

Evaluation of new **MiniCollect®** K3E K₃EDTA 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® K₃EDTA capillary blood collection tube is also featured with a co-molded cap which can easily be removed during the collection and sampling process. For analysis on instrumentation, the cap can also be pierced.

The interior of the MiniCollect® K₃EDTA tube wall is coated with tripotassium EDTA (K₃EDTA).

MiniCollect® K₃EDTA 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® K₃EDTA tube in comparison to the old design of MiniCollect® K₃EDTA tube including 50 healthy and 64 pathological donors.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	MiniCollect® K3E K ₃ EDTA 0.5 ml (item No.: 450475), old design
B	MiniCollect® K3E K ₃ EDTA 0.25-0.5 ml (item No.: 450530), 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® K3E K₃EDTA tube with the co-molded cap and integrated scoop has been demonstrated in comparison to the old MiniCollect® K3E K₃EDTA tube on the basis of the analytes tested.

Results for healthy donors:

A slight systematic deviation to higher WBCs has been found in the new MiniCollect® tube and isolated deviations in the white blood cell sub groups resulting most likely from an automated measurement procedure partly leading to separation of the whole blood specimen.

Results for pathological donors:

Two independent subjects have shown analytically significant deviations regarding WBC and RBC but still in a clinically acceptable range. The correlation between the samples was $r = 0.99$. Neither systematic deviation nor statistically significant differences have been observed either for WBC or RBC.

One donor has shown an analytical deviation during measurement of thrombocytes. Due to this single case event, an analyzer error cannot be ruled out. Nevertheless, in this case a clinical misinterpretation can be excluded.

Statistically significant deviations have been found in the measurement of neutrophile granulocytes (main population of leukocytes) without clinical significance (mean difference was in a clinical acceptable range).

A high distribution of basophile granulocytes has been observed in both samples. No statistically significant deviation has been found between both samples.

In summary, despite the deviations and results that have been found, the MiniCollect® K3E K₃EDTA with the new design is substantially equivalent to the MiniCollect® K3E K₃EDTA with the old design.

References:

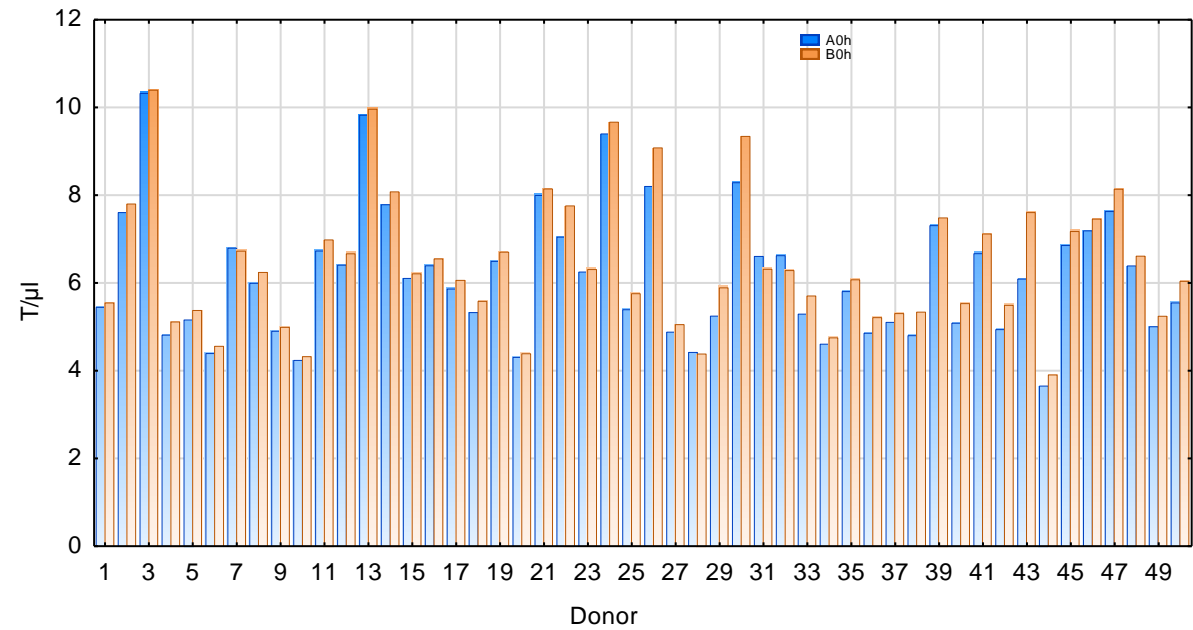
- (1) Greiner Bio-One. MiniCollect® K3E K₃EDTA Tubes. Instructions for Use. Kremsmünster, Austria. 2016.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.
- (3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning the 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:

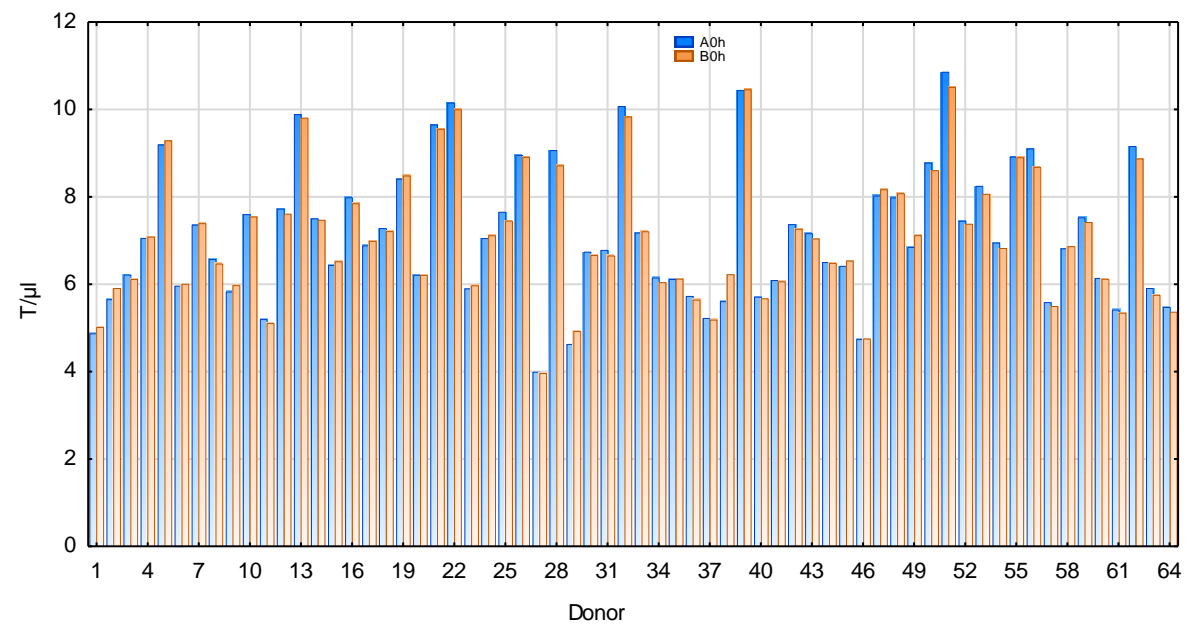
Leucocytes (WBC)

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

Healthy donors

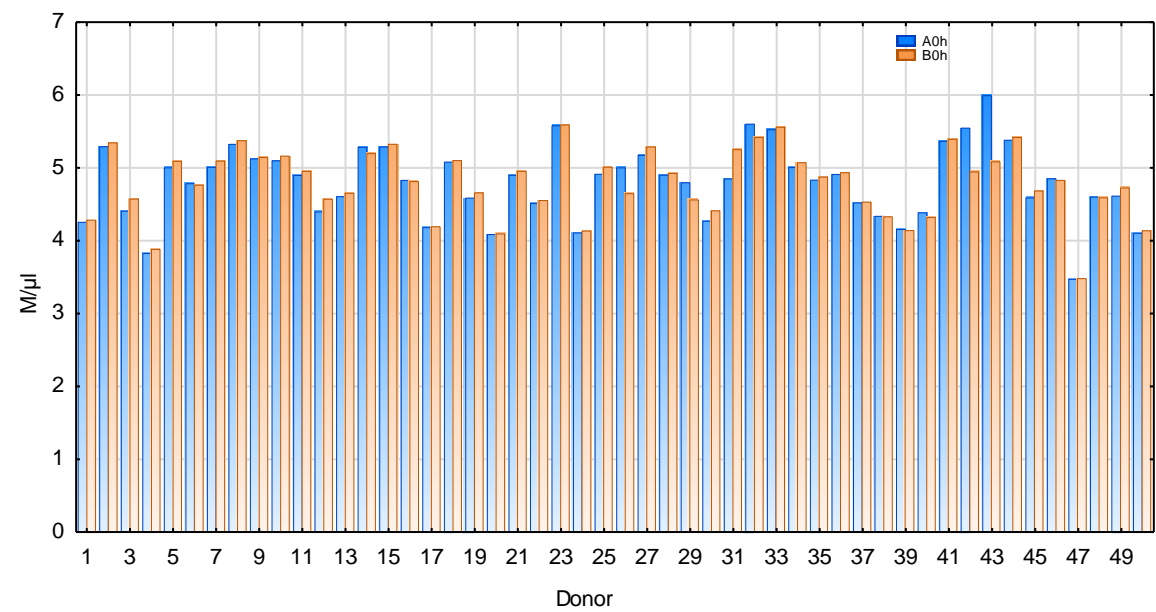


Pathological donors

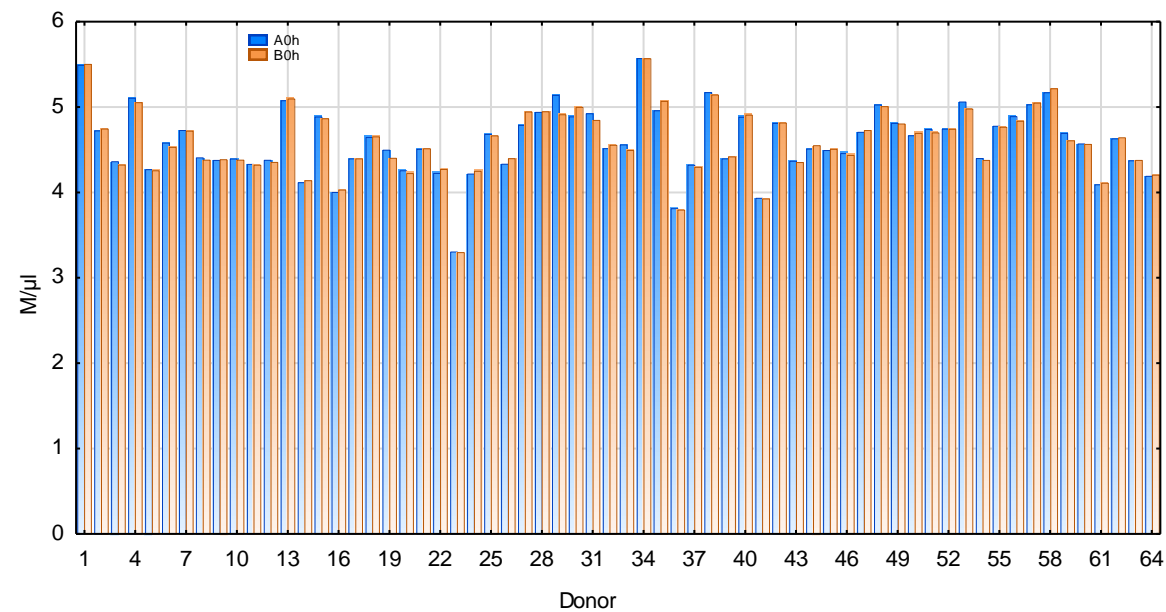


Erythrocytes (RBC)

Normal range: 4.4 - 5.9 T/l
Healthy donors



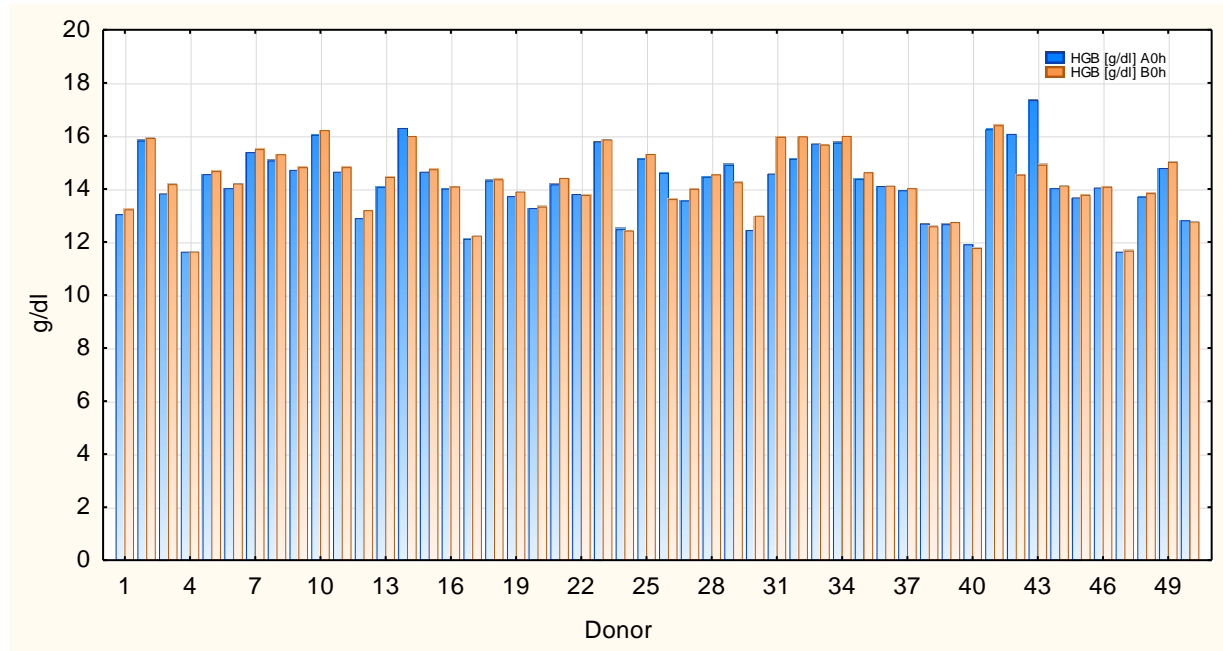
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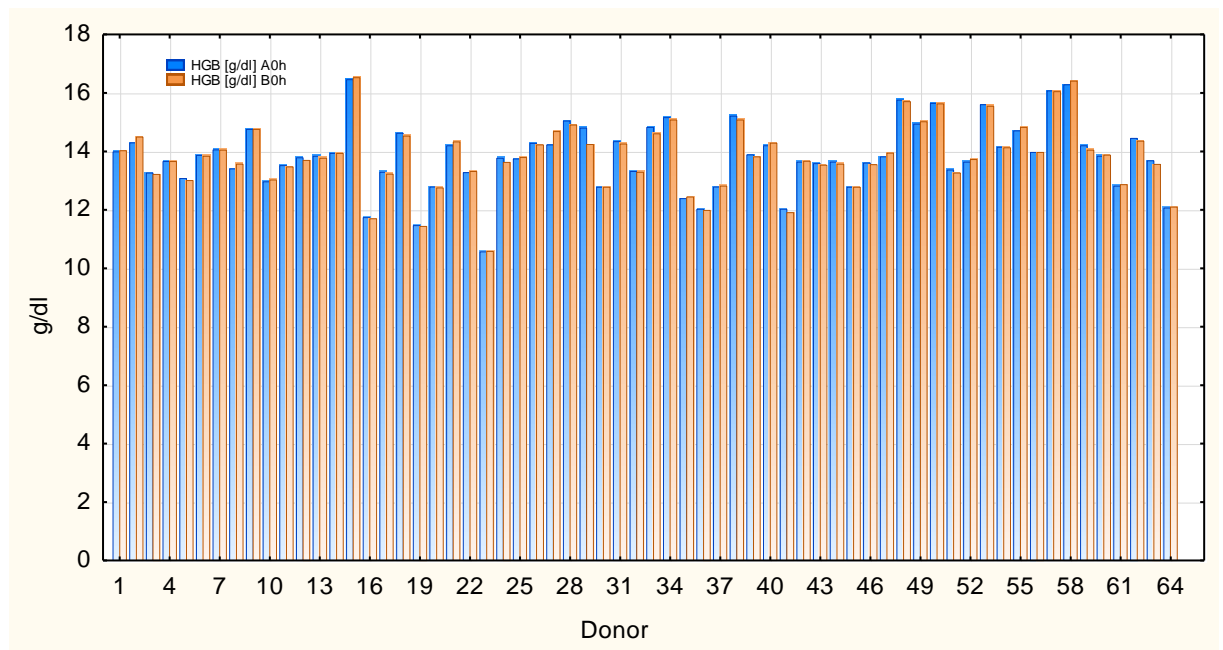
Hemoglobin

Normal range: 13-18 g/dl

Healthy donors



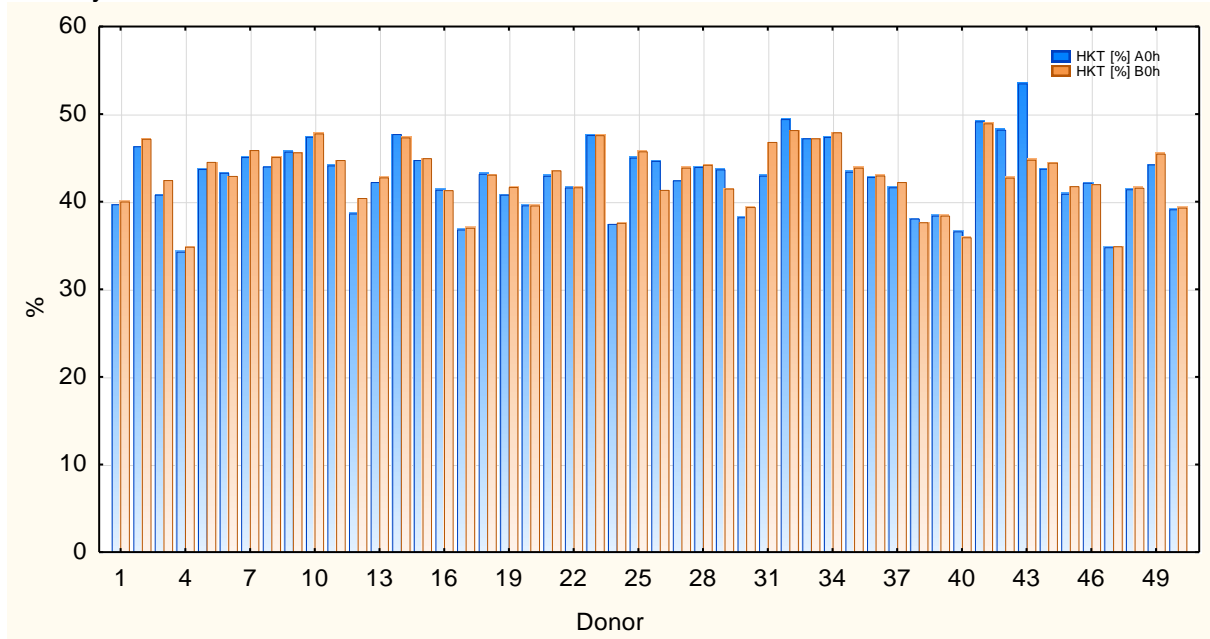
Pathological donors



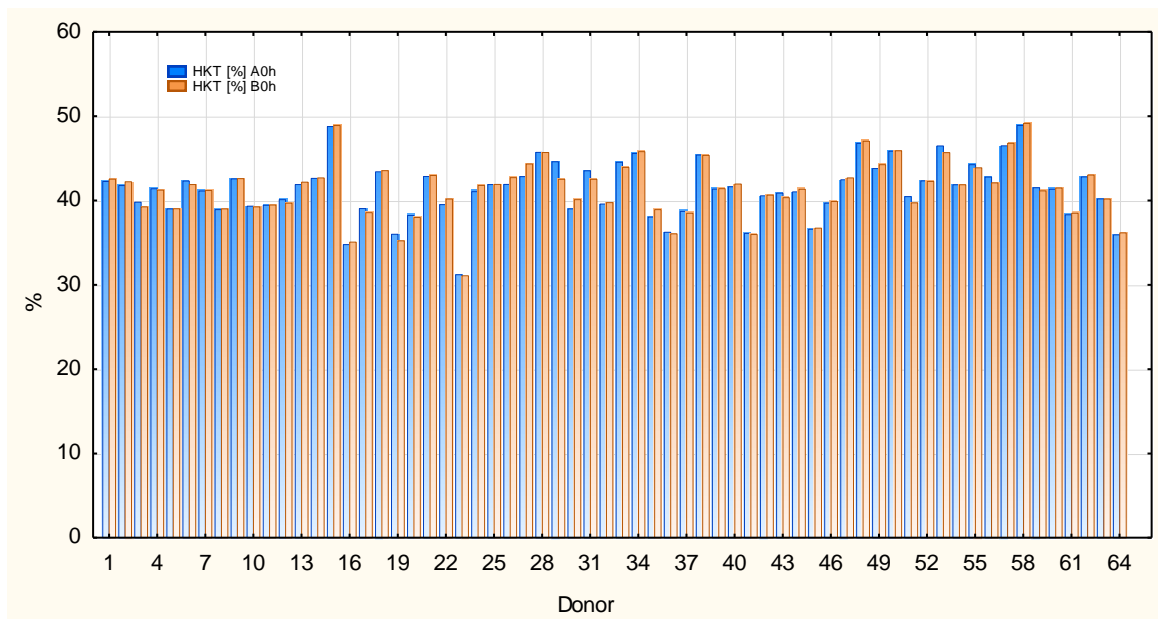
Hematocrit

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

Healthy donors



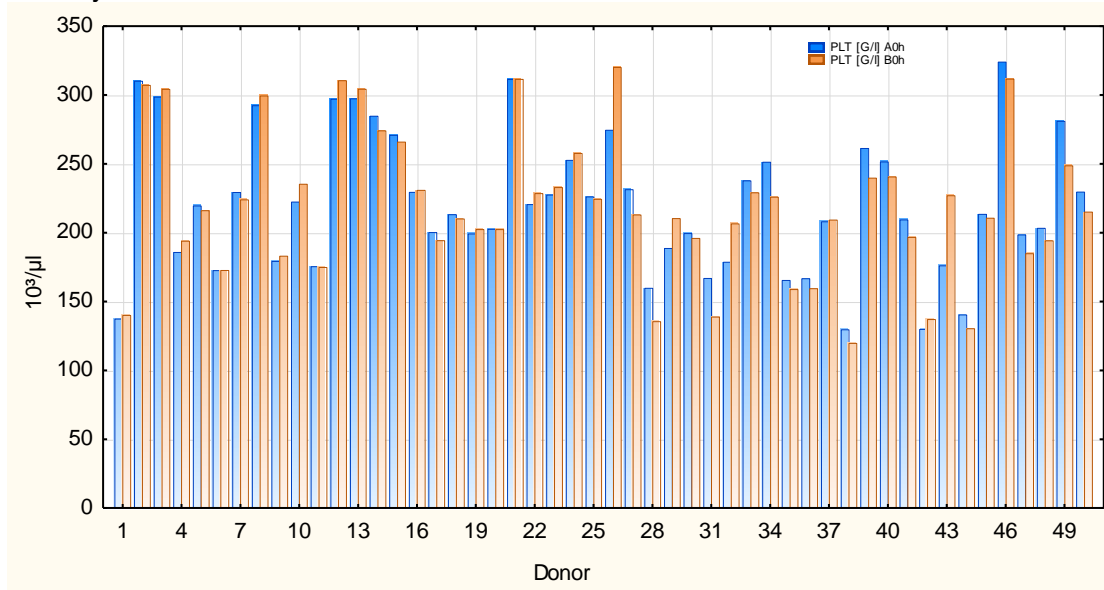
Pathological donors



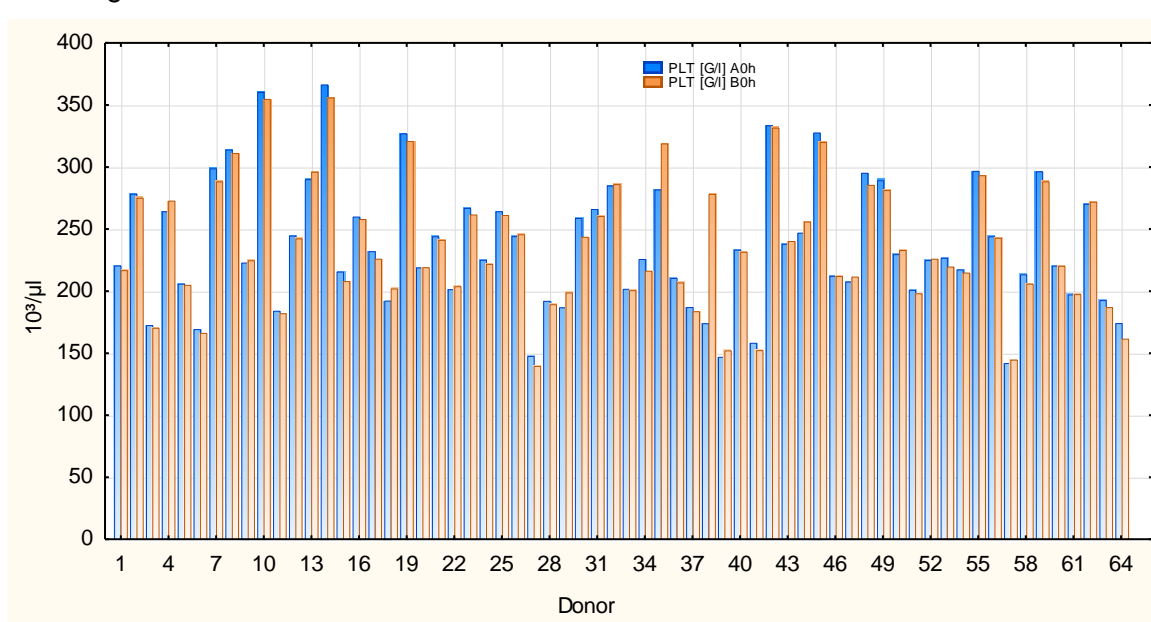
Thrombocytes (platelets)

Normal range: $10^9/l$

Healthy donors



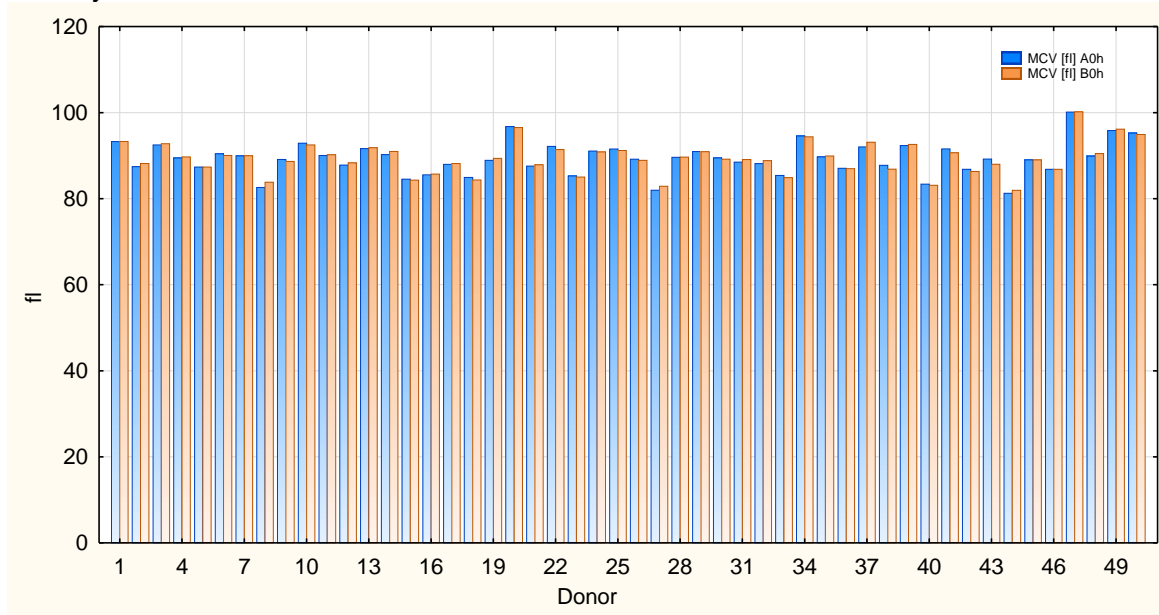
Pathological donors



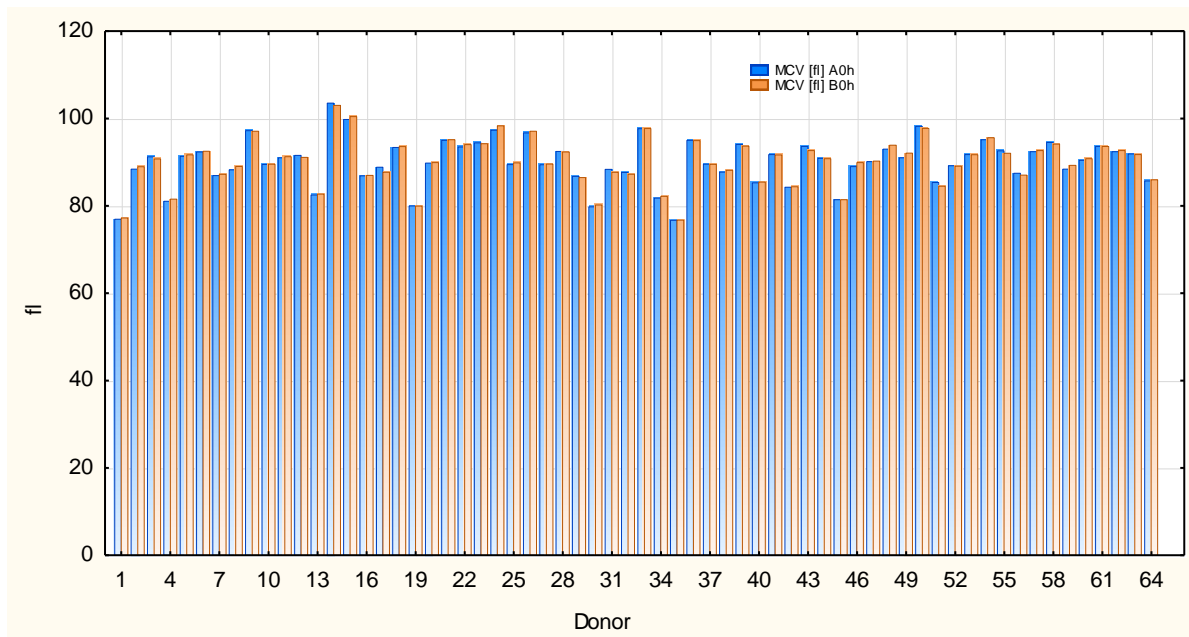
Mean cellular volume (MCV)

Normal range: 50 - 150 fL

Healthy donors



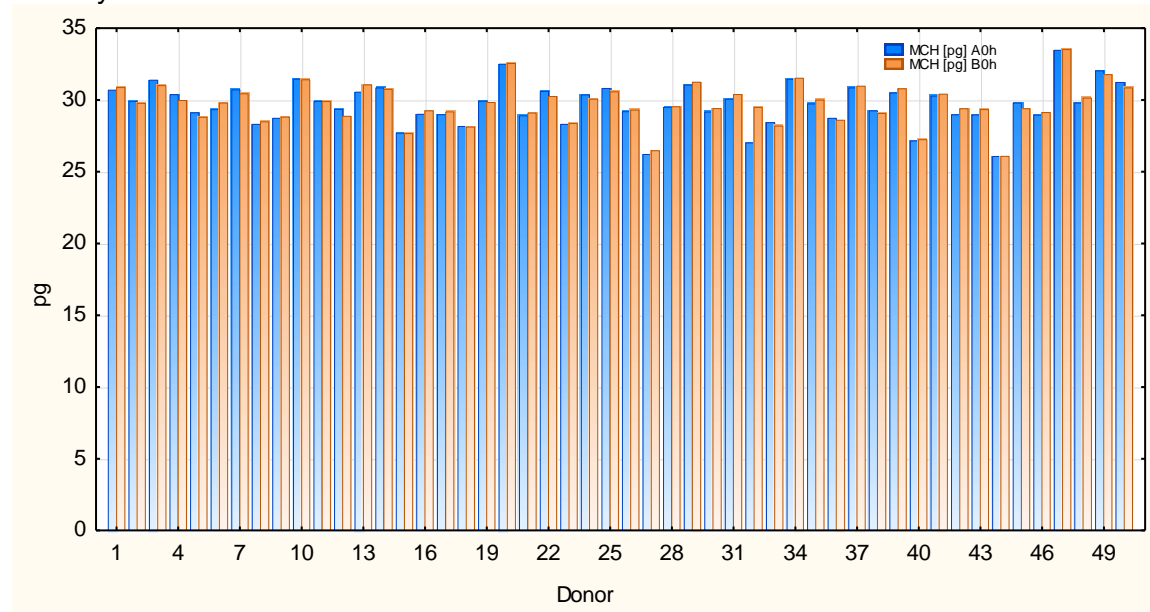
Pathological donors



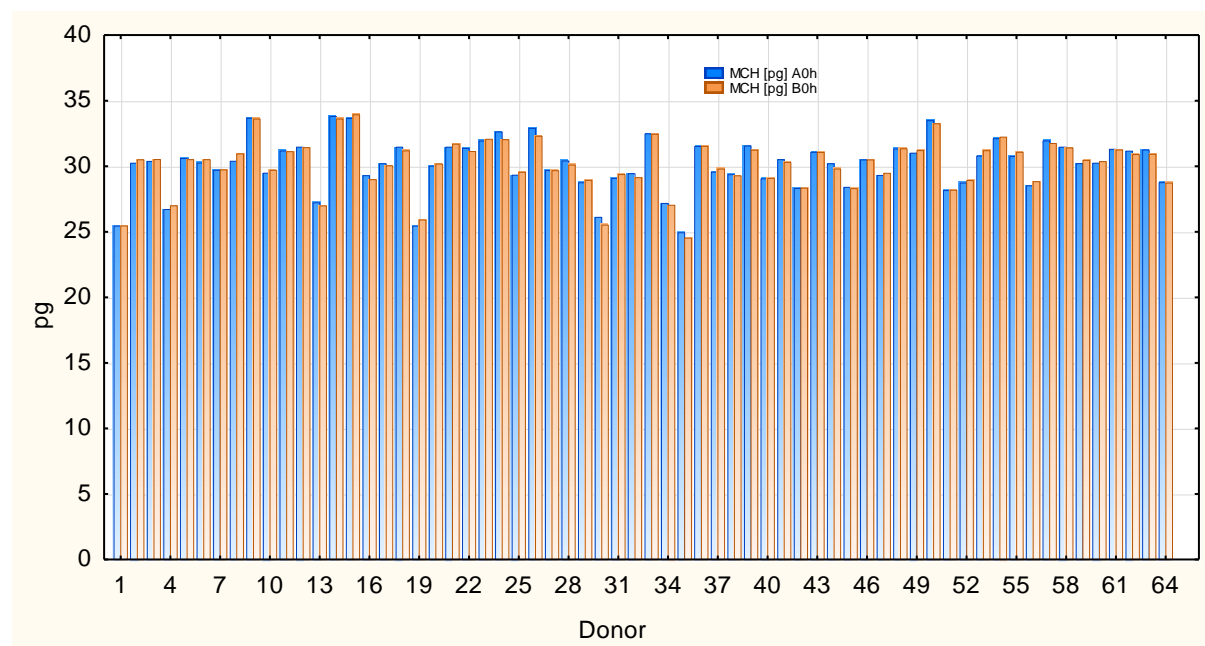
Mean Corpuscular Hemoglobin (MCH)

Normal range: 27 - 35 pg

Healthy donors



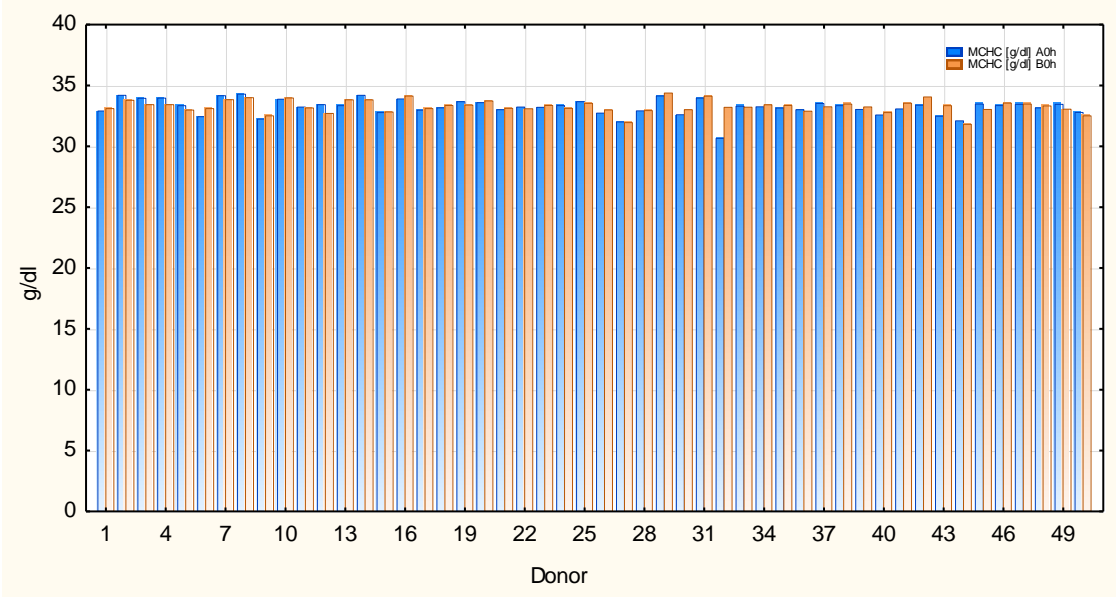
Pathological donors



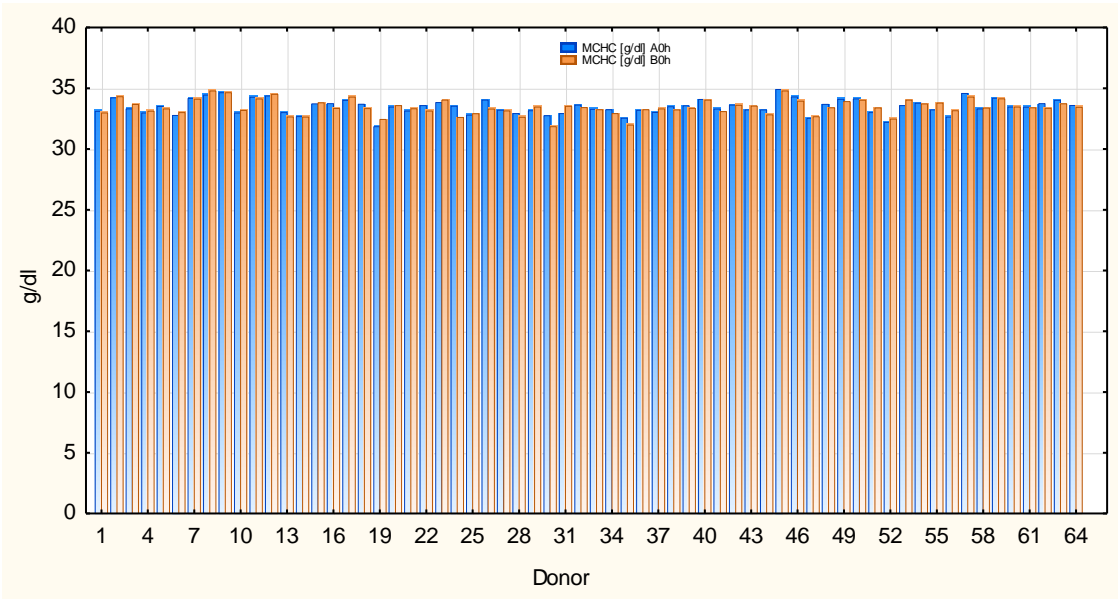
Mean Corpuscular Hemoglobin Concentration (MCHC)

Normal range: 29-36 g/dl

Healthy donors



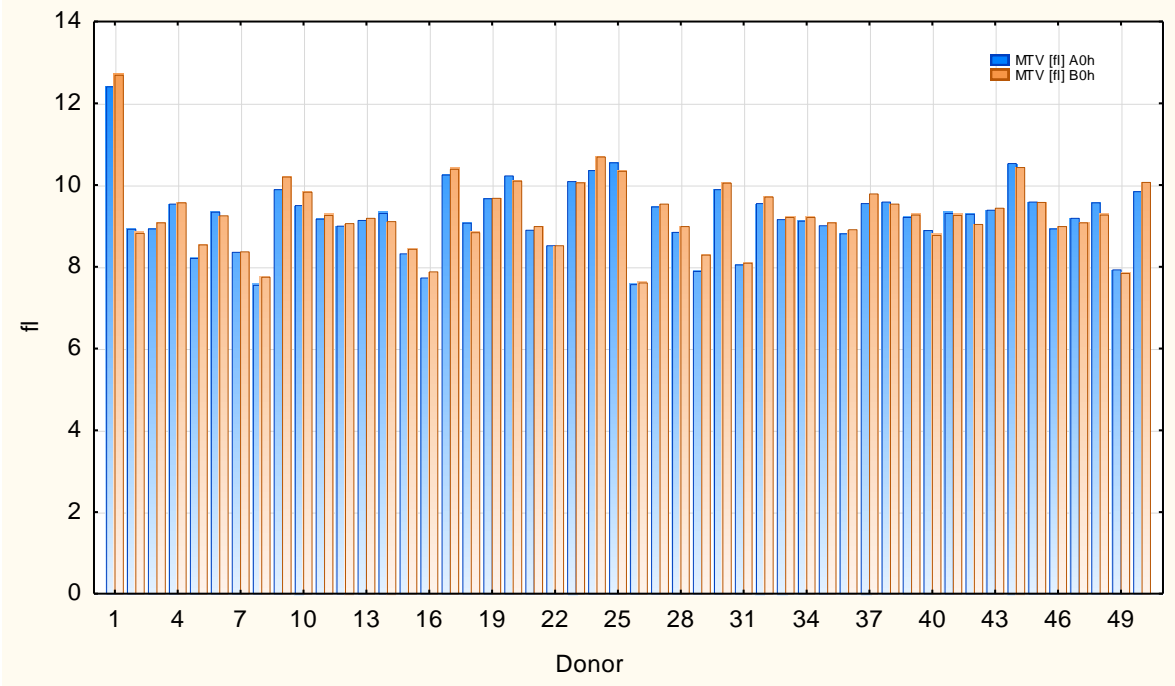
Pathological donors



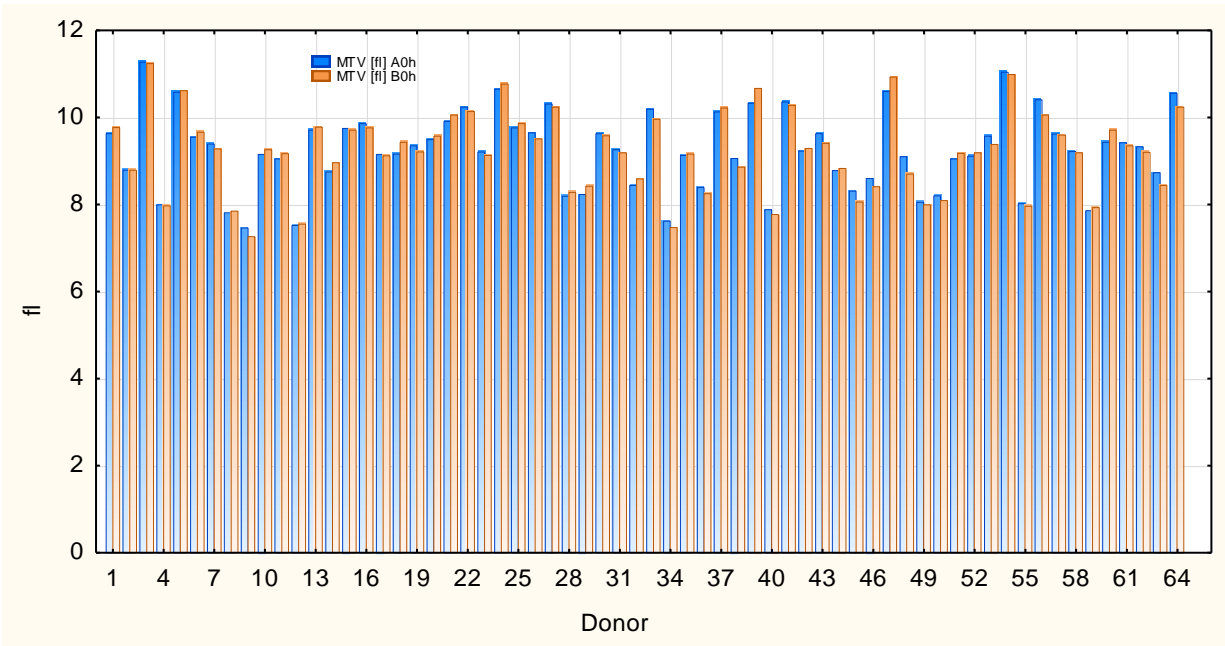
Mean platelet volume (MTV)

Normal range: 7-12 fl

Healthy donors



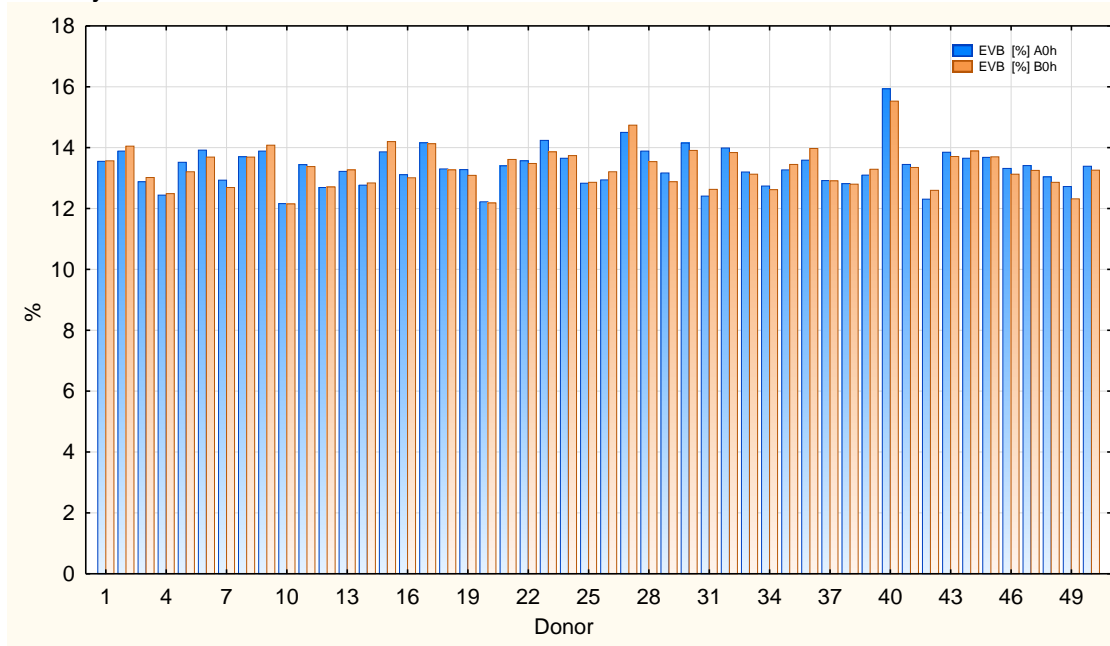
Pathological donors



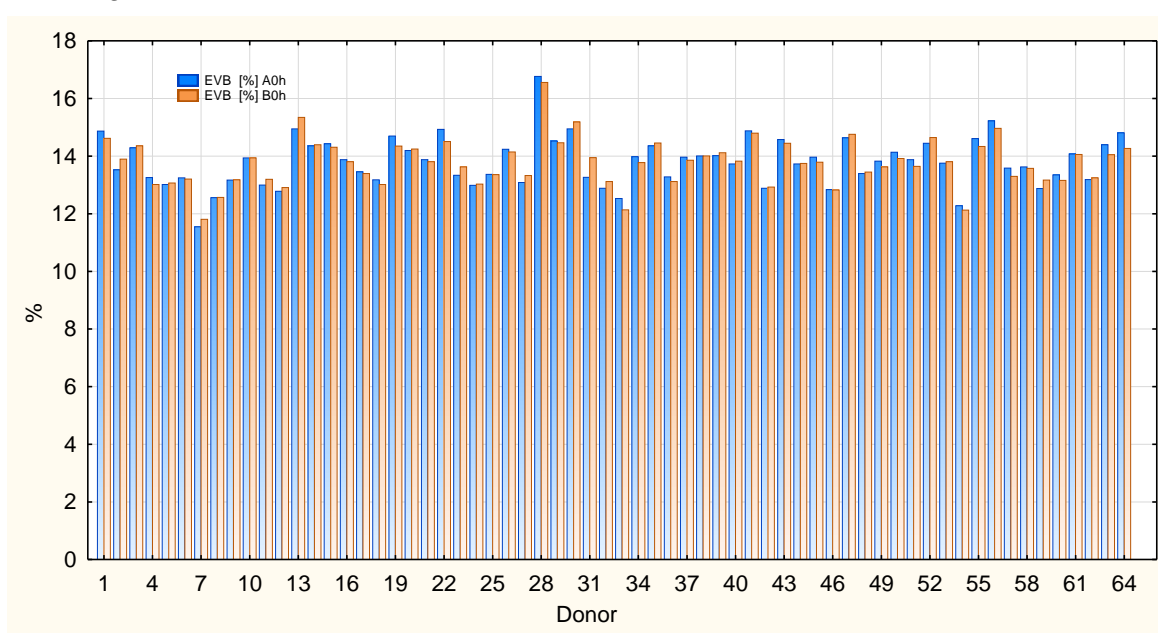
Red cell distribution with (RDW)

Normal range: 12.9-18.7 %

Healthy donors



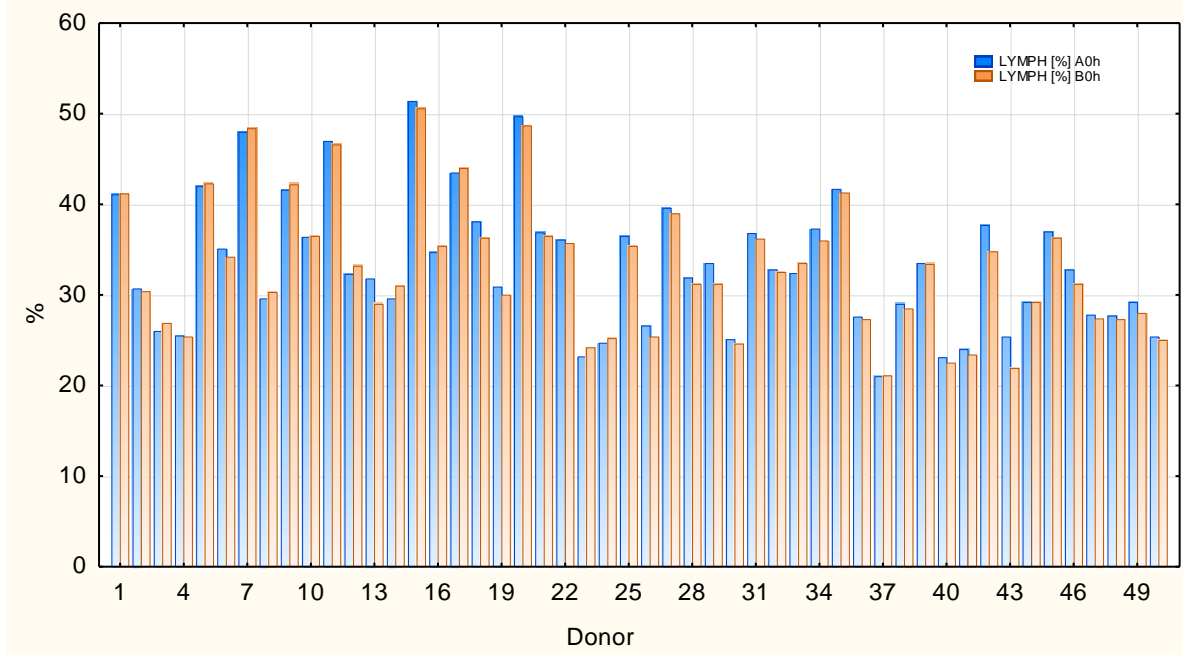
Pathological donors



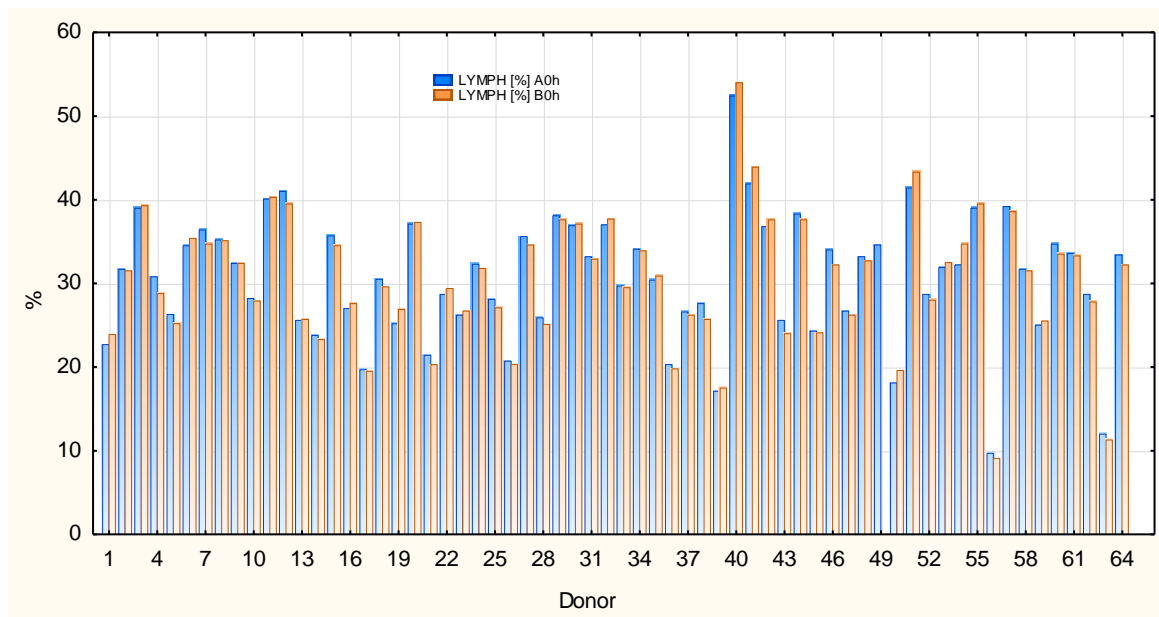
Lymphocytes

Normal range: 20-40 %

Healthy donors



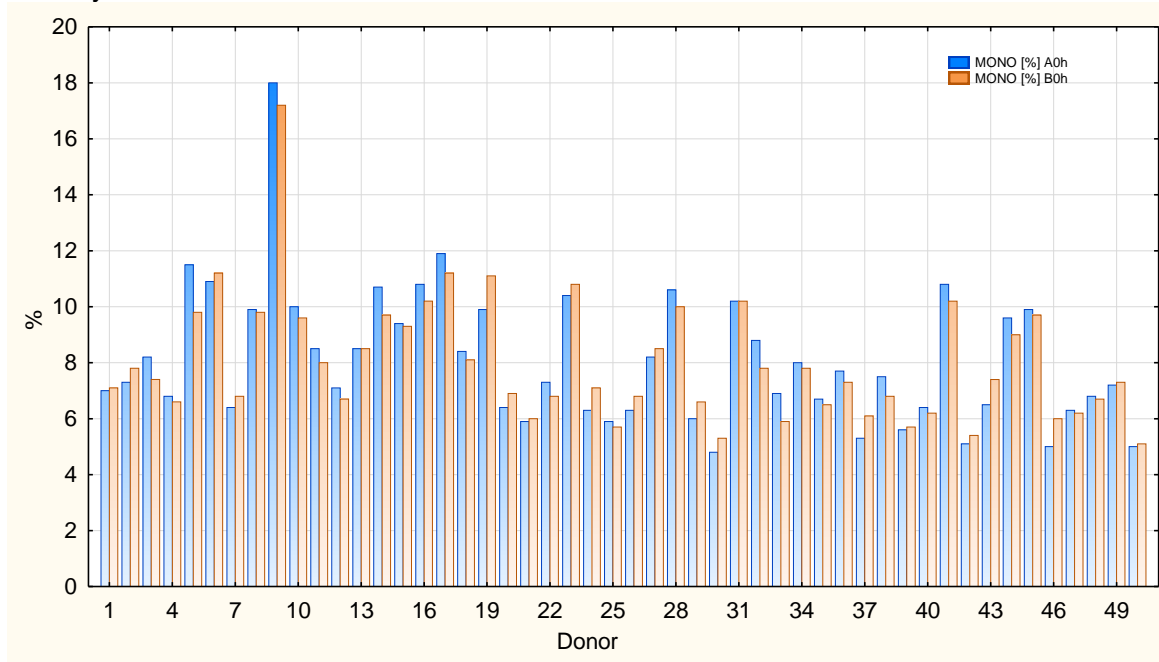
Pathological donors



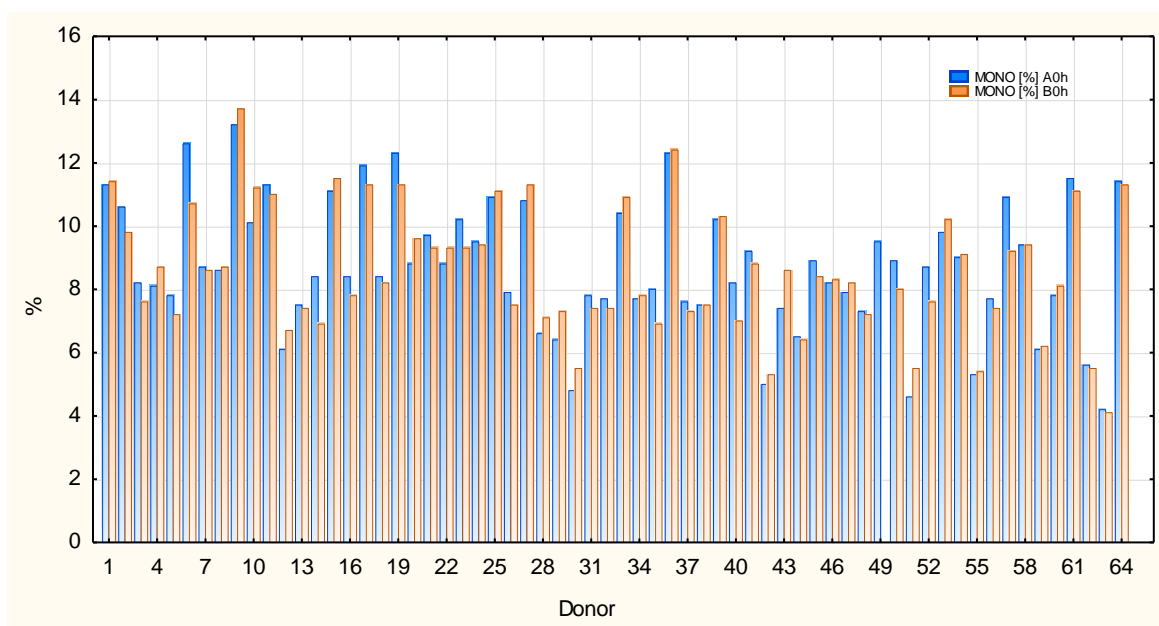
Monocytes

Normal range: 2-10 %

Healthy donors



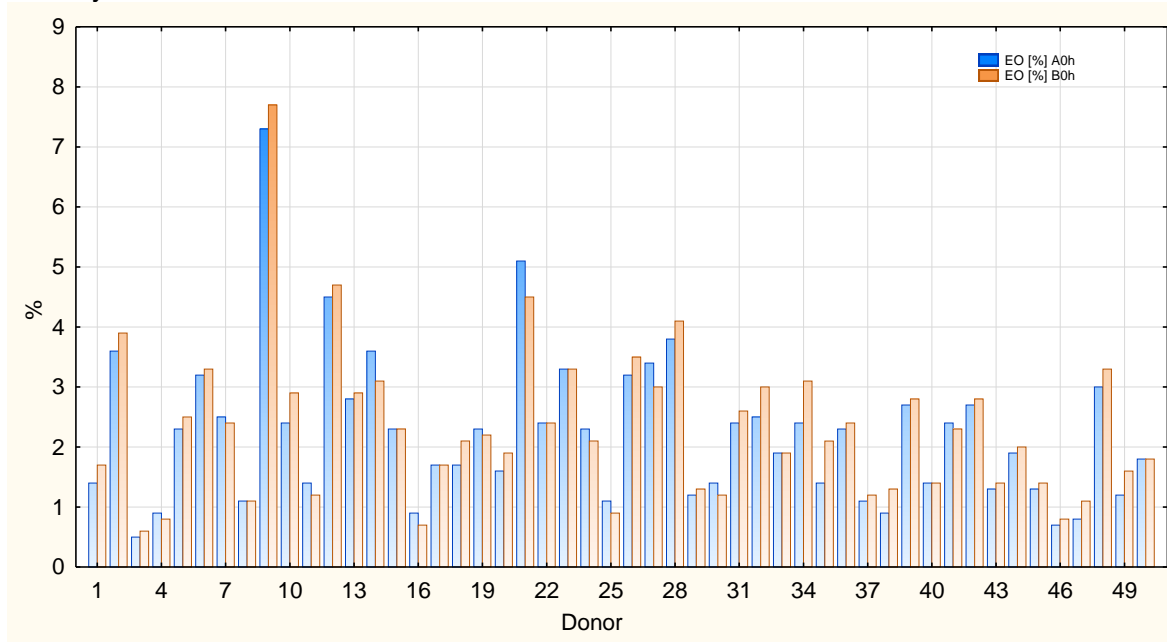
Pathological donors



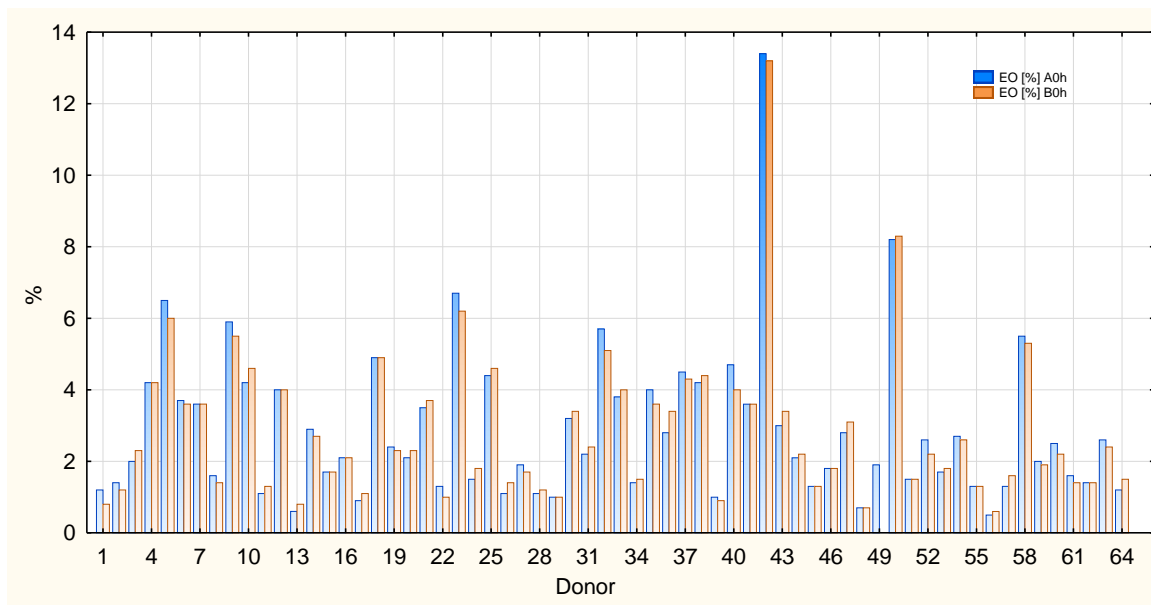
Eosinophile Granulocytes

Normal range: 1-4 %

Healthy donors



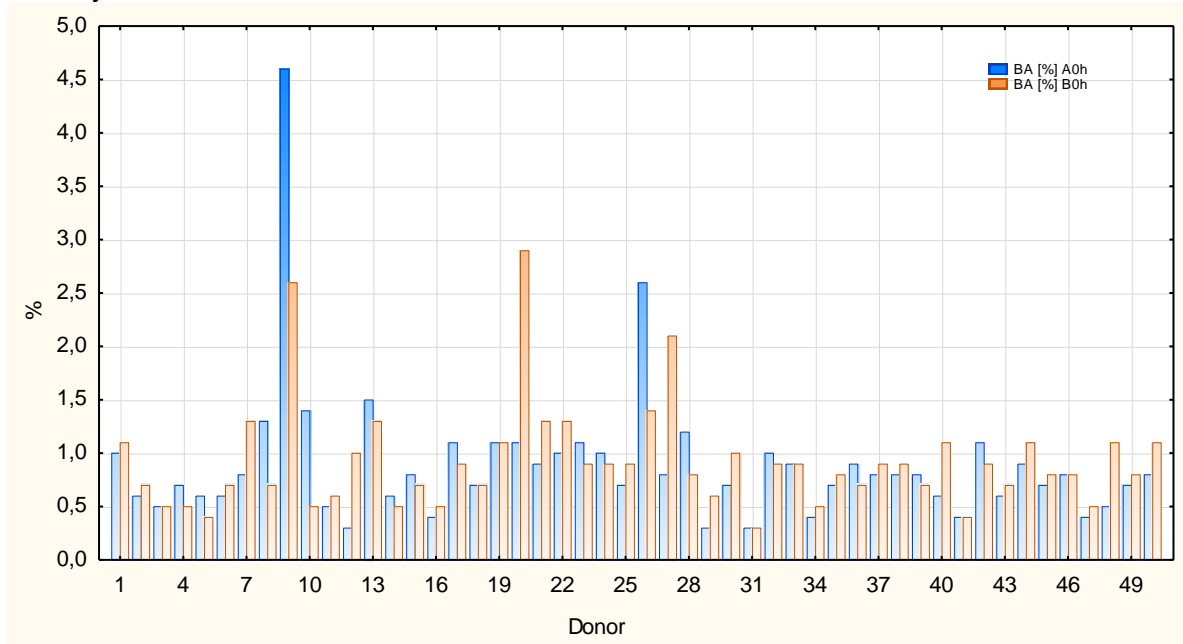
Pathological donors



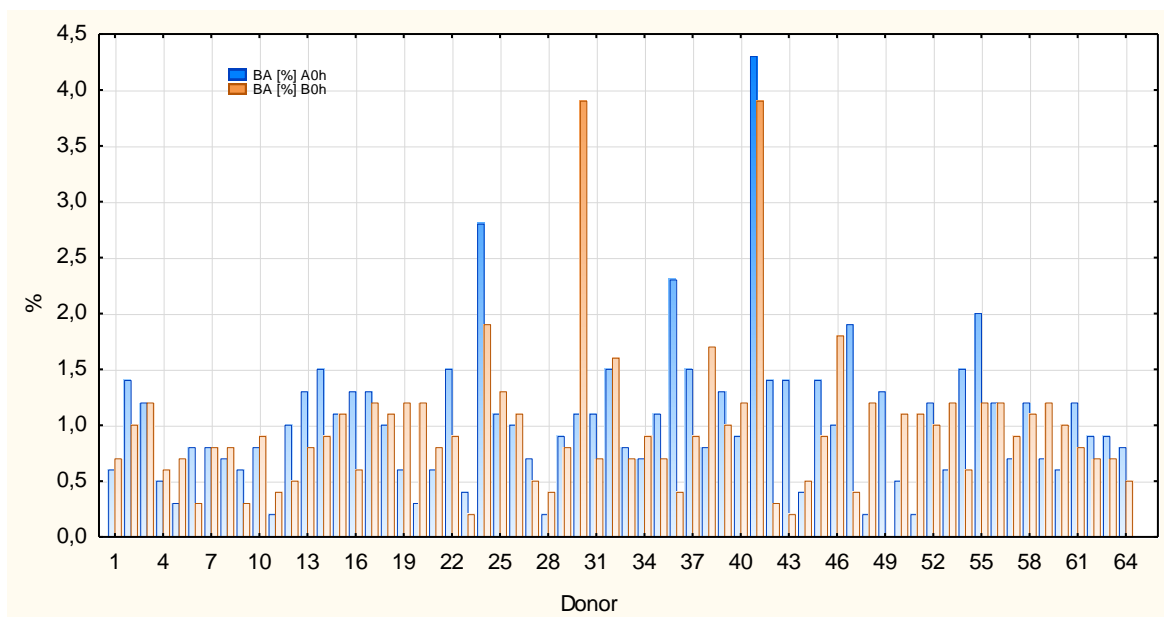
Basophile Granulocytes

Normal range: 0-1 %

Healthy donors



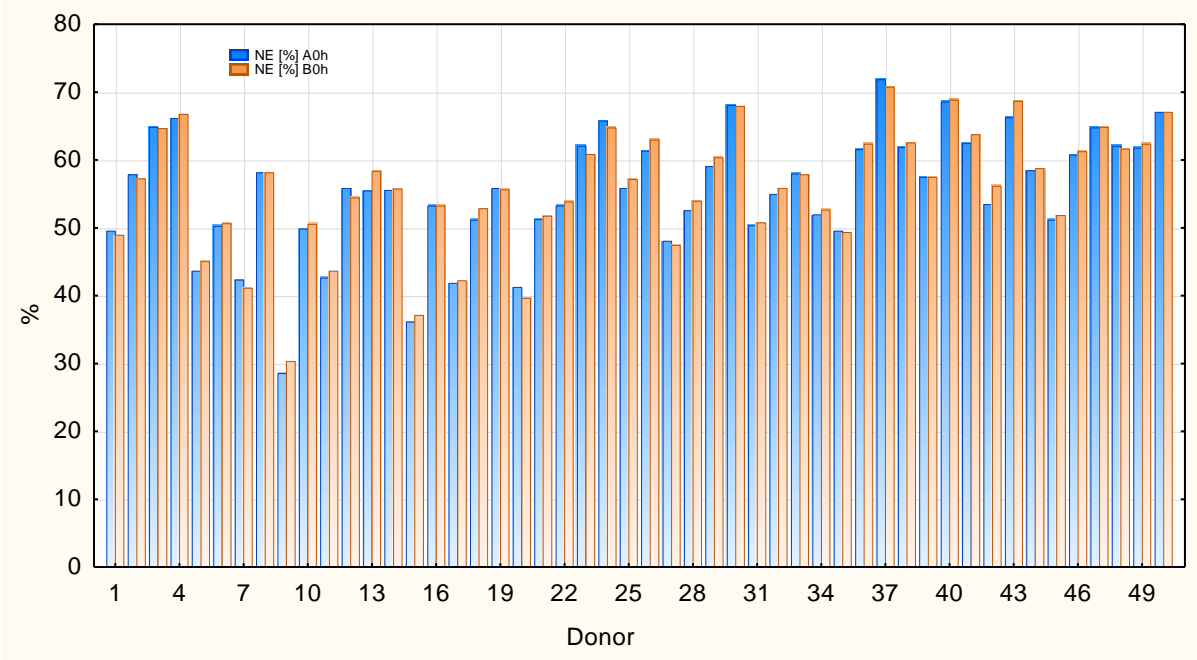
Pathological donors



Neutrophile Granulocytes

Normal range: 55-75%

Healthy donors



Pathological donors

