

Comparison of **VACUETTE**[®] Serum Gel Tubes for Common Chemistry Analytes

Background:

Greiner-Bio-One, Austria has been selling plastic evacuated tubes (**VACUETTE**[®]) for venous blood collection since 1986.

Serum Tubes with and without gel separator are coated with micronised silica particles which activate clotting when the tubes are gently inverted.

VACUETTE[®] Serum Separator Clot Activator tubes contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood clot and the serum.

During centrifugation, the gel moves upwards to the serum-cell interface where it forms a stable barrier separating the serum from the fibrin clot. This improves the serum yield and enables serum to be left in the primary tube for analysis. It further allows greater stability of certain analytes when kept under specified conditions. ^[1]

Study Objective:

The aim of this study was to show the comparable performance of two different gel polymers used in **VACUETTE**[®] Serum Separator tubes when assessed for biochemistry parameters.

Study design and procedure:

Two types of tubes were evaluated in this study:

Sample	Description	Draw Volume	Size
Sample A US P-Gel	456073 VACUETTE [®] Serum Clot Activator Separator	5 ml	13x100
Sample B European Gel	456073 VACUETTE [®] Serum Clot Activator Separator	5 ml	13x100

Venous blood collection was performed on 57 or up to 61 healthy and pathological donors using two **VACUETTE**[®] Serum Separator Tubes with a **VACUETTE**[®] Standard tube holder. The order of collection was randomized. Directly after blood collection all tubes were inverted 8 times for proper mixing. Tubes were allowed to clot for at least 30 minutes in an upright position at room temperature and then centrifuged in a cooled swing-out bucket centrifuge (20°C-24°C) at 2200 g for 15 minutes.

All samples were analyzed for the constituents listed below at the initial time point within 2 hours of blood collection and after 48 hours on a Dimension Vista from Siemens using accompanying reagents from the instrument manufacturer. Between measurements, the samples were stored in the refrigerator at 4-8°C. After 48 hours the tubes were taken out of the refrigerator and inverted gently before second analyses to avoid any concentration gradients.

The following parameters were measured:

- Alanine Aminotransferase (ALT)
- Alkaline Phosphatase (ALP)
- Alpha Fetoprotein (AFP)
- Aspartate Aminotransferase (AST)
- Albumin
- Blood Urea Nitrogen (BUN)
- Calcium
- Carcinoembryonic Antigen (CEA)
- Chloride
- Cholesterol
- Creatine Kinase
- Creatinine
- Ferritin
- Free Thyroxin (fT₄)
- Free Triiodothyronine (fT₃)
- Folic Acid
- Gamma Glutamyltransferase (GGT)
- Glucose
- Iron
- Lactate Dehydrogenase (LDH)
- Magnesium
- Phosphate
- Potassium
- Prostate Specific Antigen (PSA)

- Sodium
- Total Bilirubin
- Total Protein
- Triglyceride
- Thyroid stimulating hormone (TSH)
- Troponin I
- Uric acid
- Vitamin B12 (Cobalamin)

Results:

Comparison analysis was performed at the initial time point and at 48 hours for both gel types. Statistical evaluation was performed with the T-test ($\alpha = 0.05$) using StatSoft Software, Version 9. Pathological and normal donors were evaluated separately for statistical analysis, wherever applicable. Clinical evaluation was based on the allowed recommendation by the German Medical Association (RILIBÄK).^[2,3] Further, the quality control data were taken into consideration for interpretation of results.

One Sample A was found to be hemolyzed (Sample 15). To increase the number of pathological values for some parameters, specific donors were selected for blood collection and only a limited parameter profile was measured which can be seen in the bar charts as missing values. For the parameter Phosphate, higher deviations of the values were seen due to presumably instrument error detected by the laboratory. Quality control data were checked and showed higher coefficient of variation (CV) within the testing period. Based on outlier testing, some Phosphate values were excluded from statistical analysis. Statistically significant differences were observed for some parameters, but were not considered to be clinically significant. Both gel types showed comparable results.

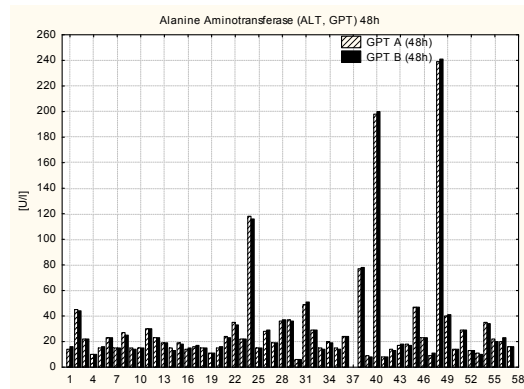
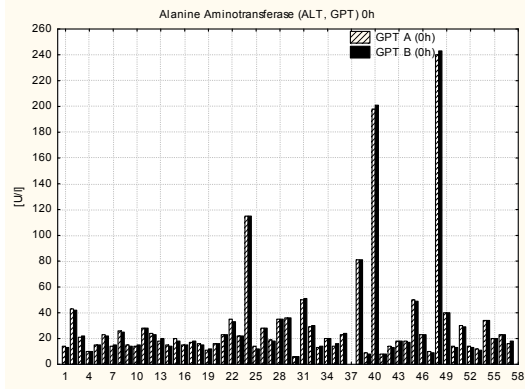
Conclusion:

The test showed that both gel types (P-Gel and European Gel) showed comparable test results at the initial time point and after 48 hours when centrifuged at 2200g for 15 minutes. Differences in results were not clinically significant.

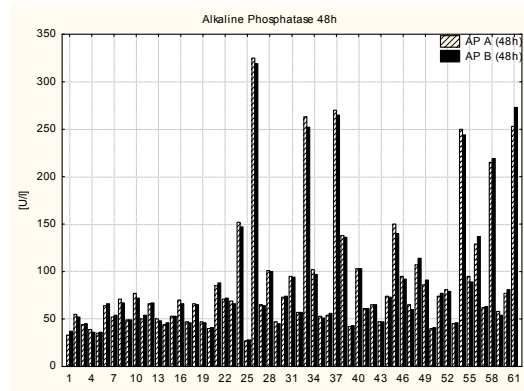
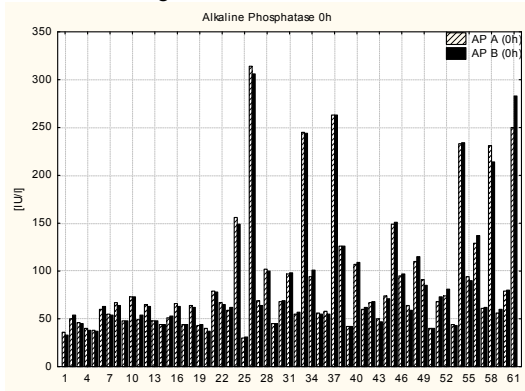
References:

- [1] Instructions for Use. Evacuated Blood Collection System. For in vitro Diagnostic Use. Rev. 13
- [2] Thomas L., Laboratory and Diagnosis. Indication and Evaluation of Laboratory Results for Medical Diagnosis. 7th edition. TH-Books.
- [3] Guideline from the medical association in Germany for quality assurance of laboratory tests. German Medical Journal. Vol. 105, Issue 7. 2008.

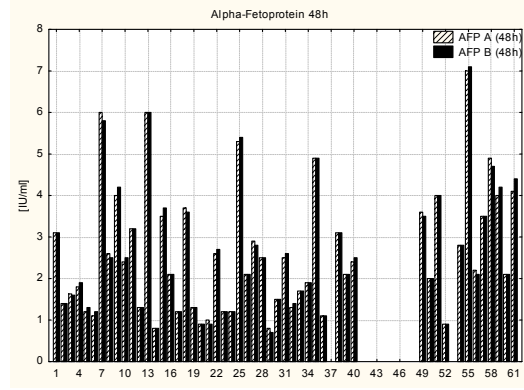
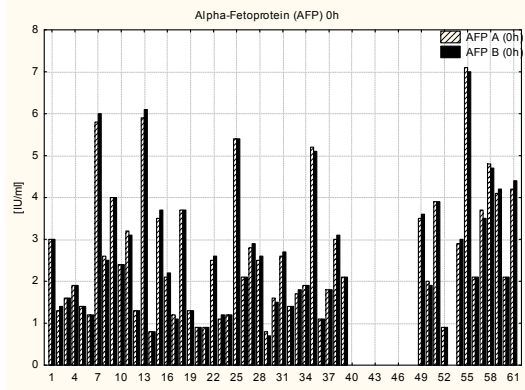
Results in Detail:
Alanine Aminotransferase (ALT, GPT)
 Reference range: 0-45 U/l



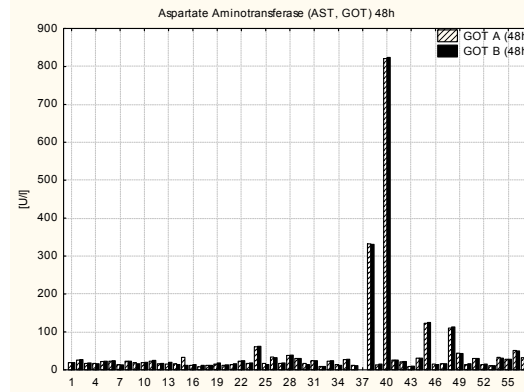
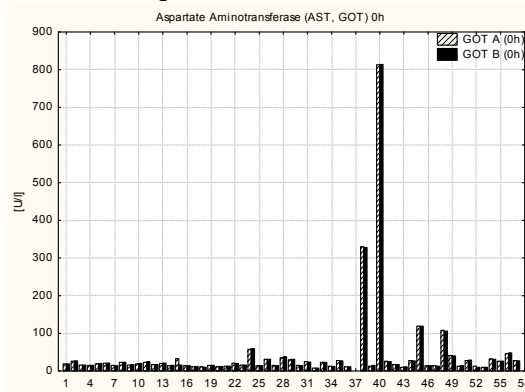
Alkaline Phosphatase
 Reference range: 50-135 U/l



Alpha-Fetoprotein (AFP)
 Reference range: 0-6.6 IU/ml

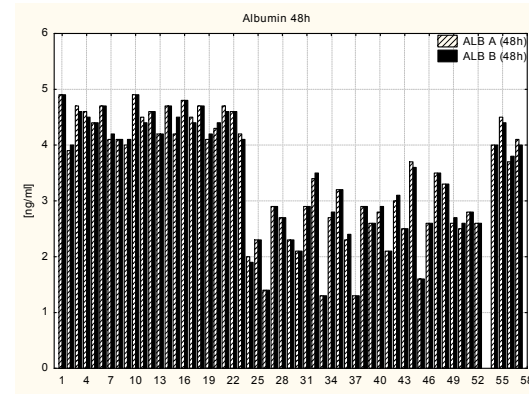
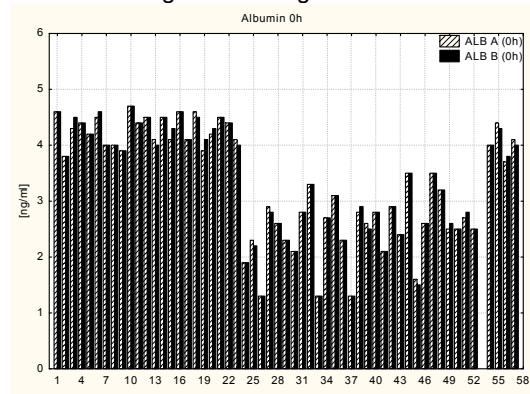


Aspartate Aminotransferase (AST, GOT)
 Reference range male: 0-35 U/l



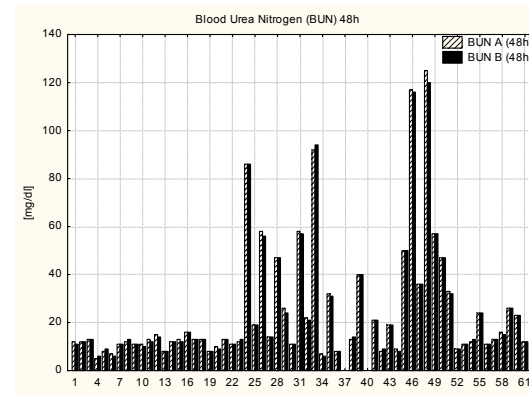
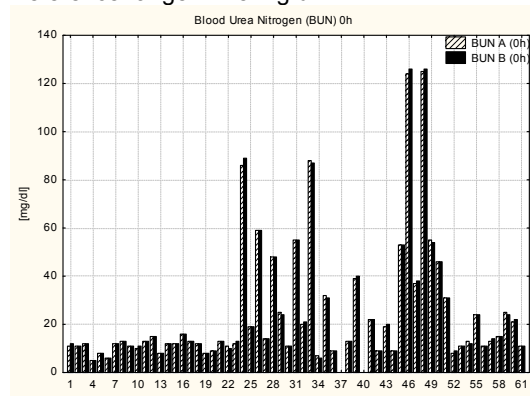
Albumin

Reference range: 3.5-5.2 ng/ml



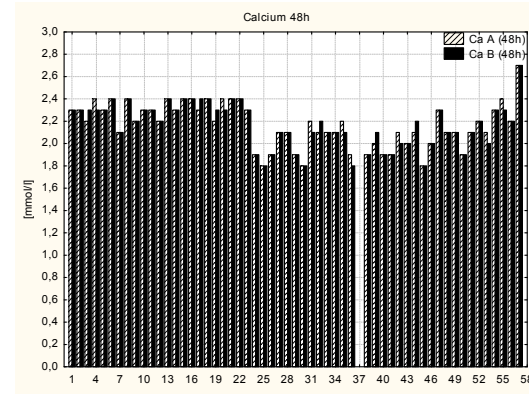
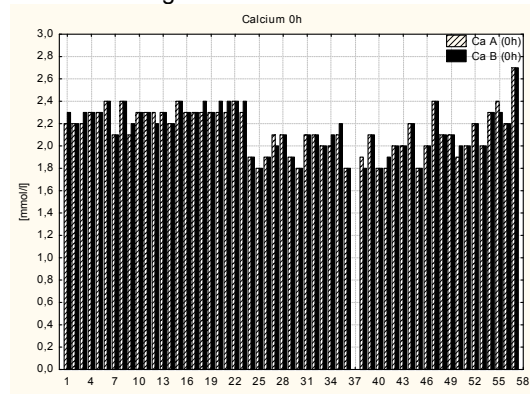
Blood Urea Nitrogen (BUN)

Reference range: 7-18 mg/dl



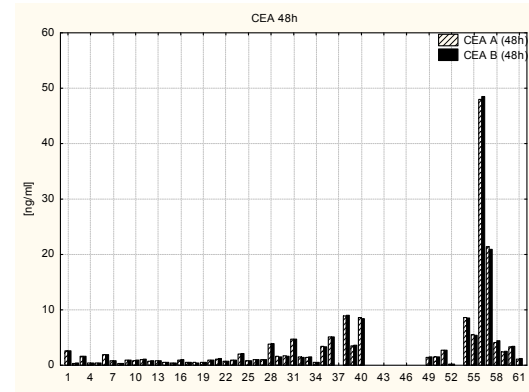
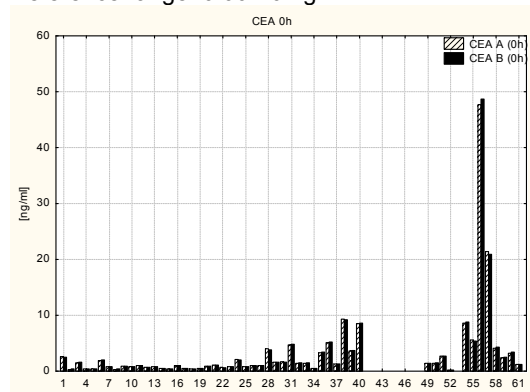
Calcium

Reference range: 2.0-2.8 mmol/l



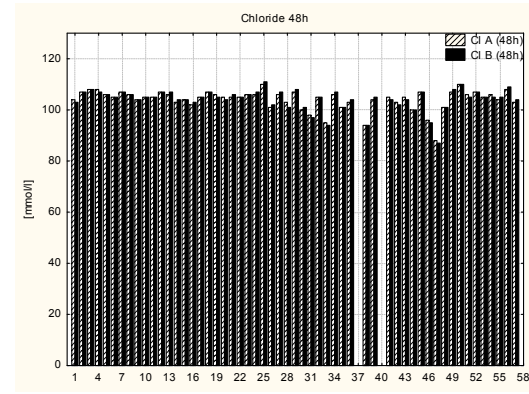
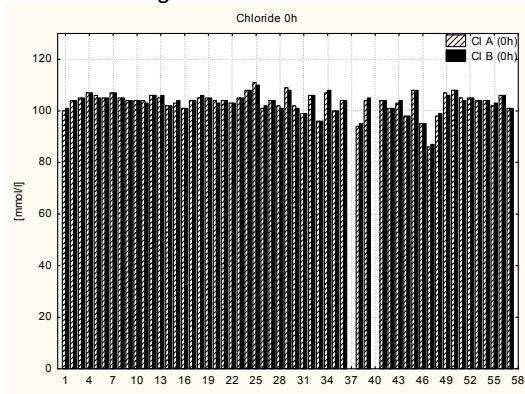
CEA

Reference range: 0.00-10 ng/ml



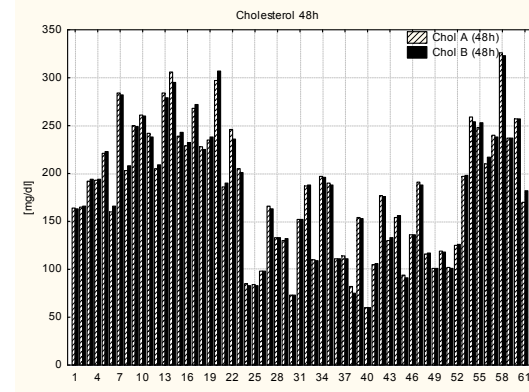
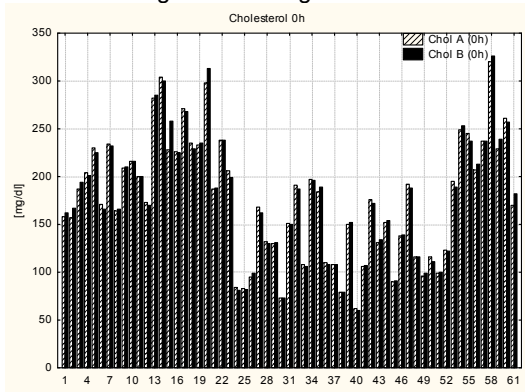
Chloride

Reference range: 95-110 mmol/l



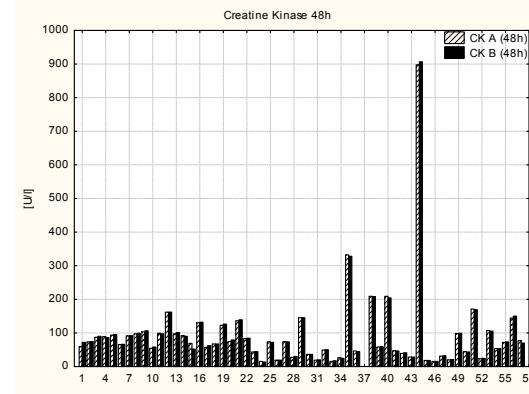
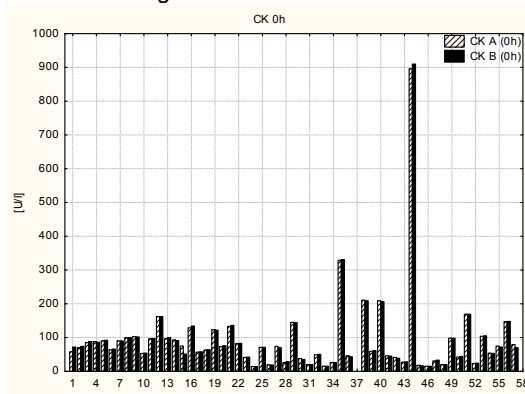
Cholesterol

Reference range: 30-200 mg/dl



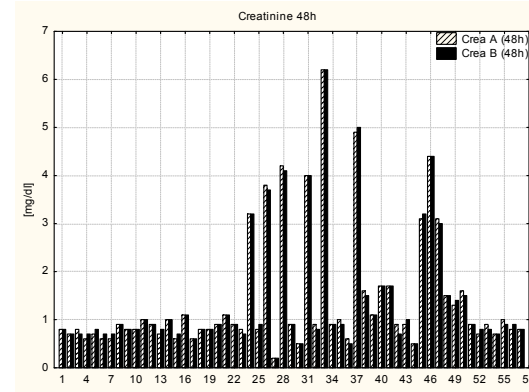
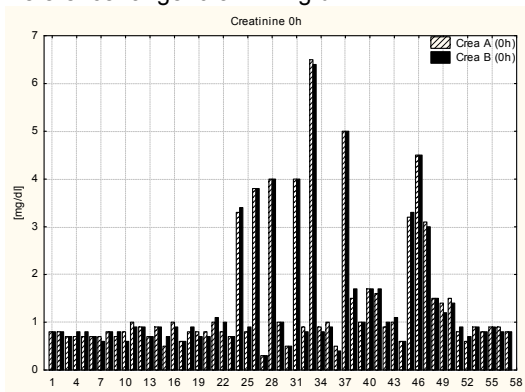
Creatine Kinase

Reference range: 0-170 U/l



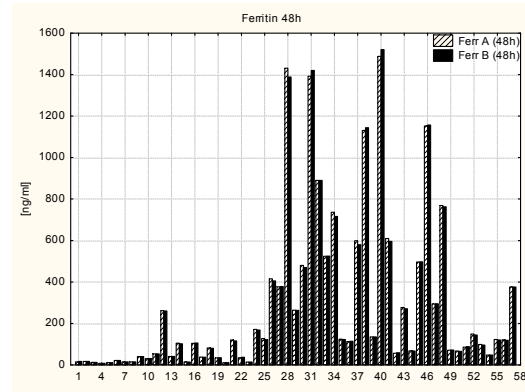
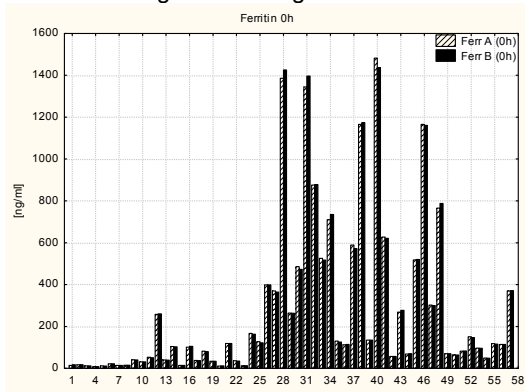
Creatinine

Reference range: 0.5-1.2 mg/dl



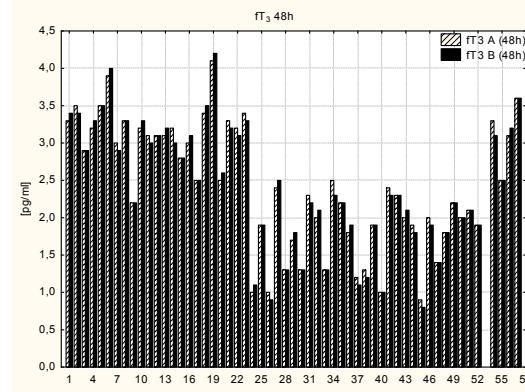
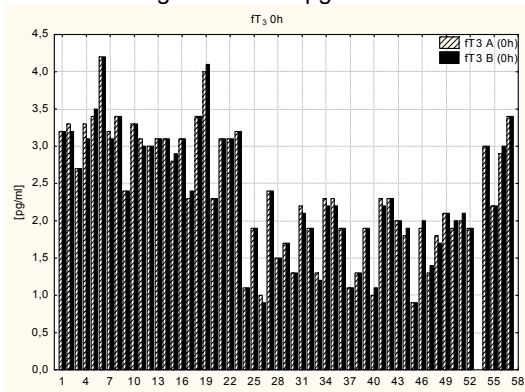
Ferritin

Reference range: 26-390 ng/ml



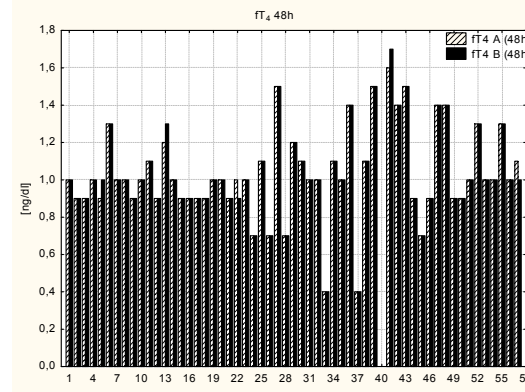
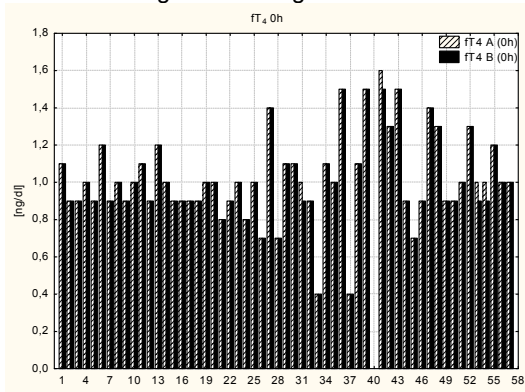
ft₃

Reference range: 2.20-4.00 pg/ml



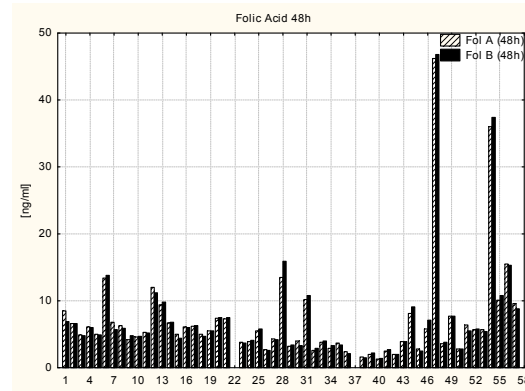
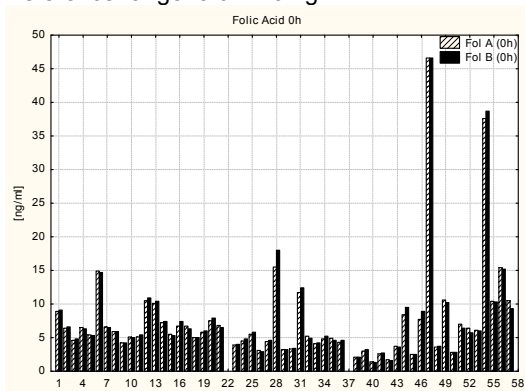
ft₄

Reference range: 0.9-1.7 ng/dl

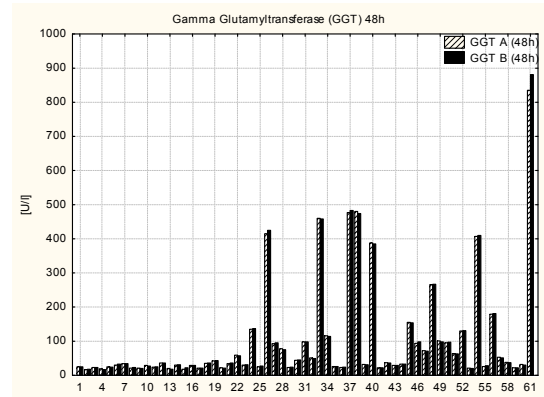
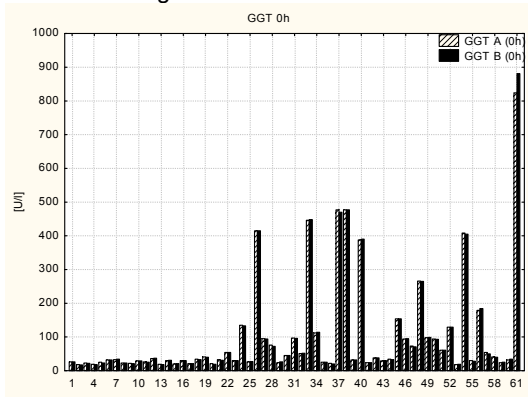


Folic Acid

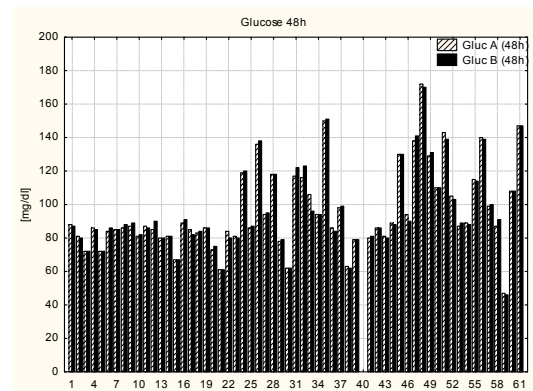
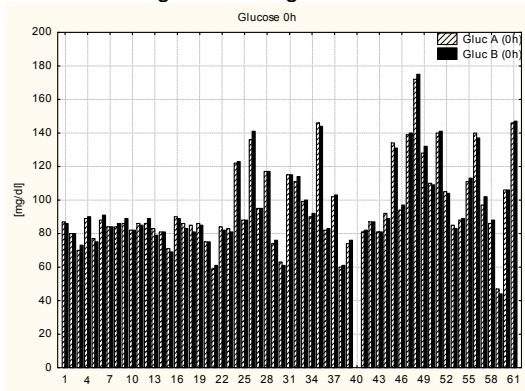
Reference range: 3.0-17.0 ng/ml



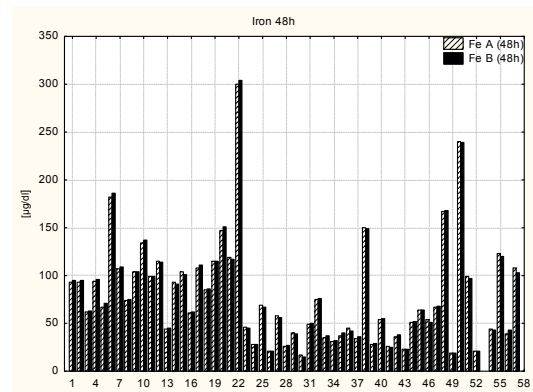
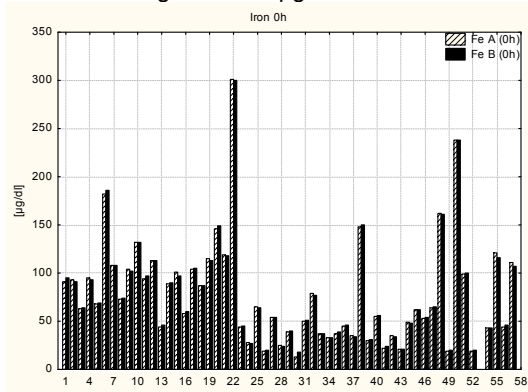
Gamma Glutamyltransferase (GGT)
Reference range male: 0-55 U/l



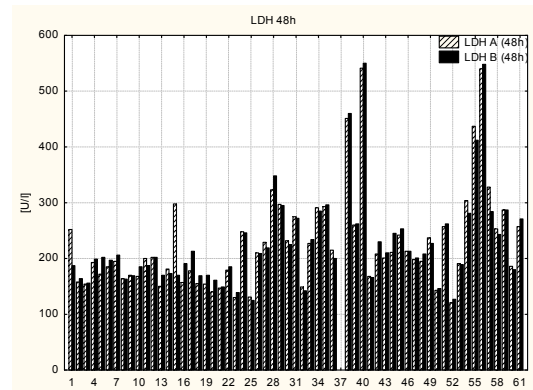
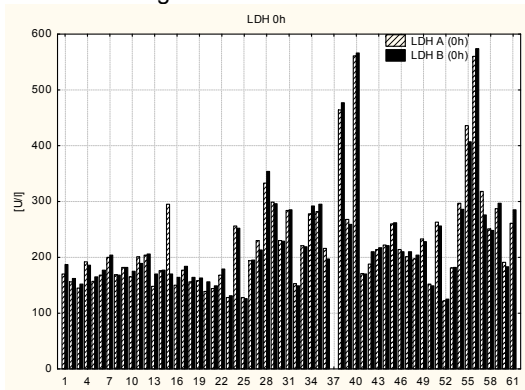
Glucose
Reference range: 60-99 mg/dl



Iron
Reference range: 65-175 µg/dl

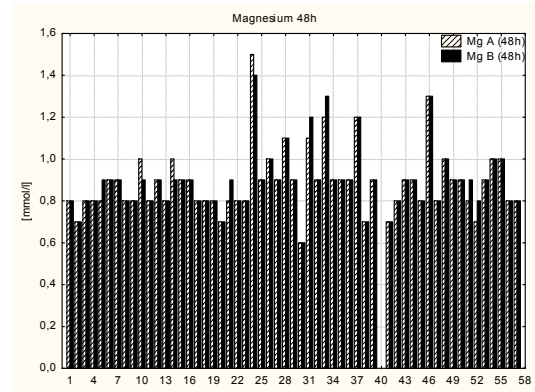
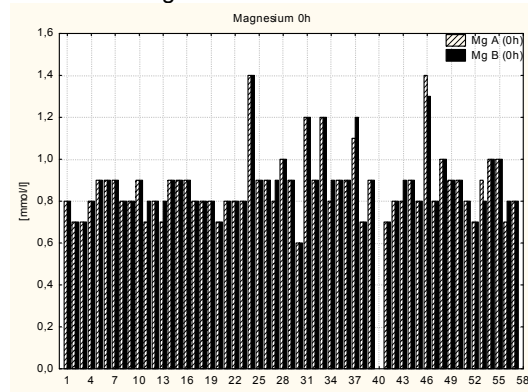


LDH
Reference range: 0-248 U/l



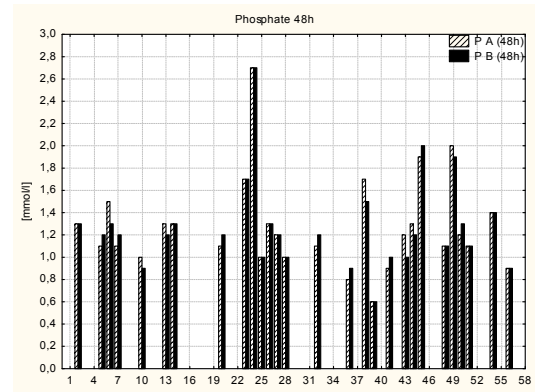
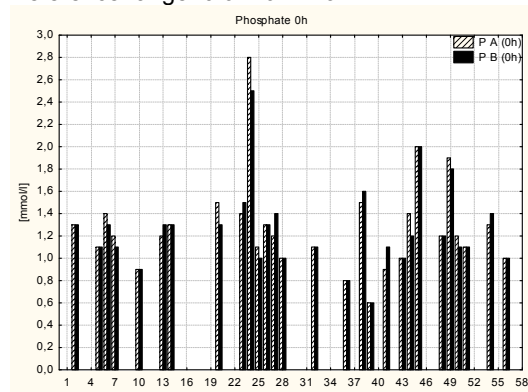
Magnesium

Reference range: 0.60-1.10 mmol/l



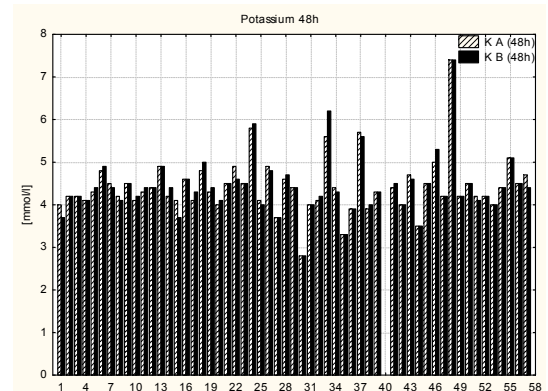
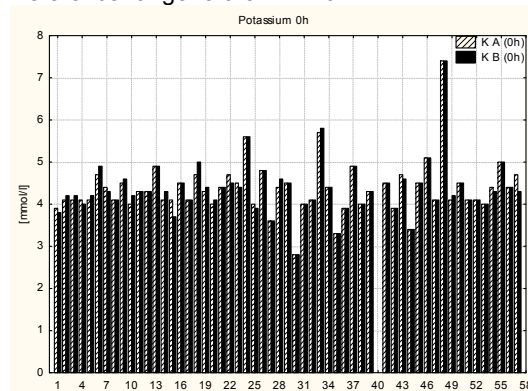
Phosphate

Reference range: 0.6-1.6 mmol/l



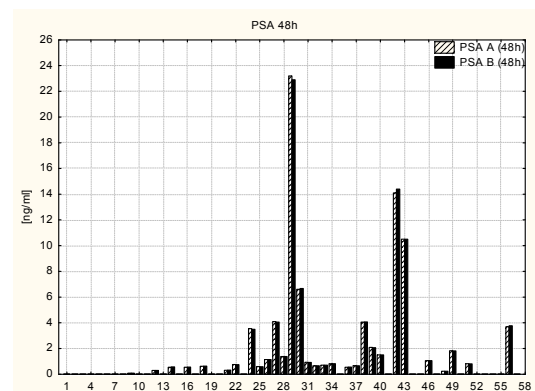
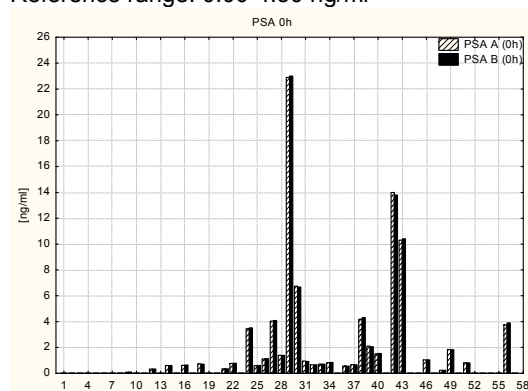
Potassium

Reference range: 3.5-5.4 mmol/l



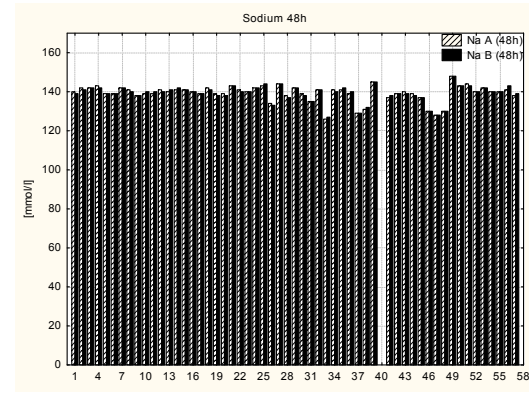
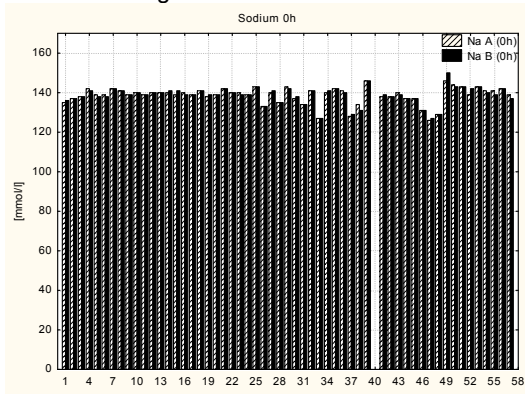
PSA

Reference range: 0.00-4.50 ng/ml



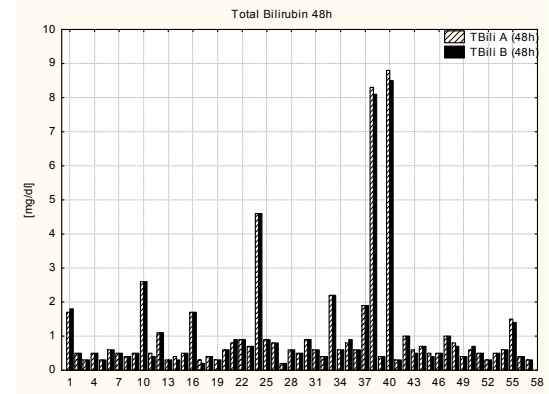
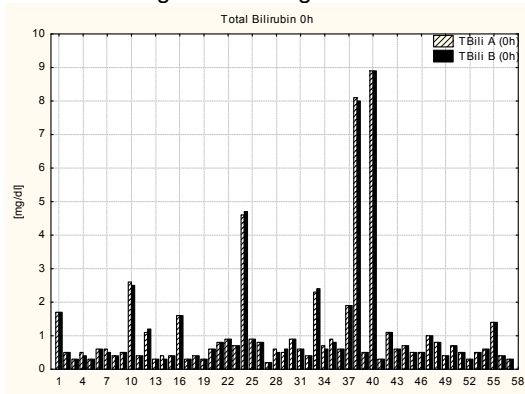
Sodium

Reference range: 132-148 mmol/l



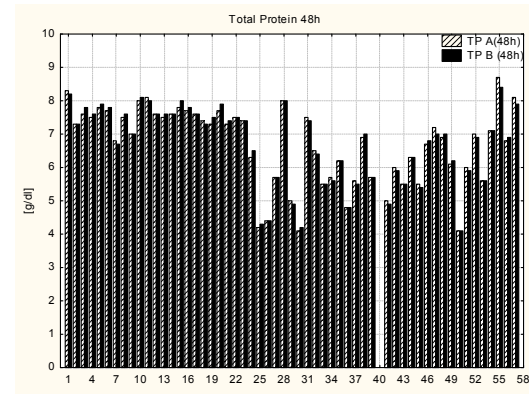
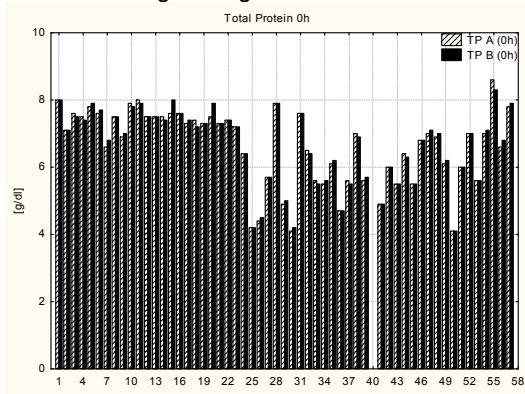
Total Bilirubin

Reference range: 0.2-1.1 mg/dl



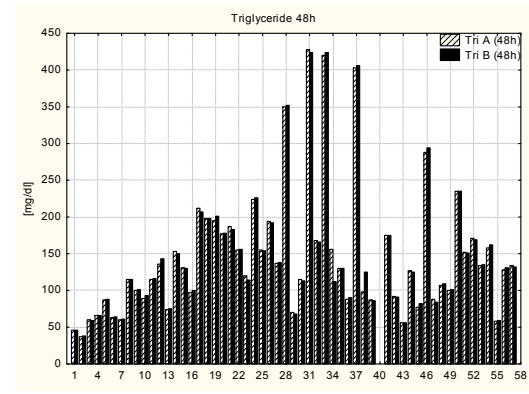
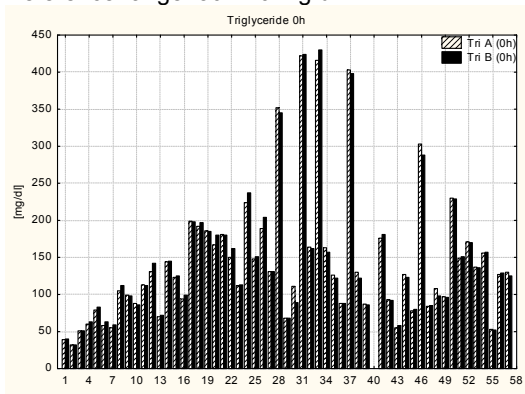
Total Protein

Reference range: 6-8 g/dl



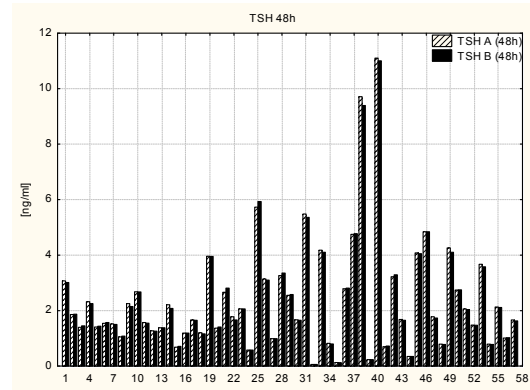
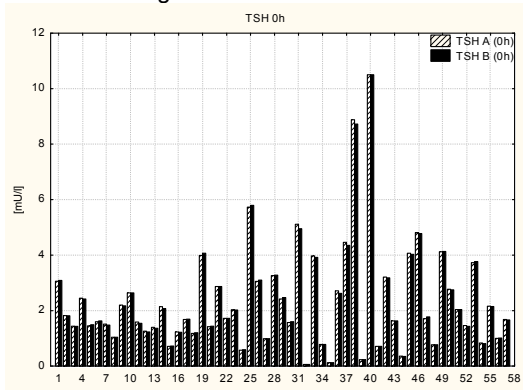
Triglyceride

Reference range: 30-170 mg/dl



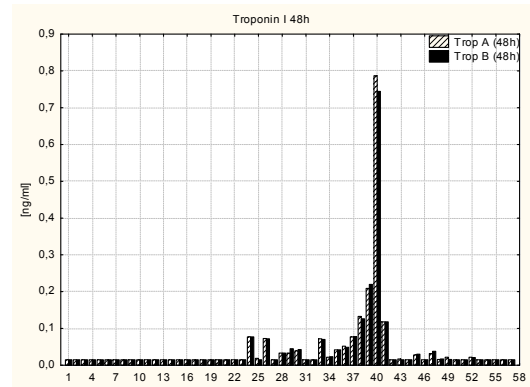
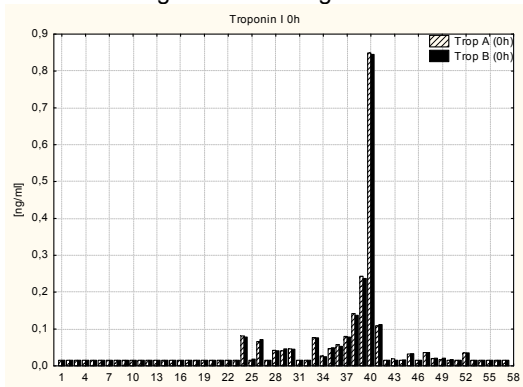
TSH

Reference range: 0.5-3.00 mU/l



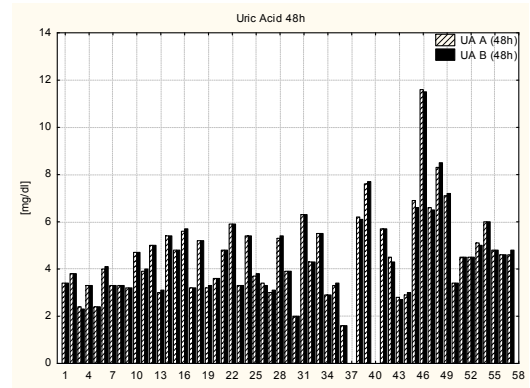
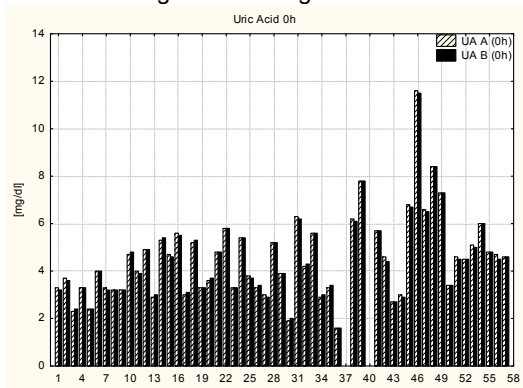
Troponin I

Reference range: 0.0-0.045 ng/ml



Uric acid

Reference range: 3.5-7.0 mg/dl



Vitamin B 12 (Cobalamin)

Reference range: 250-1300 pg/ml

