Evaluation of new **MiniCollect**® Lithium Heparin (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® 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 new MiniCollect® LH Lithium Heparin Separator tube in comparison to old design of MiniCollect® LH Lithium Heparin 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® Lithium Heparin Separator 0.8ml (Item No.: 450479), old design
B	MiniCollect® Lithium Heparin Separator 0.8 ml (Item No.: 450535), 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 centrifuged within 120 min in a temperature controlled centrifuge (15-25°C) for 10 min at 3000g. (centrifuge: Eppendorf 5810R, swing bucket) 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

Conclusion:

Performance of the new MiniCollect® LH Lithium Heparin Separator tube has been demonstrated in comparison to the old MiniCollect® LH Lithium Heparin Separator tube on the basis of the analytes tested.

Healthy subjects: On the basis of the parameter tested, the performance of both tubes was comparable, although slight deviations have been found for GGT, glucose, LDH, fT_3, TSH, potassium and LDH with a slight tendency to a systematical deviation between both tubes for glucose and uric acid as well as for potassium (within analytical tolerance range) and LDH, however without clinical significance.

Pathological subjects: Statistically significant deviations have been found for the following parameters: albumin, calcium, cholesterol, phosphate, potassium, magnesium, total protein, uric acid, TSH, CK, and total bilirubin. All statistically significant deviations have been found to be in a clinically acceptable range and the deviations were not analytically significant. The correlation of these parameters between both samples was very high ($r > 0.97$) with LDH, GGT and total bilirubin being analytically significant. The deviation found for LDH and GGT extend to both directions and indicate a random error. The deviation of total bilirubin was systematically but in a clinically acceptable range.

Deviations have been found for LDH but did not lead to any systematic differences. The mean values and standard deviations did not reveal differences at all.

Total Bilirubin indicates very slight systematic deviations, but in a clinically acceptable range.

Subject 43 has shown high deviations for the parameters ALP, ALT, AST, GGT, LDH, Triglyceride, and Urea which most likely have been caused by preanalytical errors.

In summary, despite the deviations and results that have been found, the MiniCollect® LH Lithium Heparin Separator tube with the new design is substantially equivalent to the MiniCollect® LH Lithium Heparin Separator tube with the old design.

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

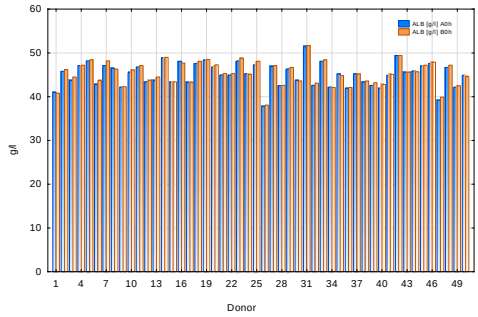
(8) H04-A6: *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens* – Approved Standard – Sixth Edition CLSO 2011

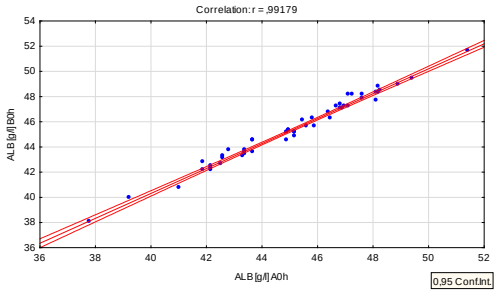
(9) RILIBÄK: Guideline of the German Medical Association for Quality Assurance.

Results in detail:

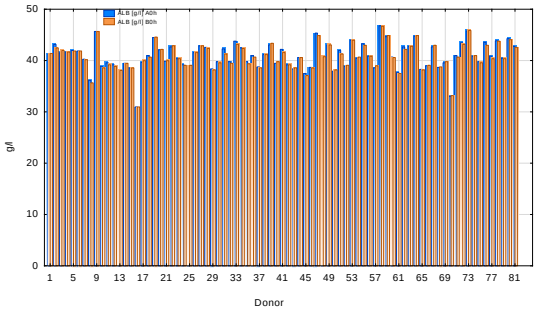
Albumin (Alb) Normal range: 35 - 52 g/l

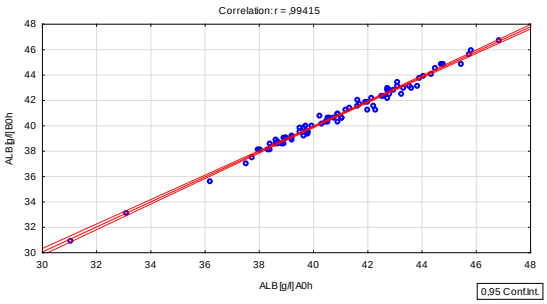
Healthy subjects





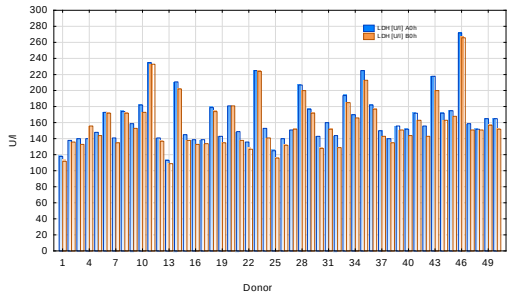
Pathological subjects

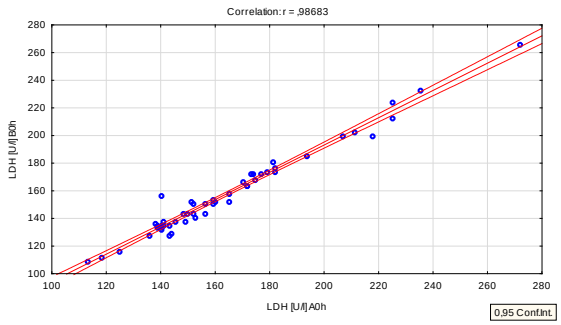




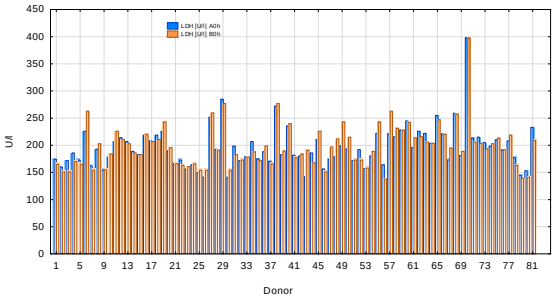
Lactate Dehydrogenase (LDH) Normal range: (f) < 247 U/l (m) < 248 U/l

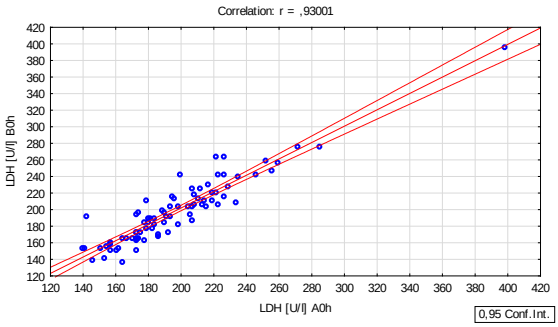
Healthy subjects





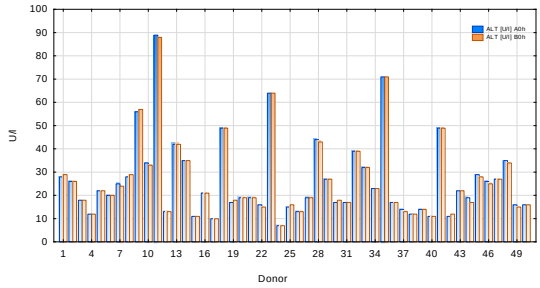
Pathological subjects

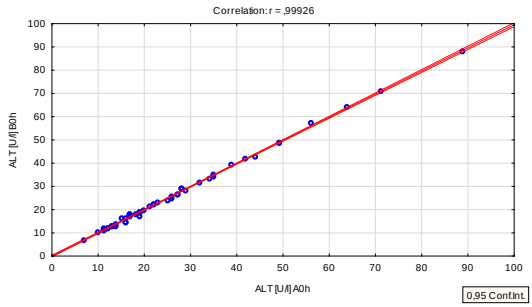




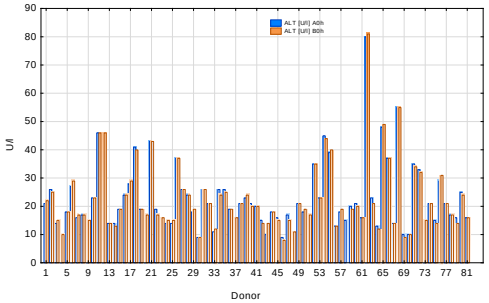
Alanine transaminase (ALT) Normal range: (m) < 50 U/l (f) < 35 U/l

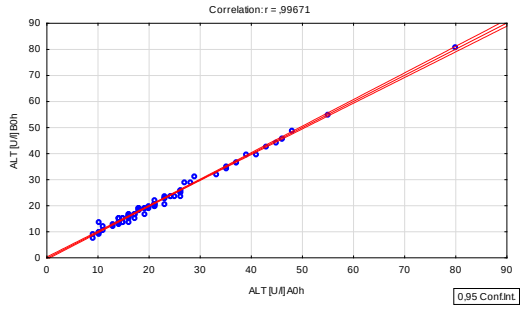
Healthy subjects





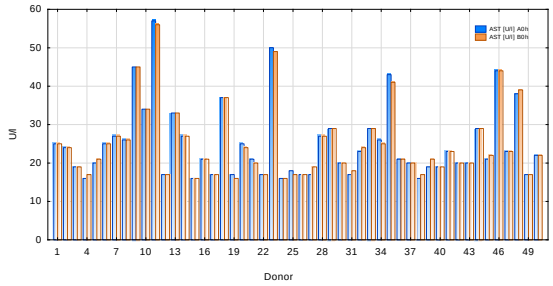
Pathological subjects

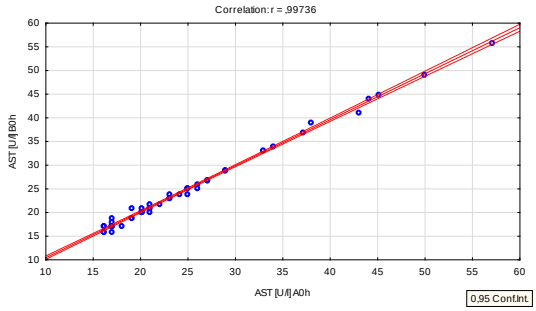




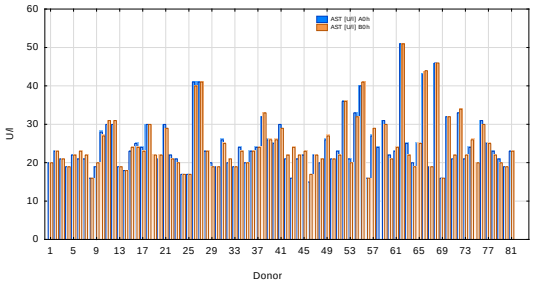
Aspartate transaminase (AST) Normal range: (m) < 50 U/l (f) < 35 U/l

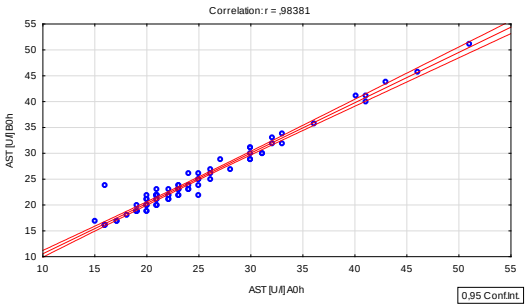
Healthy subjects





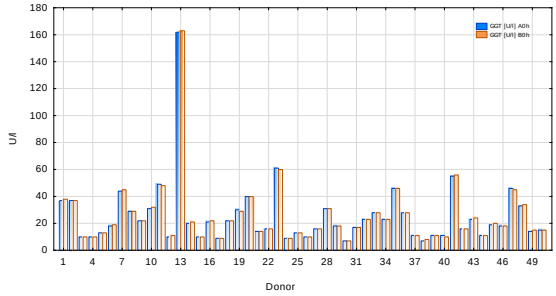
Pathological subjects

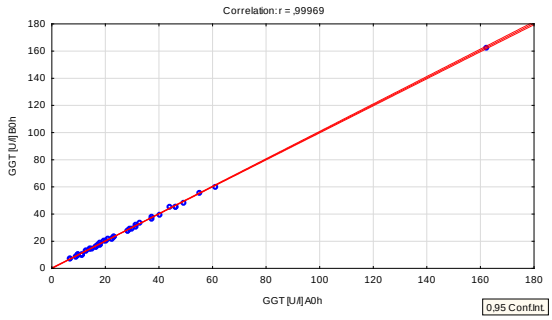




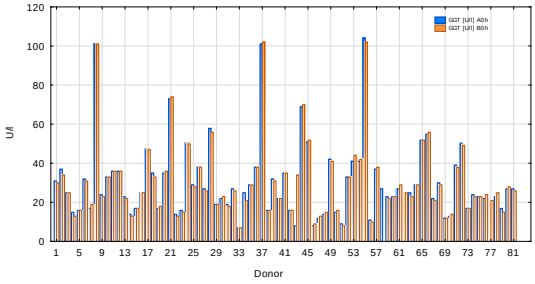
Gamma-glutamyl Transpeptidase (GGT) Normal range: (f) < 55 U/l (m) < 38 U/l

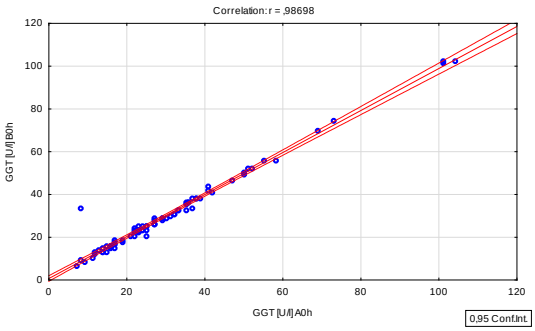
Healthy subjects





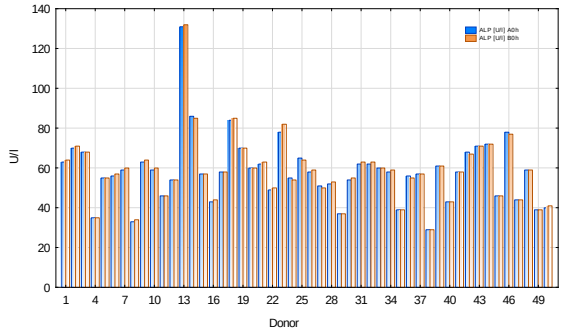
Pathological subjects

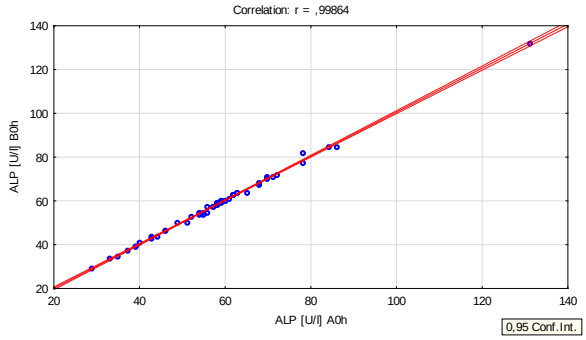




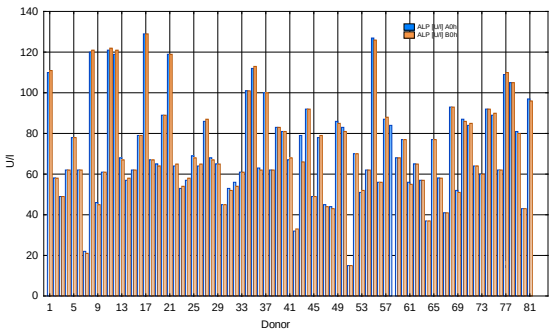
Alkaline Phosphatase (ALP) Normal range: 60 - 200 U/l

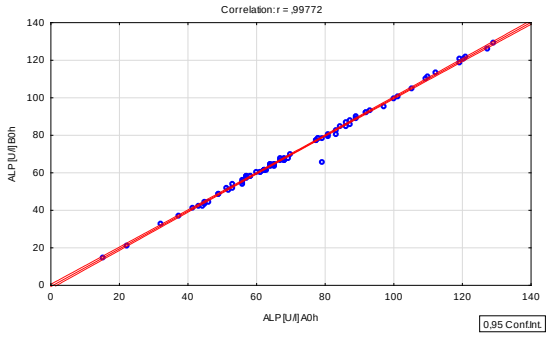
Healthy subjects





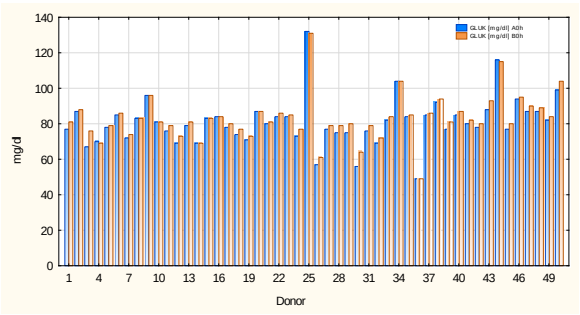
Pathological subjects

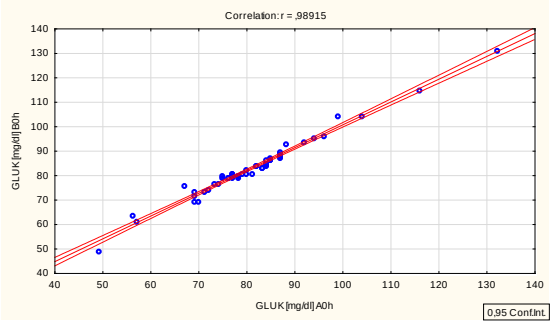




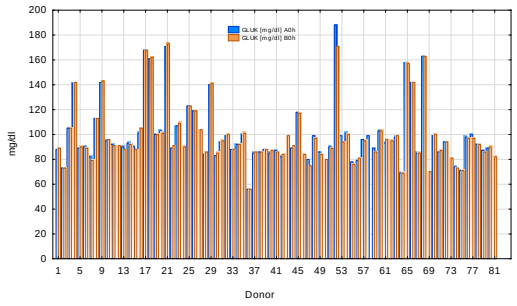
Glucose (Gluc) Normal range: 74 - 106 mg/dl

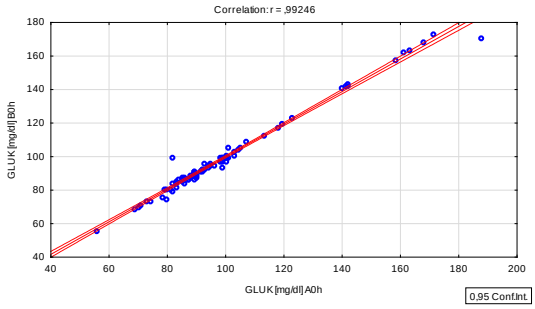
Healthy subjects





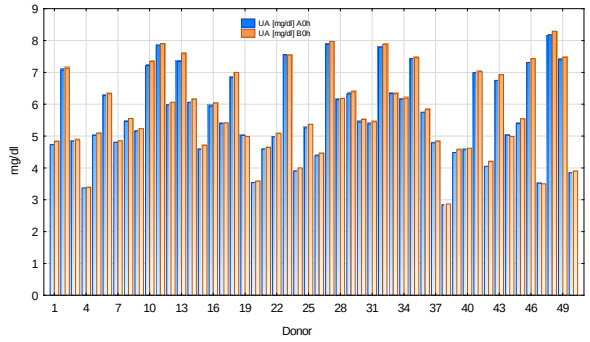
Pathological subjects

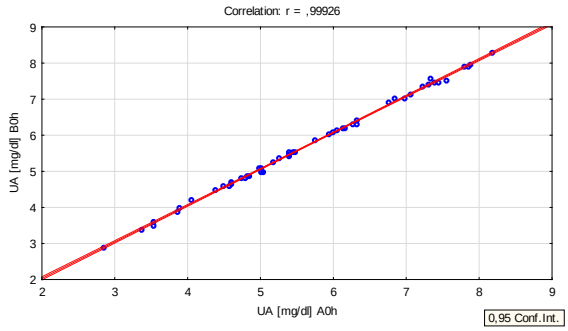




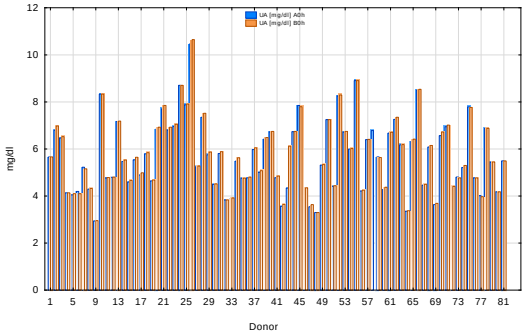
Uric Acid (UA) Normal range: (f) 3.5 - 7.2 mg/dl (m) 2.6 - 6.0 mg/dl

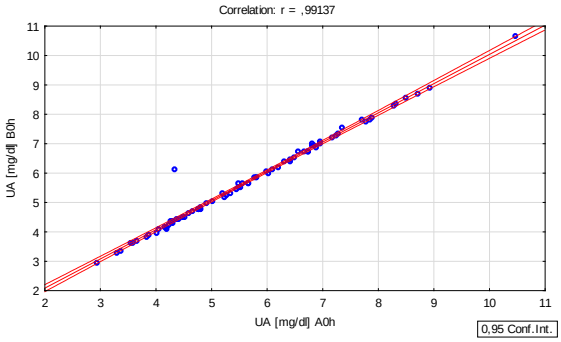
Healthy subjects





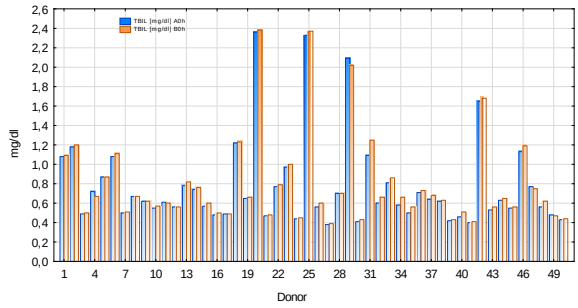
Pathological subjects

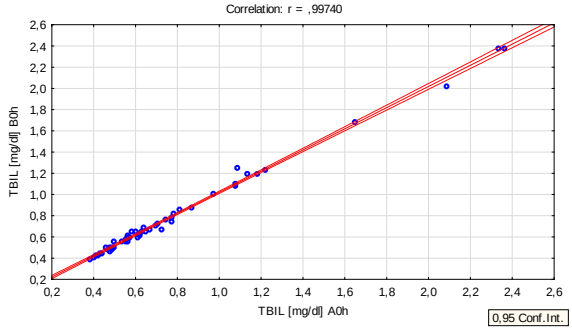




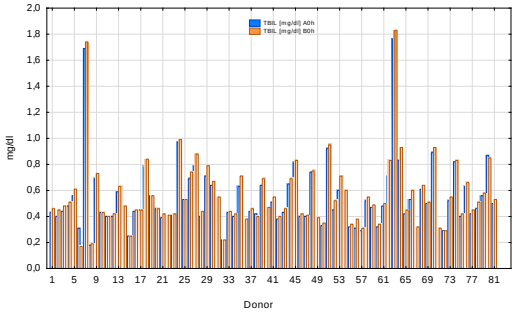
Total Bilirubin (TBili) Normal range: 0.3 - 1.2 mg/dl

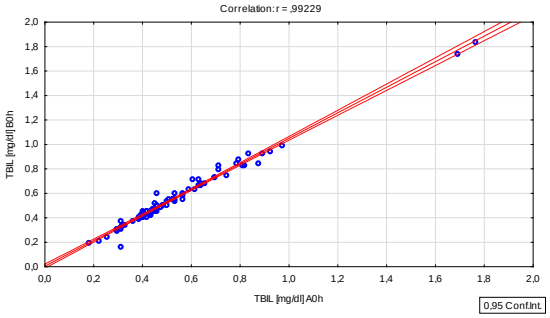
Healthy subjects





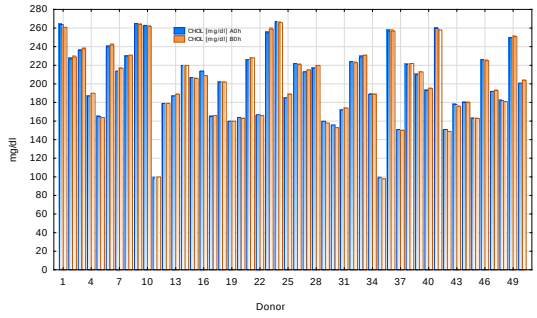
Pathological subjects

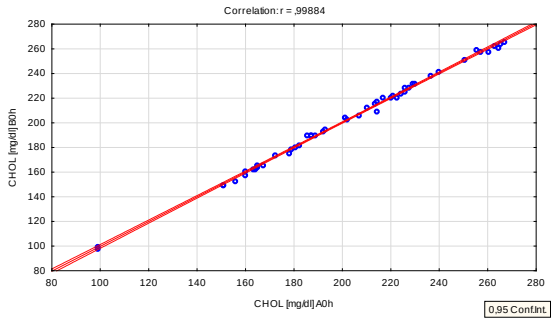




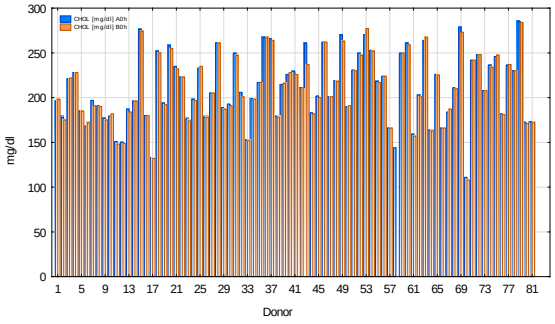
Cholesterol (Chol) Normal range: < 200 mg/dl

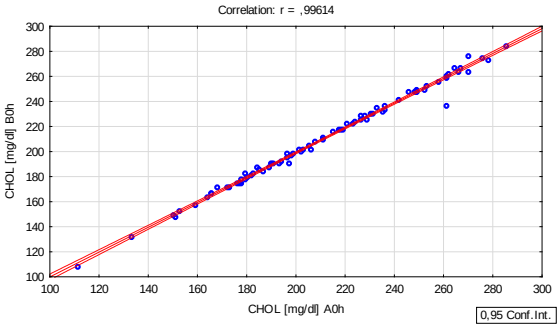
Healthy subjects





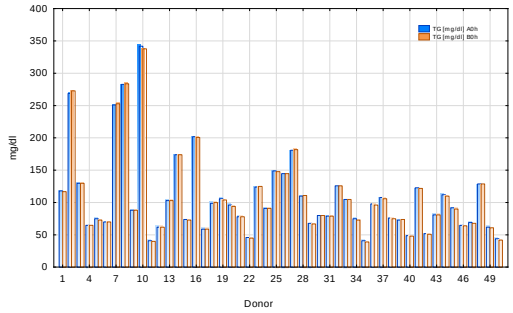
Pathological subjects

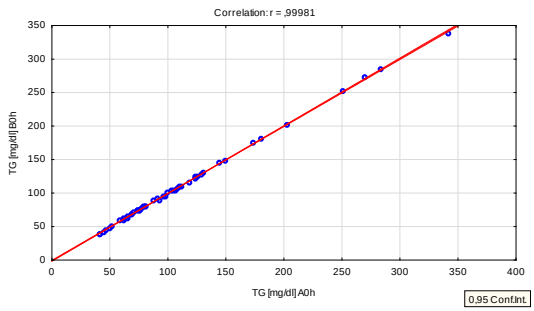




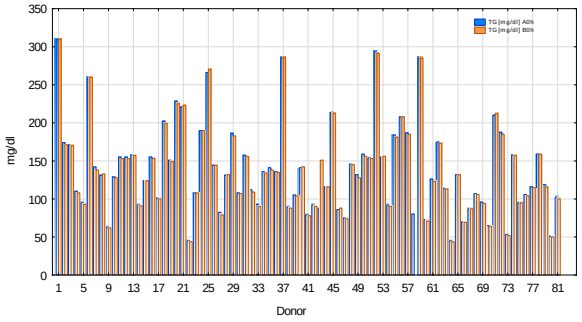
Triglyceride (TG) Normal range: normal ≤ 150 < borderline high < 200 high < 500 very high

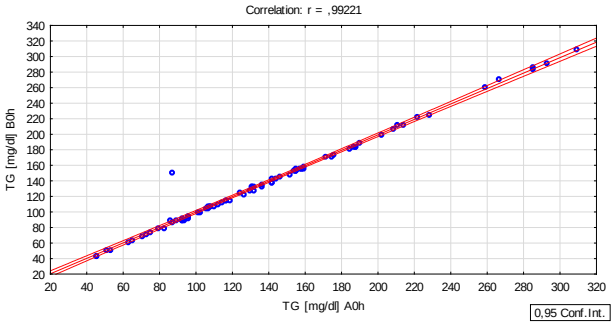
Healthy subjects





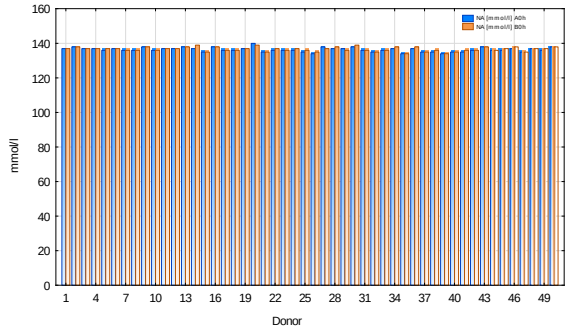
Pathological subjects

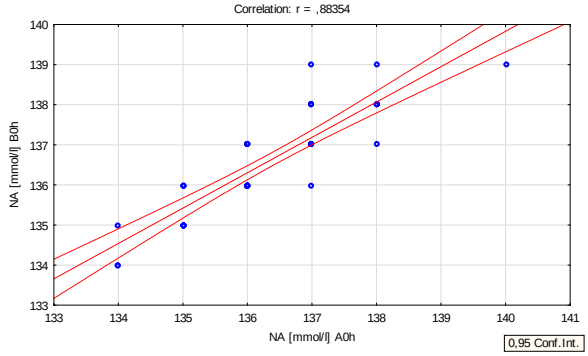




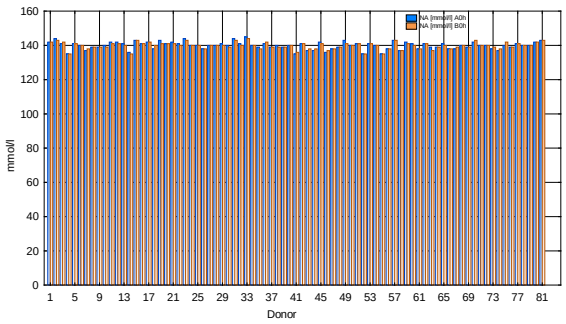
Sodium (Na) Normal range: 136 - 146 mmol/l

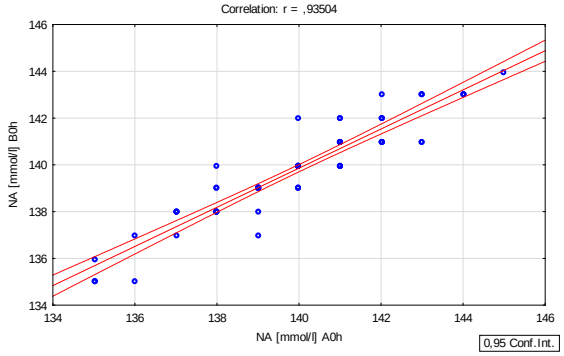
Healthy subjects





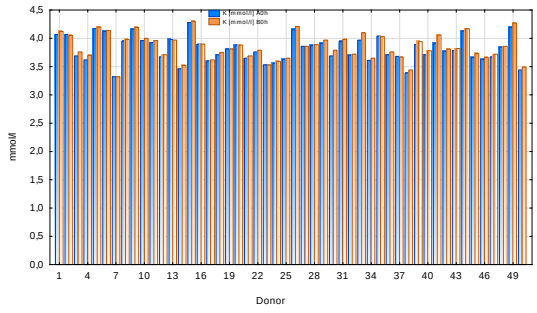
Pathological subjects

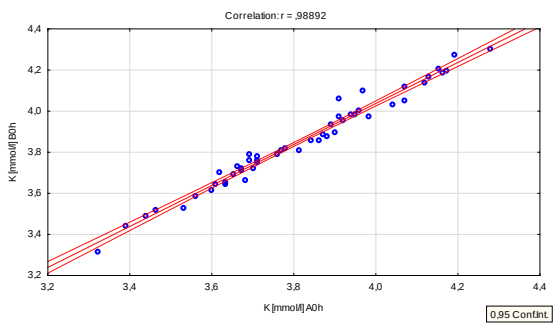




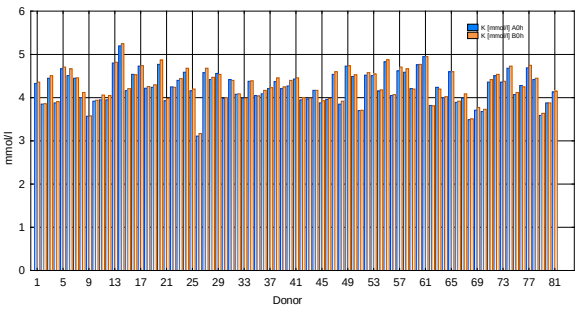
Potassium (K) Normal range: Plasma 3.4 - 4.5 mmol/l

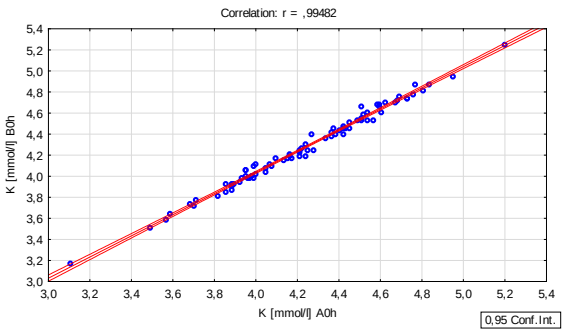
Healthy subjects





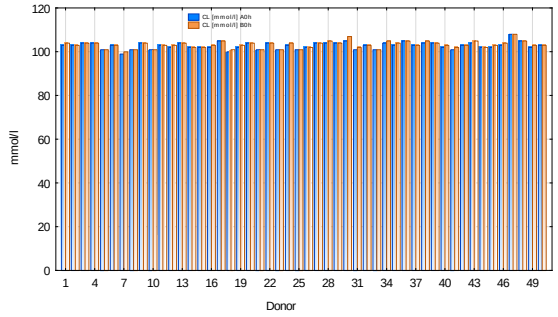
Pathological subjects

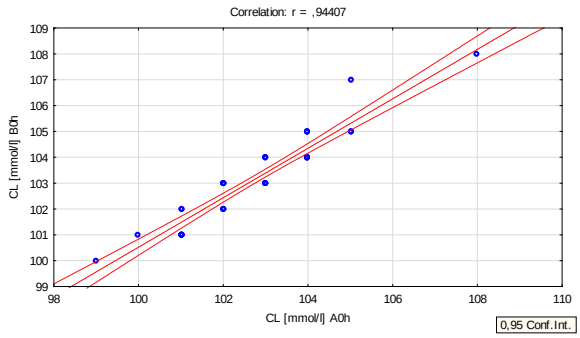




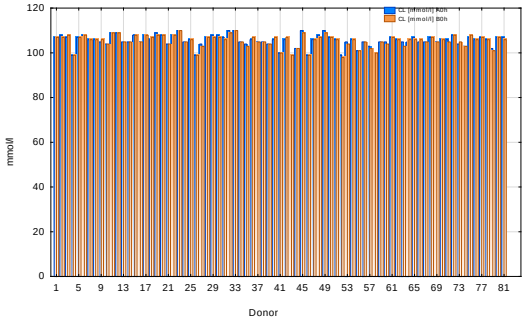
Chloride (Cl) Normal range: 101 - 109 mmol/l

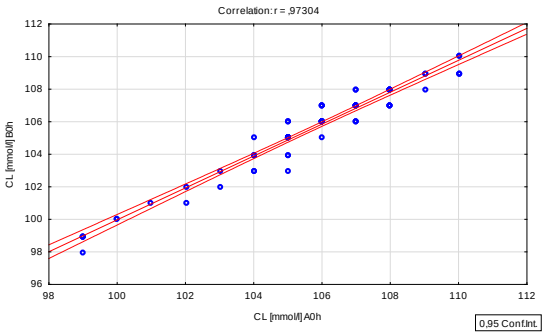
Healthy subjects





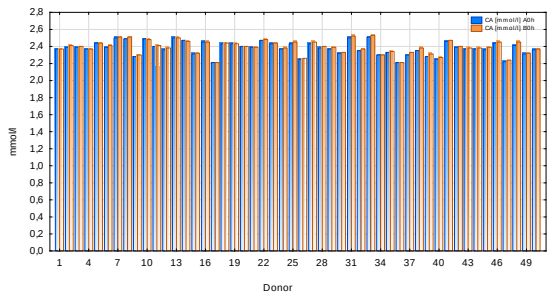
Pathological subjects

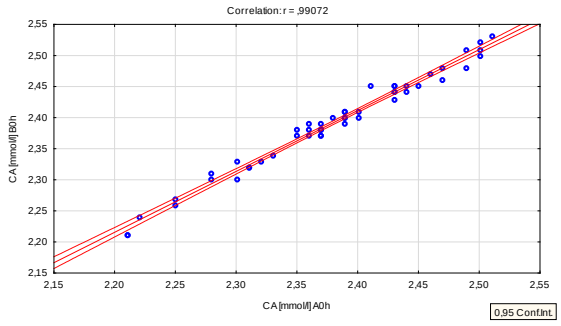




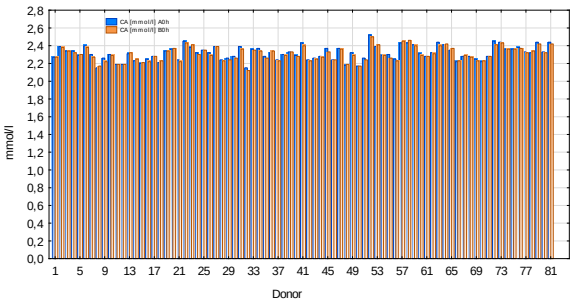
Calcium (Ca) Normal range: 2.20 - 2.65 mmol/l

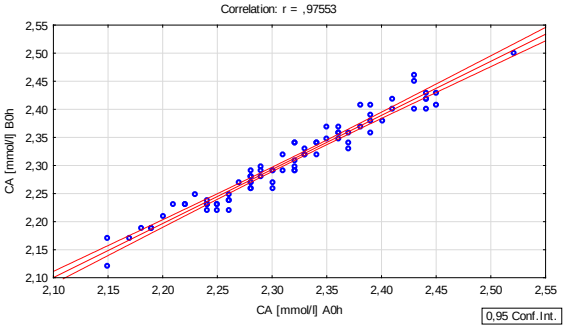
Healthy subjects





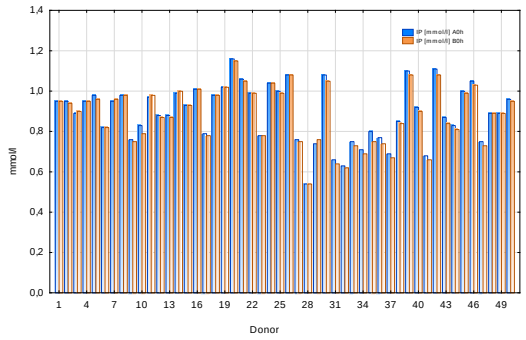
Pathological subjects

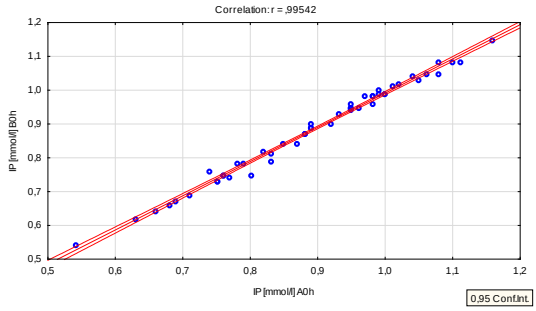




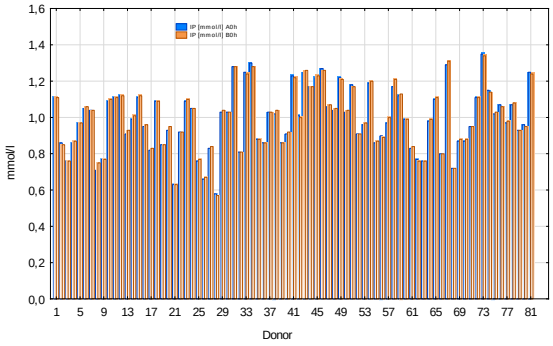
Phosphate (Phos) Normal range: 0.81 - 1.45 mmol/l

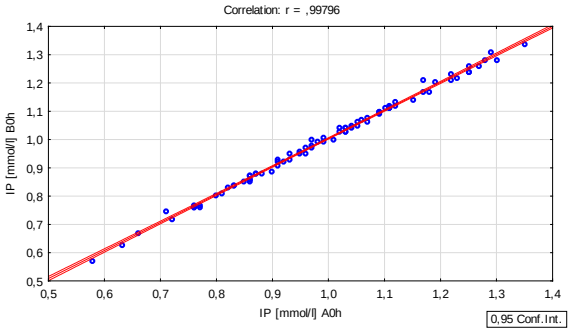
Healthy subjects





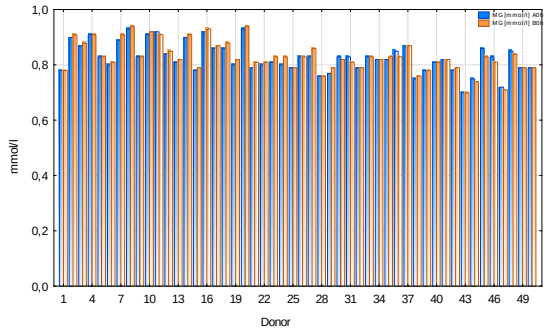
Pathological subjects

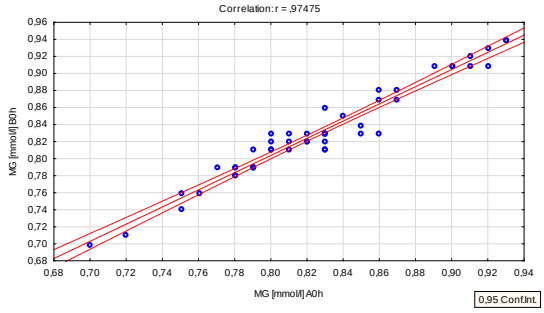




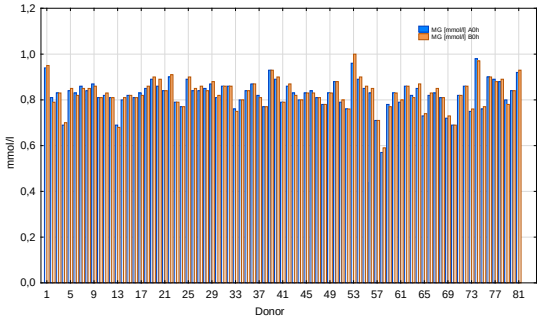
Magnesium (Mg) Normal range: (f) 0.73 - 1.06 mmol/l (m) 0.77 - 1.03 mmol/l

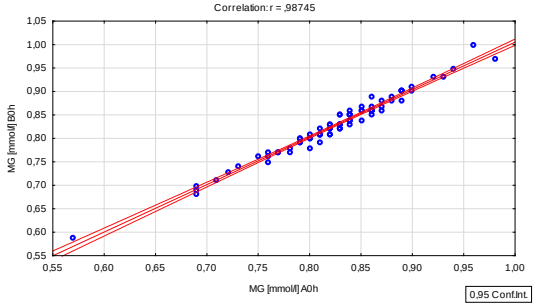
Healthy subjects





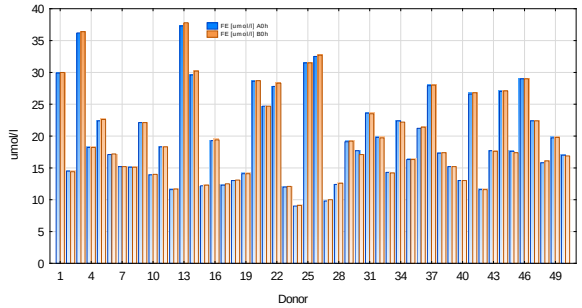
Pathological subjects

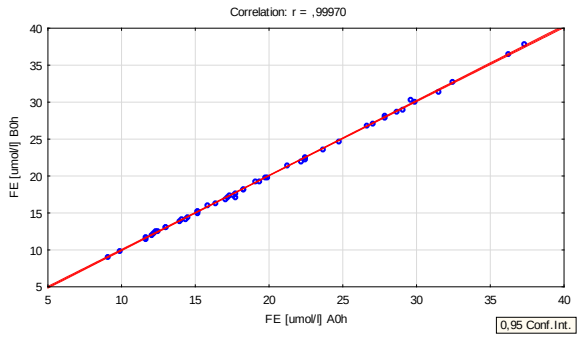




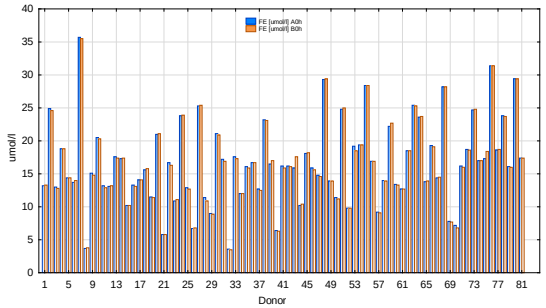
Iron Normal range: (f) 12.5 - 32.2 µmol/l (m) 10.7 - 32.2 µmol/l

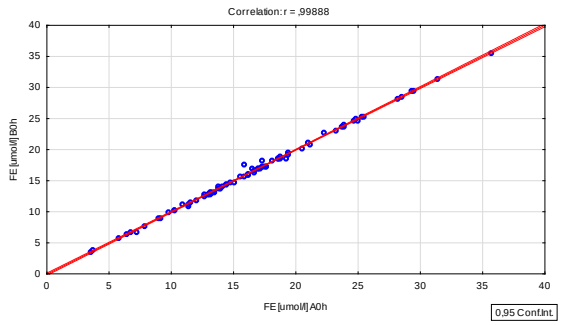
Healthy subjects





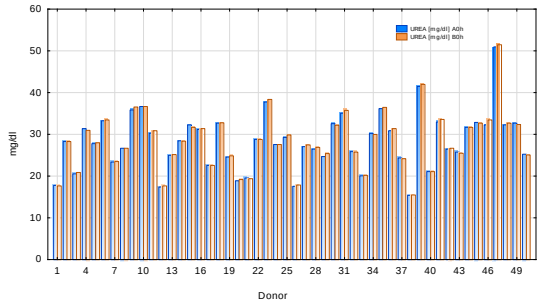
Pathological subjects

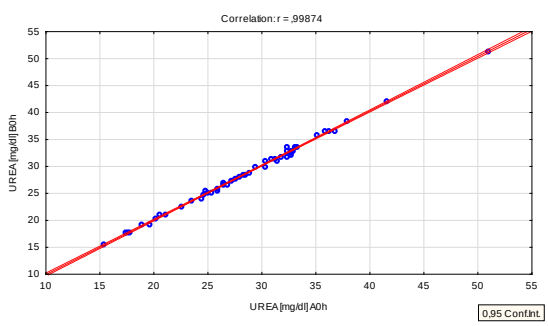




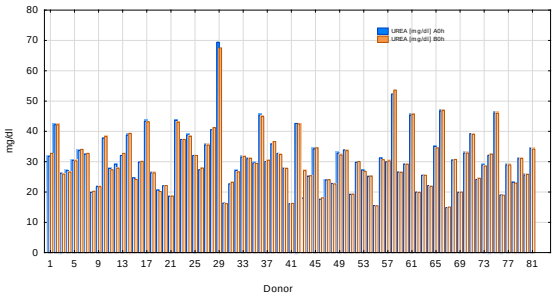
Urea Normal range: 17 - 43 mg/dl

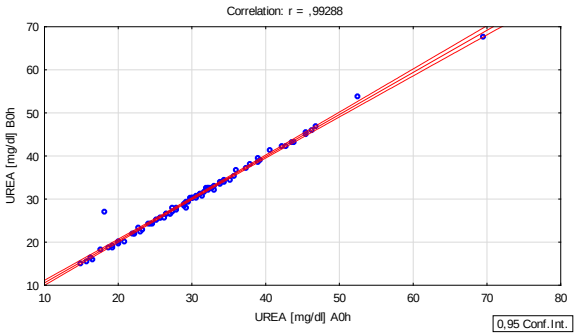
Healthy subjects





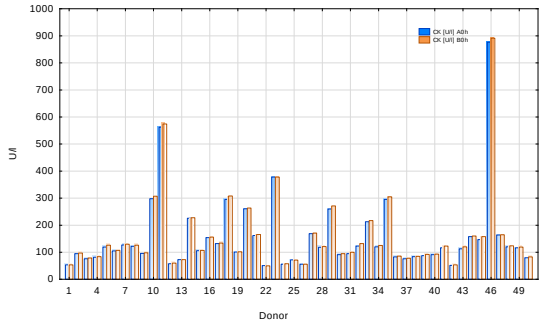
Pathological subjects

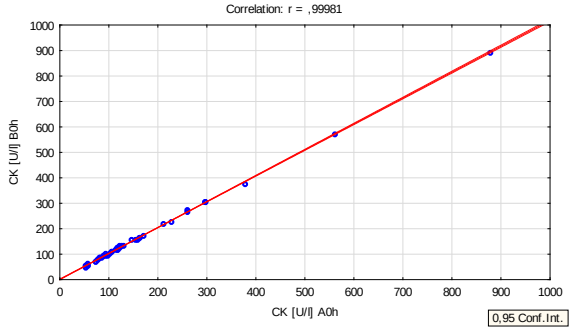




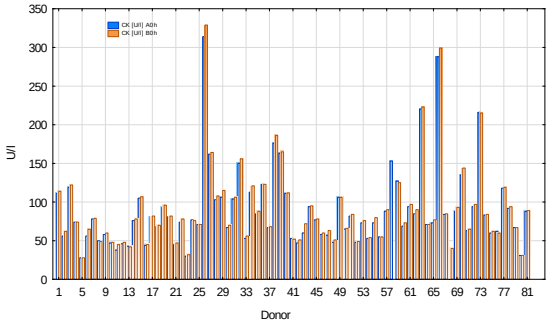
Creatine Kinase (CK) Normal range: (f) ≤ 171 U/l (m) ≤ 145 U/l

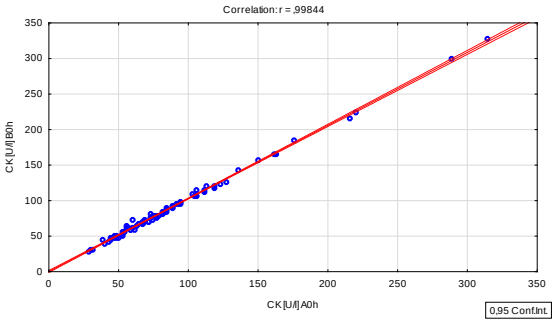
Healthy subjects





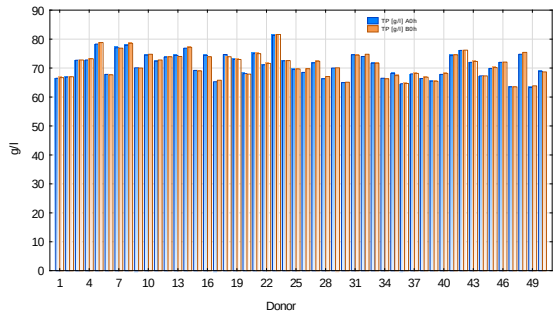
Pathological subjects

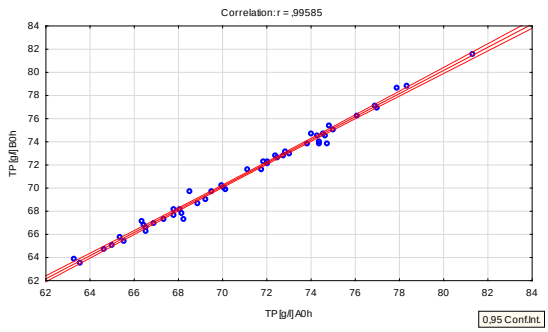




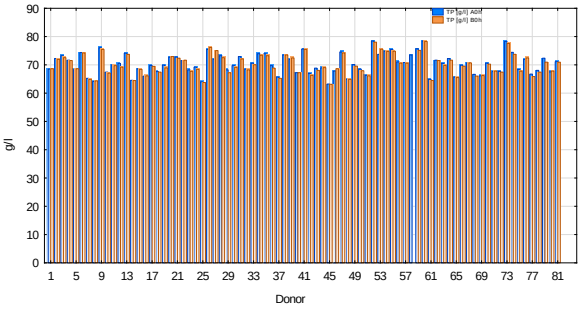
Total Protein (TP) Normal range: 66 - 83 g/l

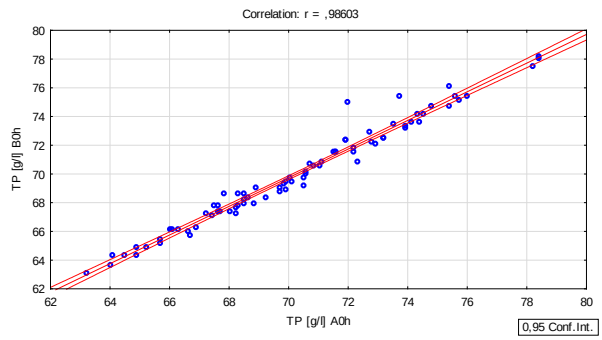
Healthy subjects





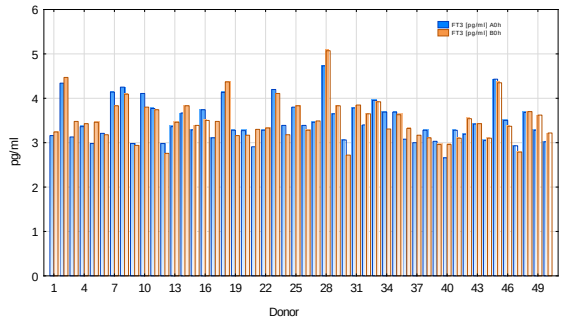
Pathological subjects

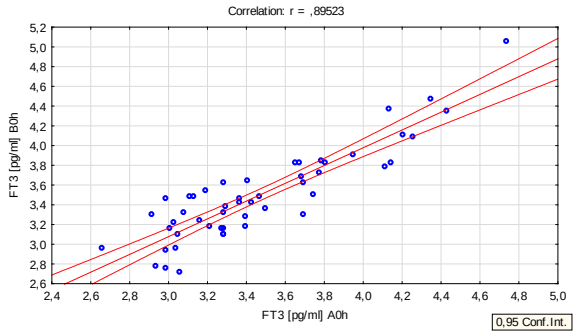




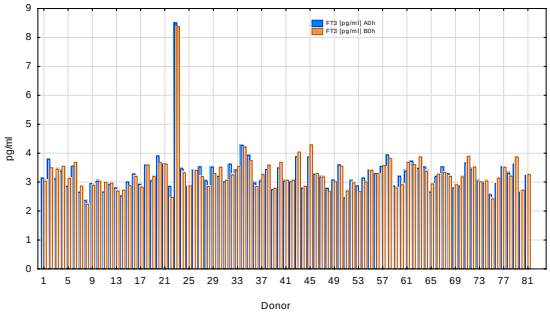
Free Triiodothyronine (fT_3) Normal range: 2.5 - 3.9 pg/ml

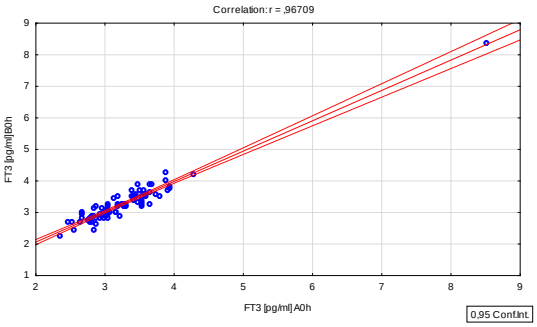
Healthy subjects





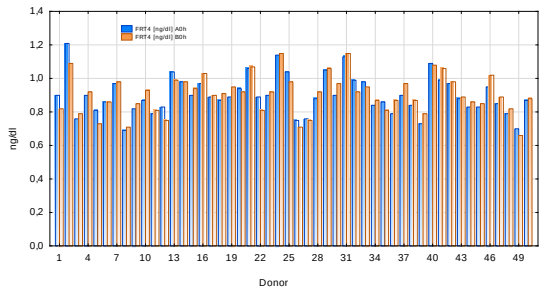
Pathological subjects

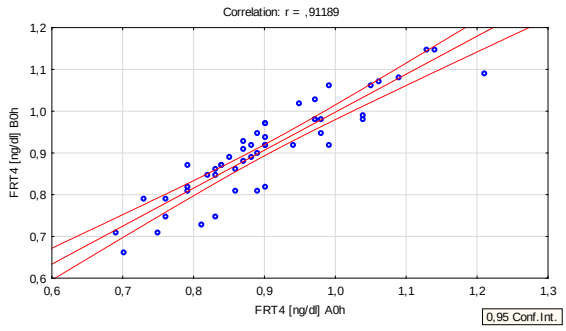




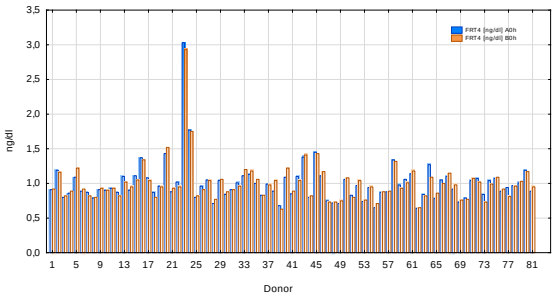
Free Thyroxine (fT_4) Normal range: 0.61 - 1.12 ng/dl

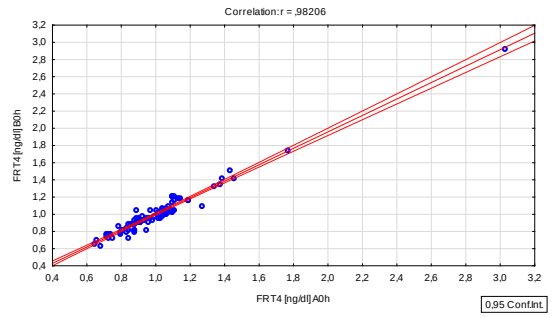
Healthy subjects





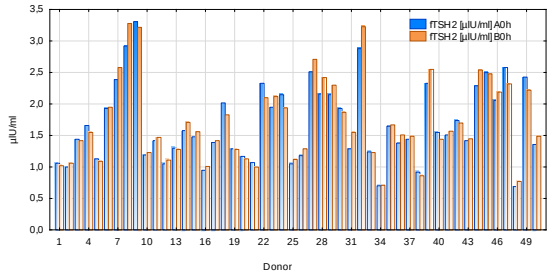
Pathological subjects

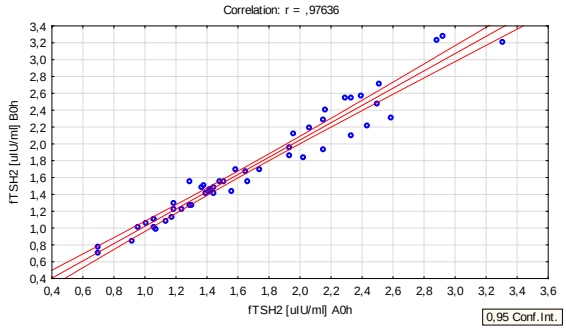




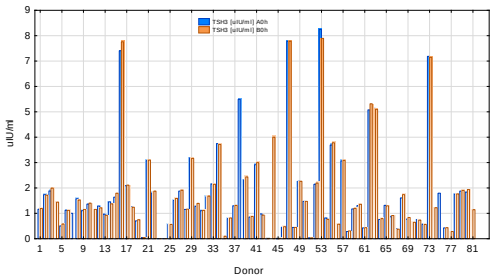
Thyroid-stimulating Hormone (TSH) Normal range: 0.1 - 3.5 µIU/ml

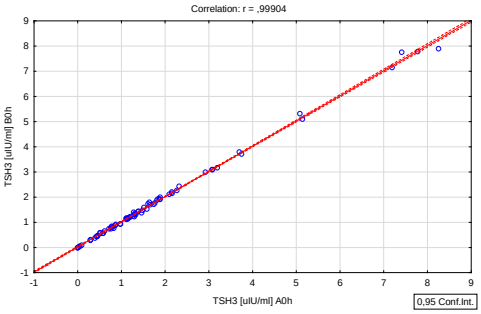
Healthy subjects





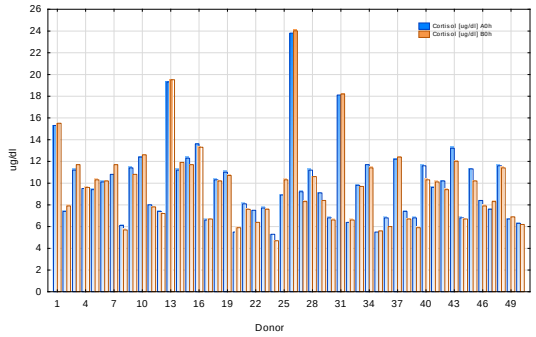
Pathological subjects

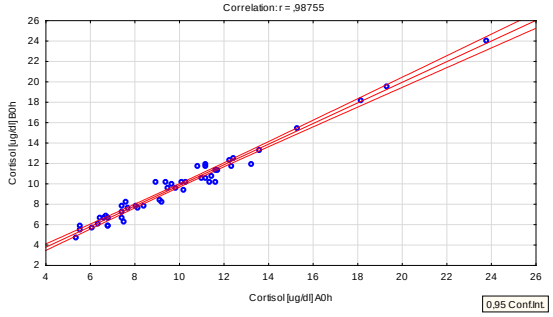




Cortisol Normal range: morning 6.7 - 22.6 µg/dl afternoon > 10 µg/dl

Healthy subjects





Pathological subjects