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Comparison of Lind-Vac venous blood tubes with reference Greiner for biochemistry tests in hospital laboratory

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Background:

Vacuum tube systems have long been accepted for safe routine sampling of blood, particularly venous blood. New manufacturers appear on the market which justifies comparison with established systems. Recently Lind-Vac in Estonia has launched their system which prompts for a comparison with that regularly in use.

Materials and methods:

Comparisons between tubes from Lind-Vac (Estonia) with those from Greiner (Austria) were carried out as described in CLSI GP34-A (Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection) and EP-9A (Method comparison and Bias Estimation using Patient Samples). Tube types were with clot activator (type 1) and with clot activator and gel (type 2). Type 1 was used for 14 analytes in 24 patients and type 2 for 13 analytes in 20 patients. Sample collections were made according CLSI H3-A6 (Procedures for the collection of Diagnostic Blood Specimens by Venipuncture) in two tubes of each type for each patient. Concentrations were measured using RX Imola Randox (Ireland) in duplicates from each sample.

Results:

Results of comparisons of tubes type 1 an 2 did not show any significant difference of the concentration between samples from Lind-Vac and Grainer tubes (p>0.05), table 1 and 2. However, the repeatability in tubes without gel were higher for Lin-Vac (p<0.05) for alkaline phosphtase (ALP), total bilirubin (TB), creatin kinase (CK), and triglycerides (TG), and higher for Grainer tubes for (p<0.05): aspartate aminotransferase (AST), urea (U) and urate (UA). For tubes with gel repeatability was higher for Lin-Vac (p<0.05) for AST, amylase and TG, and for Grainer for (p<0.05): total calcium, CK, U and UA.

Tab.1

Quality characteristics of blood samples measured in RX Imola Randox (Ireland) from biochemistry tubes from different manufactures Greiner (Austria) and Lind-Vac (Estonia)

Analyt, Units	Bias between Lind-Vac and Ref Greiner	Mean value		Quality specification (Ricos et al., 2014)			SD / CV%		p-probability of differences between the results
	B%±SEM	Lind-Vac	Ref Greiner	CV%	B %	TE %	Lind-Vac	Ref Greiner	
ALT, U/L	–0.5±0.9	28.8	29.1	9.7	11.5	27.5	1.1 (3.7%)	0.9 (2.9%)	0.3
AST, U/L	–0.1±1.2	28.3	28.7	6.2	6.5	16.7	0.8 (2.9%)	1.4 (4.8%)	0.4
Amilase, U/L	0.06±0.4	74.0	74.0	4.4	7.4	14.6	1.7 (2.3%)	1,2 (1.6%)	0.9
ALP, U/L	–0.6±0.6	143.2	144.4	3.1	9.5	14.6	3.9 (2.7%)	2.1 (1.4%)	0.3
Total Bilirubin, µmol/L	–1.2±1.2	18.8	18.8	10.9	8.9	26.9	0.8 (4.4%)	0.5 (2.7%)	0.9
Total Calcium, mmol/L	–0.5±0.7	2.3	2.3	2.7	1.7	6.1	0.04 (1.7%)	0.05 (2.1%)	0.4
CK, U/L	–0.2±1.6	135.0	134.0	11.4	11.5	30.3	4.6 (3.4%)	2.7 (2.0%)	0.4
Creatinine, µmol/L	–0.9±0.8	82.9	83.6	3,0	4.0	8.9	3.1 (3.7%)	2.6 (3.1%)	0.3
Iron µmol/L	–0.1±0.6	19.55	19.6	13.3	8.8	30.7	0.4	0.4	0.6
Total Protein, g/L	–0.1±0.5	69.8	69.7	1.38	1.36	3.6	1.0 (1.5%)	0.9 (1.4%)	0.8
Triglicerides µmol/L	–4.4±3.5	1.6	1.6	9.9	9.6	25.9	0.05 (3.2%)	0.02 (1.2%)	0.3
Urea, mmol/L	–3.1±1.2	6.4	6.6	6.0	5.57	15.5	0.2 (3,0%)	0.3 (4.7%)	0.05
Uric acid, µmol/L	1.7±3.8	317.0	315.2	4.3	4.87	11.9	16.2 (5,1%)	45.1 (14.3%)	0.4

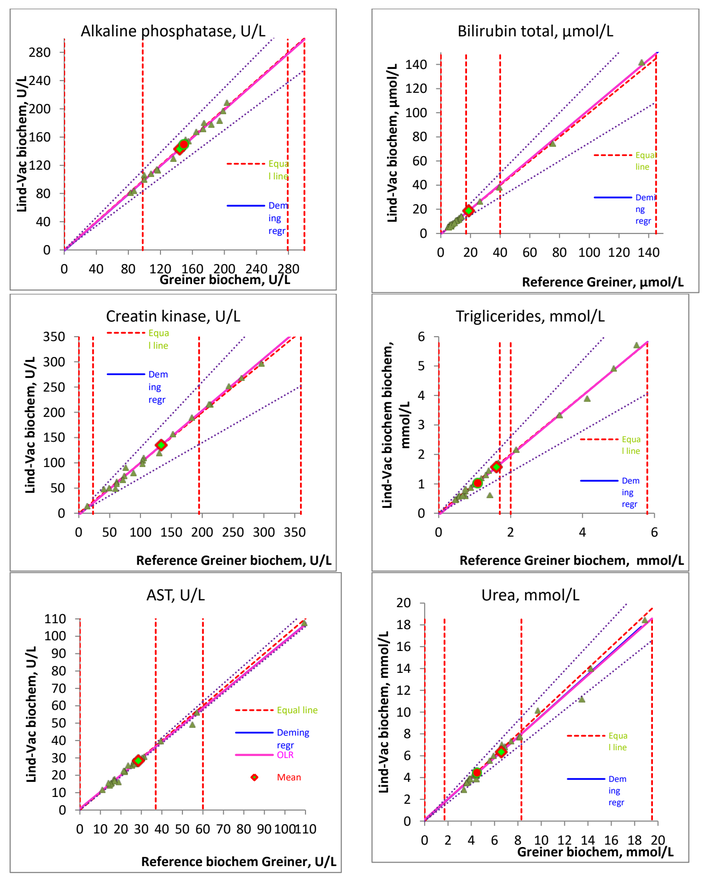
Tab.2

Quality characteristics of blood samples measured in RX Imola Randox (Ireland) from biochemistry tubes with gel from different manufactures Greiner (Austria) and Lind-Vac (Estonia)

Analyt, Units	Bias between Lind-Vac and Ref Greiner	Mean value		Quality specification (Ricos et al., 2014)			SD / CV%		p-probability of differences between the results
	B%±SEM	Lind-Vac	Ref Greiner	CV%	B %	TE %	Lind-Vac	Ref Greiner	
ALT, U/L	–0.5±0.9	37.0	37.2	9.7	11.5	27.5	1.2 (3.2%)	0.8 (2.1%)	0.4
AST, U/L	–0.4±0.7	44.7	44.9	6.2	6.5	16.7	0.8 (1.8%)	1.1 (2.4%)	0.3
Amilase, U/L	1.0±0.5	87.3	86.2	4.4	7.4	14.6	3.7 (4.9%)	2.45 (2.8%)	0.2
ALP, U/L	–01±0.5	192.8	192.4	3.1	9.5	14.6	3.1 (1.6%)	2.5 (1.3%)	0.6
Total Bilirubin, µmol/L	0.4±0.4	21.3	21.3	10.9	8.9	26.9	0.2 (1.0%)	0,3 (1.3%)	0,4
Total Calcium, mmol/L	0.2±0.4	2.1	2.1	2.7	1.7	6.1	0.04 (1.9%)	0.1 (2.9%)	0.8
CK, U/L	–1.5±1.4	171.8	173.6	11.4	11.5	30.3	2.4 (1.4%)	10.3 (5.9%)	0.8
Creatinine, µmol/L	–0.8±0.5	116.2	117.3	3,0	4.0	8.9	2.8 (2.4%)	2.6 (2.9%)	1.0
Iron µmol/L	–0.8±1.1	17.4	17.4	13.3	8.8	30.7	0.2 (1.3%)	0.3 (1.9%)	0.4
Total Protein, g/L	–0.0±0.2	70.8	70.83	1.38	1.36	3.6	0.7 (0.9%)	0.7 (2.0%)	8.9
Triglicerides µmol/L	0.7±0.3	1.5	1.5	9.9	9.6	25.9	0.03 (2,0%)	0.02 (1.3%)	0.4
Urea, mmol/L	–0.3±0.7	6.0	6.1	6.0	5.57	15.5	0.1 (1.9%)	0.2 (3.5%)	0.9
Uric acid, µmol/L	0.4±0.7	134.3	134,0	4.3	4.87	11.9	0.3 (0.2%)	1.2 (0.9%)	0.8

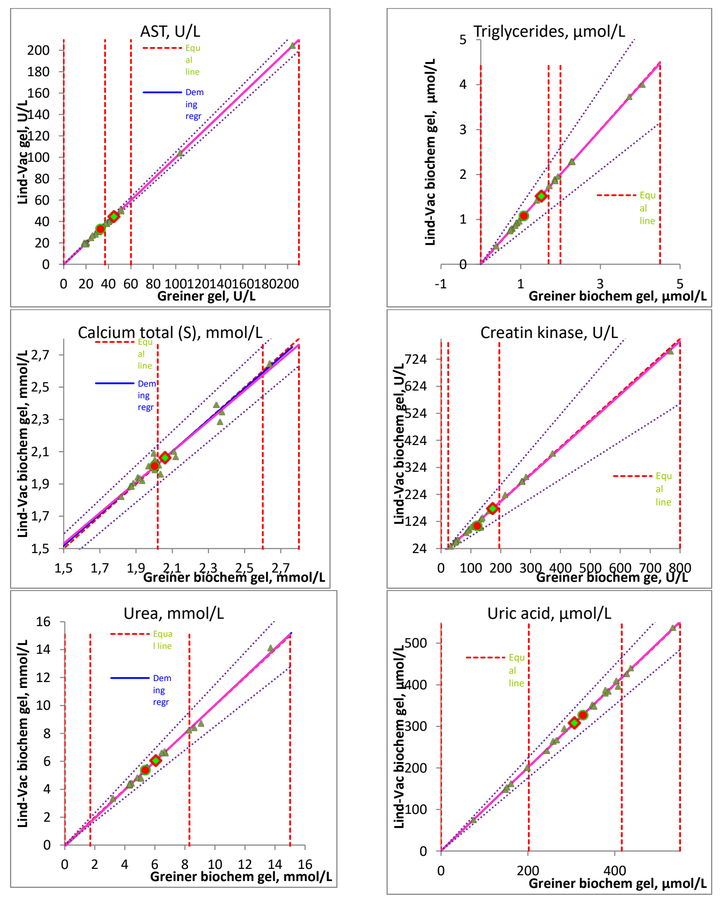
Pic.1

Regression graphs for comparison of biochemistry tubes Greiner and Lind-Vac



Pic.2

Regression graphs for comparison of biochemistry tubes with gel Greiner and Lind-Vac



Conclusion:

Greiner and Lind-Vac tubes comparison shows identical concentrations. Imprecision of the results from both types of tubes were of the same order of magnitude within quality goals and did not influence test interpretation.

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