

Evaluation of new MiniCollect® CAT Serum (Separator) Tubes

Background:

Greiner Bio-One has developed a newly designed MiniCollect® tube offering an integrated collection scoop. The 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® CAT Serum Separator capillary blood collection tube is also featured with a co-molded cap which can easily be removed during the collection and sampling process.

The interior of the tube is coated with spray-dried blood clotting activator (SiO₂). The blood clotting activator speeds up the clotting process. MiniCollect® Clot Activator Separator tubes contain an inert, acrylic gel barrier in the bottom of the tube. The specific gravity of the gel lies between the cells and serum. This separation allows serum to be aspirated directly from the MiniCollect® tube eliminating the need to transfer serum into another vessel.

MiniCollect® CAT Serum (Separator) Tubes are used to collect, transport, separate and process capillary blood for testing serum in the clinical laboratory.

Study Objective:

A clinical evaluation was carried out to compare the performance of the MiniCollect® CAT Serum Separator tube with new design in comparison to old design of MiniCollect® Z Serum Separator tube including 50 healthy and 81 pathological subjects.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	MiniCollect® Z Serum Sep. 0.8 ml (item No.: 450472), old design
B	MiniCollect® CAT Serum Sep. 0.5-0.8 ml (item No.: 450533), new design

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

Directly after blood collection with venous blood, the tubes were carefully inverted 8 times according to the instructions for use for MiniCollect® blood collection tubes. After blood collection, the tubes were allowed to sit for 30 min in an upright position. The listed analytes were tested using an AU680 and DxI800 from Beckman Coulter. Analysis was performed with the instrument's accompanying reagents.

Determined parameters:

- | | |
|------------------------------------|--|
| ▪ Albumin | ▪ Magnesium |
| ▪ Lactate Dehydrogenase (LDH) | ▪ Iron |
| ▪ Aspartate Transaminase (AST) | ▪ Urea |
| ▪ Alanine-Transaminase (ALT) | ▪ Estradiol |
| ▪ Gamma-glutamyl Transferase (GGT) | ▪ Creatine Kinase |
| ▪ Alkaline Phosphatase (ALP) | ▪ Total Protein |
| ▪ Uric Acid | ▪ free Triiodothyronine (fT ₃) |
| ▪ Total Bilirubin | ▪ free Thyroxine (fT ₄) |
| ▪ Cholesterol | ▪ Thyroid-Stimulating Hormone (TSH) |
| ▪ Triglyceride | ▪ Cortisol |
| ▪ Sodium | ▪ Glucose |
| ▪ Potassium | ▪ Progesterone |
| ▪ Chloride | ▪ Ferritin |
| ▪ Calcium | |
| ▪ Phosphate | |

Conclusion:

Performance of the new MiniCollect® CAT Serum Separator tube has been demonstrated in comparison to the old MiniCollect® Z Serum Separator tube on the basis of the analytes tested.

For three samples (16B, 21A, 49B) from pathological subjects, the sample amount was not sufficient in order to determine all parameters.

Several visually hemolytic samples have been detected: 6A, 6B / 11A, 11B / 12A, 12B / 18A, 18B / 27A, 27B / 38A, 38B / 43A, 43B.

Due to very low absolute values, rather higher analytical deviations have been found for Estradiol and, Progesterone by including male and female subjects.

Deviations as found for total bilirubin might be due to the light sensitivity.

All systematic deviations that occurred in the measurement of potassium, AST, CK, total bilirubin and phosphate are considered to be without clinical significance.

As the new design of MiniCollect® CAT Serum Separator tubes reduces the likelihood of non-visible hemolysis, slightly systematically lower values have been found for LDH and potassium.

In summary, despite the deviations and results that have been found, none are clinically significant. The MiniCollect® CAT Serum Separator with the new design is substantially equivalent to the MiniCollect® Z Serum Separator with the old design.

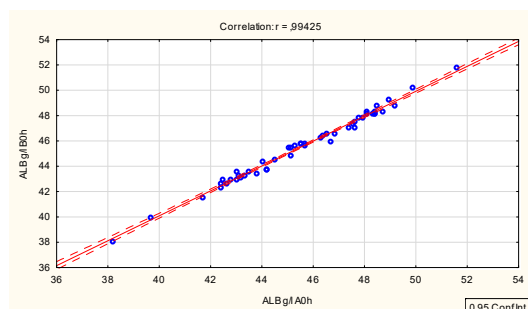
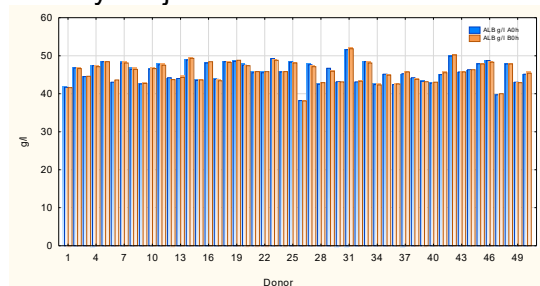
References:

- (1) Greiner Bio-One. MiniCollect® CAT Serum 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

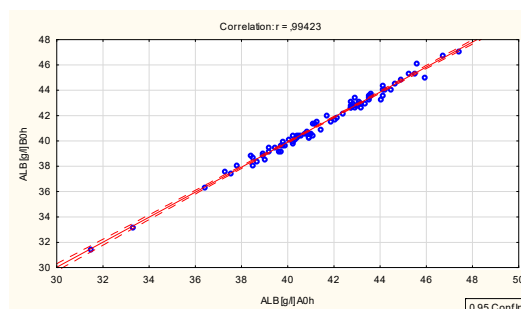
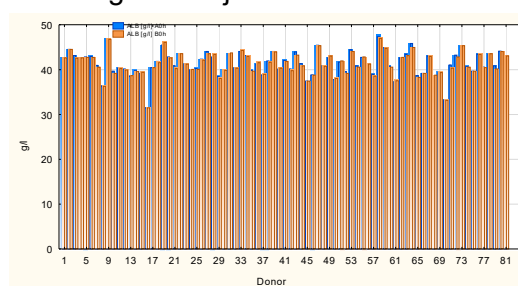
Results: Results in detail:

Albumin Normal range: 35 - 52 g/l

Healthy subjects

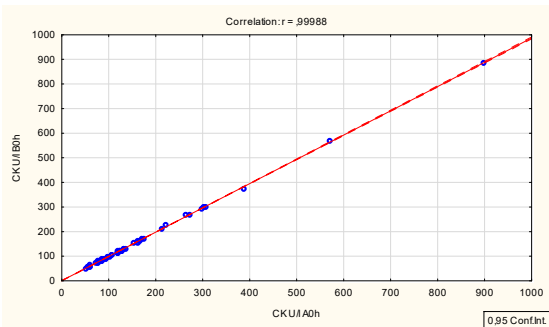
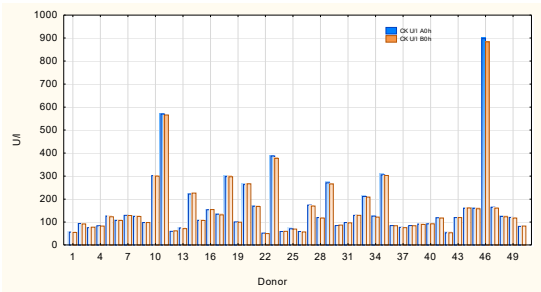


Pathological subjects

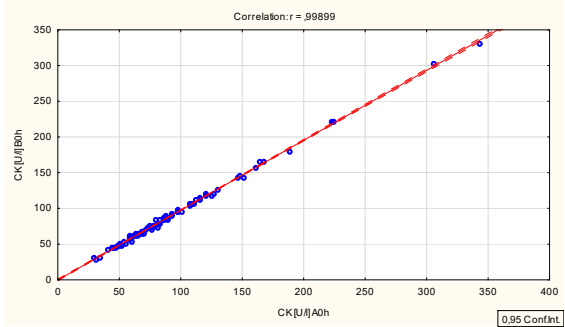
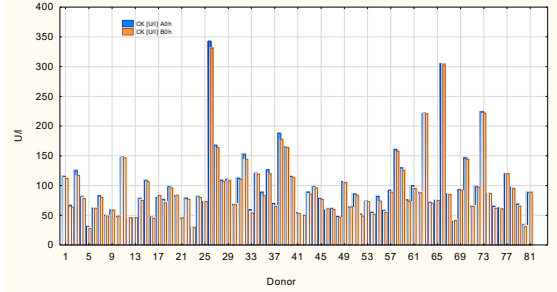


Creatine Kinase Normal range: (f) ≤ 171 U/l (m) ≤ 145 U/l

Healthy subjects

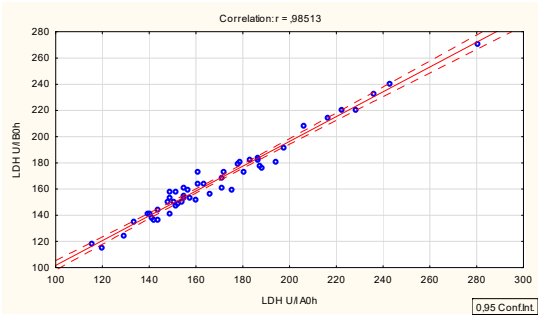
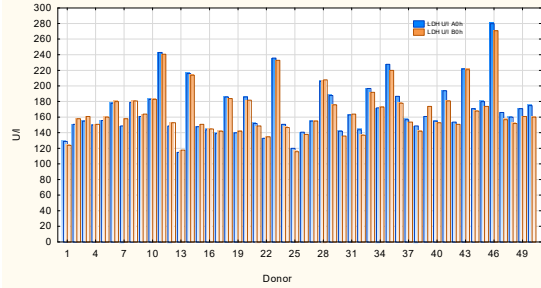


Pathological subjects

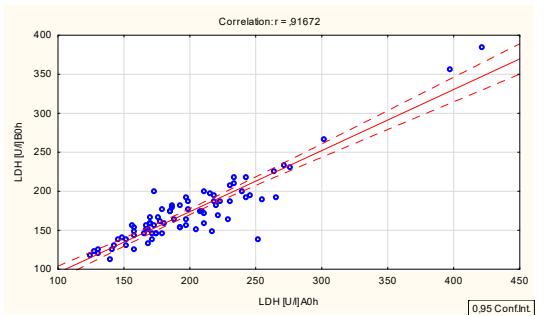
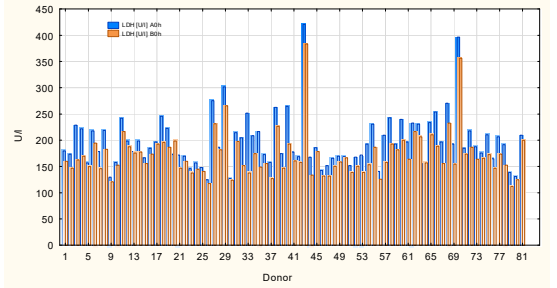


Lactate Dehydrogenase (LDH) Normal range: (f) < 247 U/l (m) < 248 U/l

Healthy subjects

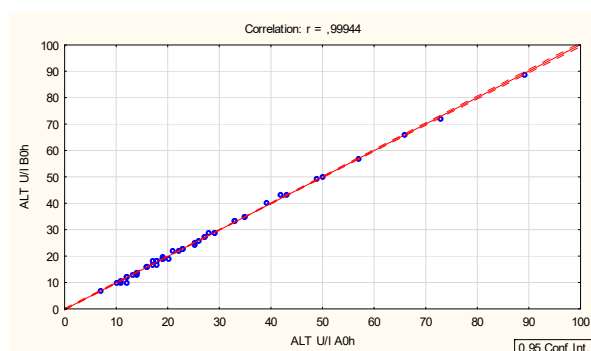
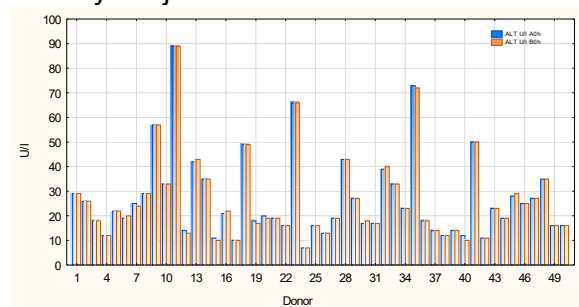


Pathological subjects

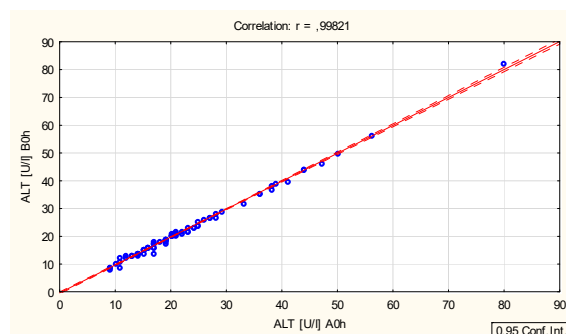
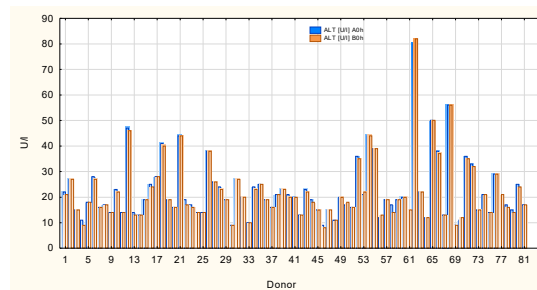


Alanine transaminase (ALT) Normal range: (m) < 50 U/l (f) < 35 U/l

Healthy subjects

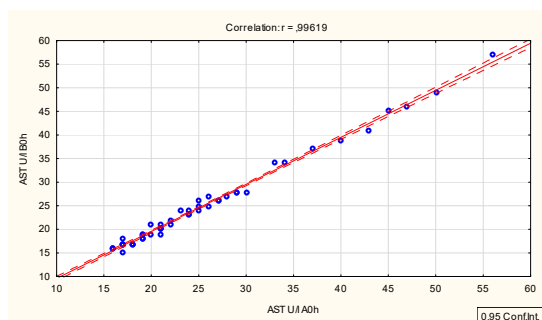
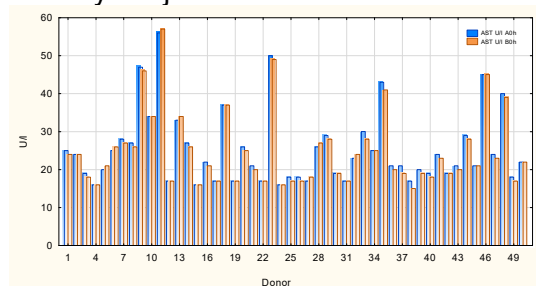


Pathological subjects

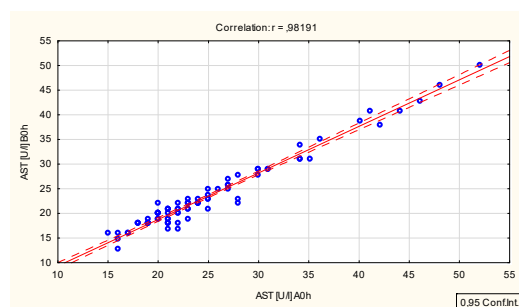
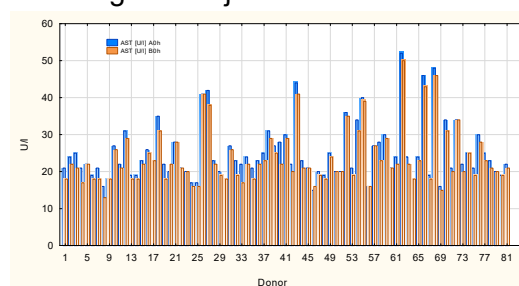


Aspartate transaminase (AST) Normal range: (m) < 50 U/l (f) < 35 U/l

Healthy subjects

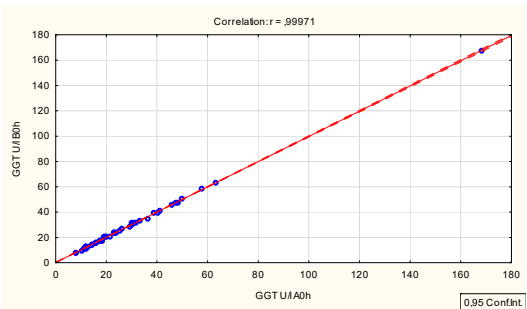
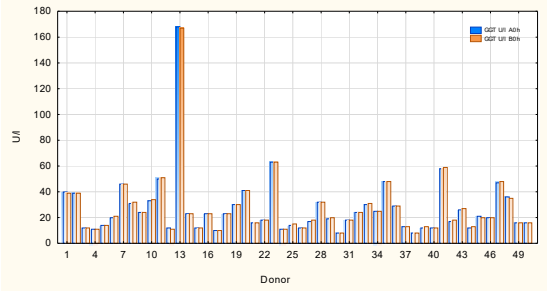


Pathological subjects

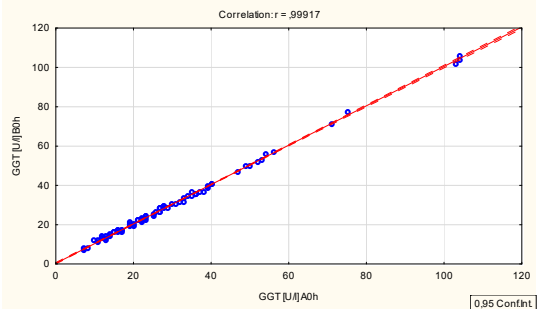
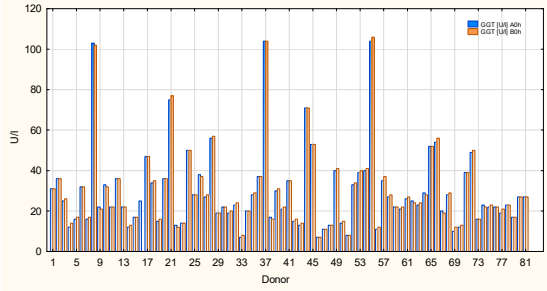


Gamma-glutamyl Transpeptidase (GGT) Normal range: (f) < 55 U/l (m) < 38 U/l

Healthy subjects

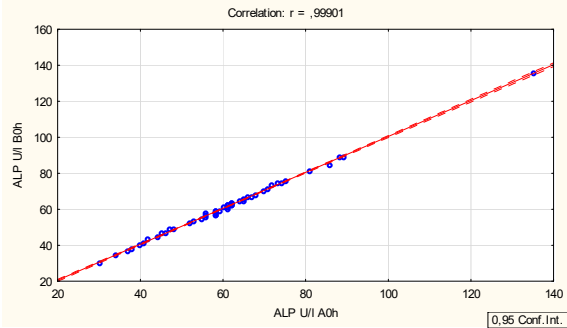
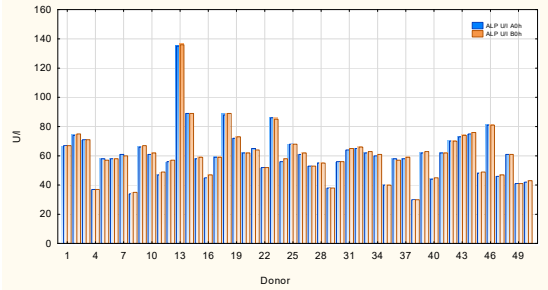


Pathological subjects

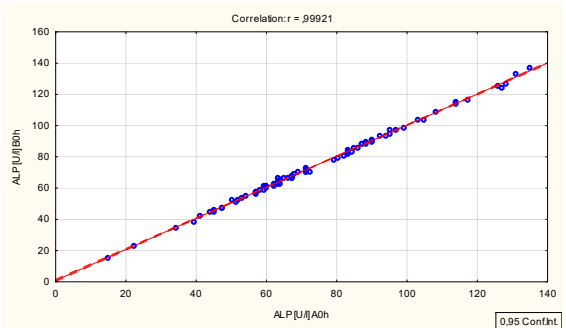
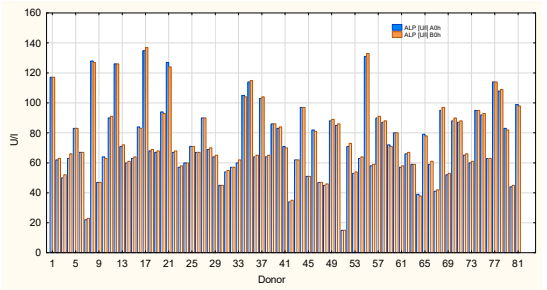


Alkaline Phosphatase (ALP) Normal range: 60 - 200 U/l

Healthy subjects

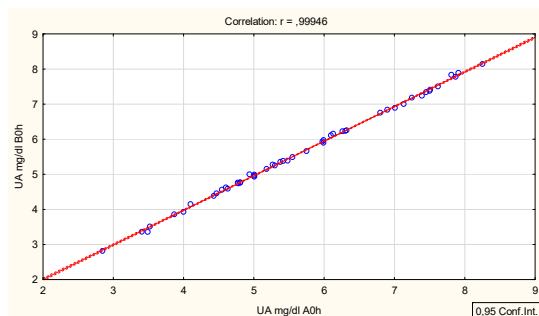
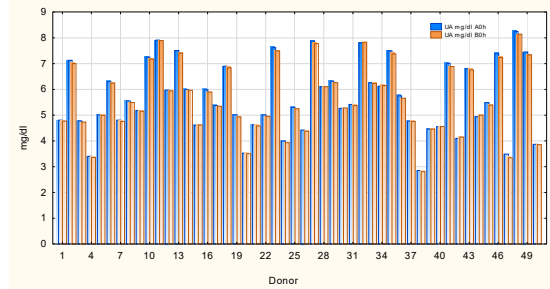


Pathological subjects

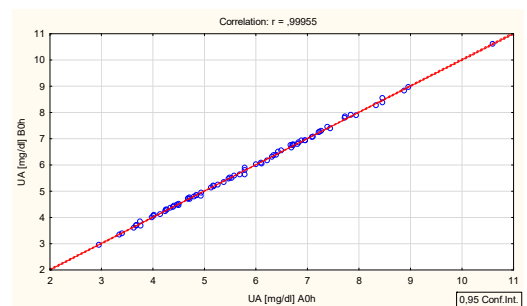
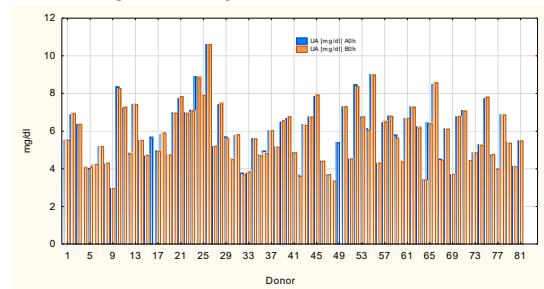


Uric Acid (UA) Normal range: (f) 3.5 - 7.2 mg/dl (m) 2.6 - 6.0 mg/dl

Healthy subjects

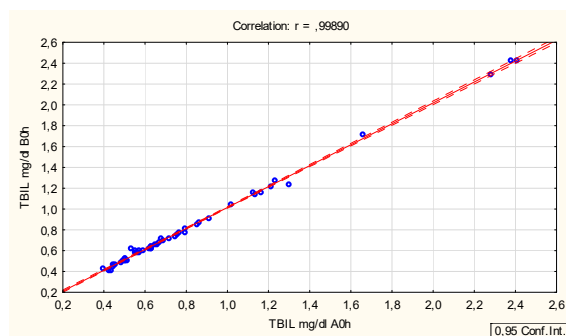
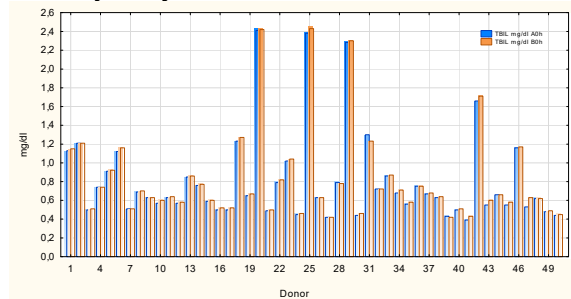


Pathological subjects

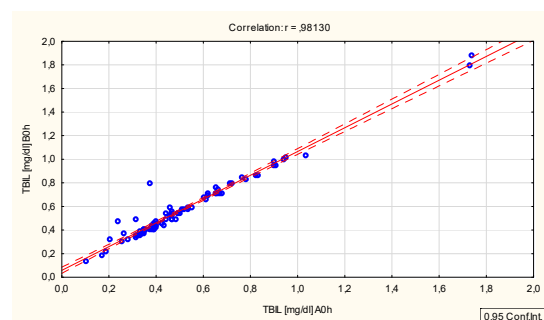
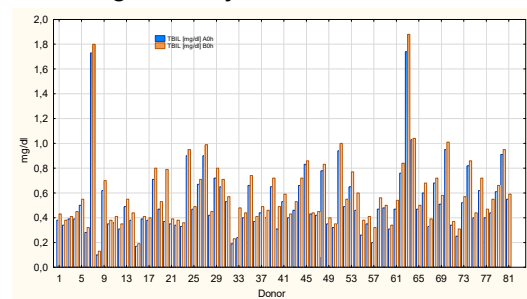


Total Bilirubin (TBili) Normal range: 0.3 - 1.2 mg/dl

Healthy subjects

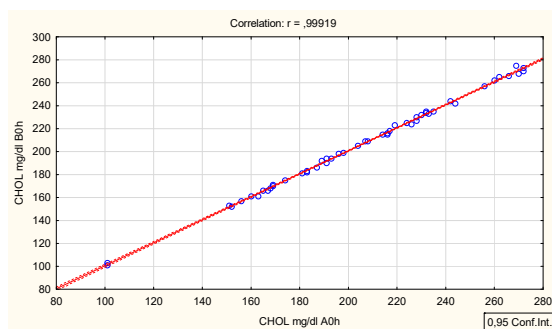
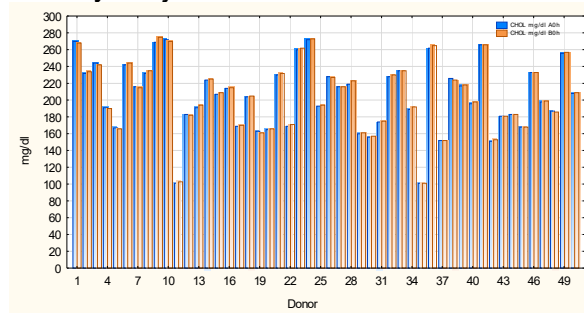


Pathological subjects

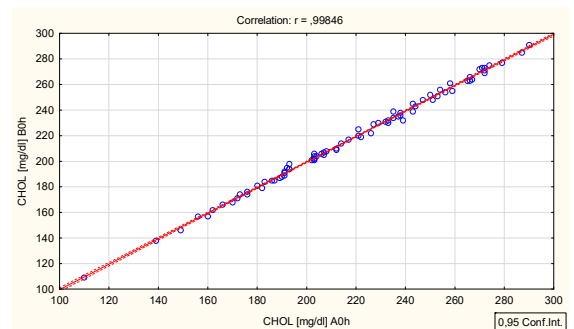
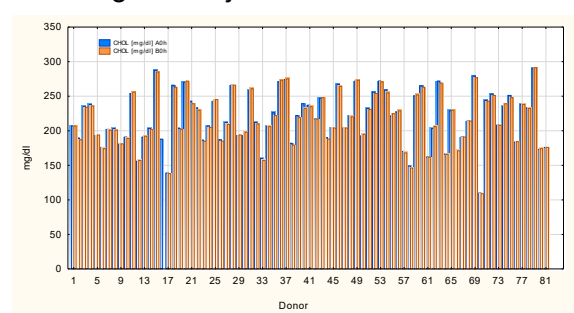


Cholesterol (Chol) Normal range: < 200 mg/dl

Healthy subjects

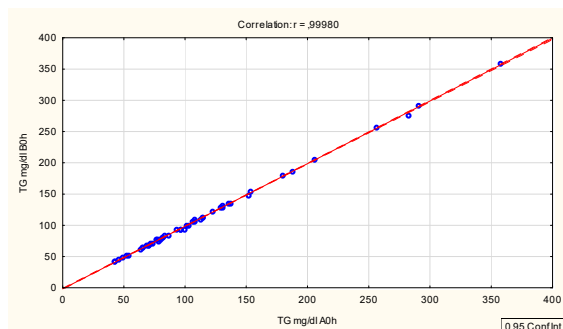
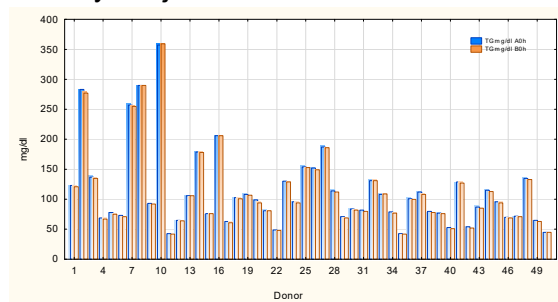


Pathological subjects

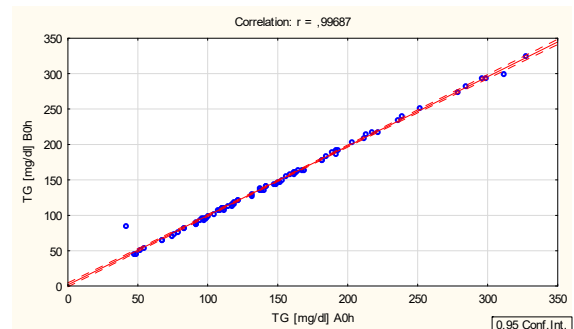
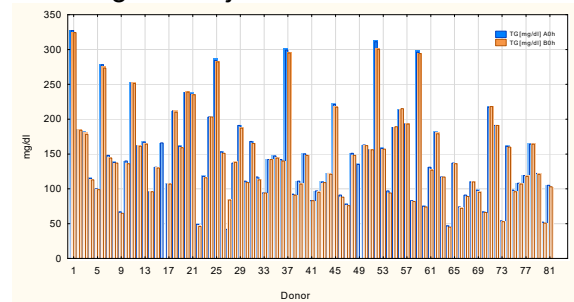


Triglyceride (TG) Normal range: normal ≤ 150 < borderline high < 200 high < 500 very high

Healthy subjects

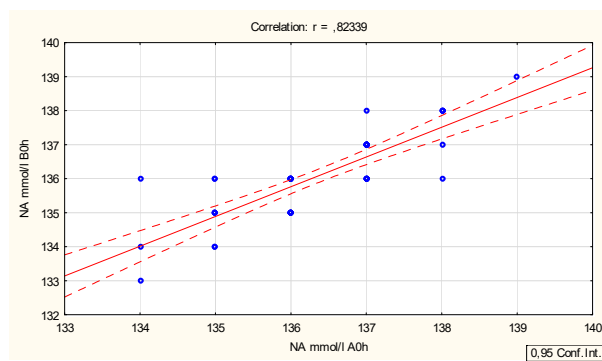
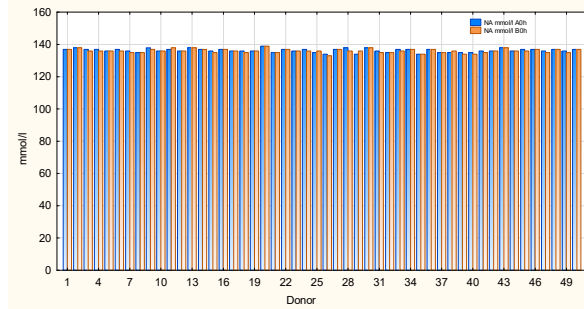


Pathological subjects

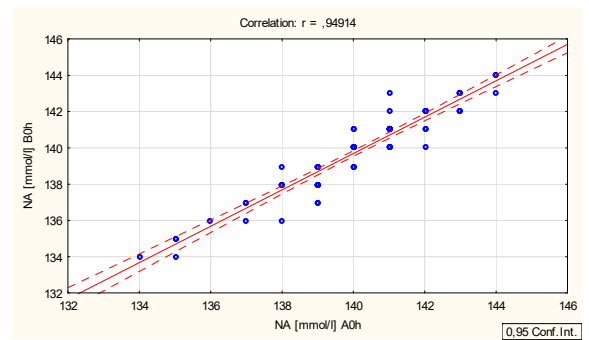
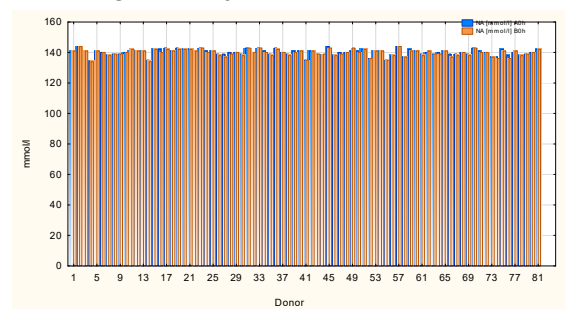


Sodium (Na) Normal range: 136 - 146 mmol/l

Healthy subjects

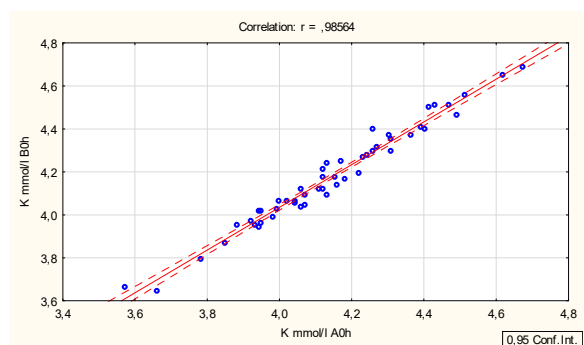
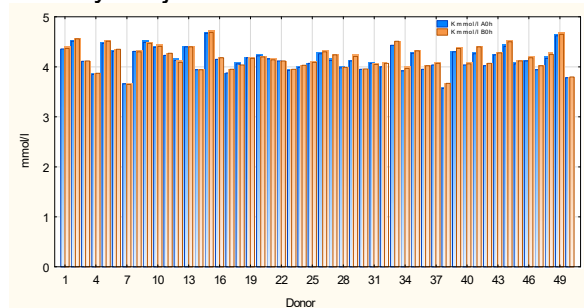


Pathological subjects

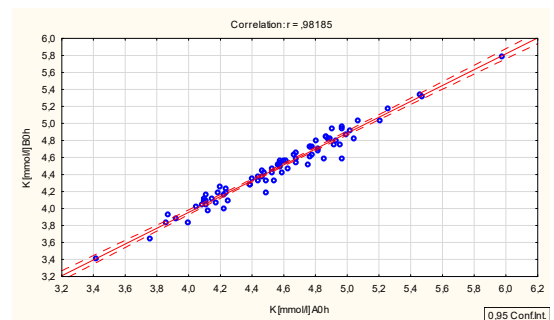
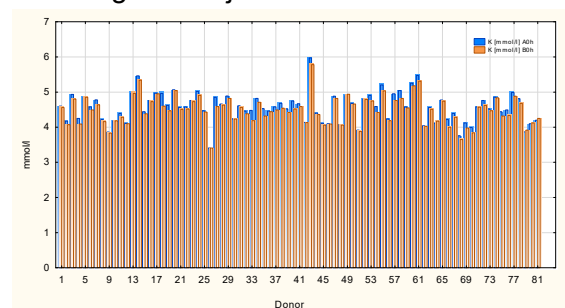


Potassium (K) Normal range: Serum 3.5 - 5.1 mmol/l

Healthy subjects

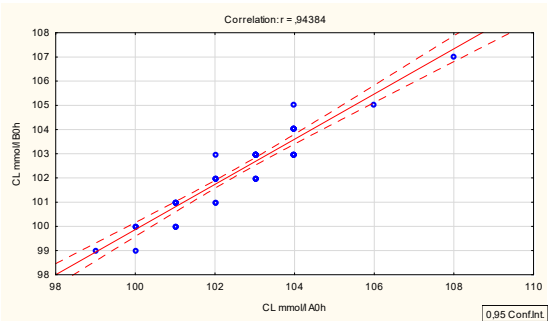
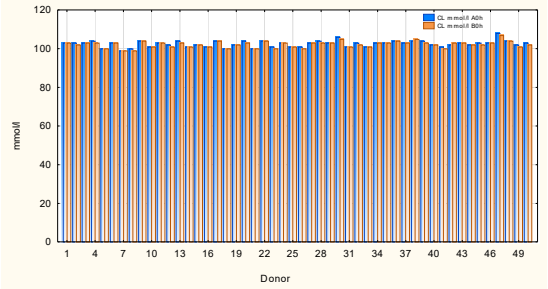


Pathological subjects

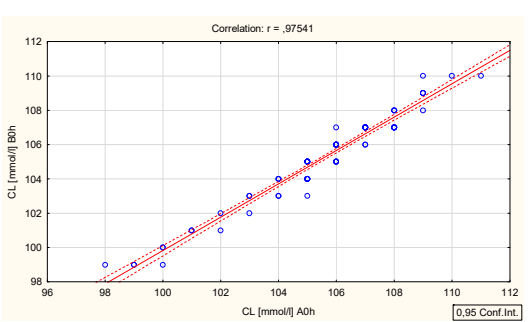
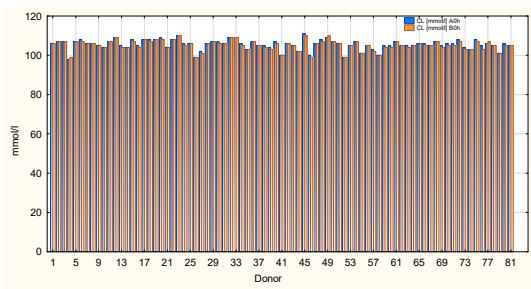


Chloride (Cl) Normal range: 101 - 109 mmol/l

Healthy subjects

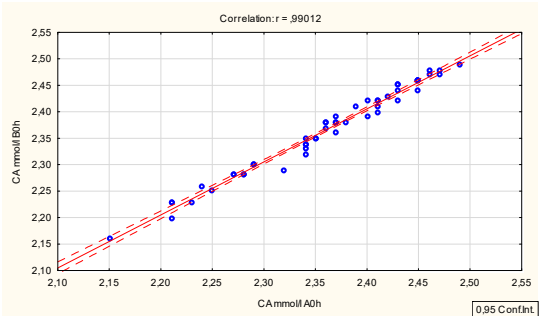
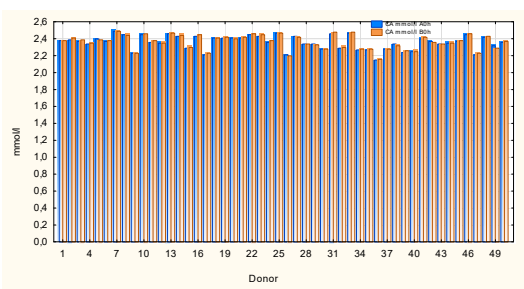


Pathological subjects

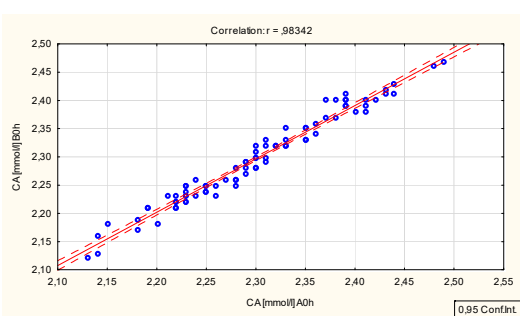
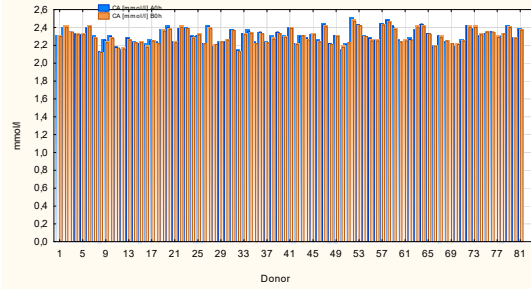


Calcium (Ca) Normal range: 2.20 - 2.65 mmol/l

Healthy subjects

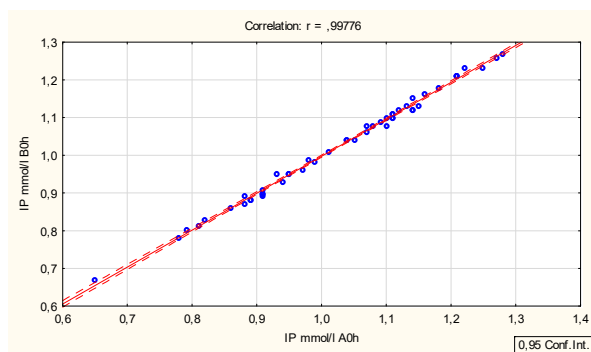
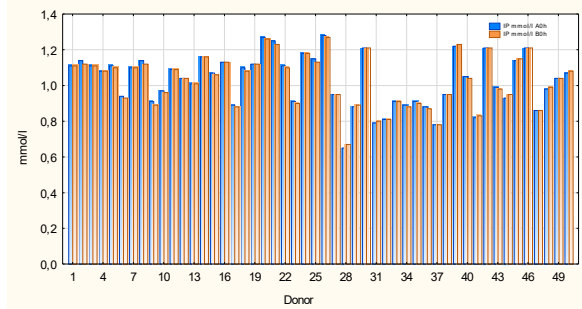


Pathological subjects

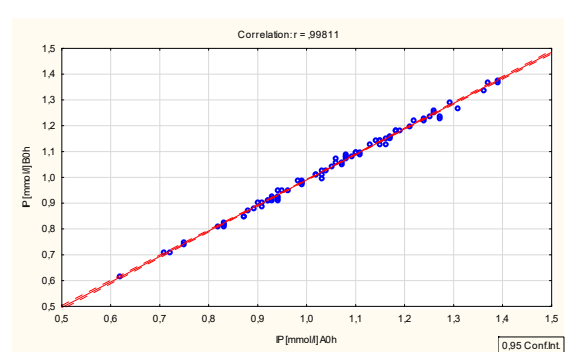
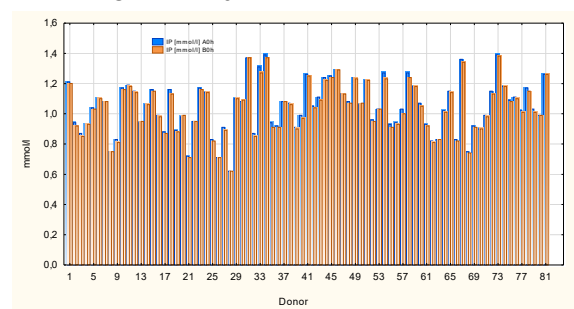


Phosphate (IP) Normal range: 0.81 - 1.45 mmol/l

Healthy subjects

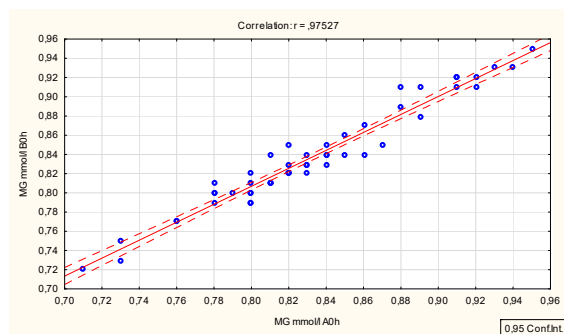
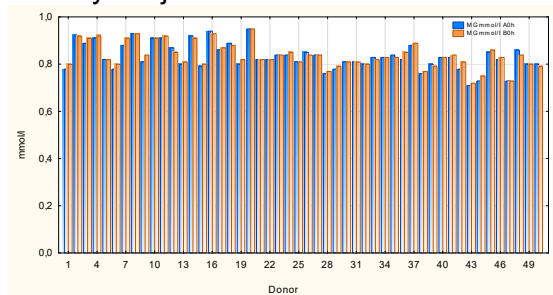


Pathological subjects

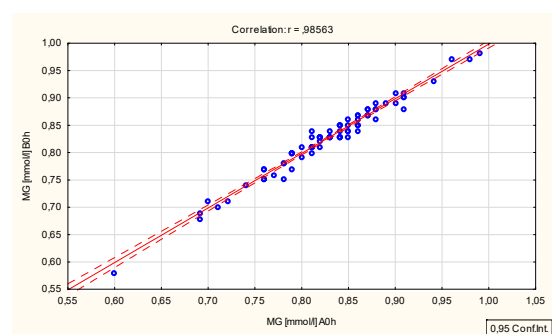
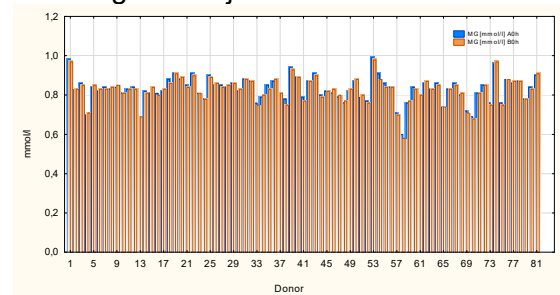


Magnesium (Mg) Normal range: (f) 0.73 - 1.06 mmol/l (m) 0.77 - 1.03 mmol/l

Healthy subjects

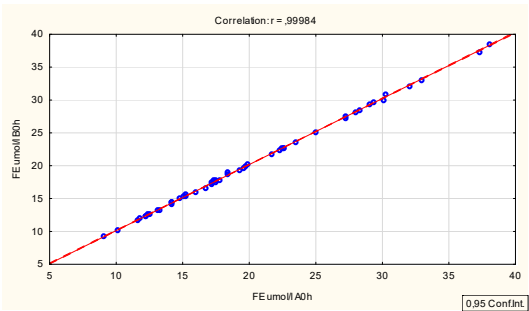
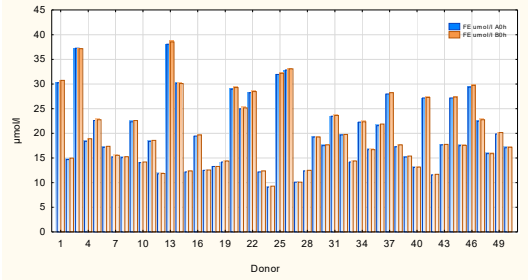


Pathological subjects

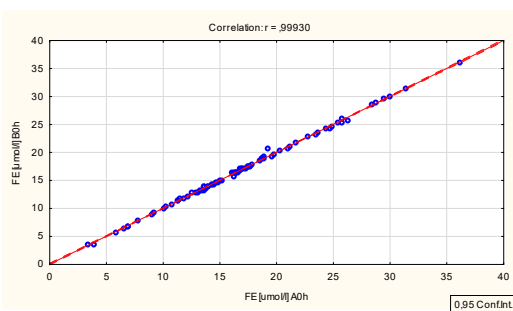
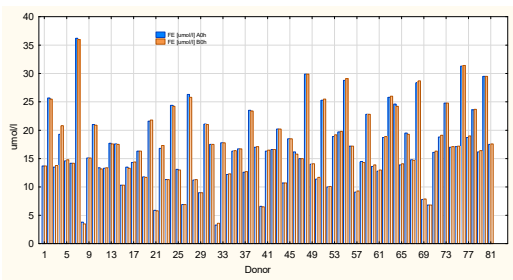


Iron (Fe) Normal range: (f) 12.5 - 32.2 $\mu\text{mol/l}$ (m) 10.7 - 32.2 $\mu\text{mol/l}$

Healthy subjects

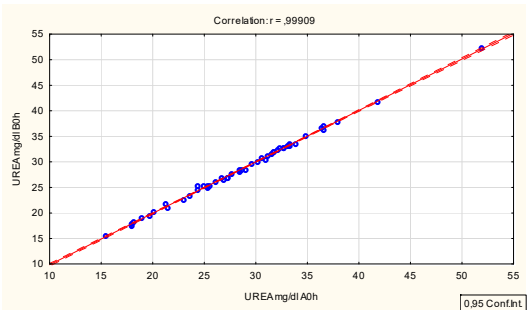
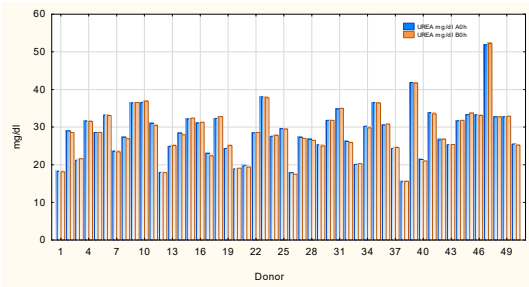


Pathological subjects

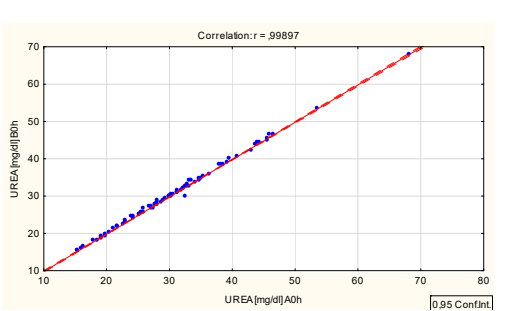
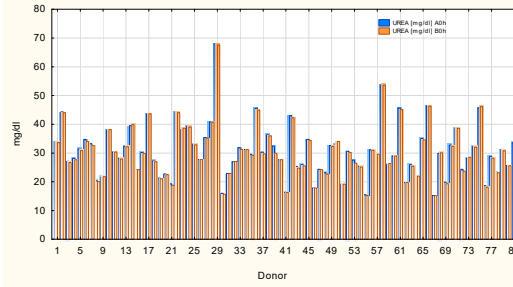


Urea Normal range: 17 - 43 mg/dl

Healthy subjects

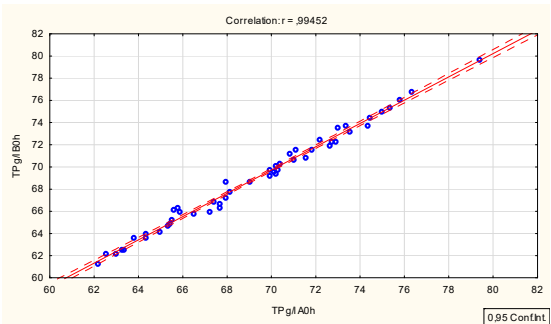
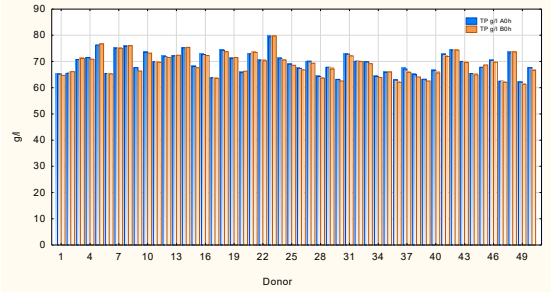


Pathological subjects

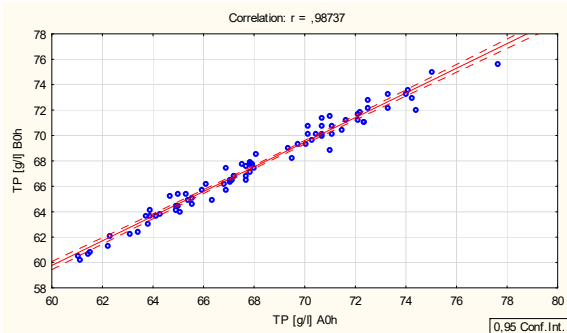
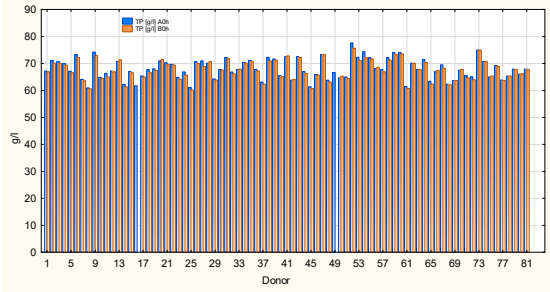


Total Protein (TP) Normal range: 66 - 83 g/l

Healthy subjects

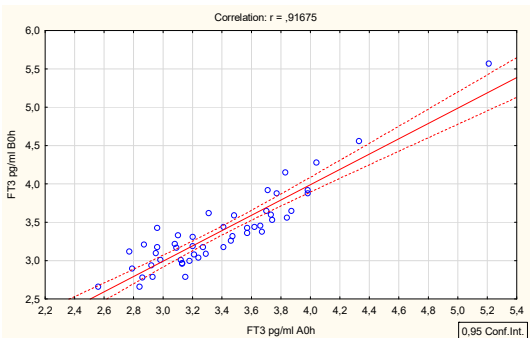
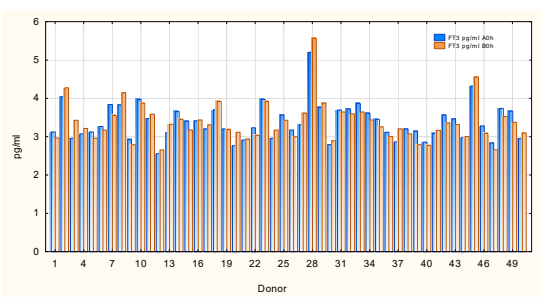


Pathological subjects

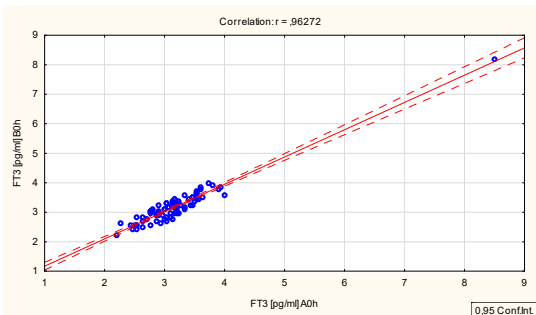
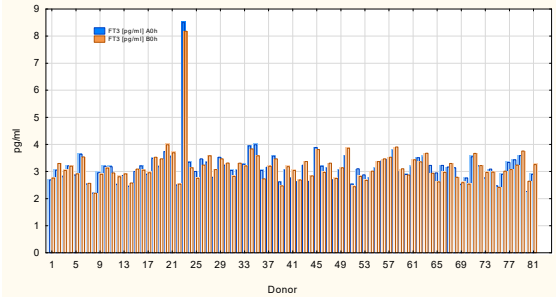


Free Triiodothyronine (fT₃) Normal range: 2.5 - 3.9 pg/ml

Healthy subjects

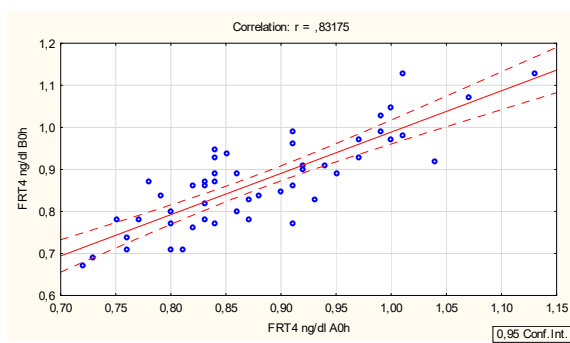
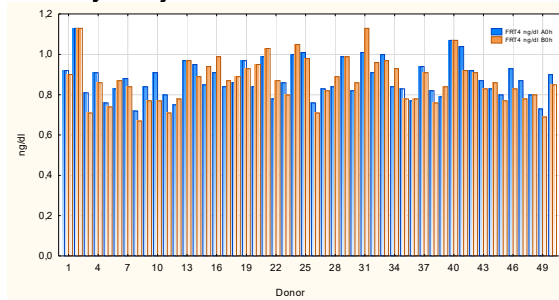


Pathological subjects

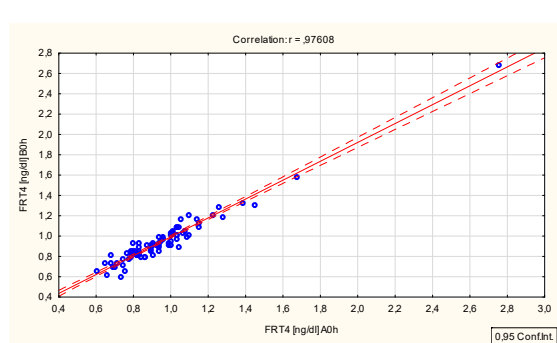
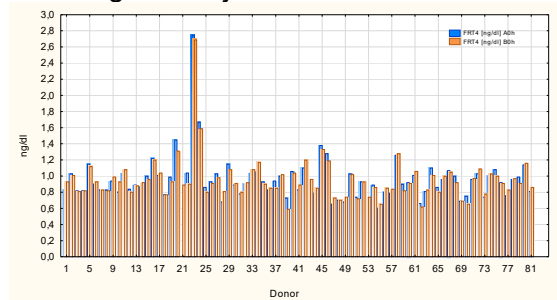


Free Thyroxine (fT₄) Normal range: 0.61 - 1.12 ng/dl

Healthy subjects

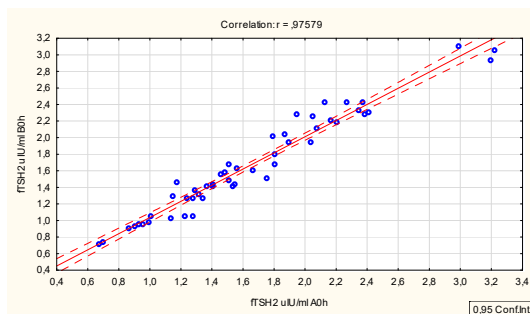
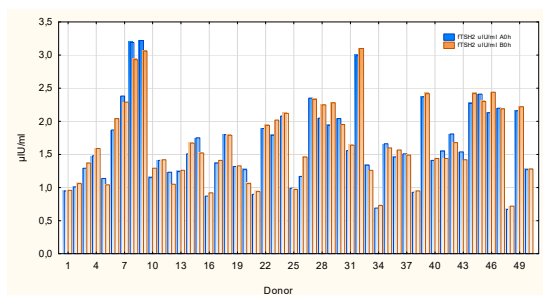


Pathological subjects

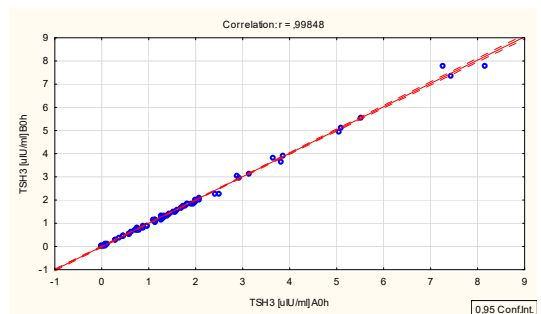
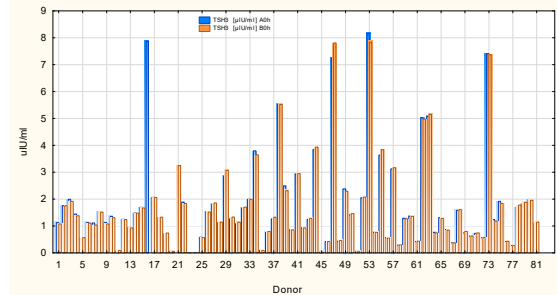


Thyroid-stimulating Hormone (TSH) Normal range: 0.1 - 3.5 µIU/ml

Healthy subjects

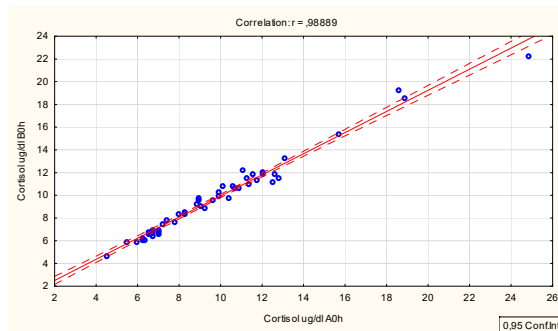
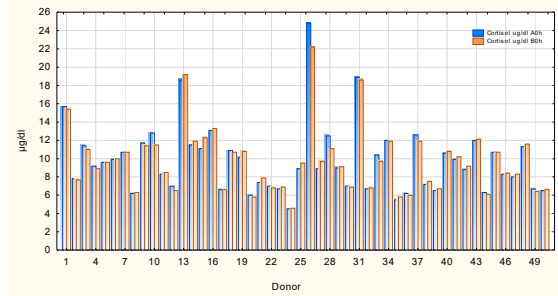


Pathological subjects

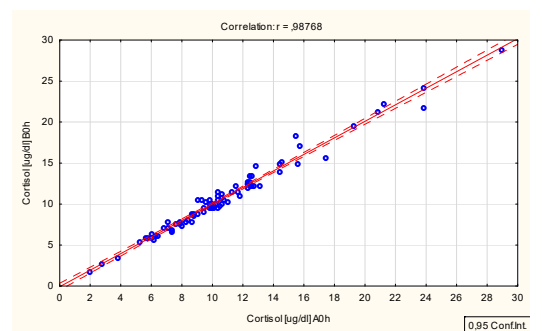
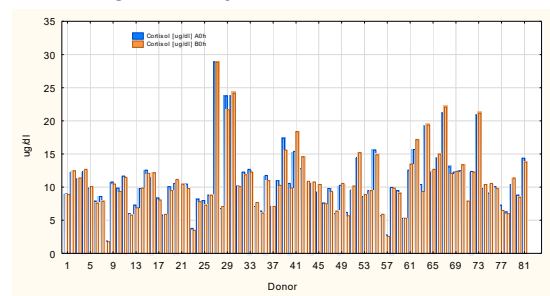


Cortisol Normal range: morning 6.7 - 22.6 µg/dl afternoon > 10 µg/dl

Healthy subjects

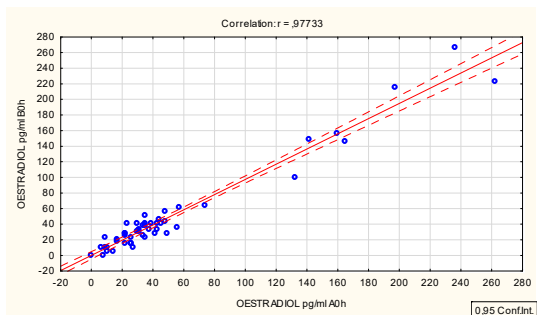
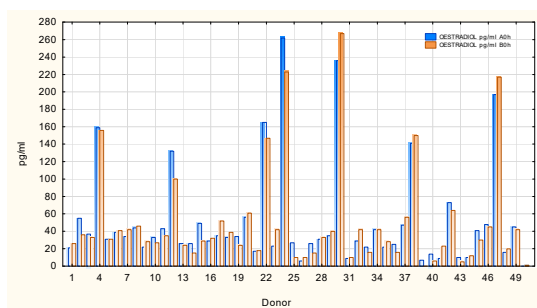


Pathological subjects

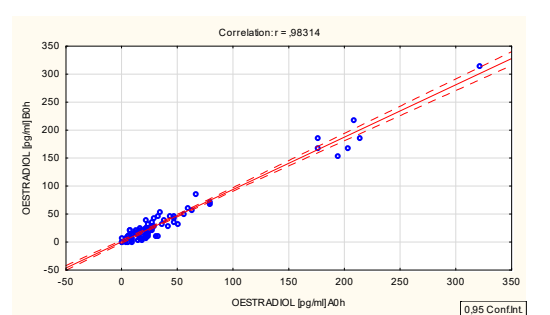
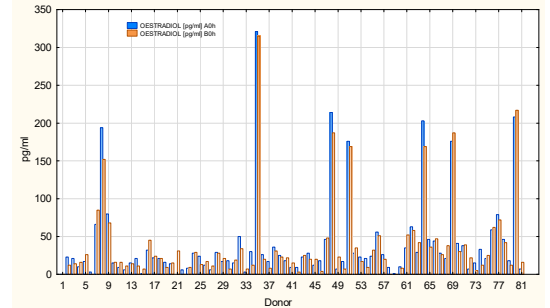


Estradiol Normal range: (m) 10 - 55 pg/ml (f) 30 -600 pg/ml

Healthy subjects

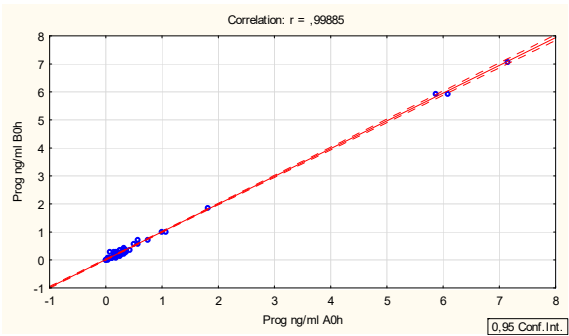
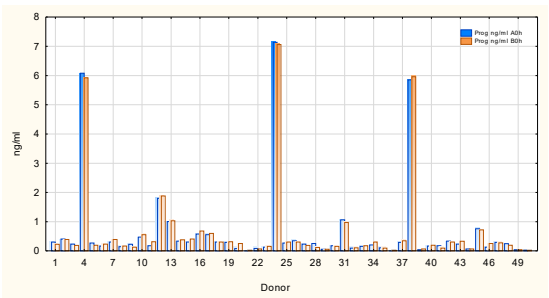


Pathological subjects

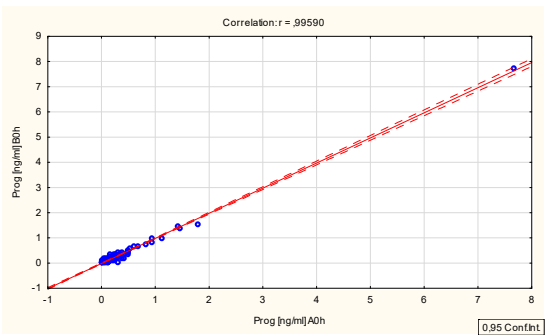
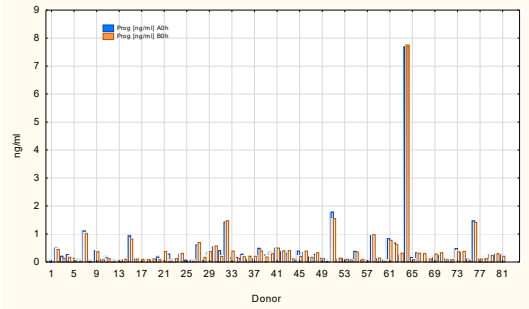


Progesterone Normal range: (f) 0.07 - 1.38 ng/ml(m) age dependent

Healthy subjects

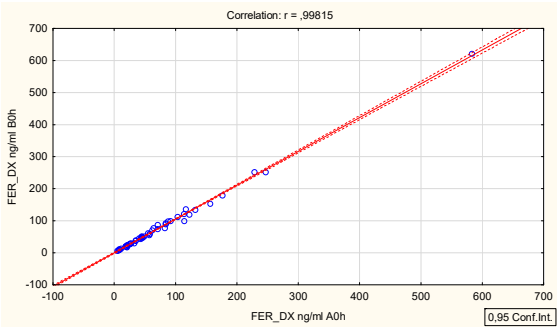
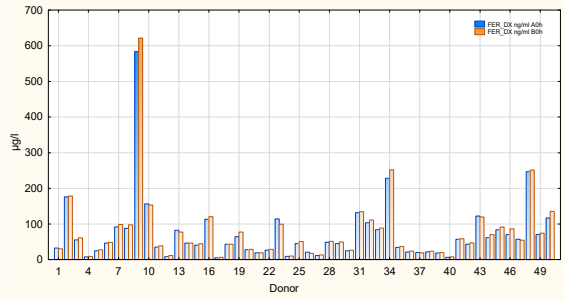


Pathological subjects

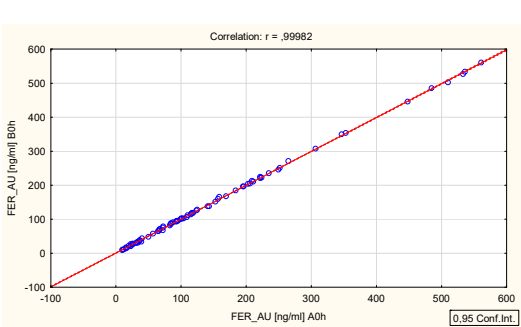
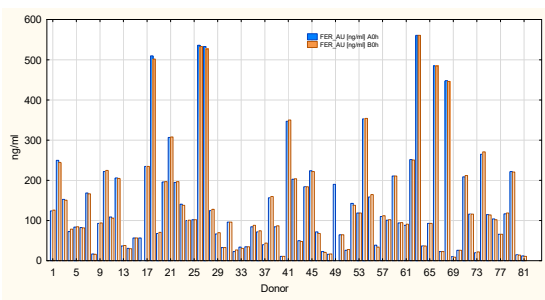


Ferritin Normal range: (f) 23.9 - 336.2 µg/l (m) 11.0 - 306.8 µg/l

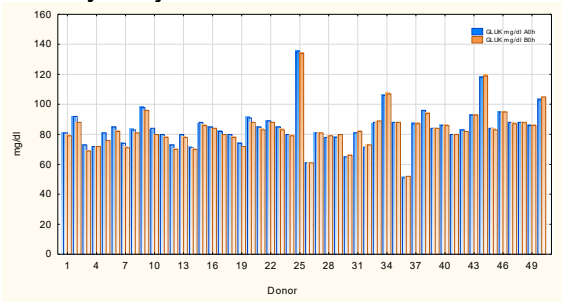
Healthy subjects



Pathological subjects



Glucose Normal range: 74 - 106 mg/dl
Healthy subjects



Pathological subjects

