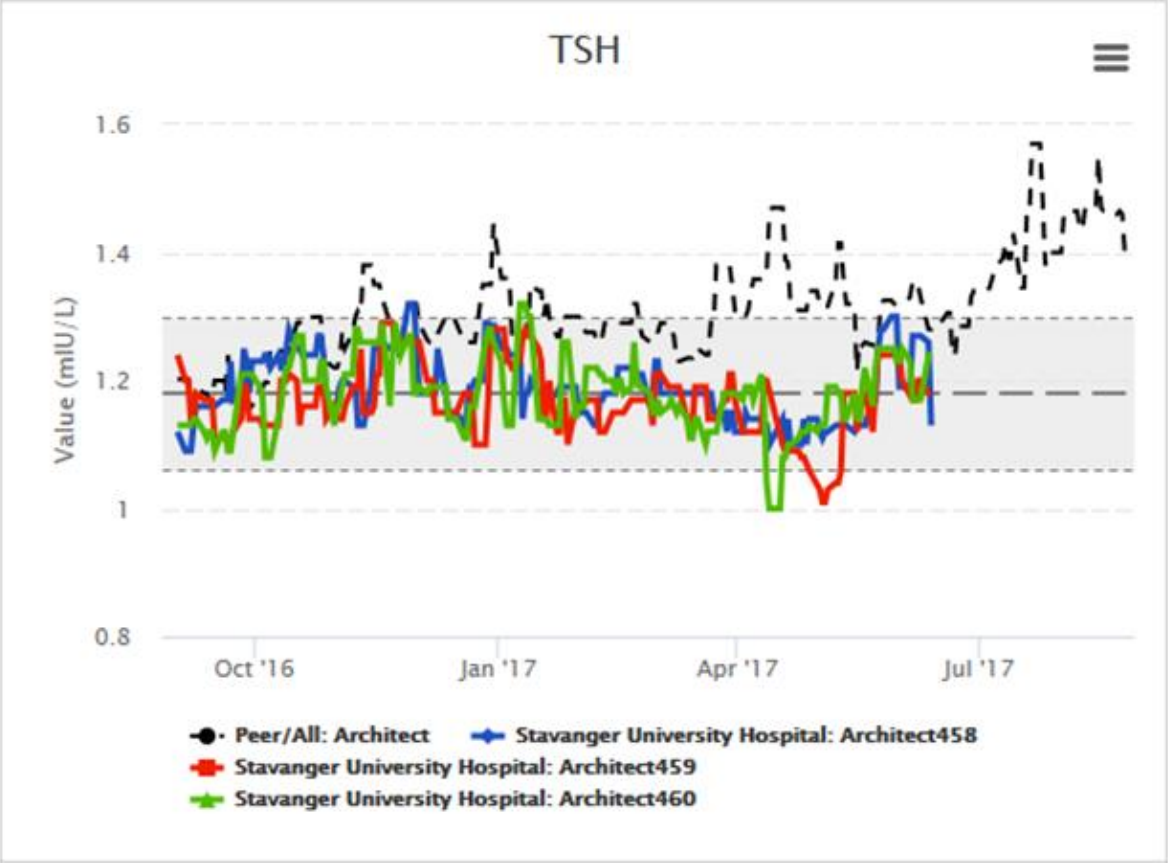
VESTRE VIKEN

Samme trend i Stavanger



VESTRE VIKEN

«Percentiler»



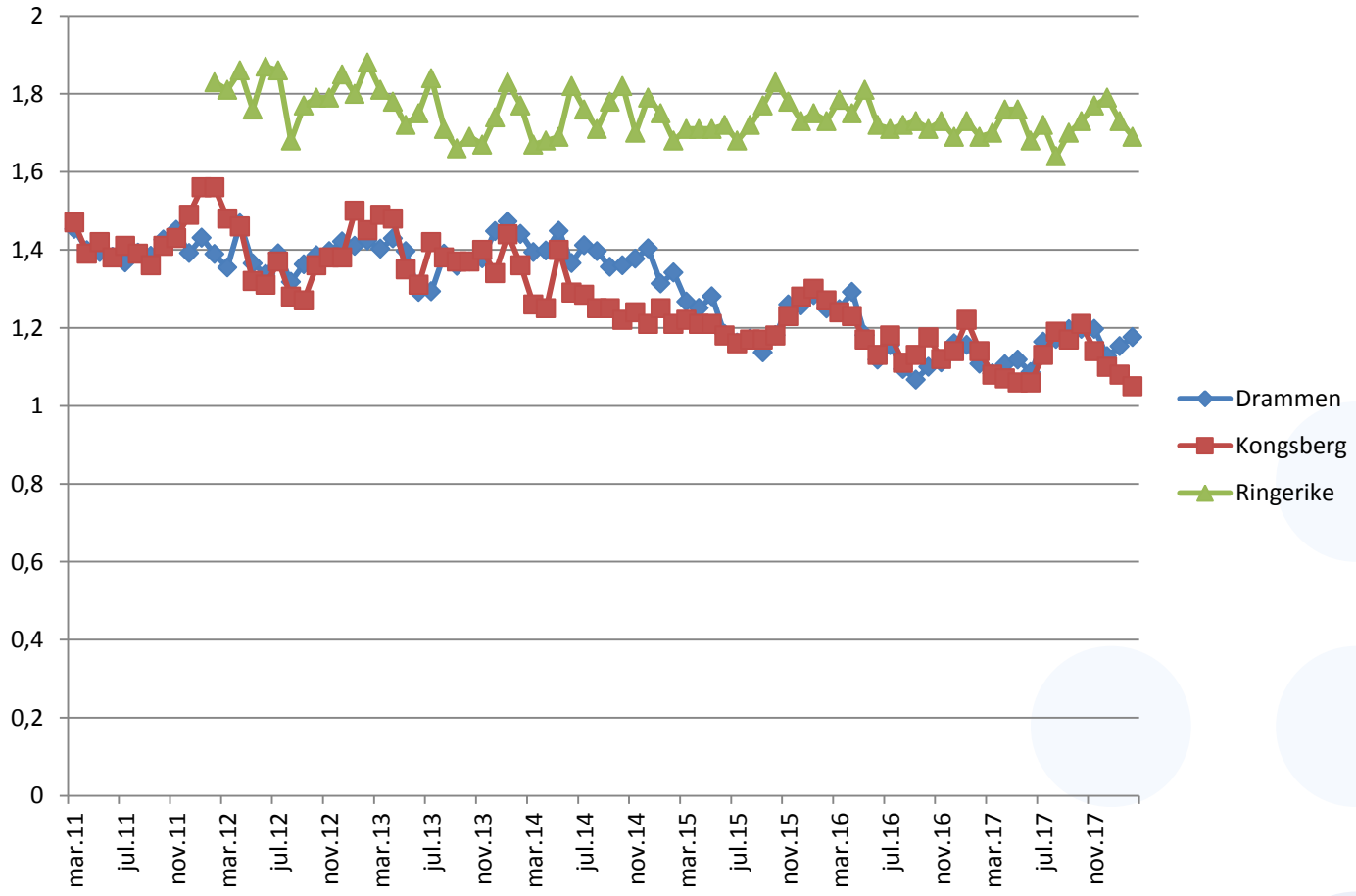
	Value	Bias (%)	Robust CV(%)
Range: all			
Your	1.18	-5.5	7.5
Peer/All	1.25	-19.9	17.0
Target	1.56	7.7	NA
Range: period			
Your	1.18	-5.5	7.5
Peer/All	1.25	-19.9	17.0
Target	1.56	7.7	NA

To mulige forklaringer..

- Analyserelatert?
- Pasientrelatert?…. har klinikerne begynt å foreskrive mer Levaxin?

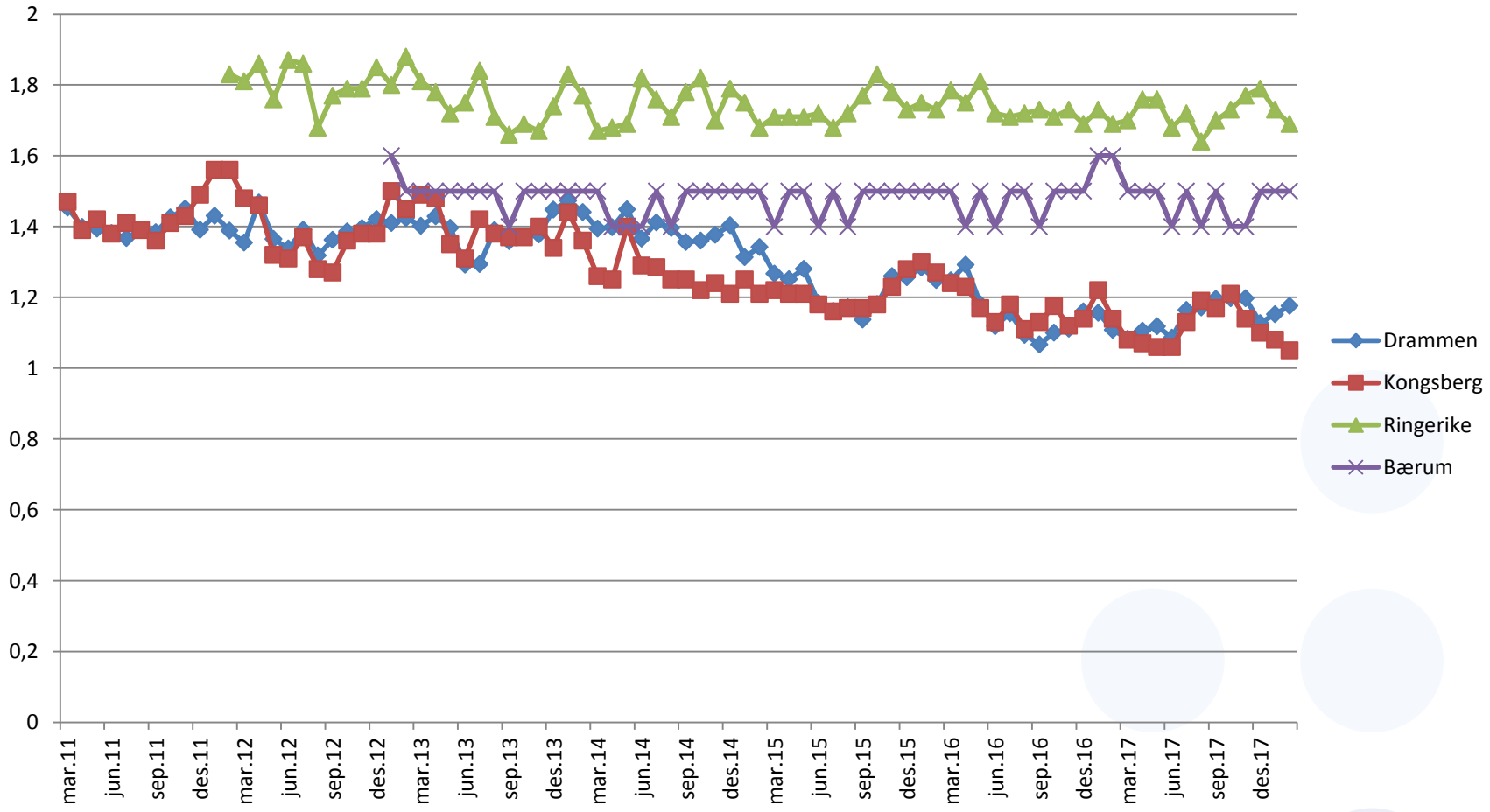
VESTRE VIKEN

Med Roche…



VESTRE VIKEN

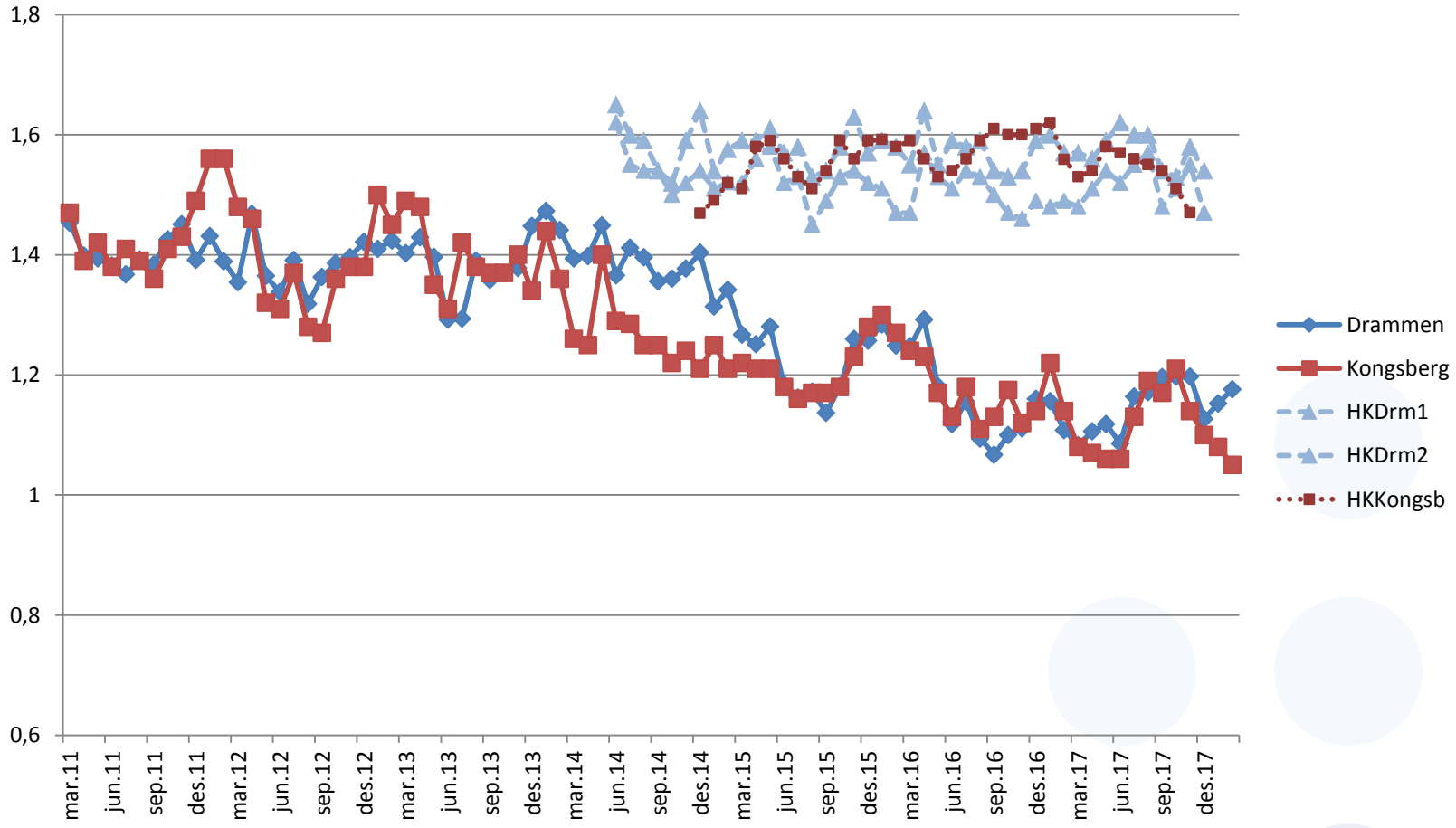
…og Siemens…



- Klinikerne/Roche og Siemens oppfører seg som før
- Må være noe Abbottrelatert..
  - ..men hva?

VESTRE VIKEN

Ekstern kvalitetskontroll -HK12/DEKS
Ingen fall

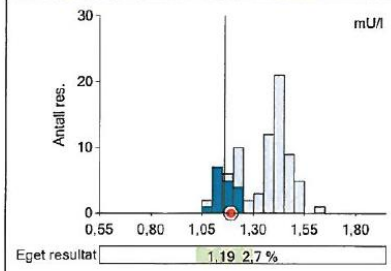


VESTRE VIKEN

Labquality

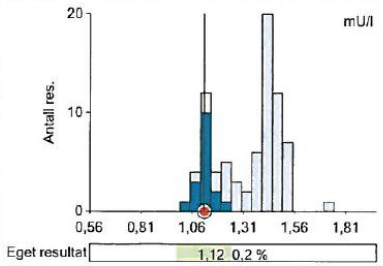
LABQUALITY — Sample 1 - Serum B, Sample 2 - Serum C — Medisinsk biokjemi, 2 nivå 2013/1 — Lab nr. 02659 — Side: 15(16)

TSH	Architect ci8200	Abbott	Abbott Architect
0033	007	14	544



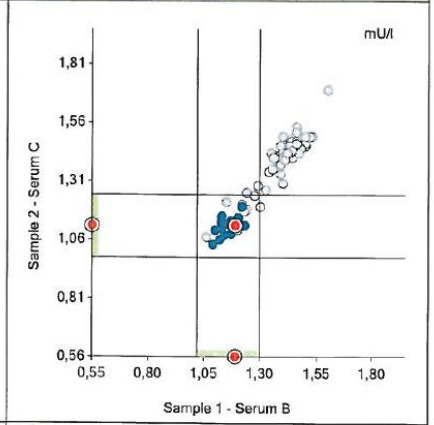
Sample 1 - Serum B
Target (X): 1,16 mU/l
Grenser (X ± 12%): 1,02 - 1,30 mU/l

	x	s	SEM	CV%	n
Egen metode	1,159	0,048	0,012	4,1	17
Alle	1,339	0,142	0,016	10,6	78



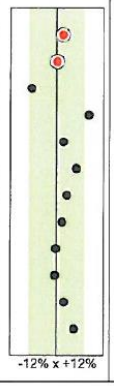
Sample 2 - Serum C
Target (X): 1,12 mU/l
Grenser (X ± 12%): 0,98 - 1,25 mU/l

	x	s	SEM	CV%	n
Egen metode	1,118	0,036	0,009	3,2	17
Alle	1,332	0,171	0,019	12,8	78

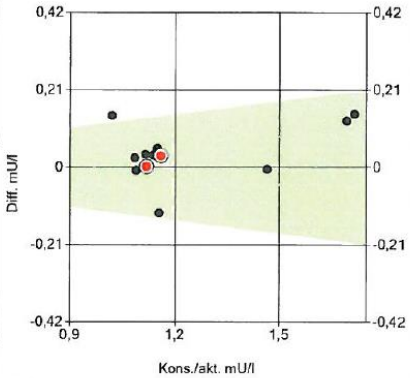


Historikk: Avvik i %

Utsend	Prøve	X	res.	Diff%	z
13/01	DeB 14	1,16	1,19	2,7	0,7
13/01	SeD 14	1,12	1,12	0,2	0,1
12/06	DeB 14	1,15	1,03	-10,7	-3,2
12/06	SeC 14	1,02	1,16	13,8	4,9
12/04	DeB 14	1,14	1,17	2,9	1,0
12/04	SeE 14	1,72	1,86	8,4	2,4
12/03	DeB 14	1,15	1,20	4,5	1,0
12/03	SeA 14	1,08	1,11	2,4	0,6
12/01	DeC 14	1,47	1,46	-0,3	-0,1
12/01	SeA 14	1,09	1,08	-0,7	-0,2
11/04	DeB 14	1,11	1,15	3,2	0,5
11/04	SeB 14	1,69	1,82	7,5	1,3



Historikk: Avvik i kons./akt. enheter

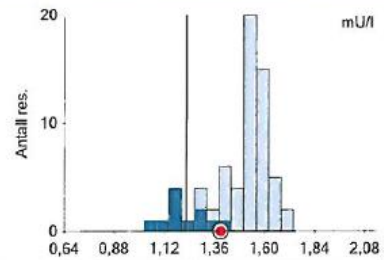


Kommentar

Når target er egen metodes mean kan det være vanskeligere å oppdage at hele metoden drifter.

VESTRE VIKEN

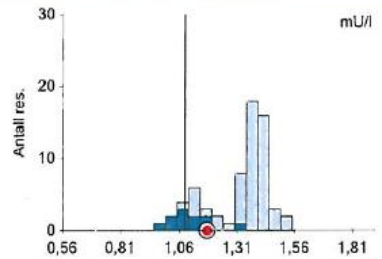
TSH 0033	Architect ci8200 015	Abbott 14	Abbott Architect 544



Eget resultat 1,39 13,5 %

Sample 1 - Serum B
Target (X): 1,22 mU/l
Grenser (X ± 12%): 1,08 - 1,37 mU/l

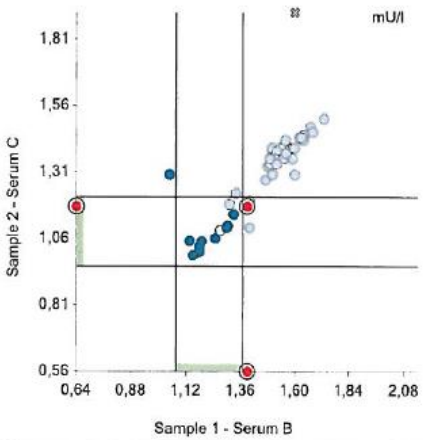
	x	s	SEM	CV%	n
Egen metode	1,225	0,112	0,034	9,1	11
Alle	1,494	0,129	0,016	8,6	66



Eget resultat 1,18 8,7 %

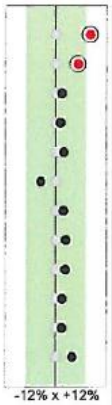
Sample 2 - Serum C
Target (X): 1,09 mU/l
Grenser (X ± 12%): 0,96 - 1,22 mU/l

	x	s	SEM	CV%	n
Egen metode	1,085	0,078	0,023	7,2	11
Alle	1,317	0,145	0,018	11,0	67

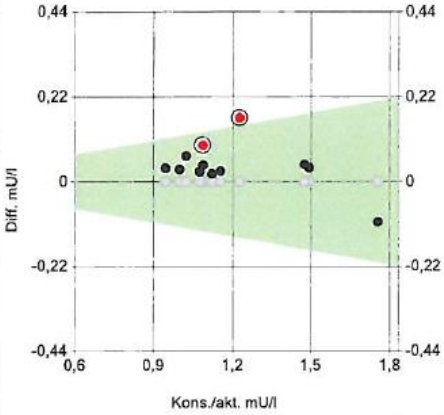


Historikk: Avvik i %

Utsend	Prøve	X	res.	Diff%	z
14/06	DeJ 14	1,22	1,39	13,5	1,5
14/06	SeA 14	1,09	1,18	8,7	1,2
14/04	DeI 14	1,49	1,53	2,5	0,6
14/04	SeA 14	1,12	1,14	1,8	0,5
14/03	DeH 14	1,00	1,03	3,2	1,2
14/03	SeB 14	1,75	1,65	-6,0	-0,9
14/01	DeI 14	1,48	1,52	3,0	0,6
14/01	SeA 14	1,09	1,13	4,0	0,9
13/06	DeH 14	0,94	0,98	3,7	1,0
13/06	SeA 14	1,07	1,10	2,4	0,7
13/04	DeB 14	1,15	1,18	2,4	0,5
13/04	SeC 14	1,02	1,09	6,5	1,6



Historikk: Avvik i kons./akt. enheter



Kommentar

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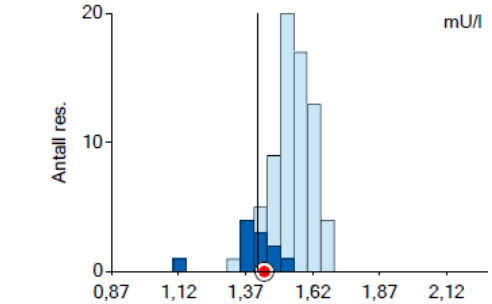
5.12.2014 © Labquality 2014

VESTRE VIKEN

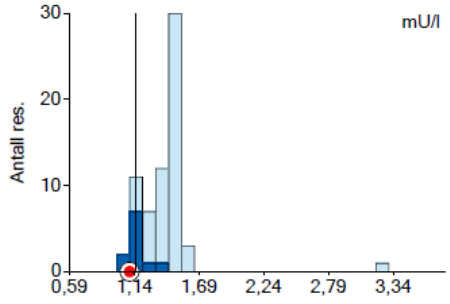
TSH	Architect ci8200	Abbott	Abbott Architect
0033	015	14	544



Eget resultat 1,44 1,8 %

Sample 1 - Serum B
Target (X): 1,41 mU/l
Grenser (X ± 12%): 1,25 - 1,58 mU/l

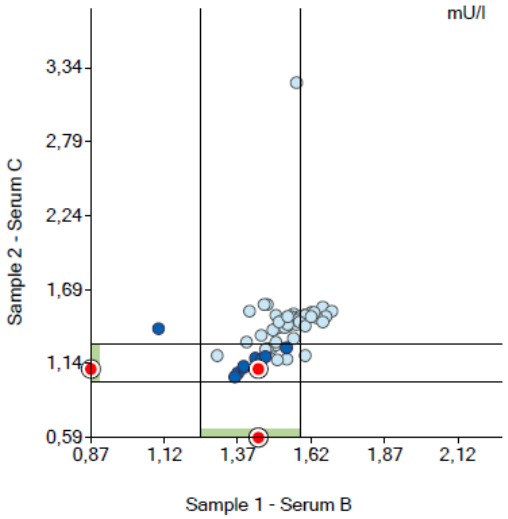
	x	s	SEM	CV%	n
Egen metode	1,415	0,059	0,018	4,2	11
Alle	1,536	0,076	0,009	5,0	73



Eget resultat 1,10 -4,1 %

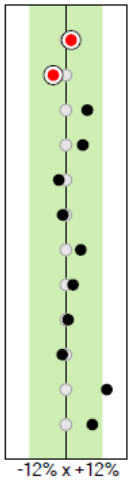
Sample 2 - Serum C
Target (X): 1,15 mU/l
Grenser (X ± 12%): 1,01 - 1,29 mU/l

	x	s	SEM	CV%	n
Egen metode	1,148	0,084	0,025	7,3	11
Alle	1,401	0,137	0,016	9,8	73

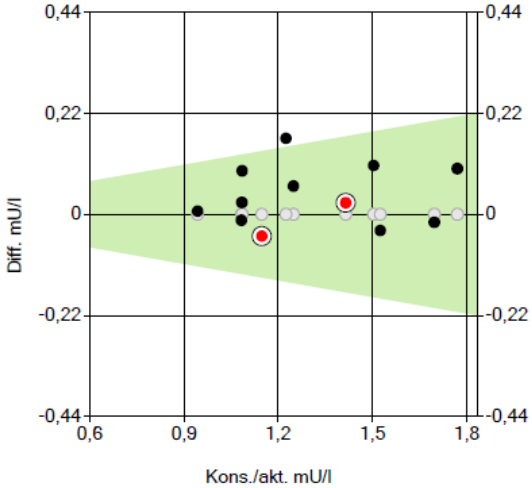


Historikk: Avvik i %

Utsend	Prøve	X	res.	Diff%	z
16/01	DeL 14	1,41	1,44	1,8	0,4
16/01	SeG 14	1,15	1,10	-4,1	-0,6
15/06	DeK 14	1,50	1,61	7,1	1,4
15/06	SeH 14	1,77	1,87	5,6	1,2
15/04	DeK 14	1,53	1,49	-2,3	-0,5
15/04	SeB 14	1,70	1,68	-1,0	-0,2
15/03	DeJ 14	1,25	1,31	4,9	1,1
15/03	SeA 14	1,08	1,11	2,4	0,5
15/01	DeH 14	0,94	0,95	0,7	0,1
15/01	SeA 14	1,08	1,07	-1,2	-0,2
14/06	DeJ 14	1,22	1,39	13,5	1,5
14/06	SeA 14	1,09	1,18	8,7	1,2



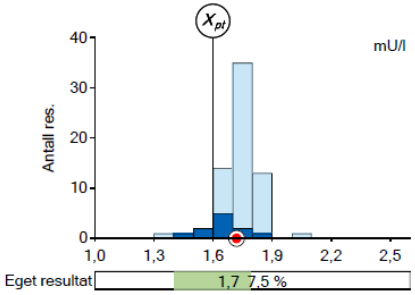
Historikk: Avvik i kons./akt. enheter



Kommentar

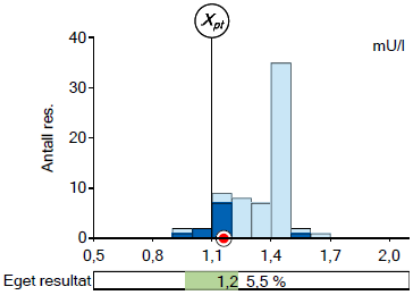
VESTRE VIKEN

TSH	Architect ci8200	Abbott	Abbott Architect
0033	015	14	544



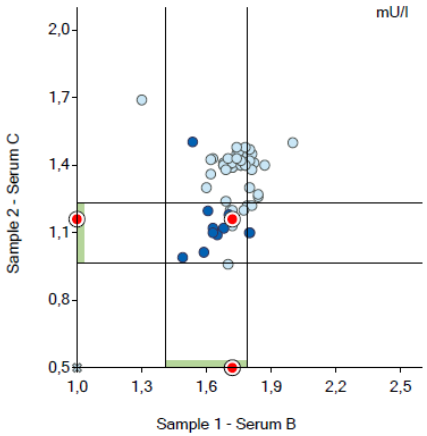
Sample 1 - Serum B
Target (X): 1,6 mU/l, X_{pt}
Grenser (X ± 12%): 1,4 - 1,8 mU/l

	x	s	SEM	CV%	n
Egen metode	1,64	0,09	0,03	5,3	11
Alle	1,73	0,07	0,01	4,2	66



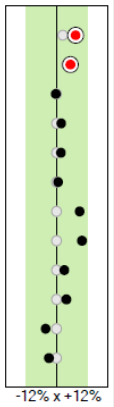
Sample 2 - Serum C
Target (X): 1,1 mU/l, X_{pt}
Grenser (X ± 12%): 1,0 - 1,2 mU/l

	x	s	SEM	CV%	n
Egen metode	1,14	0,13	0,04	11,8	11
Alle	1,34	0,14	0,02	10,4	65

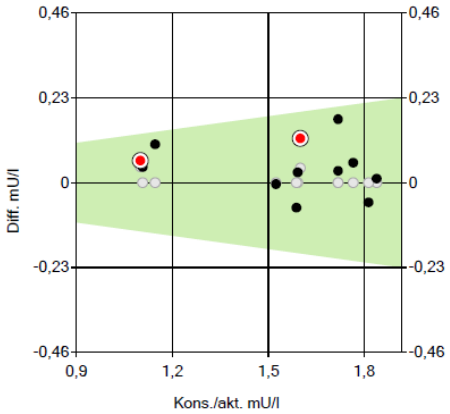


Historikk: Avvik i %

Utsend	Prøve	X	res.	Diff%	z
18/01	DeR 14	1,6	1,7	7,5	1,4
18/01	SeA 14	1,1	1,2	5,5	0,4
17/06	DeK 14	1,5	1,5	-0,3	-0,1
17/06	SeB 14	1,7	1,8	1,9	0,3
17/04	DeP 14	1,6	1,6	1,8	0,3
17/04	SeH 14	1,8	1,9	0,6	0,1
17/03	DeO 14	1,1	1,3	9,1	2,2
17/03	SeB 14	1,7	1,9	10,0	2,1
17/01	DeN 14	1,8	1,8	3,1	0,7
17/01	SeA 14	1,1	1,2	3,9	0,5
16/06	DeP 14	1,6	1,5	-4,3	-0,7
16/06	SeH 14	1,8	1,8	-2,9	-0,6
16/04	DeK 14	1,5	1,6	1,1	0,2



Historikk: Avvik i kons./akt. enheter



Kommentar

Sample 1 - Serum B, Egen metode:
The uncertainty of the assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to the small number of observations.

Sample 2 - Serum C, Egen metode:
The uncertainty of the assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to the small number of observations.

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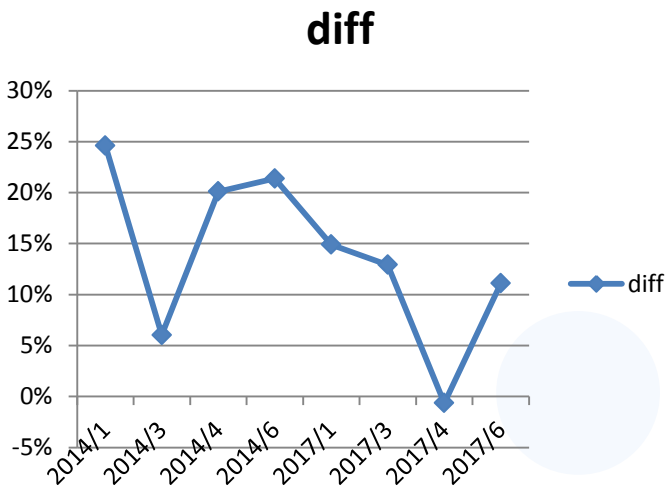
VESTRE VIKEN

Labquality numerisk oversikt Abbott vs Roche 2014 og 2017

	diff	Abbott	Roche
2014/1	25 %	1,087	1,442
2014/3	6 %	0,998	1,062
2014/4	20 %	1,12	1,402
2014/6	21 %	1,225	1,558
2017/1	15 %	1,759	2,067
2017/3	13 %	1,146	1,316
2017/4	-1 %	1,59	1,58
2017/6	11 %	1,52	1,71



Heller mindre forskjell mellom metodene enn mer.

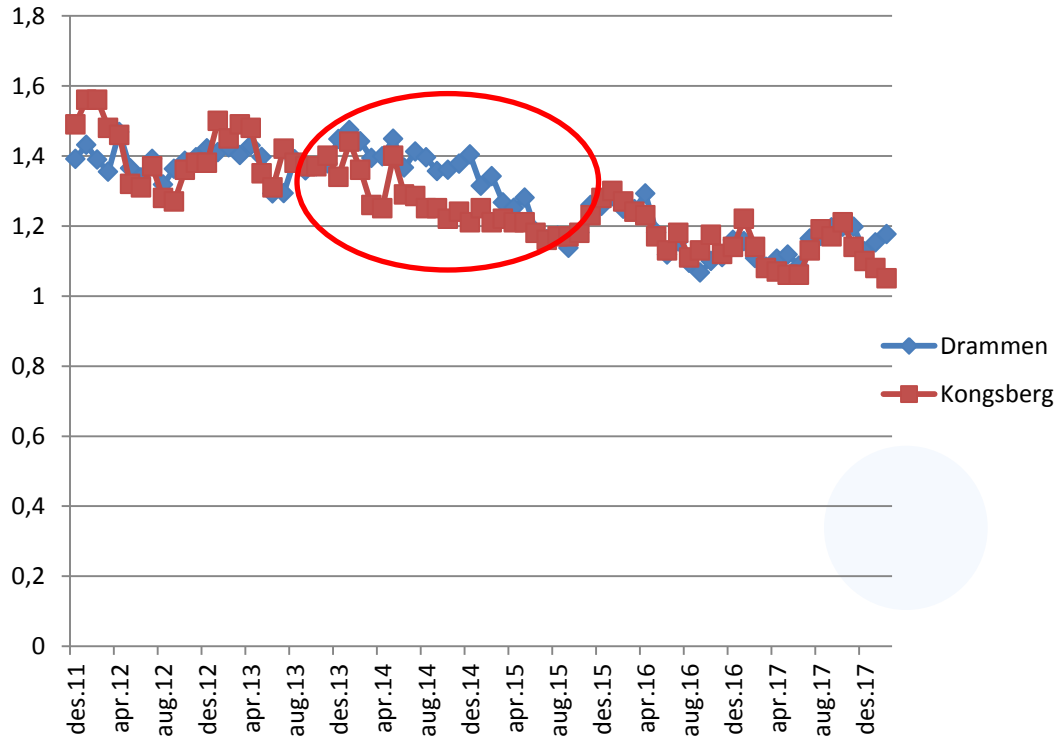
Med Abbott og «big data» på saken

- Stavanger og VestreViken i telefonmøter med Abbott:
- Alle Abbott-brukere i Norge ligger på samme lave nivå med median rundt 1,2 mU/L
- Resten av Europa (Abbottbrukere) ligger på ca 1,4mU/L

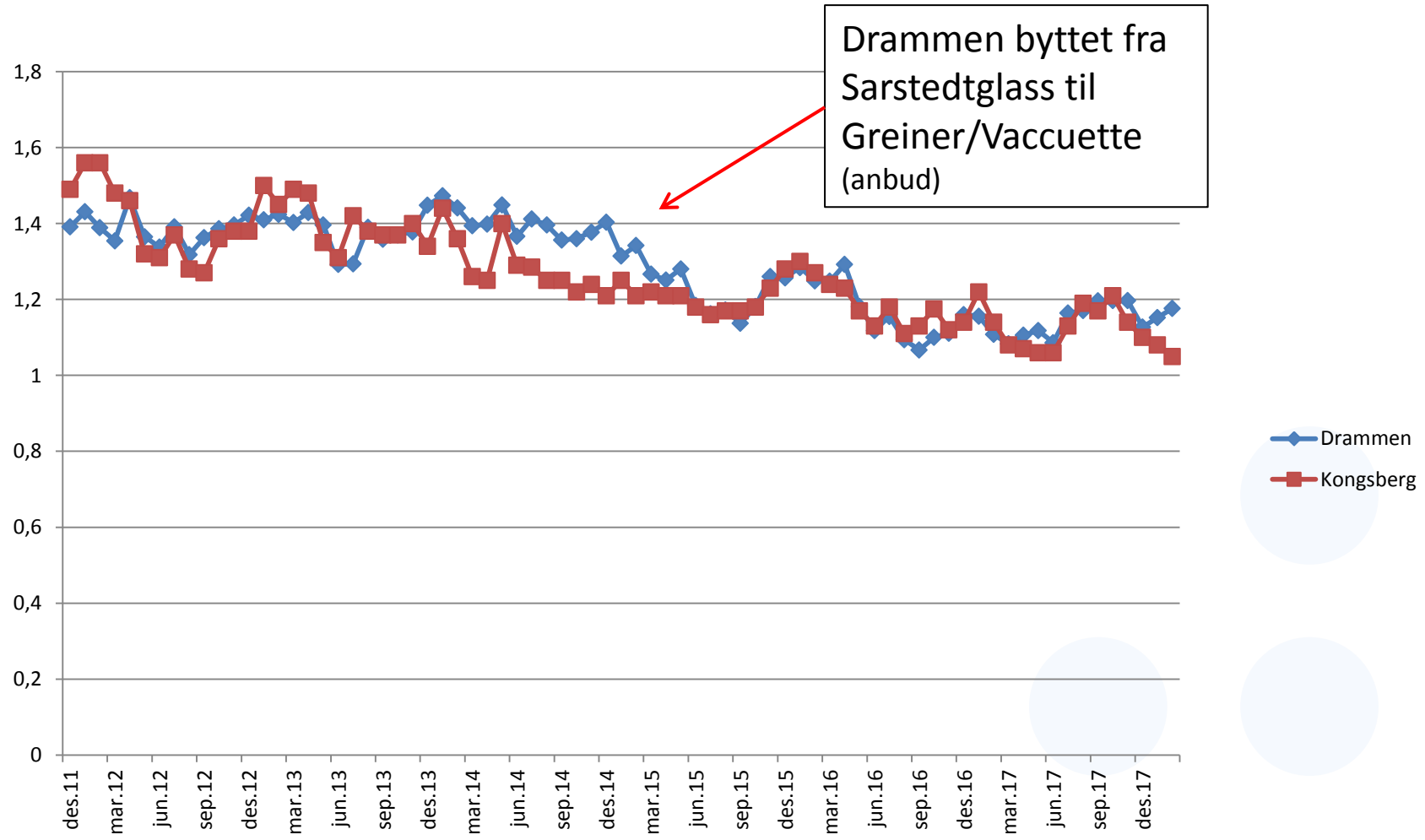
VESTRE VIKEN

Hva er forskjell på Norge og andre?

- Sannsynligvis noe annet enn reagensene
- Kan det være noe med prøveglassene??



VESTRE VIKEN



Mer Big-data fra Abbott

- Abbottkunder i Norge ligger lavere (pasientmedian) enn både Sverige og Danmark (som ikke bruker Vacuette)

VESTRE VIKEN

Tall fra Abbott

«German lab using Greiner tubes» ligger lavere (på pasientmedian) enn resten av Europa (som bruker lite Vacuette)

VESTRE VIKEN

Tall fra Abbott

Kunder i Norge vs Østerrike. De fleste kunder i Østerrike bruker også Greiner/Vacuette. Kurvene(pasientmedian) ligger ganske likt.

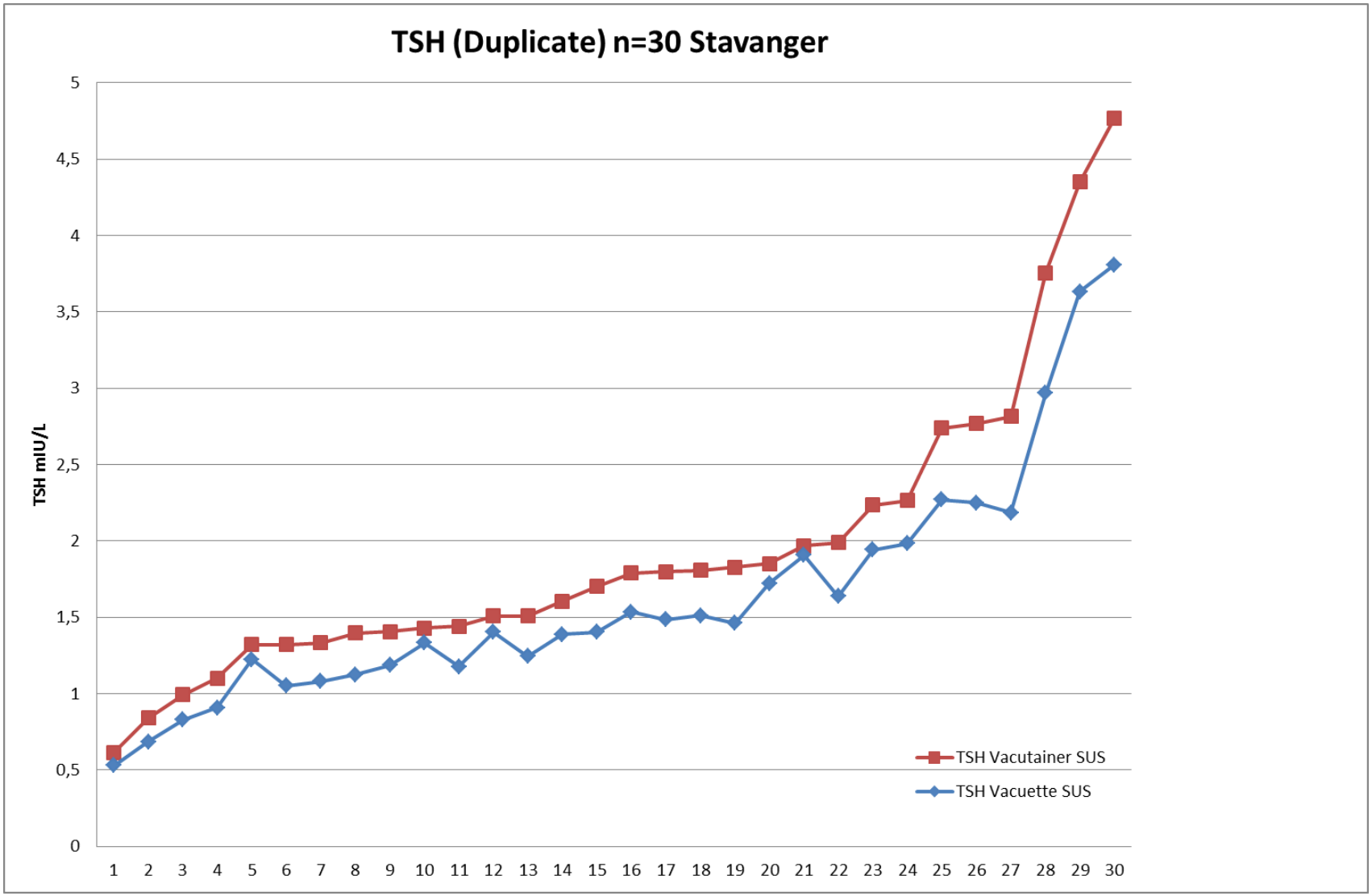
Teste ut hypotesen

- Frivillige ansatte på lab i Drammen og Stavanger donerte blod

VESTRE VIKEN

Drammen:
Serumglass m/gel
-Vacuette/Greiner
-Sarstedt
-BD Vaccutainer
Stavanger:
- Vacuette
- BDVaccutainer

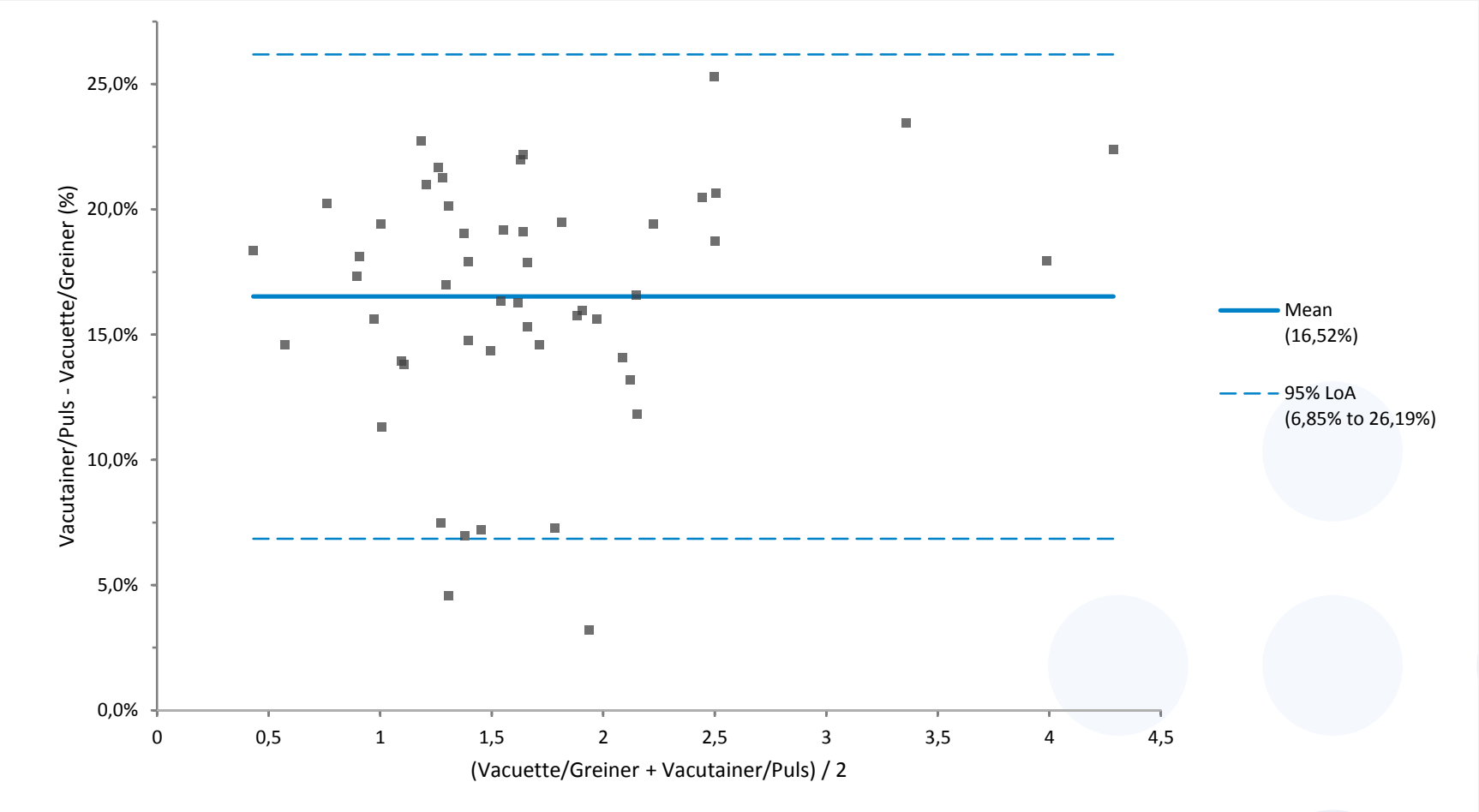
VESTRE VIKEN



VESTRE VIKEN

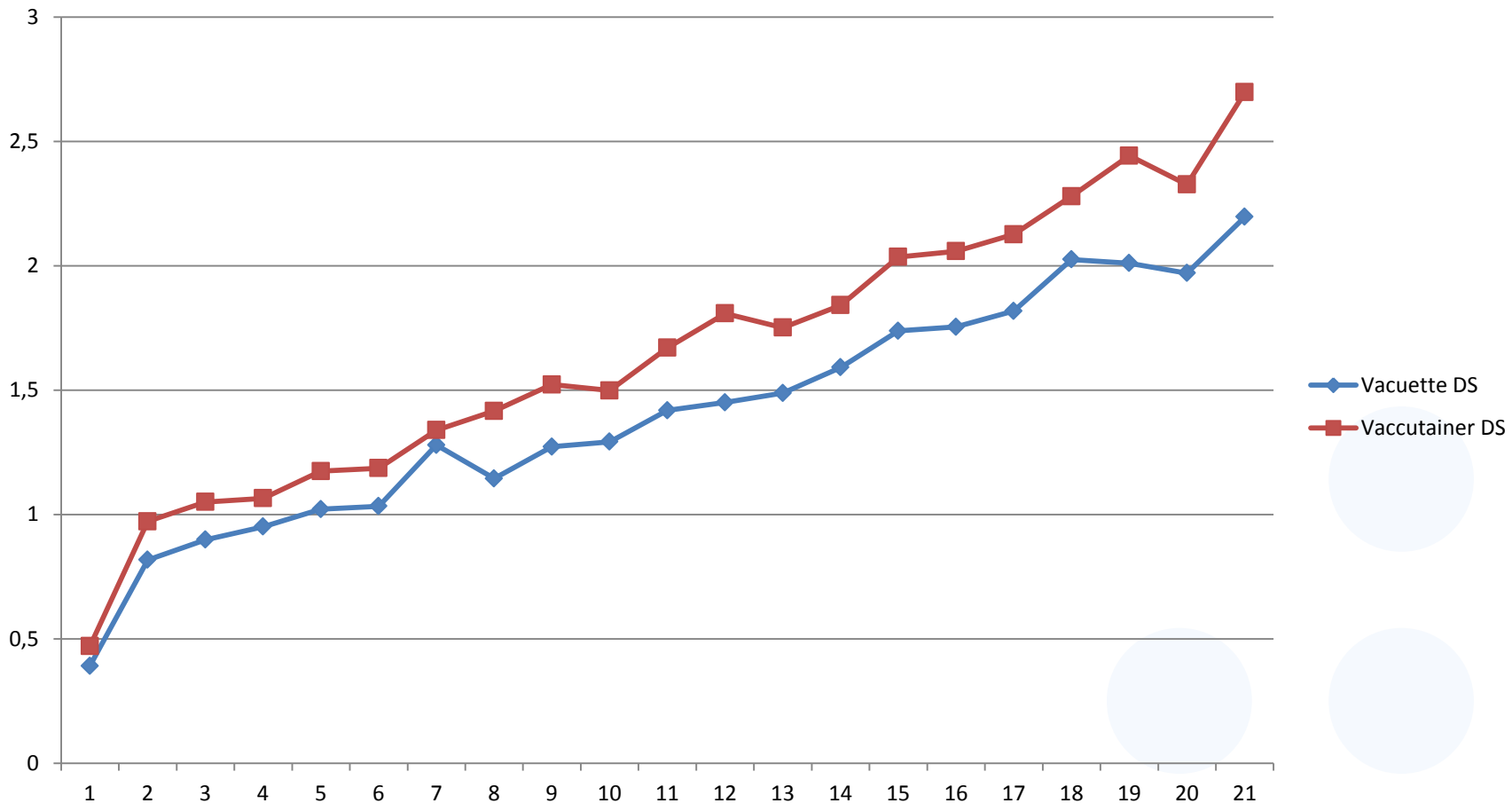
Differanseplot

Gjennomsnitt 16,5 forskjell%



VESTRE VIKEN

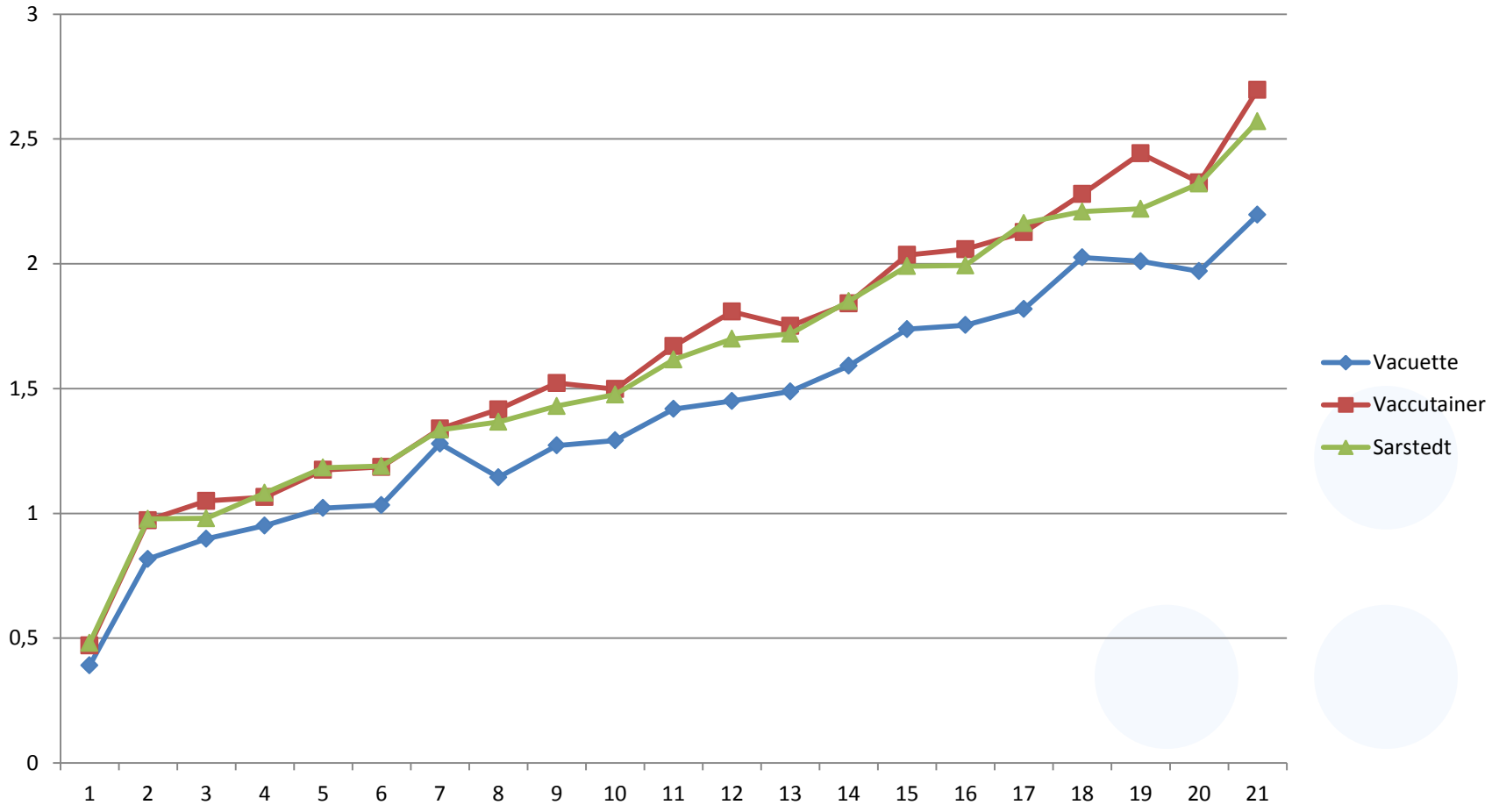
TSH Duplikat Drammen (n=21)



Gjennomsnitt 15% forskjell

VESTRE VIKEN

TSH sammenlignet 3 typer rør Drammen n=21



Klinisk betydning?

- Februar 2013:
  - 5,7% av resultatene stjernemerket høye
  - 7,9% av resultatene stjernemerket lave
  - (Populasjon ca 50-50 sykehus/PHT)
- Februar 2018:
  - 3,4% av resultatene stjernemerket høye
  - 10,2% av resultatene stjernemerket lave

Hva nå?

- Greiner (Vacuette) og Abbott ha møte/prosjekt seg i mellom
  - Finne årsak?
  - Greiner har byttet leverandør av gel (jmf Abbott) –er det årsaken? Og hva?

Muligheter

- Greiner «fikser» rørene
  - Bytter gel eller lignende. Ingen løsning foreløpig
- Vi bytter rør (anbud)
- Vi endrer referanseområde – dårlig løsning pga tre metoder i samme foretak.
  - Faktorisering? Mulig midlertidig løsning, men ikke ønskelig

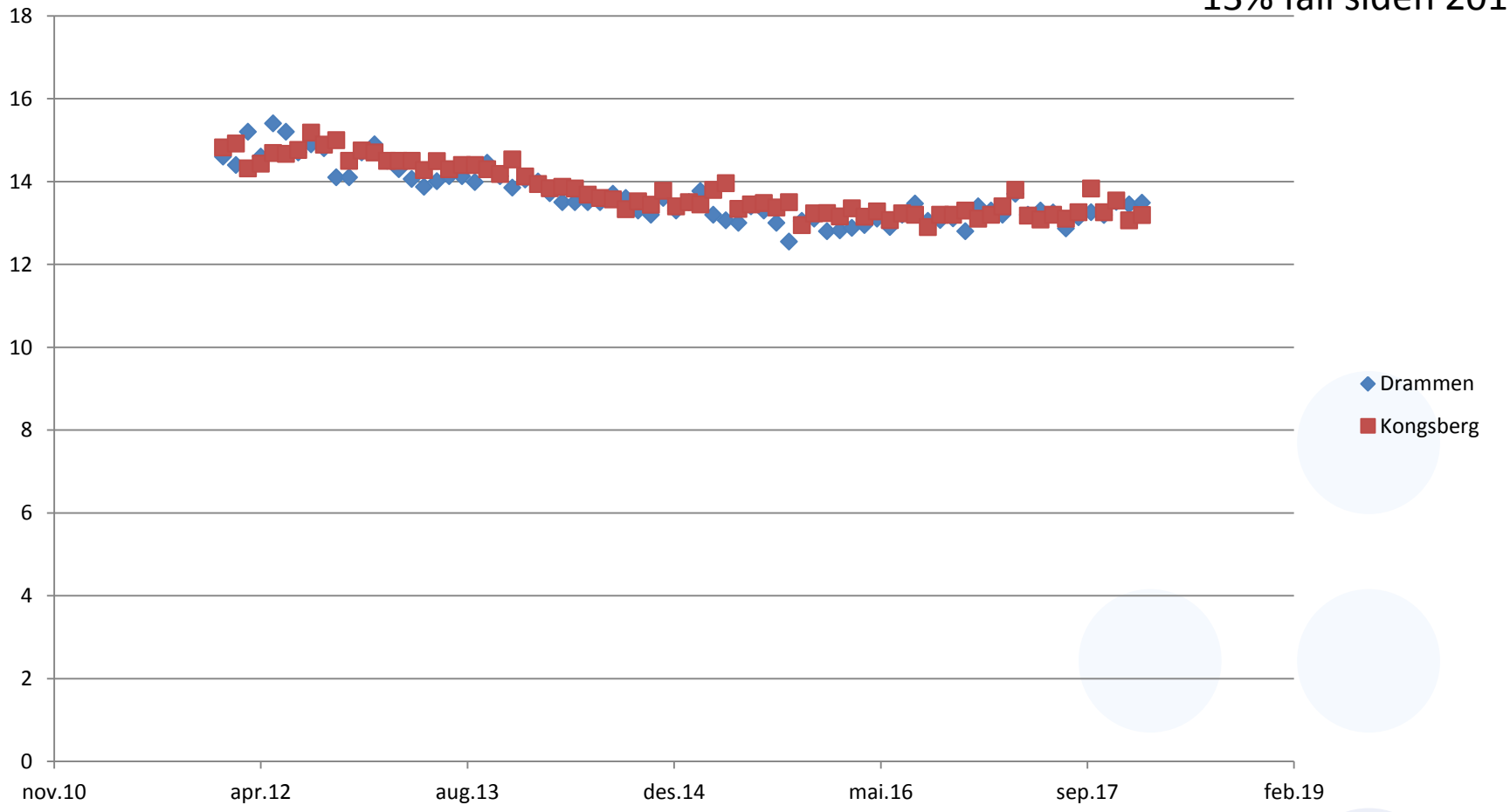
Take Home

- EKV og intern kontroll kan ikke avdekke alle avvik –heller ikke ganske store.
- Viktig å se på trender i pasientresultater
- Husk at andre «ting» enn reagenser/kalibrator/lot også kan påvirke analysene

VESTRE VIKEN

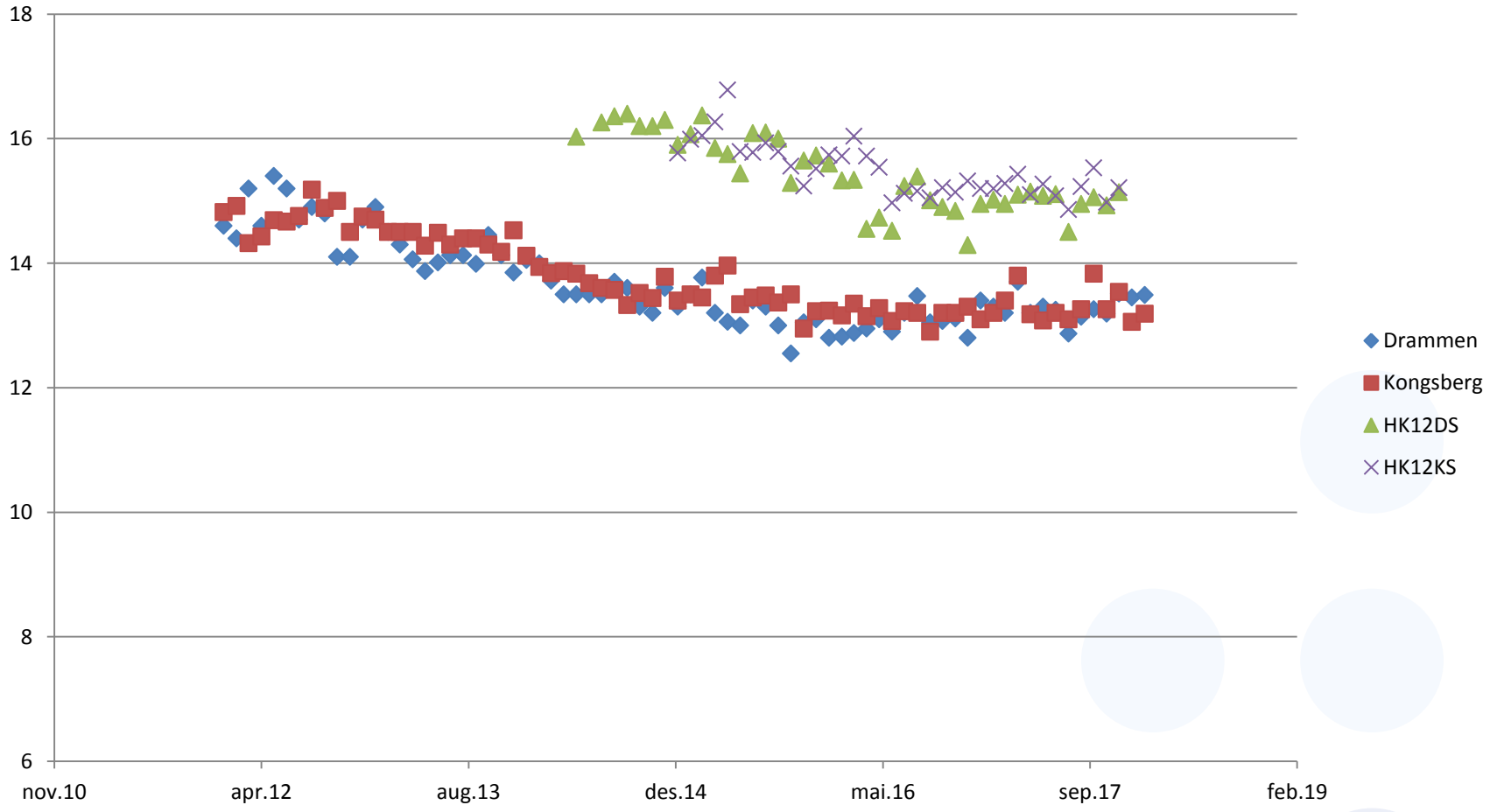
Fritt T4
jan12 til dd

13% fall siden 2012

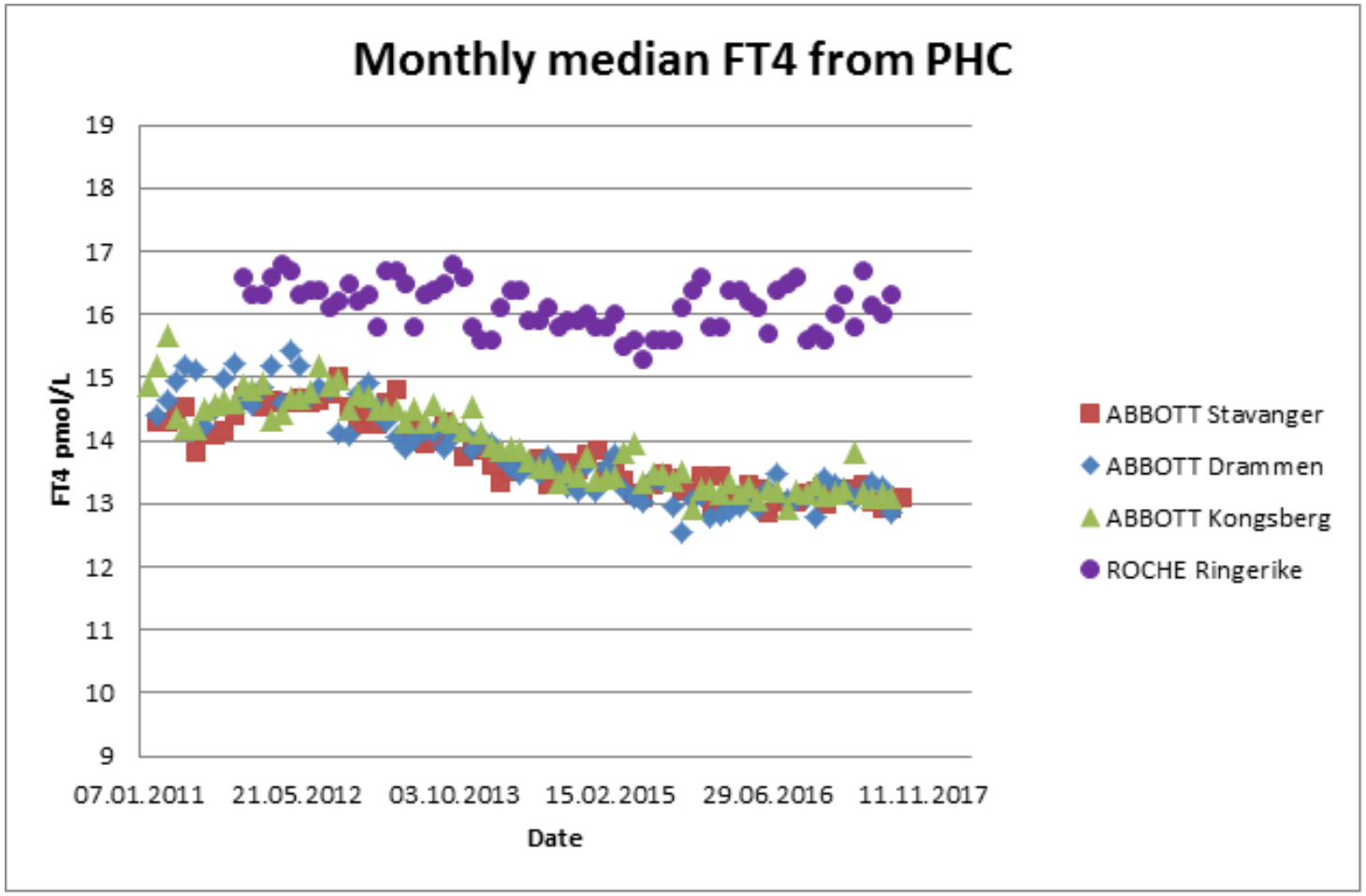


VESTRE VIKEN

Fall i HK-12 også

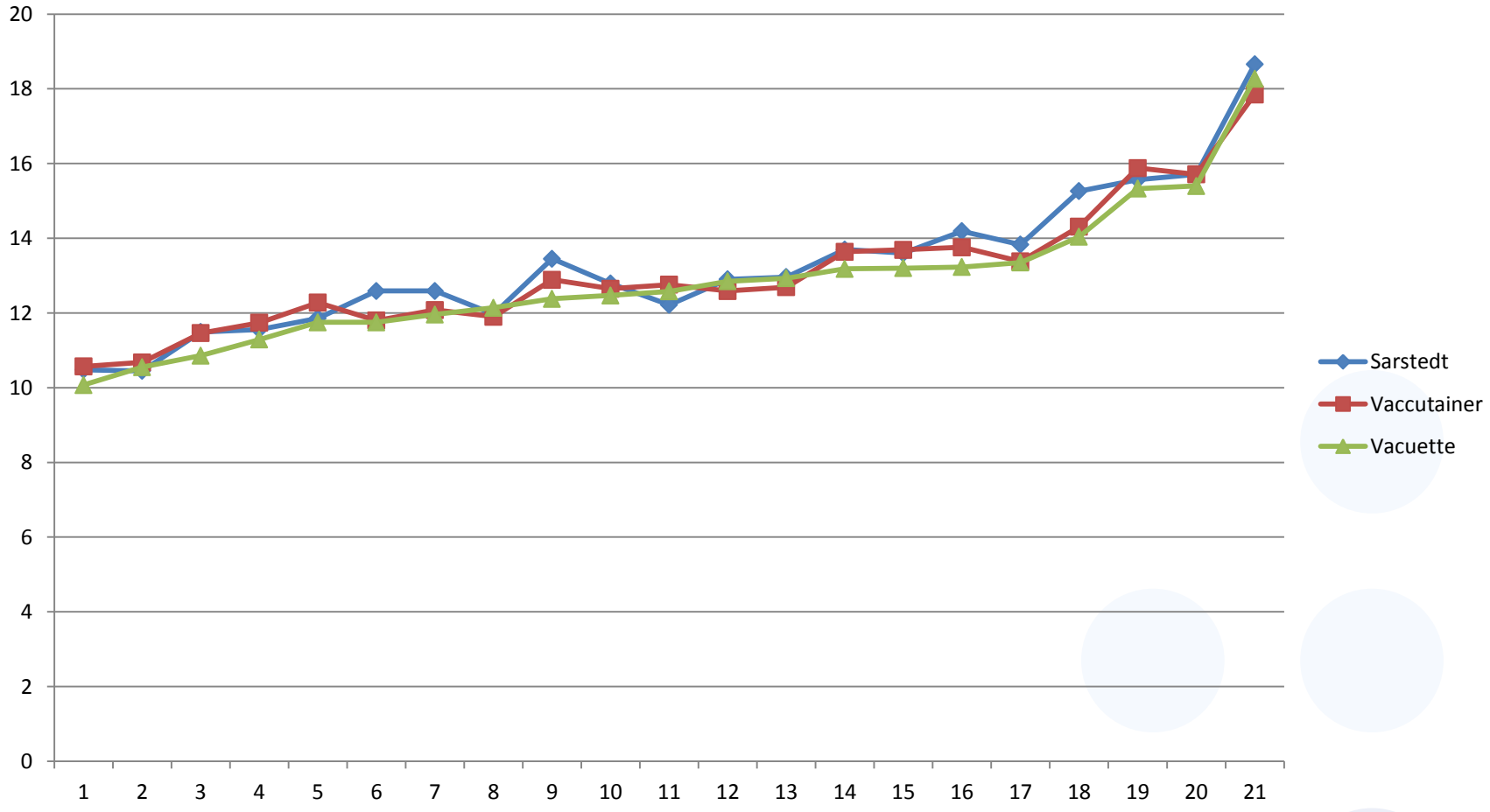


VESTRE VIKEN



VESTRE VIKEN

Sammenligne glassene

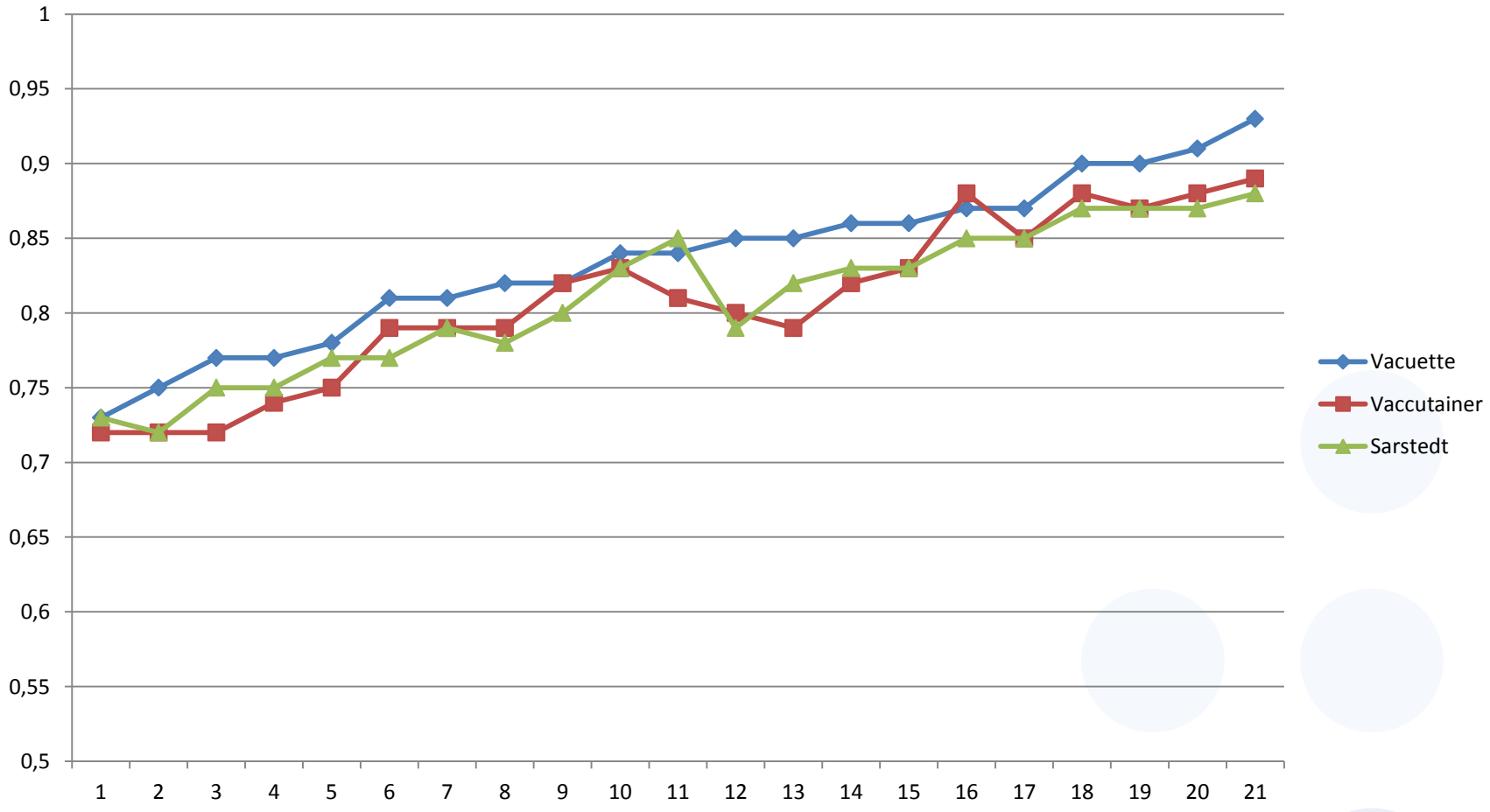


Fritt T4

- 13% fall over tid
- Fall i HK-12 også
- Ingen forskjell når sammenlignet prøveglass

- Her er det mer sannsynlig med fall i selve Abbottmetoden.
  - Lot?

VESTRE VIKEN

Hva med Magnesium?

Vacuette 3% høyere enn Vaccutainer og Sarstedt