Comparison testing of new **MiniCollect**® Lithium Heparin Separator Tubes to Microtainer ® Lithium Heparin Separator Tubes

Background:

Greiner Bio-One has developed a newly designed MiniCollect® tube offering an integrated collection scoop. One advantage of the new tube is that capillaries and funnels are not needed to facilitate blood transfer from the puncture site into the MiniCollect® tube.

The MiniCollect® Lithium Heparin Separator capillary blood collection tube is also featured with a co-molded cap which can easily be removed during the collection and sampling process.

Clotting is inhibited by the presence of a spray dried Lithium Heparin coating the interior of the tube. Heparinised plasma is the virtually cell-free supernatant following the centrifugation of whole blood. Heparin works by accelerating the inhibition of factor Xa by antithrombin III.

MiniCollect® Lithium Heparin Separator Tubes are used to collect, transport, separate and process capillary blood for testing plasma in the clinical laboratory.

Study Objective:

A clinical evaluation was carried out to compare the performance of the MiniCollect® Lithium Heparin Separator tube with new design in comparison to BD Mictrotainer® LH Lithium Heparin Separator tube including 20 healthy subjects.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	Microtainer® Lithium Heparin Separator 0.4-0.6 ml (Item No.: 365985)
B	MiniCollect® Lithium Heparin Separator 0.8 ml (Item No.: 450535)

The study has been approved by Ethics Commission. Informed consent has been given by all participants.

Directly after venous blood collection, the tubes were carefully inverted 8 times according to the instructions for use for MiniCollect® blood collection tubes. After blood collection, sample A was centrifuged in a Eppendorf 5415R centrifuge for 90 sec. at 6000g and sample B in a Hettich Rotanta 560R centrifuge for 10 min at 3000g according to the instructions given by the manufacturer. The listed analytes were tested using an AU680 and DxI800 from Beckman Coulter. Analysis was performed with the instruments´ accompanying reagents.

Determined parameters:

- Albumin
- Alkaline phosphatase (ALP)
- Lactate Dehydrogenase (LDH)
- Alanine Transaminase (ALT)
- Aspartate Transaminase (AST)
- Gamma-glutamyl Transpeptidase (GGT)
- Uric Acid
- Total Bilirubin
- Cholesterol
- Triglyceride
- Sodium
- Potassium
- Chloride
- Calcium
- Phosphate

- Magnesium
- Iron
- Glucose
- Urea
- Creatine Kinase
- Total Protein
- free Triiodothyronine (fT_3)
- free Thyroxine (fT_4)
- Thyroid-Stimulating Hormone
- Cortisol
- Ferritin
- Vitamin B_{12}

Conclusion:

The performance of the MiniCollect® LH Lithium Heparin Separator tube has been demonstrated to be comparable to the BD Microtainer® LH Lithium Heparin Separator tube on the basis of the analytes tested.

Statistically significant deviations without clinical significance and slightly systematic deviations have been found for the following parameters: ALB, ALP, Ca, Chol, Cl, Fe, Ferr, IP, K, Mg, Na, TG, TP, UA, Cortisol, fT_3.

Due to the light sensitivity, elevated deviations for TBil have been found up to 21%.

Highest deviations found for AST (16.7%) and LDH (18.5%) for subject 19 resulted from a slightly hemolytic sample.

In summary, the MiniCollect® LH Lithium Heparin Separator tube with the new design is substantially equivalent to the BD Microtainer® LH Lithium Heparin Separator tube.

References:

(1) Greiner Bio-One. MiniCollect® Lithium Heparin Tubes. Instructions for Use. Kremsmünster, Austria. 2016.

(2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.

(3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning the quality assurance of quantitative analyses of Medical Laboratories, Germany (2001). Rev.2003

(4) ISO 6710:1995(E), *Single-use containers for venous blood specimen collection*. International Standard. 1995

(5) EP07-A2: *Interference Testing in Clinical Chemistry*; Approved Guideline – Second Edition, CLSI 2011.

(6) EP09-A2-IR: *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline — Second Edition (Interim Revision). CLSI 2011.

(7) H01-A6: *Tubes and Additives for Venous and Capillary Blood Specimen Collection*; Approved Standard – Sixth Edition CLSI 2011

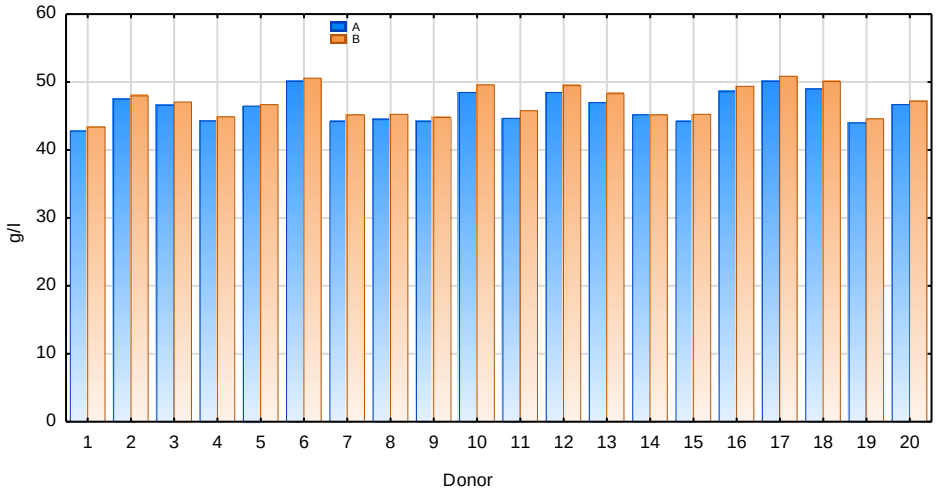
(8) H04-A6: *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens* – Approved Standard – Sixth Edition CLSO 2011

(9) RILIBÄK: Guideline of the German Medical Association for Quality Assurance.

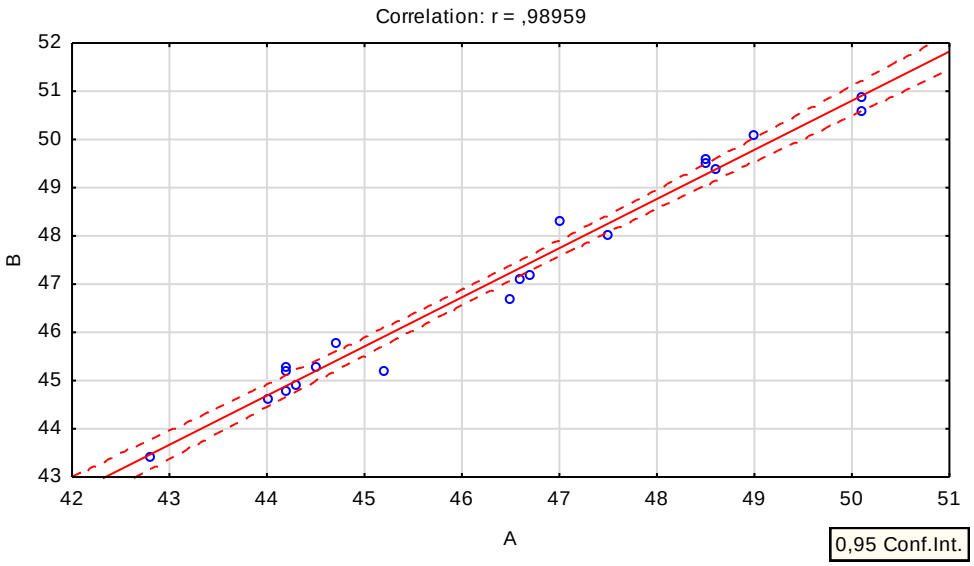
Results in detail:

Albumin (Alb) Normal range: 35 - 52 g/l

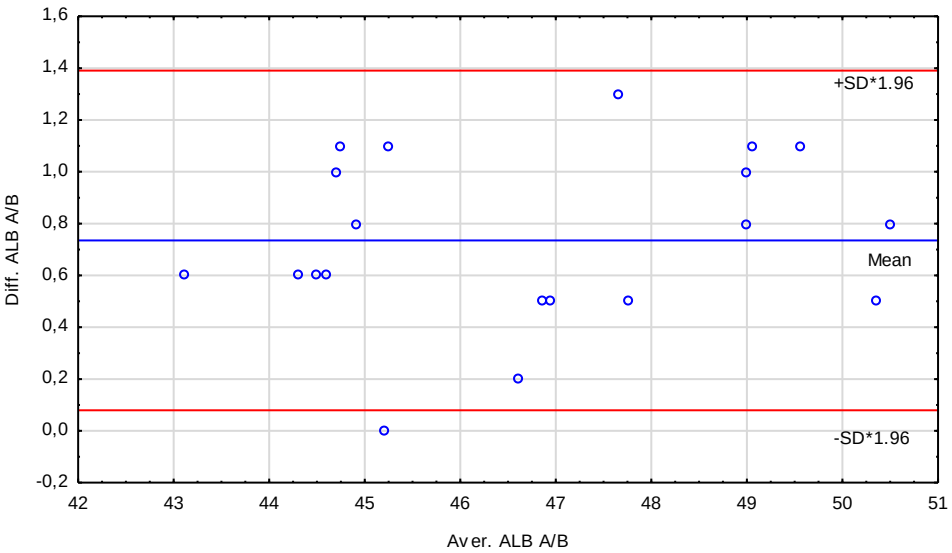
Bar chart



Correlations: ALB [g/l] A/B

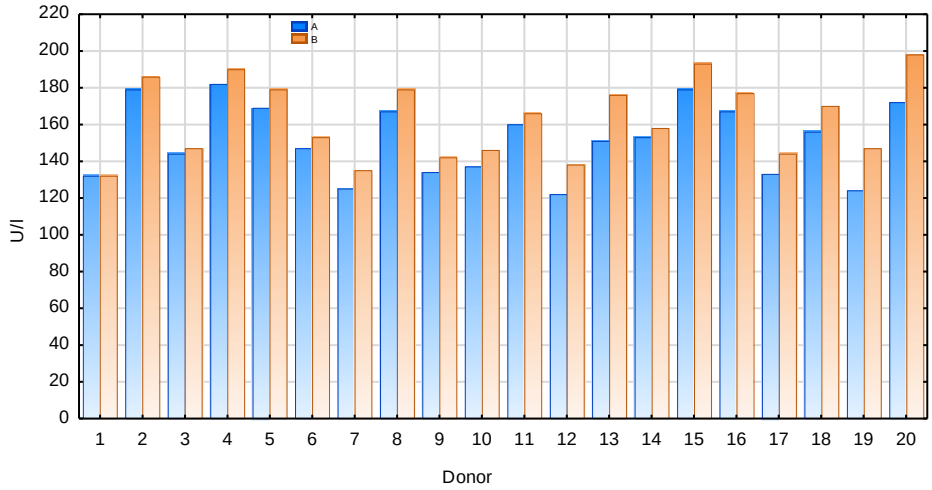


Bland Altman: ALB [g/l] A/B

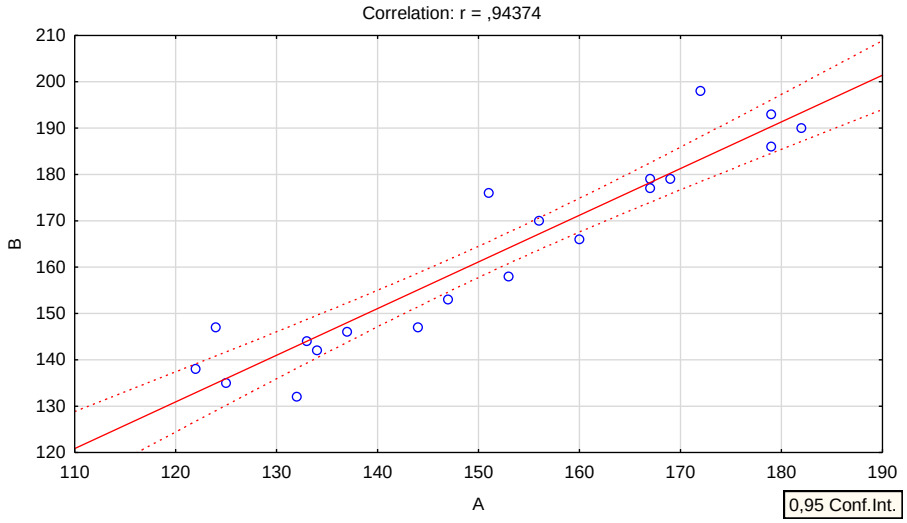


Lactate Dehydrogenase (LDH) Normal range: (f) < 247 U/l (m) < 248 U/l

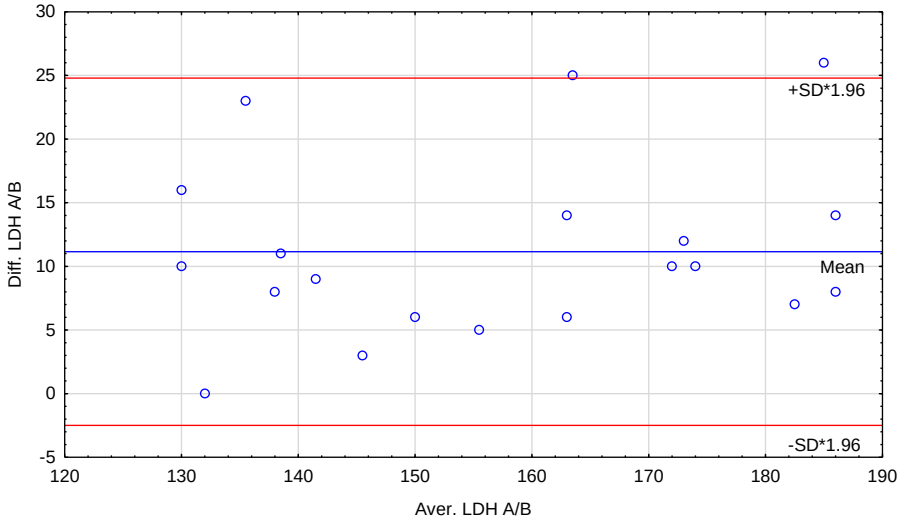
Bar chart



Correlations: LDH [U/l] A/B

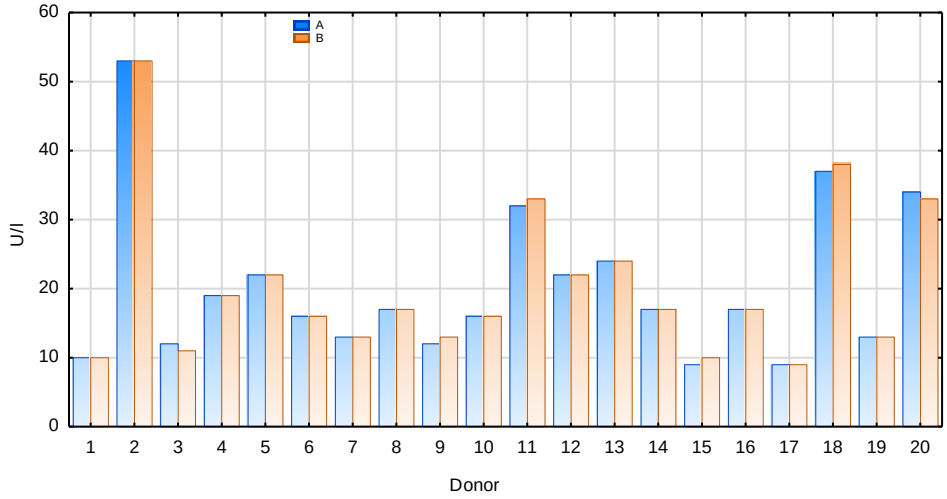


Bland Altman: LDH [U/l] A/B

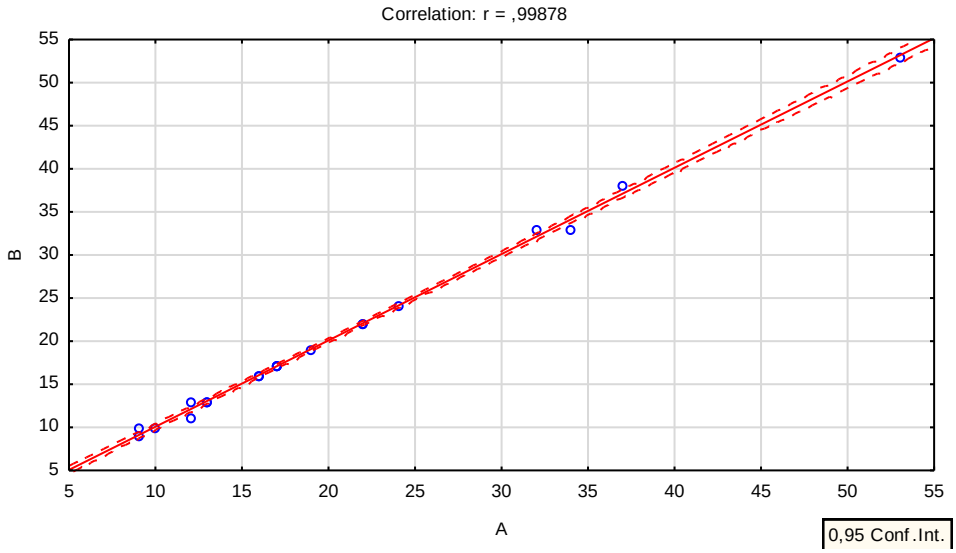


Alanine transaminase (ALT) Normal range: (m) < 50 U/l (f) < 35 U/l

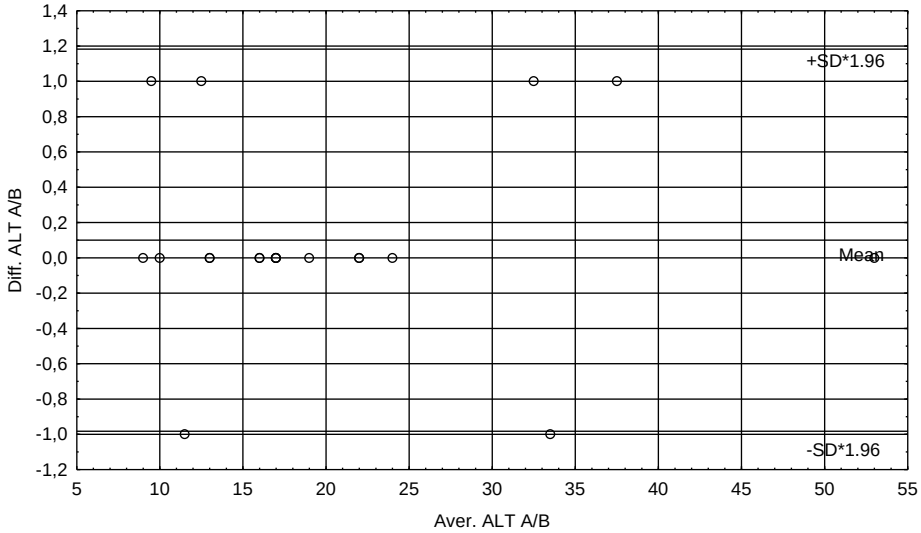
Bar chart



Correlations: ALT [U/l] A/B

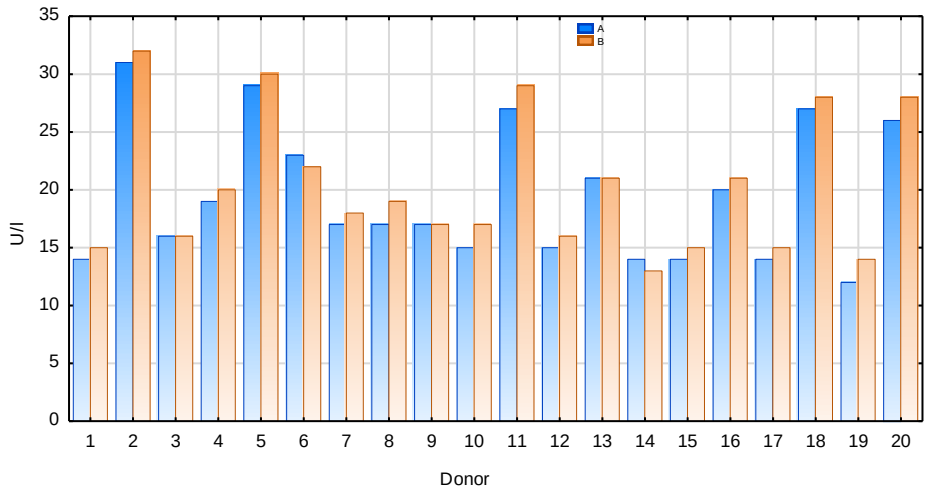


Bland Altman: ALT [U/l] A/B

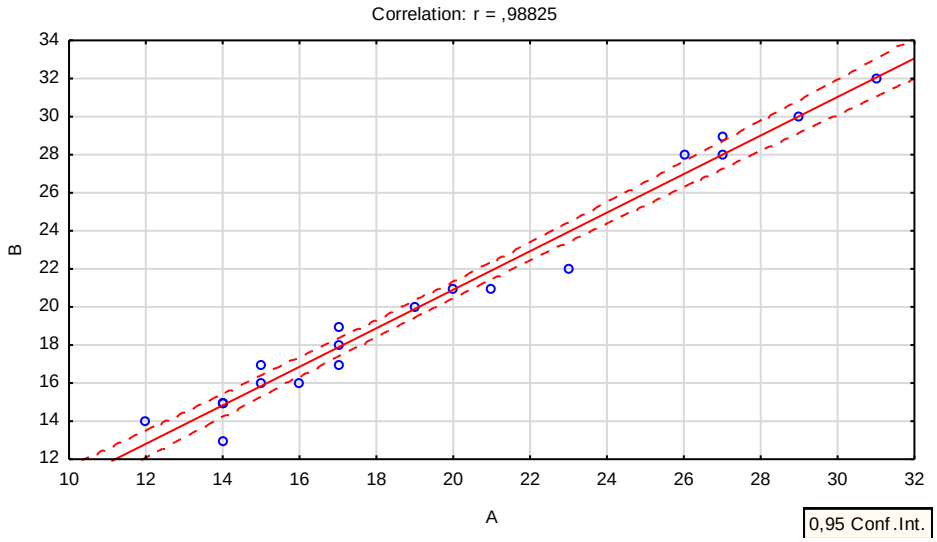


Aspartate transaminase (AST) Normal range: (m) < 50 U/l (f) < 35 U/l

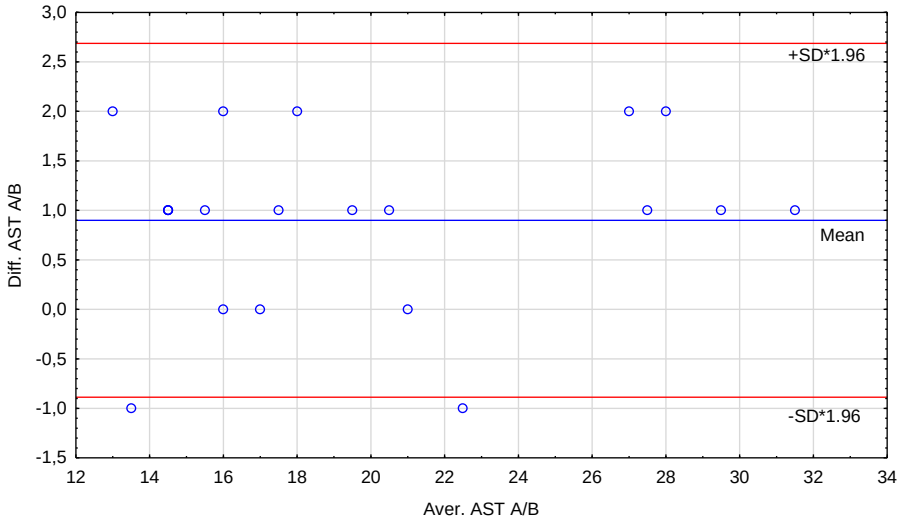
Bar chart



Correlations: AST [U/l] A/B

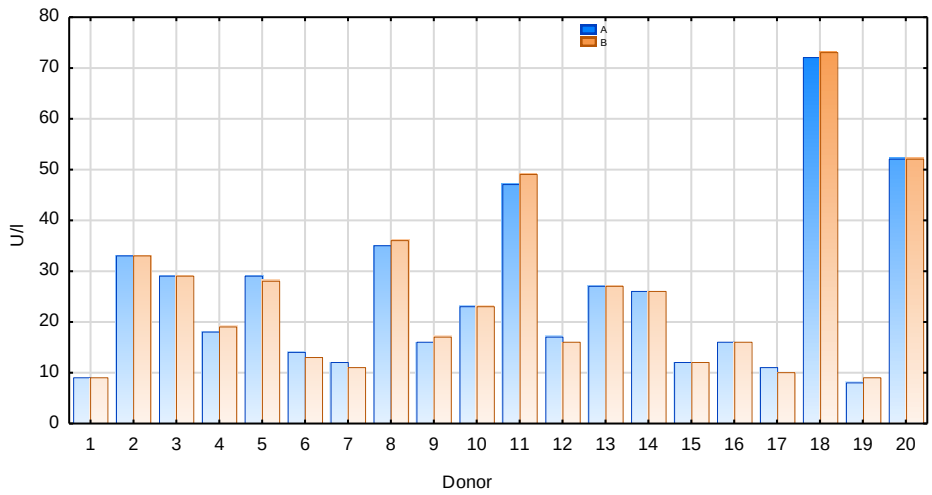


Bland Altman: AST [U/l] A/B

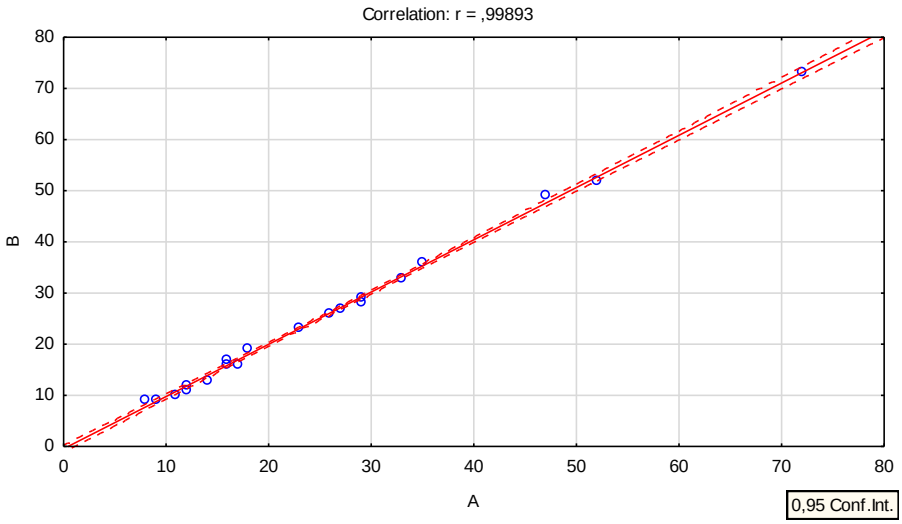


Gamma-glutamyl Transpeptidase (GGT) Normal range: (f) < 55 U/l (m) < 38 U/l

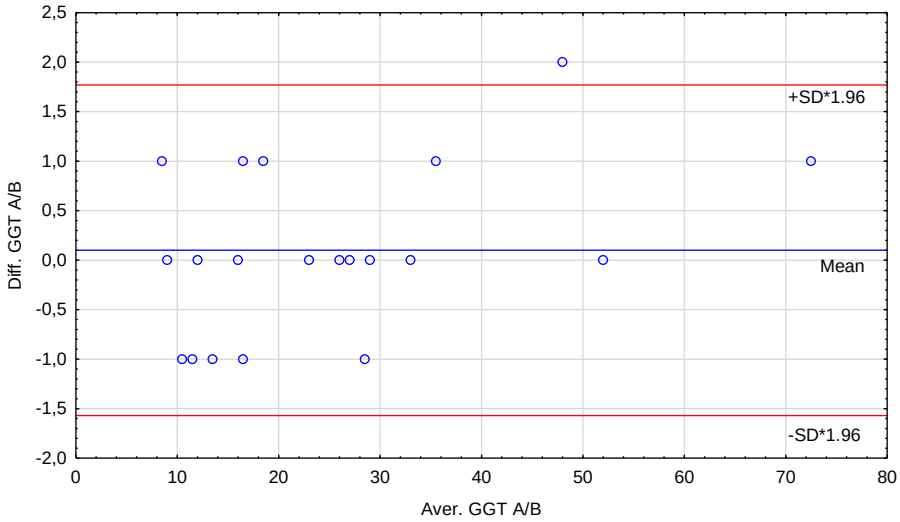
Bar chart



Correlations: GGT [U/l] A/B

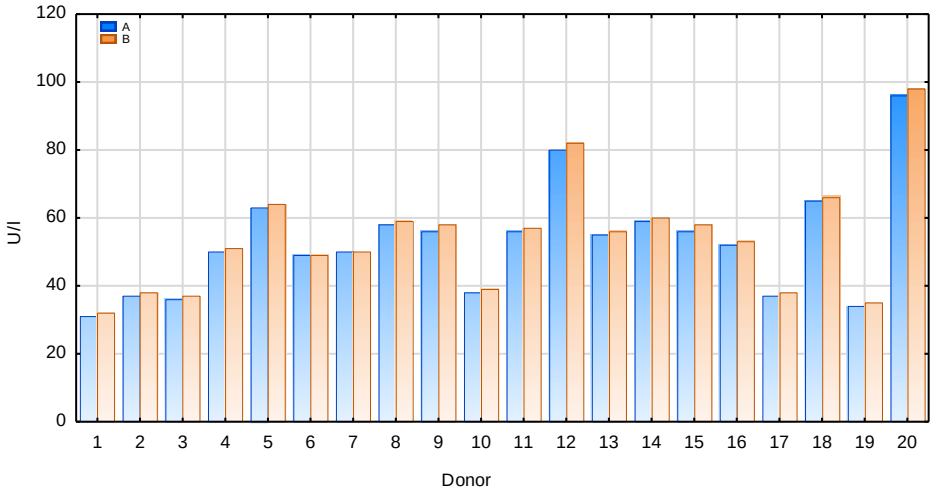


Bland Altman: GGT [U/l] A/B

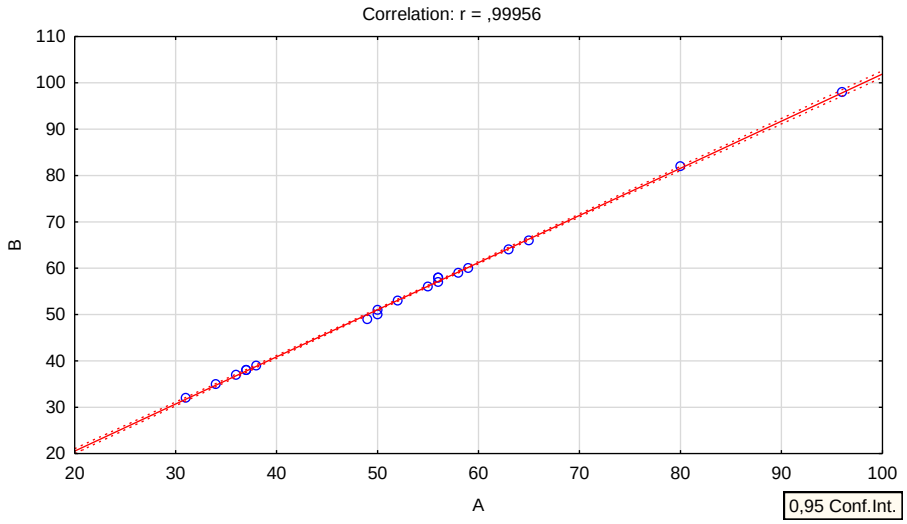


Alkaline Phosphatase (ALP) Normal range: 60 - 200 U/l

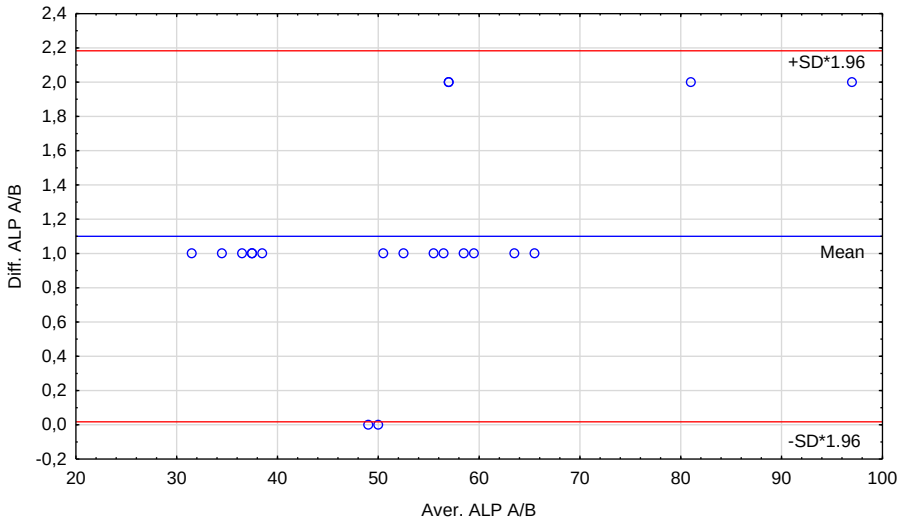
Bar chart



Correlations: ALP [U/l] A/B

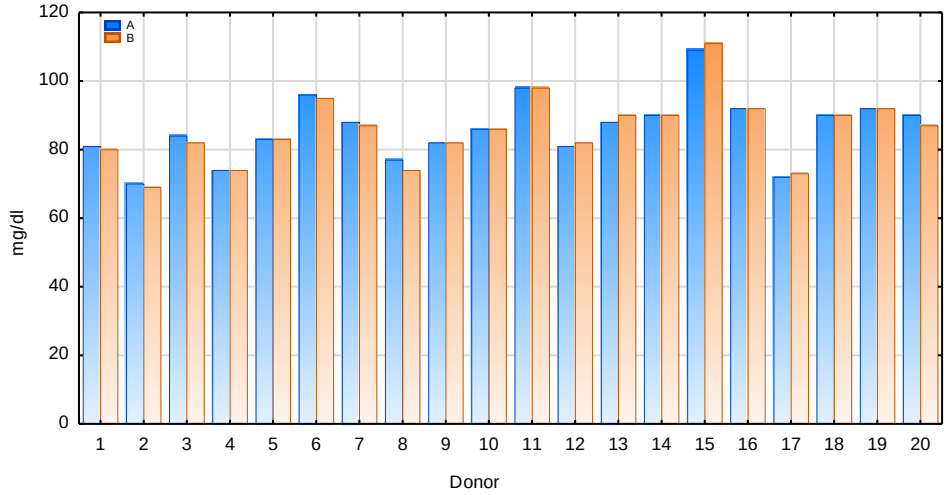


Bland Altman: ALP [U/l] A/B

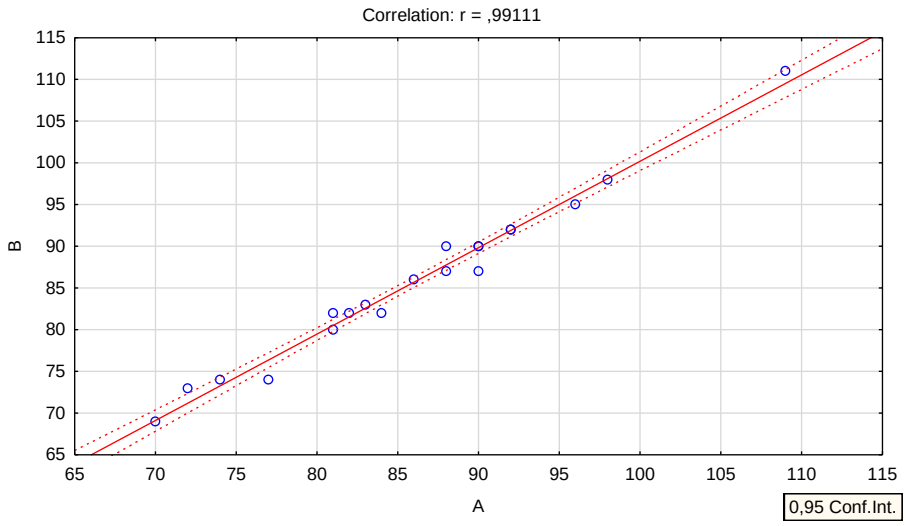


Glucose (Gluc) Normal range: 74 - 106 mg/dl

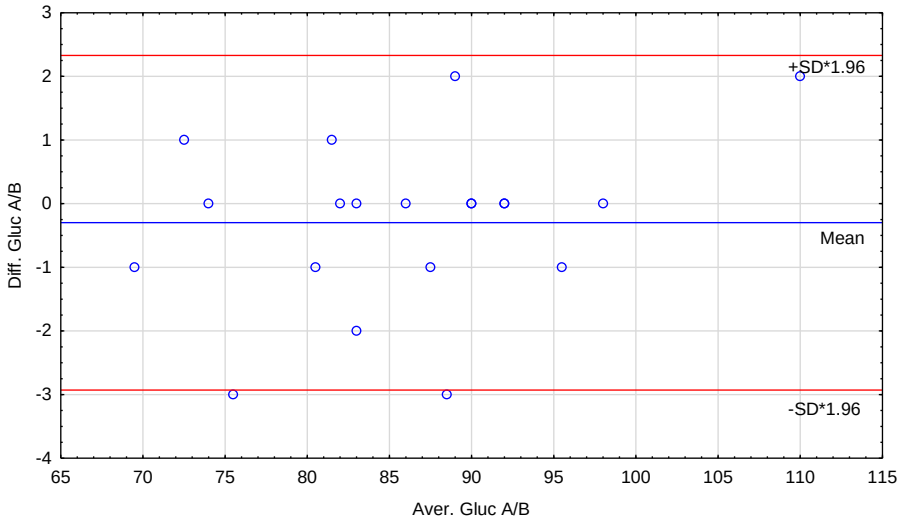
Bar chart



Correlations: Gluc [mg/dl] A/B

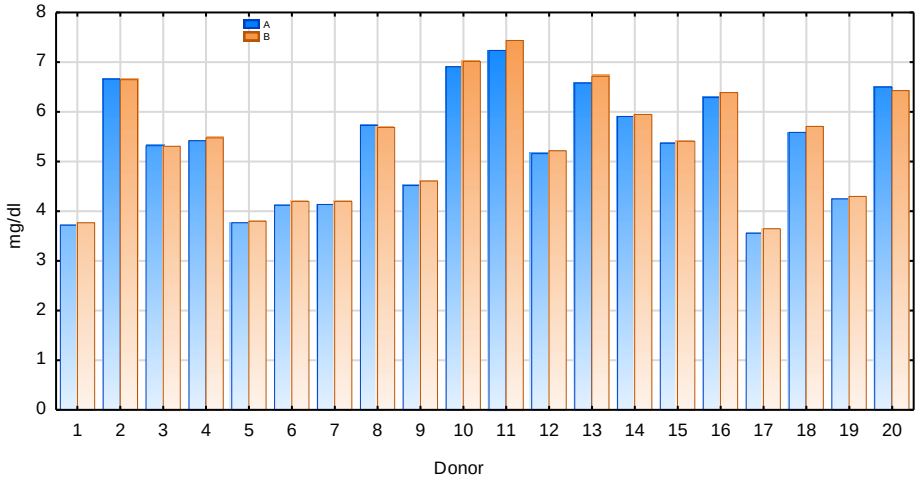


Bland Altman: Gluc [mg/dl] A/B

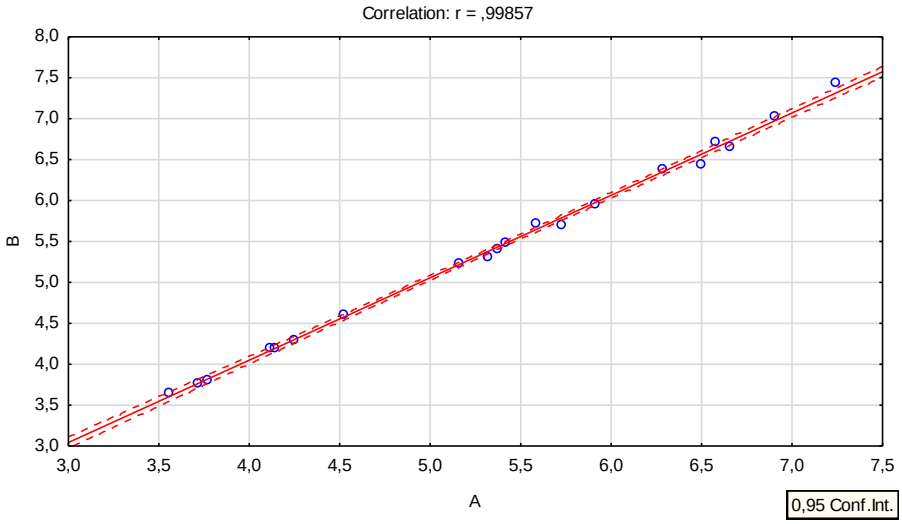


Uric Acid (UA) Normal range: (f) 3.5 - 7.2 mg/dl (m) 2.6 - 6.0 mg/dl

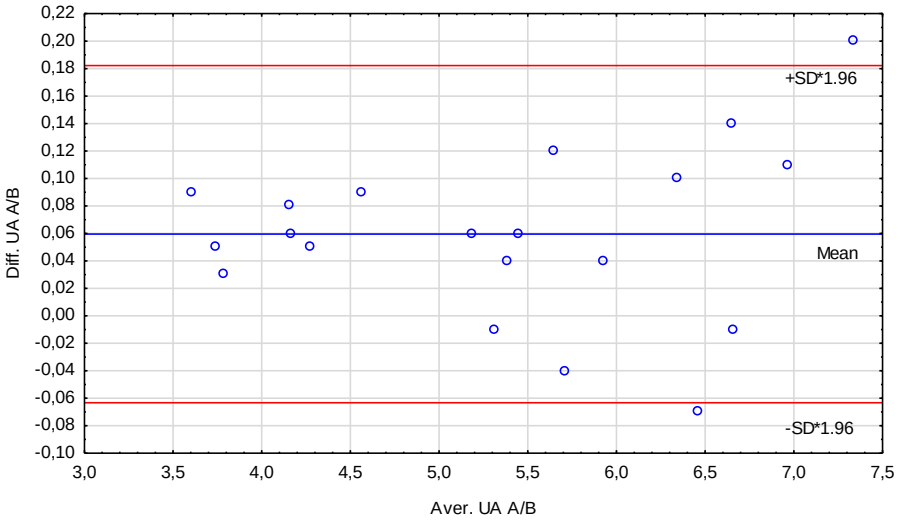
Bar chart



Correlations: UA [mg/dl] A/B

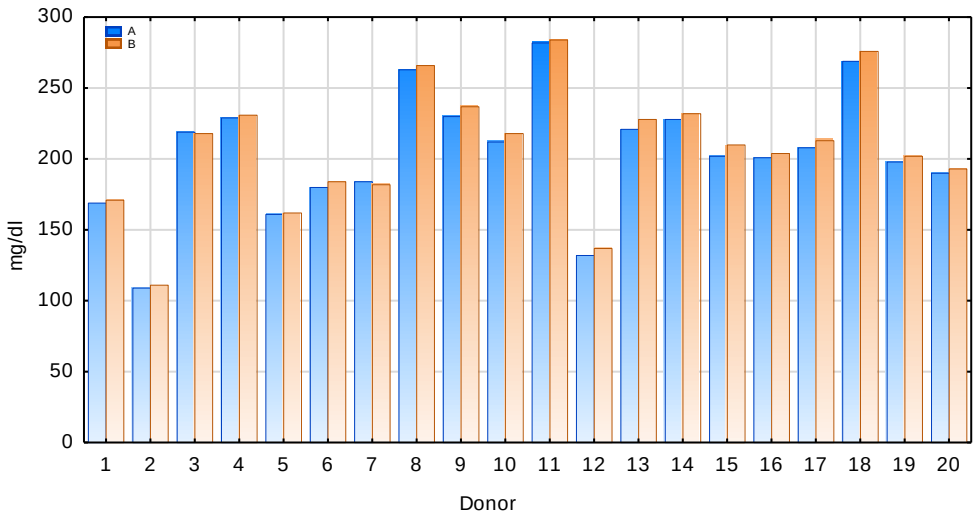


Bland Altman: UA [mg/dl] A/B

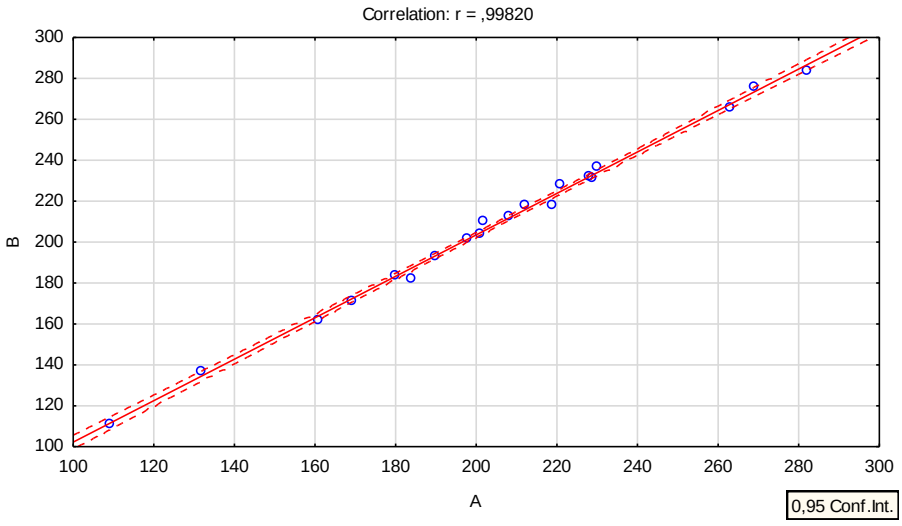


Cholesterol (Chol) Normal range: < 200 mg/dl

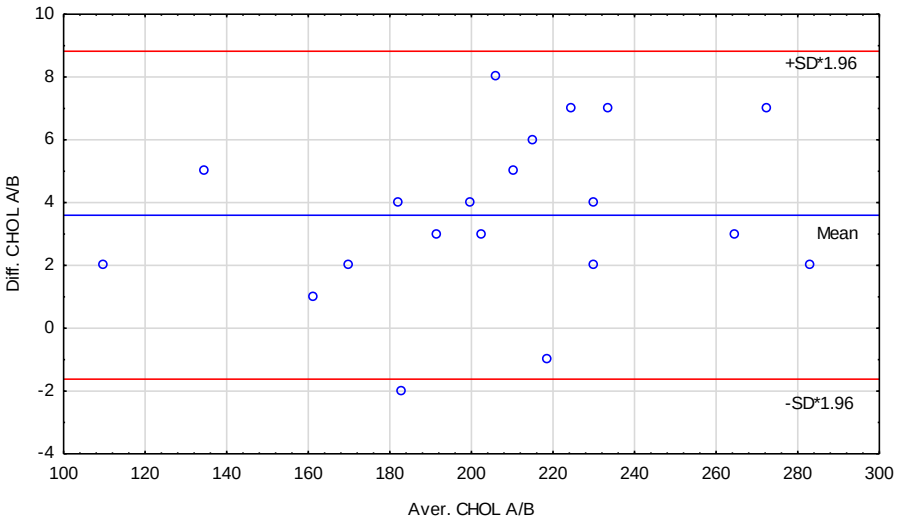
Bar chart



Correlations: CHOL [mg/dl] A/B

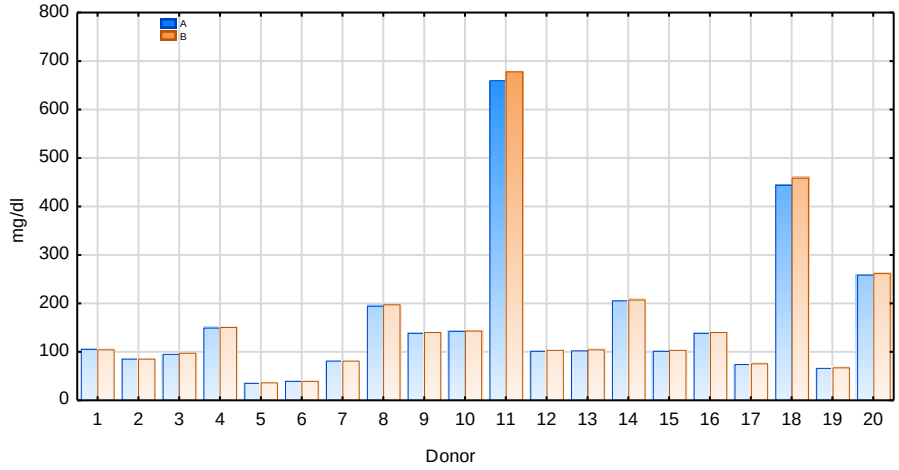


Bland Altman: CHOL [mg/dl] A/B

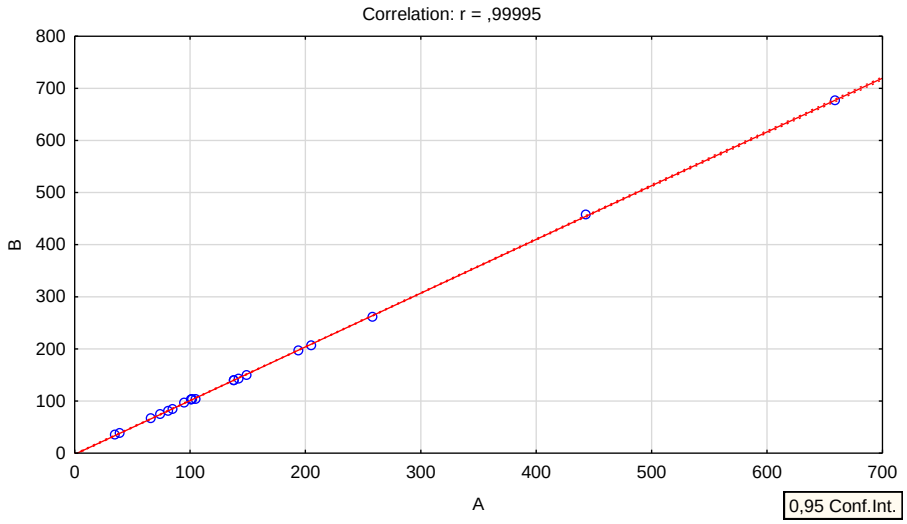


Triglyceride (TG) Normal range: normal ≤ 150 < borderline high < 200 high < 500 very high

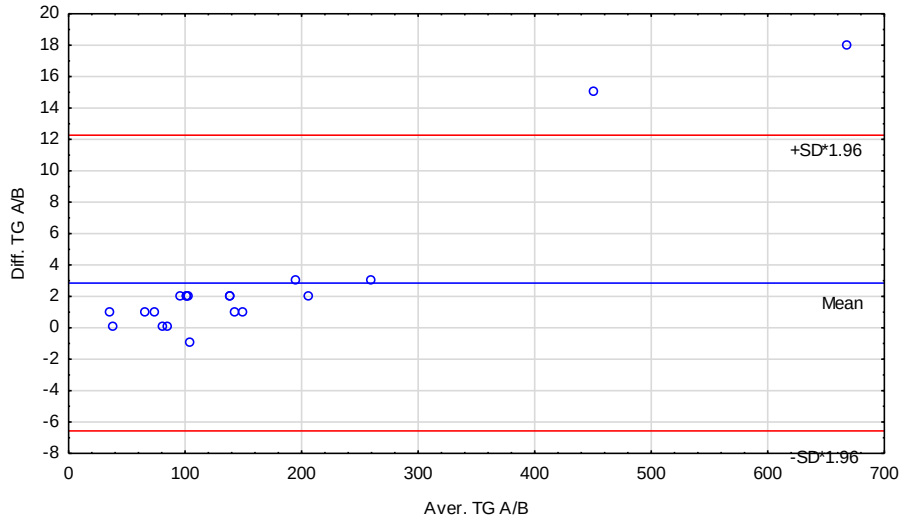
Bar chart



Correlations: TG [mg/dl] A/B

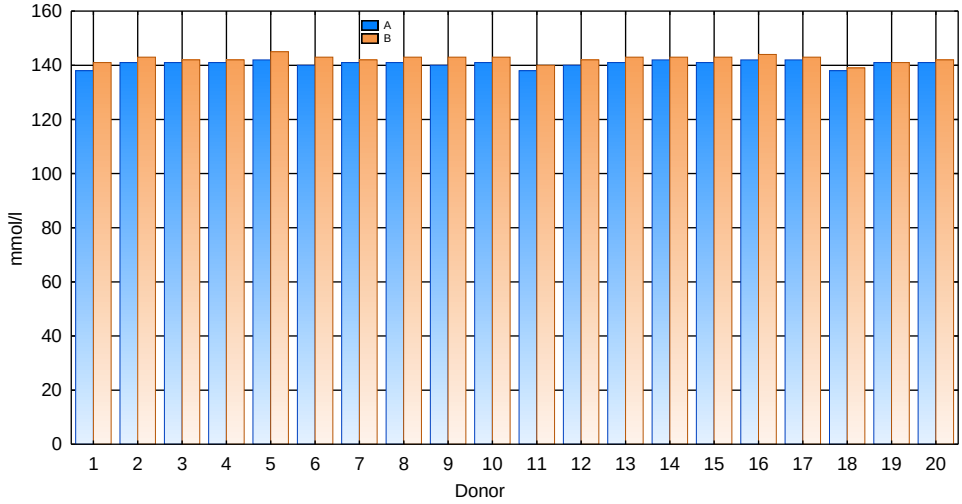


Bland Altman: TG [mg/dl] A/B

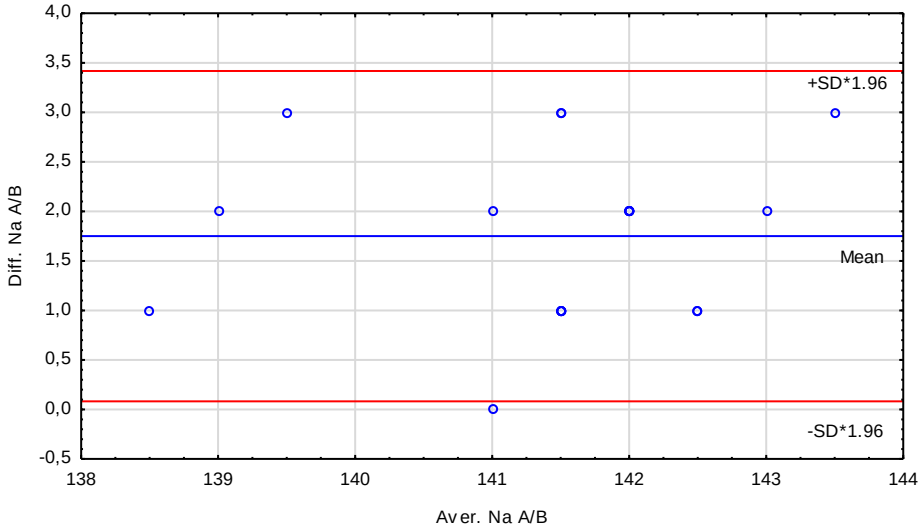


Sodium (Na) Normal range: 136 - 146 mmol/l

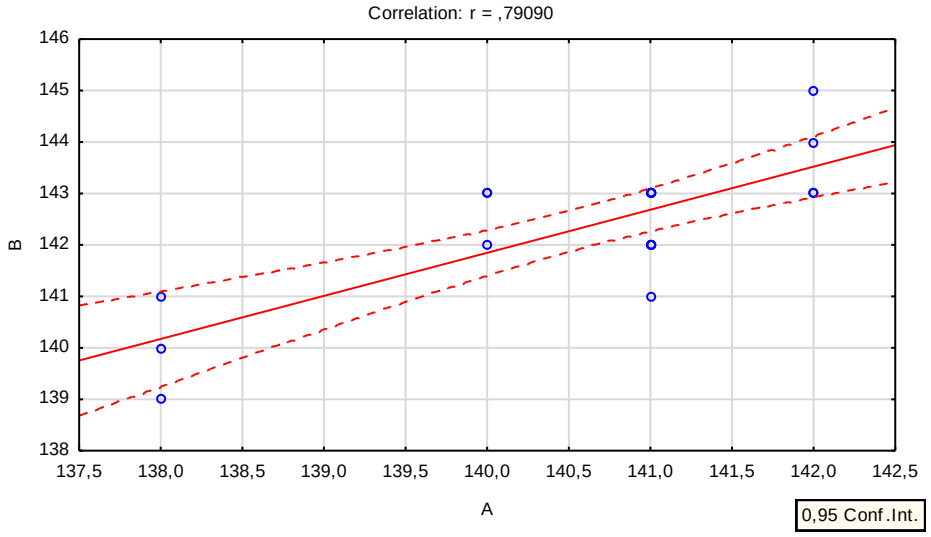
Bar chart



Bland Altman: Na [mmol/l] A/B

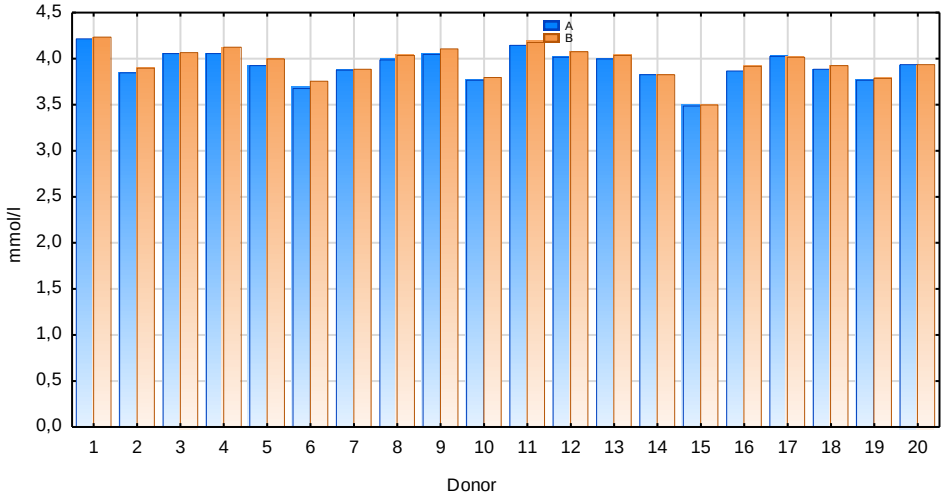


Correlations: Na [mmol/l] A/B

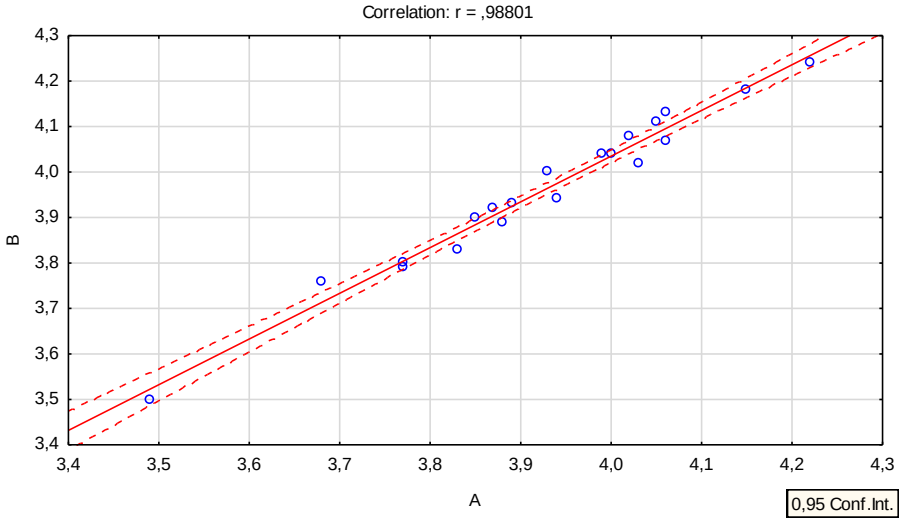


Potassium (K) Normal range: Plasma 3.4 - 4.5 mmol/l

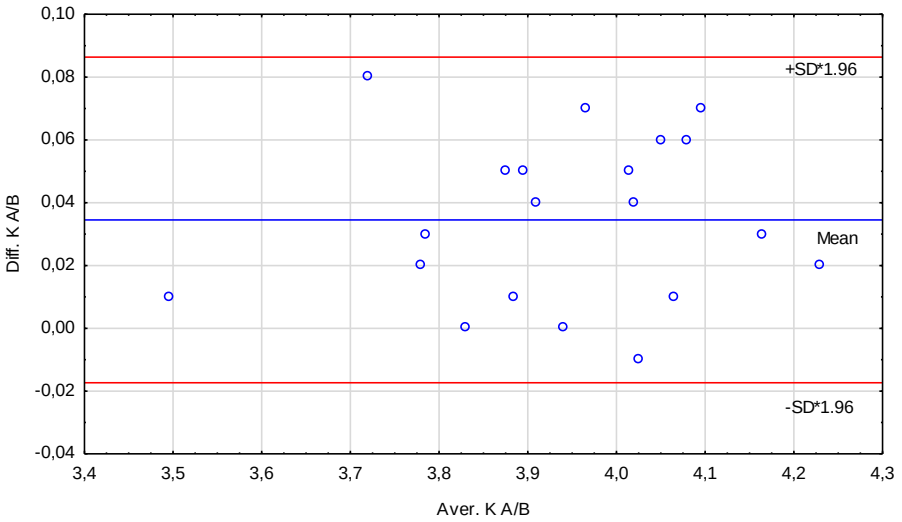
Bar chart



Correlations: K [mmol/l] A/B

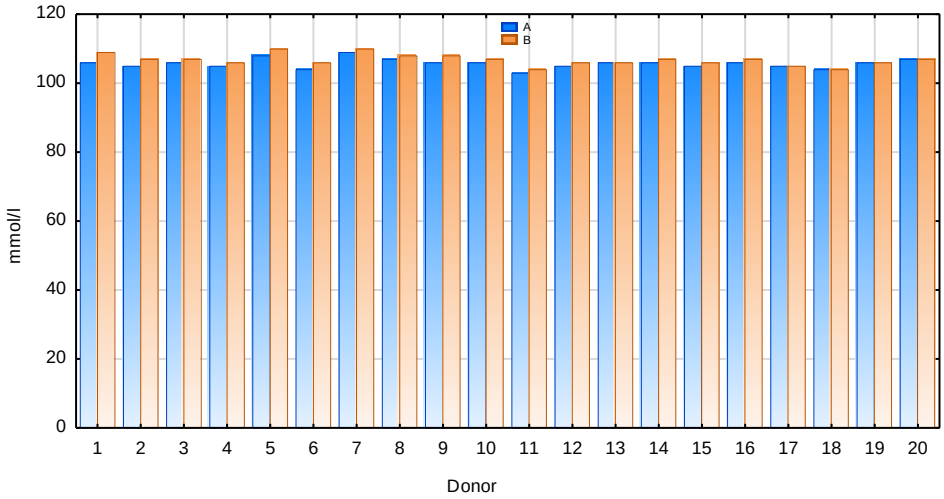


Bland Altman: K [mmol/l] A/B

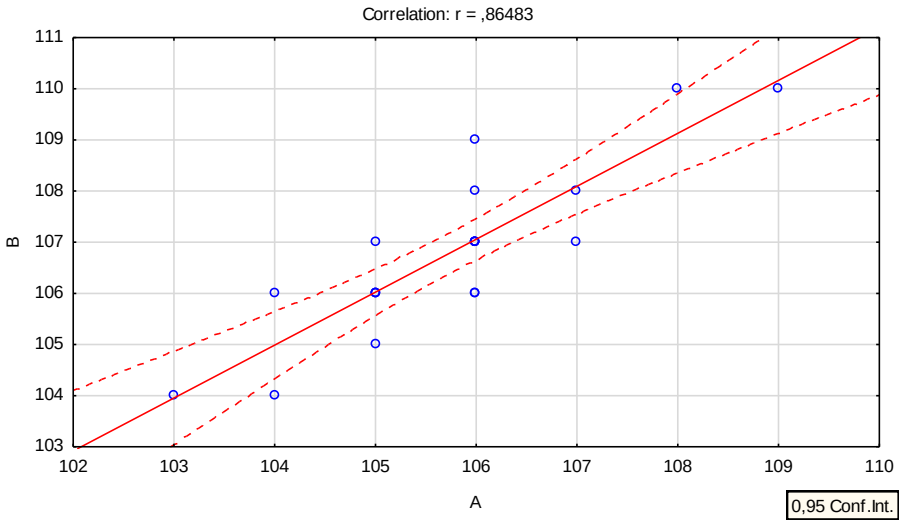


Chloride (Cl) Normal range: 101 - 109 mmol/l

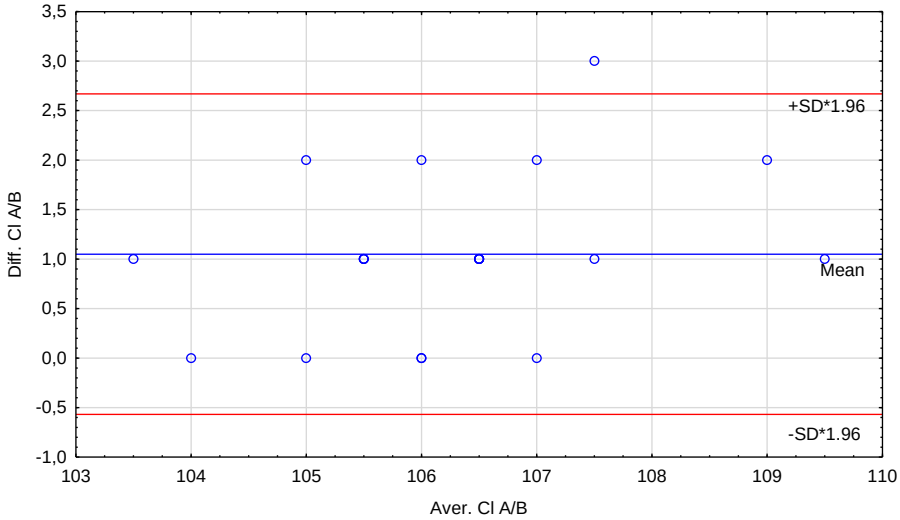
Bar chart



Correlations: Cl [mmol/l] A/B

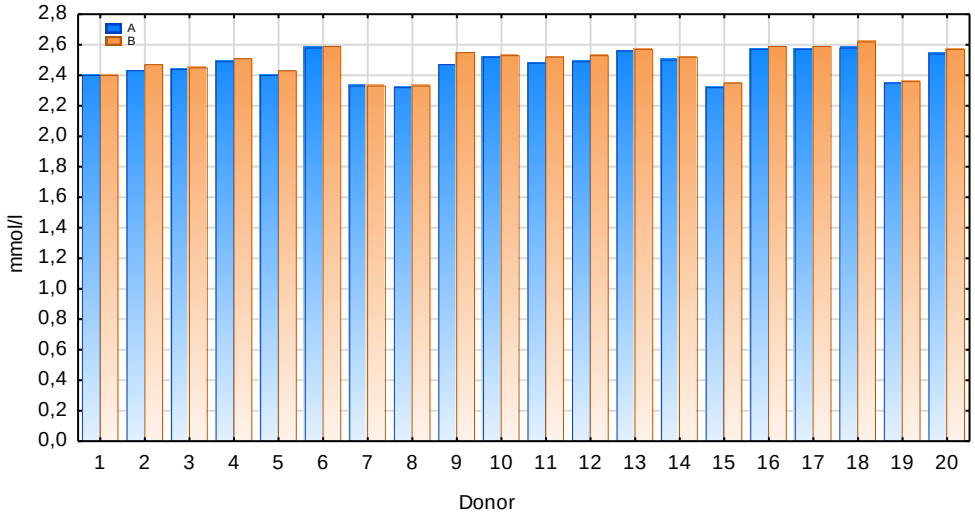


Bland Altman: Cl [mmol/l] A/B

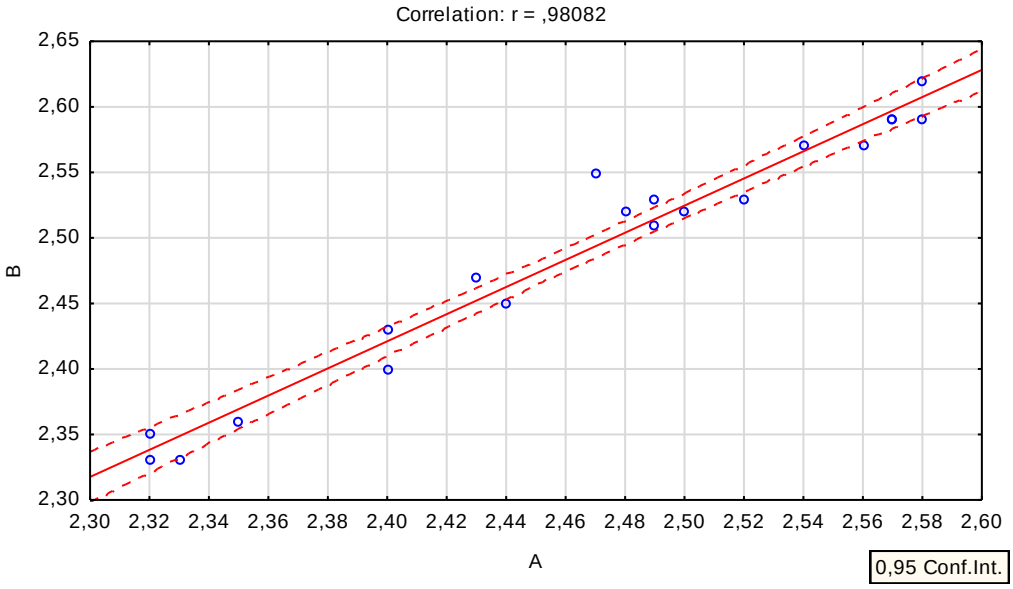


Calcium (Ca) Normal range: 2.20 - 2.65 mmol/l

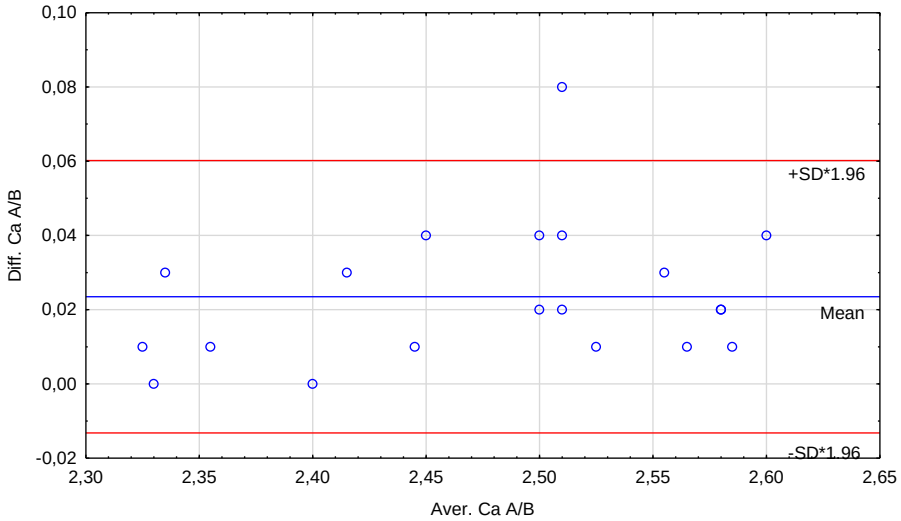
Bar chart



Correlations: Ca [mmol/l] A/B

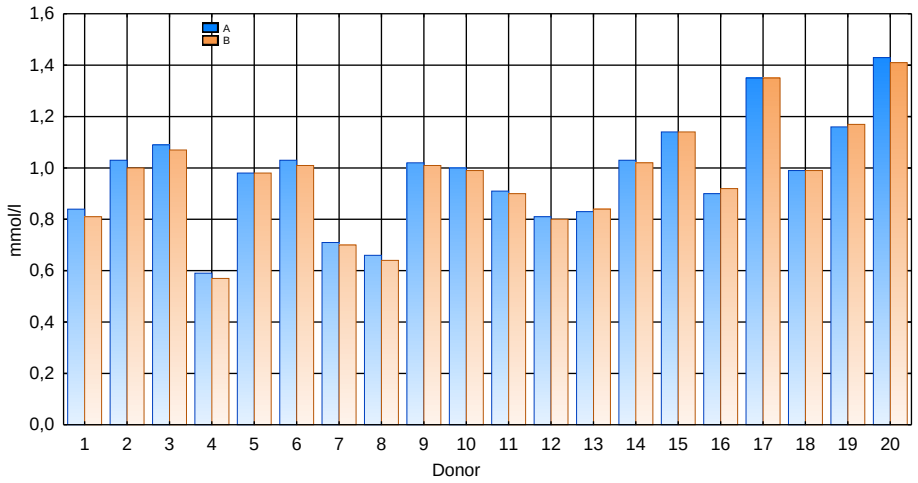


Bland Altman: Ca [mmol/l] A/B

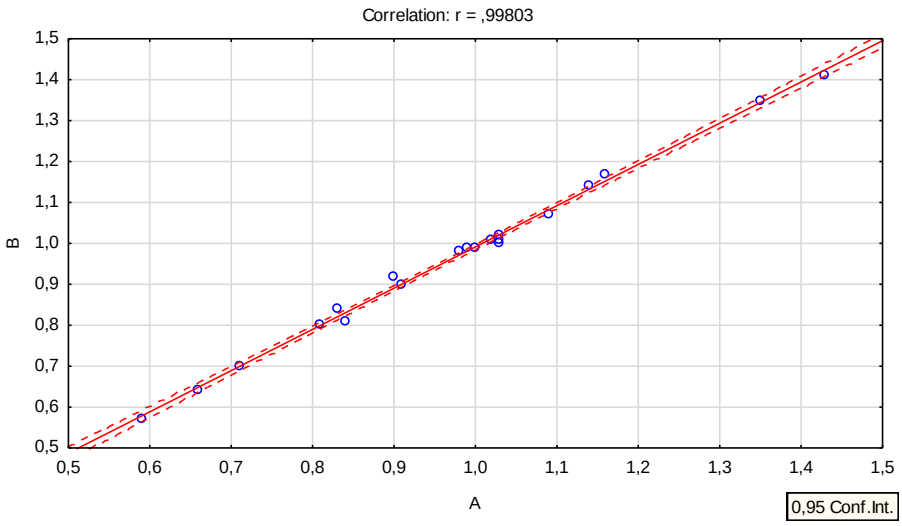


Phosphate (Phos) Normal range: 0.81 - 1.45 mmol/l

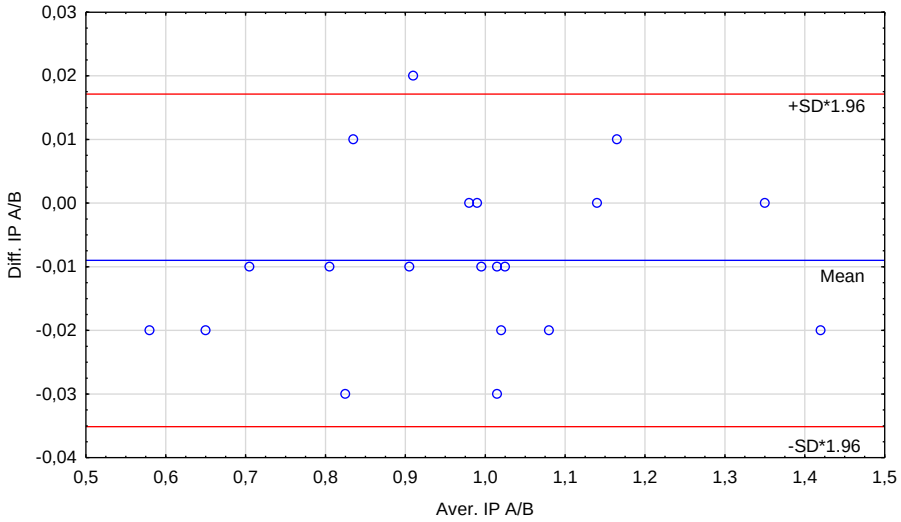
Bar chart



Correlations: IP [mmol/l] A/B

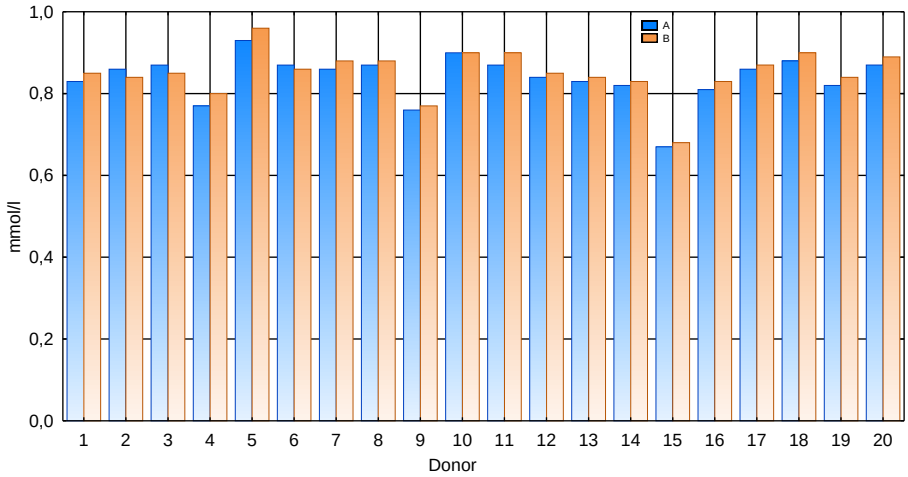


Bland Altman: IP [mmol/l] A/B

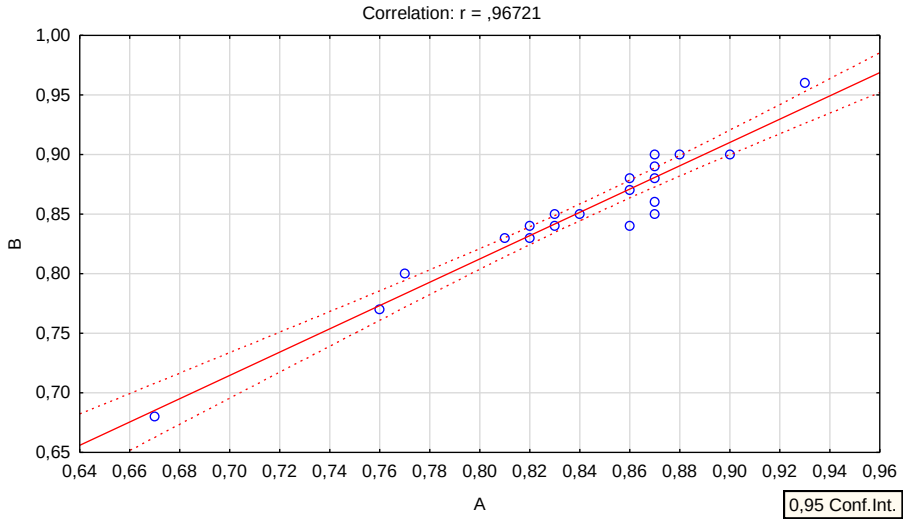


Magnesium (Mg) Normal range: (f) 0.73 - 1.06 mmol/l (m) 0.77 - 1.03 mmol/l

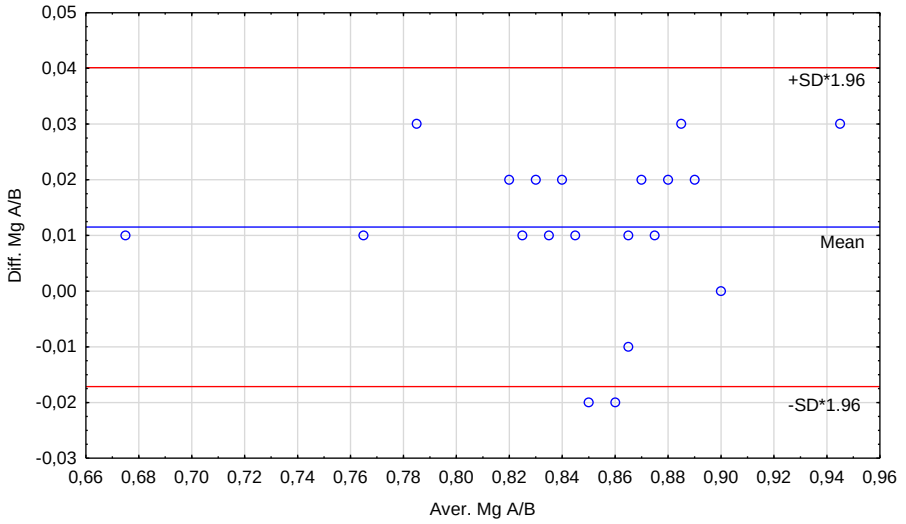
Bar chart



Correlations: Mg [mmol/l] A/B

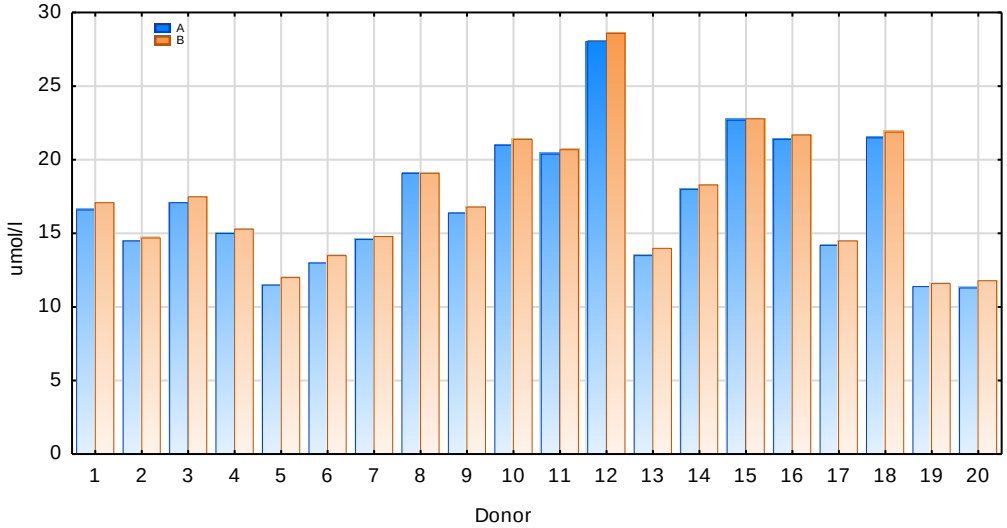


Bland Altman: Mg [mmol/l] A/B

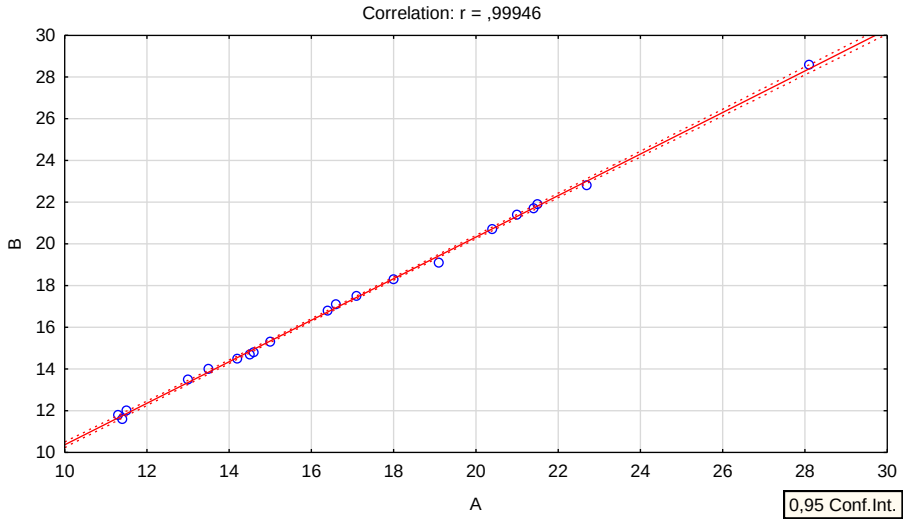


Iron Normal range: (f) 12.5 - 32.2 µmol/l (m) 10.7 - 32.2 µmol/l

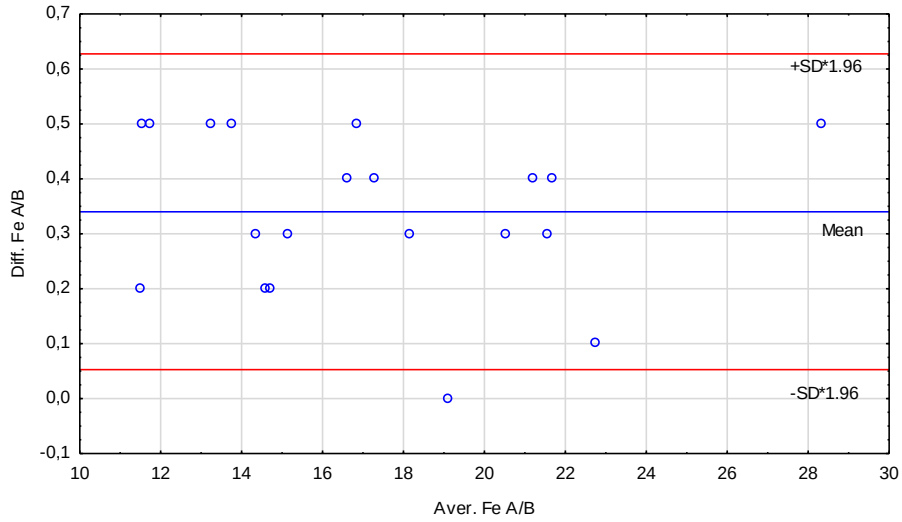
Bar chart



Correlations: Fe [umol/l] A/B

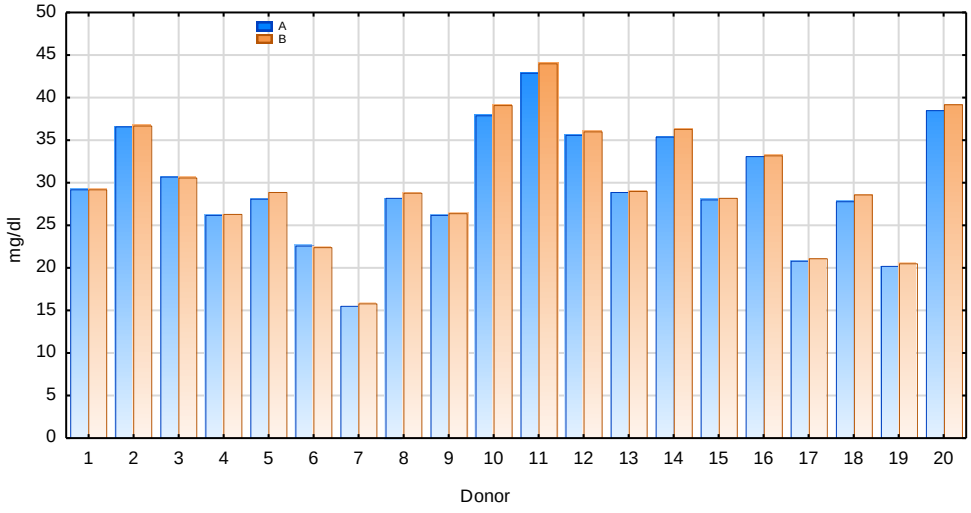


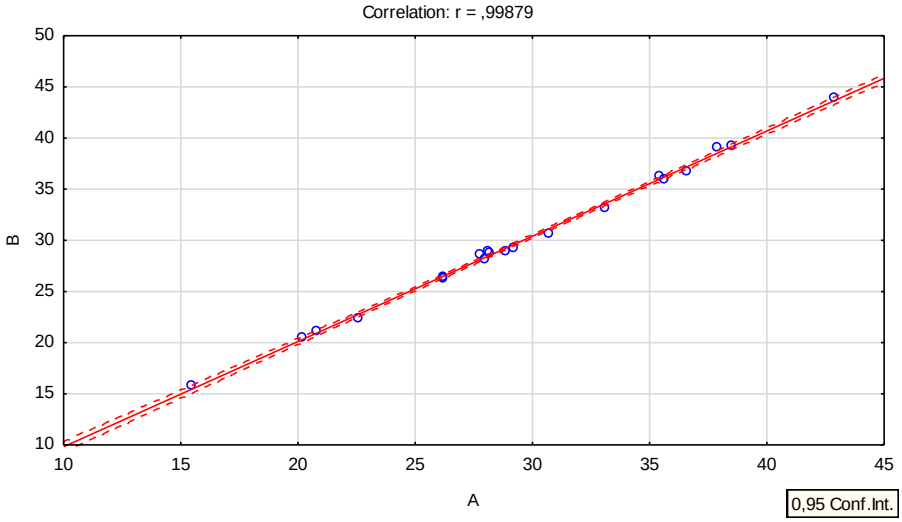
Bland Altman: Fe [umol/l] A/B



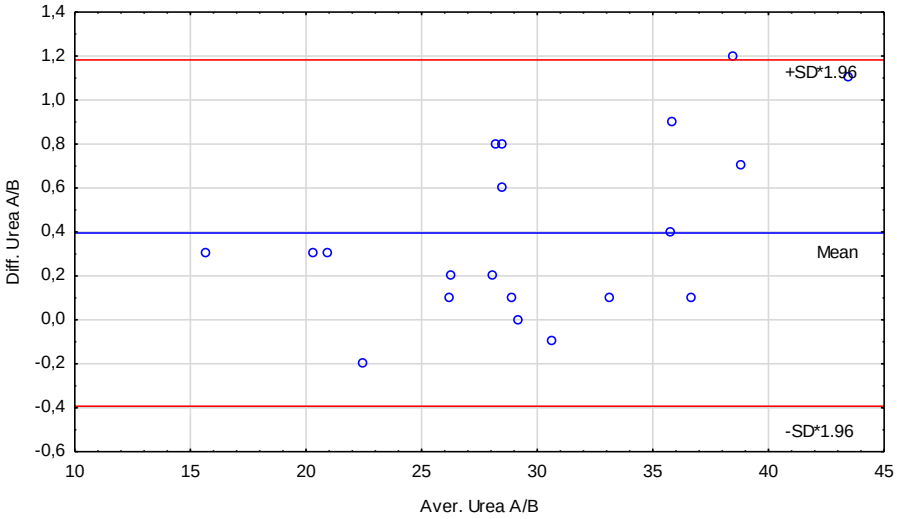
Urea Normal range: 17 - 43 mg/dl

Bar chart



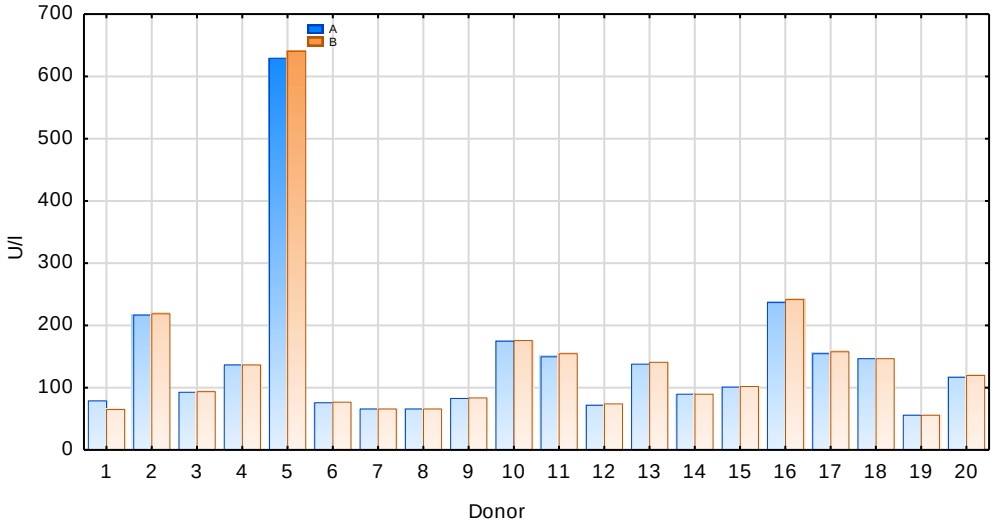


Bland Altman: Urea [mg/dl] A/B

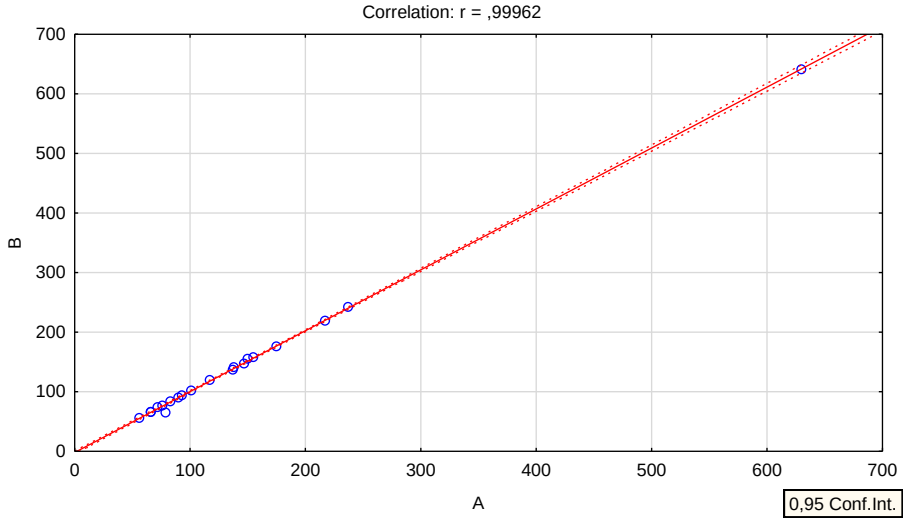


Creatine Kinase (CK) Normal range: (f) ≤ 171 U/l (m) ≤ 145 U/l

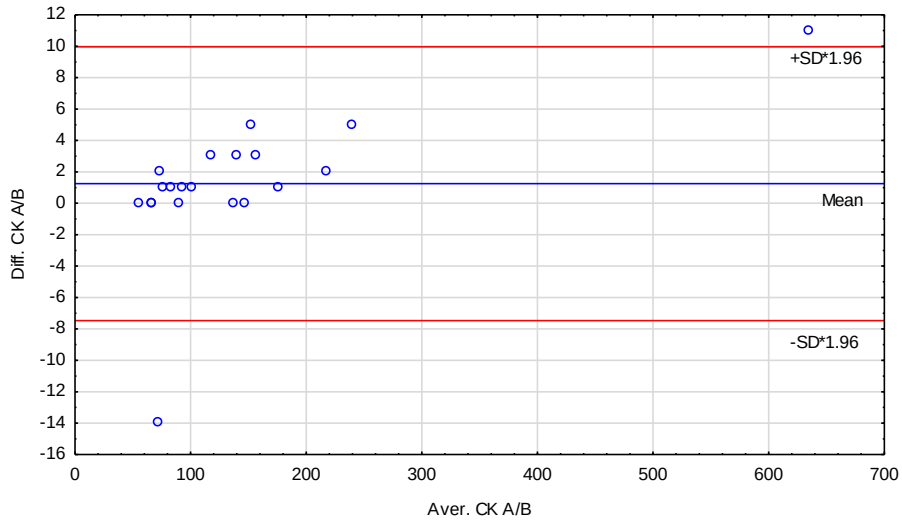
Bar chart



Correlations: CK [U/l] A/B

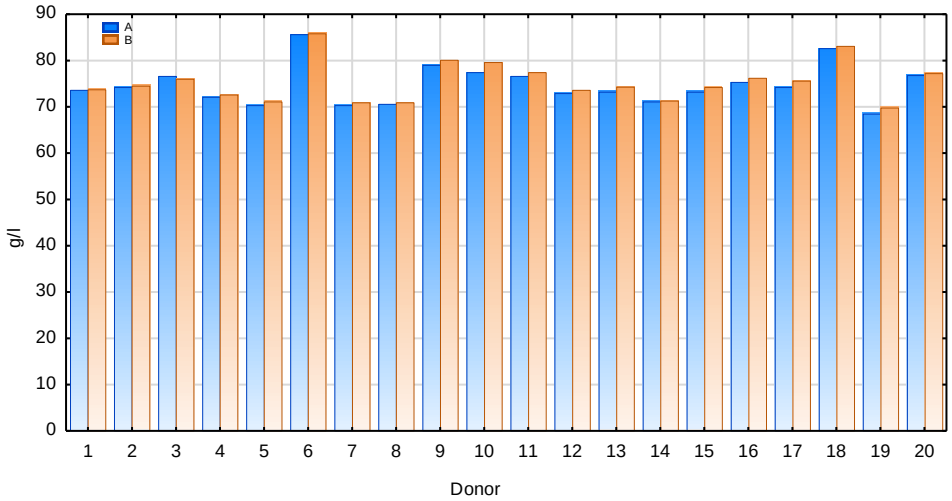


Bland Altman: CK [U/l] A/B

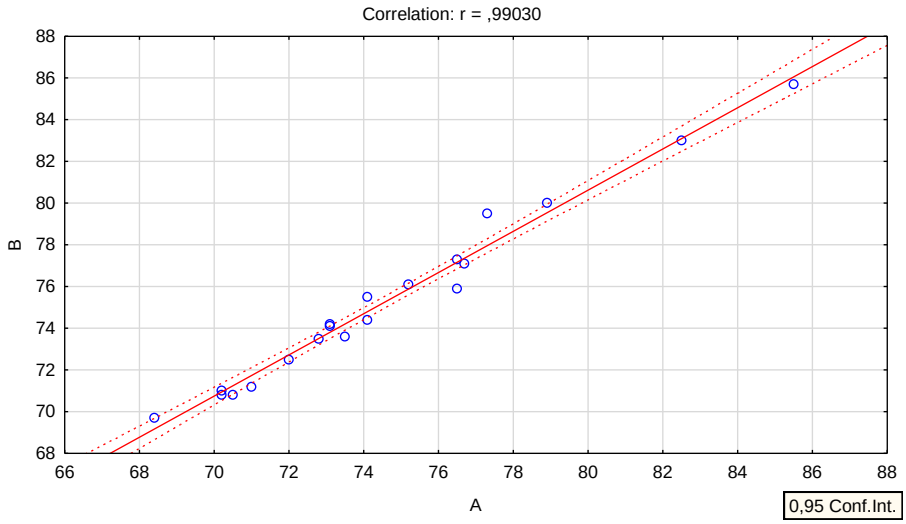


Total Protein (TP) Normal range: 66 - 83 g/l

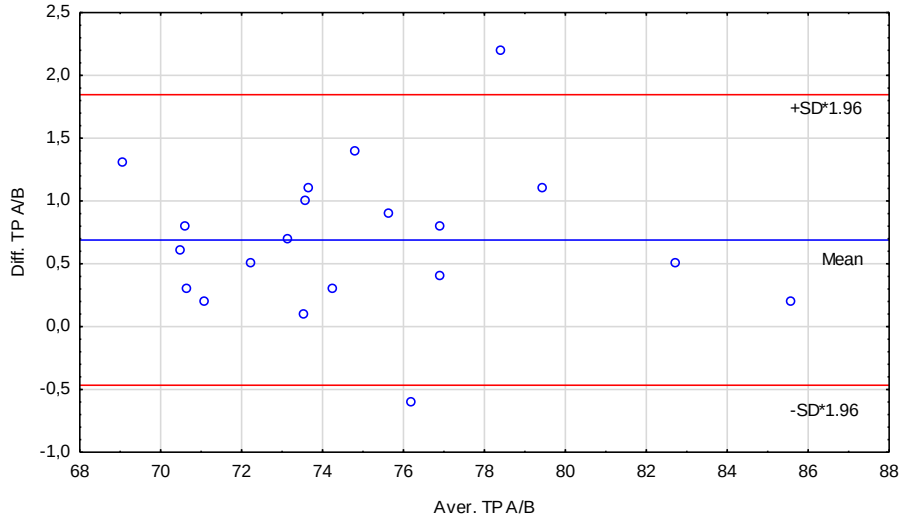
Bar chart



Correlations: TP [g/l] A/B

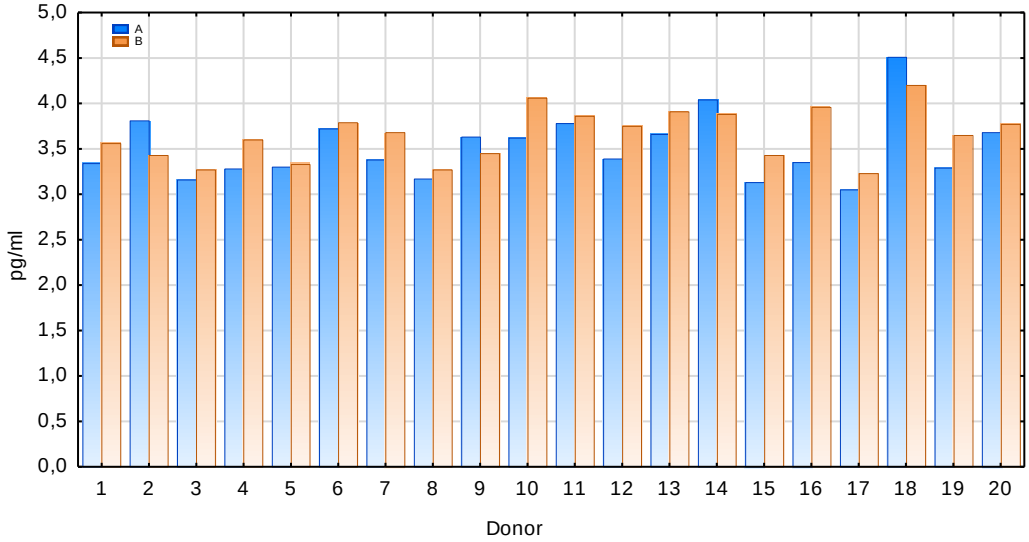


Bland Altman: TP [g/l] A/B

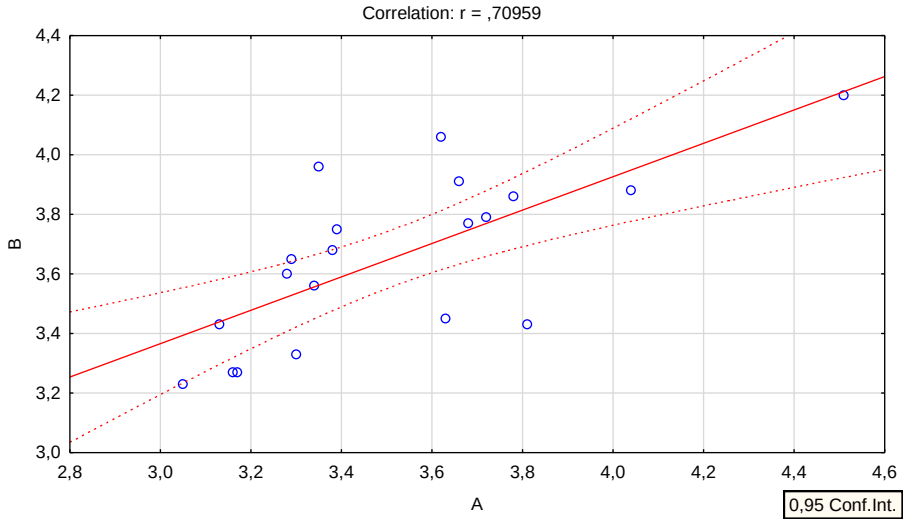


Free Triiodothyronine (fT_3) Normal range: 2.5 - 3.9 pg/ml

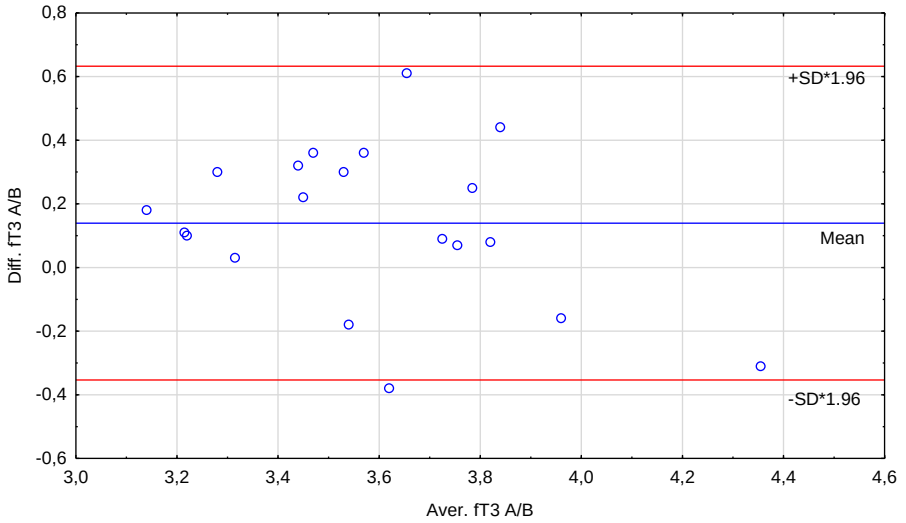
Bar chart



Correlations: fT3 [pg/ml] A/B

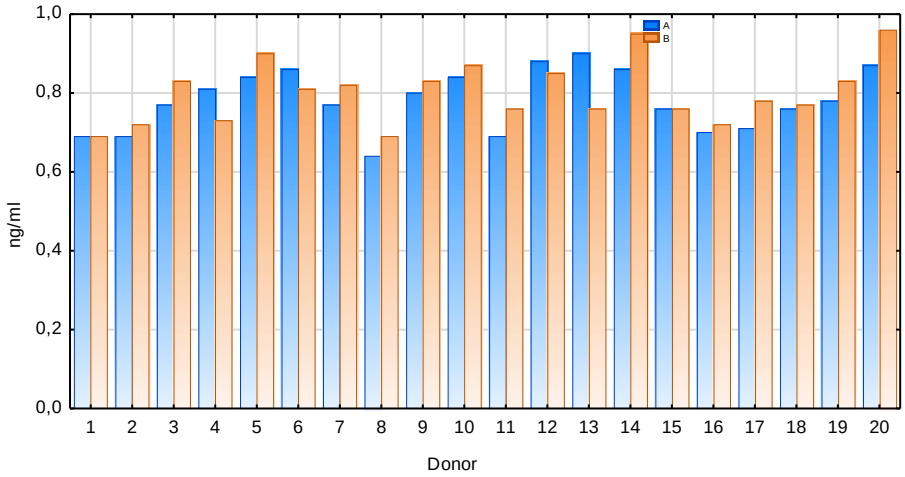


Bland Altman: fT3 [pg/ml] A/B

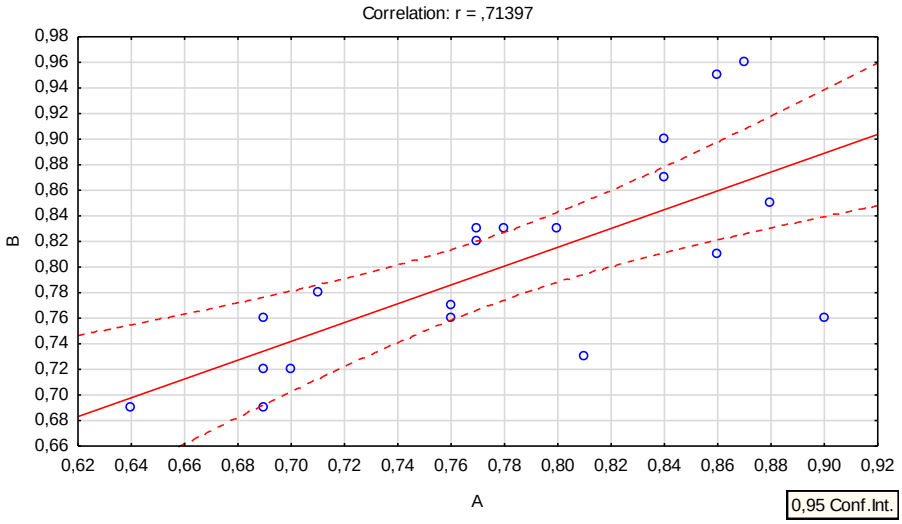


Free Thyroxine (fT_4) Normal range: 0.61 - 1.12 ng/dl

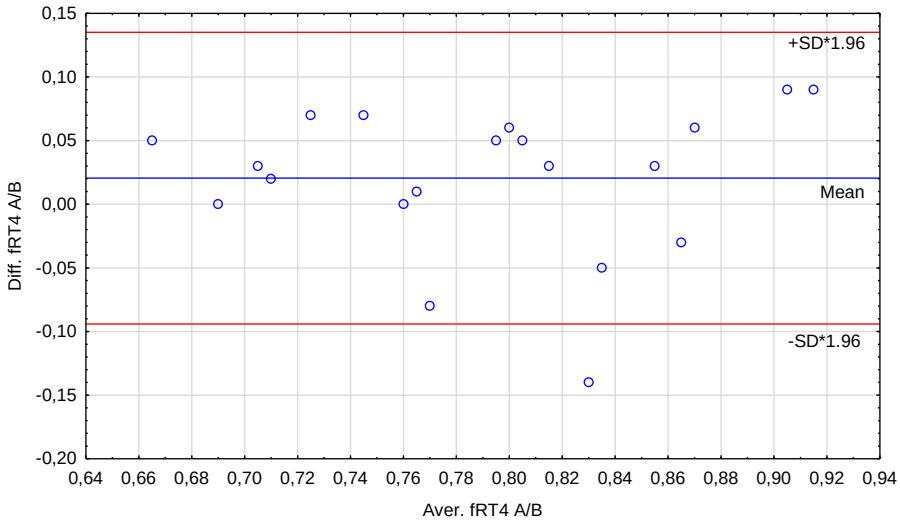
Bar chart



Correlations: fRT4 [ng/ml] A/B

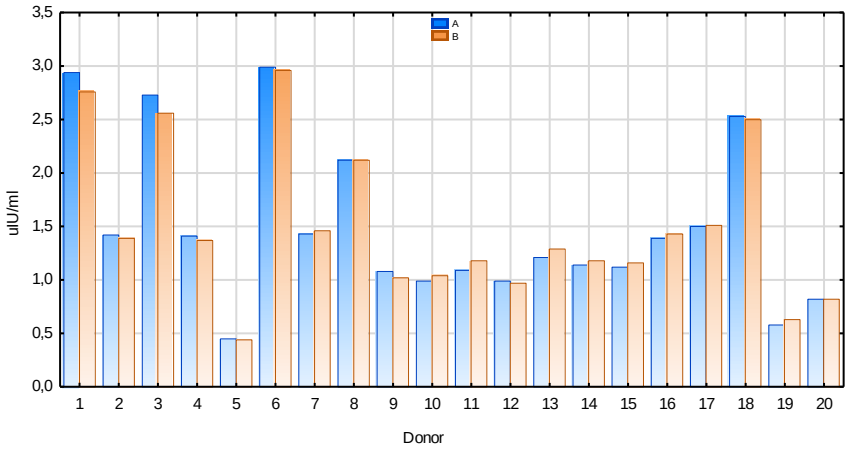


Bland Altman: fRT4 [ng/ml] A/B

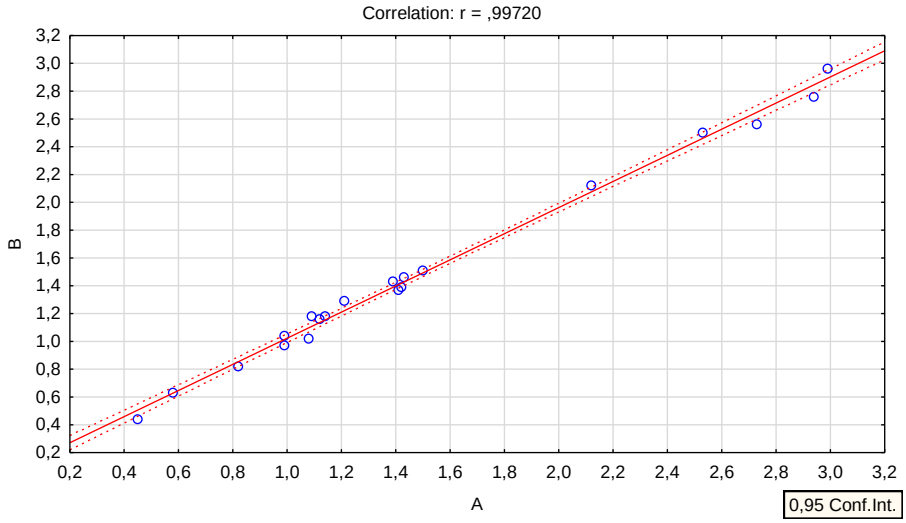


Thyroid-stimulating Hormone (TSH) Normal range: 0.1 - 3.5 µIU/ml

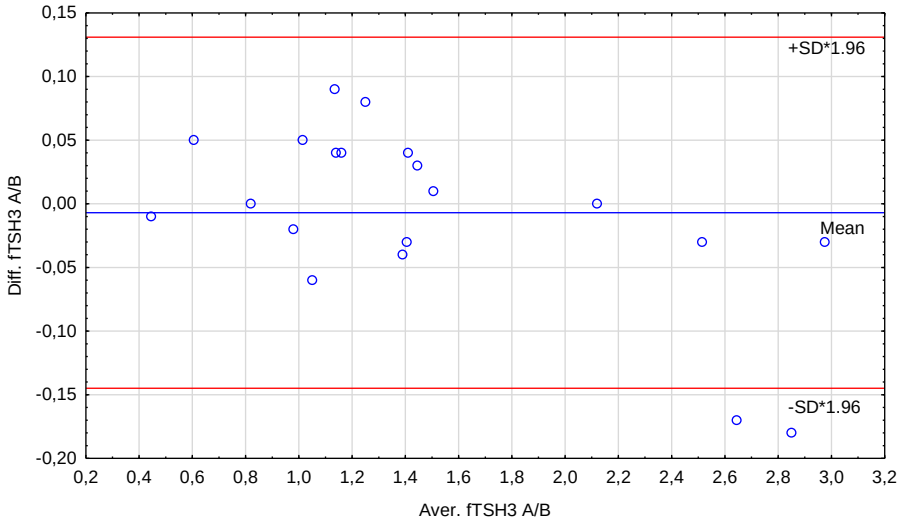
Bar chart



Correlations: fTSH3 [uIU/ml] A/B

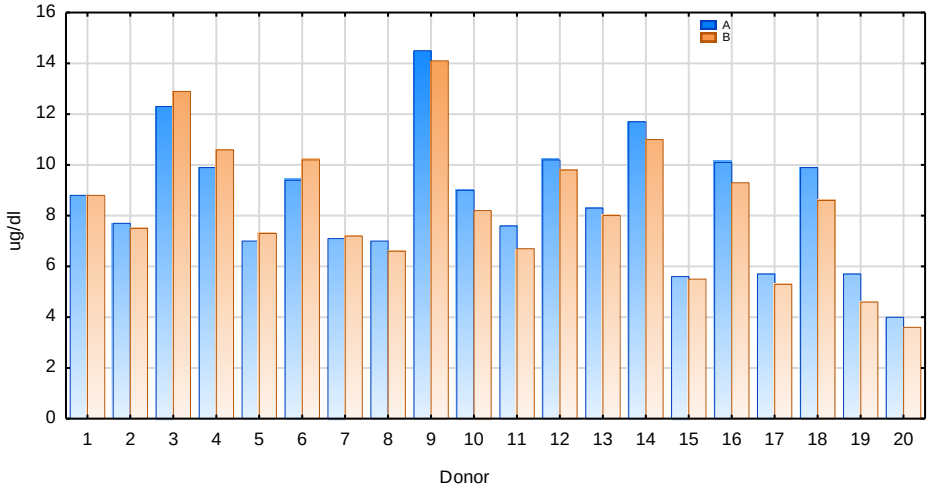


Bland Altman: fTSH3 [uIU/ml] A/B

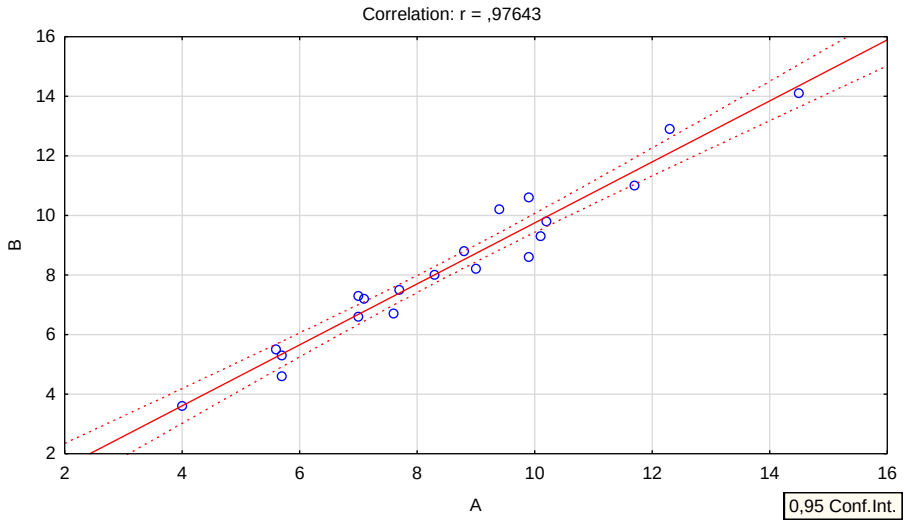


Cortisol Normal range: morning 6.7 - 22.6 µg/dl afternoon > 10 µg/dl

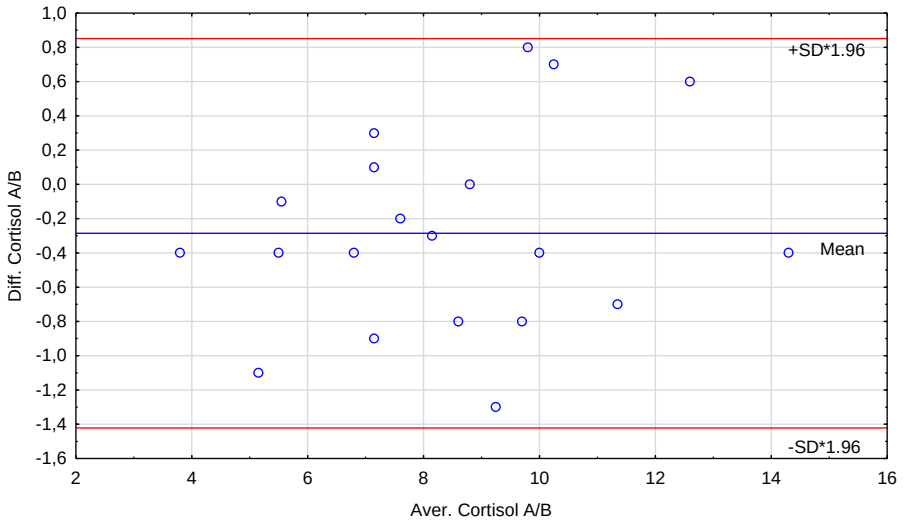
Bar chart



Correlations: Cortisol [ug/dl] A/B

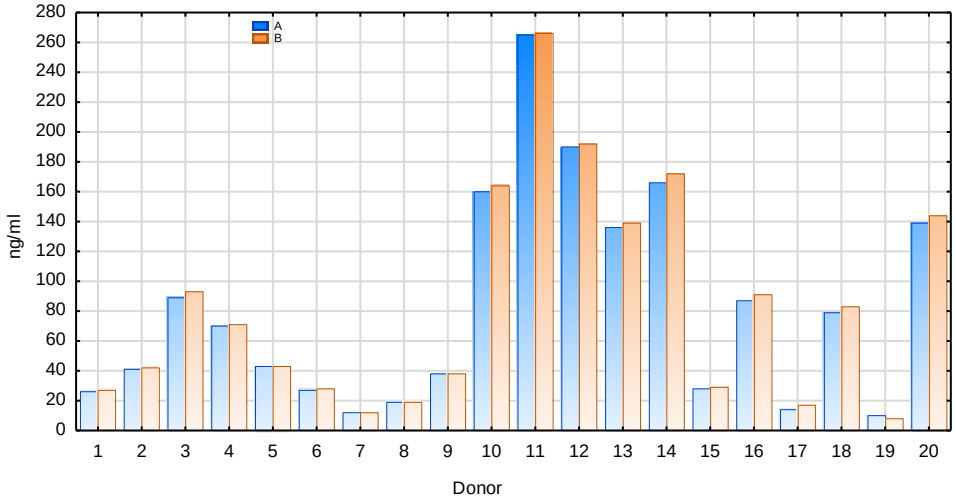


Bland Altman: Cortisol [ug/dl] A/B

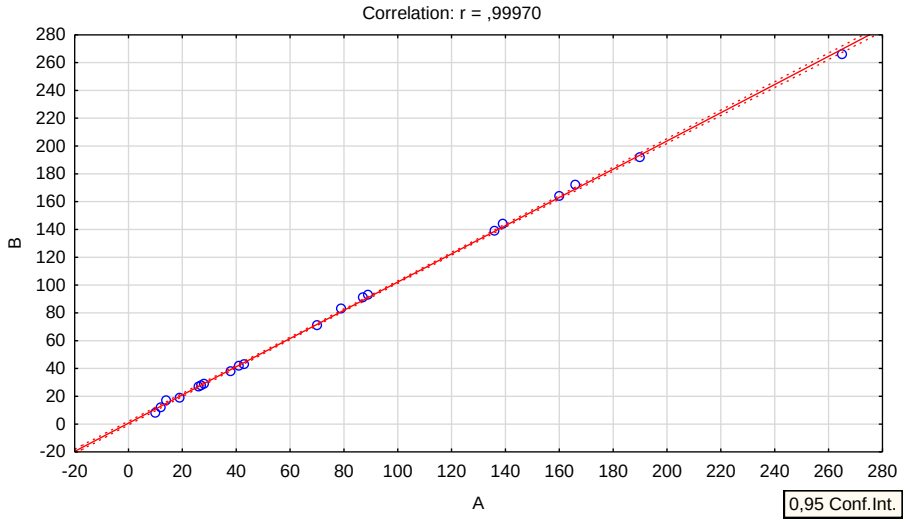


Ferritin: Normal range: (f) 20 - 250 µg/l (m) 10 - 120 µg/l

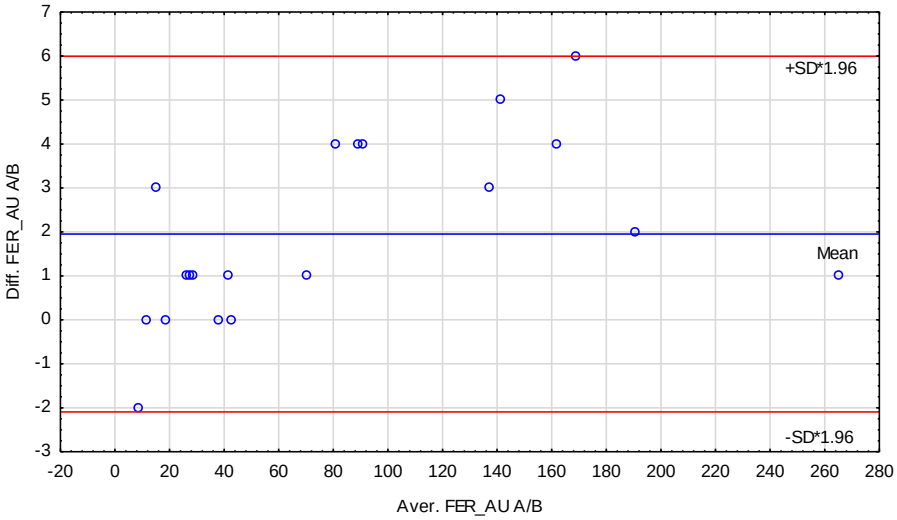
Bar chart



Correlations: FER [ng/ml] A/B

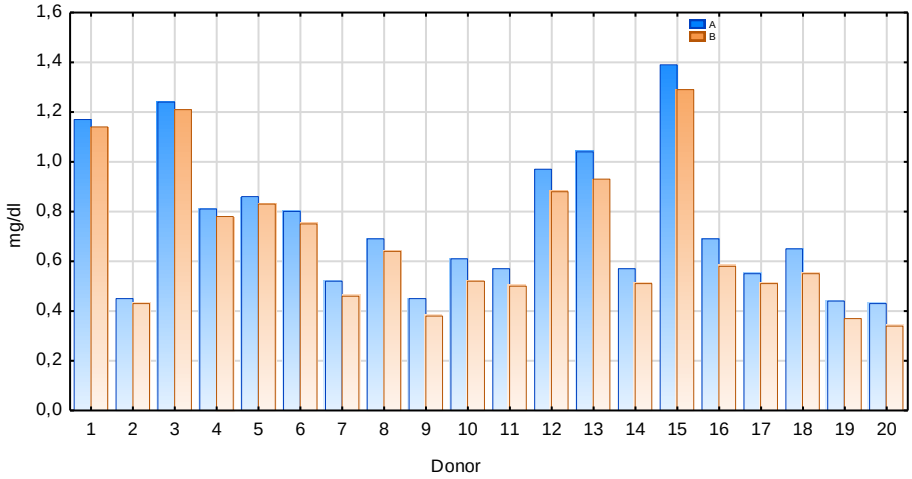


Bland Altman: FER [ng/ml] A/B

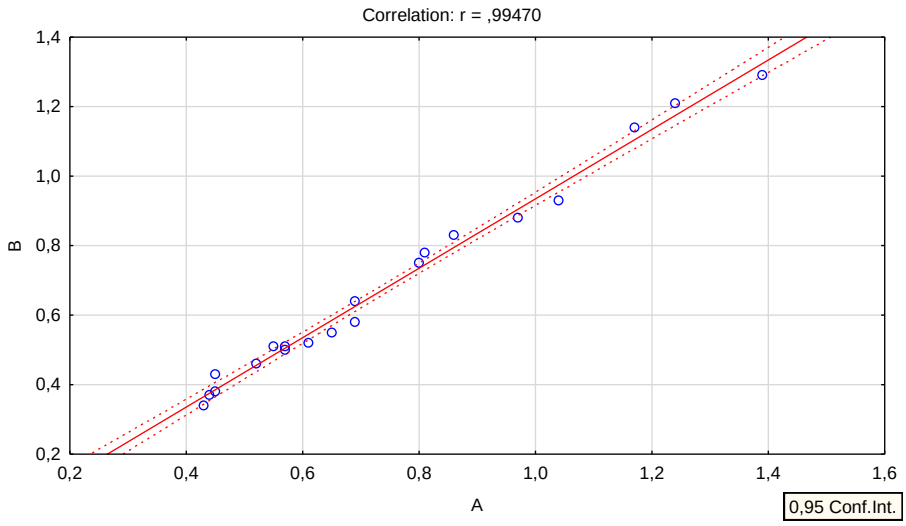


Total Bilirubin: Normal range: 0.3 - 1.2 mg/dl

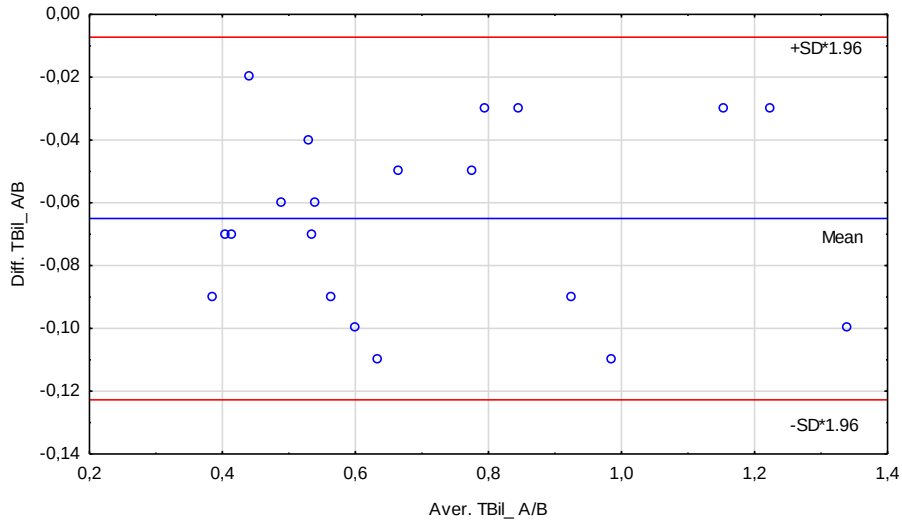
Bar chart



Correlations: TBil_ [mg/dl] A/B

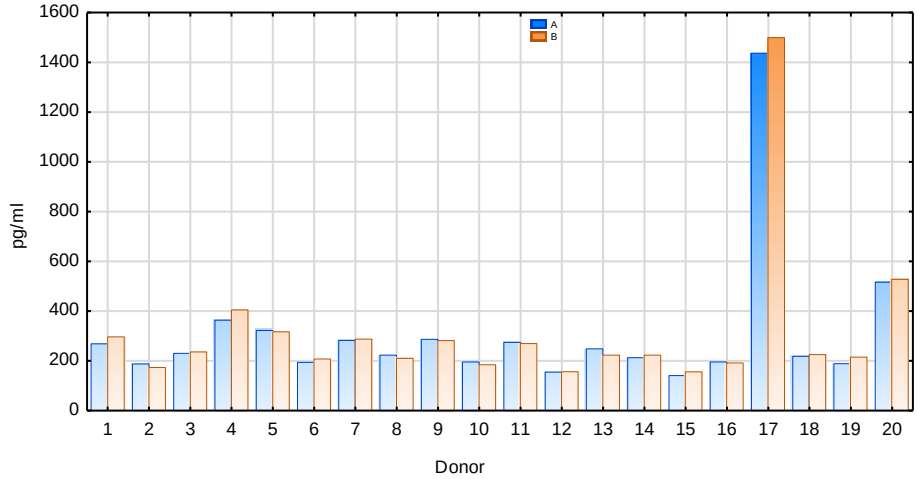


Bland Altman: TBil_ [mg/dl] A/B

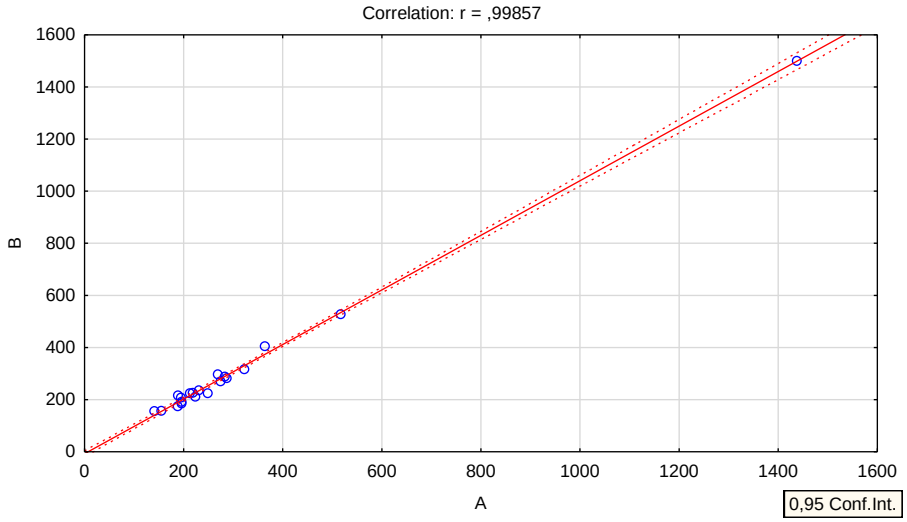
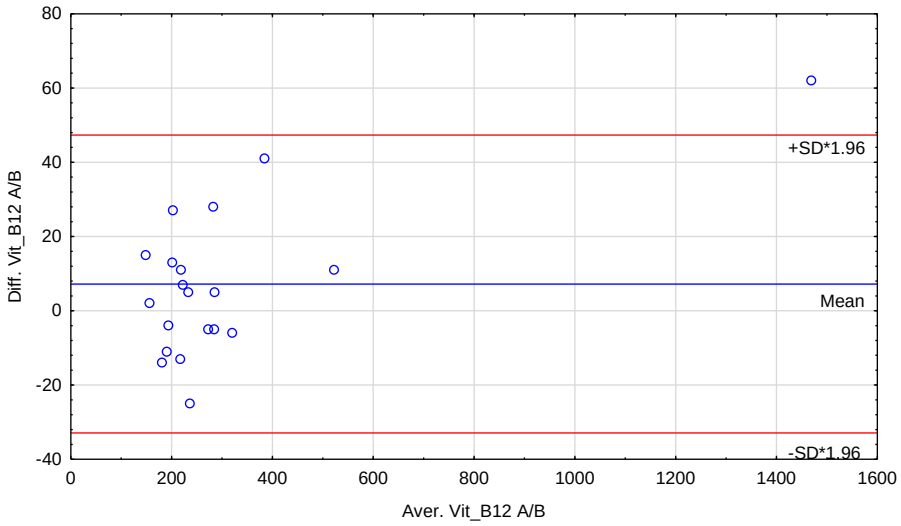


Vit B_{12} (Cobalamine): Normal range: 180 - 914 pg/ml

Bar chart



Correlations: Vit B_{12} [pg/ml] A/B



Bland Altman: Vit B_{12} [pg/ml] A/B