

# Comparison testing of new MiniCollect® CAT Serum Separator Tubes to Microtainer® Serum 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® 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 (SiO<sub>2</sub>). 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 BD Microtainer® Serum Separator tube including 20 healthy subjects.

## **Study design:**

The following tube types were used in this study:

Sample ID	Description
A	Microtainer® Serum Sep. 0.4- 0.6 ml (item No.: 365967)
B	MiniCollect® CAT Serum Sep. 0.5-0.8 ml (item No.: 450533)

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, the tubes were allowed to sit for 30 min in an upright position. 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 from Beckman Coulter. Analysis was performed with the instrument's accompanying reagents.

### Determined parameters:

- Lactate Dehydrogenase (LDH)
- Total Bilirubin
- Sodium
- Potassium
- Chloride
- Calcium
- Phosphate
- Urea
- Total Protein
- Glucose

### Conclusion:

The performance of the new MiniCollect® CAT Serum Separator tube has been demonstrated to be comparable to the BD Microtainer® Serum Separator tube on the basis of a representative biochemical profile.

The highest deviation was found for LDH (11%) resulting from a slightly hemolytic sample.

The statistically significant deviations such as found for P, TBil, TP and urea are not clinically significant.

In summary, the MiniCollect® CAT Serum Separator tube with the new design is substantially equivalent to the Microtainer® Serum Separator tube.

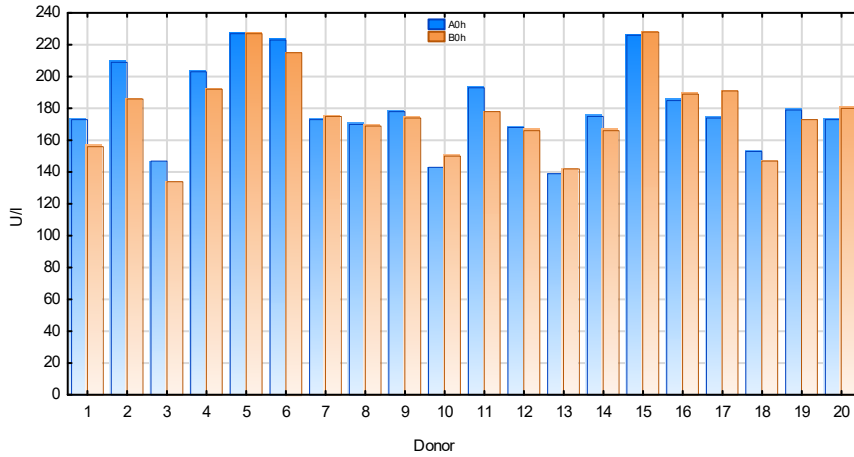
### *References:*

- (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

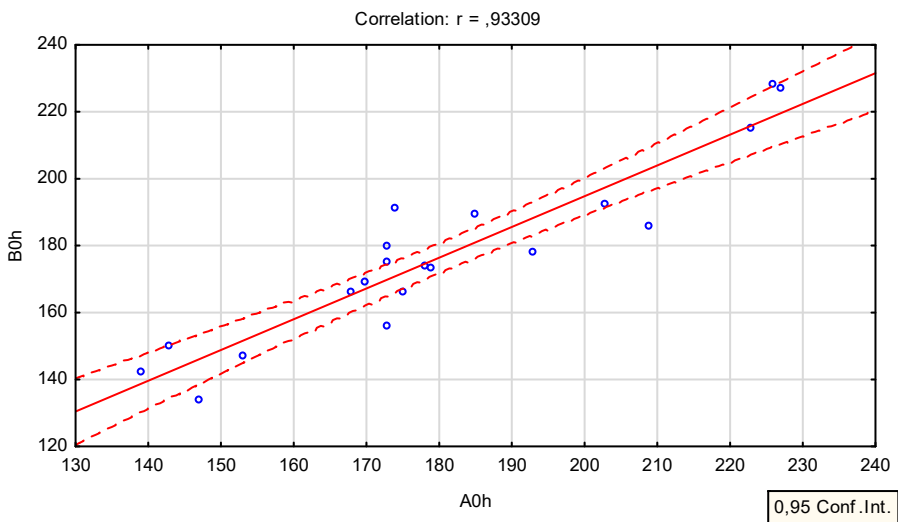
**Results in detail:**

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

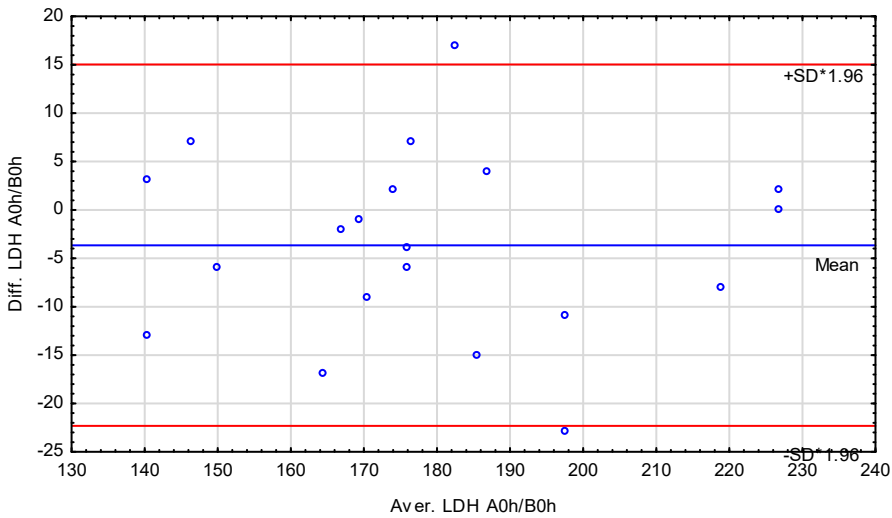
Bar chart:



Correlations: LDH [U/l] A0h/B0h

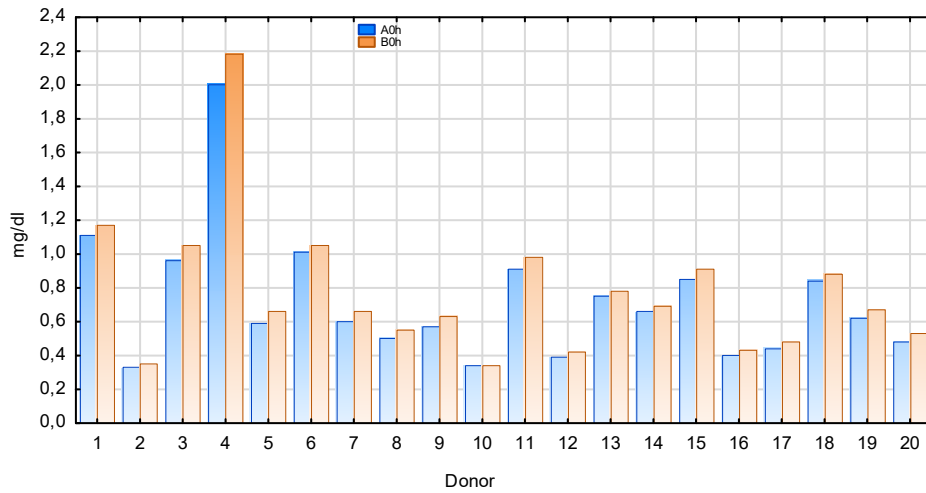


Bland Altman: LDH [U/l] A0h/B0h

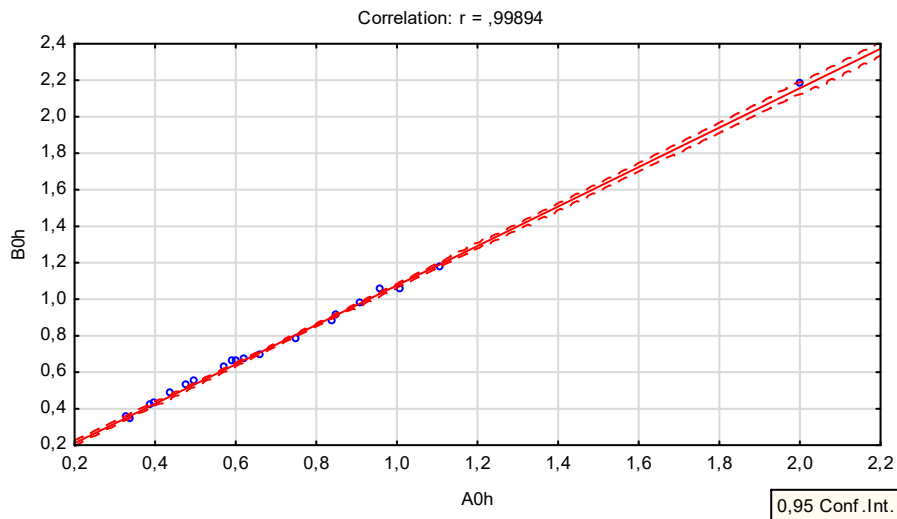


**Total Bilirubin (TBili) Normal range: 0.3 - 1.2 mg/dl**

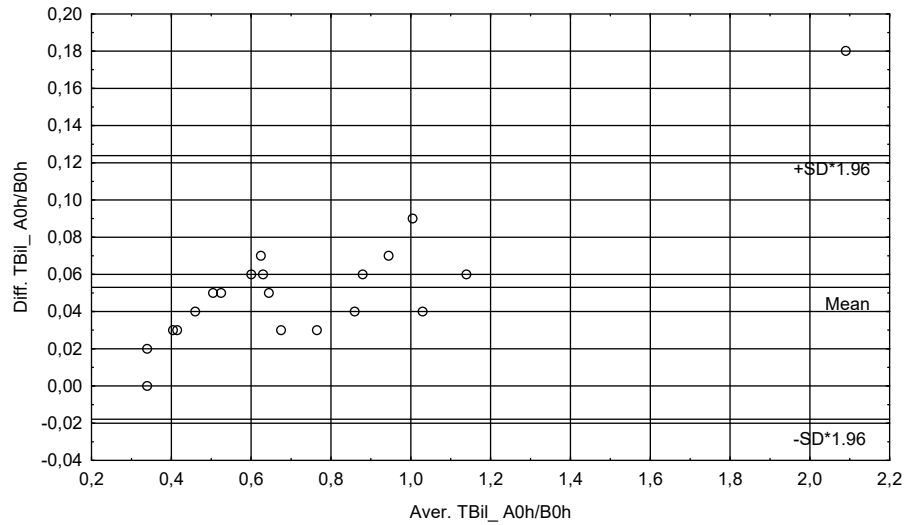
Bar chart:



Correlations: TBil [mg/dl] A0h/B0h

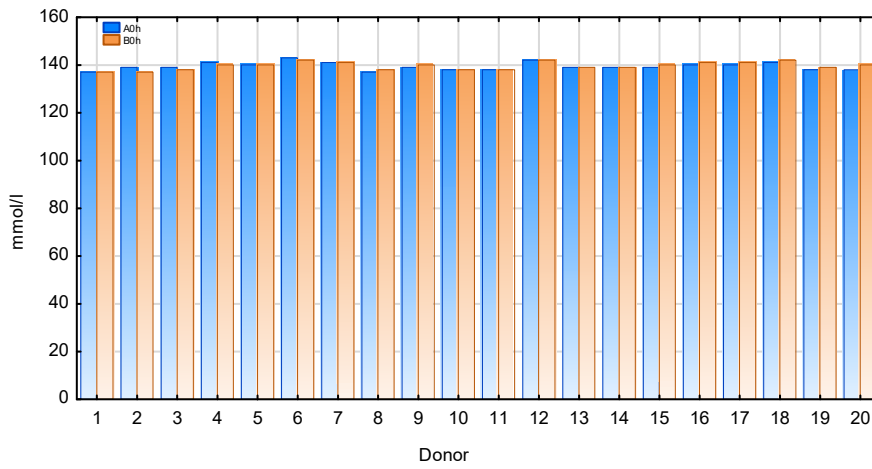


Bland Altman: TBil [mg/dl] A0h/B0h

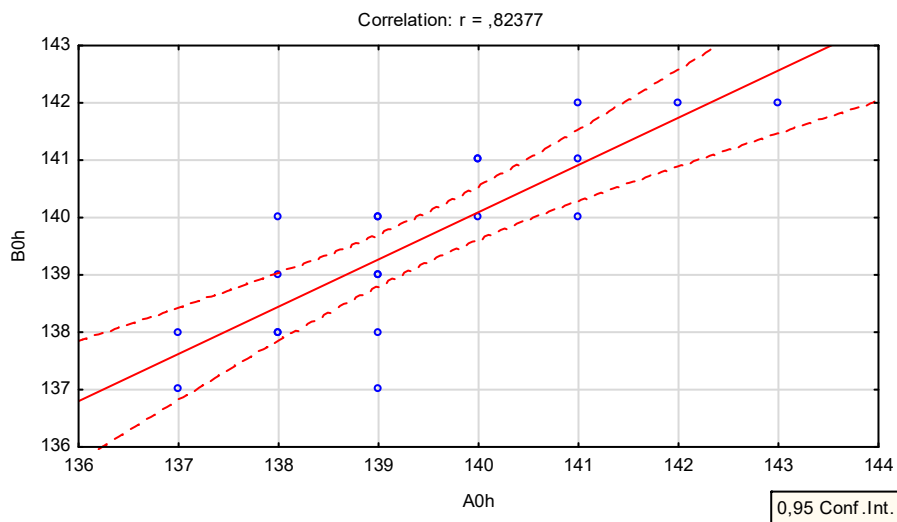


**Sodium (Na)** Normal range: 136 - 146 mmol/l

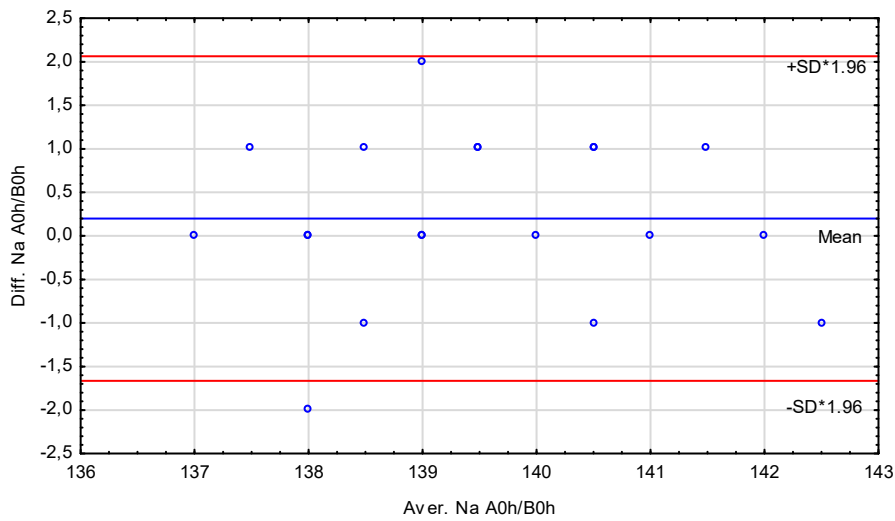
Bar chart:



Correlations: Na [mmol/l] A0h/B0h

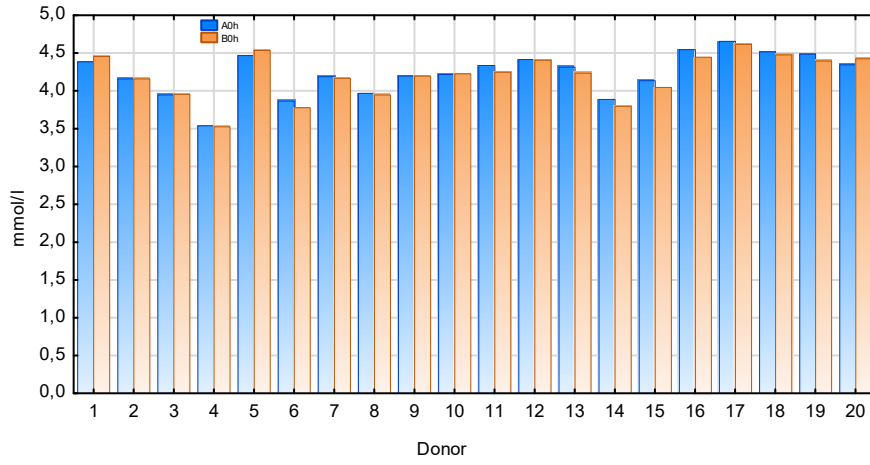


Bland Altman: Na [mmol/l] A0h/B0h

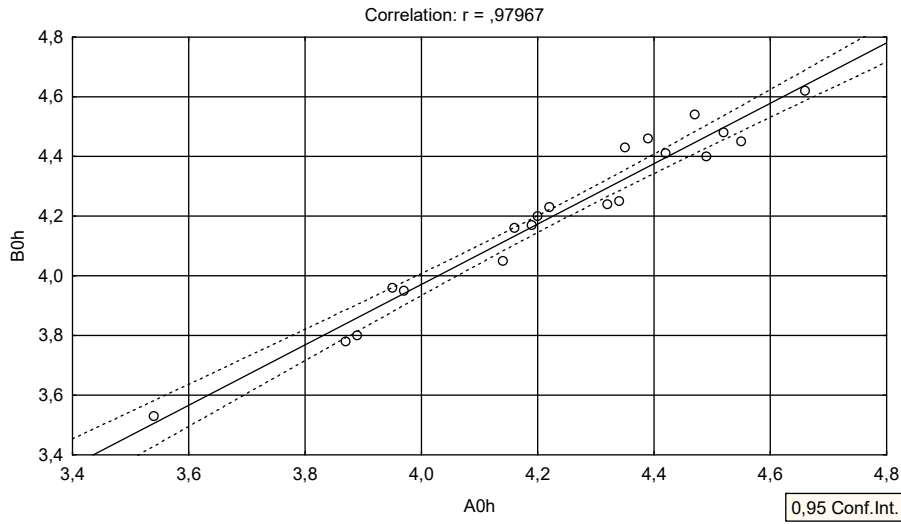


**Potassium (K)** Normal range: Serum 3.5 - 5.1 mmol/l

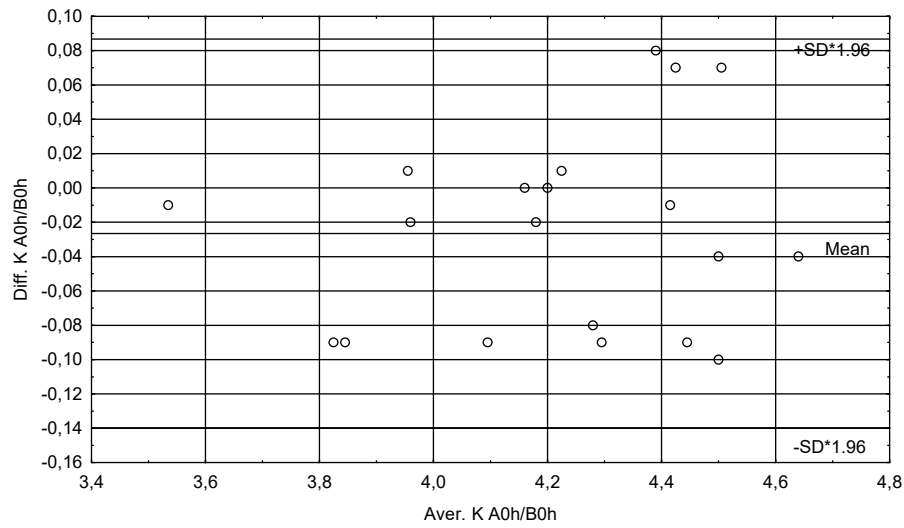
Bar chart:



Correlations: K [mmol/l] A0h/B0h

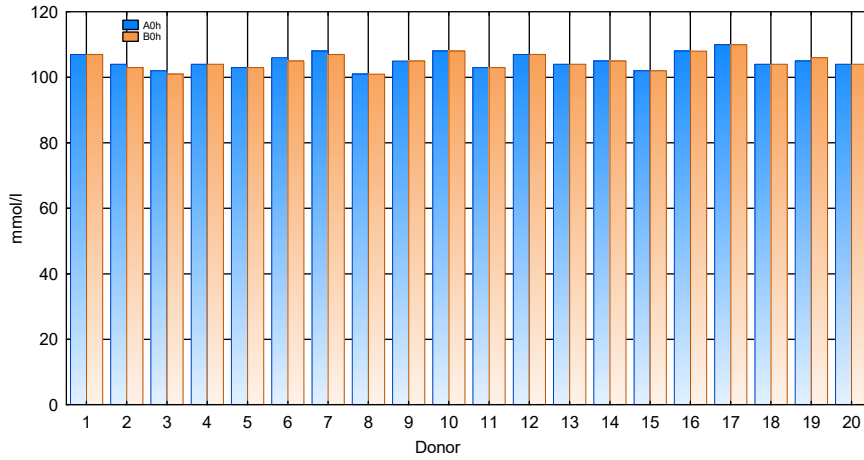


Bland Altman: K [mmol/l] A0h/B0h

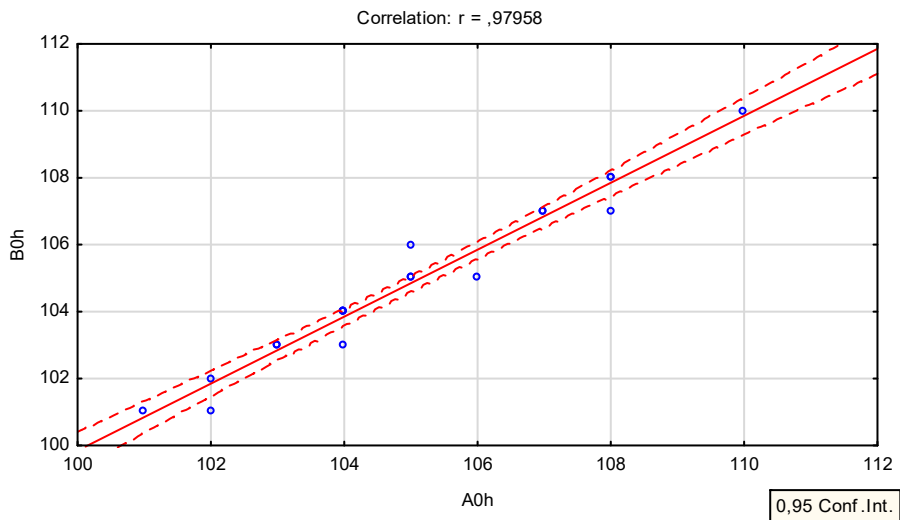


**Chloride (Cl)** Normal range: 101 - 109 mmol/l

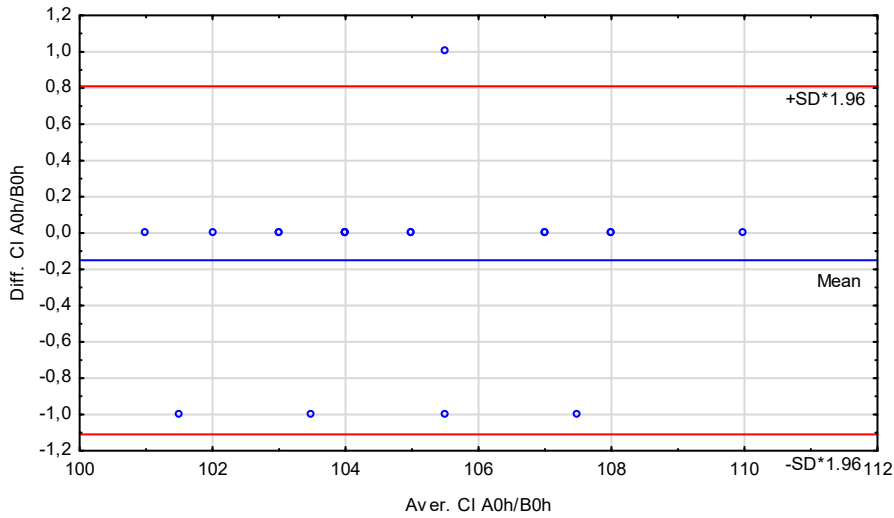
Bar chart:



Correlations: Cl [mmol/l] A0h/B0h

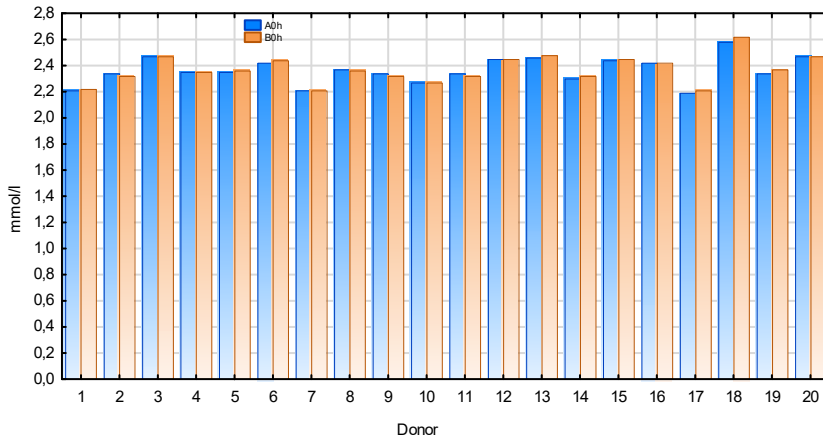


Bland Altman: Cl [mmol/l] A0h/B0h

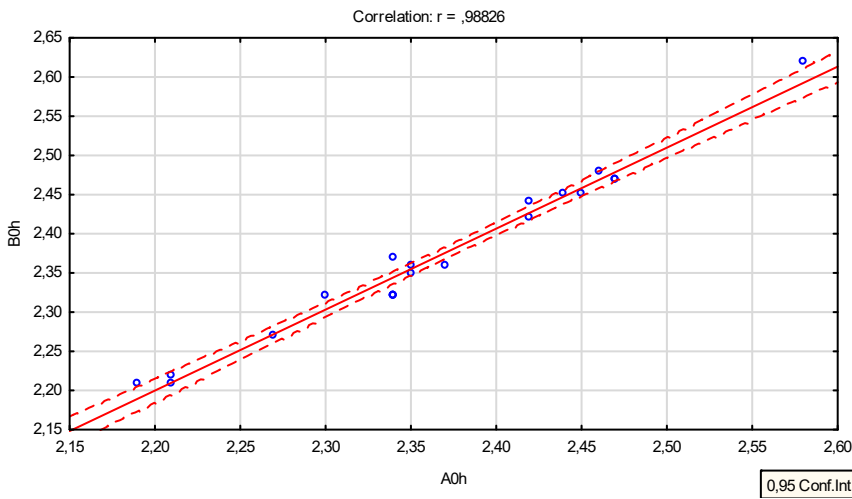


**Calcium (Ca)** Normal range: 2.20 - 2.65 mmol/l

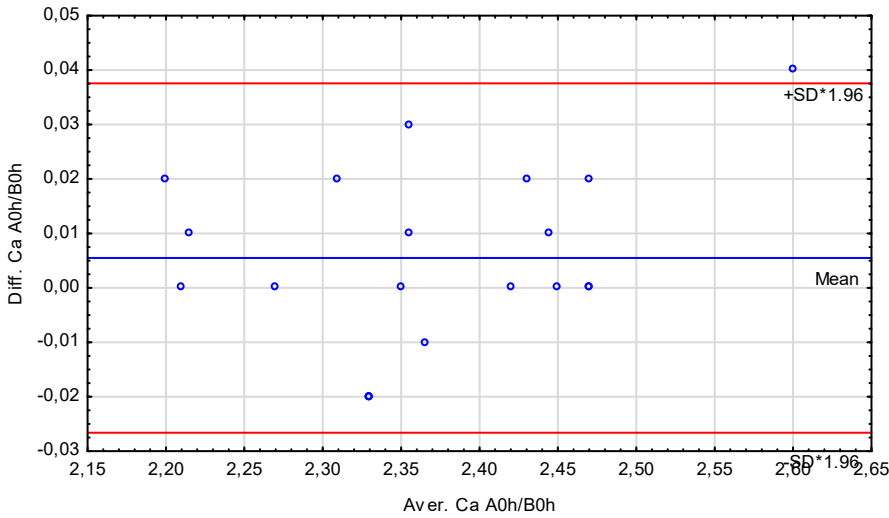
Bar chart:



Correlations: Ca [mmol/l] A0h/B0h



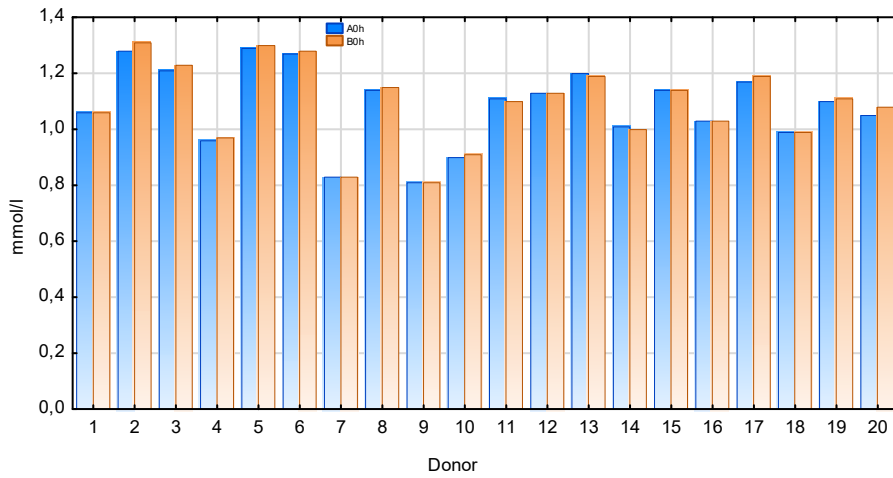
Bland Altman: Ca [mmol/l] A0h/B0h



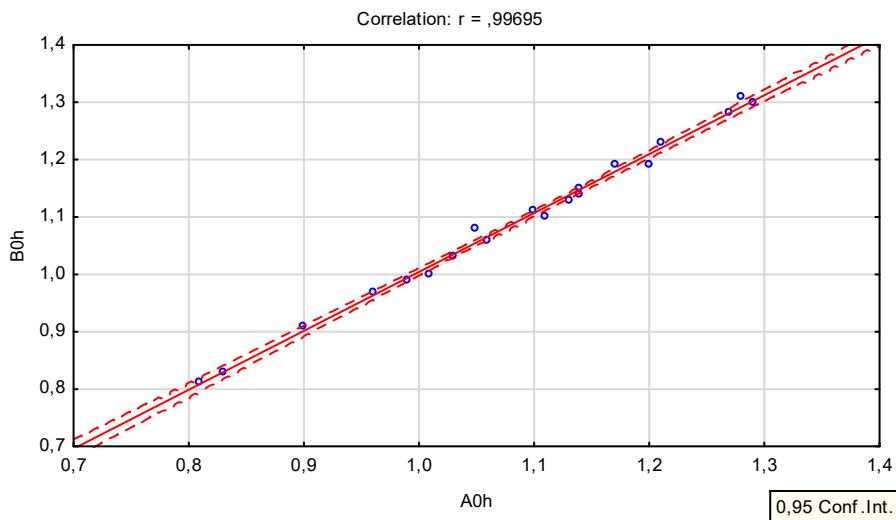


**Phosphate (IP) Normal range: 0.81 - 1.45 mmol/l**

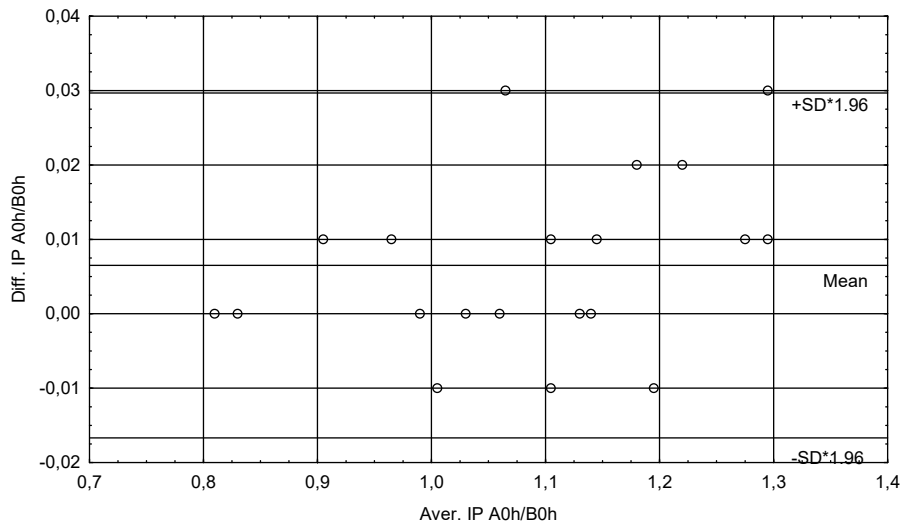
Bar chart:



Correlations: IP [mmol/l] A0h/B0h

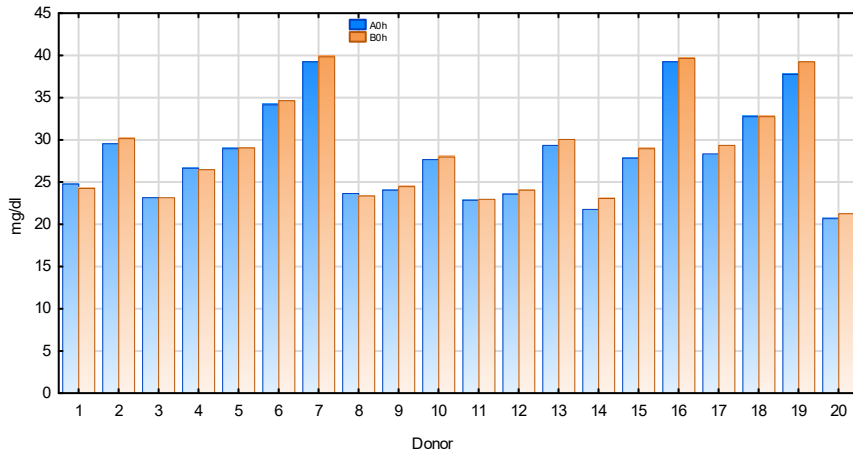


Bland Altman: IP [mmol/l] A0h/B0h

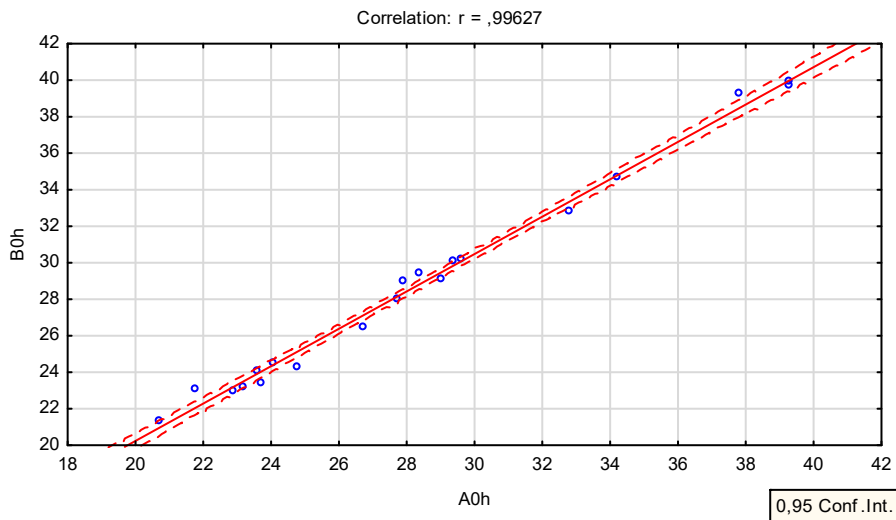


Urea Normal range: 17 - 43 mg/dl

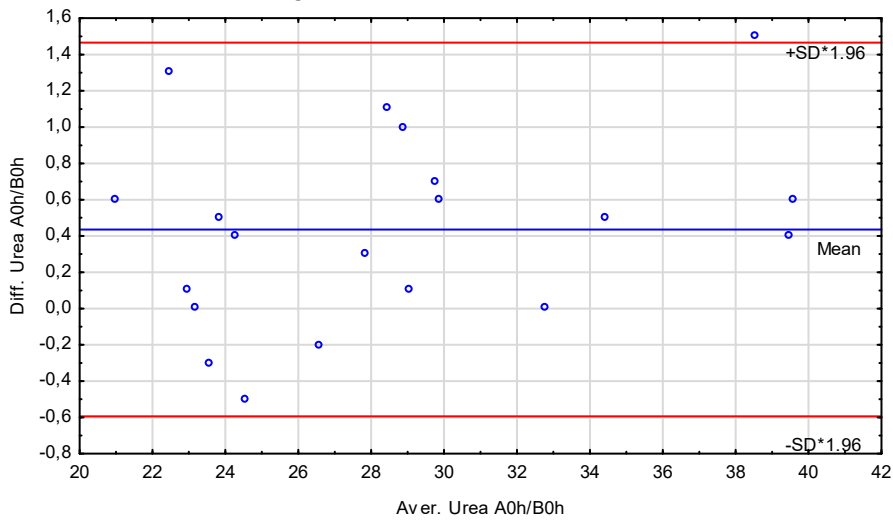
Bar chart:



Correlations: Urea [mg/dl] A0h/B0h

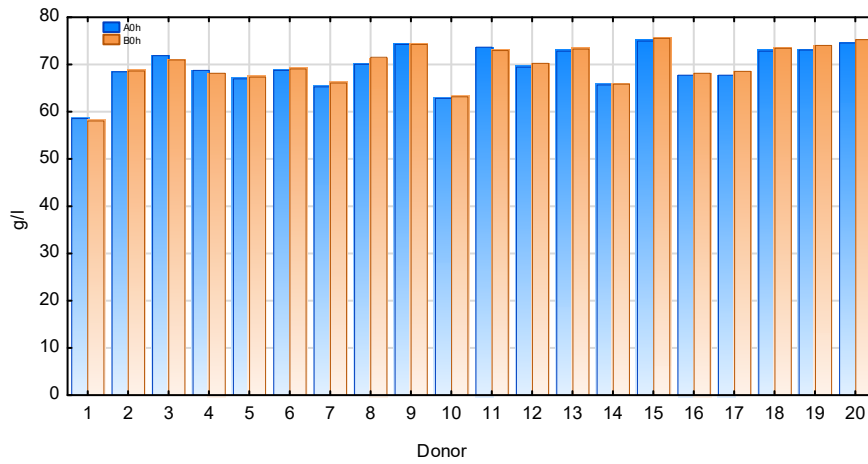


Bland Altman: Urea [mg/dl] A0h/B0h

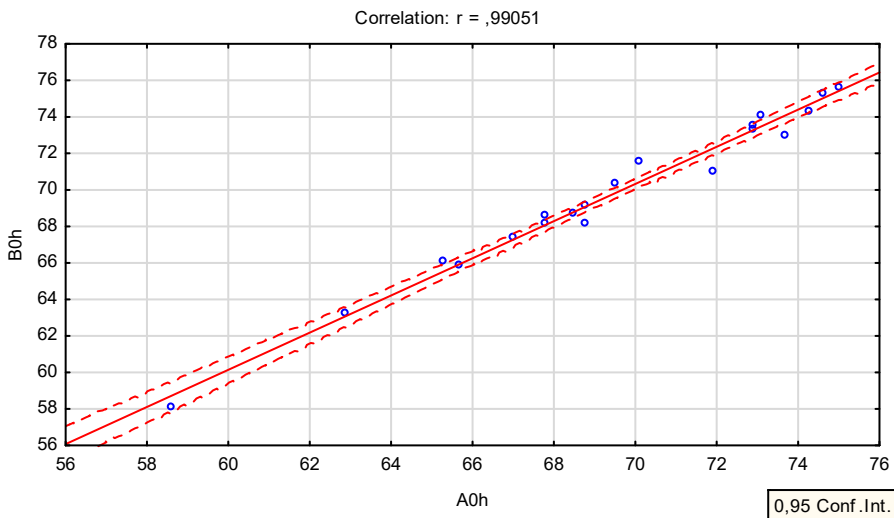


**Total Protein (TP) Normal range: 66 - 83 g/l**

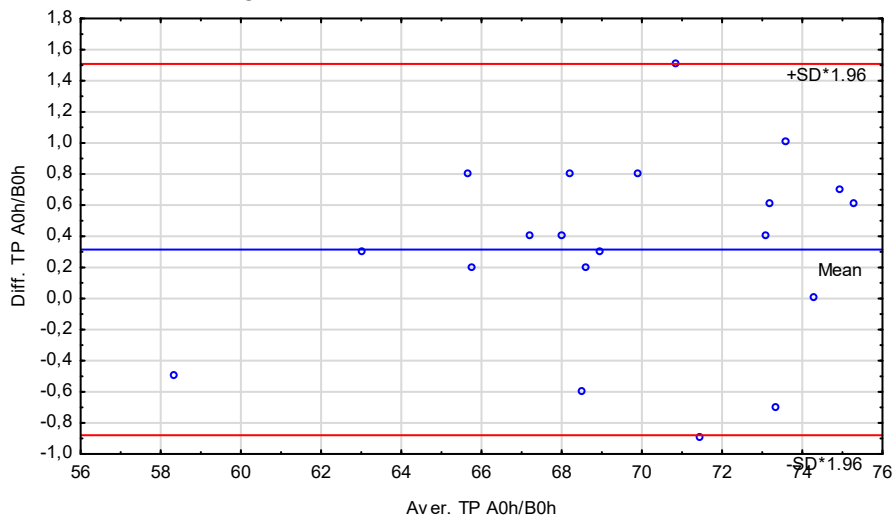
Bar chart:



Correlations: TP [g/l] A0h/B0h

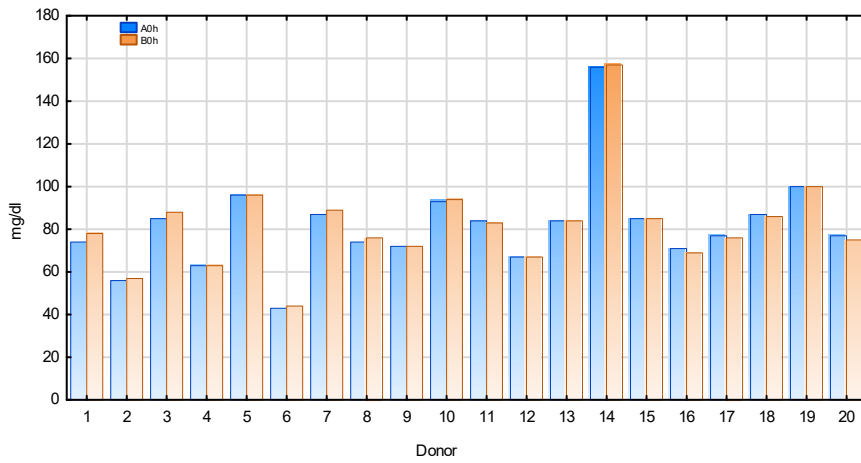


Bland Altman: TP [g/l] A0h/B0h

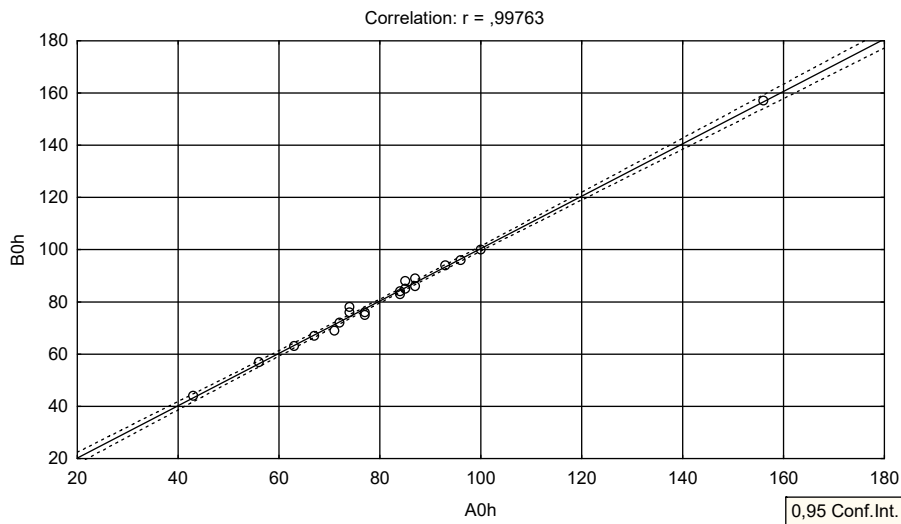


Glucose Normal range: 74 - 106 mg/dl

Bar chart:



Correlations: Gluc [mg/dl] A0h/B0h



Bland Altman: Gluc [mg/dl] A0h/B0h

