Traceability in External Quality Assessment:

How Weqas ensures traceability in EQA and stresses its importance to users

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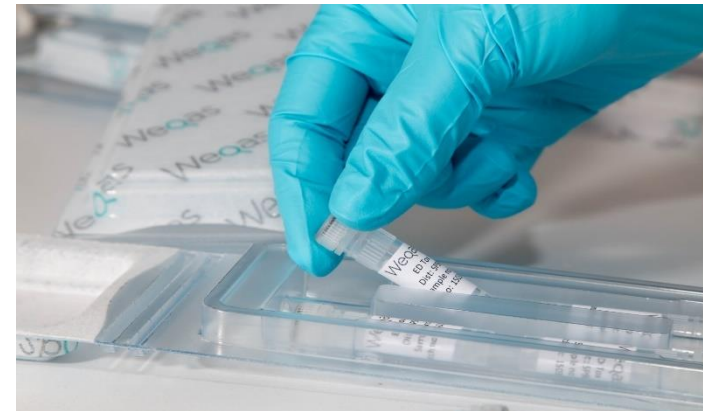
Weqas

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www.weqas.com

Programme Design: Lab and PoCT

Serum Chemistry

Lipids / Bilirubin

ED Toxicology

Urine Chemistry / Oxalate & Citrate

Blood Gases / Co-oximetry

Endocrine / Haematinics / Cardiac Marker / BNP

Homocysteine / Bile Acids / Serum ACE / Serum HCG / Porphyrin / Ammonia / CRP / TDM / IS

HbA1c

POCT Creatinine

Urine Drugs of Abuse

Common Report format (quantitative)

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Multiple samples are important

- Identifies components of both Imprecision and Inaccuracy (*traceability across the measurement range*)

- Identifies systematic errors

- Assesses method linearity – required for ISO 15189

- Powerful error detection tool

Value of Reference Targets

- Traceable to higher order

- Establishes method traceability for the lab – requirement of ISO 15189

- Highlights the pitfalls of using the trimmed overall mean as an accuracy target in EQA Schemes

- Useful in the post market vigilance of the IVD - Directive

- Required for UK MAPS

Detailed in Participants Manual and on website

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Reference Methods

Flame Atomic Absorption/ Emission Spectrometry

- Sodium, Potassium, Calcium
- Magnesium, Lithium

IFCC Enzymes

- AST, ALT, LDH, GGT

- HbA1c *

* Provided by IFCC Ref lab, Netherlands

ID-MS

- Progesterone
- Testosterone
- Cortisol
- Bile Acids
- Creatinine
- Cholesterol**
- Glucose
- Urate
- Triglyceride
- HDL ***

** Currently provided by CDC lab Rotterdam & Weqas Ref Lab

***Currently provided by CDC lab Rotterdam

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Drugs Of Abuse / Therapeutic Drug Monitoring: Gravimetric values

Measurand (DOA; Urine)	Range Covered	Measurand (TDM; Serum)	Range Covered
Amphetamine	0 – 3000 µg/L	Amikacin	0 – 35 mg/L
Benzodiazepine	0 – 1000 µg/L	Carbamazepine	0 – 20 mg/L
Barbiturate	0 - 1000 µg/L	Digoxin	0 – 6 ug/L
Buprenorphine	0 - 50 µg/L	Gentamicin	0 - 20 mg/L
Cocaine	0 - 1000 µg/L	*Lamotrigine	0- 30 mg/L
Cannabis	0 - 150 µg/L	Lithium	0 – 2.5 mmol/L
6-Acetylmorphine (heroin)	0 - 50 µg/L	Methotrexate	0 -1.5 umol/L
Ketamine	0 - 3000 µg/L	Phenobarbital	0 - 65 mg/L
Methadone	0 - 1000 µg/L	Phenytoin	0 - 30 mg/L
EDDP	0 - 1000 µg/L	*Teicoplanin	0 - 70 mg/L
Methamphetamine	0 - 3000 µg/L	Theophylline	0 - 30 mg/L
Opiates	0 – 3000 µg/L	Tobramycin	0 - 15 mg/L
Phencyclidine (PCP)	0 - 100 µg/L	Valproic acid	0 - 175 mg/L
Tricyclic antidepressants	0 - 3000 µg/L	Vancomycin	0 - 50 mg/L
MDMA	0 – 3000 µg/L		
Amphetamines Group Screen	Qualitative only		

- High order drug/metabolite gravimetrically added to base material
- Pools mixed with the negative base material to produce a panel of intermediate pools.
- The "weighed-in" value incorporating purity of the spike used as target value.
- All microbalances are calibrated by ISO17025 accredited organisation

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The WEQAS Report
Target values used in Statistical Analysis

Hierarchy

Reference values – used for bias plot /SDI calculation and σ score

Method mean – used for SDI calc if no ref and n>8

Overall mean – used for SDI calc and bias plot if no ref and n <8

Analyser mean – on report for information only

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Analytical Specification Requirements

The National QA Advisory Panel in the UK has devised a **M**inimum **A**nalytical **P**erformance **S**pecification (MAPS) which has been adopted since 2010

	Concentration	Allowable Bias vs Reference Value	Allowable variability	Allowable Total Error
Total Cholesterol	5.0 mmol/L [Desirable[1]]	4.00%	2.70%	8.50%
HDL-Cholesterol	1.0 mmol/L [Desirable[1]]	5.20%	3.60%	11.10%
	1.0 mmol/L [Achievable]	10.00%	3.60%	15.90%
Glucose	7.0 mmol/L [Desirable[1]]	2.20%	2.90%	6.90%
	2.0 mmol/L [Achievable]	+/- 10% absolute		
HbA1c	50 mmol/mol [Desirable[1]]	2.2%*	2.5%*	6.3%*
	50 mmol/mol [Achievable]	3.60%	2.50%	7.70%
Creatinine	75 umol/L [Desirable[1]]	3.80%	2.70%	8.20%
	75 umol/L [Achievable]	5.00%	2.70%	9.50%

Scheme: Mainline Chemistry. Distribution Code: PQ.
Distribution Date: 2/06/14. Final. Report Issued: 1/07/14

Creatinine (µmol/L)		1	2	3	4	Analyte SDI
Reported Result		245	40	452	314	
Method Corrected Result		245.0	40.0	452.0	314.0	
Kinetic Jaffe	Mean	247.1	43.2	448.4	313.1	
	SD	6.9	4.6	18.2	10.1	
	Number	53	52	54	53	
	Uncert.	0.94	0.64	2.48	1.38	
Architect	Mean	249.6	44.1	464.3	320.9	
	SD	5.1	0.9	7.1	4.2	
	Number	9	8	9	9	
	Uncert.	1.71	0.33	2.37	1.39	
Overall	Mean	245.5	40.9	448.3	313.0	
	SD	7.6	4.7	17.0	10.4	
	Number	244	239	250	247	
	Uncert.	0.49	0.30	1.08	0.66	
Reference Values ID-GCMS		245.9	41.6	443.9	310.5	
Ref. Value Uncertainty		1.52	0.26	2.75	1.92	
Non-scoring Reference Values						
WeQas SD		9.7	5.1	21.1	12.7	
SDI		-0.09	-0.31	0.38	0.28	0.27

Sigma Metrics

Critical Level 1: 75 µmol/L

Minimum Acceptable score	1.67	Critical Level 1 Sigma score	2.1
MAPS Allowable TE	9.5%		
MAPS Allowable bias %	5.0%	Lab |bias| %	2.9%
MAPS Allowable CV %	2.7%	Lab CV %	3.2%

Please note: Linear regression uses CF corrected data.

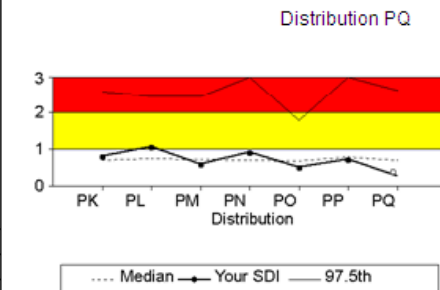**"True" Value**

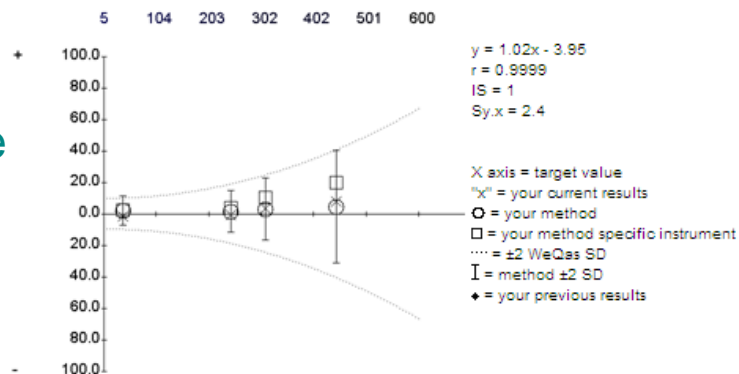**Performance Criteria Target ± 9.5%**

Total Error

SDI is a measurement of your total error and will include both in

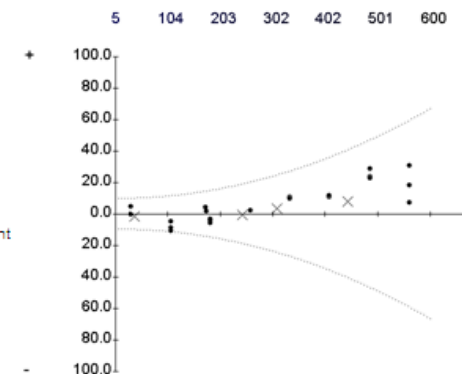| This Distribution PQ |
|---|
| Your average analyte SDI for the 4 samples is 0.27 |

Previous SDI

Distribution PQ

PK PL PM PN PO PP PQ
Distribution

···· Median —•— Your SDI —— 97.5th

Assesses how far the lab's results are away from the "true" value and general performance over time.

This Distribution PQ

y = 1.02x - 3.95
r = 0.9999
IS = 1
Sy.x = 2.4

X axis = target value
"x" = your current results
O = your method
□ = your method specific instrument
···· = ±2 WeQas SD
I = method ±2 SD
♦ = your previous results

Previous Distributions

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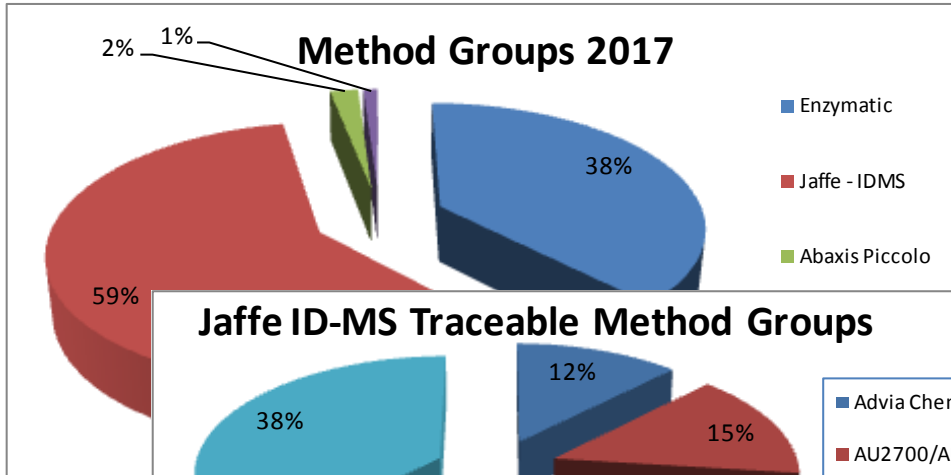# Traceability Communication to Users

Reports sent to participants, published at conferences, journals, website etc.

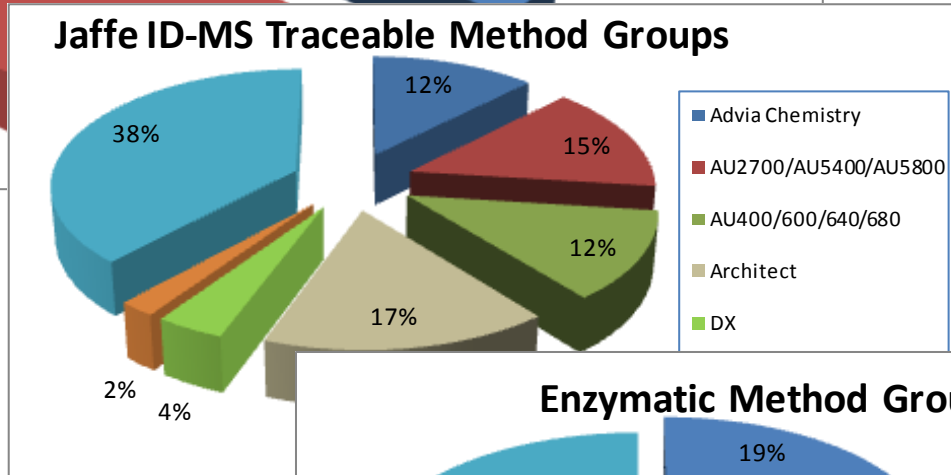Annual Participant Meeting often features talks on traceability

Example:
Creatinine (presented at Euromedlab, Athens)

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EQA Assigned Method Groups

Method Groups 2017

2% 1%

- Enzymatic
- Jaffe - IDMS
- Abaxis Piccolo

38%

59%

Jaffe ID-MS Traceable Method Groups

12%

15%

12%

38%

17%

2%

4%

- Advia Chemistry
- AU2700/AU5400/AU5800
- AU400/600/640/680
- Architect
- DX

Enzymatic Method Groups

19%

6%

3%

5%

67%

- Advia Chemistry
- AU2700/AU5400/AU5800
- AU400/600/640/680
- Modular
- Cobas C Module

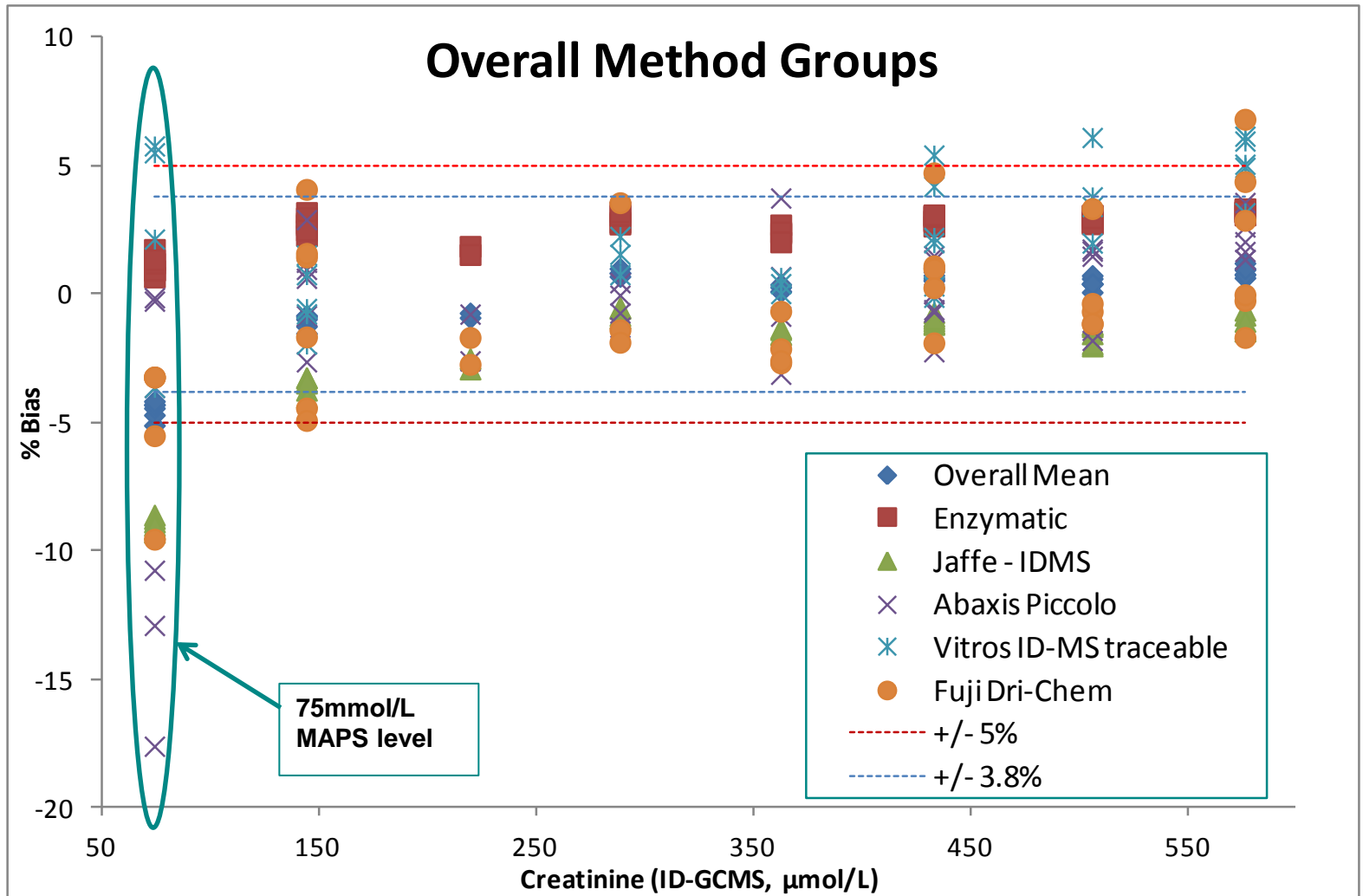Enzymatic methods users: the number of users risen from 20% in 2012 to 38% in 2017

Major group is the Roche Cobas, which will influence the Jaffe overall mean
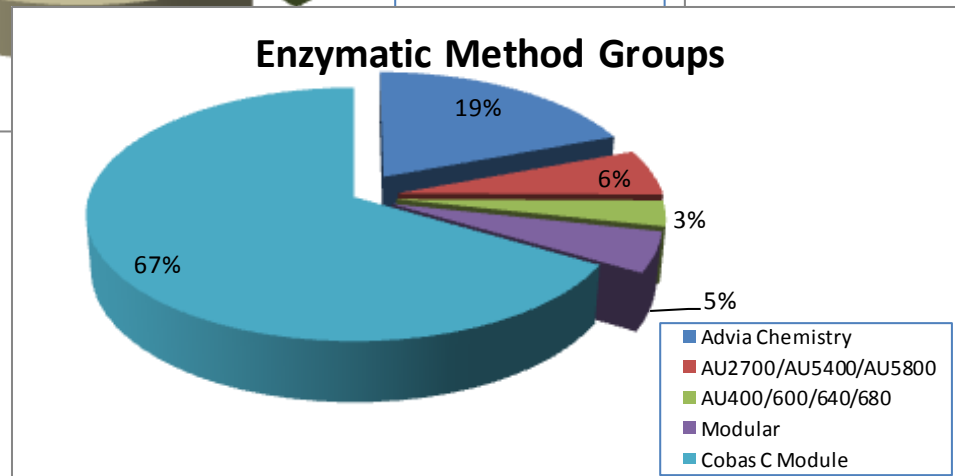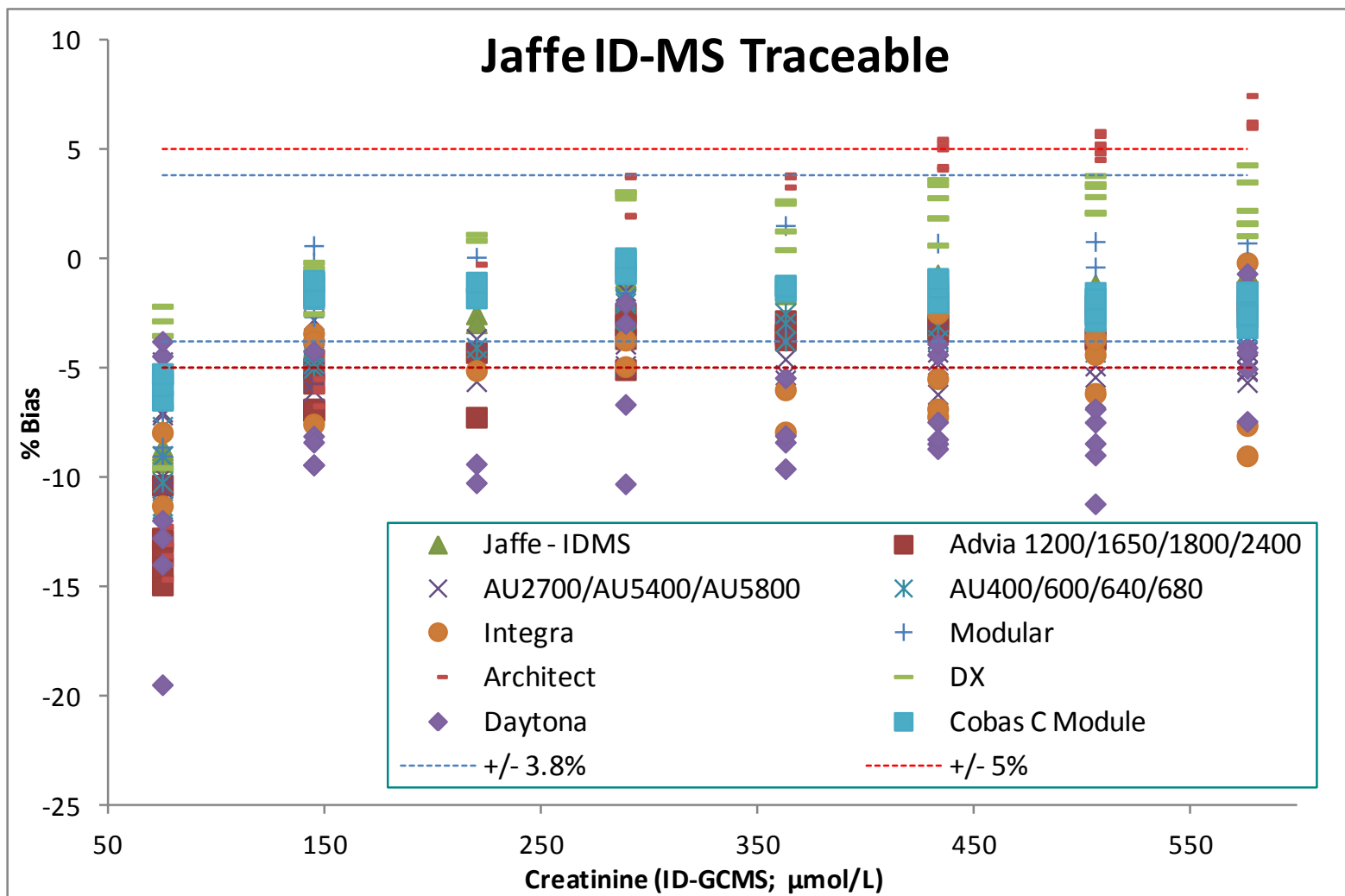
Major group again is the Roche Cobas, which will influence the enzymatic overall mean
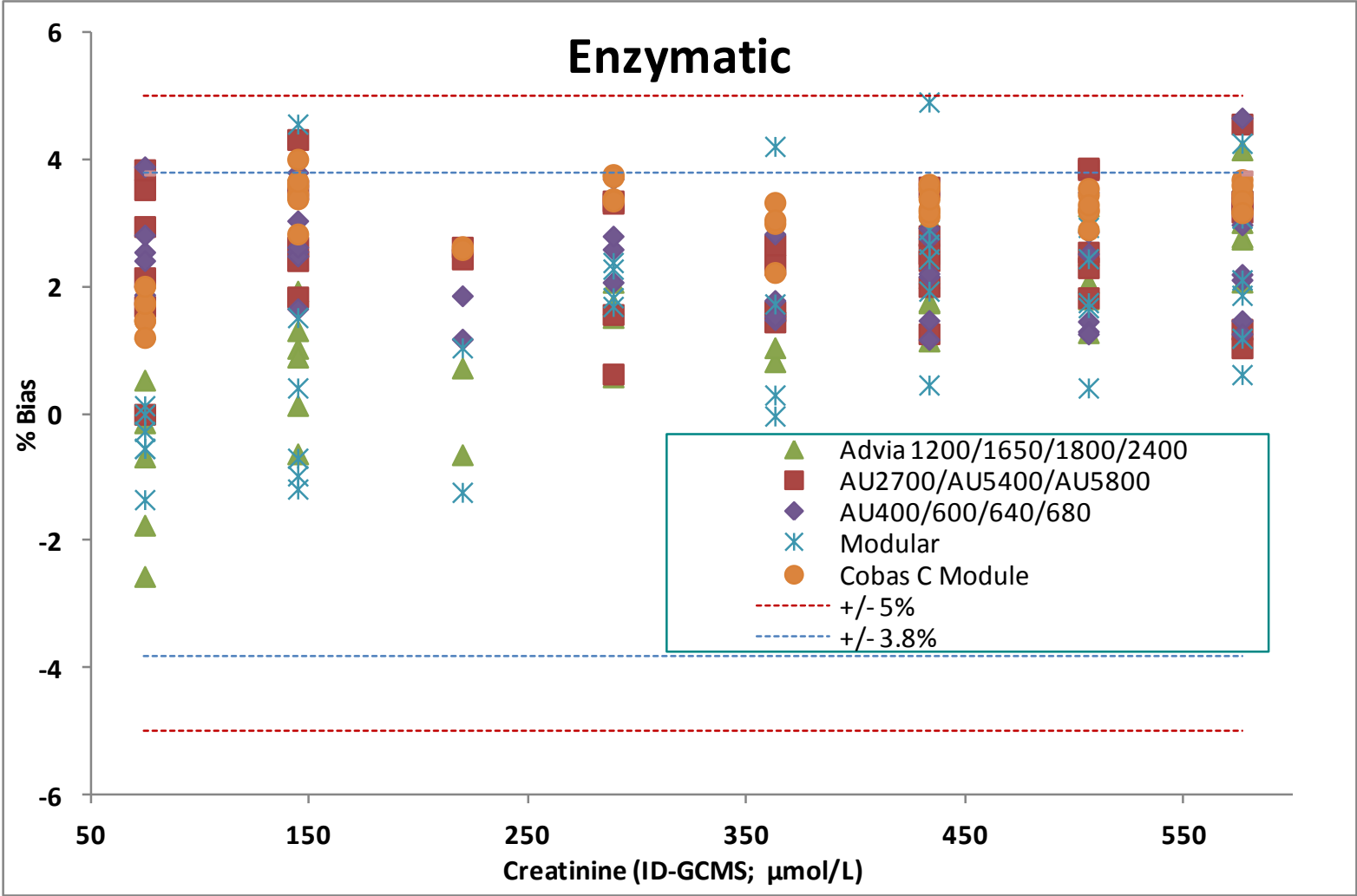
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Overall Method Groups Bias Plot

Jaffe ID-MS Traceable Bias Plot

Enzymatic: Bias Plot

In Summary

- Laboratories are scored against Reference Measurement Values where available

- Gravimetric spiking of material with higher order material is used as an alternative traceable target

- Both Reference Measurement and gravimetric target values aid in identification of methods where traceable calibration may be an issue

- Traceability of methods is therefore assured aiding ISO 15189 accreditation for laboratories

- The use of reference targets as opposed to comparison with mean data eloquently highlights the variability of results and reduces the pitfalls of laboratory trimmed data comparisons

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Thank you for your attention