

The Alzheimer's Association quality control program

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QC program facts

- Initiated by the Alzheimer's Association in 2009 and 100 laboratories are now listed in the database.
- Three rounds/year with three samples: two unique and one longitudinal.
- Presently four different assay platforms by three companies (Fujirebio Europe, MesoScaleDiscovery, and ROCHE).
- Coordinated from Neurochemistry Laboratory in Mölndal, Sweden.
- Two publications:
Mattsson, N. et al, Alzheimer's & Dementia 2011;7:386-395
Mattsson, N. et al, Alzheimer's & Dementia 2013;9:251-261

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The Alzheimer's Association QC Program

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The UGOT CSF project



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alzheimer's association®

The Alzheimer's Association QC program for CSF biomarkers

BACKGROUND

The CSF biomarkers tau and amyloid β ($A\beta$) show promise as tools in the diagnostic work-up patients with suspected Alzheimer's disease (AD) and to monitor treatment effects in AD clinical trials. However, recent multi-center studies have shown that the levels of these CSF biomarkers vary between different research centers and laboratories. This variation in CSF biomarker levels between laboratories complicates multicenter research studies and trials and also precludes the introduction of generally applicable cut-off levels

Alz Ass QC program News

INNOTEST SOP's

Worksheets for the new INNOTESt kits with ready to use calibrators can be found [HERE](#).

Göteborg 2014-05-06

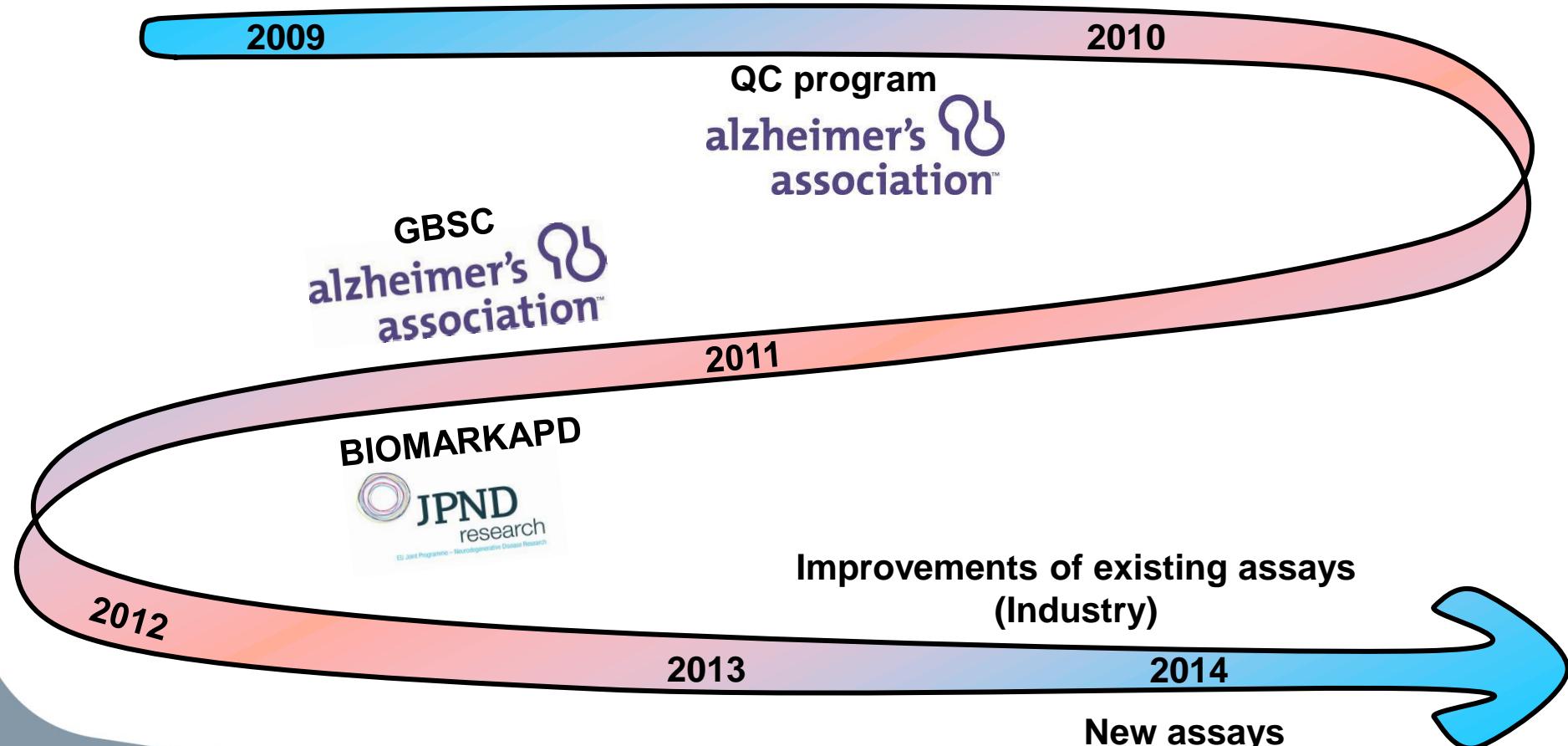
Second round for 2014

It is now time to analyze the May samples (2014-15A, 2014-15B and 2011 QC-L). Please use the new report form version 3.3 when reporting results.

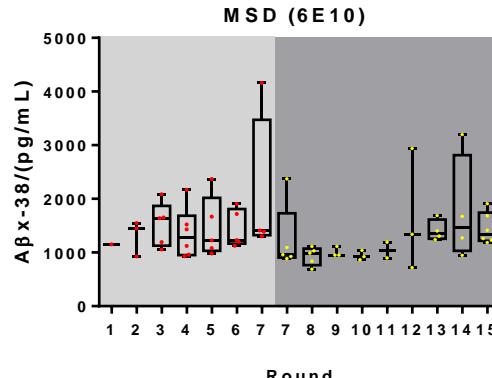
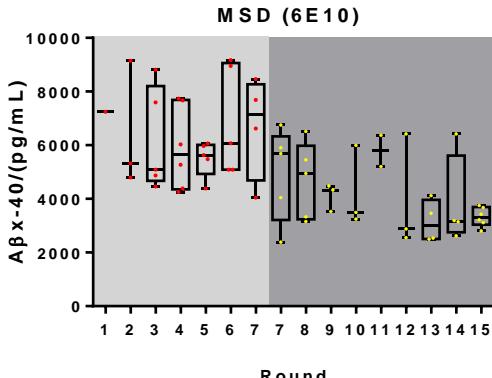
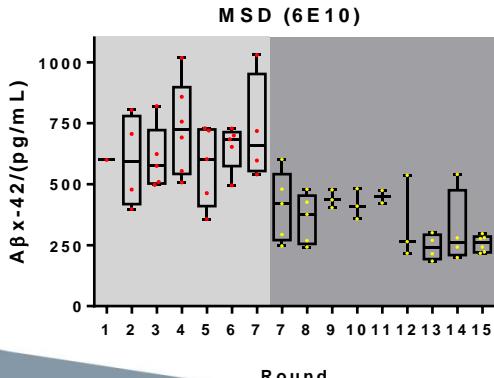
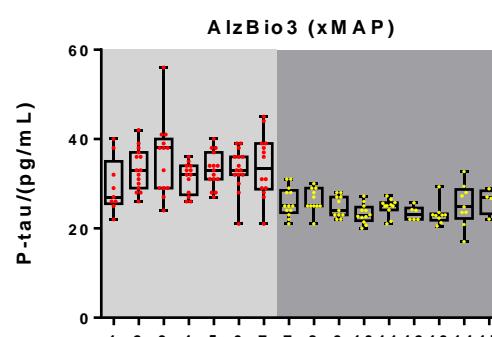
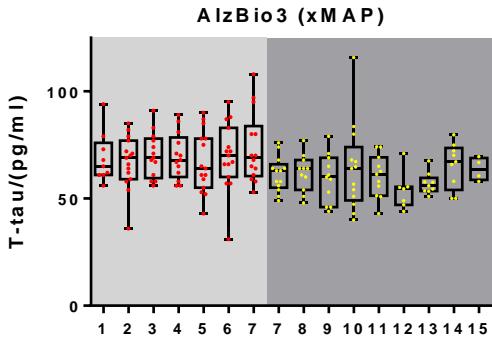
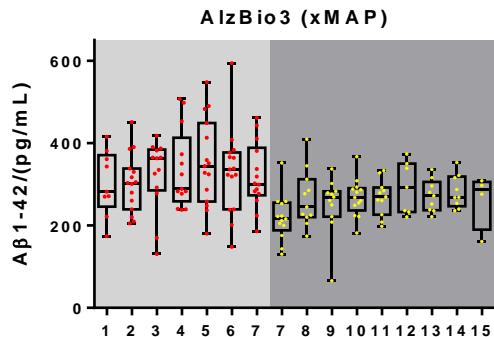
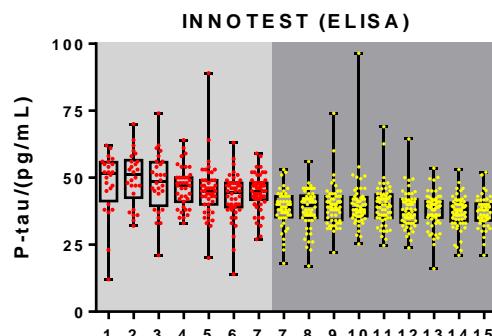
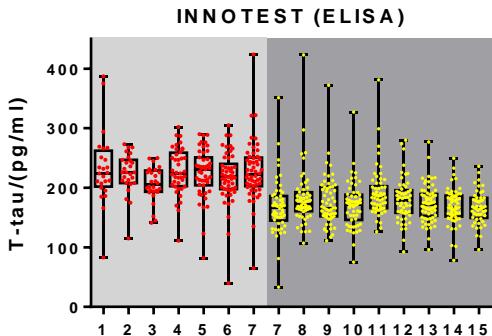
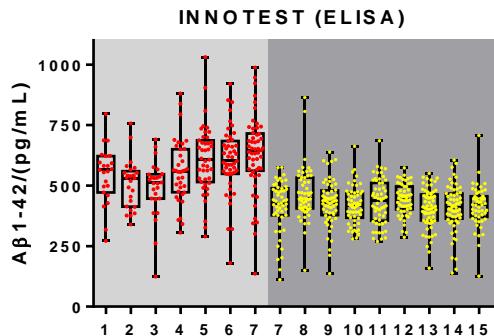
Download the report form [HERE](#).

Göteborg 2014-05-06

Past, present, and future



Results (QC-L)



The big picture

QC-program

New assays

Assay improvements

High variability

Certified reference
material/method

Standard operating
procedures

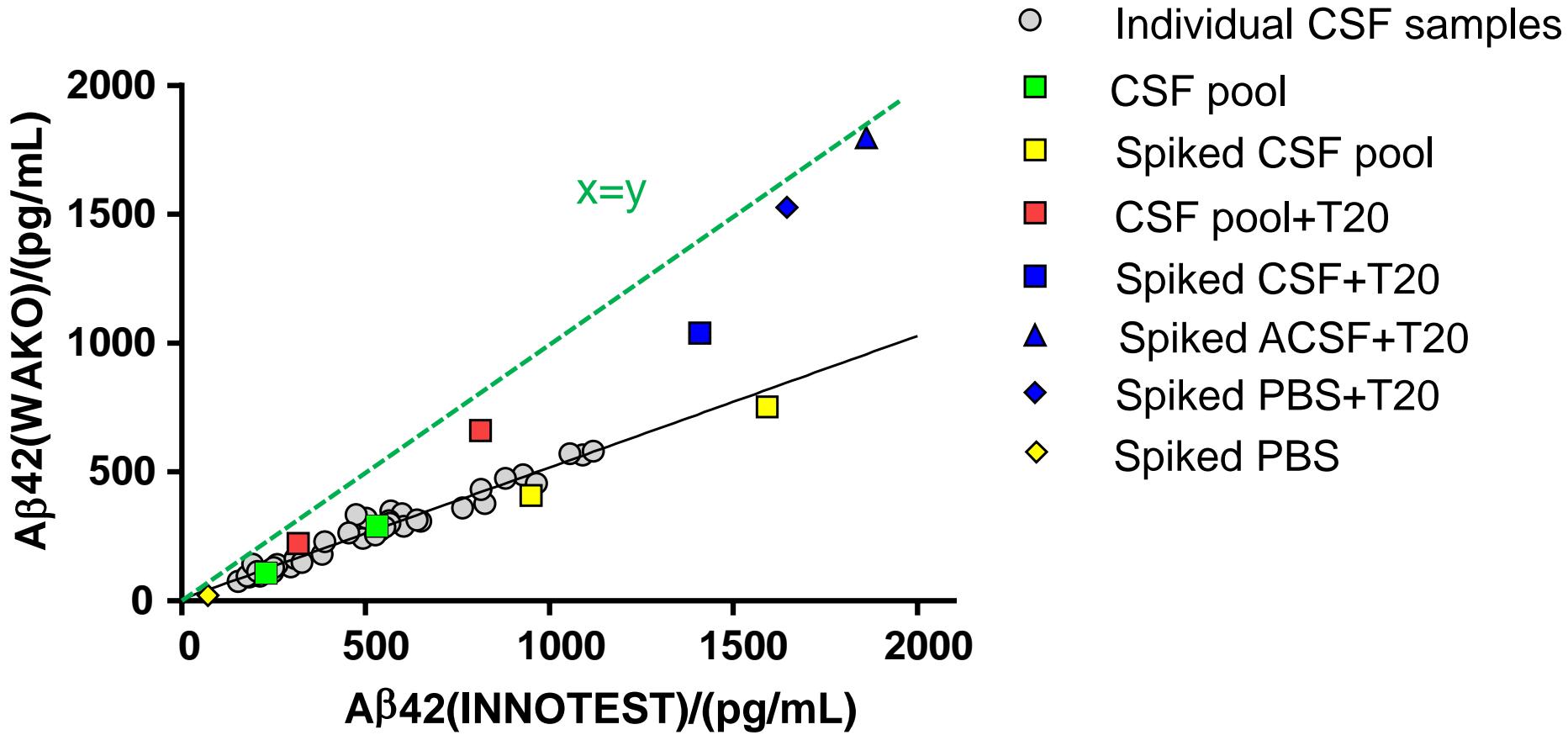
Commutability I

48 individual samples

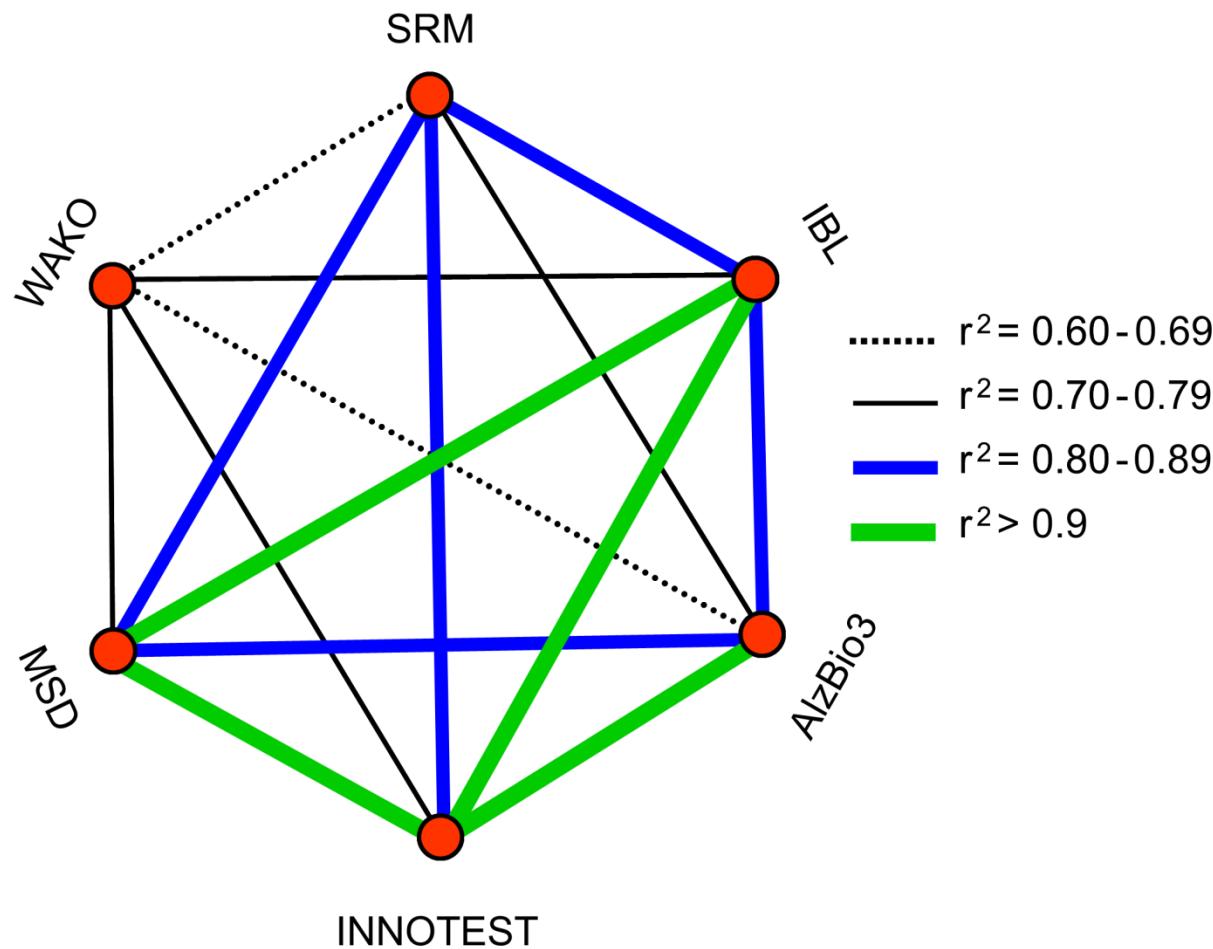
16 more or less artificial samples

Analyzed using five different commercial assays and an in-house SRM

Commutability I



Commutability I



Commutability 2

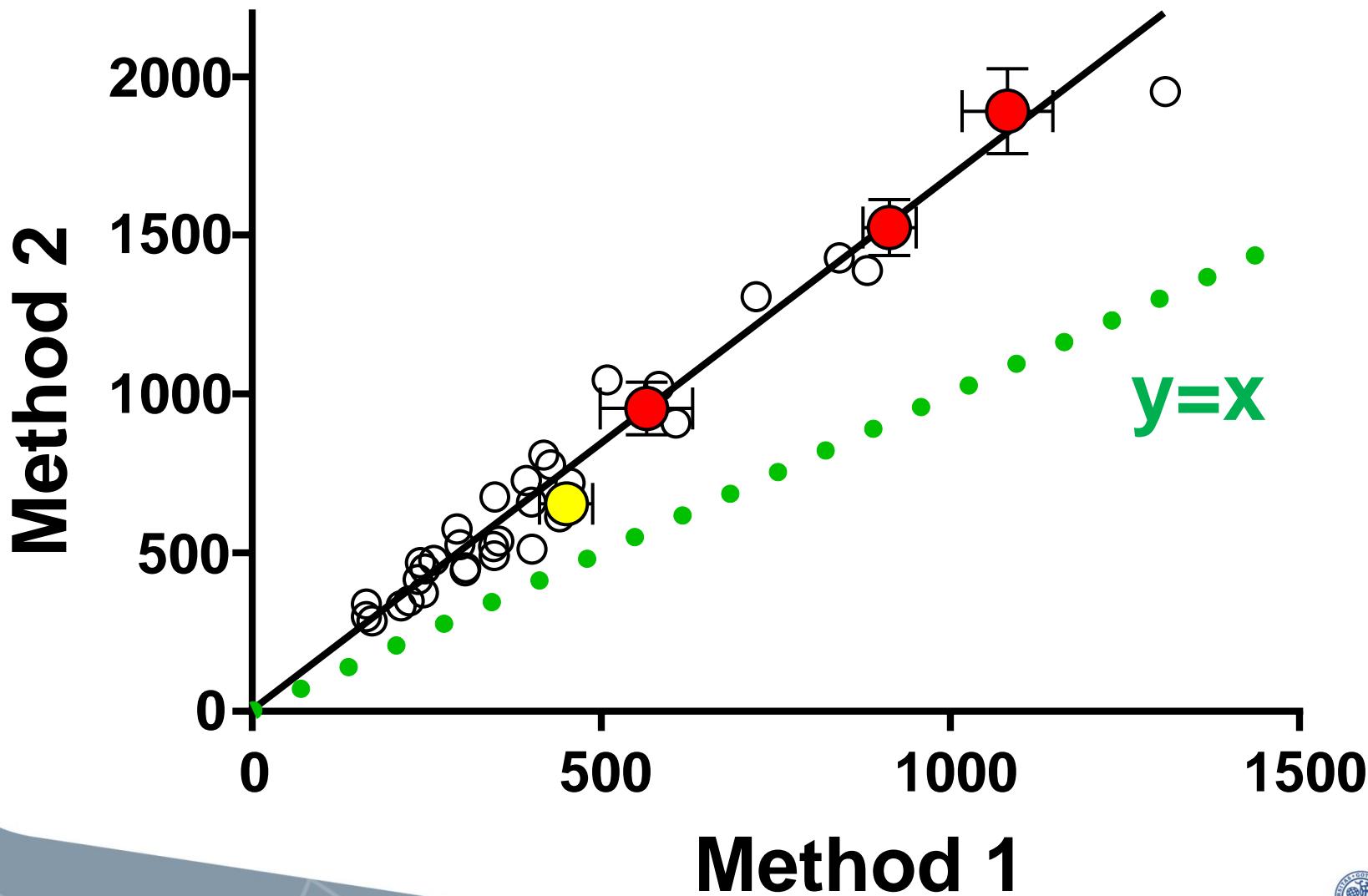
Assays assessed for Commutability

Assay	Manufacturer	Shipped volume (μ l)	T-tau	A β (x) 1-42	Assay assessed by
Innotest AlzBio3	Fujirebio	1x250	X	X	Dr Les Shaw UPenn
Innotest ELISA (ready to use calibrators)	Fujirebio	1x250	X	X	Neurochem Möldal
Human V-PLEX Kit	Meso Scale Discovery	1x250	X	X	Dr Robert Umek
ELISA	ADx/EUROIMMUN	1x250	X	X	Dr Eugeen Vanmechelen
VITROS 3600	Saladax	2x250		X	Dr Salvatore Salamone
Cobas	ROCHE	1x250		X	Kairat Madin
Simoa	Quanterix	1x250		X	Neurochem Möldal
ELISA	IBL	1x250		X	Anja Matzen
SRM	In house	2x250		X	Neurochem Möldal
MS reference method	In house			X	ROCHE

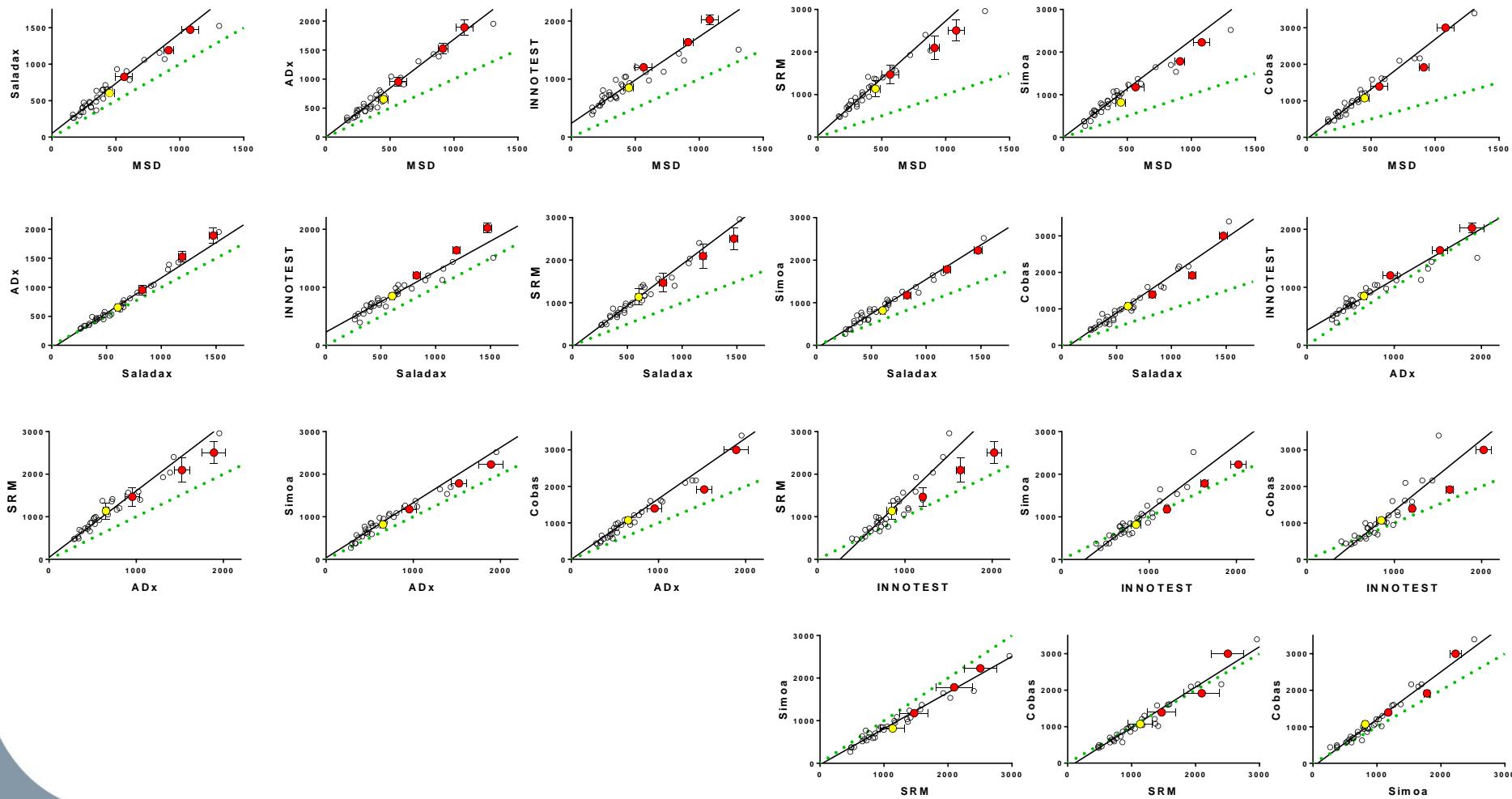
Plate layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	Neat	1	9	17	25	S1	Neat	1	9	17	25
B	S2	Spiked 1	2	10	18	26	S2	Spiked 1	2	10	18	26
C	S3	Spiked 2	3	11	19	27	S3	Spiked 2	3	11	19	27
D	S4	Spiked 3	4	12	20	28	S4	Spiked 3	4	12	20	28
E	S5	Neat	5	13	21	29	S5	Neat	5	13	21	29
F	S6	Spiked 1	6	14	22	30	S6	Spiked 1	6	14	22	30
G	S7	Spiked 2	7	15	23	31	S7	Spiked 2	7	15	23	31
H	Blank	Spiked 3	8	16	24	32	Blank	Spiked 3	8	16	24	32

Example



Method comparisons



Correlation matrix (Spearman's r)

	MSD	Saladax	ADx	INNOTESt	SRM	Simoa	Cobas
MSD		0.95	0.95	0.92	0.96	0.97	0.97
Saladax	0.95		0.98	0.96	0.97	0.97	0.97
ADx	0.95	0.98		0.95	0.97	0.97	0.97
INNOTESt	0.92	0.96	0.95		0.91	0.94	0.93
SRM	0.96	0.97	0.97	0.91		0.97	0.97
Simoa	0.97	0.97	0.97	0.94	0.97		0.97
Cobas	0.97	0.97	0.97	0.93	0.97	0.97	
Average	0.95	0.97	0.96	0.94	0.96	0.96	0.96