



LUPUS ANTICOAGULANT TESTING

Remarkable observations in ECAT surveys

Piet Meijer
ECAT Foundation
Leiden
The Netherlands



Classification Lupus Anticoagulant samples

Sample	Negative	Borderline	Positive
Neg. Cotrol	96%	2%	2%
Weakly pos.	15 – 30%	10 – 20%	45 – 70%
Positive	5%	6%	89%
Strongly pos.	0%	< 0.5%	> 99.5%



Classification weakly positive samples

Sample	Number	Negative	Borderline	Positive
2009-3	317	18%	20%	62%
2010-2	363	32%	21%	47%



Classification weakly positive samples

Is there a relationship with the number of test panels applied?



Number of test panels

Sample	Final Classification	1	2	3
2009-3	-	23%	56%	21%
	+	26%	48%	26%
2010-2	-	18%	54%	28%
	+	26%	47%	27%



Classification weakly positive samples

Is there a relationship with the test selection?



Screening assays

Survey	APTT	DRVVT	KCT	dAPTT	dPT	SCT
2009-3	39.5%	45%	6%	3.5%	6%	-
2010-2	38%	47%	5%	2.5%	5%	2.5%



Test combinations

Survey 2010-2	APTT / DRVVT	Only APTT	Only DRVVT
Negative	72%	4%	19%
Positive	62%	4%	24%



Classification weakly positive samples

Is there a relationship with the test results?

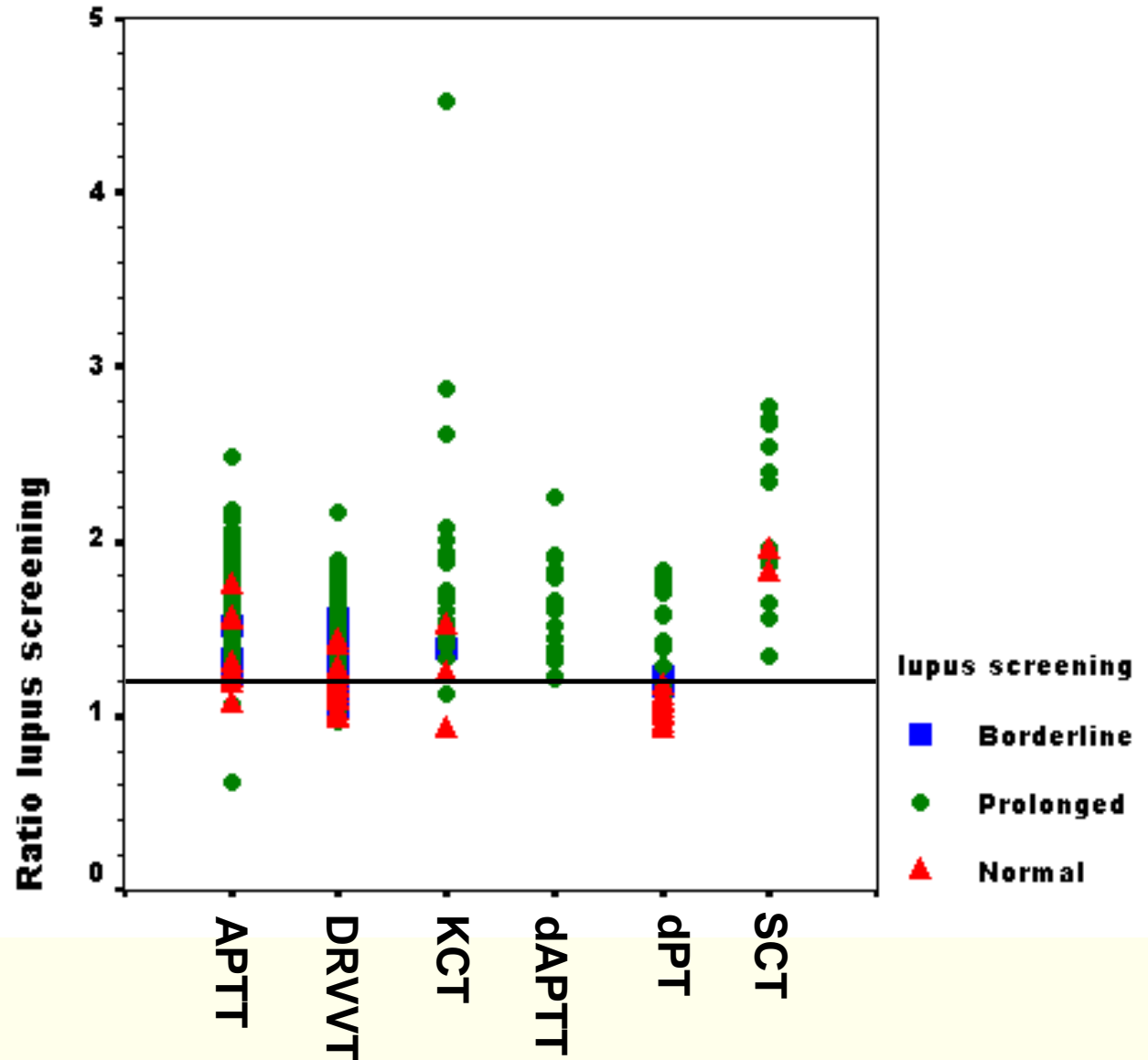


Screening assays

Survey	2009-3	2010-2
APTT	1.78 (0.98 – 2.49)	1.60 (0.60 – 2.50)
DRVVT	1.53 (0.96 – 2.24)	1.44 (1.00 – 2.20)
KCT	2.32 (1.02 – 4.52)	1.74 (0.90 – 4.50)
dAPTT	1.81 (1.02 – 2.65)	1.59 (1.20 – 2.30)
dPT	1.17 (0.97 – 2.13)	1.28 (0.90 – 1.80)
SCT	-	2.07 (1.30 – 2.80)

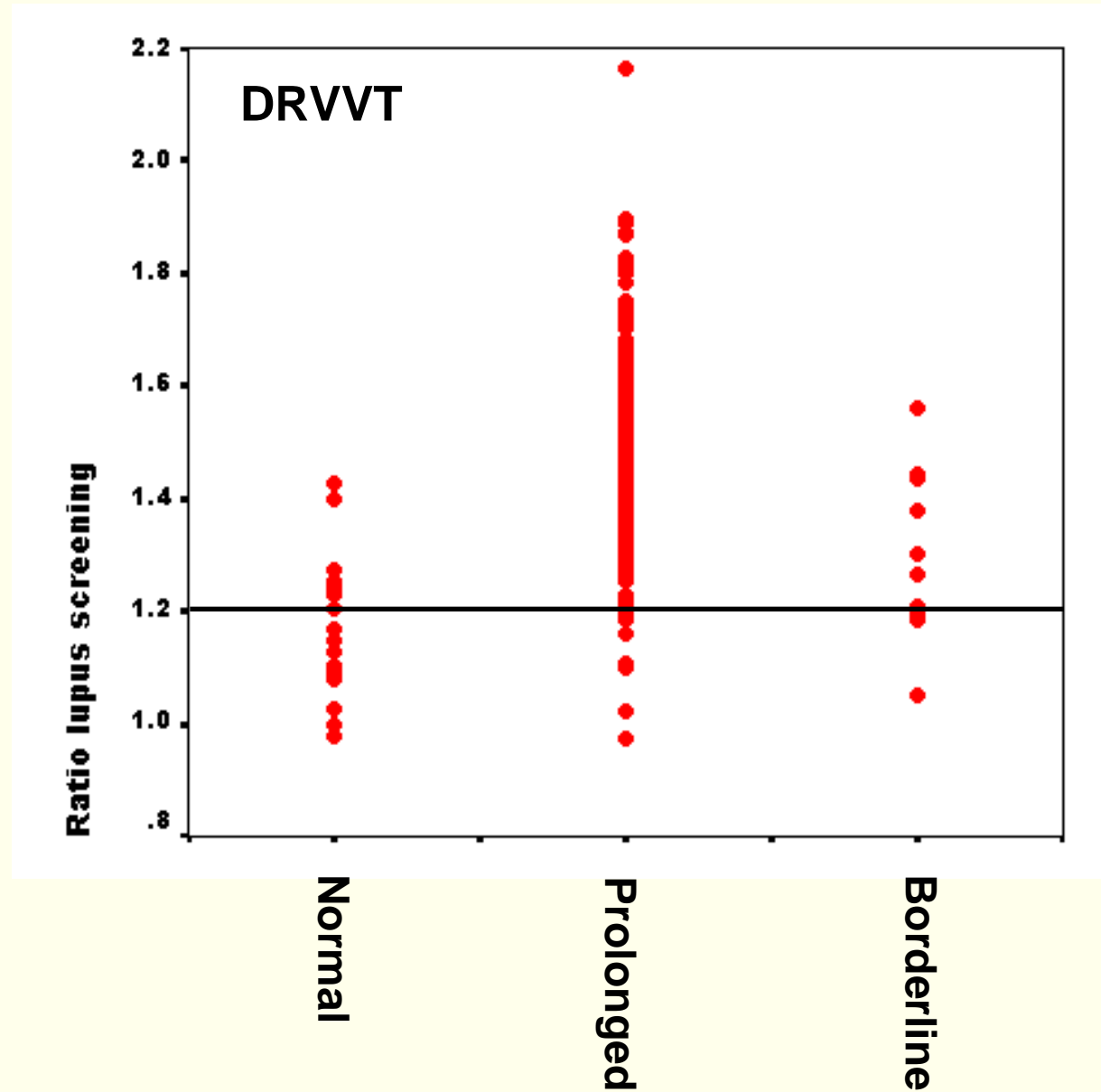


2010-2





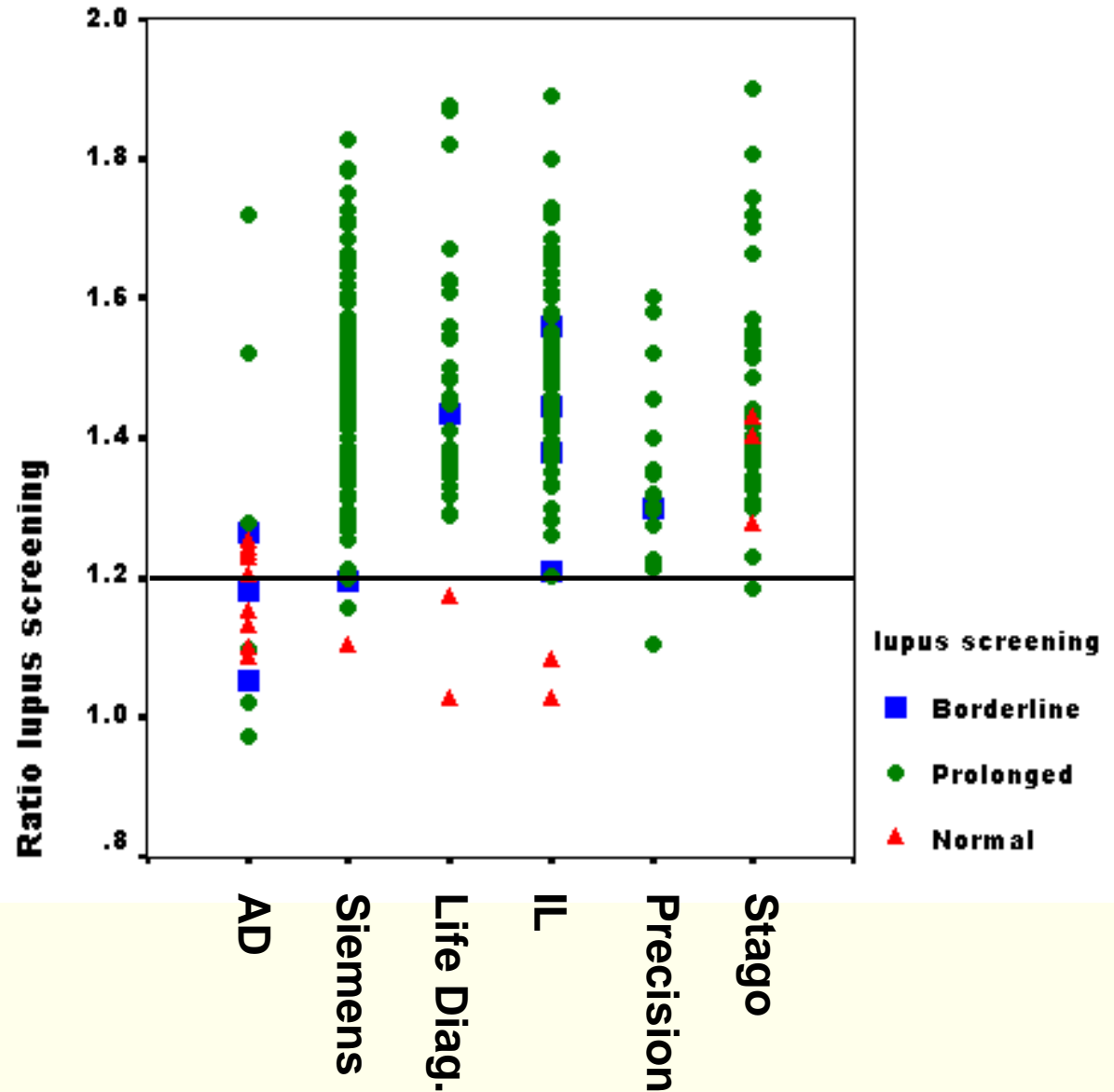
2010-2





2010-2

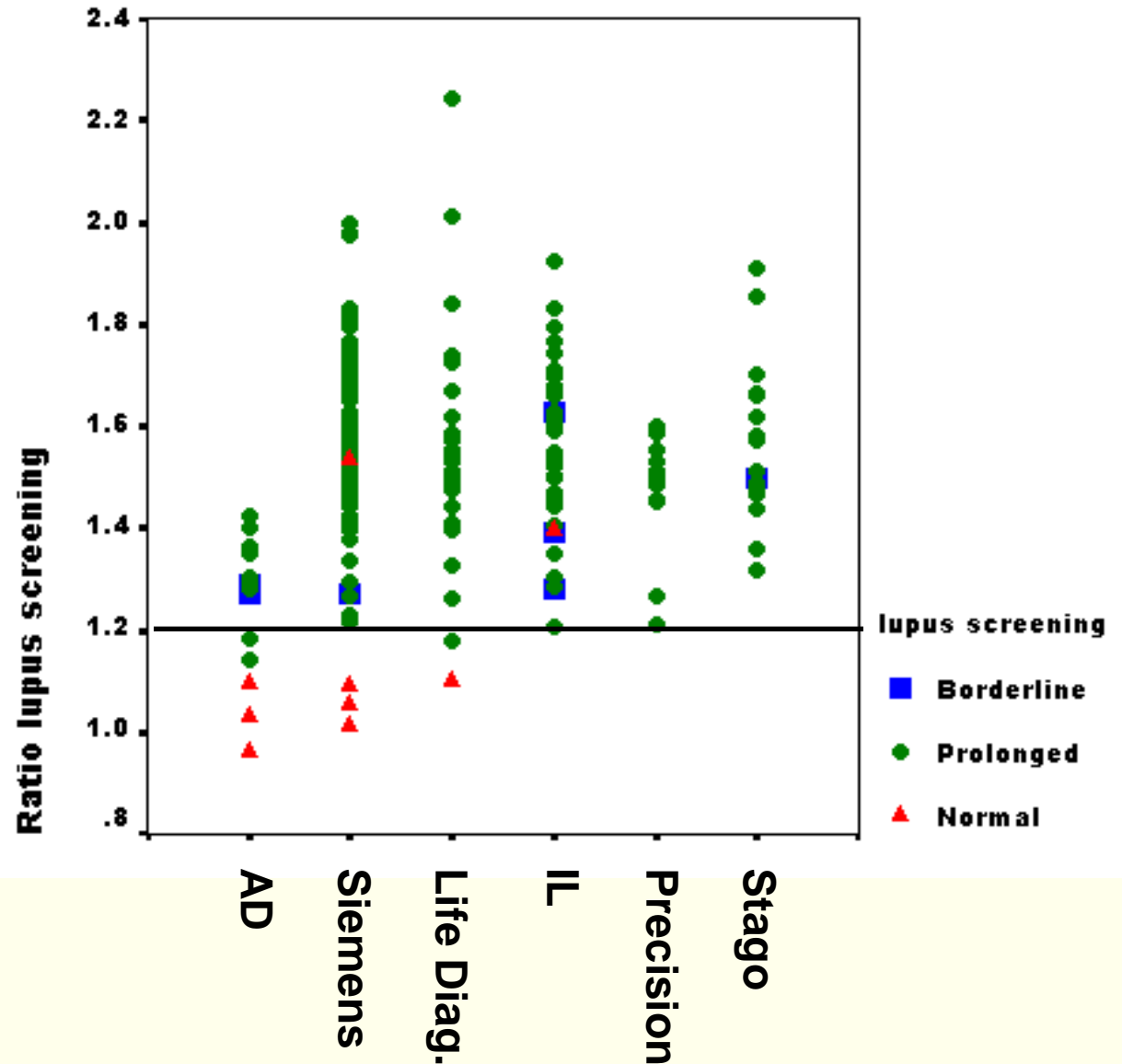
Test	Mean
AD	1.21
Siemens	1.45
Life Diag.	1.46
IL	1.48
Precision	1.34
Stago	1.46





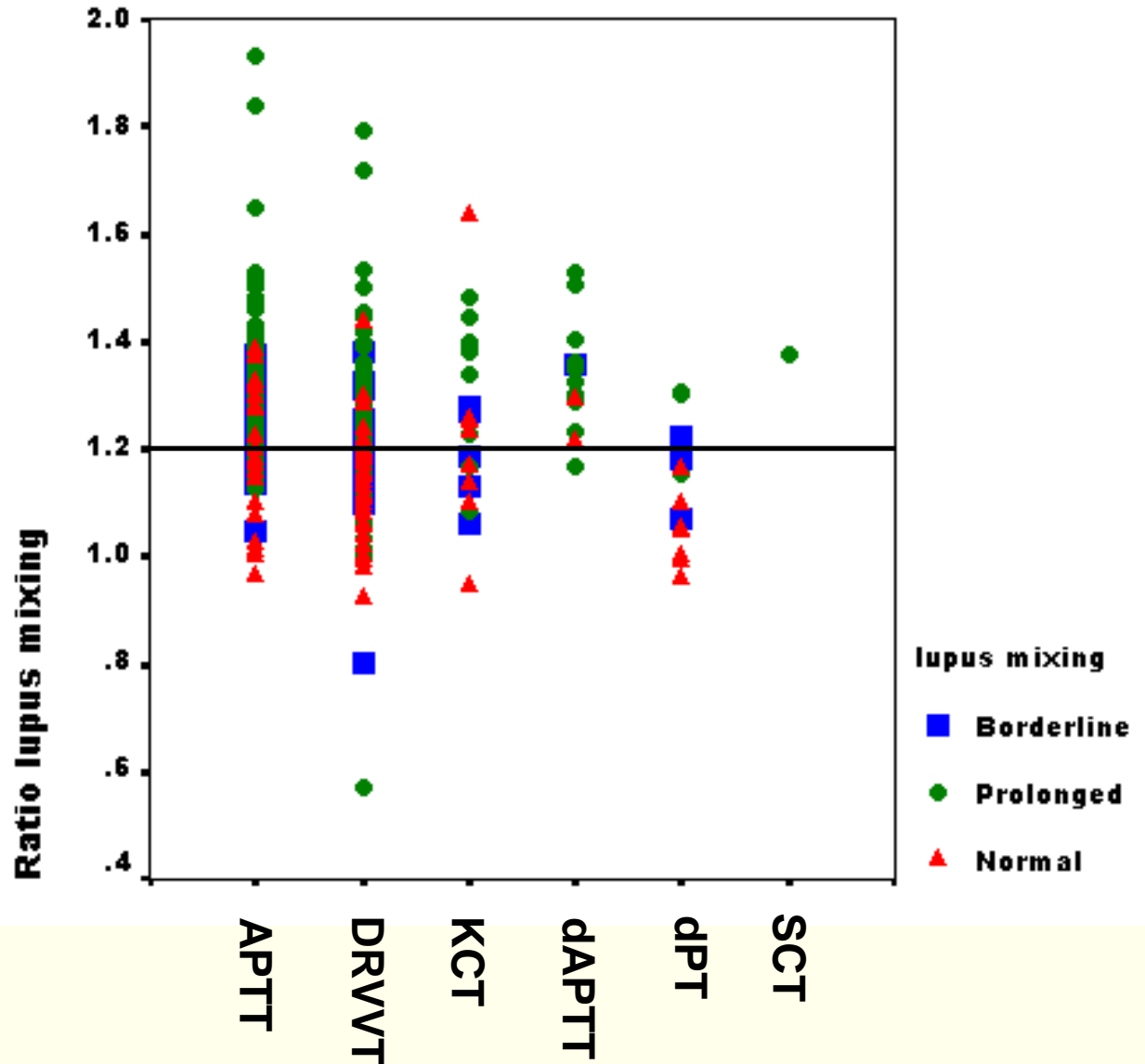
2009-3

Test	Mean
AD	1.24
Siemens	1.56
Life Diag.	1.54
IL	1.56
Precision	1.47
Stago	1.56





2010-2

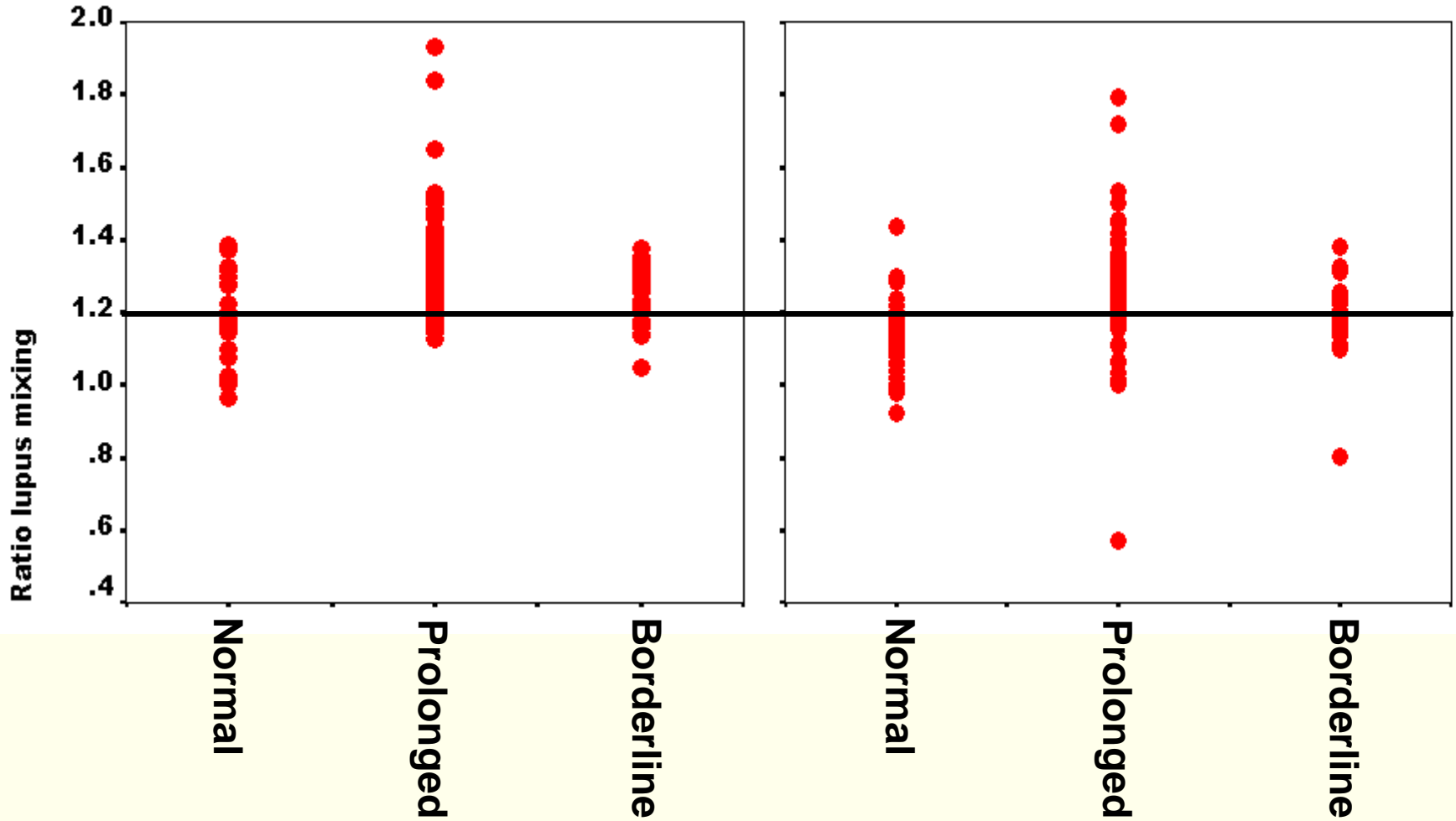




2010-2

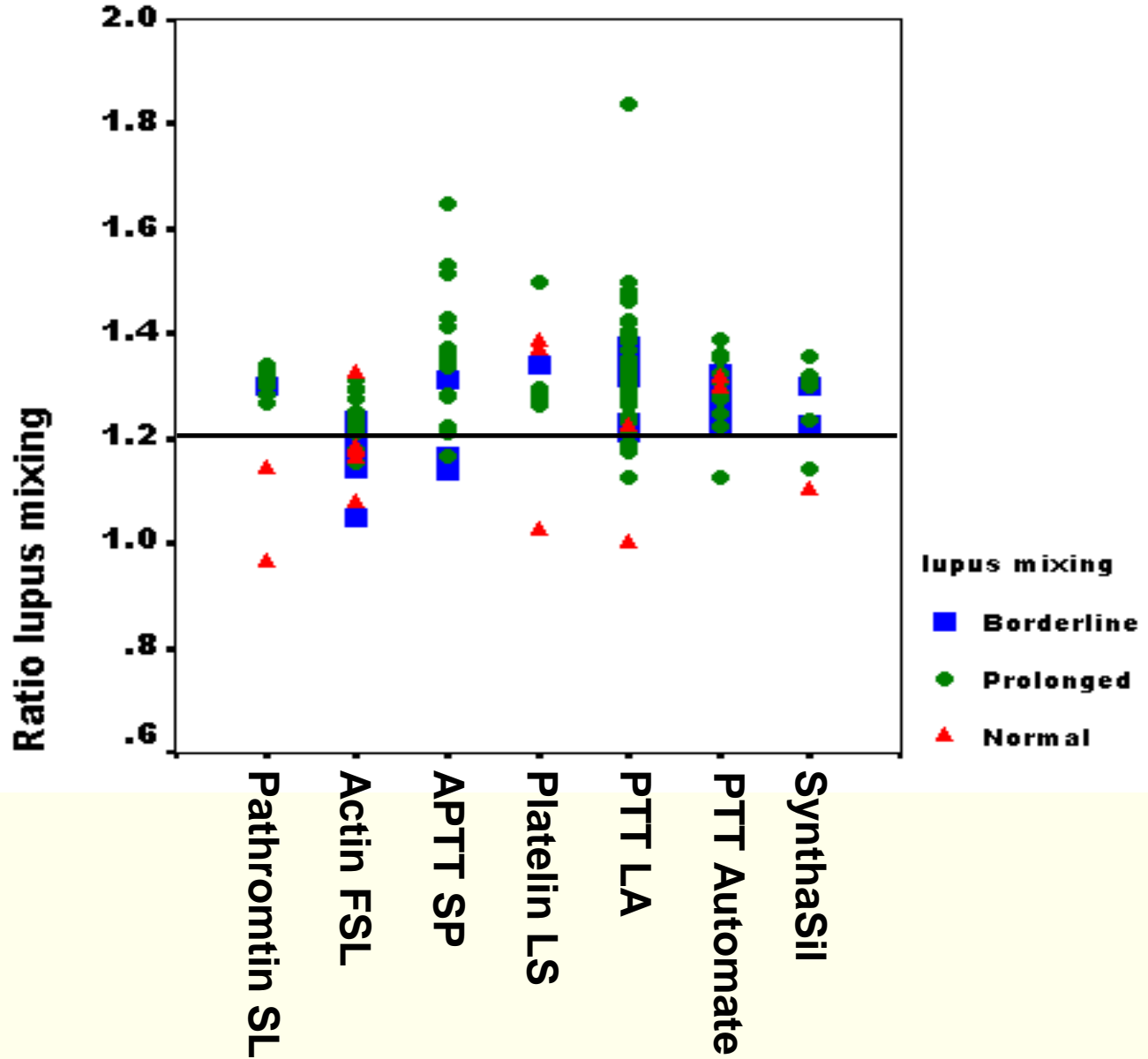
APTT

DRVVT



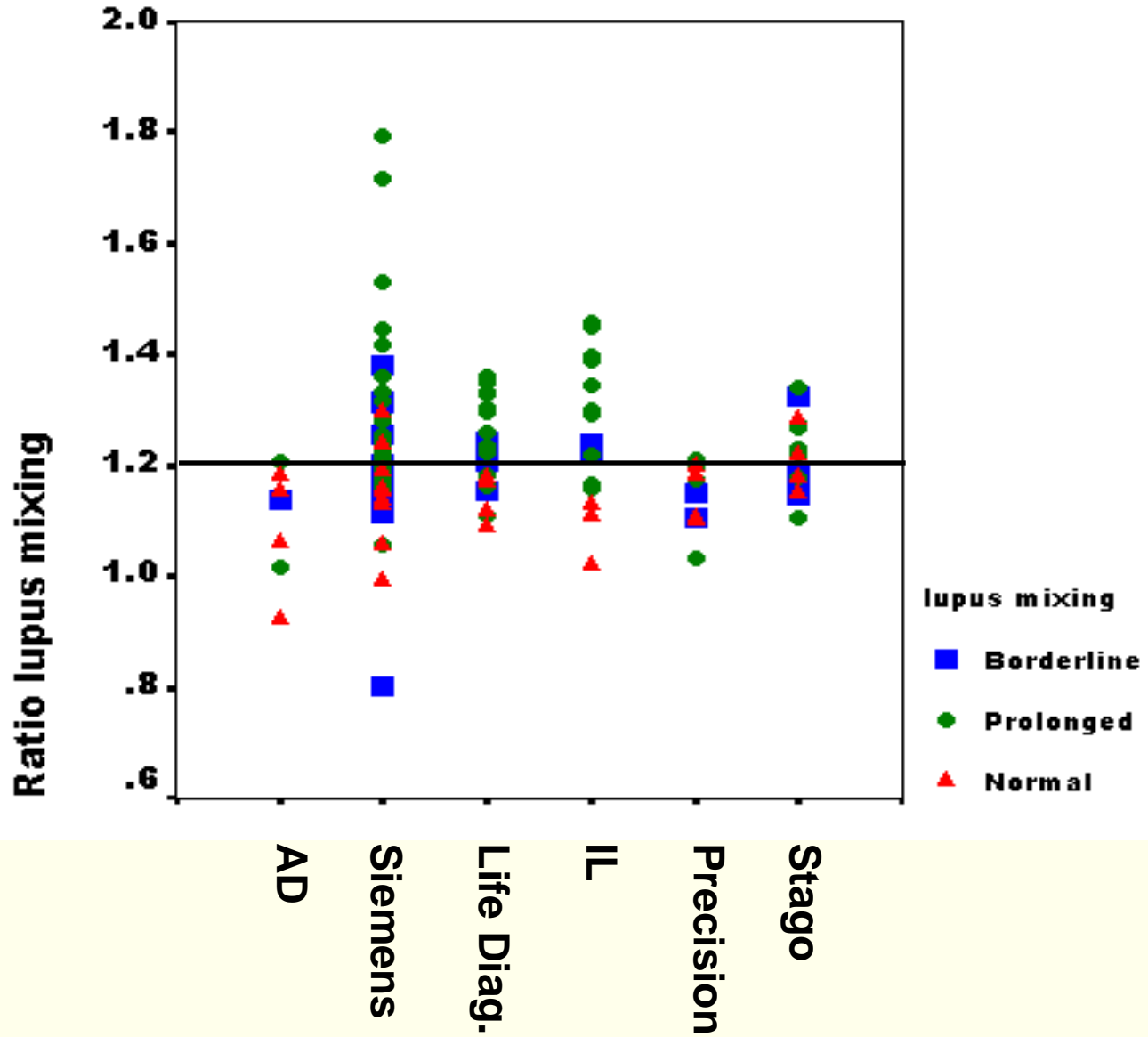


2010-2



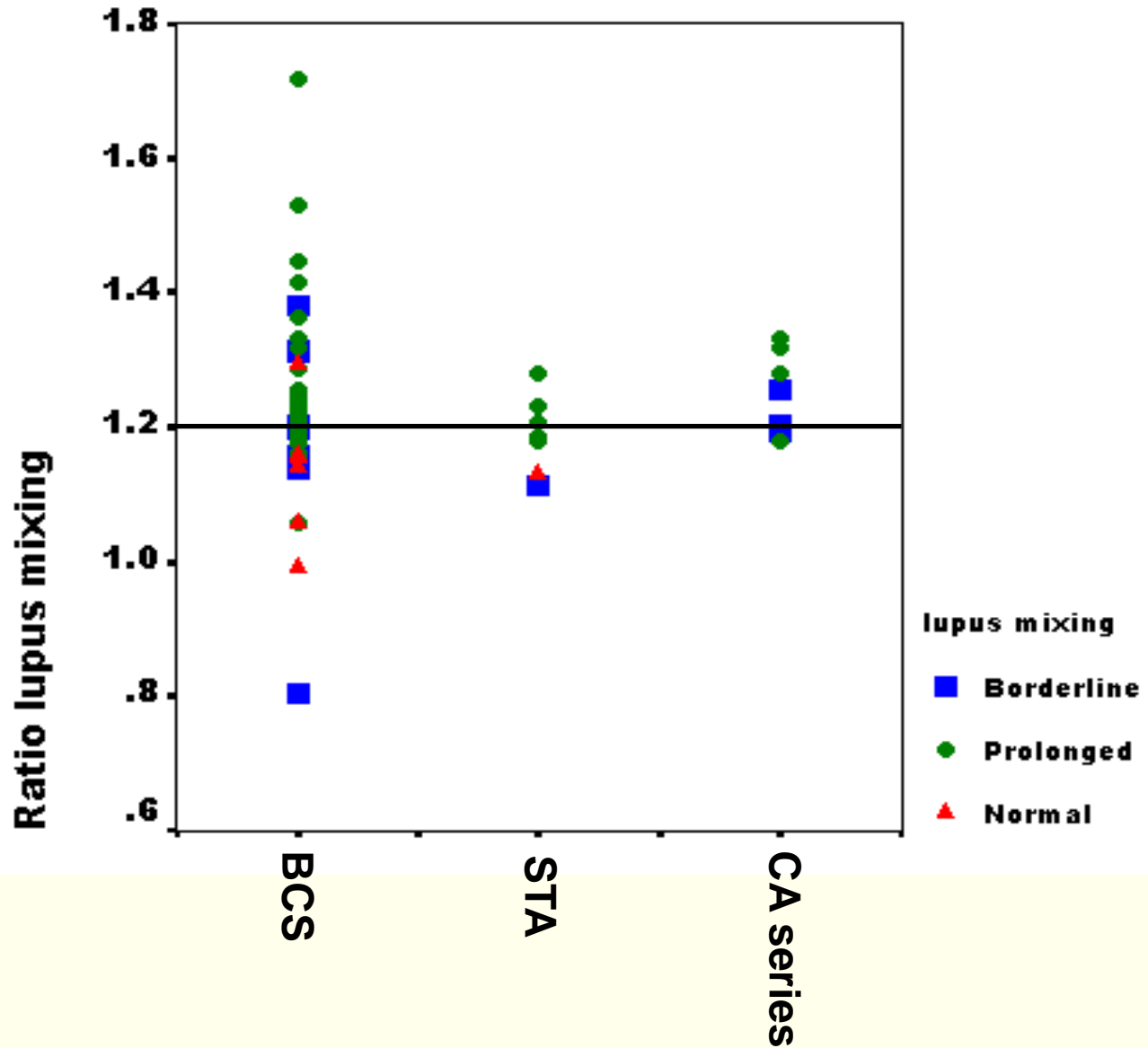


2010-2





2010-2

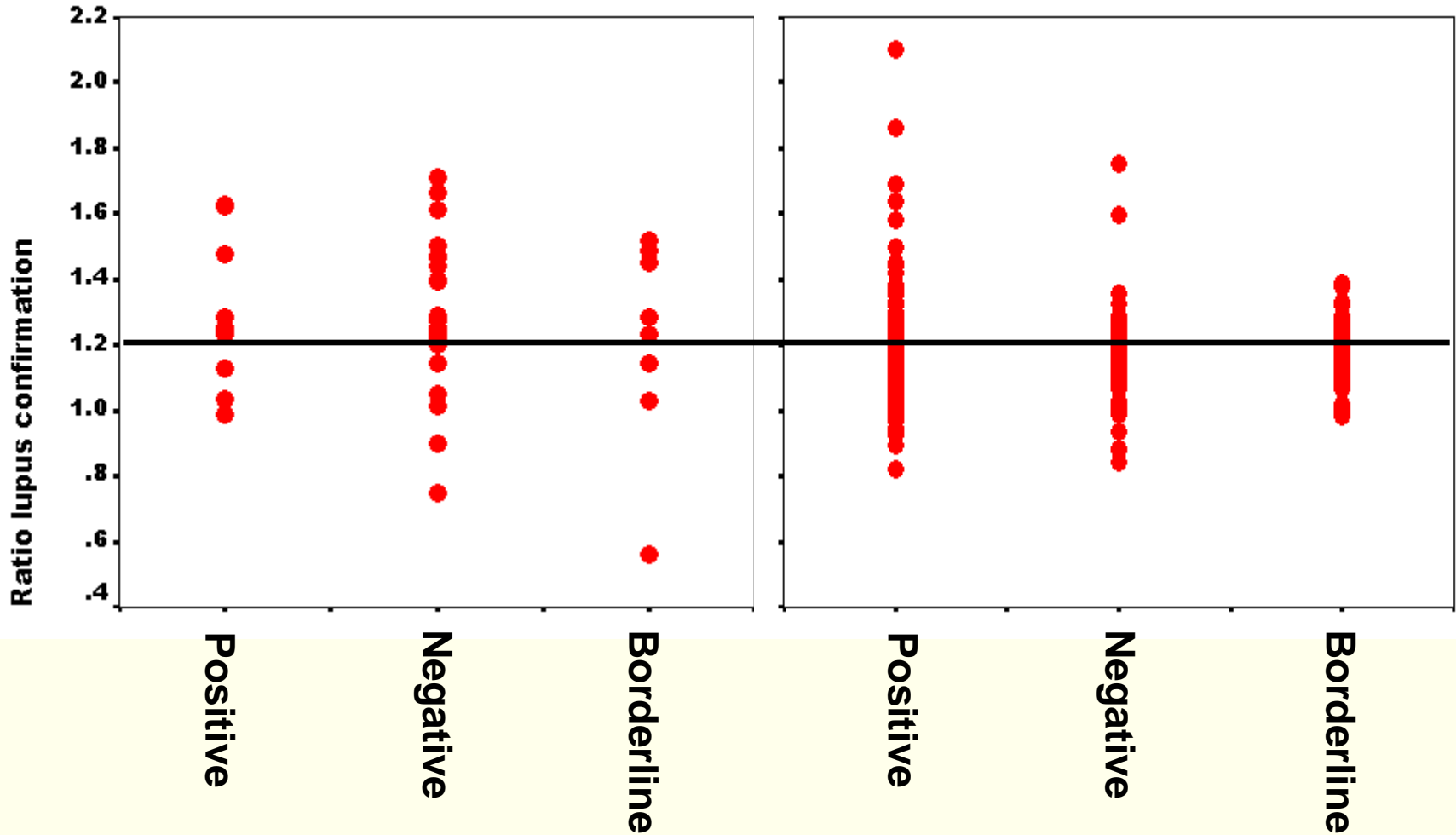




2010-2

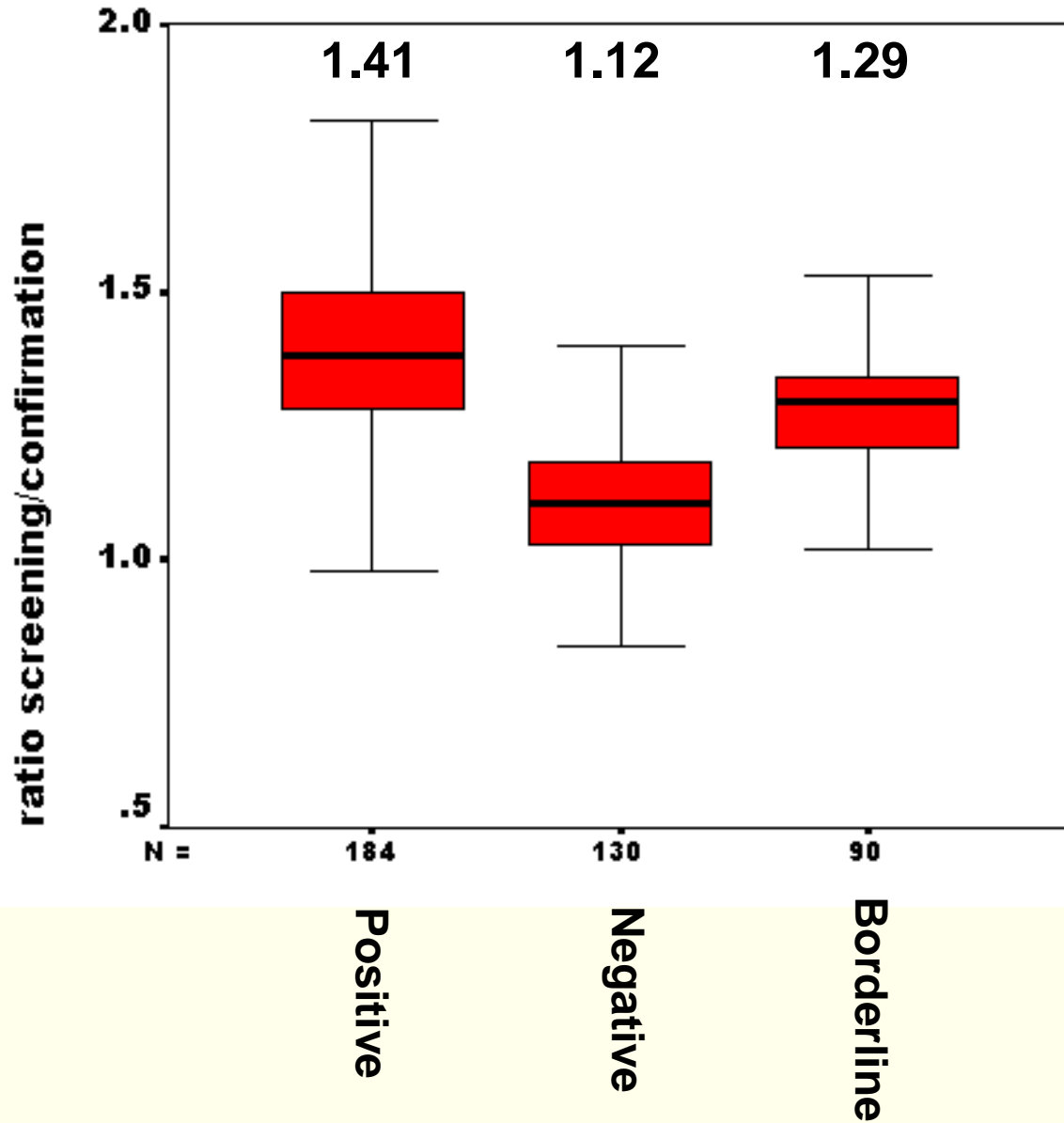
APTT

DRVVT





2010-2

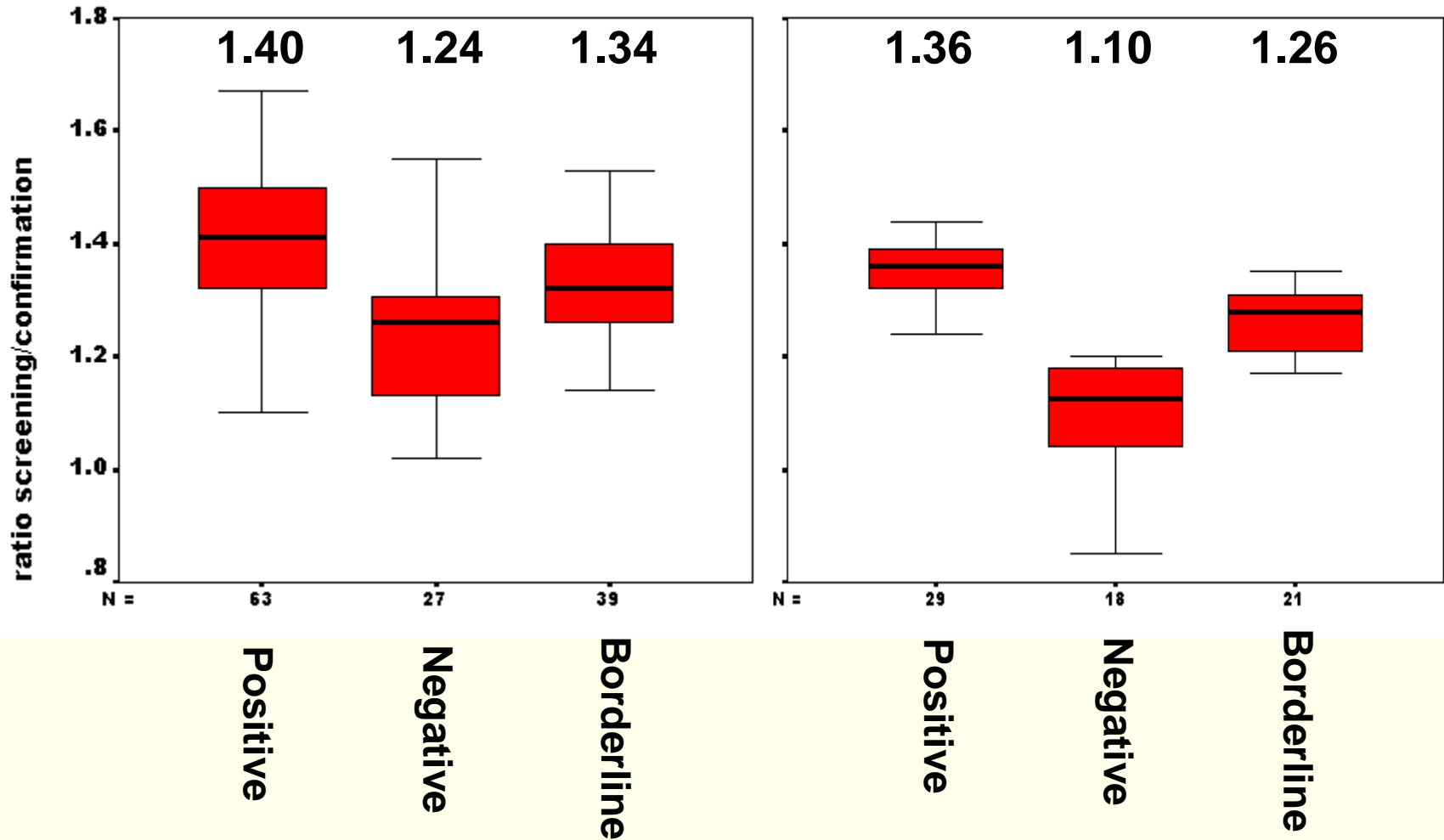




2010-2

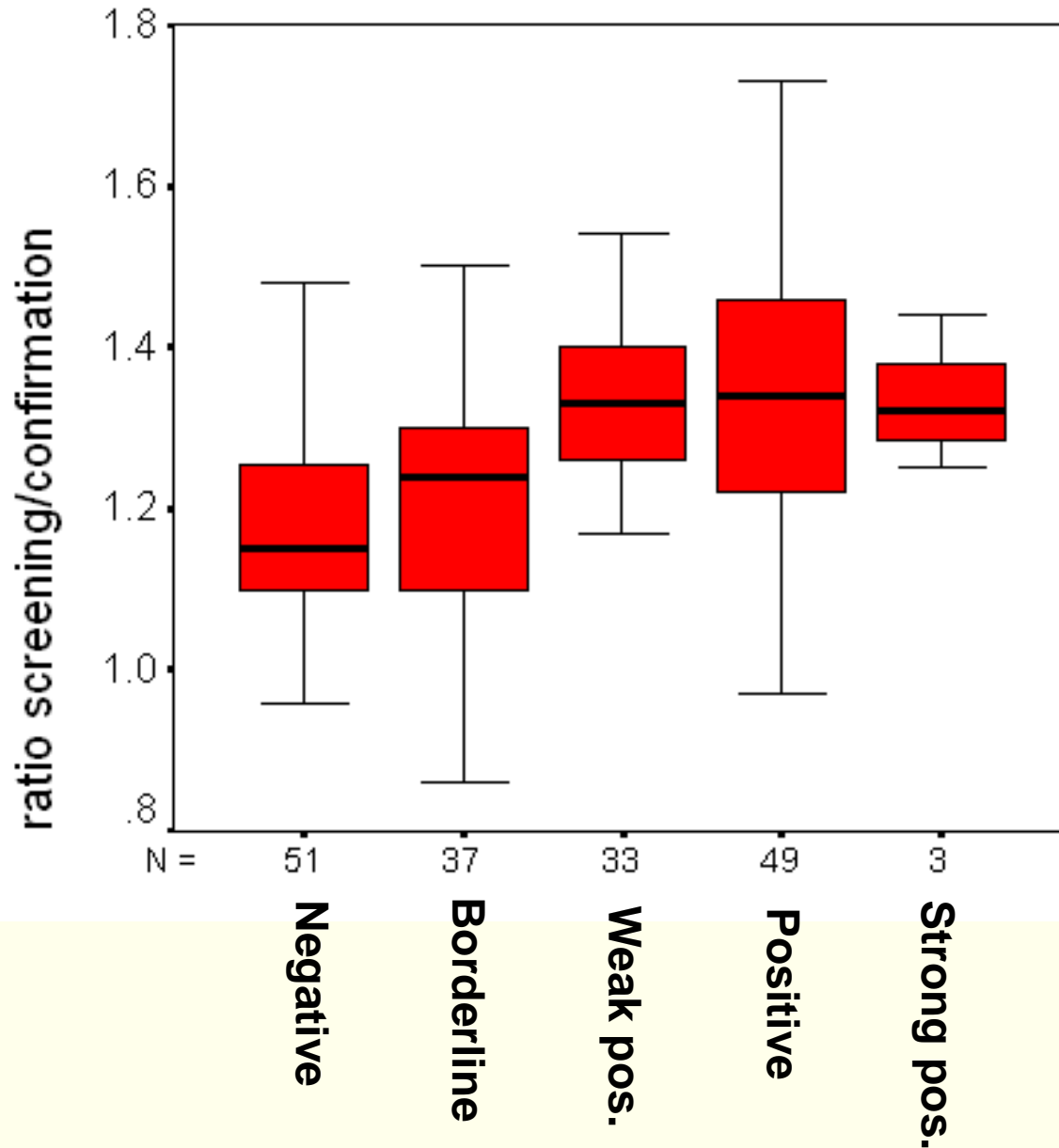
Siemens

IL





2010-2





N = 271

37%	11%	2009-3				
		Neg	Border	Weak	Pos	Strong
18%	15%					
2010-2	Neg	32	19	15	17	2
	Border	12	16	11	14	2
	Weak	5	11	14	19	2
	Pos	3	10	13	39	10
	Strong	0	1	0	4	0



Conclusion (1)

- **Up to 30% of the participants classified a weakly positive sample as negative.**
- **There is no relationship with the number of test panels performed.**
- **No pronounced relationship with the test selection.**
- **Wide variation in test results both within assay and method groups.**

Causes: quality of normal plasma ???

variation in lot number reagents ???

- **Lack of clear criteria for normal vs prolonged ; negative vs positive.**



COMPARISON RESULTS 2009-4 AND 2010-1



COMPARISON RESULTS 2009-4 AND 2010-1

Sample	:	Lupus Control Low (Technoclone)
2009-4	:	310 participants
2010-1	:	362 participants
Both	:	259 participants



COMPARISON RESULTS 2009-4 AND 2010-1

2009-4	2010-1					
	Normal	Borderline	Weakly Positive	Positive	Strongly Positive	No classification
Normal	5	2	1	5	0	0
Borderline	1	4	2	0	0	0
Weakly Positive	1	7	15	19	1	0
Positive	3	6	17	99	17	0
Strongly Positive	0	0	2	18	28	1
No classification	1	0	0	1	0	3

60% identical classification

4 % normal ↔ positive

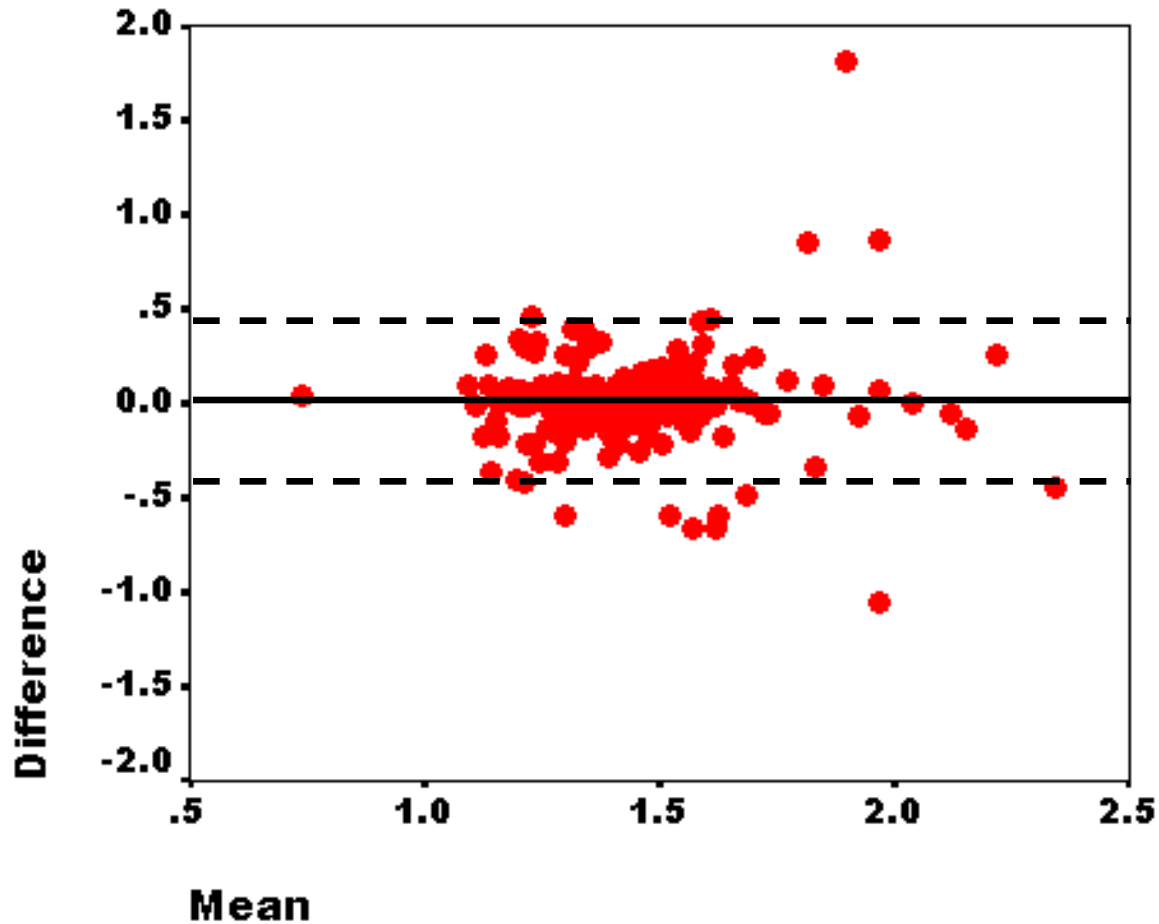
6 % borderline ↔ positive

29 % within positive



COMPARISON RESULTS 2009-4 AND 2010-1

Ratio screen / confirm





Conclusion (2)

- **40% of the participants had a different classification within two consecutive surveys with the same sample.**
- **Considerable variation in the ratio screen/confirm between the two surveys.**



Conclusion (3)

We need:

- Better and stable tests
- Better performance
- Better criteria for classification



THANK YOU FOR YOUR ATTENTION