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.

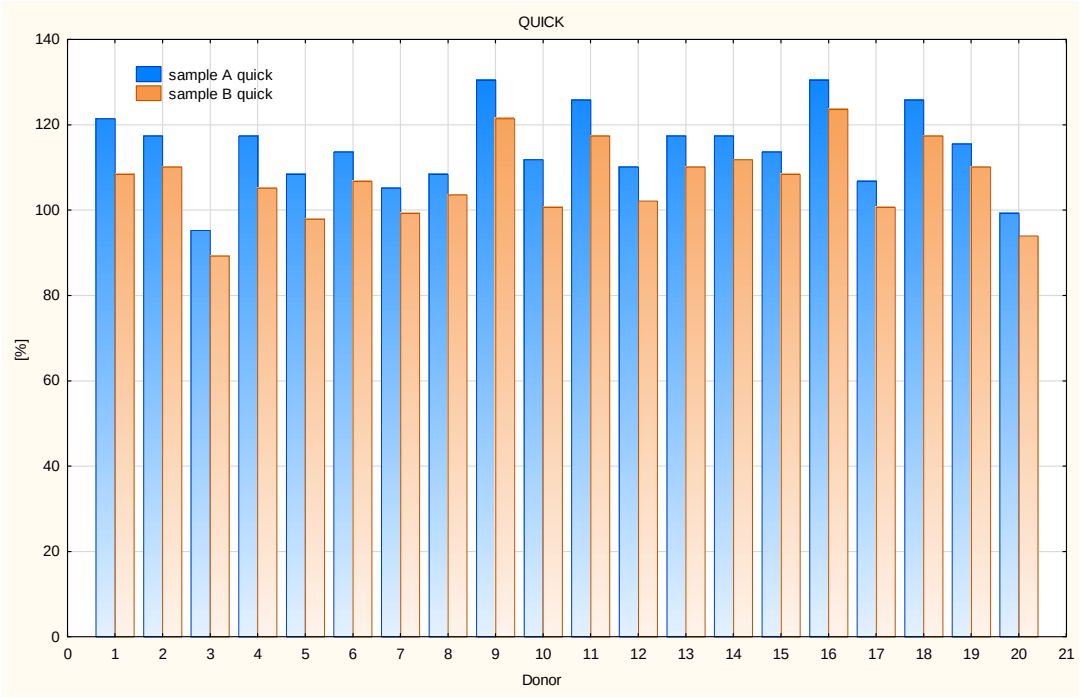
(7) H01-A6: *Tubes and Additives for Venous and Capillary Blood Specimen Collection*; Approved Standard – Sixth Edition CLSI 2011

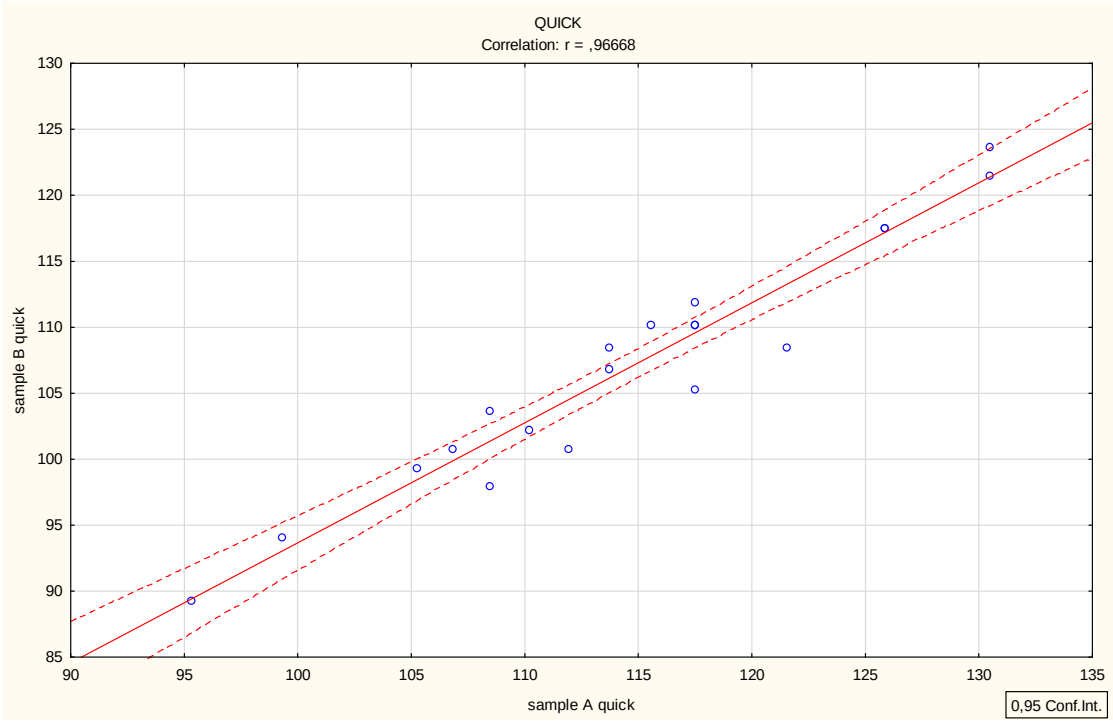
(8) H04-A6: *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens* – Approved Standard – Sixth Edition CLSO 2011

(9) RILIBÄK: Guideline of the German Medical Association for Quality Assurance

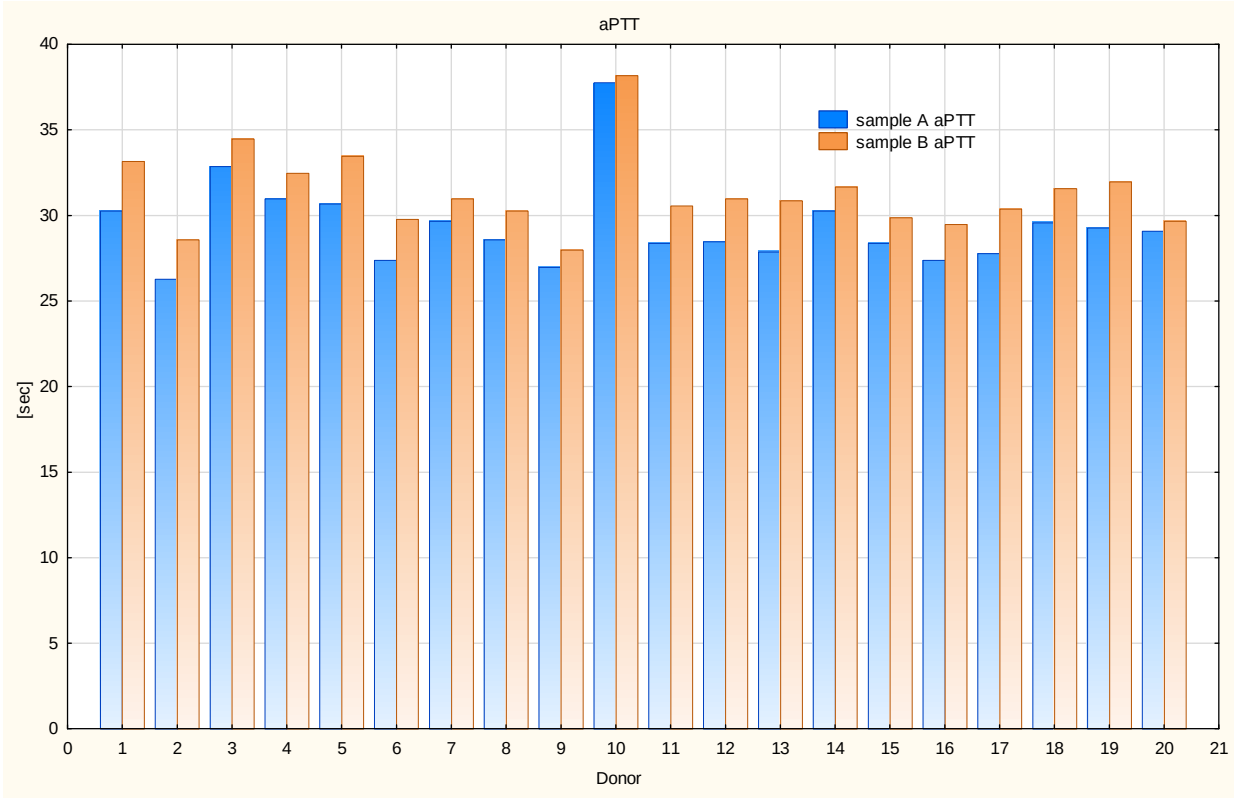
Results in detail:

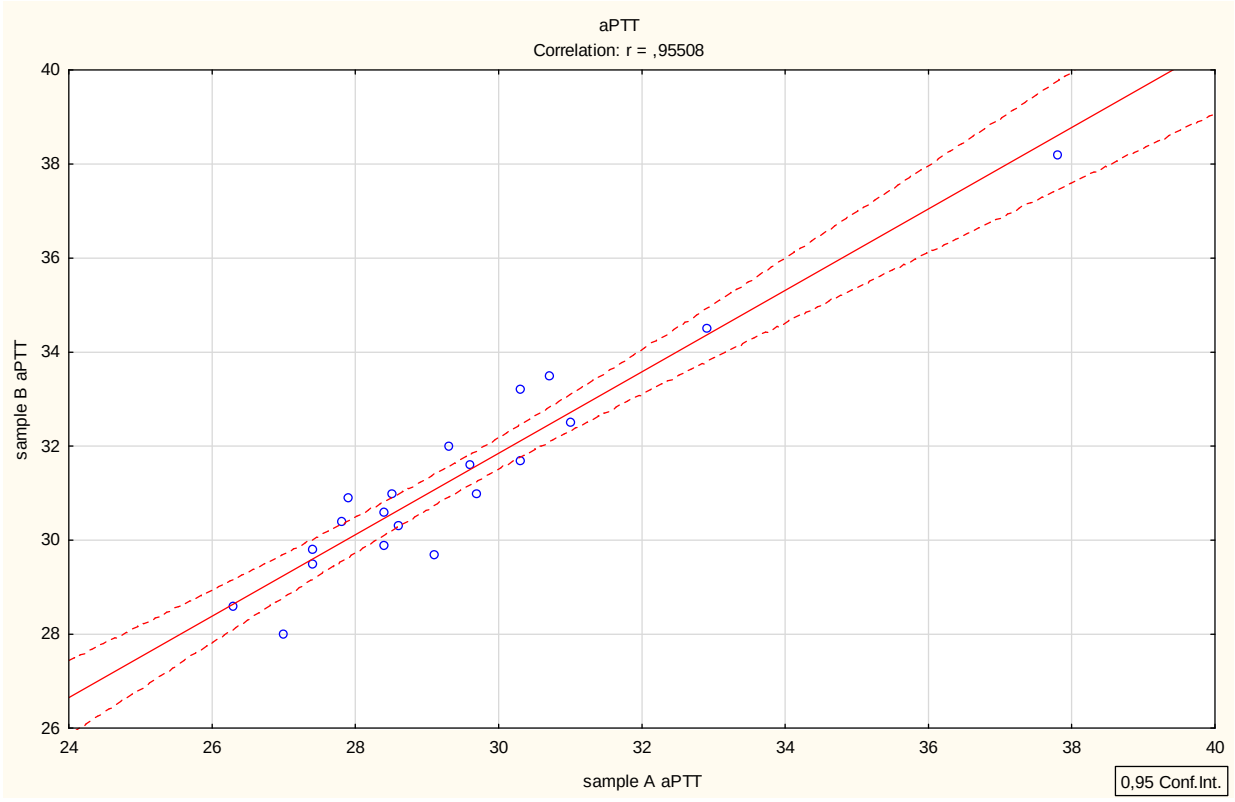
Prothrombin time (Quick) (Normal range: 80-130%)



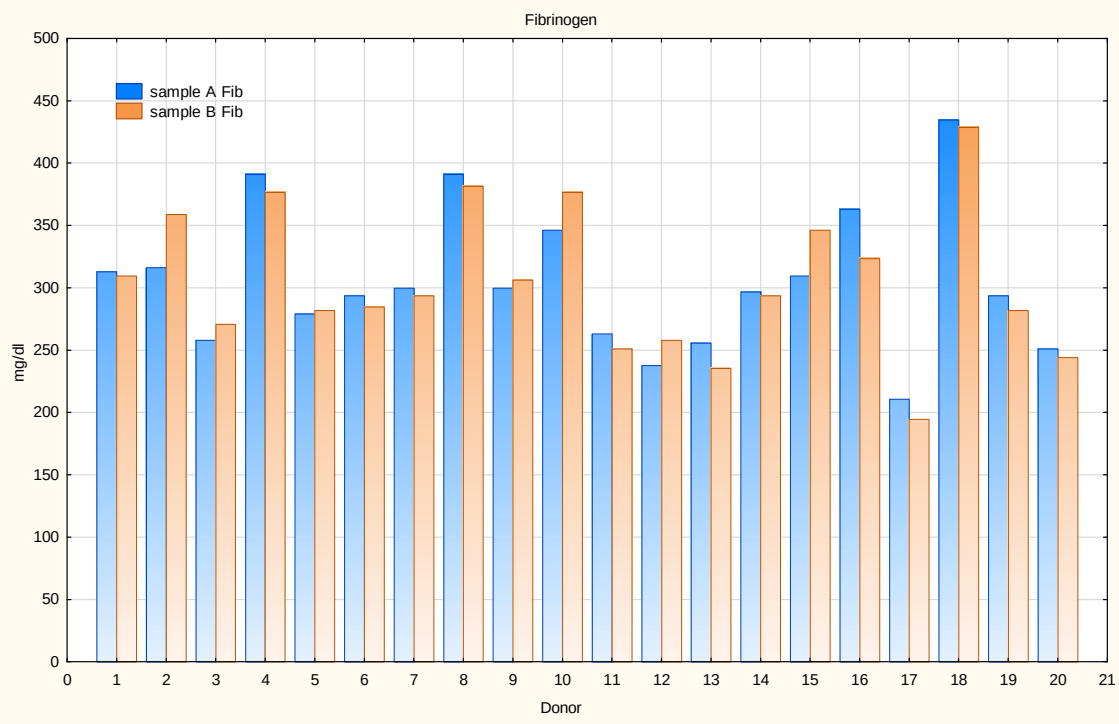


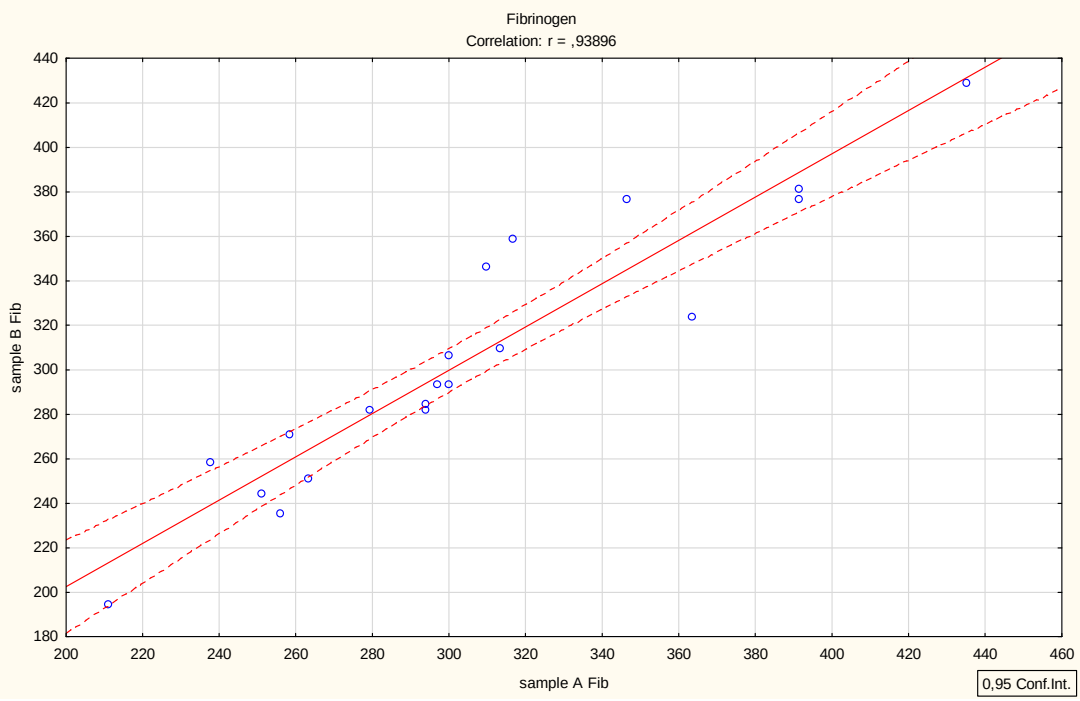
aPTT (Normal range: 25-37 sec.)



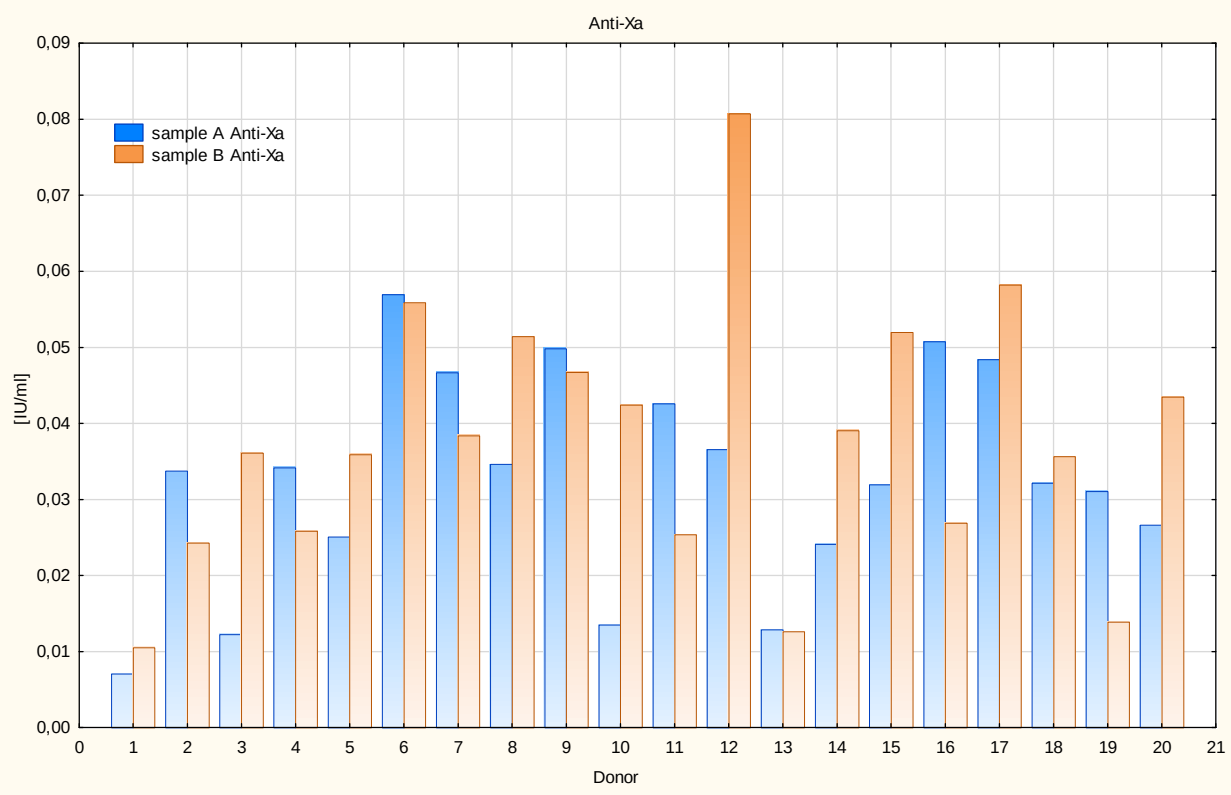


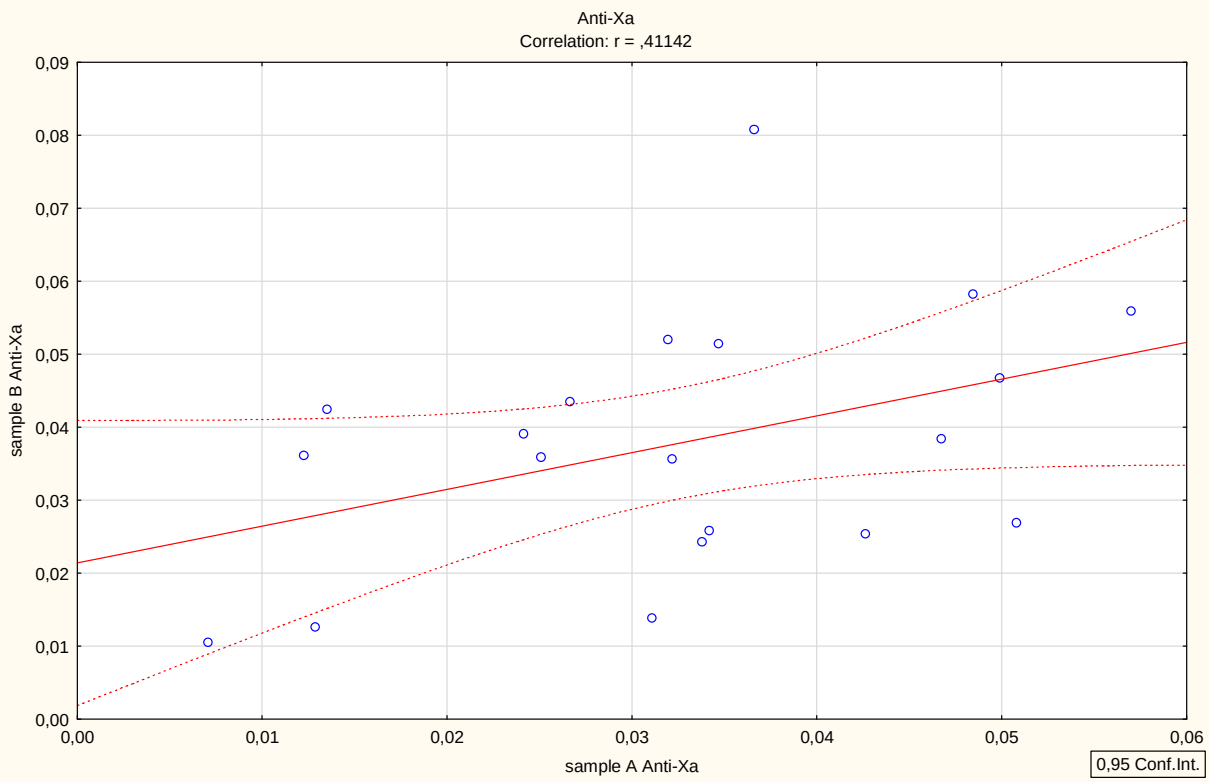
Fibrinogen (Normal range: 1.89-5.94 g/l)





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)