

Evaluation of new **MiniCollect®** K₂E K₂EDTA 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® K₂EDTA 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® K₂EDTA tube wall is coated with dipotassium EDTA (K₂EDTA).

MiniCollect® K₂EDTA 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 new MiniCollect® K₂EDTA tube in comparison to the old design of MiniCollect® K₂EDTA tube including 50 healthy and 65 pathological donors.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	MiniCollect® K ₂ E K ₂ EDTA 0.5 ml, (item No.: 450480), old design
B	MiniCollect® K ₂ E K ₂ EDTA 0.25-0.5 ml (item No.: 450532), 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. 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:

Performance of the new MiniCollect® K2E K₂EDTA tube with the co-molded cap and integrated scoop has been demonstrated in comparison to the old MiniCollect® K2E K₂EDTA tube on the basis of the analytes tested.

Results for healthy donors:

A few analytical deviations have been found most likely due to separation processes of the whole blood specimen during automated measurement process.

Results for pathological donors:

One value of pathological donors is missing for determination of granulocytes. Four subjects have shown analytically significant deviations regarding hemoglobin and thrombocytes but in a clinically acceptable range. The correlation between the samples was found to be excellent ($r > 0.99$). Neither systematic deviations nor statistically significant differences have been found.

High single deviations have been shown for lymphocytes, monocytes, eosinophile and basophile granulocytes, however without any significant differences.

Statistically significant deviations have been found in the measurement of MCV, platelets, neutrophils without clinical significance (mean difference was in a clinical acceptable range) and comparable distribution of the data. No systematic deviations have been observed.

A high distribution of basophile granulocytes has been observed in both samples. Neither statistically significant nor systematic deviations have been found between both samples.

In summary, despite the deviations and results that have been found, the MiniCollect® K2E K₂EDTA with the new design is substantially equivalent to the MiniCollect® K2E K₂EDTA with the old design.

References:

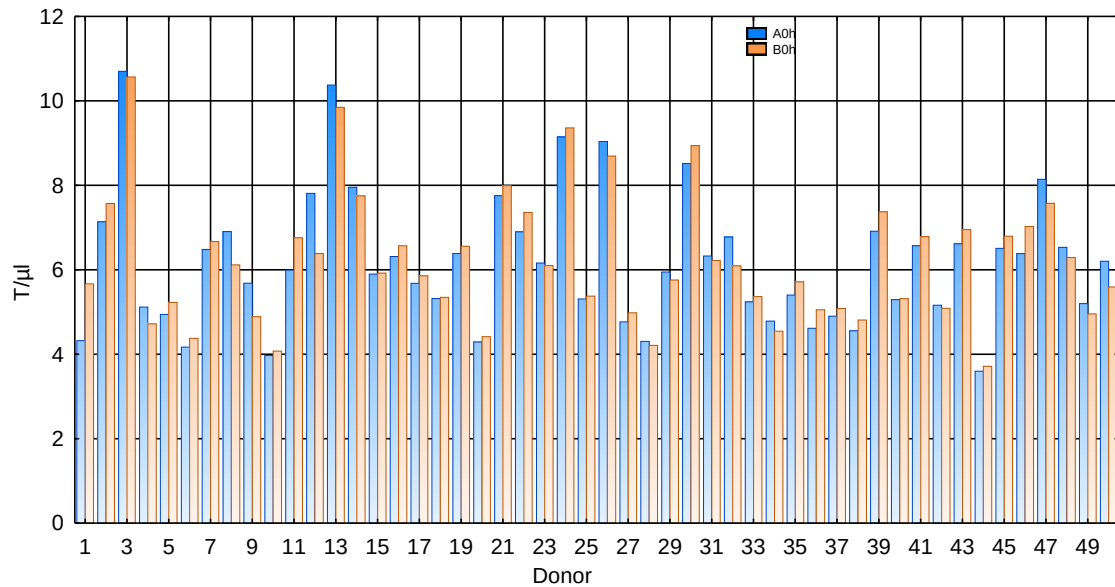
- (1) Greiner Bio-One. MiniCollect® K2E K₂EDTA Tubes. Instructions for Use. Kremsmünster, Austria. 2016.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.
- (3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning the 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:

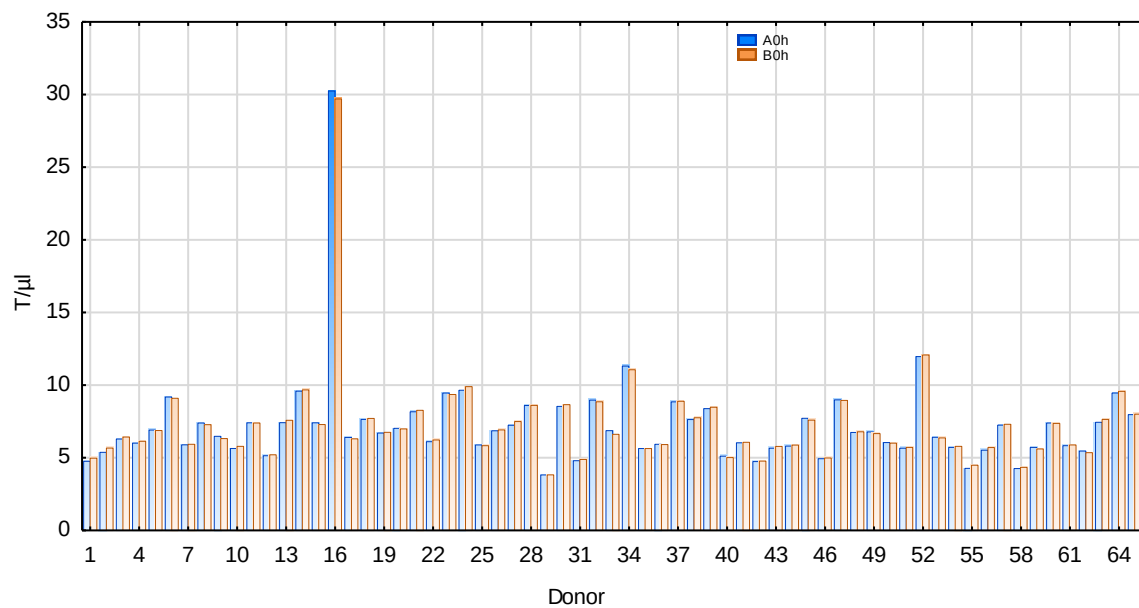
Leucocytes (WBC)

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

Healthy donors

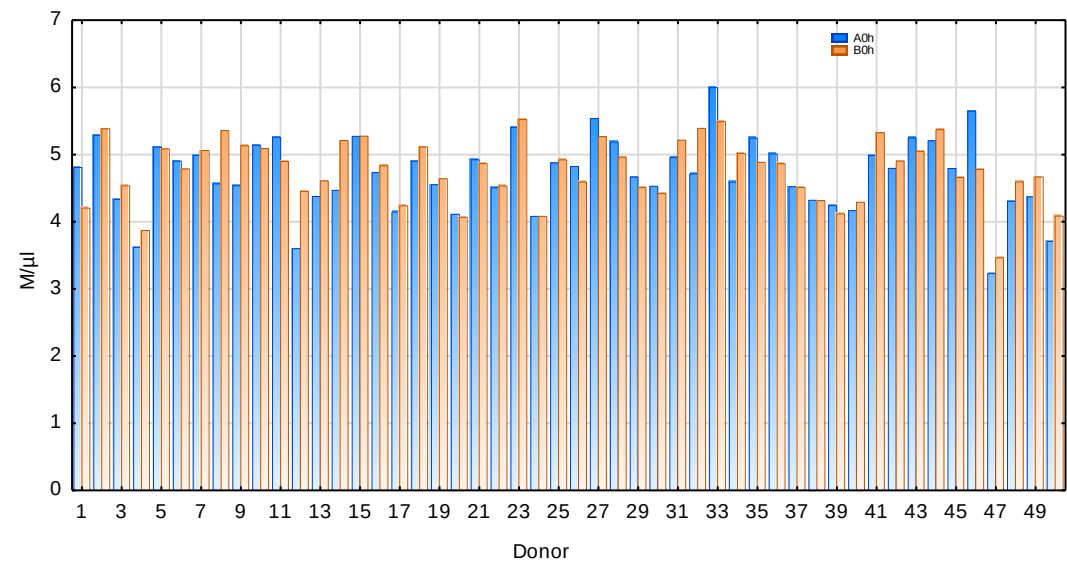


Pathological donors

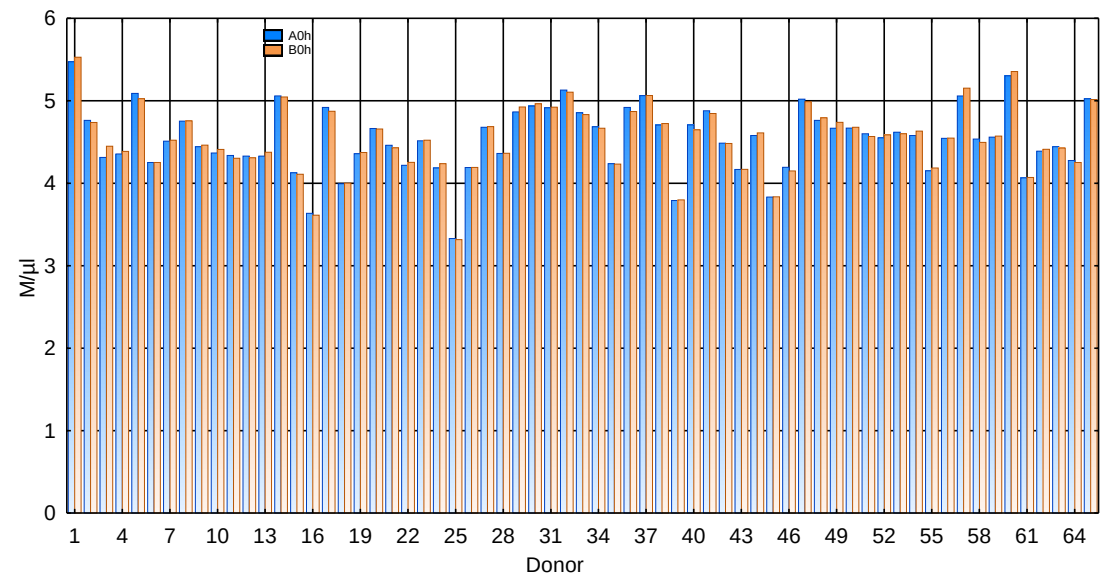


Erythrocytes (RBC)

Normal range: 4.4 - 5.9 T/l
Healthy donors



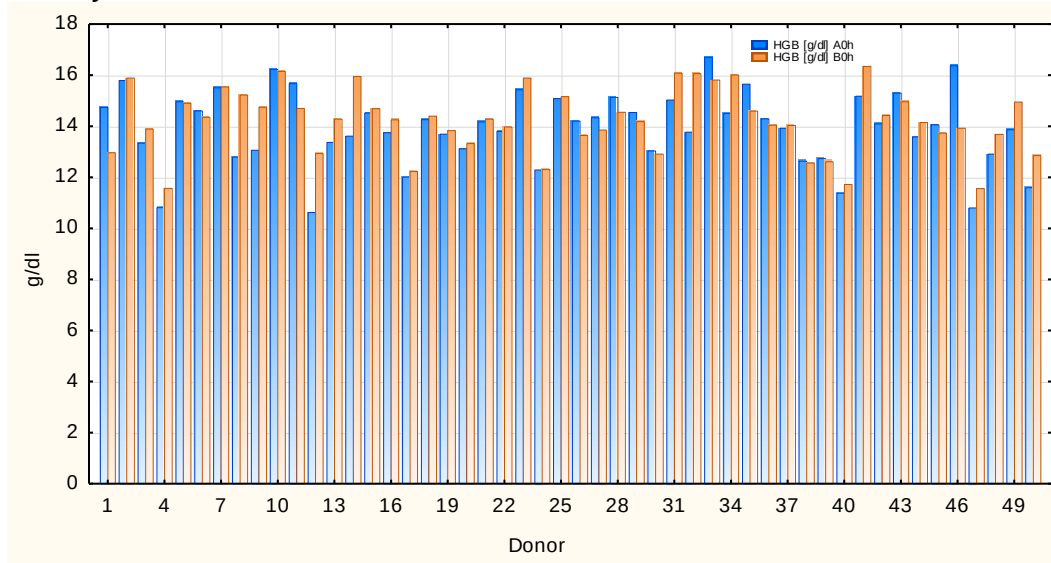
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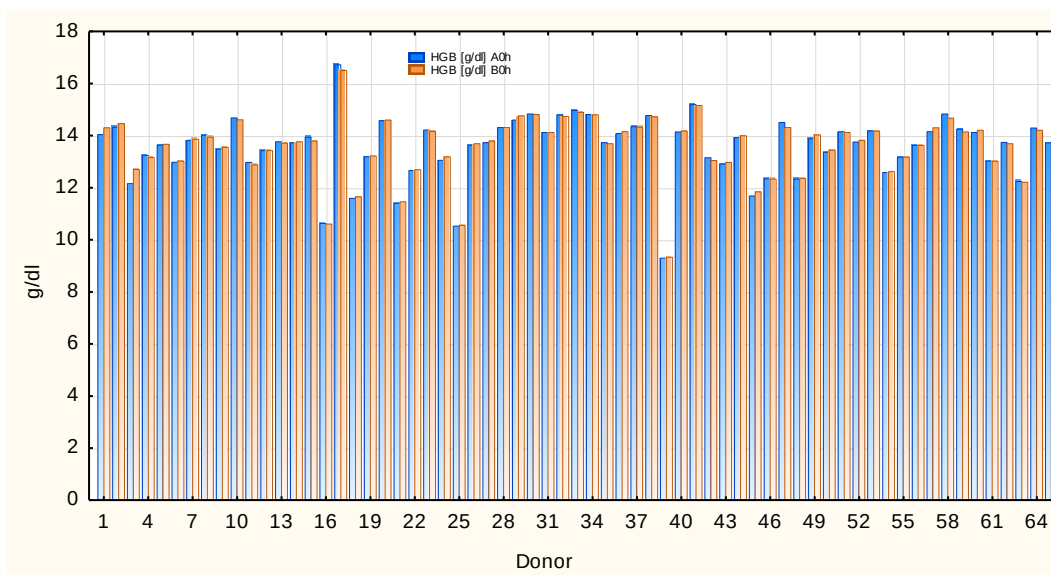
Hemoglobin

Normal range: 13-18 g/dl

Healthy donors



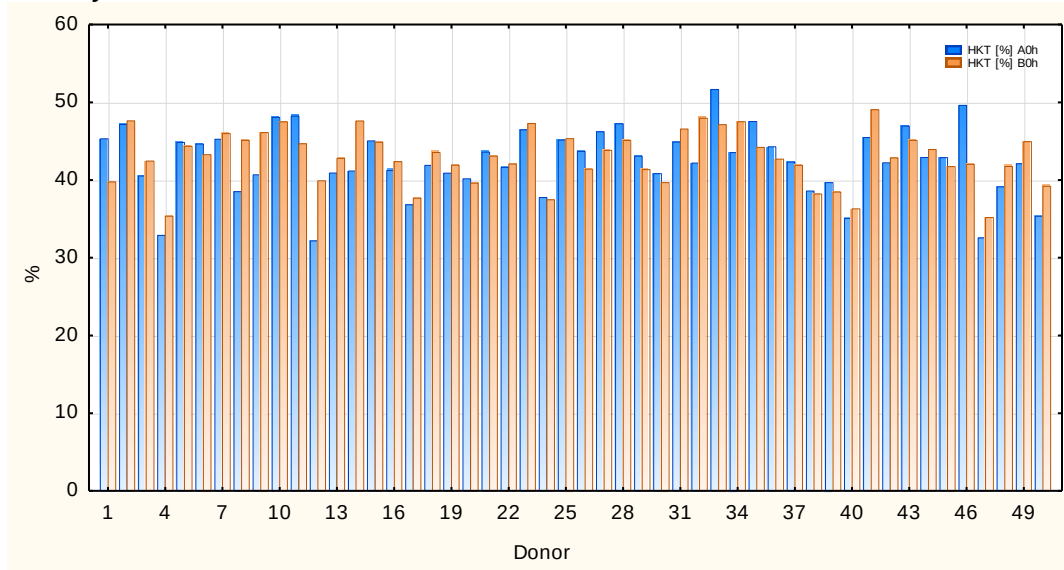
Pathological donors



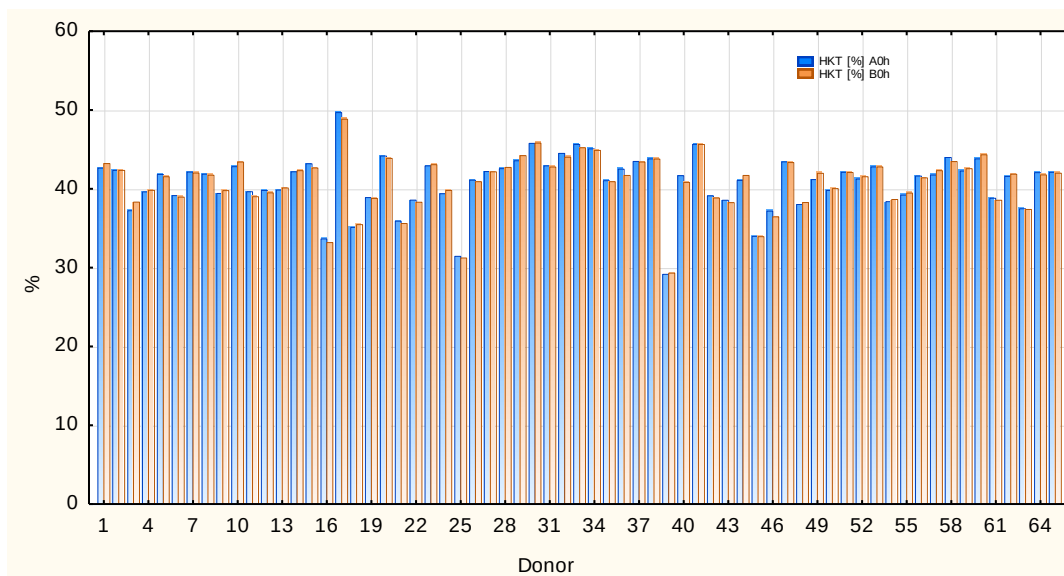
Hematocrit

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

Healthy donors



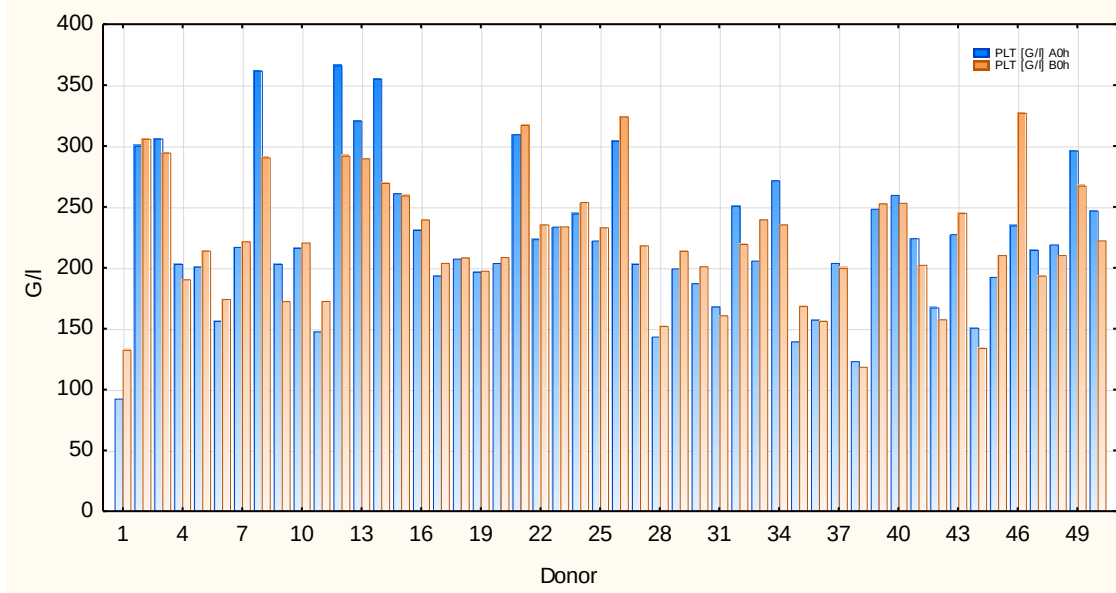
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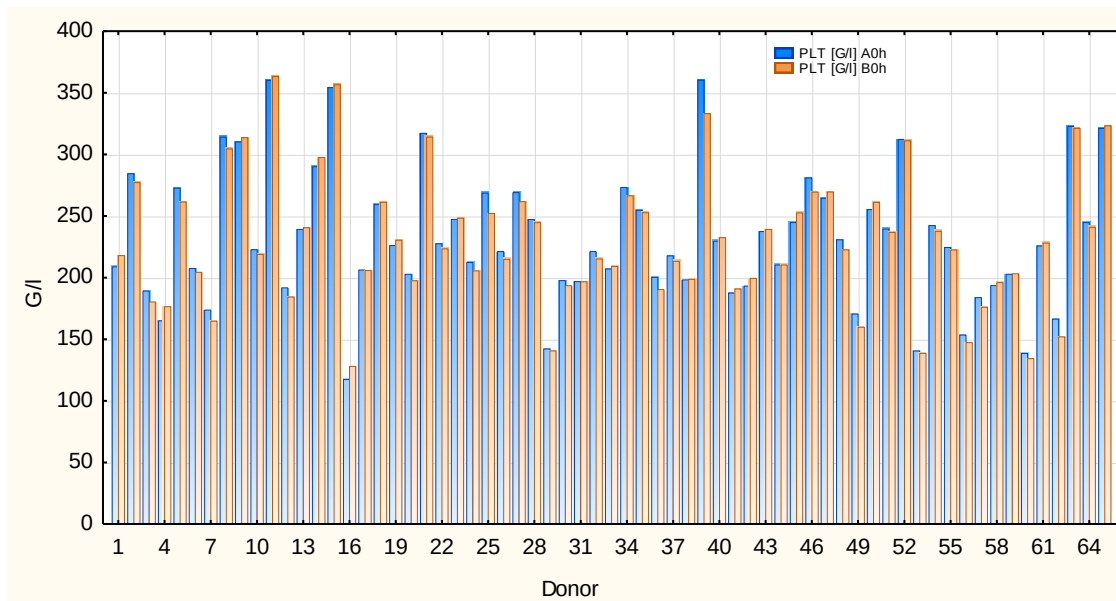
Thrombocytes (platelets)

Normal range: $10^9/l$

Healthy donors



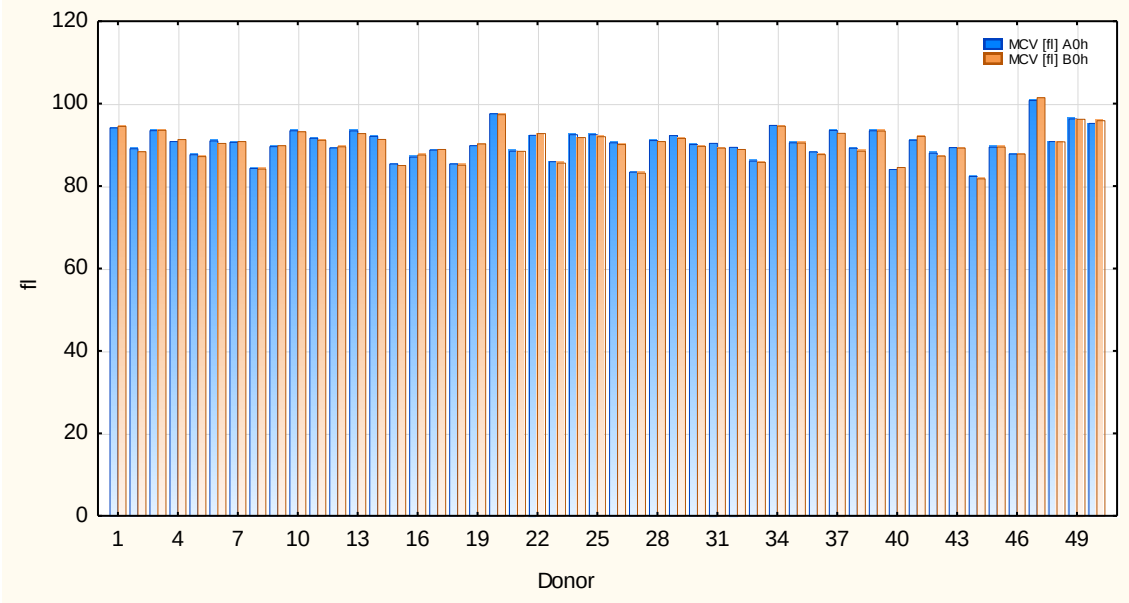
Pathological donors



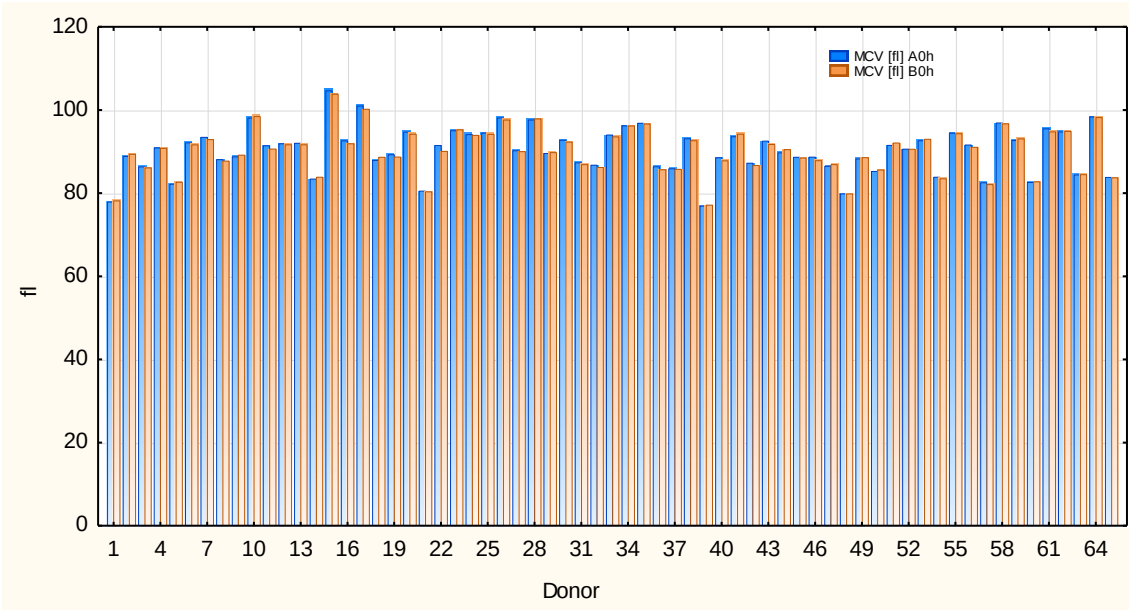
Mean cellular volume (MCV)

Normal range: 50 - 150 fL

Healthy donors



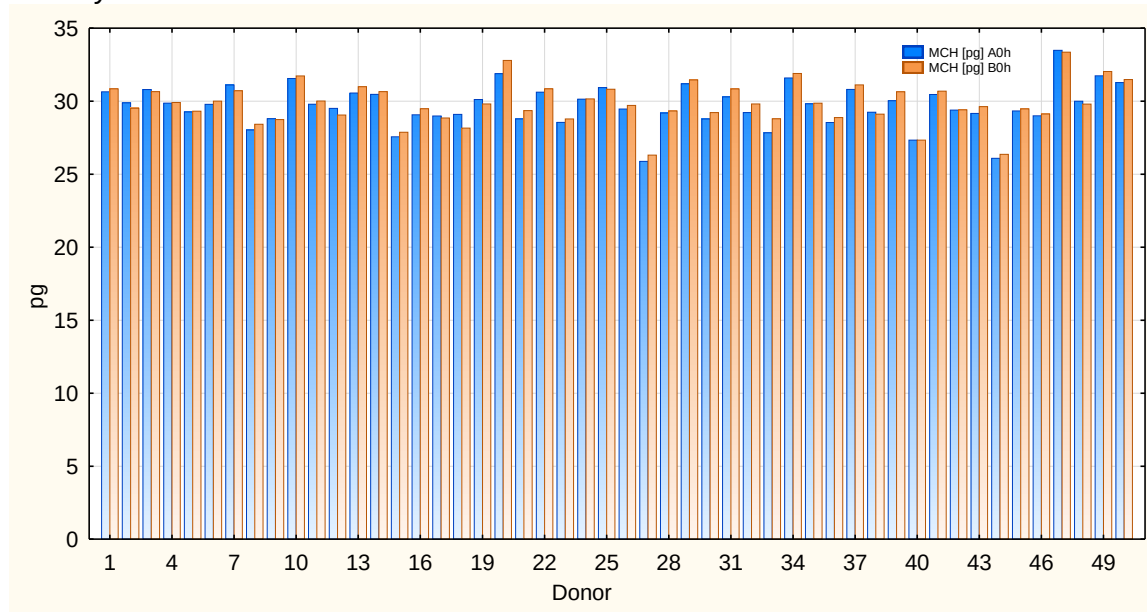
Pathological donors



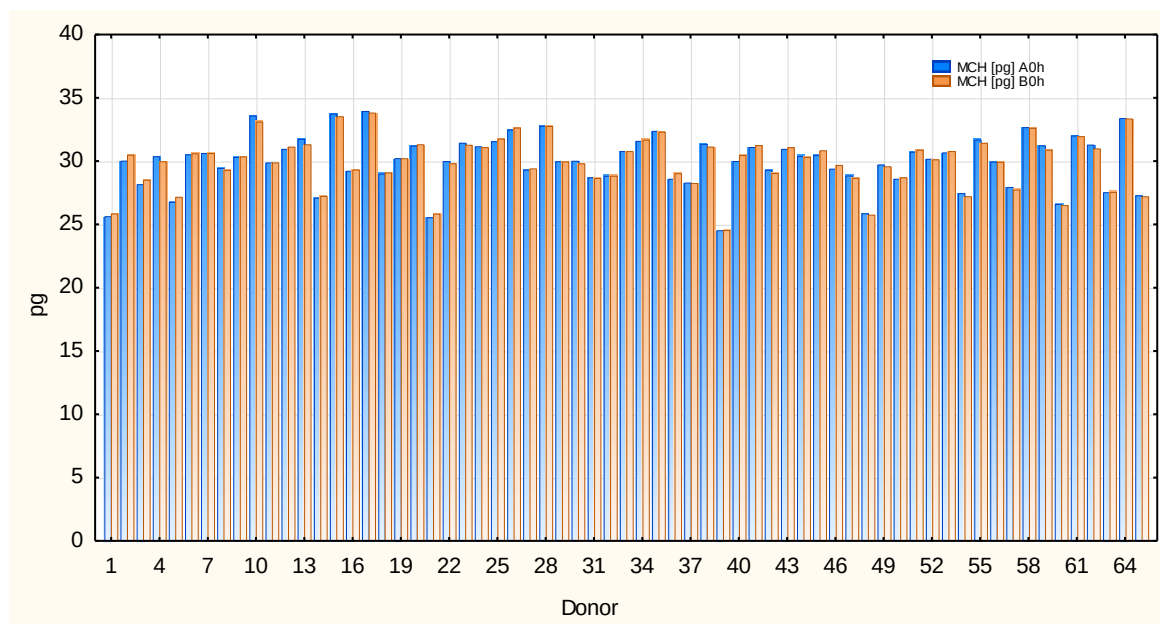
Mean Corpuscular Hemoglobin (MCH)

Normal range: 27 - 35 pg

Healthy donors



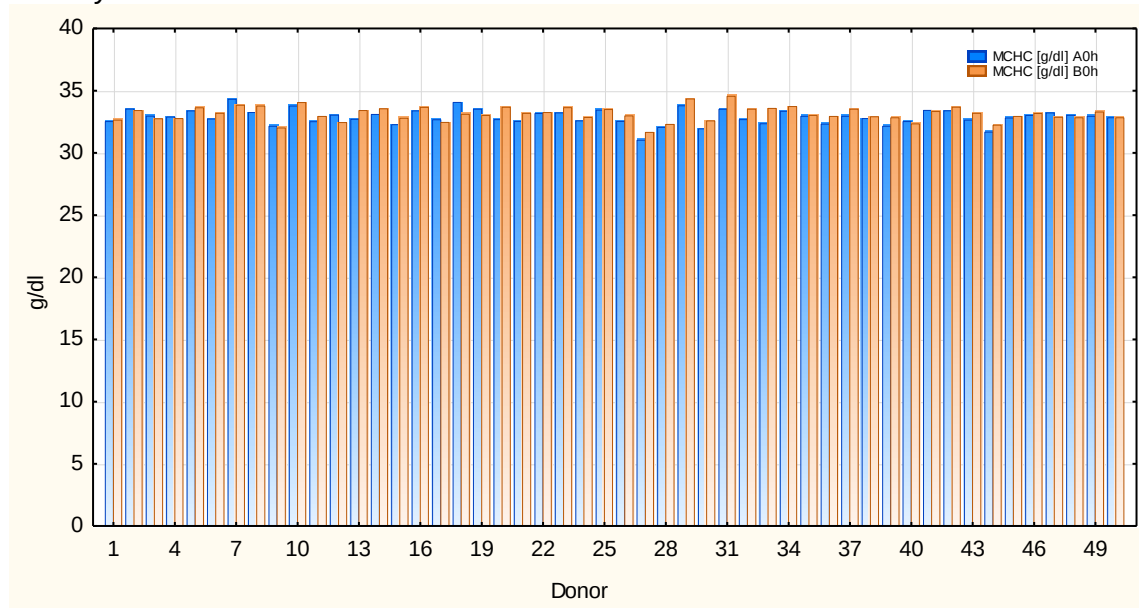
Pathological donors



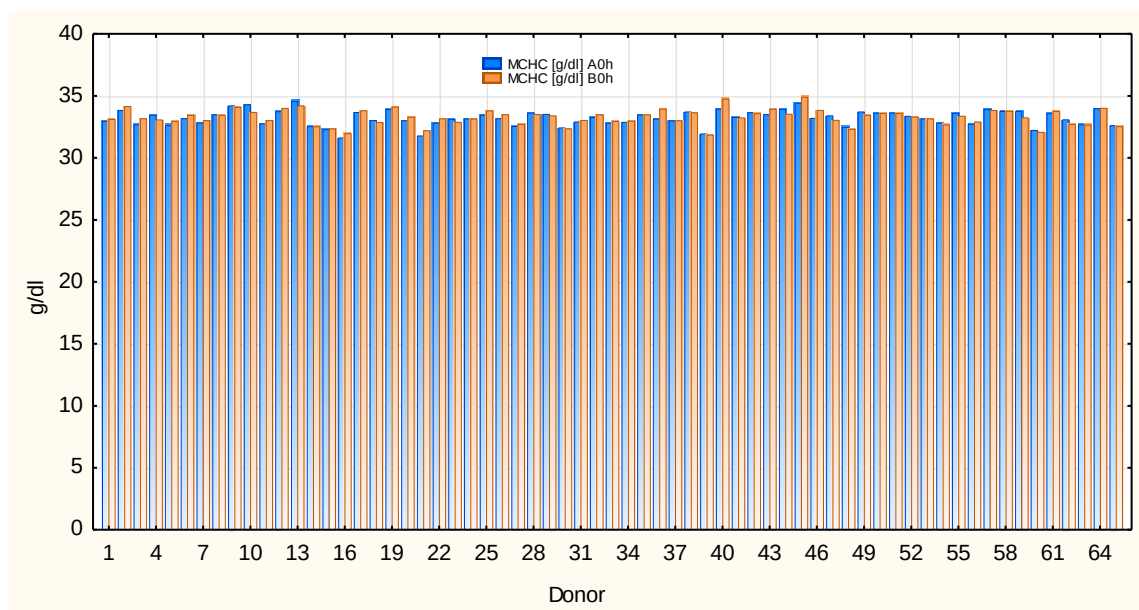
Mean Corpuscular Hemoglobin Concentration (MCHC)

Normal range: 29-36 g/dl

Healthy donors



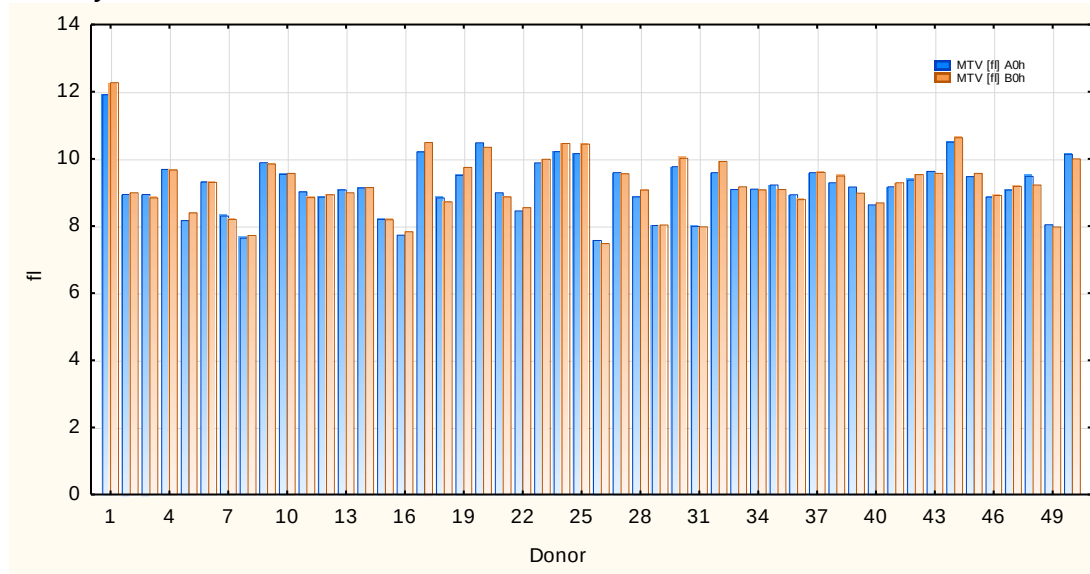
Pathological donors



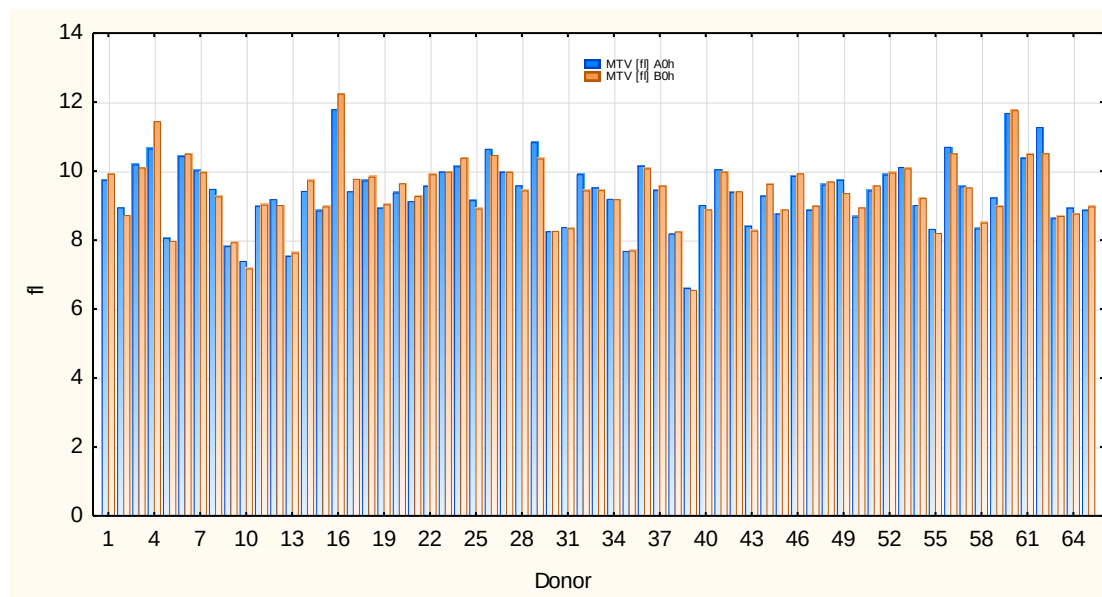
Mean platelet volume (MTV)

Normal range: 7-12 fl

Healthy donors



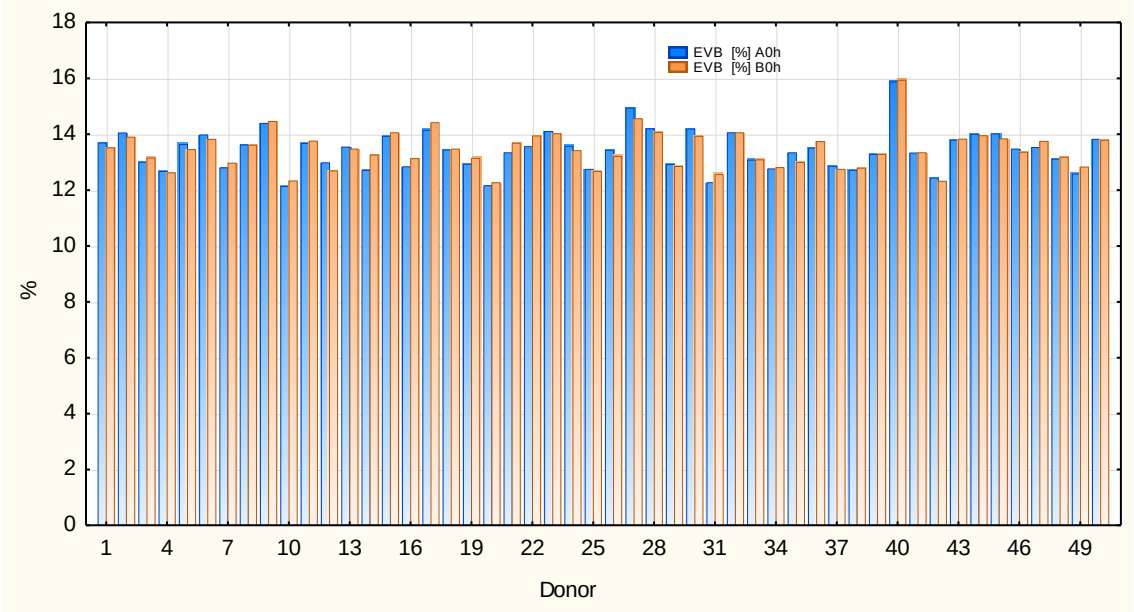
Pathological donors



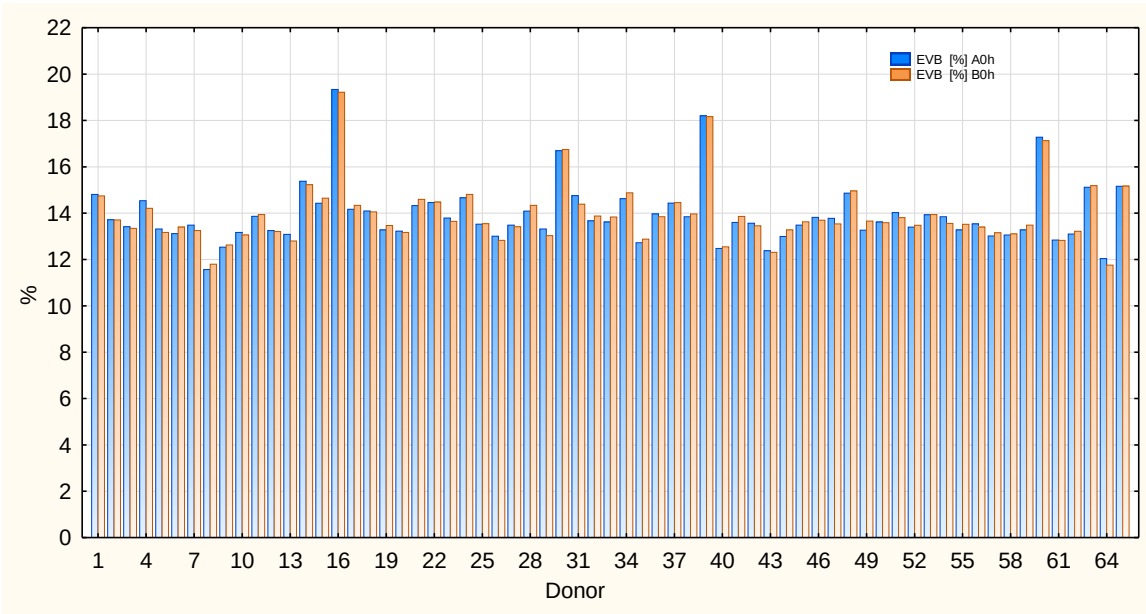
Red cell distribution with (RDW)

Normal range: 12.9-18.7 %

Healthy donors



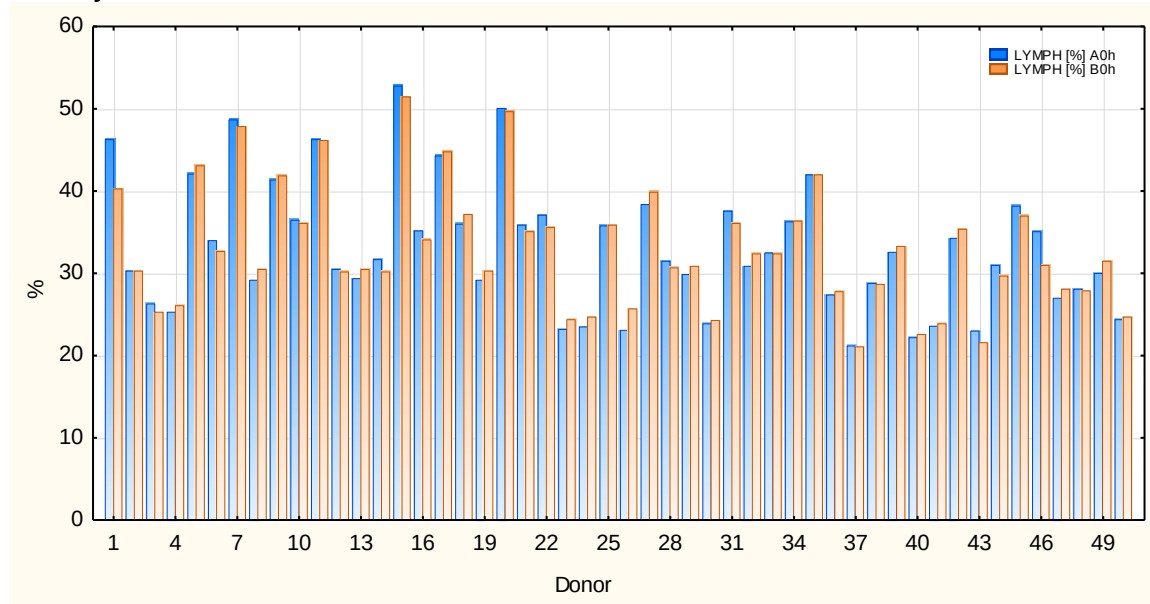
Pathological donors



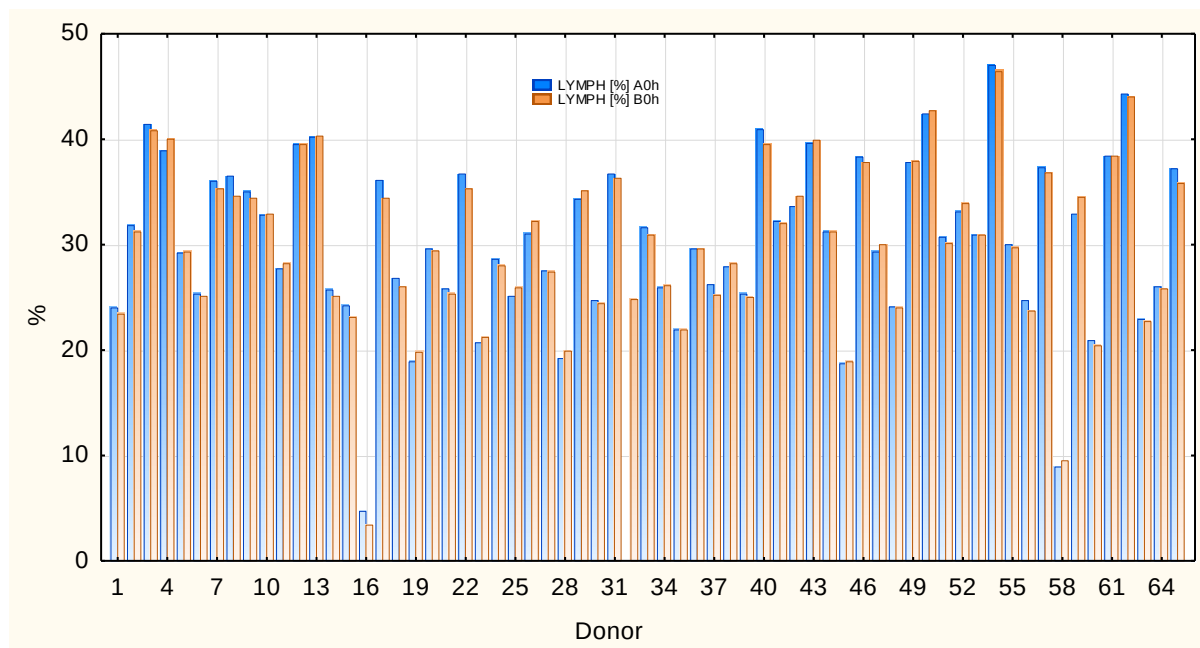
Lymphocytes

Normal range: 20-40 %

Healthy donors



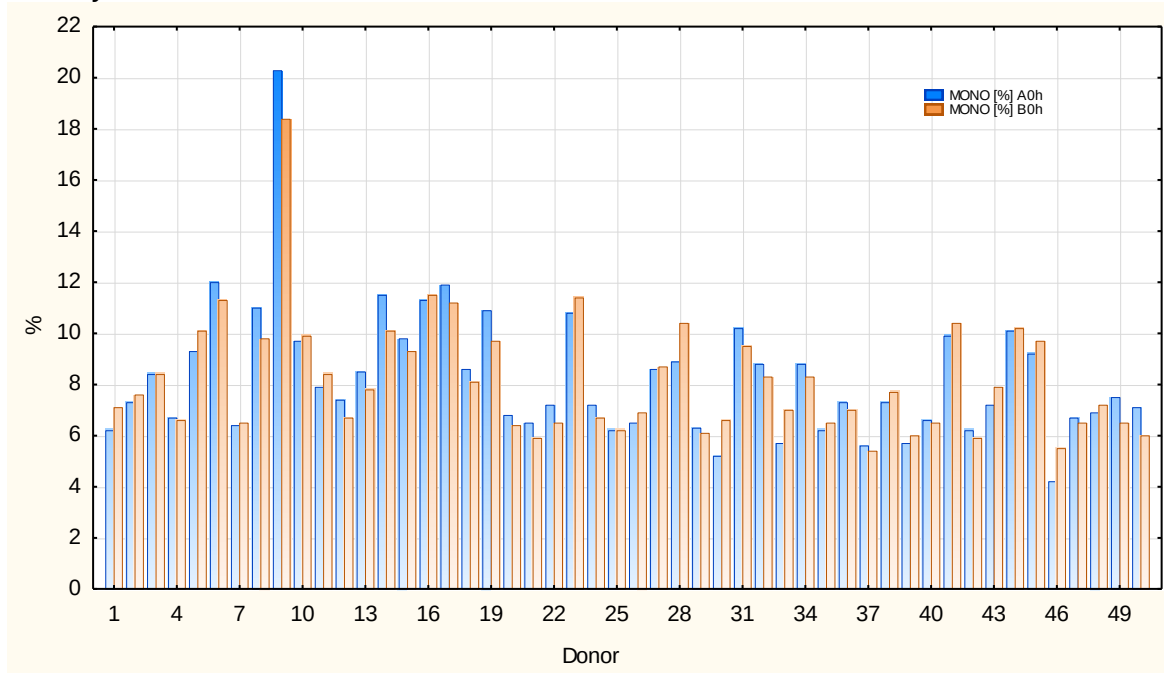
Pathological donors



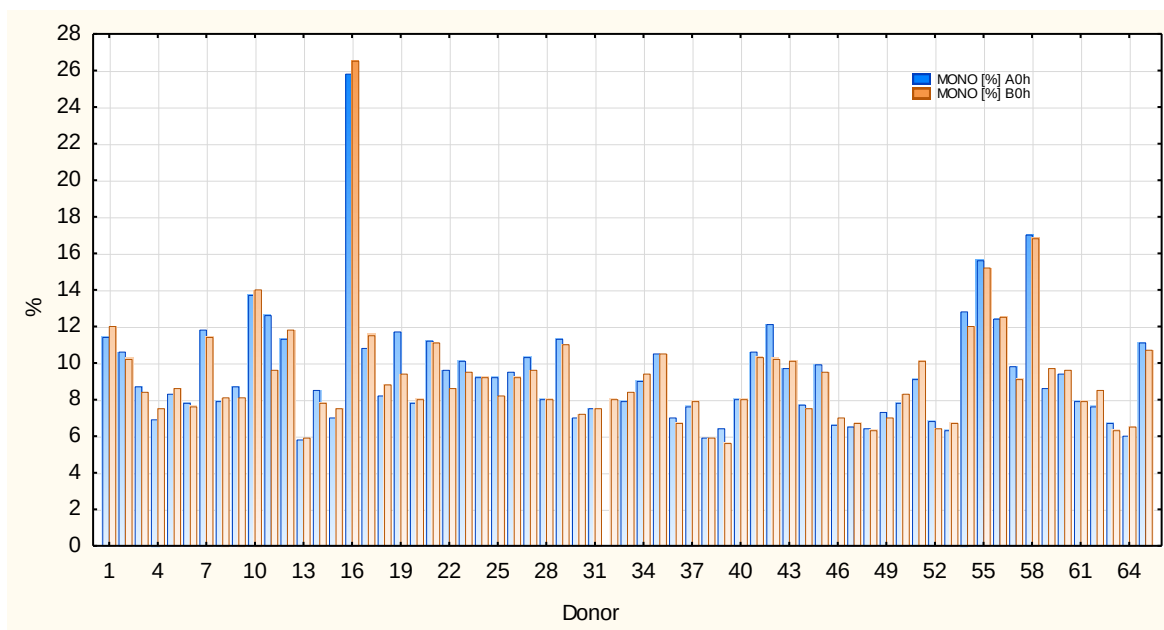
Monocytes

Normal range: 2-10 %

Healthy donors



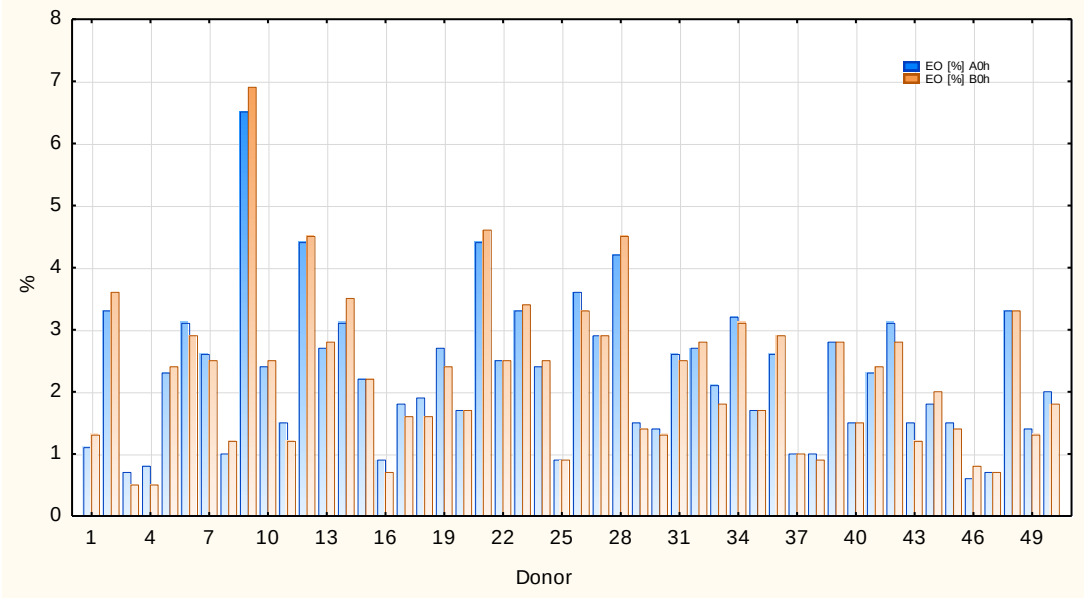
Pathological donors



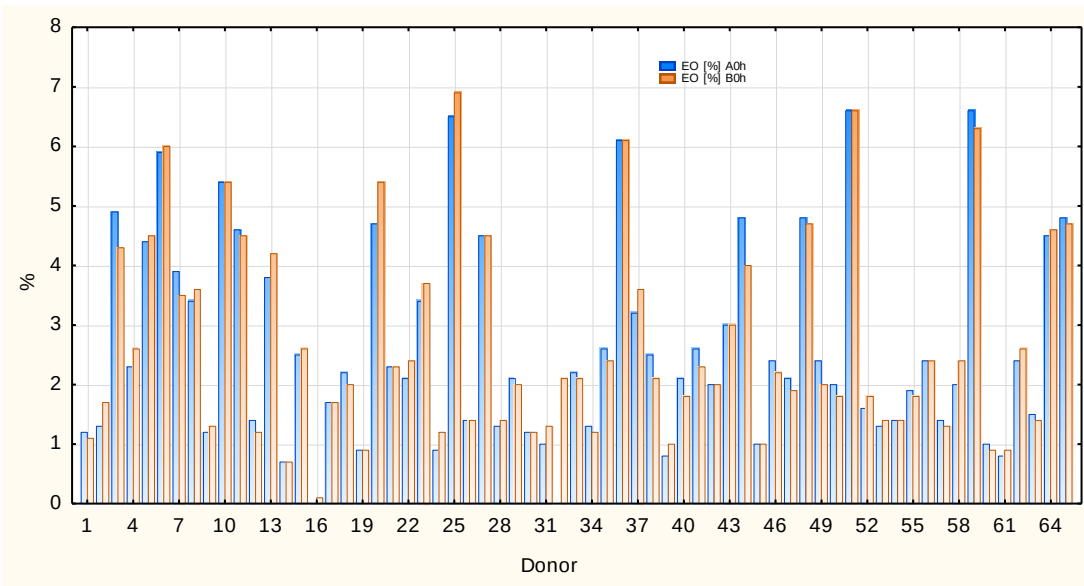
Eosinophile Granulocytes

Normal range: 1-4 %

Healthy donors



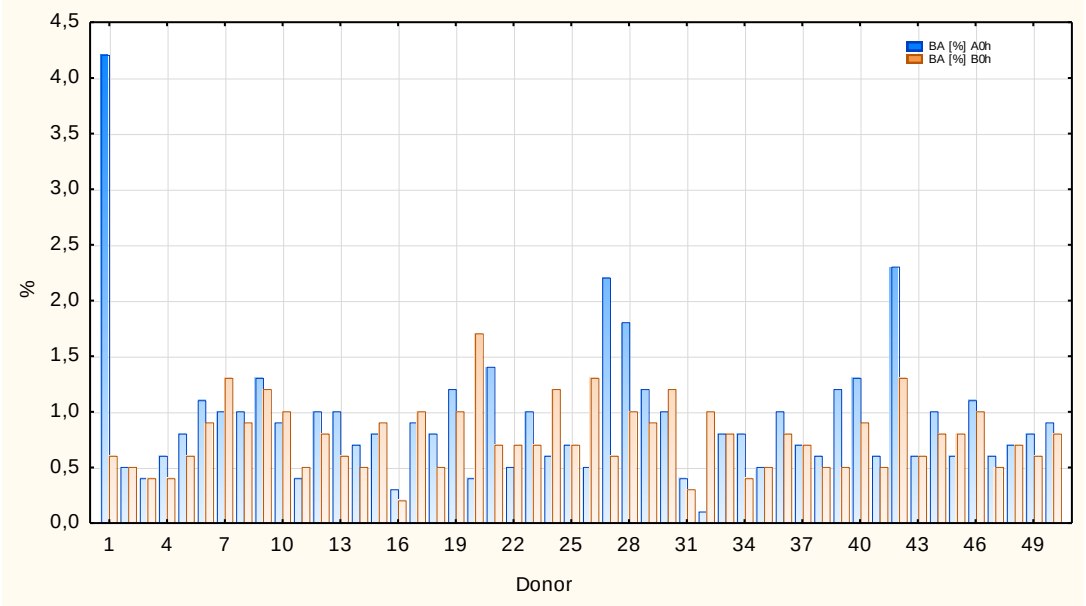
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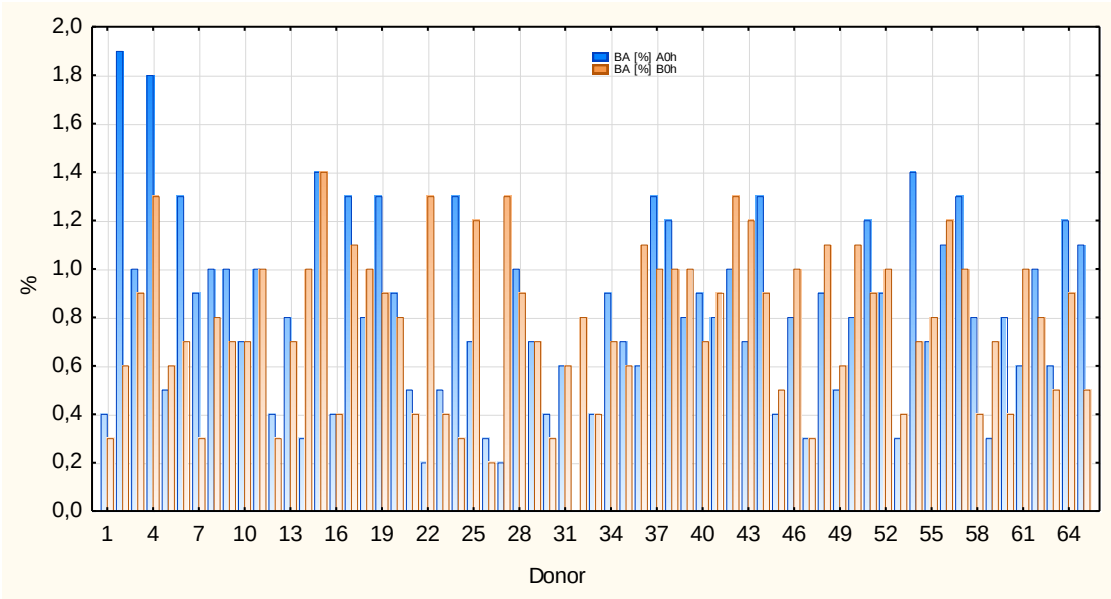
Basophile Granulocytes

Normal range: 0-1 %

Healthy donors

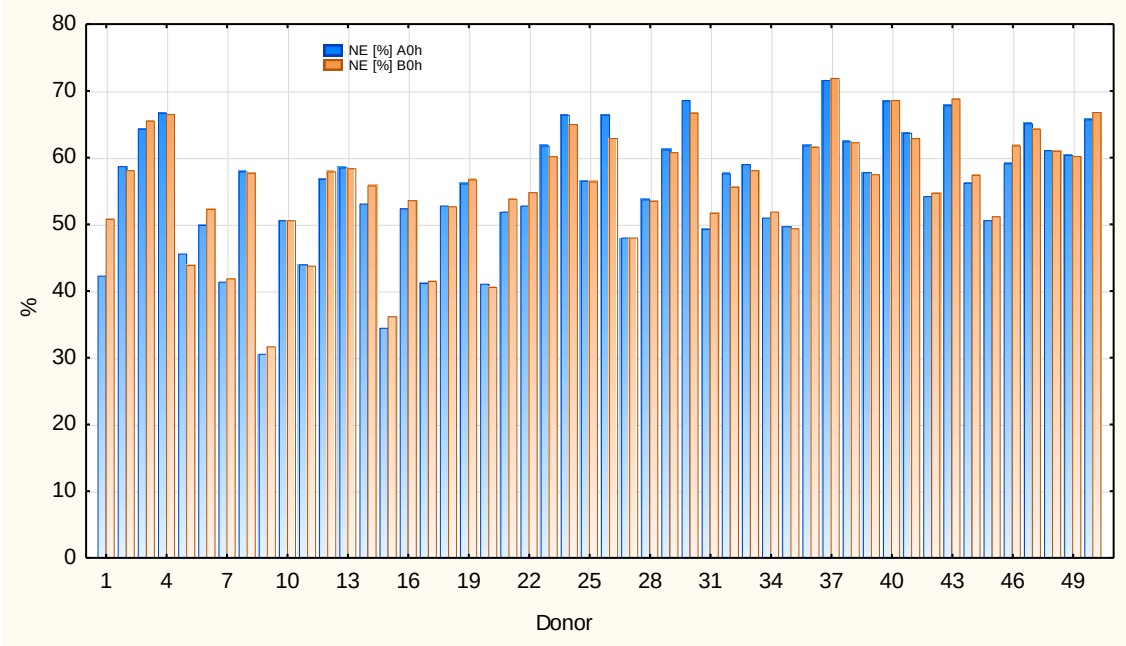


Pathological donors



Neutrophiles

Normal range: 55-75%
Healthy donors



Pathological donors

