

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

Background:

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

The anticoagulant heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood/ plasma sample making it ideal for rapid analysis and analysis of blood from patients under anticoagulant therapy.

VACUETTE[®] Lithium Heparin separator tubes contain a barrier gel in the tube. The specific gravity of this material lies between the blood cells and plasma.

During centrifugation the gel moves upwards providing a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container for analysis.^[1]

Study Objective:

The aim of this study was to demonstrate comparable performance of two different gel polymers used in **VACUETTE**[®] Lithium Heparin 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)	456087 VACUETTE [®] Lithium Heparin Separator Tube	5 ml	13x100
Sample B (European Gel)	456087 VACUETTE [®] Lithium Heparin Separator Tube	5 ml	13x100

Venous blood collection was performed on 30 or up to 36 healthy and pathological donors using two **VACUETTE**[®] Lithium Heparin Tubes with a **VACUETTE**[®] Standard tube holder. The order of collection was randomized. Directly after blood collection all tubes were inverted 8 times to mix the blood and the chemical additive. Samples were centrifuged in a cooled swing-out bucket centrifuge (20°C-24°C) at 2200g for 15 minutes to separate plasma from cellular components.

All sample tubes were analyzed for the components listed below at the initial time point within 2 hours of blood collection and after 48 hours on the Roche Cobas Integra 800 and Elecsys 2010 using accompanying reagents from the corresponding instrument manufacturers. 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 the second analysis to avoid any concentration gradients.

The following parameters were measured:

- Alanine Aminotransferase (ALT)
- Alkaline Phosphatase (ALP)
- Aspartate Aminotransferase (AST)
- Blood Urea Nitrogen (BUN)
- Calcium
- Carcinoembryonic Antigen (CEA)
- Chloride
- Cholesterol
- Creatine Kinase
- Creatinine
- Ferritin
- Free Thyroxin (fT₄)
- Free Triiodothyronine (fT₃)
- 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 T-hs
- Uric acid

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. One Sample B was found to be hemolyzed (Donor 28). Pathological and normal donors were evaluated separately for statistical analysis, wherever applicable. Outlier testing was performed and wherever applicable considered for interpreting the results. Statistical significant differences could be observed for some parameters, but those were not considered to be clinically significant. Clinical evaluation was based on the allowed recommendation by the German Medical Association (RILIBÄK).^[2, 3] Both gel types showed equivalent 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.

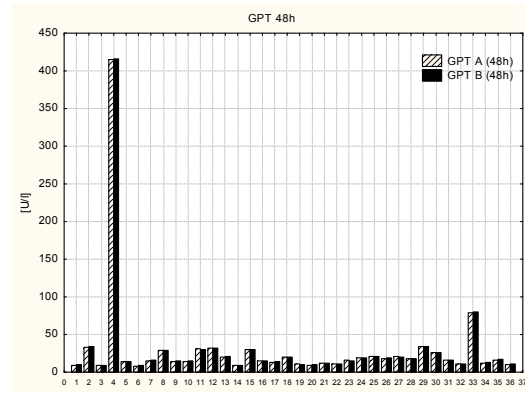
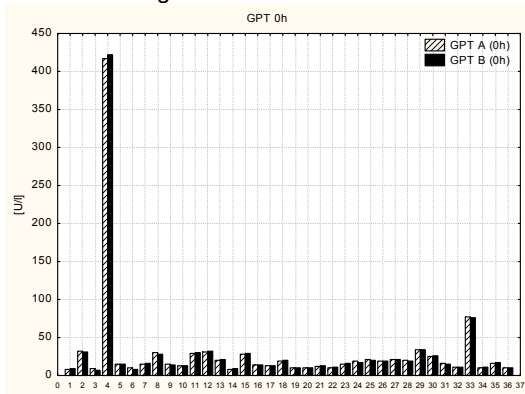
References:

[1] Instructions for Use. Evacuated Blood Collection System. For in vitro Diagnostic Use. Rev. 13

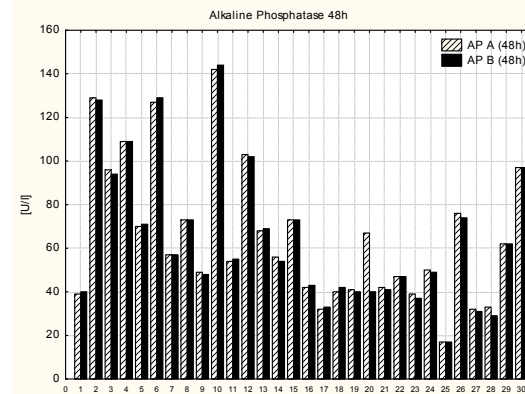
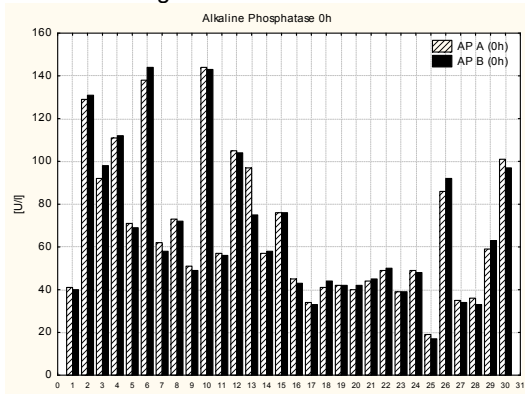
[2] Thomas L., Laboratory and Diagnosis. Indication and Evaluation of Laboratory Results for Medical Diagnosis. 7th edition. TH-Books.

[3] Guideline from the medical association in Germany for quality assurance of laboratory tests. German Medical Journal. Vol. 105, Issue 7. 2008.

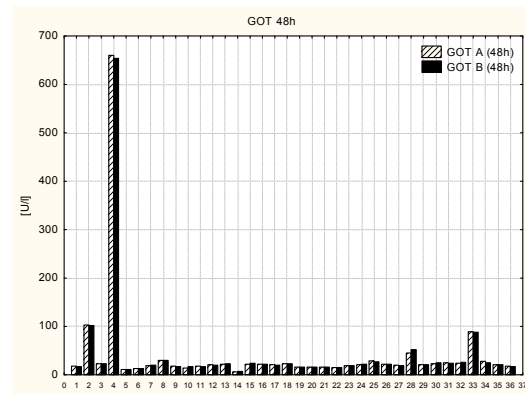
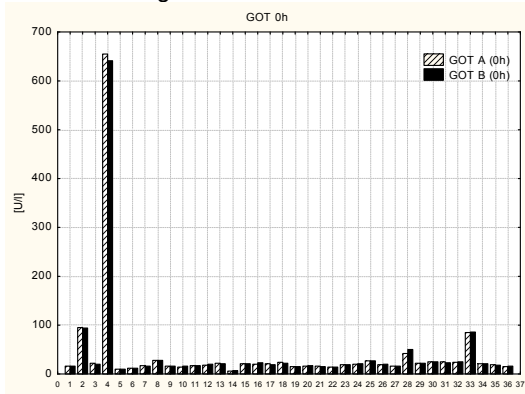
Alanine Aminotransferase (ALT, GPT)
Reference range: 10-50 U/l



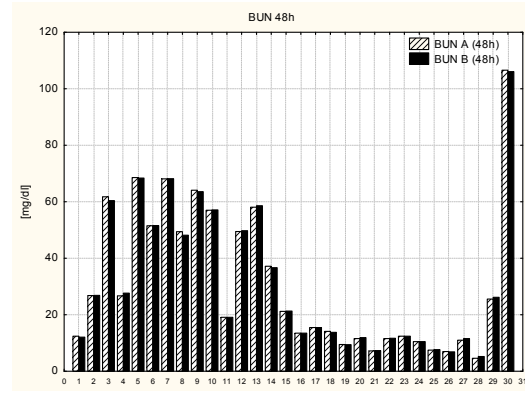
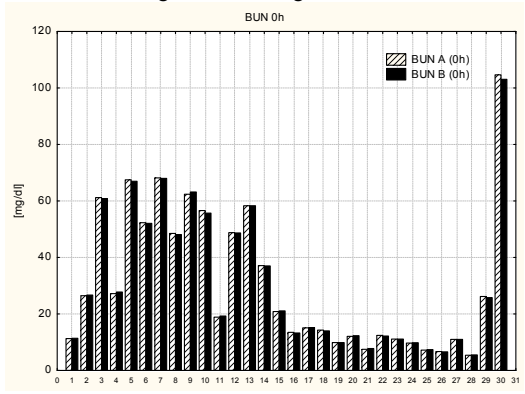
Alkaline Phosphatase
Reference range: 40-129 U/l



Aspartate Aminotransferase (AST, GOT)
Reference range male: 10-35 U/l

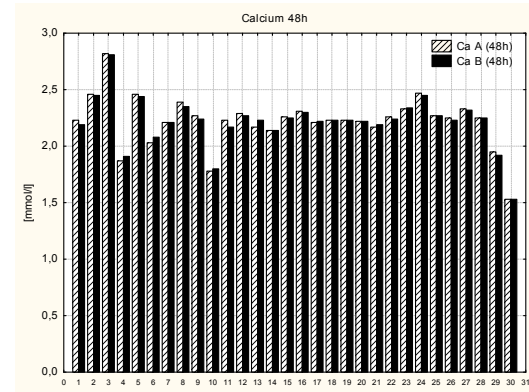
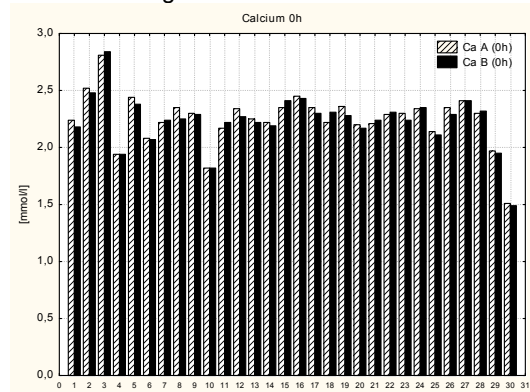


Blood Urea Nitrogen (BUN)
Reference range: 6.0-20 mg/dl



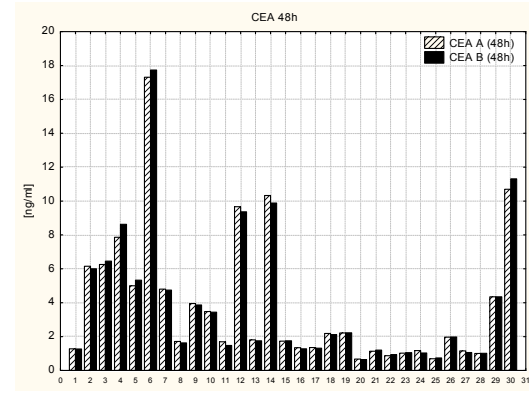
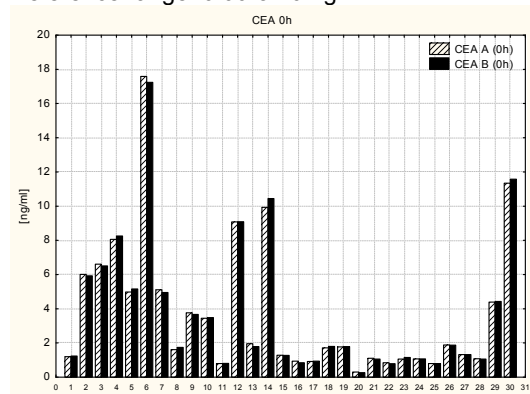
Calcium

Reference range: 2.10-2.42 mmol/l



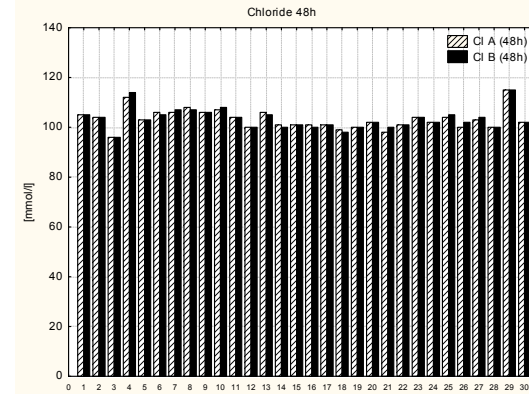
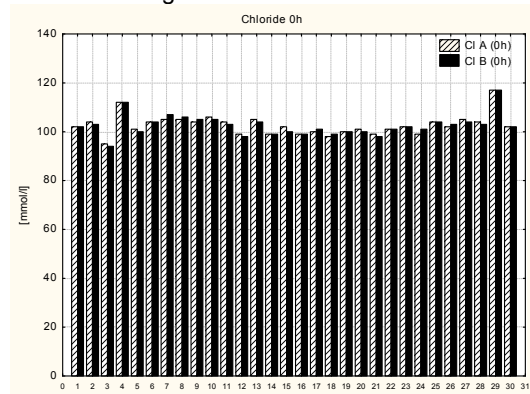
Carcinoembryonic Antigen (CEA)

Reference range: 0.00-3.40 ng/ml



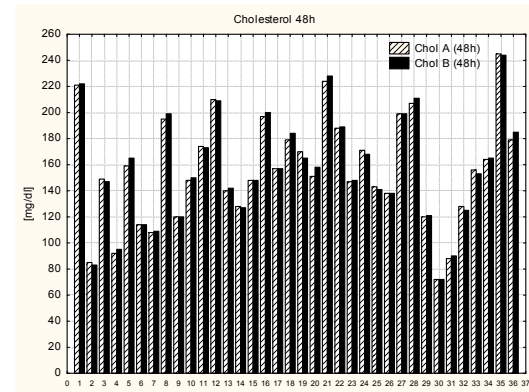
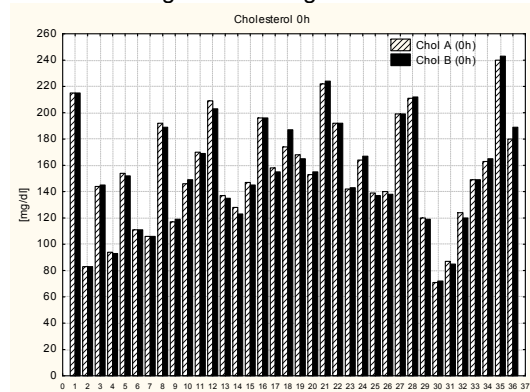
Chloride

Reference range: 98-107 mmol/l



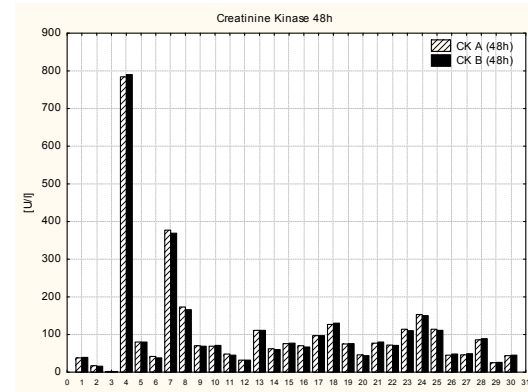
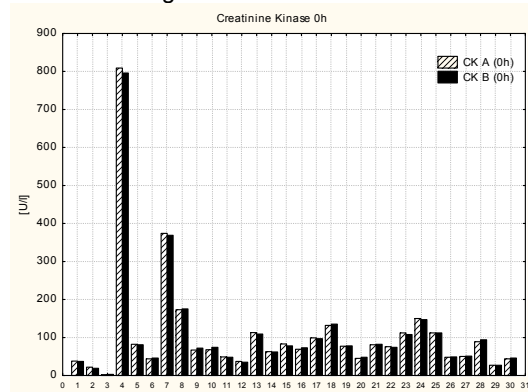
Cholesterol

Reference range: 50-200 mg/dl



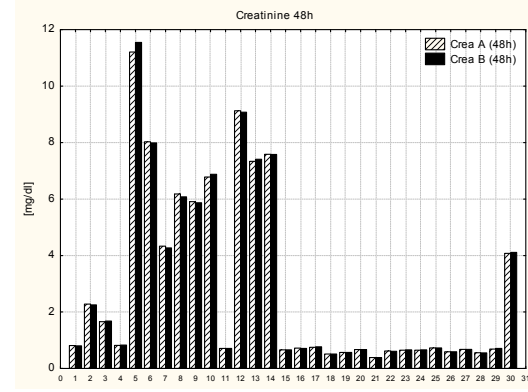
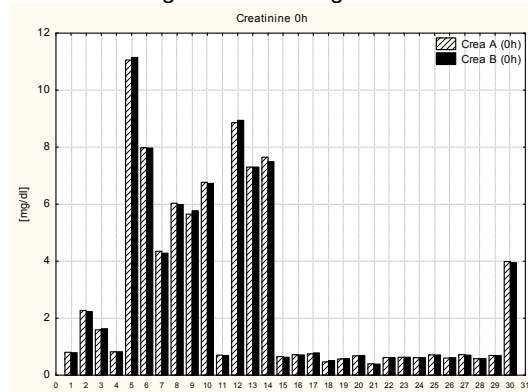
Creatine Kinase

Reference range: 38-171 U/l



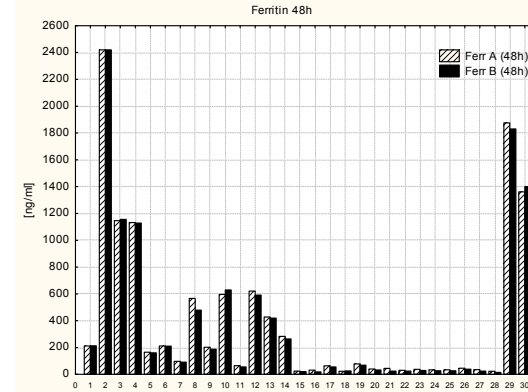
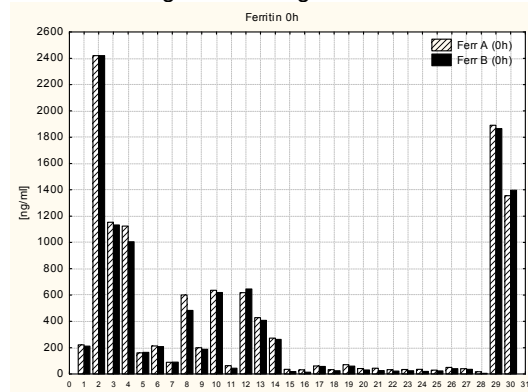
Creatinine

Reference range: 0.67-1.17 mg/dl



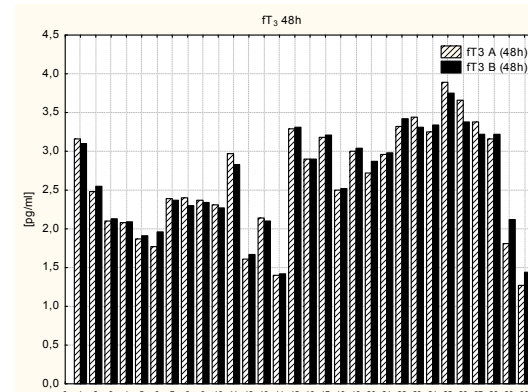
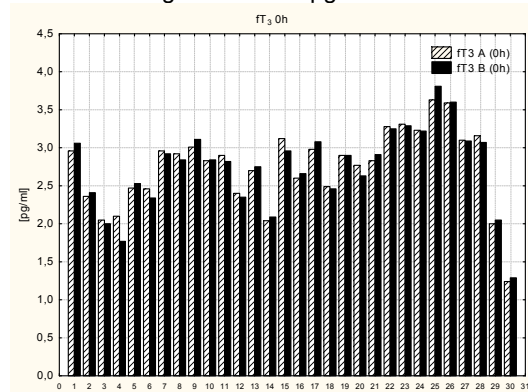
Ferritin

Reference range: 20-300 ng/ml



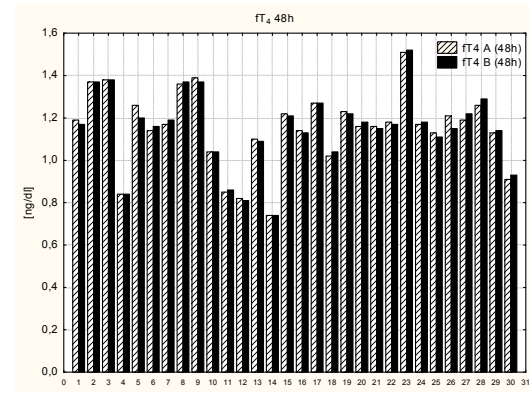
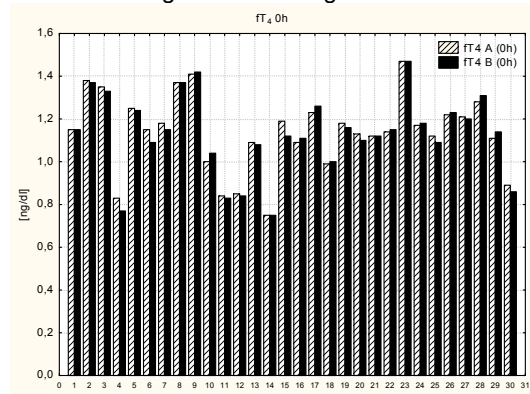
ft₃

Reference range: 2.00-4.40 pg/ml



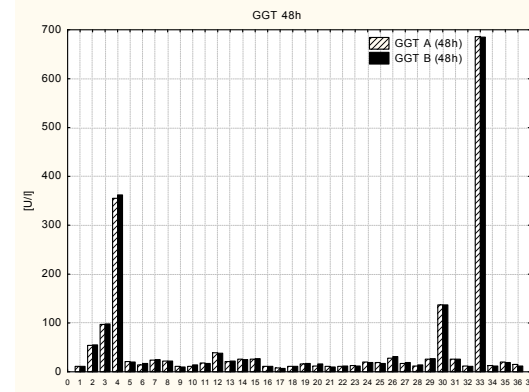
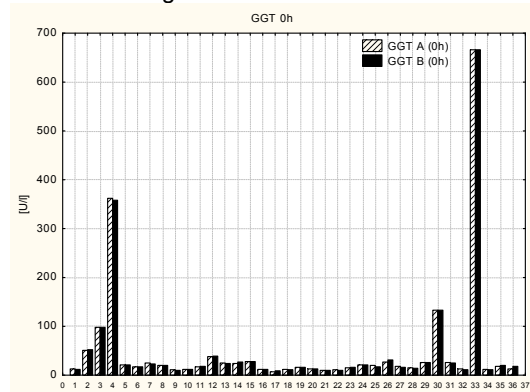
fT₄

Reference range: 0.93-1.70 ng/dl



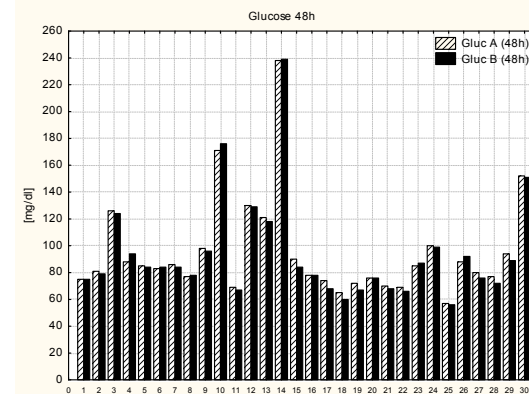
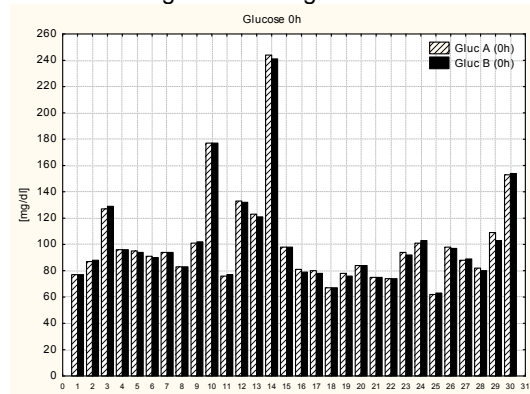
Gamma Glutamyltransferase (GGT)

Reference range male: 10-55 U/l



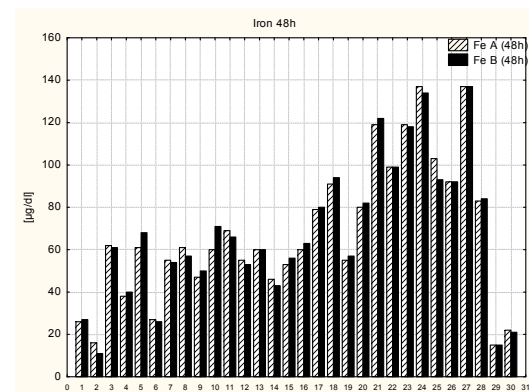
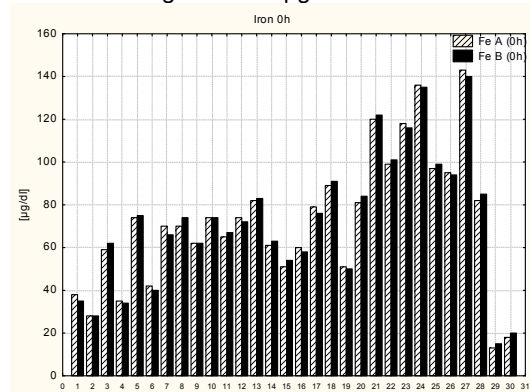
Glucose

Reference range: 85-100 mg/dl

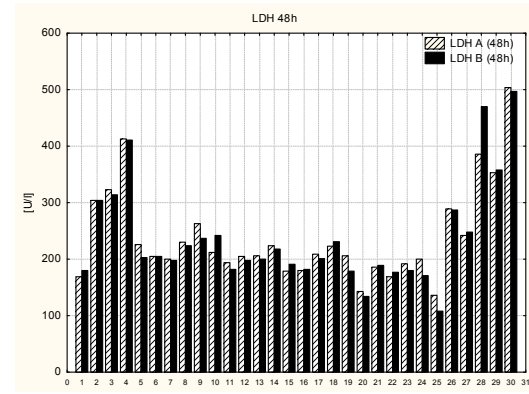
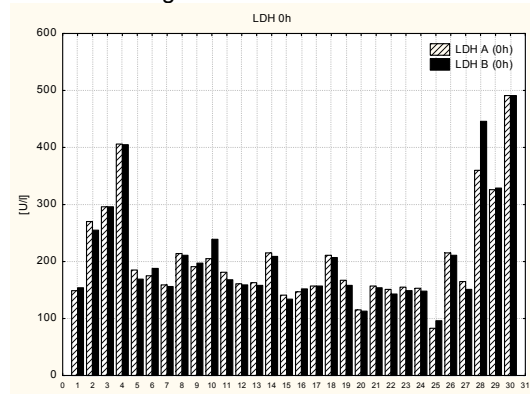


Iron

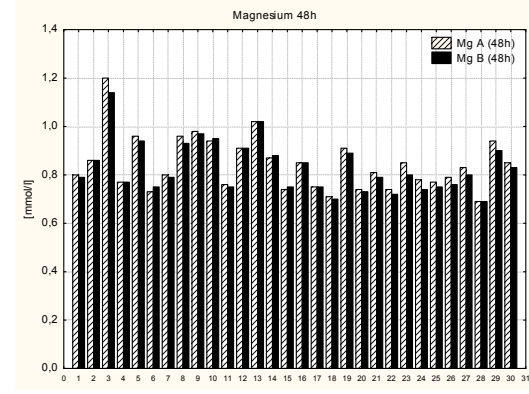
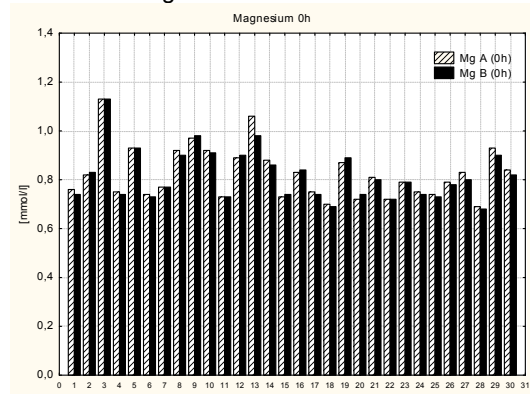
Reference range: 59-158 µg/dl



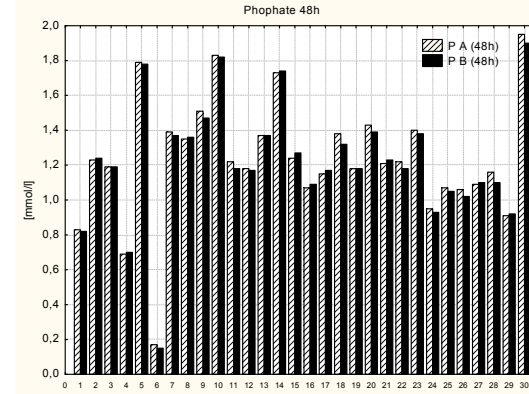
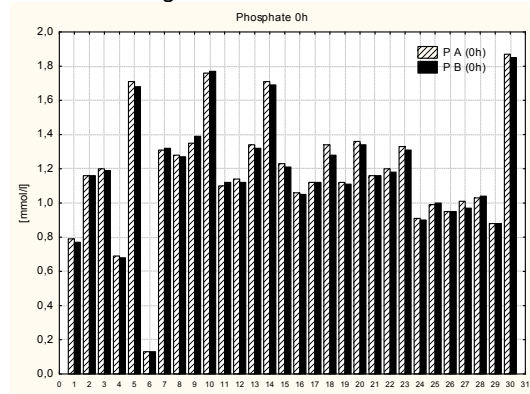
Lactate Dehydrogenase (LDH)
Reference range: 138-248 U/l



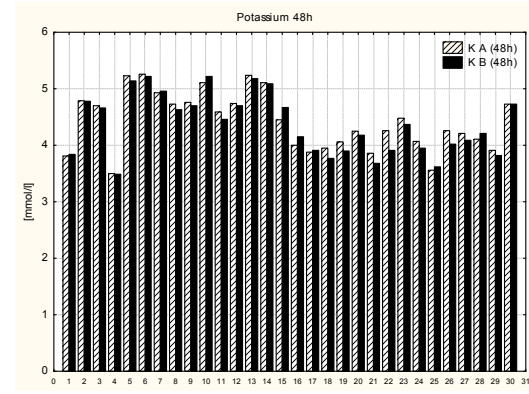
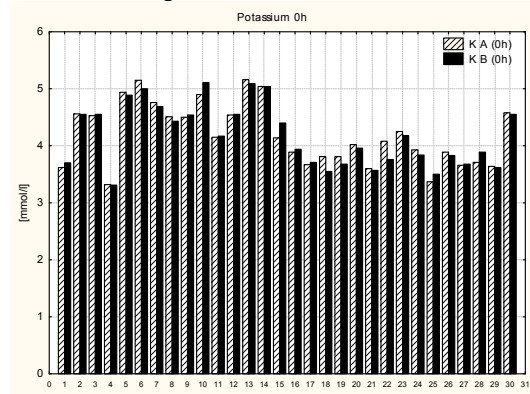
Magnesium
Reference range: 0.65-1.05 mmol/l



Phosphate
Reference range: 0.87-1.45 mmol/l

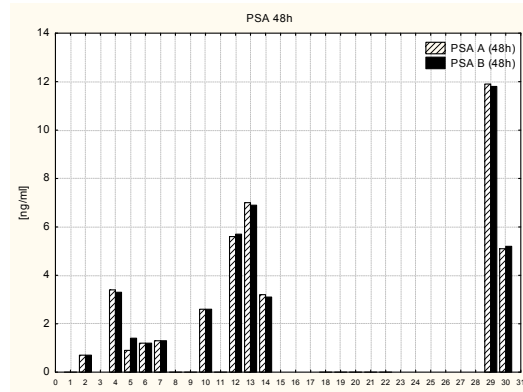
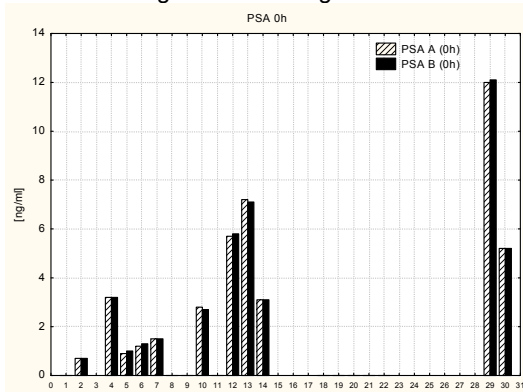


Potassium
Reference range: 3.5-5.1 mmol/l



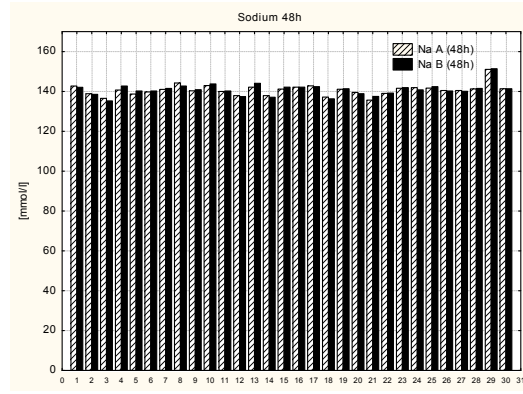
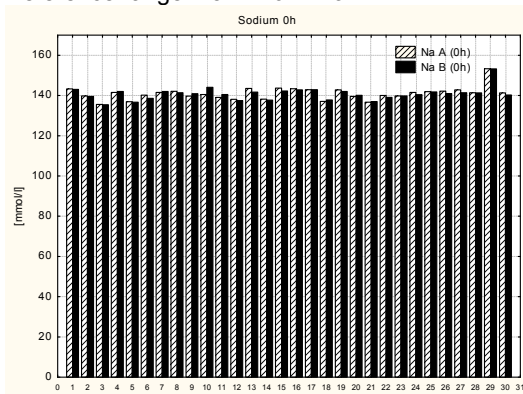
Prostate Specific Antigen (PSA ECLIA)

Reference range: 0.00-4.50 ng/ml



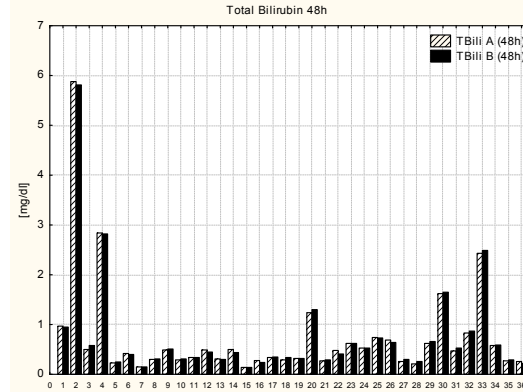
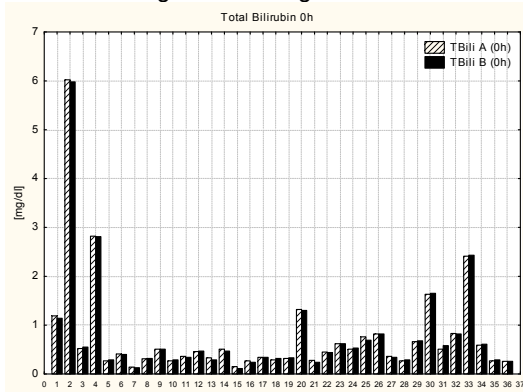
Sodium

Reference range: 132-146 mmol/l



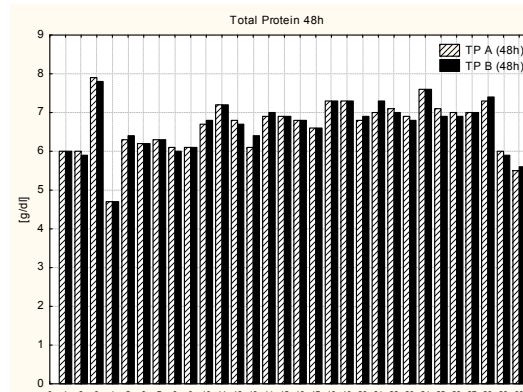
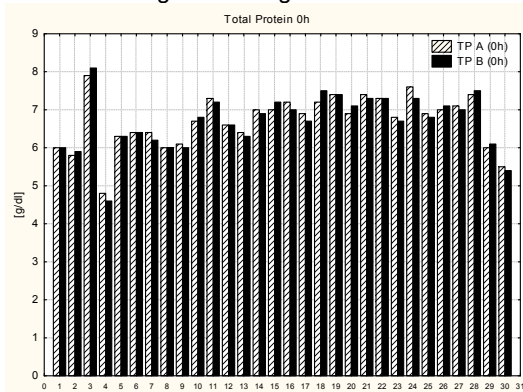
Total Bilirubin

Reference range: 0.0-1.2 mg/dl



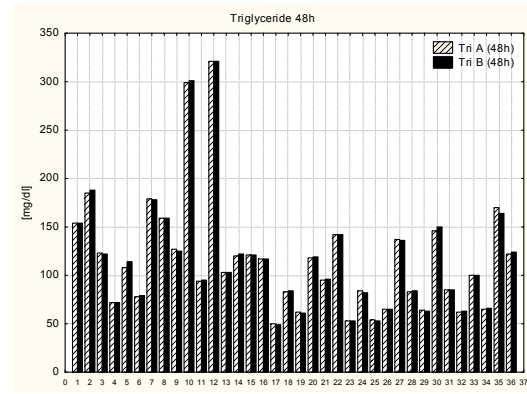
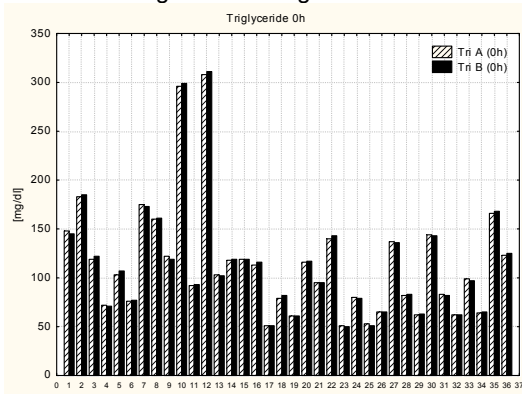
Total Protein

Reference range: 6.4-8.3 g/dl



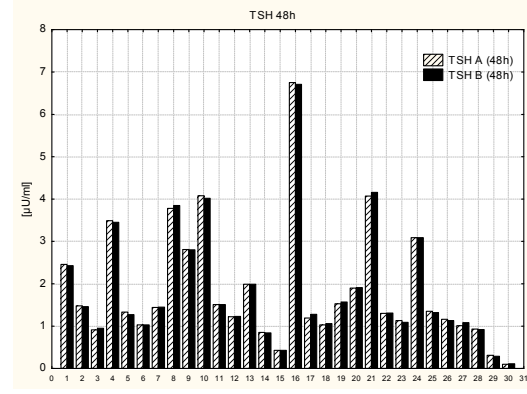
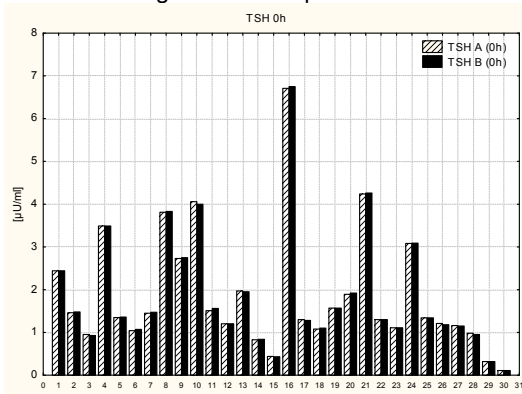
Triglyceride

Reference range: 50-200 mg/dl



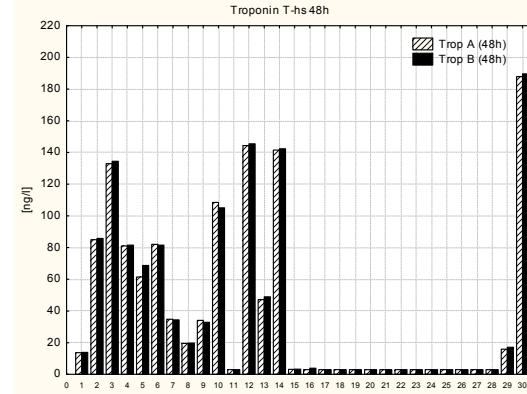
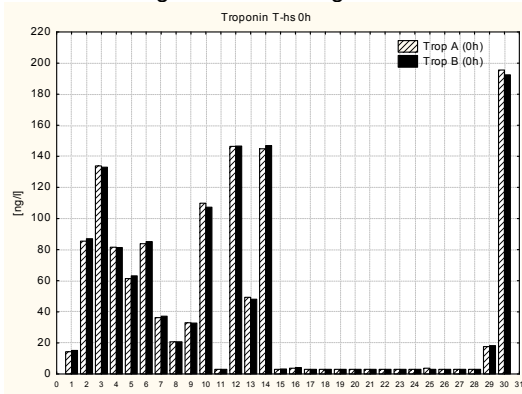
Thyroid stimulating hormone (TSH)

Reference range: 0.27-4.20 μ U/ml



Troponin T-hs

Reference range: 0.00-14.00 ng/l



Uric acid

Reference range: 0.00-8.4 mg/dl

