

Evaluation of new **MiniCollect**[®] 9NC Coagulation Tubes

Background:

Venous blood with sodium citrate is the most commonly obtained examination sample for coagulation determinations. The additive functions as an anticoagulant by chelating calcium.

Greiner Bio-One has developed a newly designed MiniCollect[®] 9NC Coagulation tube offering an integrated collection scoop. The MiniCollect[®] 9NC Coagulation blood collection tube is also featured with a colour coded co-molded cap which can easily be removed during the collection and sampling process.

MiniCollect[®] Coagulation tubes are plastic, non-evacuated, sterile low sample volume tubes with a pre-defined nominal volume for achieving correct additive concentrations. The MiniCollect[®] 9NC Coagulation tube wall contains a 3.2% tri-sodium citrate dehydrate/citric acid monohydrate solution in accordance with the requirements of the international standards for evacuated blood collection systems - ISO 6710, CLSI H01-A6.

MiniCollect[®] 9NC Coagulation Tube is intended for collection of citrate anticoagulated whole blood samples for coagulation assays.

Study Objective:

A clinical evaluation was carried out to compare the performance of the MiniCollect[®] 9NC Coagulation tube with new design in comparison to the VACUETTE[®] 9NC Coagulation tube by enrolling 20 healthy donors.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	VACUETTE [®] 9NC Coagulation (3.2%) 1 ml, (item No.: 454320)
B	MiniCollect [®] 9NC Coagulation (3.2%) 1 ml (item No.: 450539), new design

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 5 times according to the instructions for use for MiniCollect[®] blood collection tubes. The tubes were centrifuged within 2h after blood collection in a temperature controlled centrifuge (15-24°C, swing-out bucket, Eppendorf 5415R) for 10 min at 3000g. Analysis was performed on an ACL Top[®] 500 with the instrument's accompanying reagents.

Determined parameters:

- Prothrombin time (PT)
- International normalized ratio (INR)
- Activated partial thromboplastin time (aPTT)
- Fibrinogen
- Factor Anti-Xa

Conclusion:

Performance of the new MiniCollect® 9NC Coagulation tube with integrated scoop and co-molded cap demonstrated equivalent performance to the VACUETTE® 9NC Coagulation tube for the coagulation parameters tested.

aPTT:

Statistically significant deviations ($P < 0.5$) have been found between VACUETTE® 9NC Coagulation tube and MiniCollect® 9NC Coagulation tube with the new design. The deviations between both tubes were not clinically significant. Therefore equivalent performance can be confirmed for MiniCollect® 9NC Coagulation tube with new design and VACUETTE® 9NC Coagulation tube.

Anti-Xa:

Equivalent performance has been demonstrated between all samples. A slight deviation has been found in VACUETTE® tubes compared to MiniCollect® tubes without statistical significance and in a clinically acceptable range.

Fibrinogen:

Equivalent performance has been observed between all samples.

Prothrombin Time (PT, QUICK) and INR:

Statistically significant and systematic deviations have been observed between VACUETTE® 9NC Coagulation tubes and MiniCollect® 9NC Coagulation tubes regarding PT and INR. The difference has been assessed as being clinically not significant.

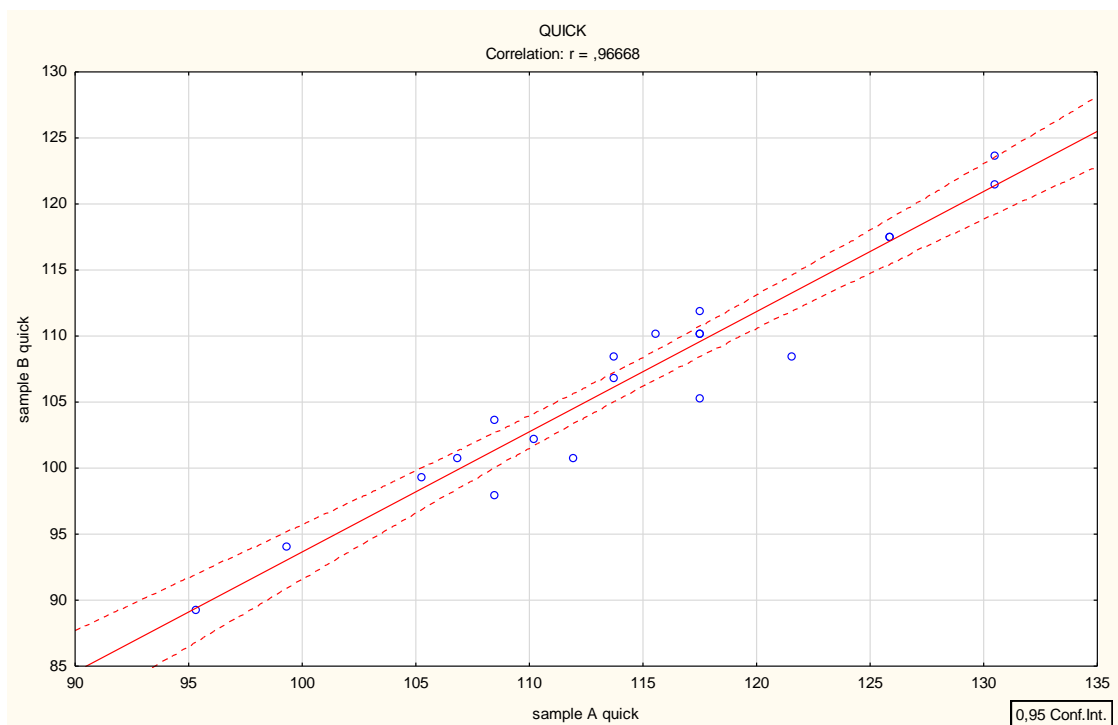
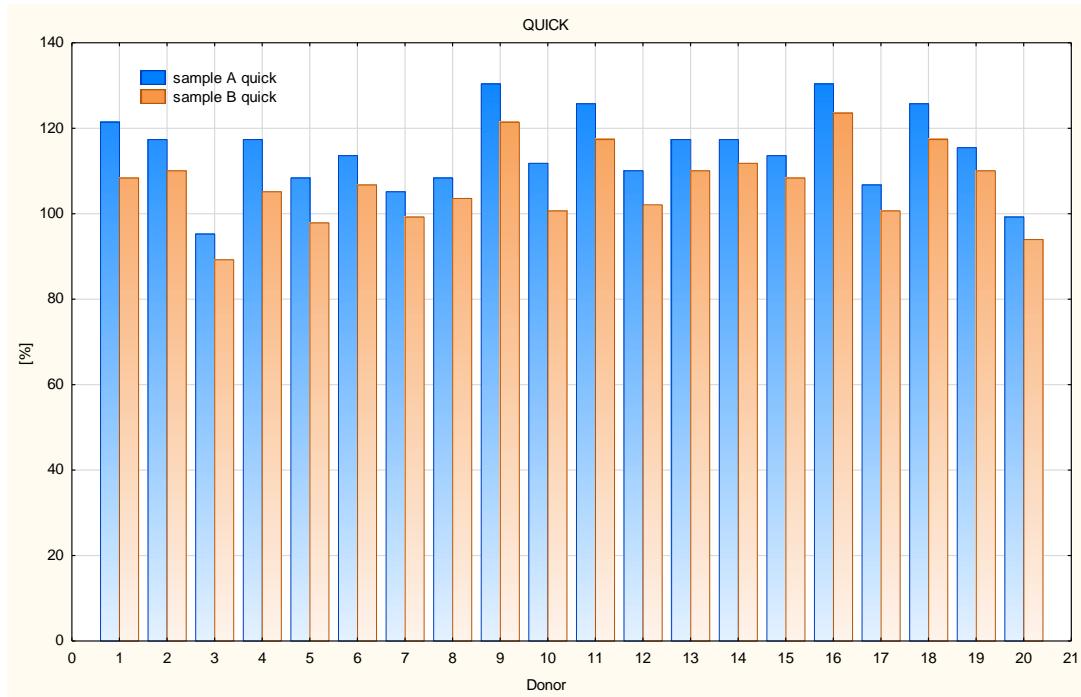
In summary, despite the deviations and results that have been found, the MiniCollect® 9NC Coagulation tube with new design is substantially equivalent to the VACUETTE® 9NC Coagulation tube.

References:

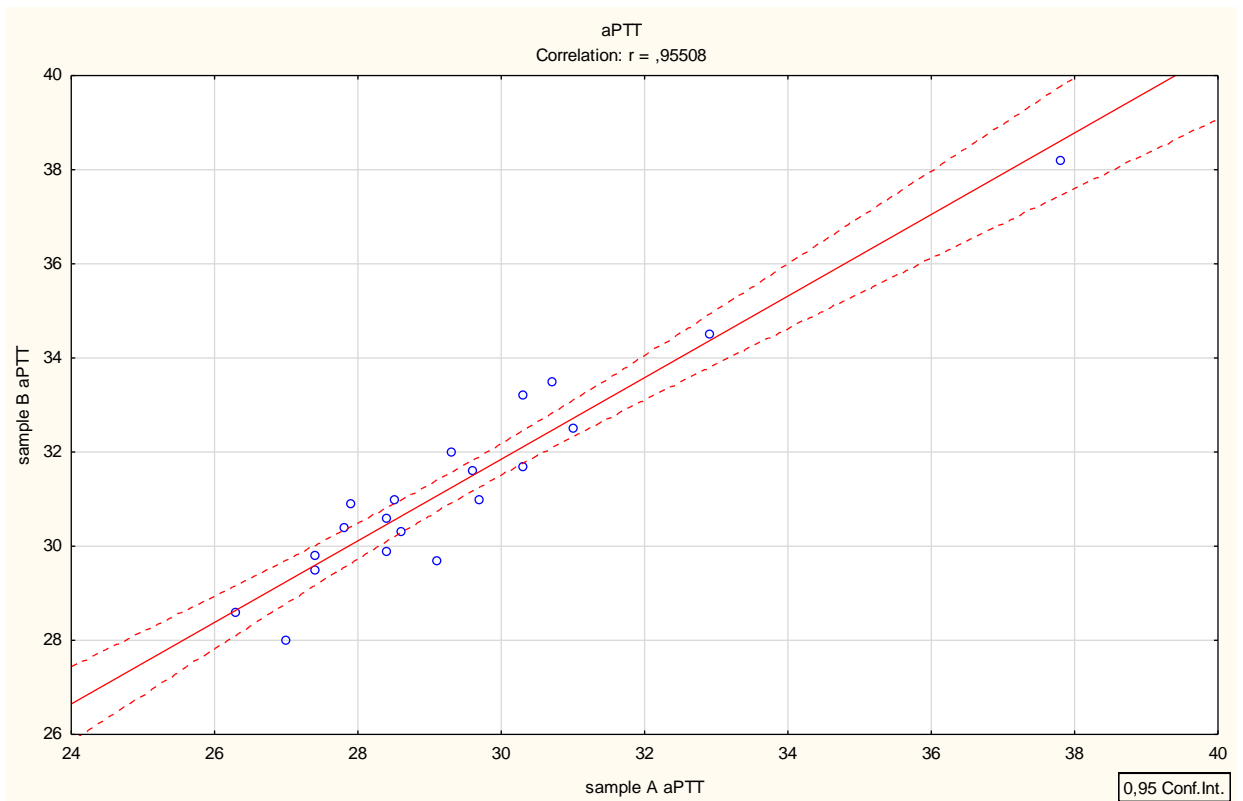
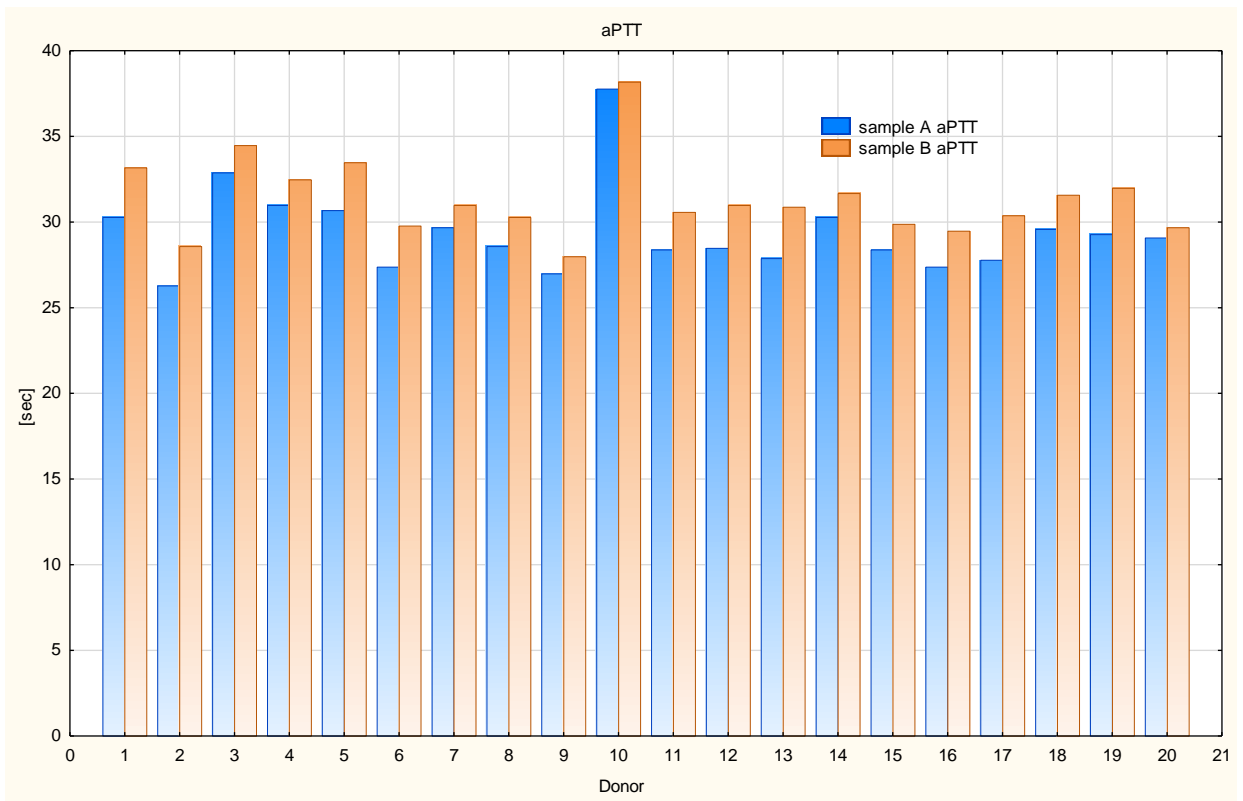
- (1) Greiner Bio-One. MiniCollect® 9NC Coagulation Tubes. Instructions for Use. Kremsmünster, Austria. 2016.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.
- (3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning 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:

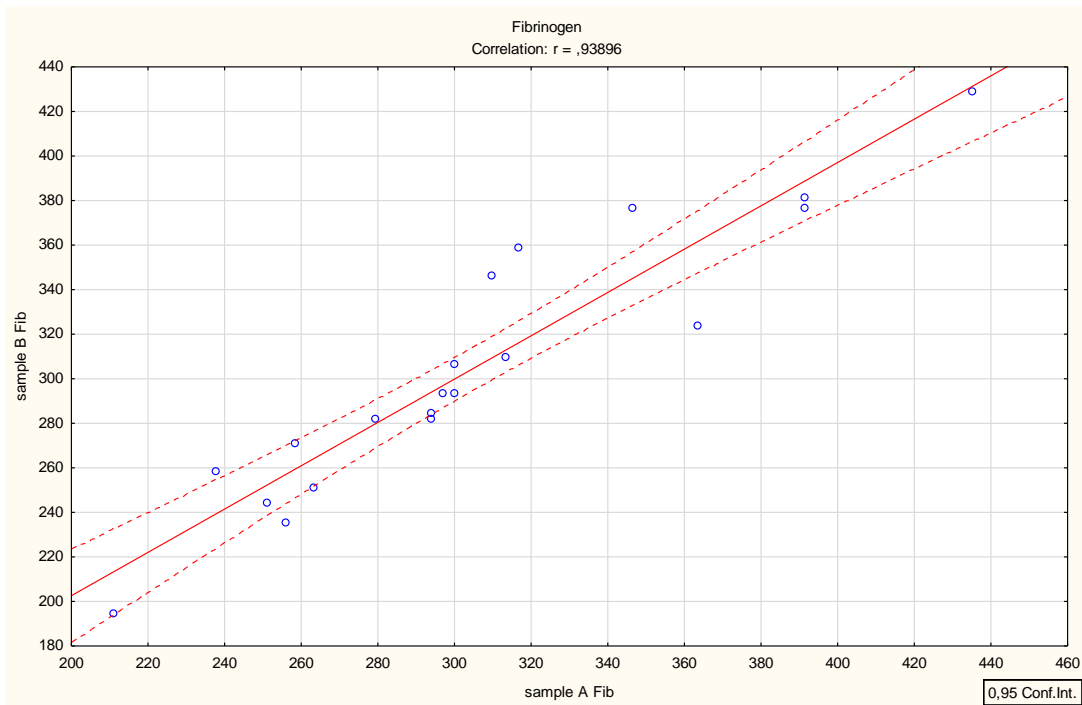
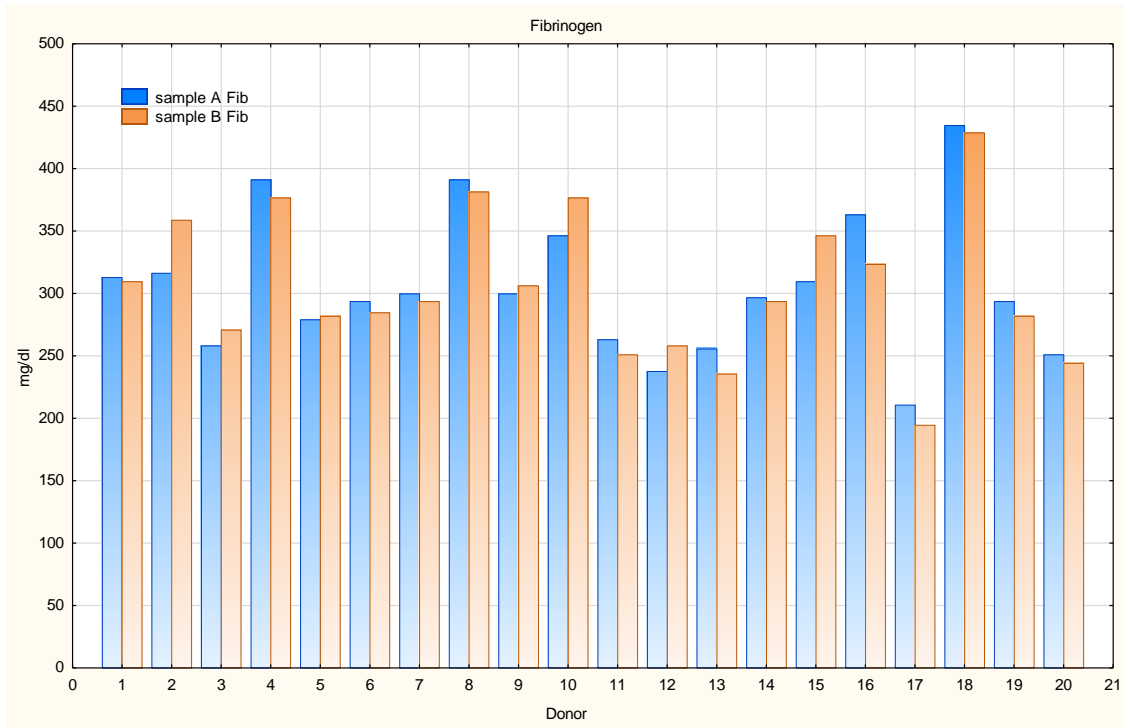
Prothrombin time (Quick) (Normal range: 80-130%)



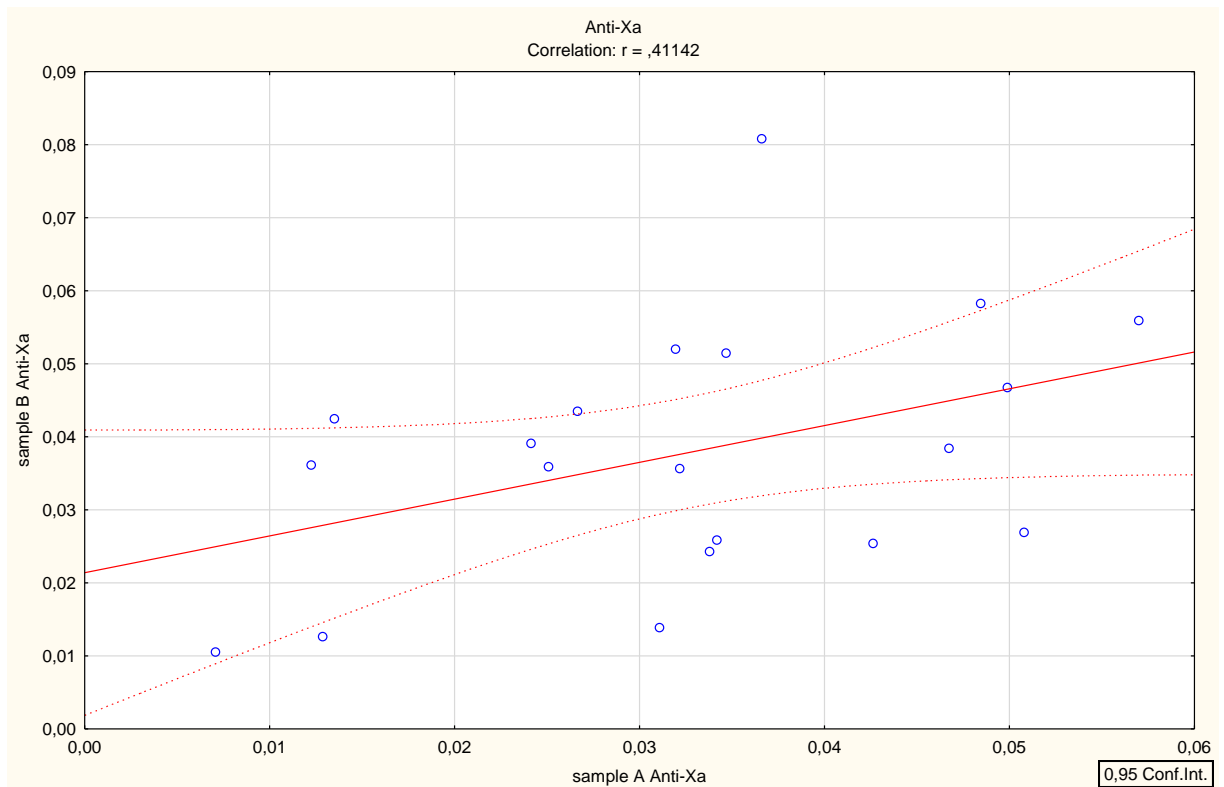
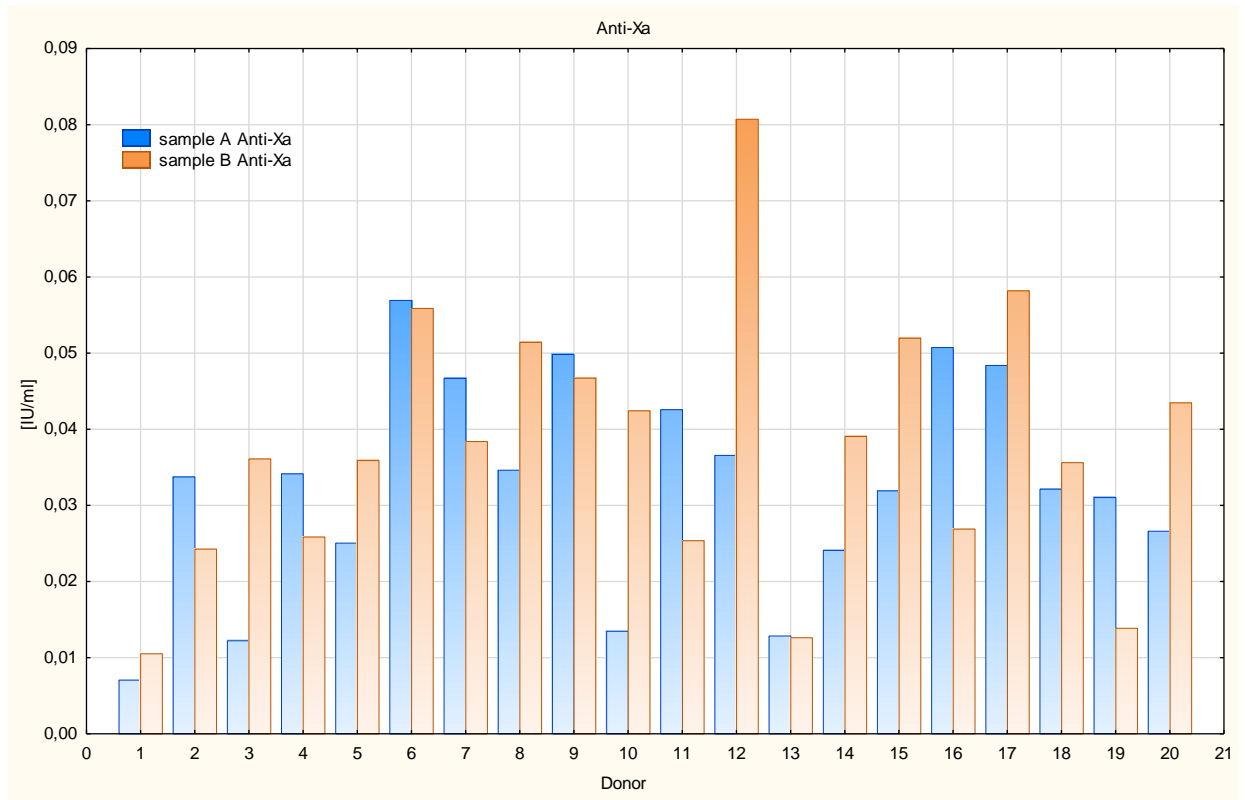
aPTT (Normal range: 25-37 sec.)



Fibrinogen (Normal range: 1.89-5.94 g/l)



Factor Anti-Xa (Normal range: 0.4 - 1 IU/ml (therapeutic) 0.2-0.4 IU/ml (prophylactical))



International normalized ratio (INR) Normal range: ~1 (0.8 - 1.2)

