

# SEQC EXTERNAL QUALITY ASSURANCE PROGRAMS

## Commutable Serum with Reference Values (SCR) Impact on standardization

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- The **Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC)** was founded in 1976. The aim of the Society was promoting the professional development, research and education in this fields oriented towards the benefit of patients.
- SEQC has nearly 2284 members who are university graduates coming indistinctly from schools of medicine, pharmacy or science (chemical or biological).
- The Society is organized into **Commissions** and **Working Groups**, which are grouped in **Committees**, coordinated by a Board of Directors.
- The **External Quality Programs Committee** organizes External Quality Assurance Programs (EQAP). This Committee has implemented a quality management system, whose aim is design, organization and implementation of EQAP. These programs are certified according to ISO 9001:2008 standard.

### Program

- Characteristics and Objectives
- Scheme design
- Analytes included
- Characteristics of the control material
- Quality Certificates (ISO 9001:2008)

[www.contcal.org](http://www.contcal.org)

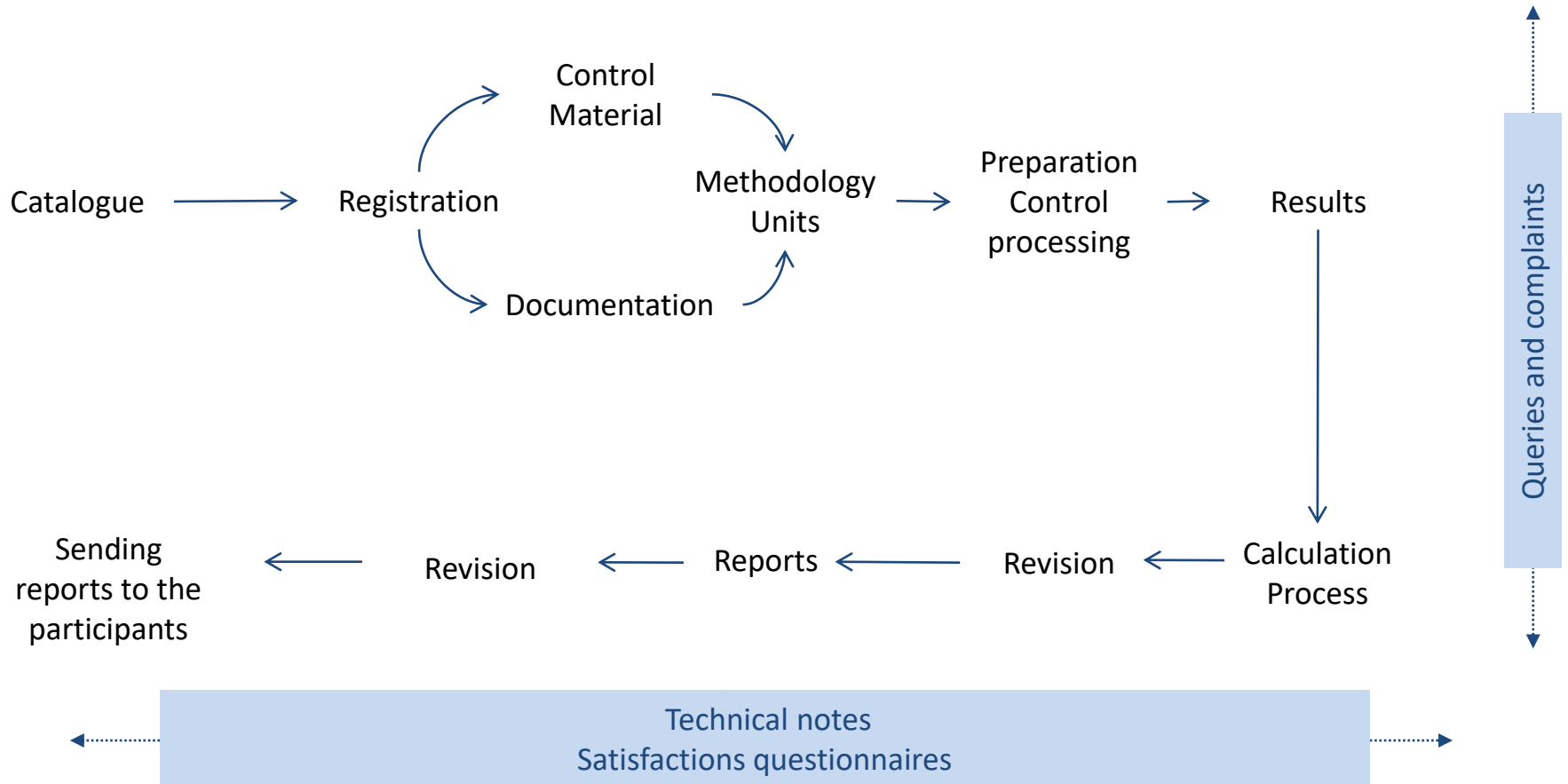
SECTION	PROGRAM	ANALYTE NUMBER	REGISTRATIONS
EXTRA ANALYTICAL PHASE	PREANALYTICAL	19	62
	MANAGEMENT LABORATORIES INDICATORS	28	34
BIOCHEMISTRY	SERUM	36	841
	COMMUTABILITY SERUM WITH REFERENCE VALUES	18	102
	URINE	14	492
	HORMONS	31	390
	THERAPHEUTICS DRUGS	12	158
	PROTEINS	21	309
	BLOOD GAS - POCT	9	544
	CARDIAC MARKERS	7	333
	TUMORAL MARKERS	13	273
	HEMOGLOBIN	1	292
	URINE DRUGS	9	188
MONOCLONALS COMPONENTS	10	106	

SECTION	PROGRAM	ANALYTE NUMBER	REGISTRATIONS
MICROBIOLOGY	BACTERIOLOGY	2	78
	MYCOLOGY	1	39
	MICROSCOPY	1	45
SEROLOGY	BRUCELLA	1	88
	TREPONEMA	5	99
	TOXOPLASMA	1	96
	RUBELLA	1	96
	HEPATITIS B	2	153
	HEPATITIS C	1	146
	HIV	1	146
TRACE ELEMENTS (OELM)	SERUM / WHOLE BLOOD / URINE	39	81
AUTOIMMUNITY ALLERGY (UKNEQAS)	21 PROGRAMMES	69	749

[www.contcal.org](http://www.contcal.org)

[www.trace-elements.eu](http://www.trace-elements.eu)

[www.immquas.org.uk](http://www.immquas.org.uk)



- SCR (EQAP level 1) was developed as a pilot program in 2015, in collaboration with SKML. This program is focused on the biochemistry fields.
- SCR has been offered in the 2016 SEQC -EQAP catalogue.

- ✓ Commutable samples (human serum)
- ✓ Assigned value by reference methods
- ✓ Replicated analysis

Allows to...

- Know the absolute trueness of laboratory results
- Learn about the level of standardization of analytical procedures
- Identify laboratories and methods with poor performance
- Promote the use of standardized methods
- Eliminate non-standardized methods



### Analytes

- Total Bilirubin
- Calcium
- Chloride
- Creatinine
- Glomerular filtration rate
- Glucose
- Magnesium
- Potassium
- Protein

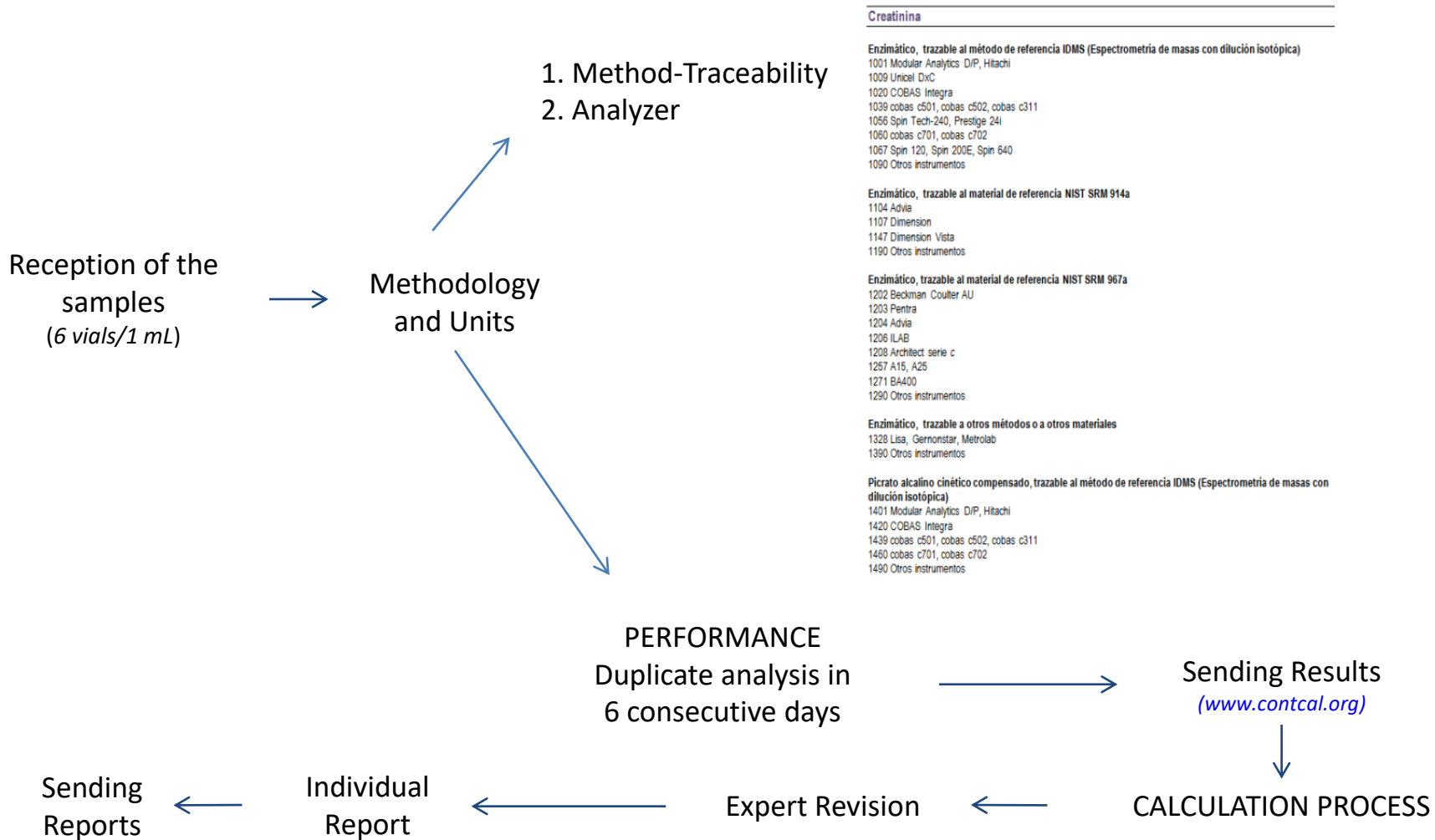


### Analytes

- Sodium
- Urate
- $\alpha$ -Total amylase
- ALT
- AST
- CK
- Alkaline phosphatase
- Gamma-Glutamyltransferase
- Lactate dehydrogenase

### Characteristics of the Program

- ❖ 87 participants
- ❖ Survey: April 2015
- ❖ Individual report: July 2015
- ❖ Global report: December 2015



Creatinina	
<b>Enzimático, trazable al método de referencia IDMS (Espectrometría de masas con dilución isotópica)</b>	
1001	Modular Analytics D/P, Hitachi
1009	Unicel DxC
1020	COBAS Integra
1039	cobas c501, cobas c502, cobas c311
1056	Spin Tech-240, Prestige 24i
1060	cobas c701, cobas c702
1067	Spin 120, Spin 200E, Spin 640
1090	Otros instrumentos
<b>Enzimático, trazable al material de referencia NIST SRM 914a</b>	
1104	Advia
1107	Dimension
1147	Dimension Vista
1190	Otros instrumentos
<b>Enzimático, trazable al material de referencia NIST SRM 967a</b>	
1202	Beckman Coulter AU
1203	Pentra
1204	Advia
1206	ILAB
1208	Architect serie c
1257	A15, A25
1271	BA400
1290	Otros instrumentos
<b>Enzimático, trazable a otros métodos o a otros materiales</b>	
1328	Lisa, Gernonstar, Metrolab
1390	Otros instrumentos
<b>Picrato alcalino cinético compensado, trazable al método de referencia IDMS (Espectrometría de masas con dilución isotópica)</b>	
1401	Modular Analytics D/P, Hitachi
1420	COBAS Integra
1439	cobas c501, cobas c502, cobas c311
1460	cobas c701, cobas c702
1490	Otros instrumentos

The **Individual report** includes, for each analyte and control sample result, the following information:

- ✓ assigned value by reference method
- ✓ laboratory inaccuracy against the reference value
- ✓ average of the peer group (same method and traceability).
- ✓ deviation percentage (DP) of peer group mean vs the reference value (RV)

Additionally laboratory imprecision (average of all control samples) is also shown.

The **global report** studies the degree of standardization of the methods and instruments used by participating laboratories.

Manufacturer	Instrument
Abbott Diagnostics	Architect c8000, ci 8200, c16000
Beckmann Coulter	AU 400, 5430, 5800, 5832
Horiba ABX	Pentra 200, 400
Instrumentation Laboratory	ILAB
Ortho Clinical Diagnostics	Vitros 250, 5600
Roche Diagnostics	Cobas 6000, c501
Roche Diagnostics	Cobas 8000, c701, c702,
Roche Diagnostics	Cobas Integra 400+
Siemens Healthcare S.L.	Advia 1800, 2400, XPT
Siemens Healthcare S.L.	Dimension RXL, EXL
Siemens Healthcare S.L.	Vista 500 ó 1500
Spinreact	Spin 640

Electrolyte	Reference method	Reference laboratory
Ca	Atomic Absorption Spectrometry	INSTAND e.V., Düsseldorf, Germany
Cl	ICP-IDMS	INSTAND e.V., Düsseldorf, Germany
Mg	ICP-IDMS	INSTAND e.V., Düsseldorf, Germany
K	ICP-IDMS	INSTAND e.V., Düsseldorf, Germany
Na	ICP-IDMS	INSTAND e.V., Düsseldorf, Germany

Substrate	Reference method	Reference laboratory
Bilirubin	IFCC Reference Method	DGKL, Hannover, Germany
Creatinine	IDMS	DGKL, Bonn, Germany
Glucose	GC-IDMS	INSTAND e.V., Düsseldorf, Germany
Protein	Modified Biuret Method	INSTAND e.V., Düsseldorf, Germany
Urate	HPLC	Erasmus Medical Centre, Rotterdam, Netherlands

Enzymes	Reference method	Reference laboratory
ALT	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands
$\alpha$ -Amylase	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands
AST	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands
ALP	IFCC Primary Reference Method	Unknown
CK	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands
GGT	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands
LDH	IFCC Primary Reference Method	Haga Hospital. The Hague. The Netherlands

Summary evaluation:

1. Overall results
2. Results by method
3. Results by instrument



CALCULATION	INTERPRETATION
Deviation % of a result vs RV	Biological variation specification for total error*
Deviation % of a peer group mean vs RV	Biological variation specification for systematic error*

\*Minchinela J, Ricós C, Perich C, Fernández-Calle P, Álvarez V, Doménech MV, Simón M, Biosca C, Boned B, Cava F, García-Lario JV, Fernández-Fernández MP. Biological variation database and quality specifications for imprecision, bias and total error (desirable and minimum). The 2014 update. <http://www.westgard.com/biodatabase-2014-update.htm>

### I. Almost standardized test analytes

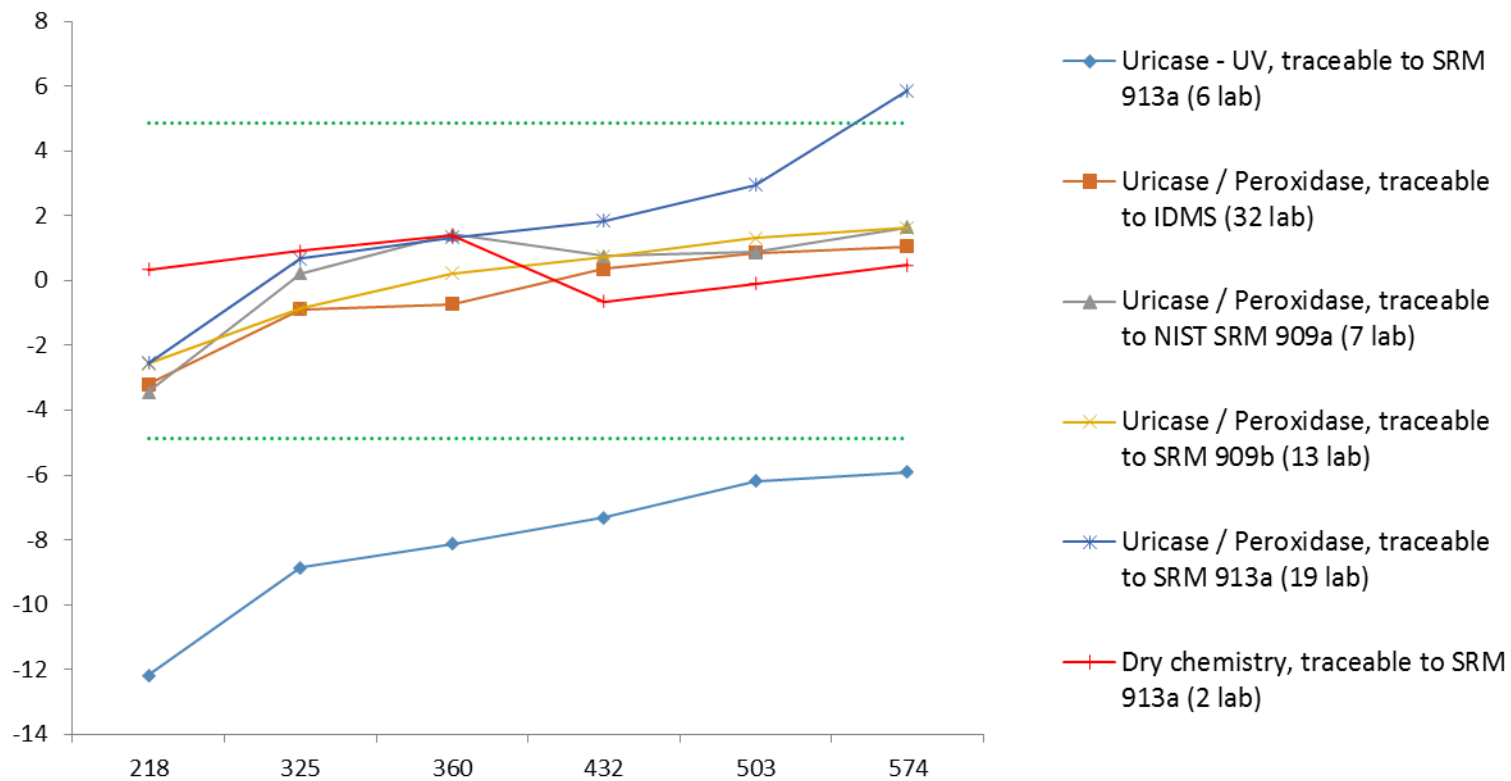
- ✓ Bilirubin
- ✓ CK
- ✓ Glucose
- ✓ Potassium
- ✓ Protein
- ✓ Sodium
- ✓ Urate

### II. Non standardized test analytes

- ✓  $\alpha$ -Amylase
- ✓ ALT/AST
- ✓ ALP
- ✓ Chloride
- ✓ Calcium
- ✓ Creatinine
- ✓  $\gamma$ -GT
- ✓ LDH

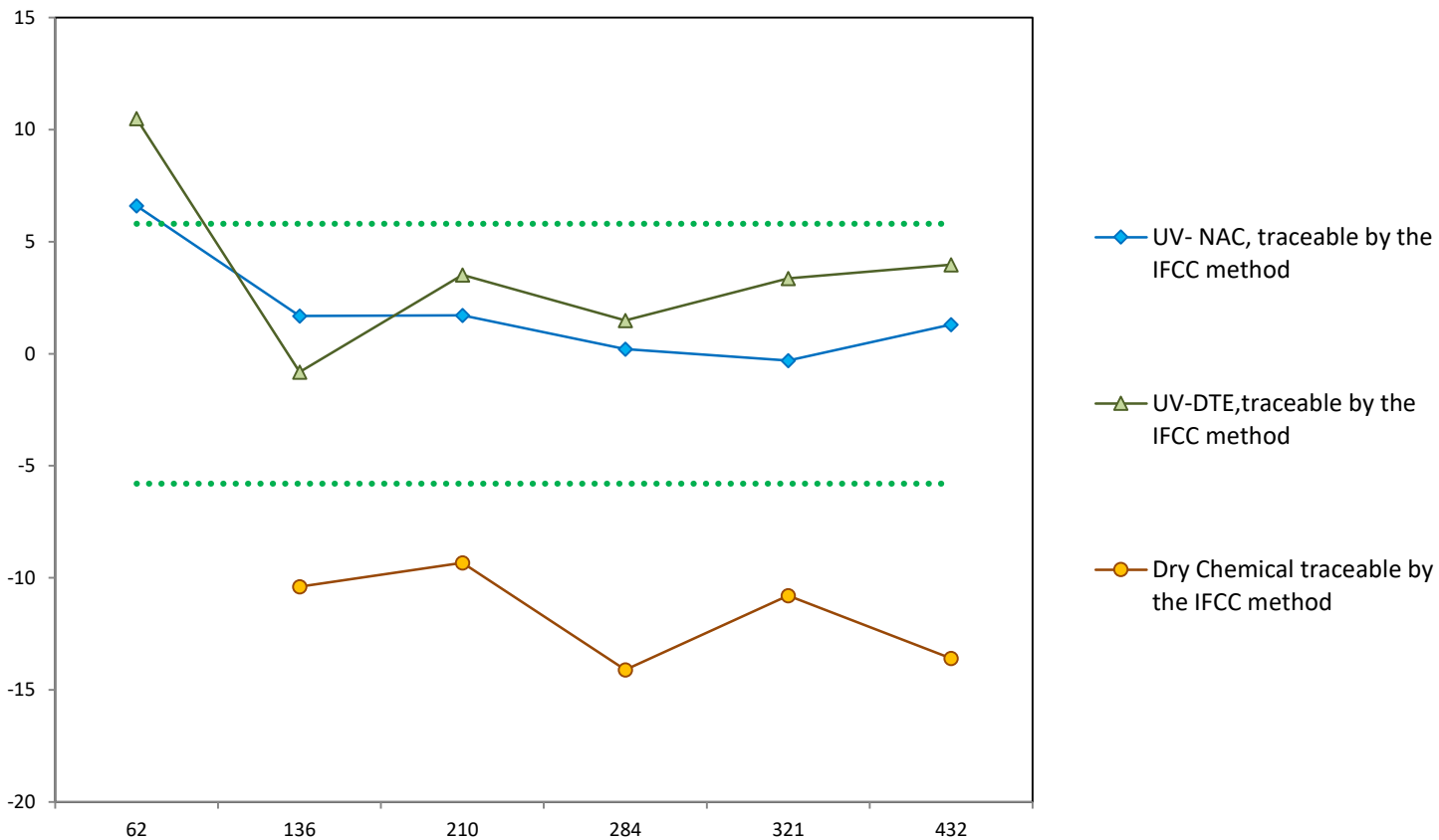
Method	No. lab	Instrument
Uricase - UV, traceable to NIST SRM 913a	6	Dimension Vista, Dimension EXL
Uricase / Peroxidase, traceable to IDMS	32	Architect ci8200, AU400, AU5400, AU-5800, Cobas 501, Cobas 702, Cobas 6000, Cobas 8000, Cobas Integra, Spin-640
Uricase / Peroxidase, traceable to NIST SRM 909a	7	Architect c16000, Cobas c501, Cobas c701, Cobas 8000, ILAB 650
Uricase / Peroxidase, traceable to NIST SRM 909b	13	Advia 1800, Advia 2400, Cobas c501, Cobas c701, Cobas 6000, Cobas 8000, Cobas Integra 400 plus
Uricase / Peroxidase, traceable to NIST SRM 913a	19	Advia 2400, Advia XPT, Architect c8000, Architect c16000, Dimension EXL
Dry chemistry, traceable to NIST SRM 913a	2	Vitros 250, Vitros 5600

DP of the peer group mean vs RV



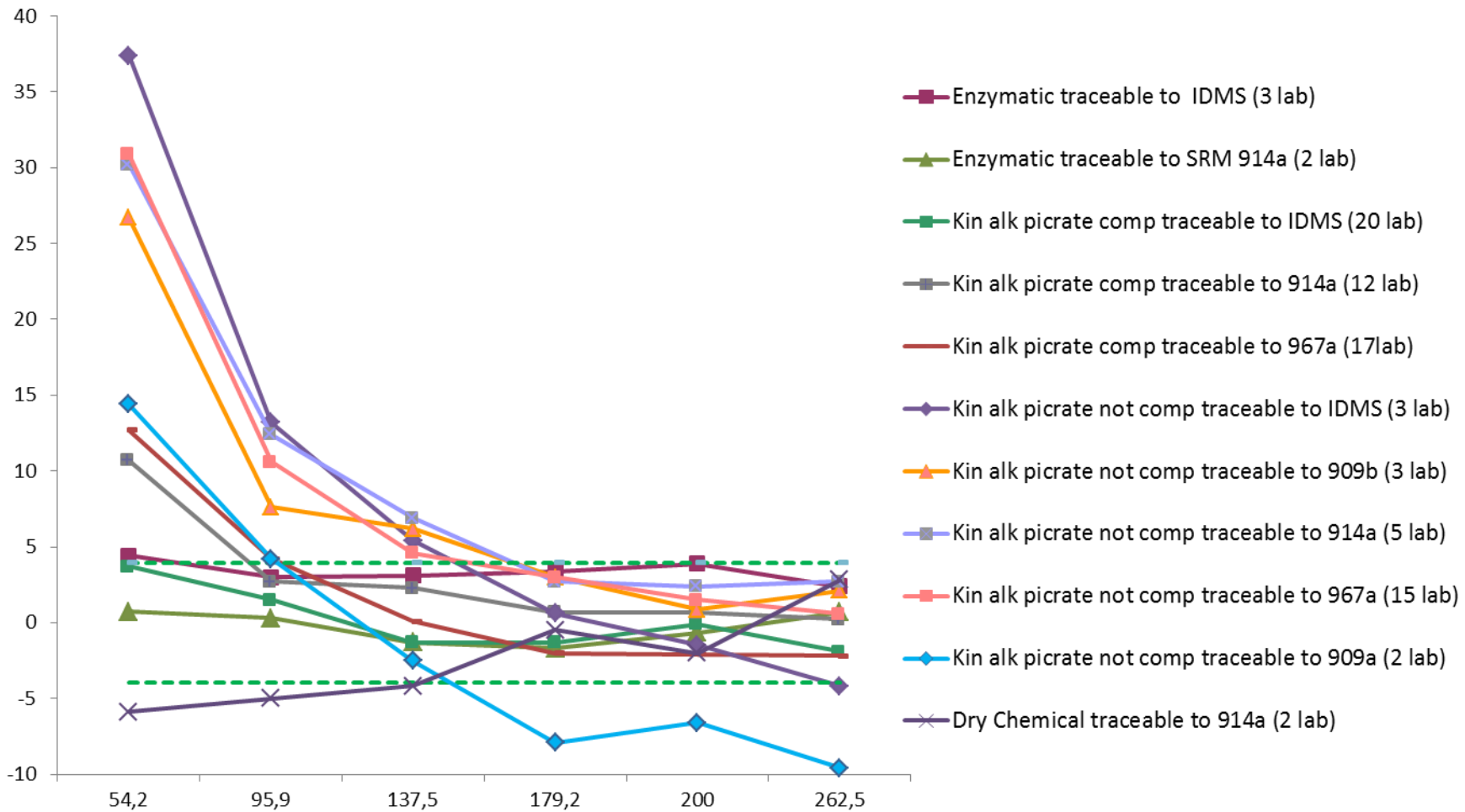
Method	No. lab	Instrument
UV, N-Acetil-cistein activator, traceable to IFCC method	70	Cobas 8000 & c701 & c702 (14), Cobas 6000 & c501 (13), Advia (10), Archictect (9), Beckman Coulter AU (8), Vista (4), Cobas Integra 400 (3), Pentra 400 (2), Dimension EXL (1), Spin 640 (1), without model (5)
UV, Dithioeritritol activator (DTE), traceable to IFCC method	1	BeckmanCoulter AU (1)
Dry chemistry, traceable to IFCC method	1	Vitros (1)
Other method, traceable to IFCC method	1	Vista (1)

DP of the peer group mean vs RV



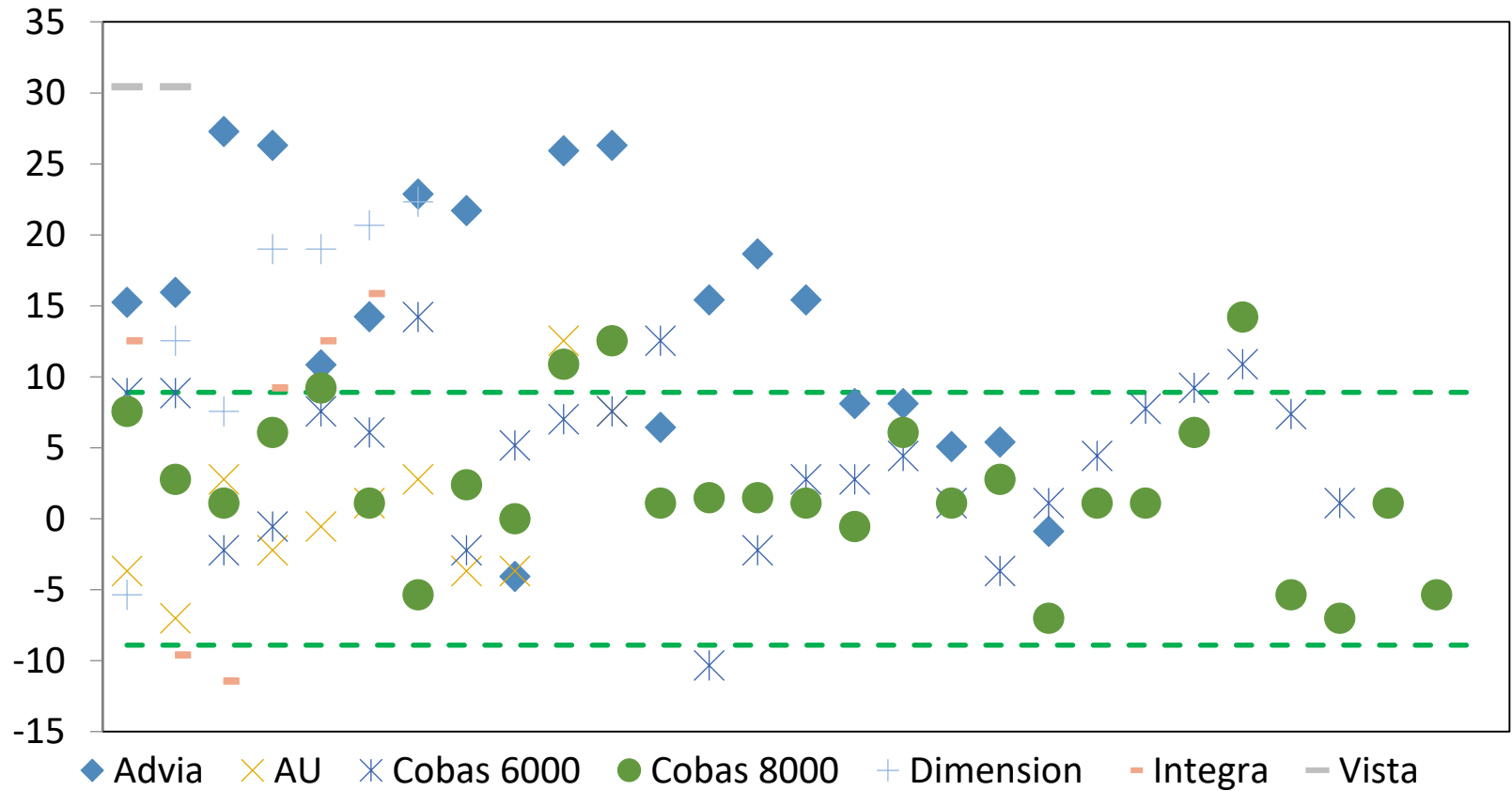
Method	No. Labs	Instrument
Enzymatic, traceable to IDMS method	3	Cobas 8000, Cobas 6000
Enzymatic, traceable to SRM 914a	2	Vista
Enzymatic, traceable to SRM 967a	1	Pentra 200
Kinetic alkaline picrate compensated, traceable to IDMS	20	Cobas 8000, Cobas 6000, Cobas Integra
Kinetic alkaline picrate compensated, traceable to SRM 909b	1	AU
Kinetic alkaline picrate compensated, traceable to SRM 914a	12	Cobas 6000, Cobas 8000, Vista, Dimension EXL, Advia, AU
Kinetic alkaline picrate compensated, traceable to SRM 967a	17	AU, Advia, Cobas 6000, Cobas Integra
Kinetic alkaline picrate not compensated, traceable to IDMS	3	Spin 640, Architect
Kinetic alkaline picrate not comp, traceable to SRM 909a	2	ILAB 650
Kinetic alkaline picrate not comp, traceable to SRM 909b	3	AU
Kinetic alkaline picrate not comp, traceable to SRM 914a	5	Vista, Advia, Ci8200, EXL
Kinetic alkaline picrate not comp, traceable to SRM 967a	15	Architect, Pentra, Ci 8200, AU
Dry chemistry, traceable to SRM 914a	2	Vitros 250 y 5600

### DP of the peer group mean vs RV

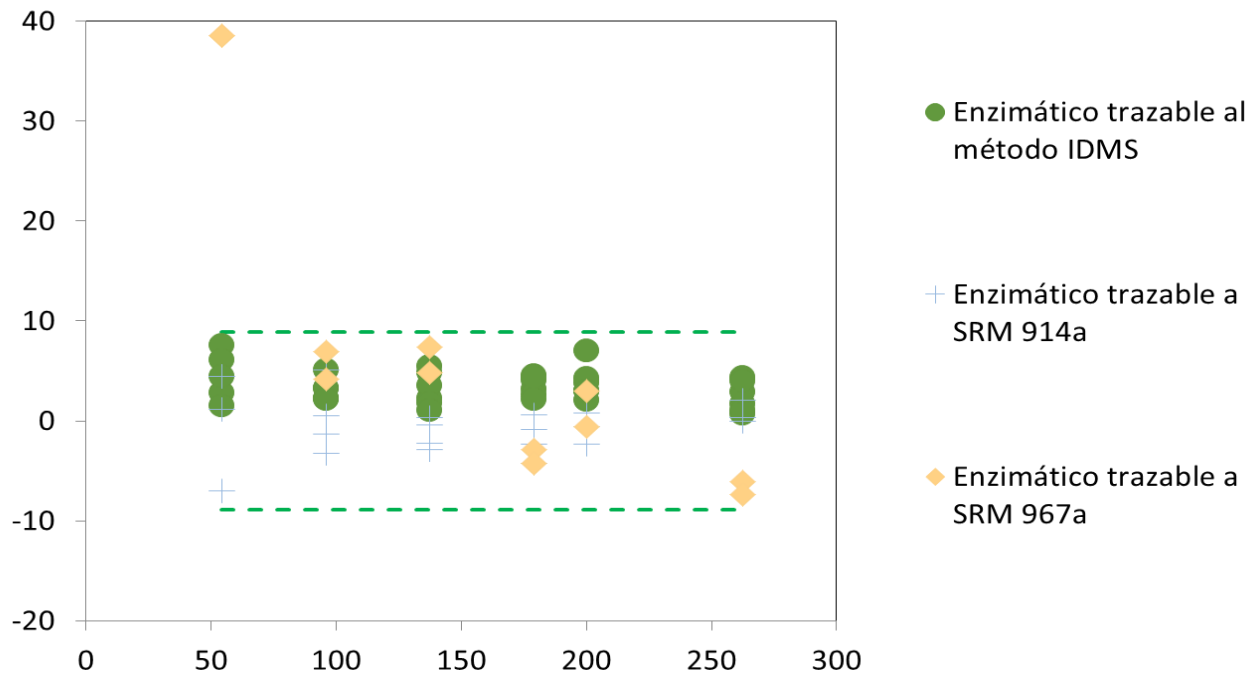




Alkaline picrate compensated method  
54.2  $\mu\text{mol/L}$  (0,61 mg/dL)

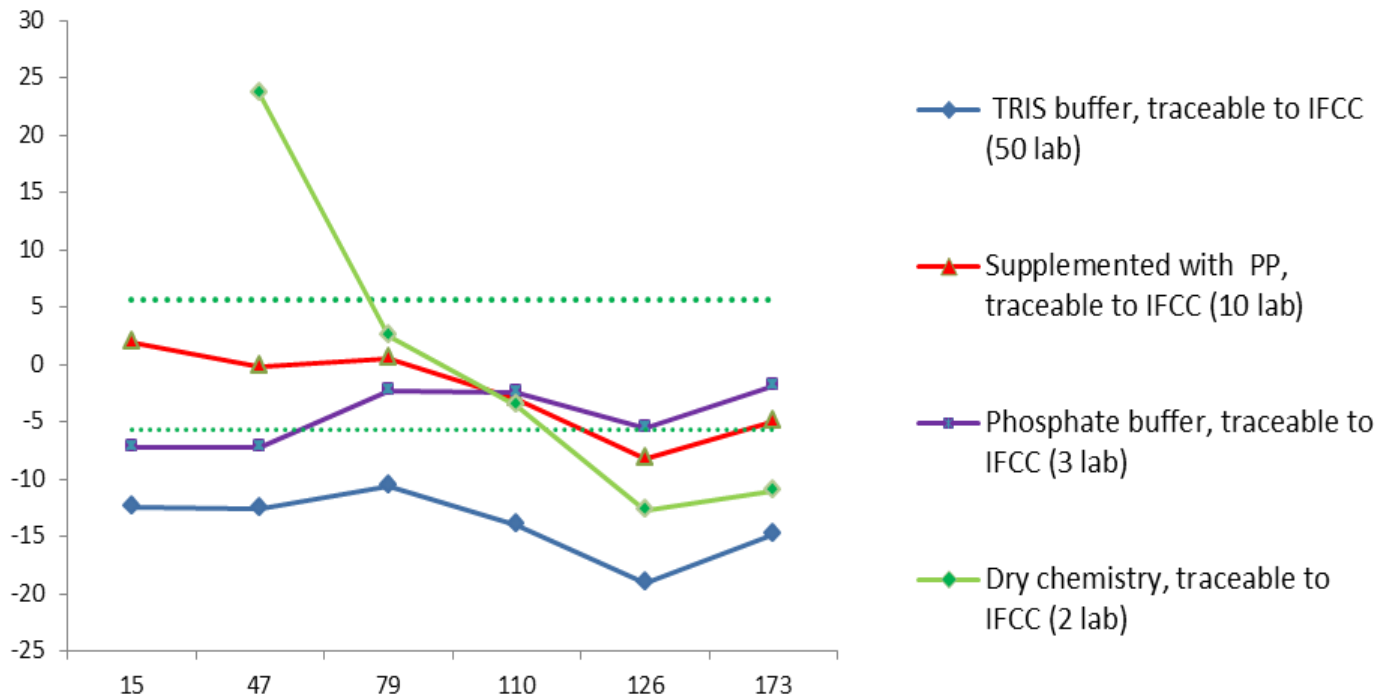


Enzymatic method  
54.2  $\mu\text{mol/L}$  (0,61 mg/dL)



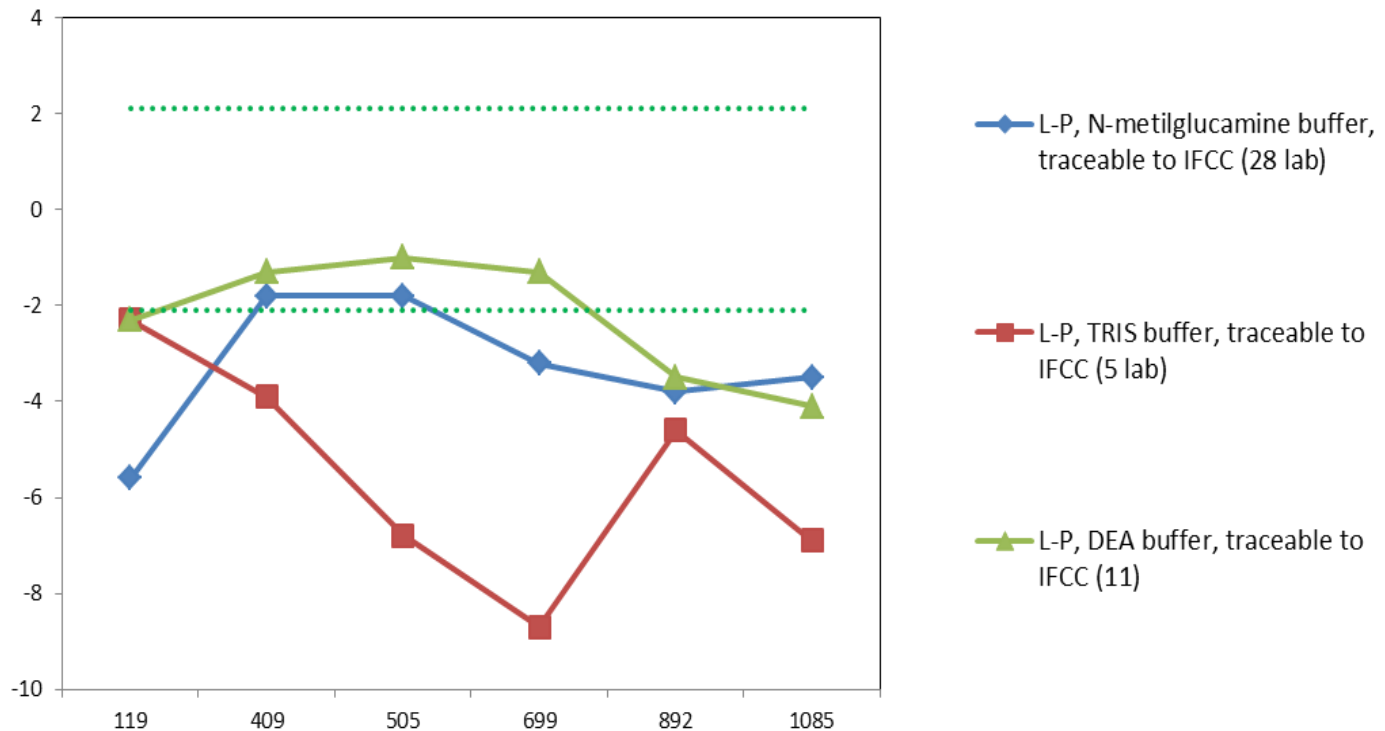
Method	No. lab	Instrument
Phosphate buffer, traceable to IFCC method	3	AU (2), Advia (1)
TRIS buffer, traceable to IFCC method	50	Advia (5), Architect (3), AU (3), Cobas 6000 & c501 (14), Cobas 8000 & c701 (14), Cobas Integra 400+ (3), ILAB 650 (1), Pentra (3), Spin (1), Vitros (2)
Supplemented with piridoxal phosphate, traceable to IFCC method	10	Advia (2), AU (2), Dimension EXL (1), Vista (5)
Dry chemistry, traceable to IFCC method	2	Vitros (2)

DP of the peer group mean vs RV



Method	No. lab	Instrument
Pyruvate to Lactate, phosphate buffer, traceable to IFCC method	6	Cobas serie 5000 (4), serie 8000 (1), Pentra 400 (1)
Pyruvate to Lactate, TRIS buffer, traceable to IFCC method	1	Advia 2400 (1)
Pyruvate to Lactate, BIS-TRIS-Propane buffer, traceable to IFCC method	3	Advia 2400 (1), AU 5800 (2)
Pyruvate to Lactate, imidazol buffer, traceable to IFCC method	1	Spin640(1)
Lactate to Pyruvate, N-metilglucamine buffer, traceable to IFCC method	28	Cobas 6000 (6), 8000 (11), Integra 400+ (1), AU (2), Dimension (6)
Lactate to Pyruvate, TRIS buffer, traceable to IFCC method	5	Advia 2400(5)
Lactate to Pyruvate, dietanolamine (DEA) buffer, traceable to IFCC method	11	Architect (9), Vista 1500 (1), Advia (1)

DP of the peer group mean vs RV



- ✓ Short length of study , 15 days (punctual problems in equipment/calibrators)
- ✓ Difficult for laboratories to codify correctly, with the consequent probability of creating heterogeneous groups with dispersed results.
- ✓ Wide dispersion of methods for some analytes (calibrator traceability and instruments), producing small groups that could lead to poor reliable results

## PROVIDERS

- Clear and updated information on calibrators traceability (specifying reference method and / or reference material) should be given in the insert.

## LABORATORY

- To use standardized and recommended methods, i.e. AST/ALT with pyridoxal phosphate.
- To abandon obsolete methods, i.e. alkaline picrate for creatinine, substrate pyruvate for LDH.

## EQAP ORGANIZERS

- Should develop level 1 programs, when possible.



- Web Site of the Quality Programs [www.contcal.org](http://www.contcal.org)
- Web Site from the Society (SEQC) [www.seqc.es](http://www.seqc.es)
- Contact e-mail [calidad@seqc.es](mailto:calidad@seqc.es)
- Telephone number **+34 93 446 26 70**

**THANKS A LOT FOR YOUR ATTENTION**