

# Comparison testing of new **MiniCollect<sup>®</sup>** K<sub>2</sub>E K<sub>2</sub>EDTA Tubes to **Microtainer<sup>®</sup>** K<sub>2</sub>E K<sub>2</sub>EDTA Tubes

## **Background:**

Greiner Bio-One has developed a newly designed MiniCollect<sup>®</sup> 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<sup>®</sup> tube.

The MiniCollect<sup>®</sup> K<sub>2</sub>EDTA 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 MiniCollect<sup>®</sup> K<sub>2</sub>EDTA tube wall is coated with dipotassium EDTA (K<sub>2</sub>EDTA).

MiniCollect<sup>®</sup> K<sub>2</sub>EDTA Blood Collection Tubes are used to collect, transport, store and evaluate capillary blood specimens for hematology tests.

## **Study Objective:**

A clinical evaluation was carried out to compare the performance of the MiniCollect<sup>®</sup> K<sub>2</sub>EDTA tube with new design in comparison to BD Microtainer<sup>®</sup> K<sub>2</sub>EDTA tube including 20 healthy subjects.

## **Study design:**

The following tube types were used in this study:

Sample ID	Description
A	Microtainer <sup>®</sup> K <sub>2</sub> E K <sub>2</sub> EDTA 0.25-0.5 ml, (item No.: 365974)
B	MiniCollect <sup>®</sup> K <sub>2</sub> E K <sub>2</sub> EDTA 0.25-0.5 ml (item No.: 450532)

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<sup>®</sup> blood collection tubes. The tubes were transported to a laboratory within 6 hours after blood collection. A complete blood count was performed using the DxH 800 from Beckman Coulter. Analysis was performed with the instrument's accompanying reagents.

It is necessary to mix the samples immediately before analysis. All samples were mixed by a gentle tap immediately before analysis.

## **Determined parameters:**

- Leucocytes
- Erythrocytes
- Hemoglobin
- Hematocrit
- Platelets
- Mean cellular volume
- Mean cellular hemoglobin
- Mean cellular hemoglobin concentration
- Mean platelet volume (MTV)
- Red cell distribution with (RDW)
- Lymphocytes
- Neutrophiles
- Eosinophiles
- Monocytes
- Basophiles

## **Conclusion:**

The performance of the MiniCollect® K2E K<sub>2</sub>EDTA tube has been demonstrated to be comparable to the BD Microtainer® K2E K<sub>2</sub>EDTA tube on the basis of the analytes tested.

Statistically significant differences were found for WBC. The deviation is in the clinically acceptable range according to RILIBÄK (< 6.5%). The correlation is very high ( $r > 0.99$ ). No other statistically significant differences were found. The distribution for basophile granulocytes (BA) was found to be higher in MiniCollect® tubes without any clinical relevance.

In summary, the MiniCollect® K2E K<sub>2</sub>EDTA tube with the new design is substantially equivalent to the BD Microtainer® K2E K<sub>2</sub>EDTA tube.

## ***References:***

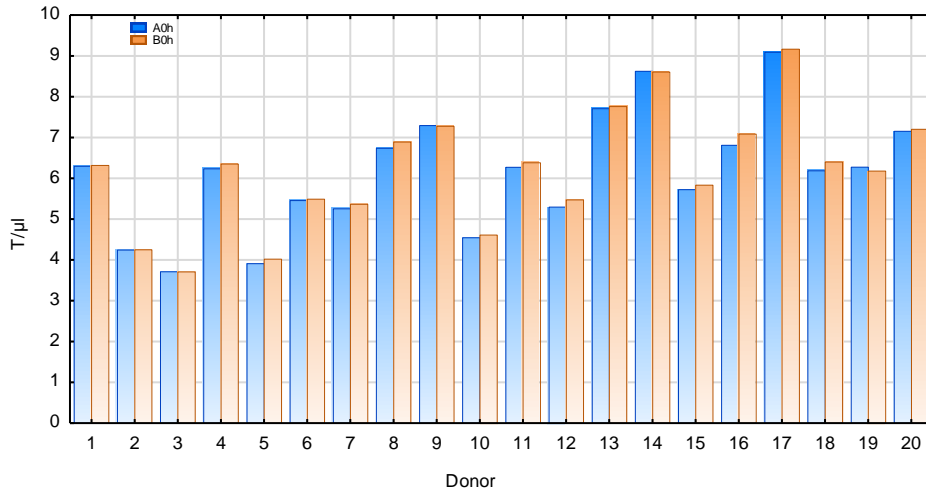
- (1) Greiner Bio-One. MiniCollect® K2E K<sub>2</sub>EDTA Tubes. Instructions for Use. Kremsmünster, Austria. 2016.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.
- (3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning 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:**

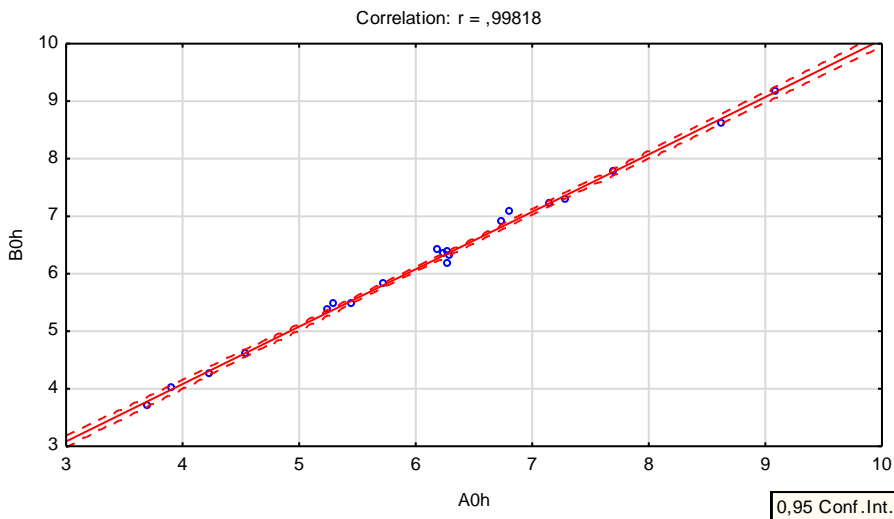
Leucocytes (WBC)

Normal range: 4-10  $10^9/l$

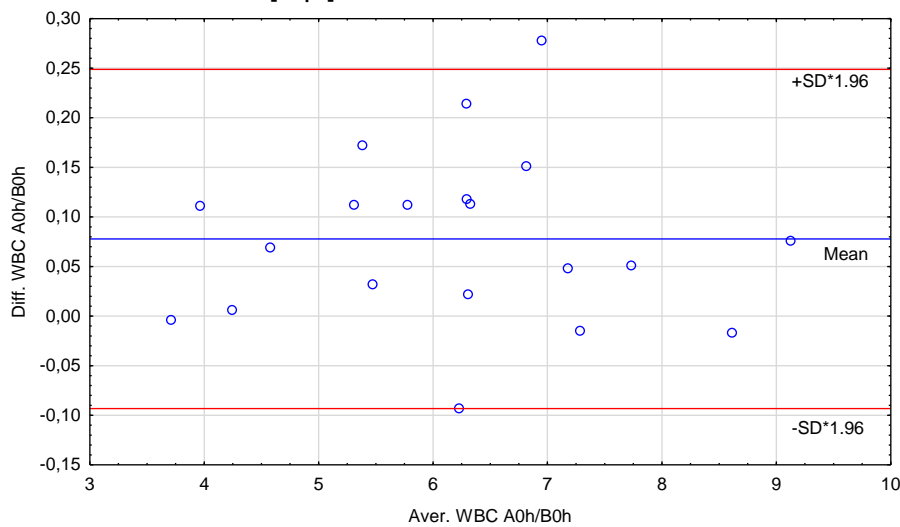
Bar chart:



Correlations: WBC [T/μl] A0h/B0h



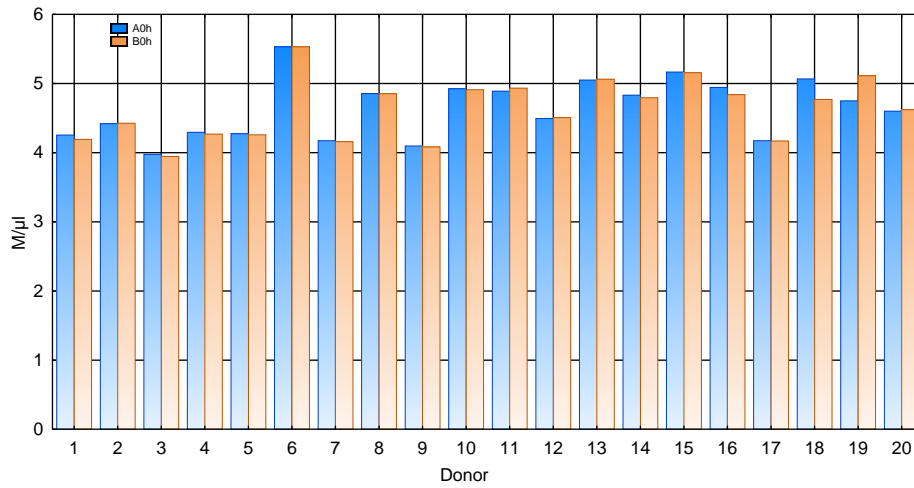
Bland Altman: WBC [T/μl] A0h/B0h



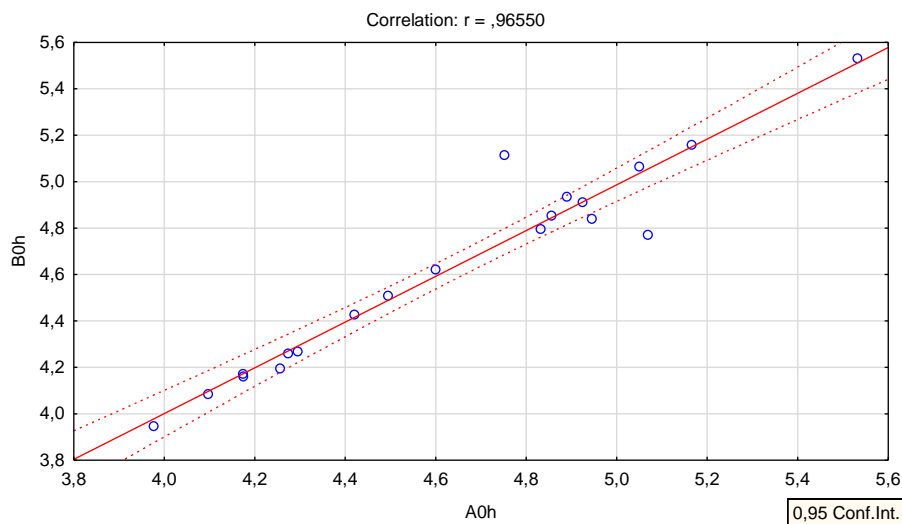
# Erythrocytes (RBC)

Normal range: 4.4 - 5.9 T/l

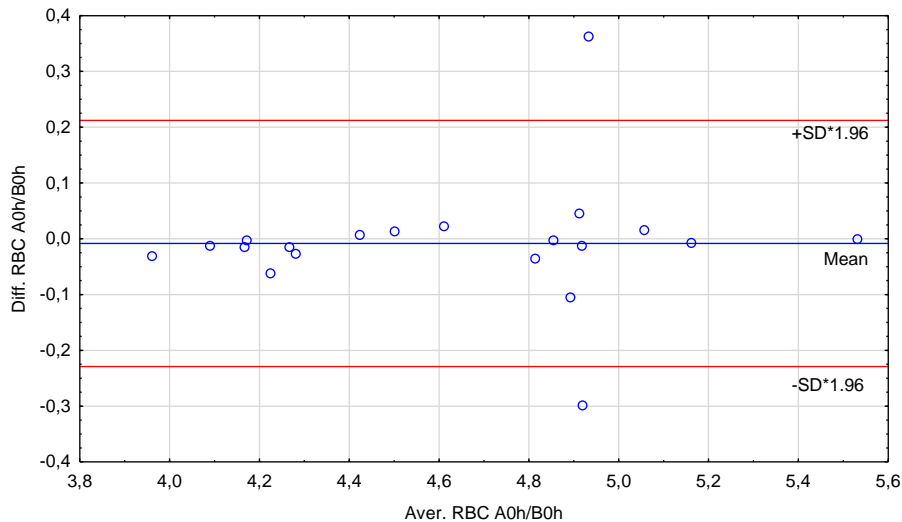
Bar chart:



Correlations: RBC [M/μl] A0h/B0h



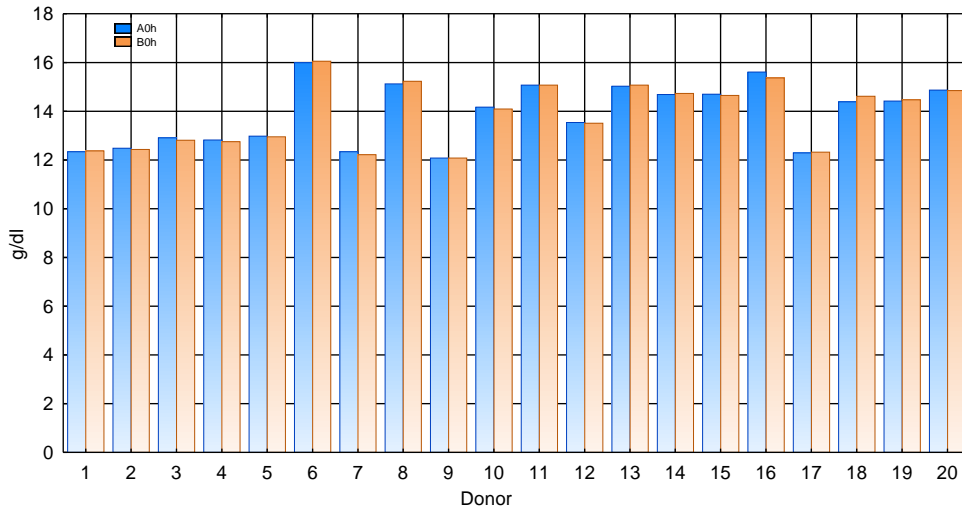
Bland Altman: RBC [M/μl] A0h/B0h



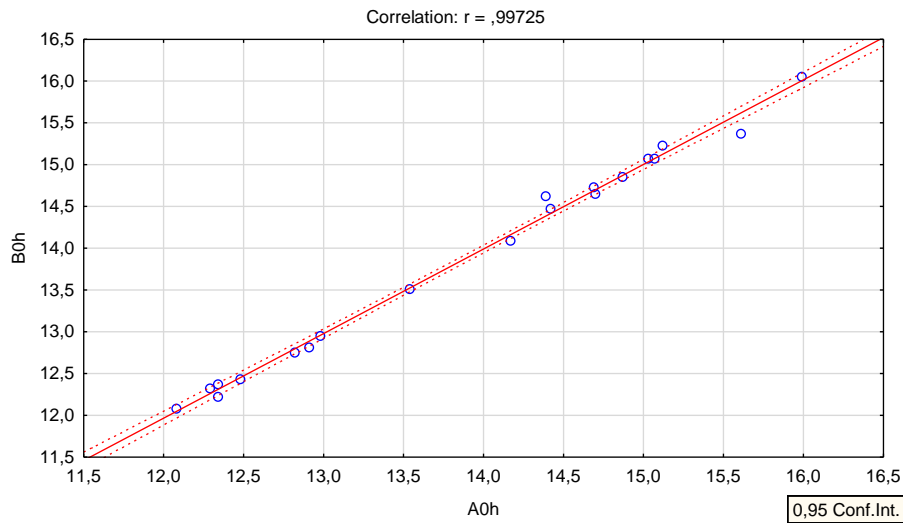
# Hemoglobin

Normal range: 13-18 g/dl

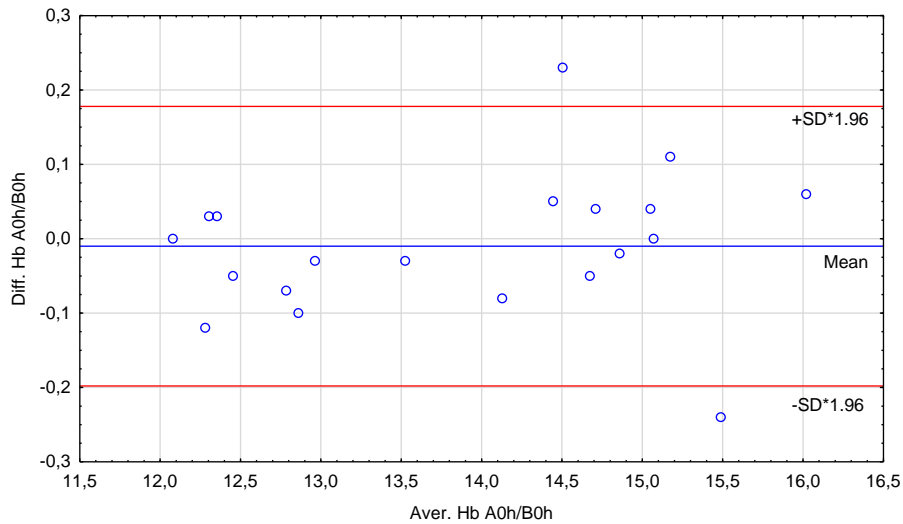
Bar chart:



Correlations: Hb [g/dl] A0h/B0h



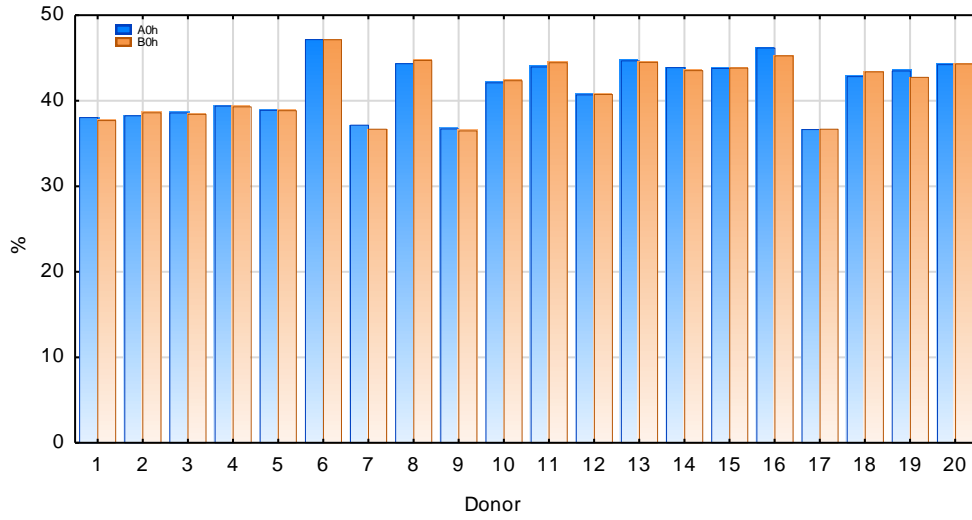
Bland Altman: Hb [g/dl] A0h/B0h



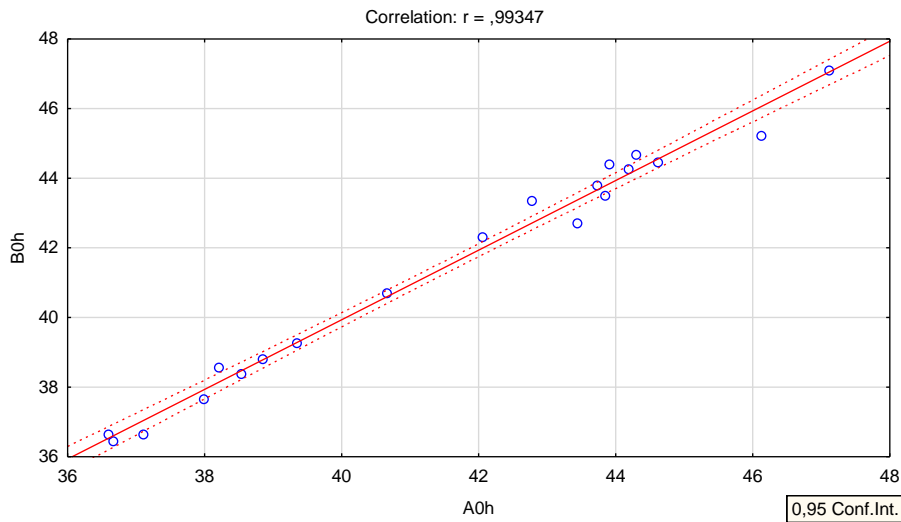
# Hematocrit

Normal range: (m) 40 - 54 % (f) 37 - 47 %

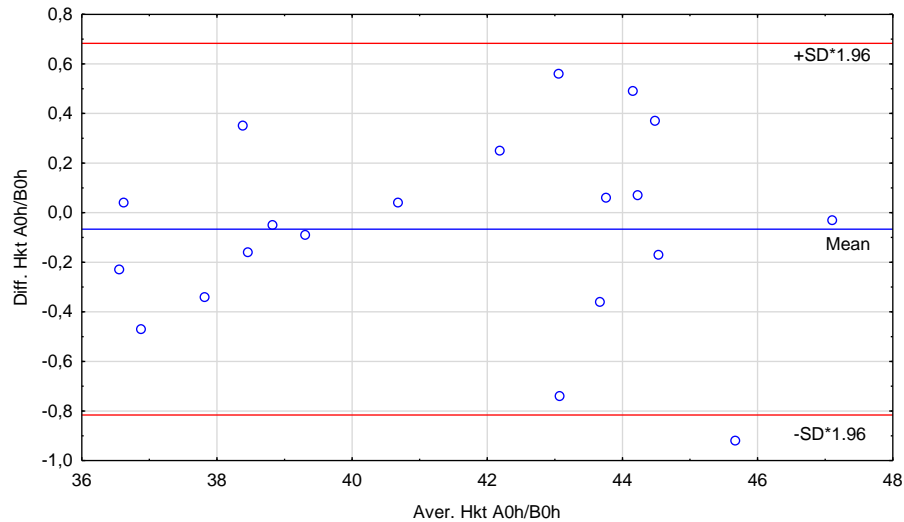
Bar chart:



Correlations: Hkt [%] A0h/B0h



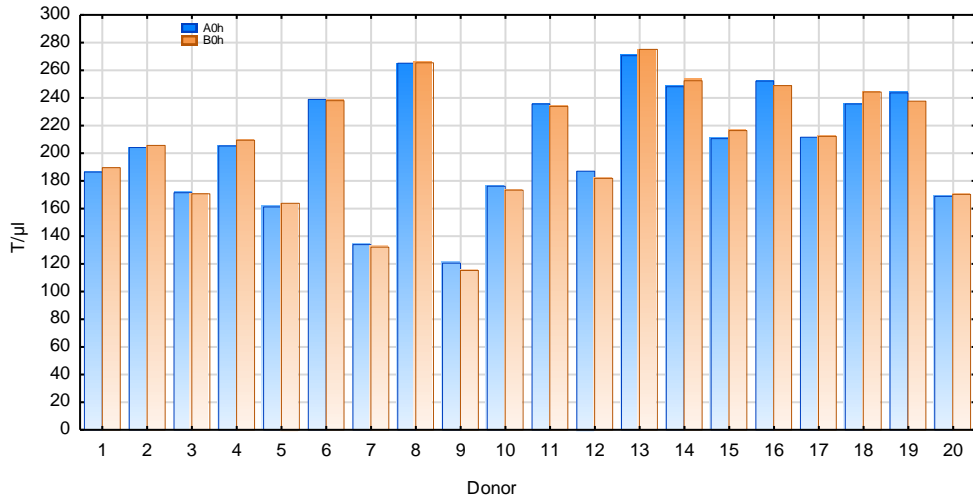
Bland Altman: Hkt [%] A0h/B0h



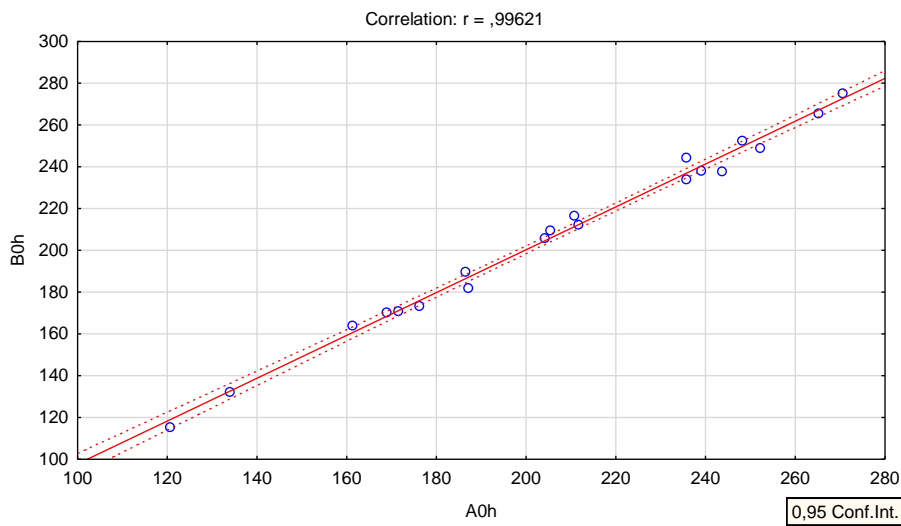
# Thrombocytes (platelets)

Normal range: 150-300 x 10<sup>9</sup>/l

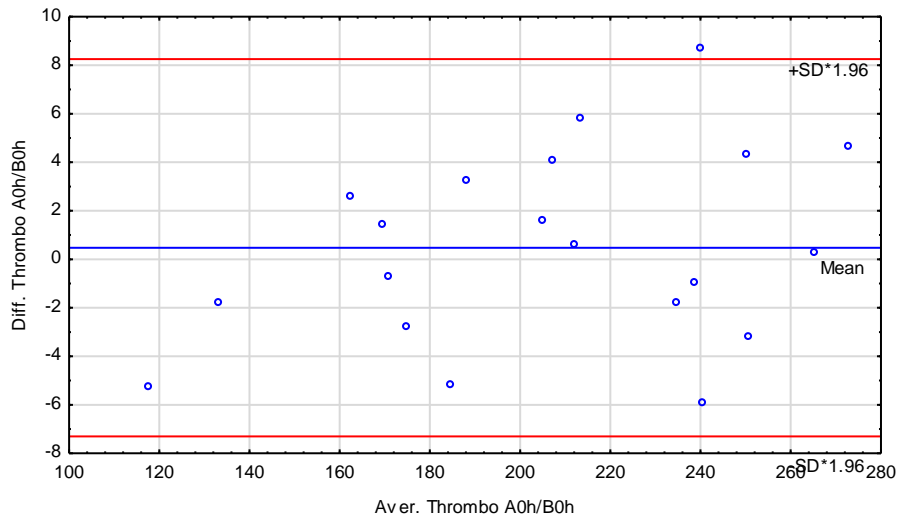
Bar chart:



## Correlations: Thrombo [T/μl] A0h/B0h



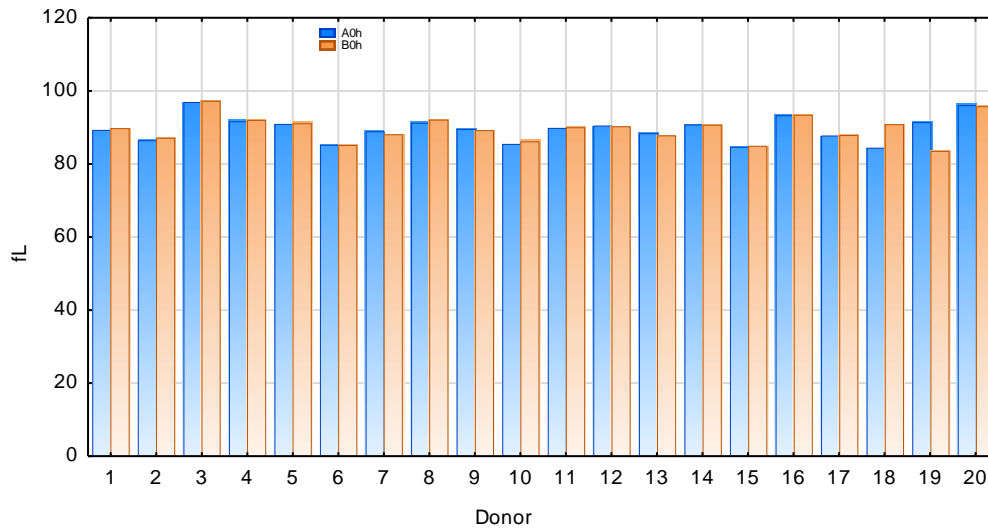
## Bland Altman: Thrombo [T/μl] A0h/B0h



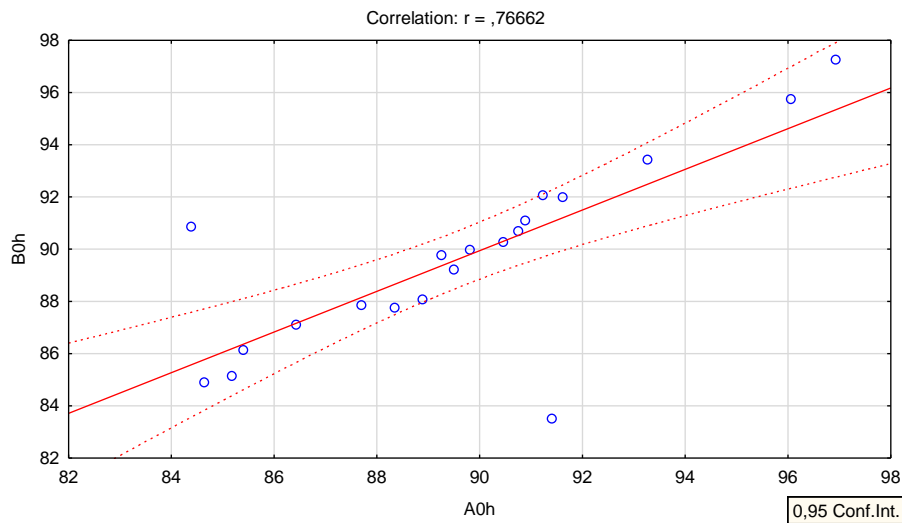
### Mean cellular volume (MCV)

Normal range: 50 - 150 fL

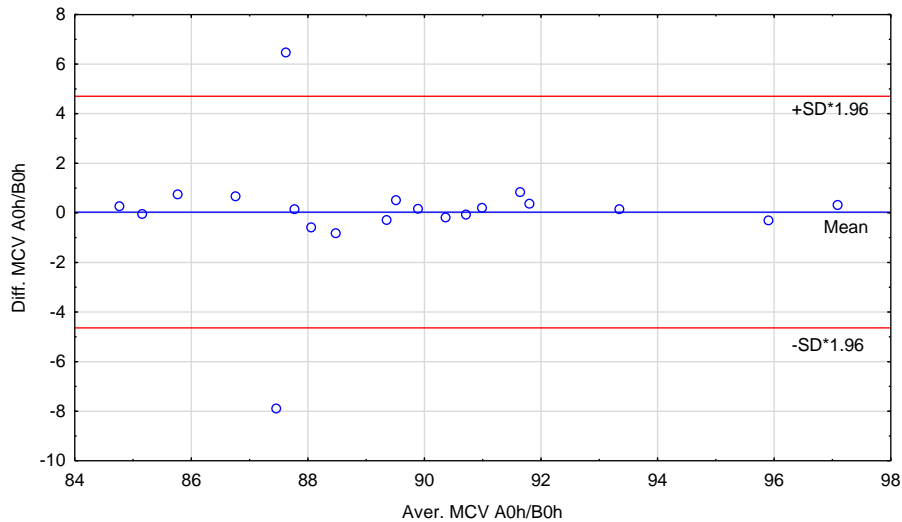
Bar chart:



### Correlations: MCV [fL] A0h/B0h



### Bland Altman: MCV [fL] A0h/B0h

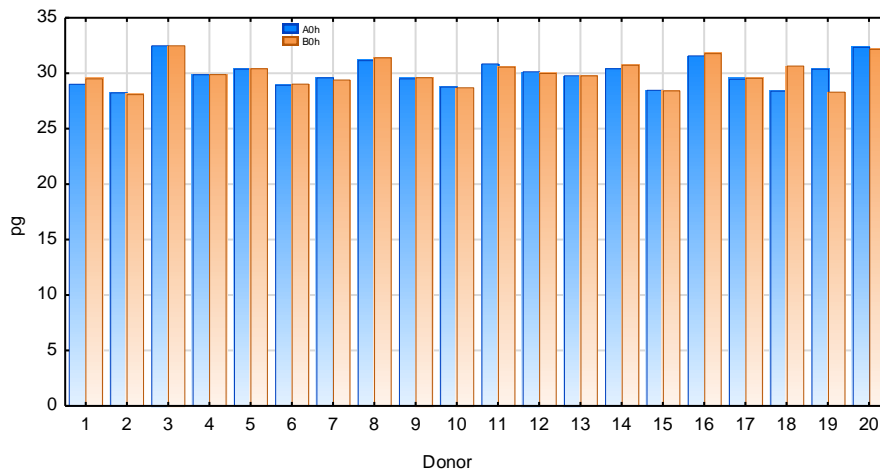




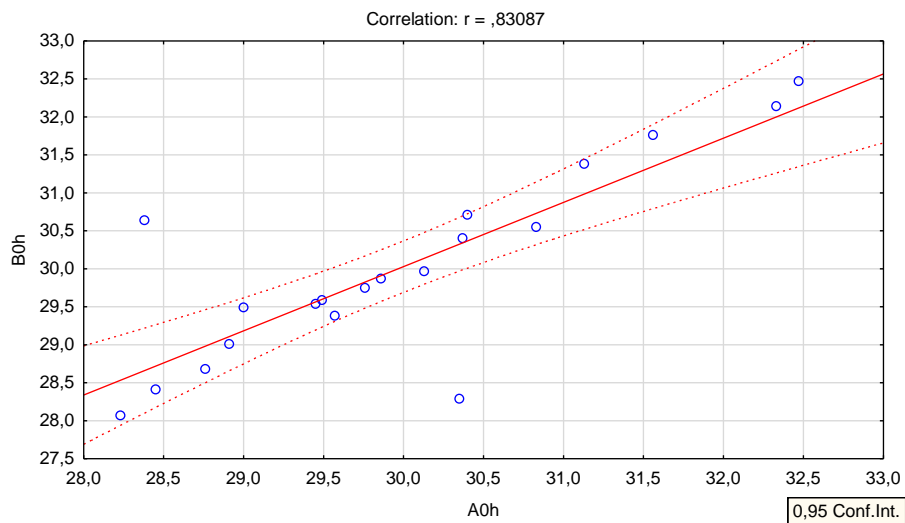
## Mean Corpuscular Hemoglobin (MCH)

Normal range: 27 - 35 pg

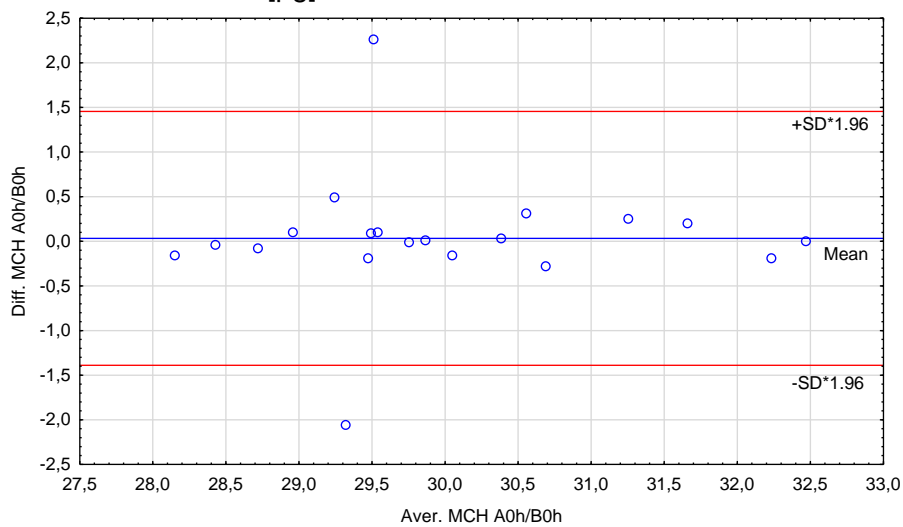
Bar chart:



## Correlations: MCH [pg] A0h/B0h



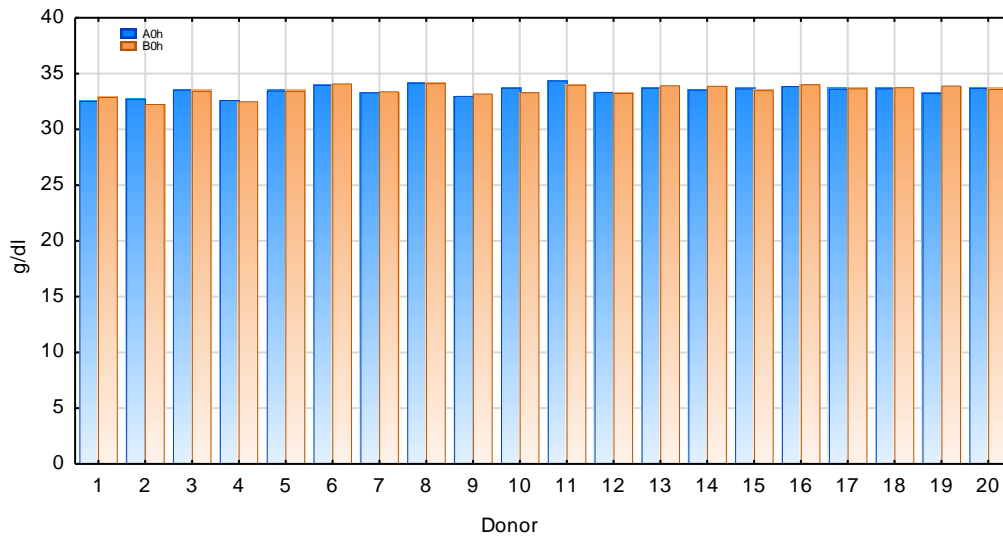
## Bland Altman: MCH [pg] A0h/B0h



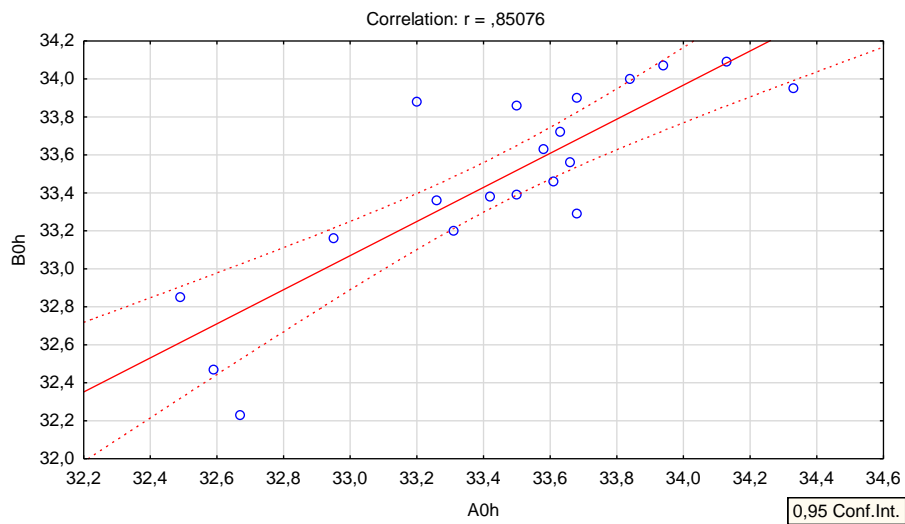
## Mean Corpuscular Hemoglobin Concentration (MCHC)

Normal range: 29-36 g/dl

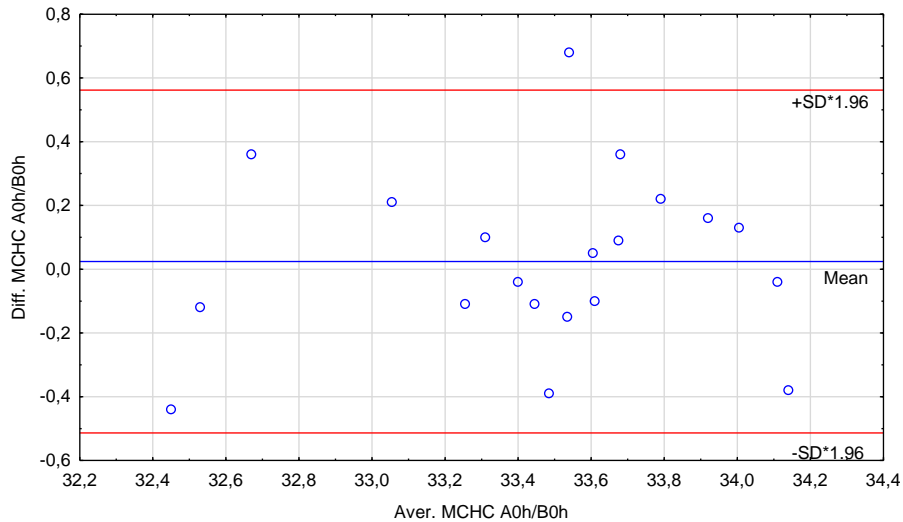
Bar chart:



Correlations: MCHC [g/dl] A0h/B0h



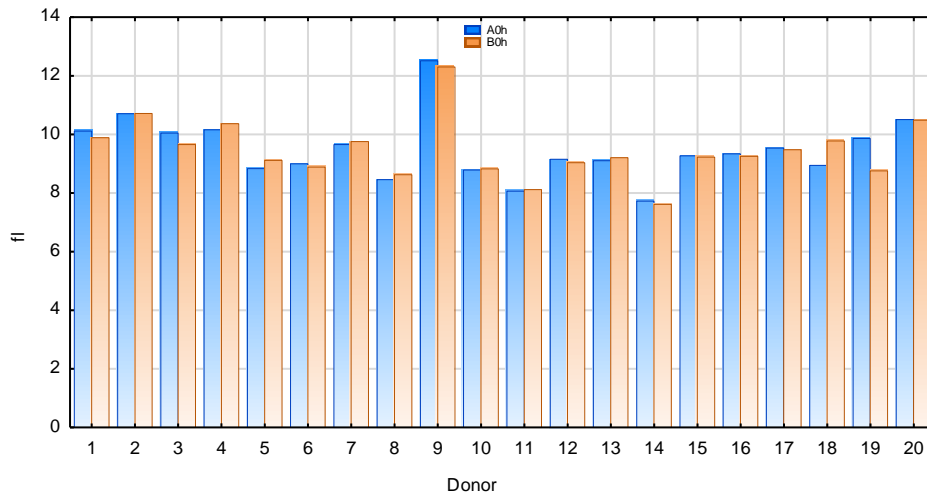
Bland Altman: MCHC [g/dl] A0h/B0h



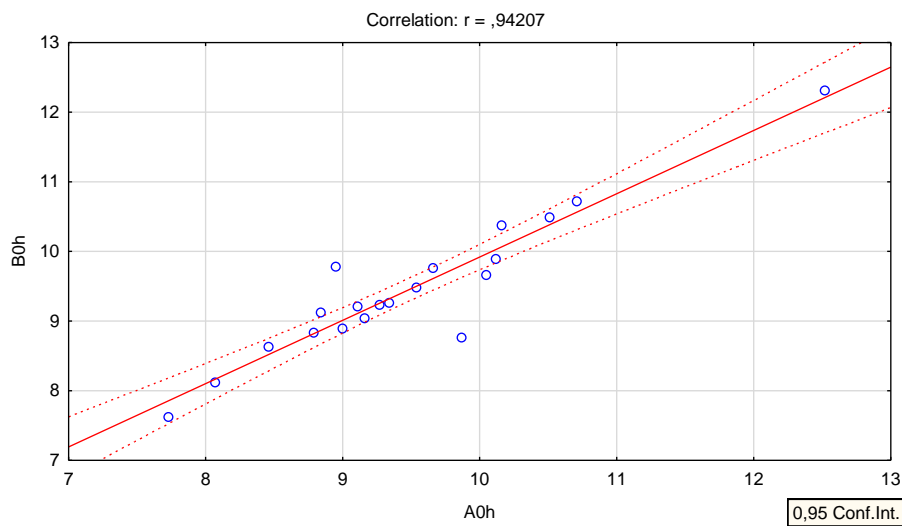
### Mean platelet volume (MTV)

Normal range: 7-12 fl

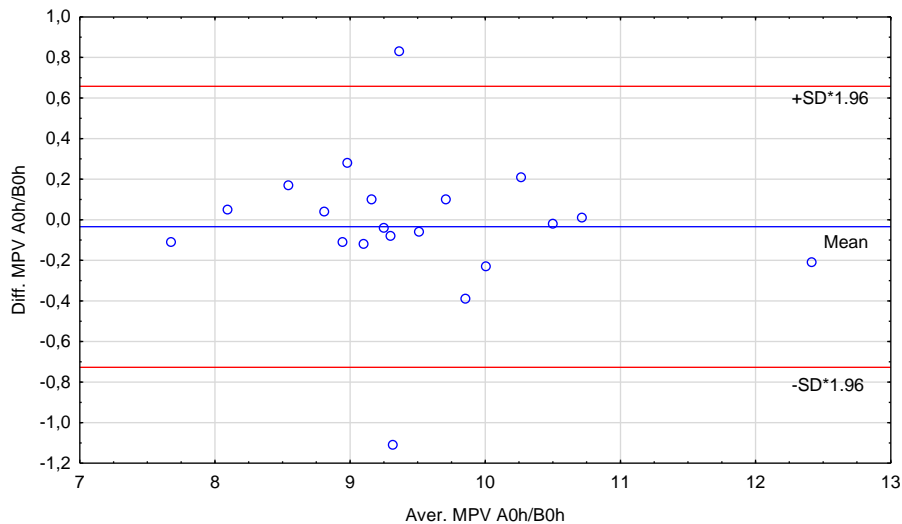
Bar chart:



Correlations: MPV [fL] A0h/B0h



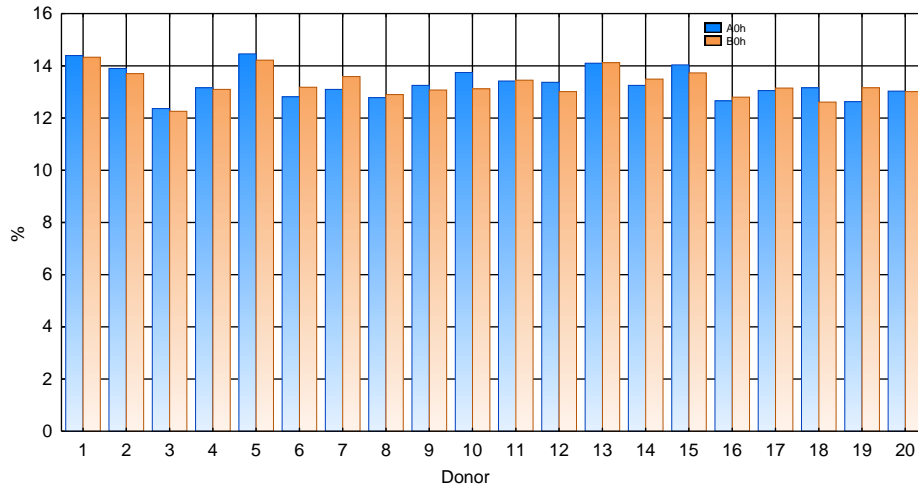
Bland Altman: MPV [fL] A0h/B0h



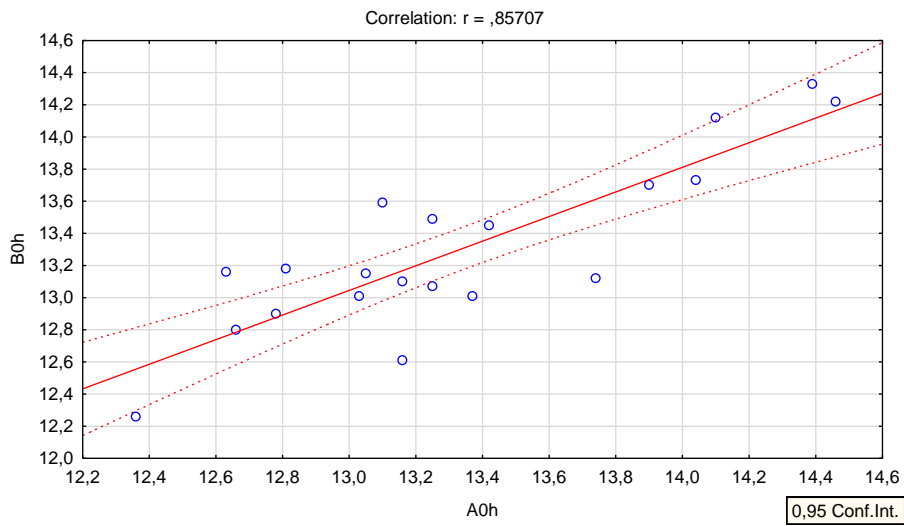
## Red cell distribution with (RDW)

Normal range: 12.9-18.7 %

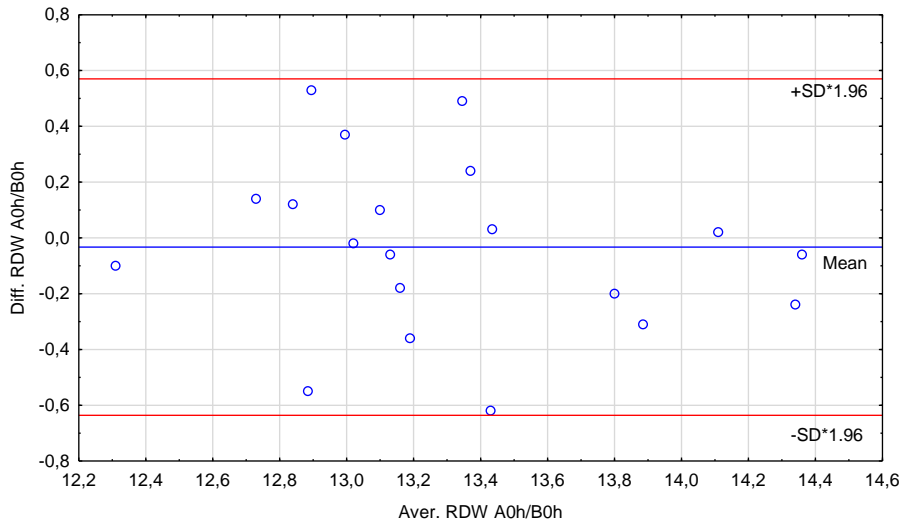
Bar chart:



Correlations: RDW [%] A0h/B0h



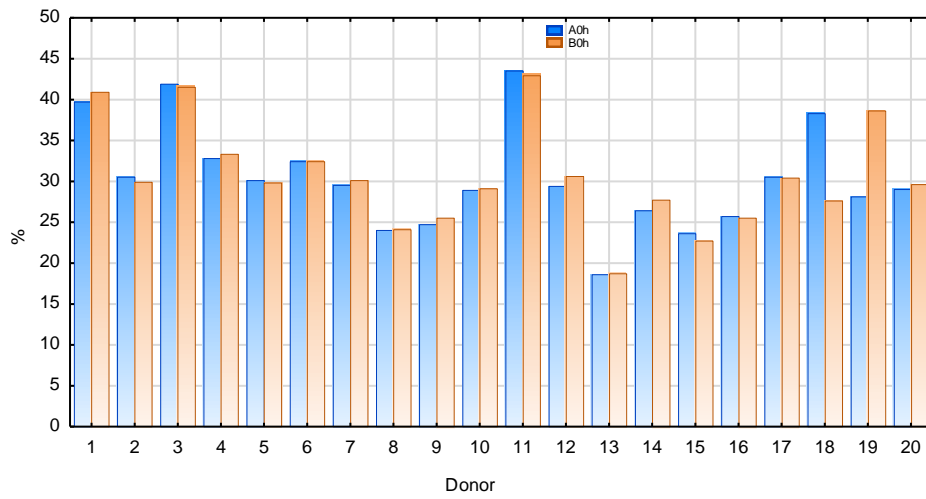
Bland Altman: RDW [%] A0h/B0h



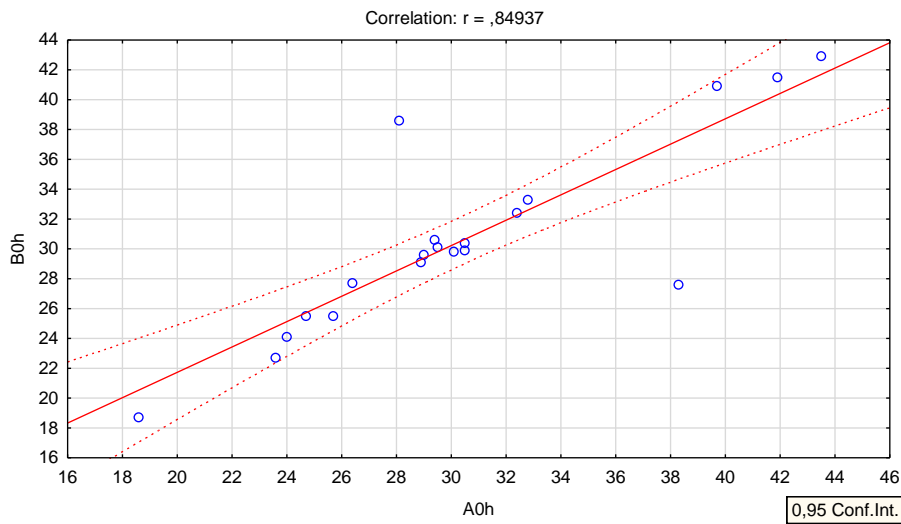
# Lymphocytes

Normal range: 20-40 %

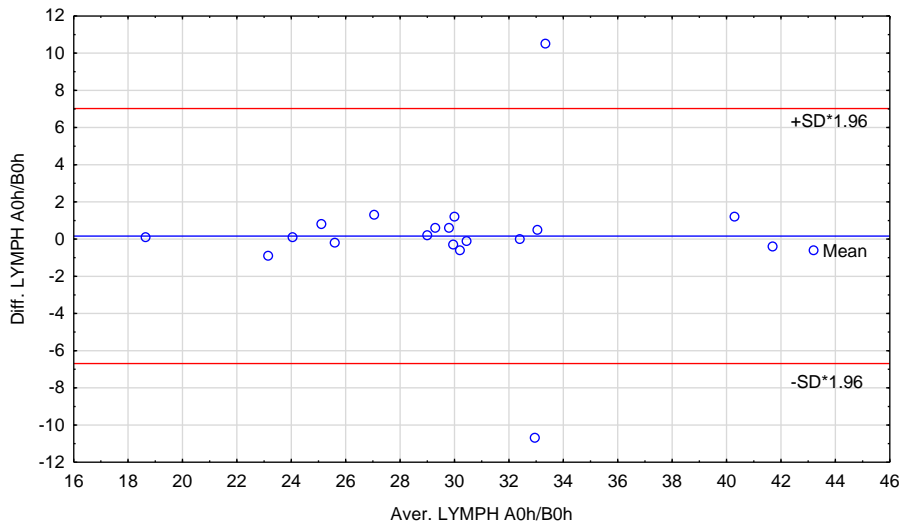
Bar chart:



## Correlations: LYMPH [%] A0h/B0h



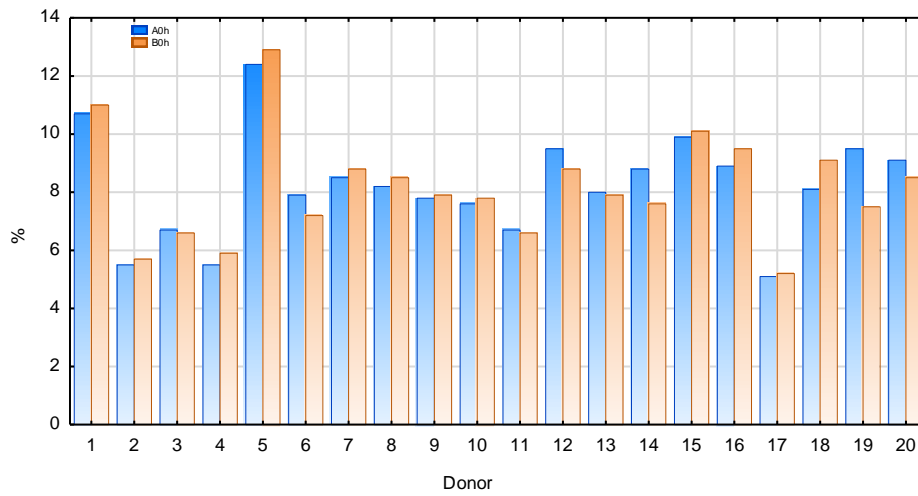
## Bland Altman: LYMPH [%] A0h/B0h



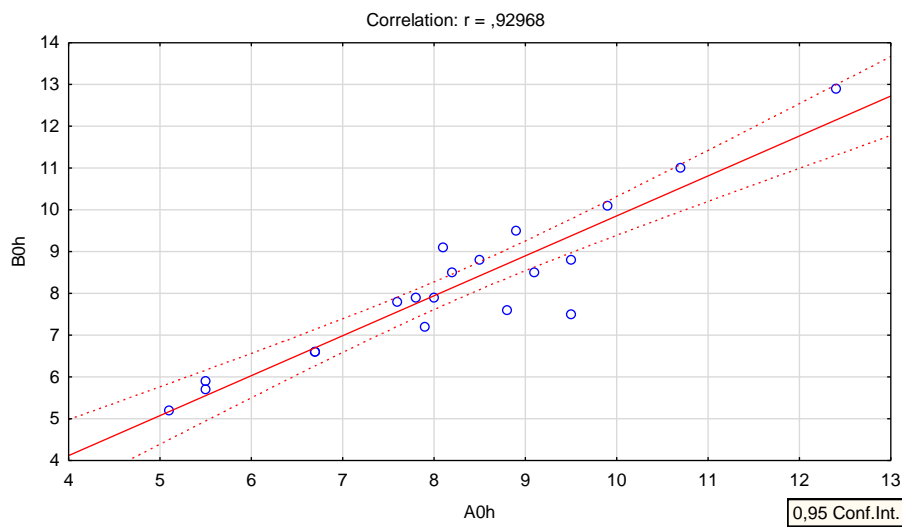
# Monocytes

Normal range: 2-10 %

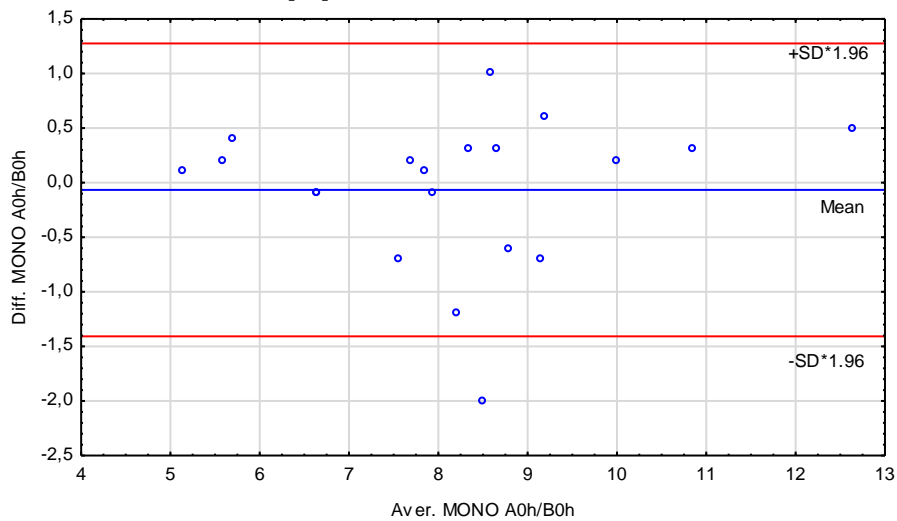
Bar chart:



Correlations: MONO [%] A0h/B0h



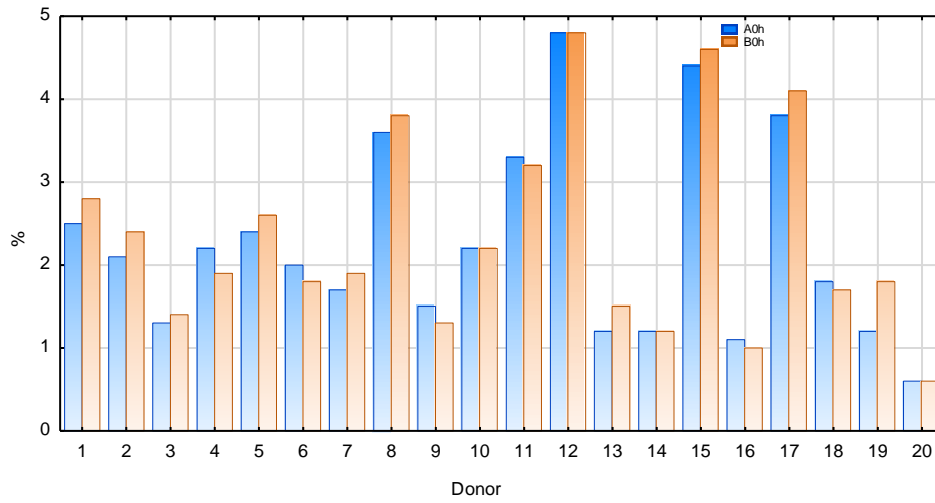
Bland Altman: MONO [%] A0h/B0h



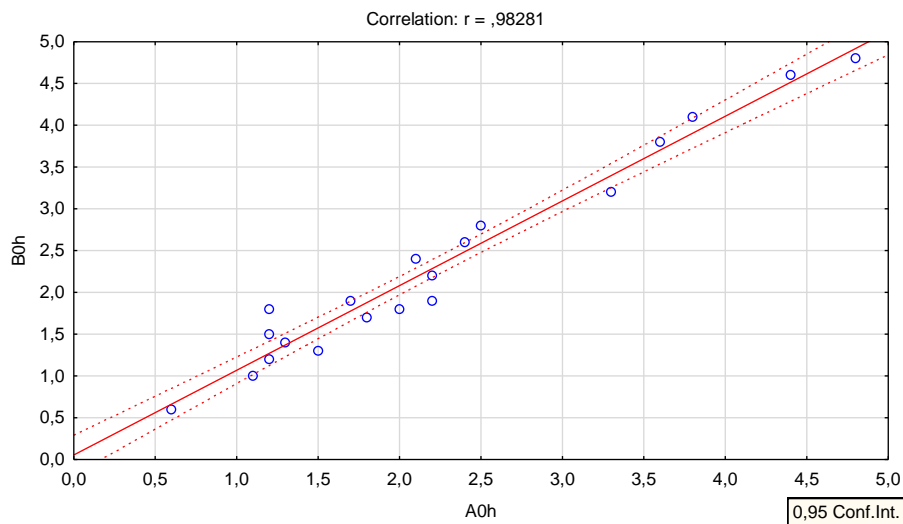
# Eosinophile Granulocytes

Normal range: 1-4 %

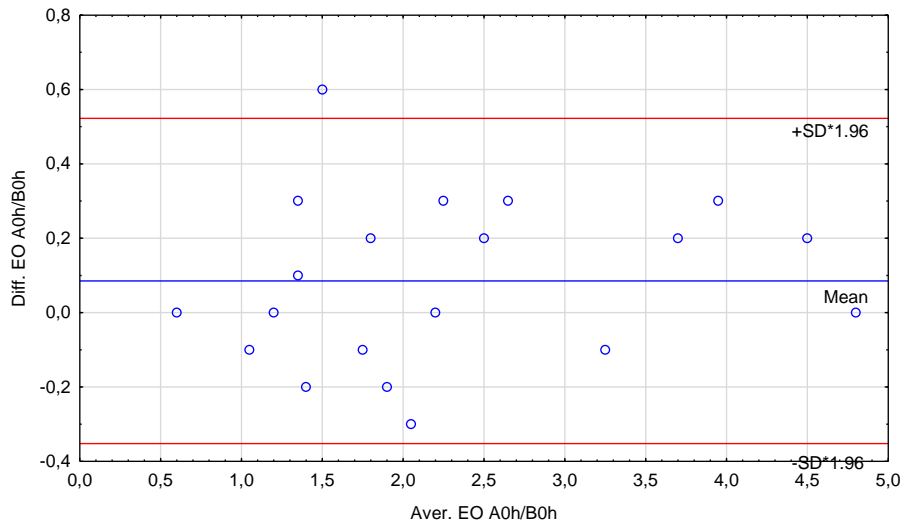
Bar chart:



Correlations: EO [%] A0h/B0h



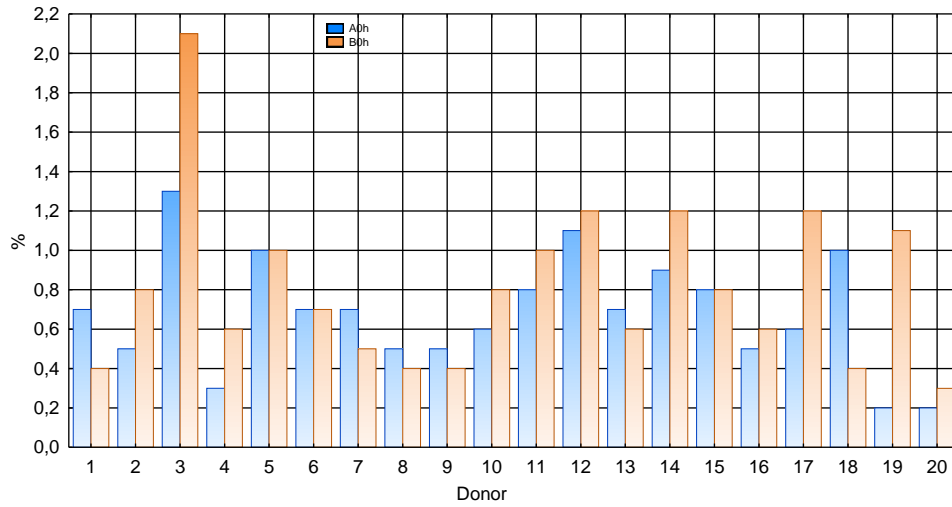
Bland Altman: EO [%] A0h/B0h



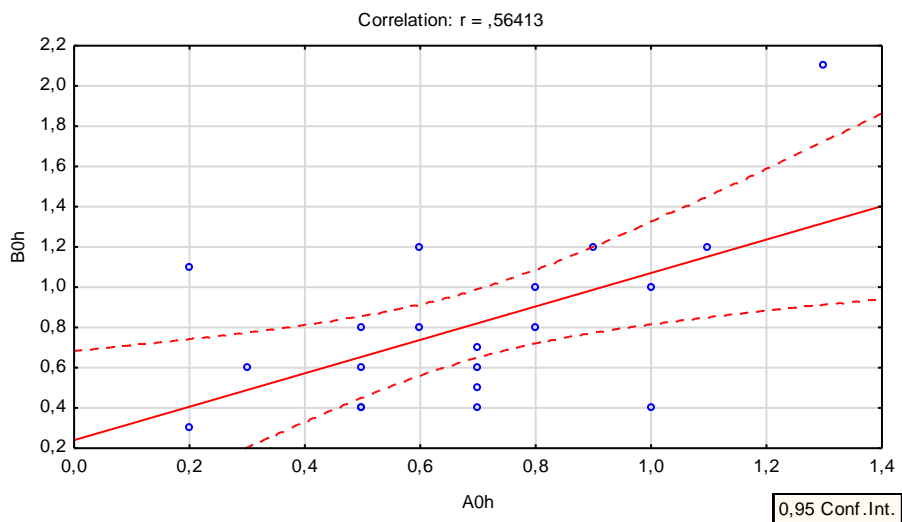
# Basophile Granulocytes

Normal range: 0-1 %

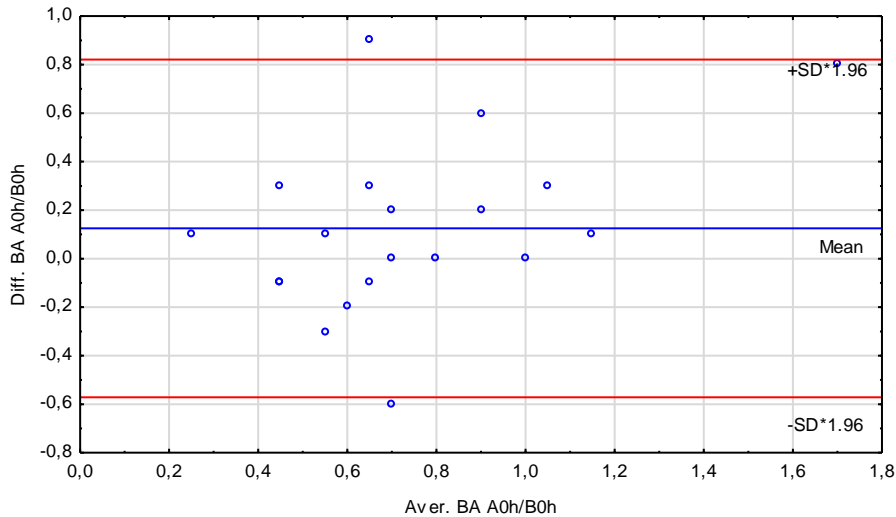
Bar chart:



Correlations: BA [%] A0h/B0h



Bland Altman: BA [%] A0h/B0h

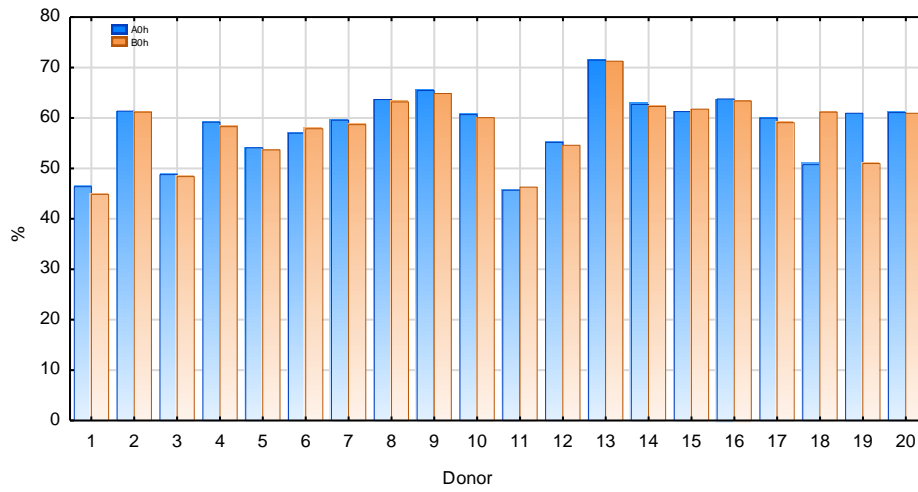




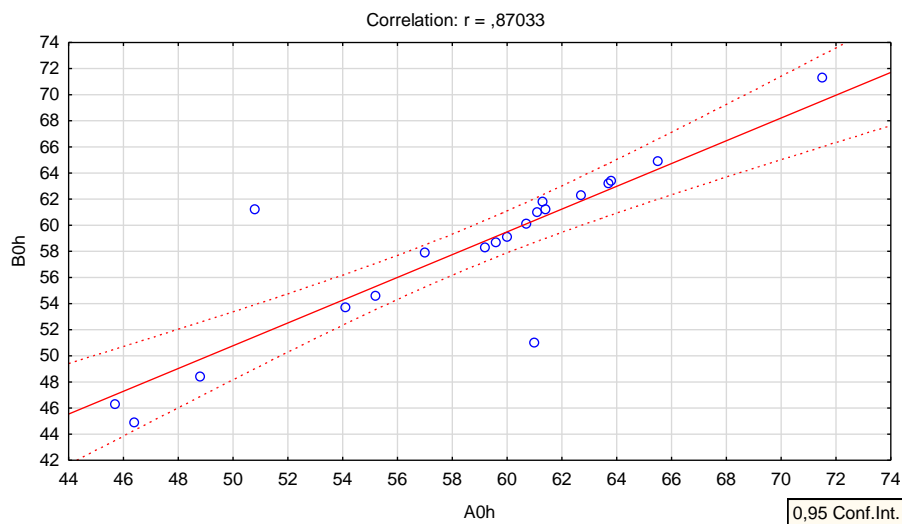
# Neutrophiles

Normal range: 55-75%

Bar chart:



Correlations: NE [%] A0h/B0h



Bland Altman: NE [%] A0h/B0h

