Stability of VACUETTE® CAT Serum Separator Clot Activator Tubes with shortened centrifugation times

Background:

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

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

VACUETTE® CAT 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:

Centrifugation time is a critical issue for reducing turn-around-time in laboratory workflow. A clinical study was carried out to evaluate two different centrifugation conditions in order to improve efficiency in laboratory processes. [2,3]

Study design and procedure:

Venous blood was collected from 40 presumably healthy donors into four VACUETTE® CAT Serum Separator Clot Activator tubes (456073, 13/100, 5 ml) using VACUETTE® Safety Blood Collection Sets with Holder (item # 450085). Two different VACUETTE® Separator tubes (Sample A US P-Gel and Sample B European Gel) were included in this test. A discard tube was used to guarantee appropriate filling of the tubes. The order of collection was randomized. Directly after blood collection all the tubes were inverted 8 times for proper mixing. Tubes were allowed to clot for at least 30 min at room temperature in an upright position and then centrifuged with a Rotanta 460R centrifuge from Hettich at two different centrifugation conditions (see Table 1).

Table 1: Centrifugation

Sample	RCF (x g)	Time	Temp [°C]
Sample A P-Gel	1800g	10 min	20 °C
Sample A P-Gel	1800g	5 min	20 °C
Sample B Gel	1800g	10 min	20 °C
Sample B P-Gel	1800g	5 min	20 °C

All sample tubes were analyzed for the constituents listed below at the initial time point within 2 hours of blood collection and after 48 hours on the Olympus AU640 analyzer (chemistry assays) or the Abbott AxSYM® analyzer (immunoassay assays) using accompanying reagents from the instrument manufacturers. Between measurements, the samples were stored in the refrigerator at 4-8 °C.

The following parameter were measured:

- Alanine Aminotransferase (ALT)
- Albumin
- Alkaline Phosphatase (ALP)
- Aspartate Aminotransferase (AST)
- Calcium
- Chloride
- Cholesterol
- Creatine Kinase (CK)
- Creatinine
- Gamma Glutamyltransferase (GGT)

- Glucose
- Iron
- Lactate Dehydrogenase (LDH)
- Magnesium
- Phosphate
- Potassium
- Sodium
- Total Bilirubin
- Total Protein
- Triglyceride
- Thyroid stimulating hormone (TSH)
- Urea
- Uric acid
- Free Triiodothyronine (fT_3)
- Free Thyroxin (fT_4)

Results:

Comparison analysis was performed at the initial time point and at 48 hours. Statistical evaluation was performed with the T-test ($\alpha = 0.05$) using StatSoft Software, Version 9. One sample B centrifuged at 1800g for 10 minutes was found to be hemolyzed (donor 17) and was removed from the statistical data pool for Potassium after outlier testing. Also, for some donor values for immunoassay parameters at 48 hours are missing due to insufficient sample volume. Clinical evaluation was based on the allowed recommendation by the German Medical Association (RILIBÄK) [4]. No clinically significant differences were observed with either gel type for the two centrifugation settings of 1800g for 10 minutes and 1800g for 5 minutes at the initial time point or after 48 hours.

Conclusion:

In this study, both gel types used in the VACUETTE® CAT Serum Separator Clot Activator tubes showed comparable results for the two tested centrifugation conditions of 1800g for 10 minutes and 1800g for 5 minutes for the tested biochemical parameters at the initial time point and 48 hours. Differences in results were not clinically significant.

References:

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

[2] O'Keane M. P., Evaluation of three different specimen types (serum, plasma, lithium heparin and serum gel separator) for analysis of certain analytes: clinical significance of differences in results and efficiency in use. Clin. Chem. Labor. Med. (44), 5 662-668

[3] Thomas L., Labor und Diagnose. Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. 7.Aufl. TH-Books Verlagsgesellsch.

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

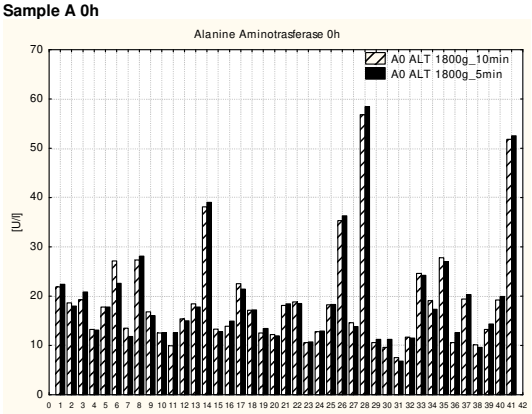
[5] Olympus product insert.

[6] AxSYM® product insert.

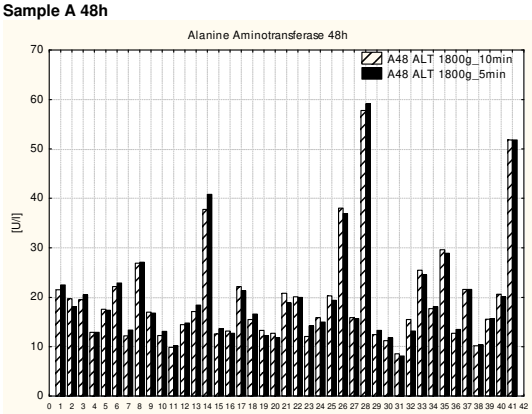
Alanine Aminotransferase (ALT, GPT)

Reference range male: <35 U/l
Reference range female: < 31 U/l [5]

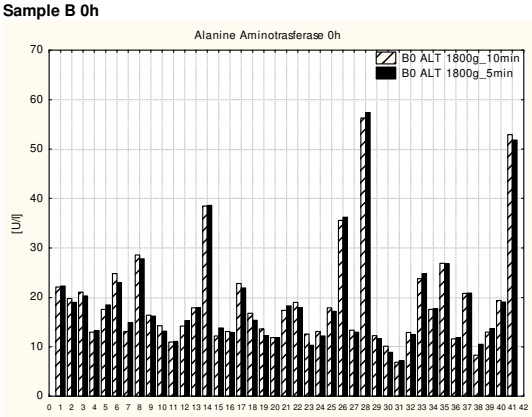
Sample A 0h



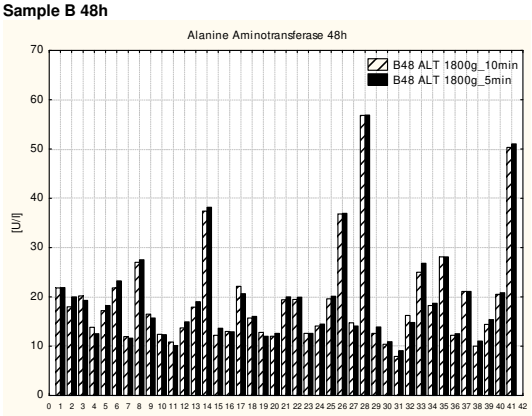
Sample A 48h



Sample B 0h



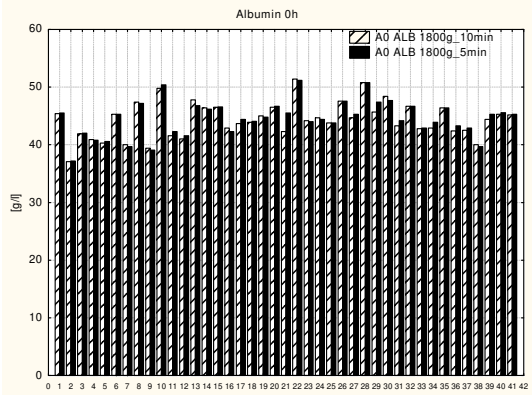
Sample B 48h



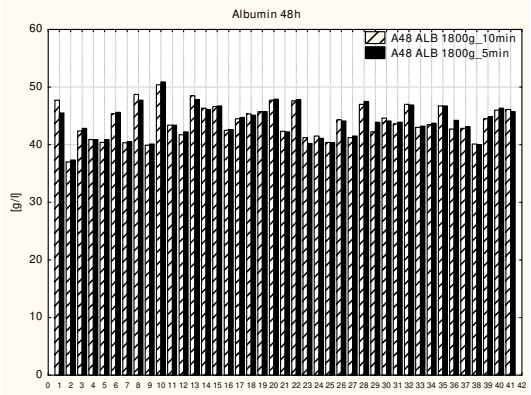
Albumin

Reference range: 35-53 g/l [5]

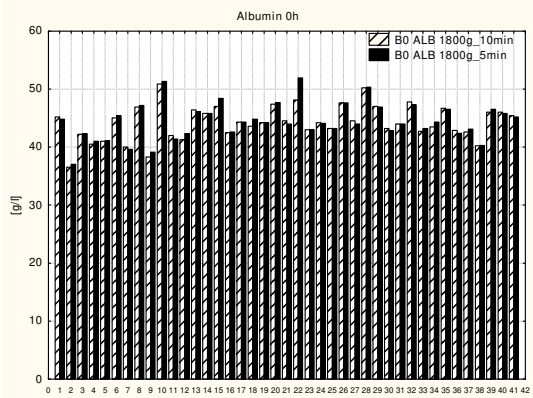
Sample A 0h



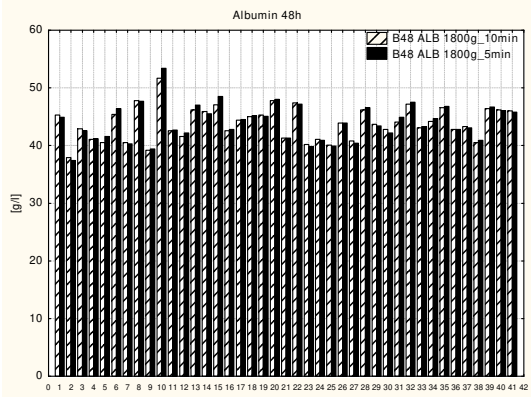
Sample A 48h



Sample B 0h



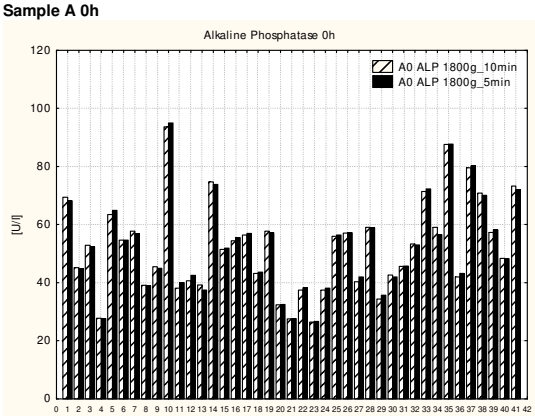
Sample B 48h



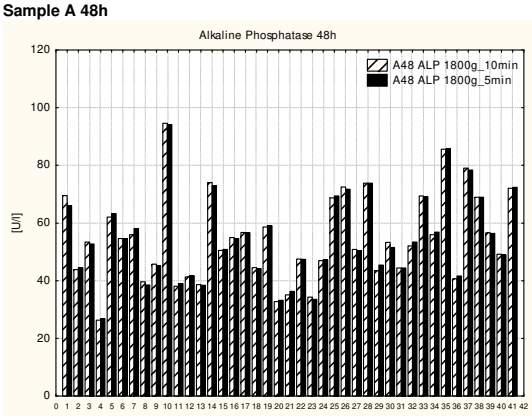
Alkaline Phosphatase:

Reference range male: 40-130 U/l
Reference range female: 55-105 U/l [5]

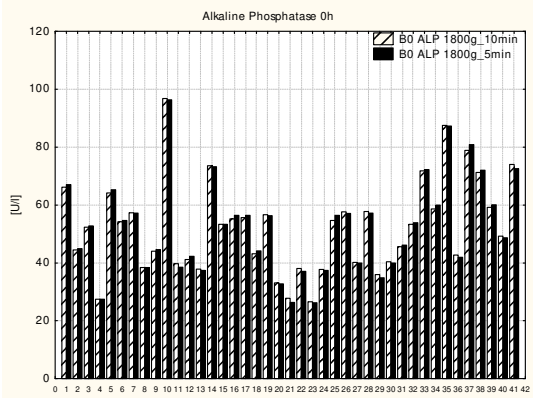
Sample A 0h



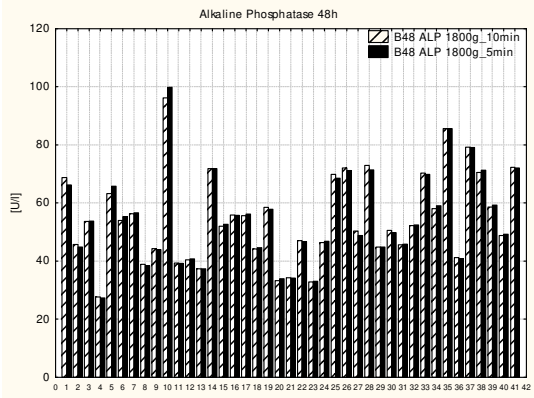
Sample A 48h



Sample B 0h



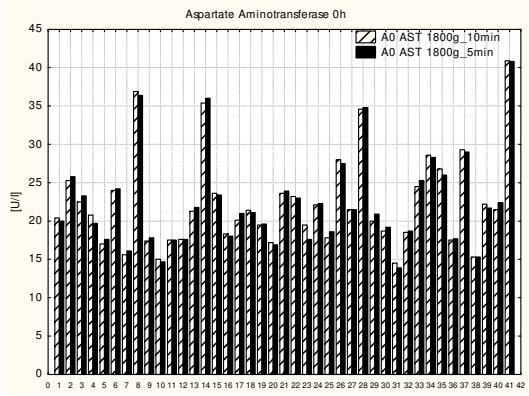
Sample B 48h



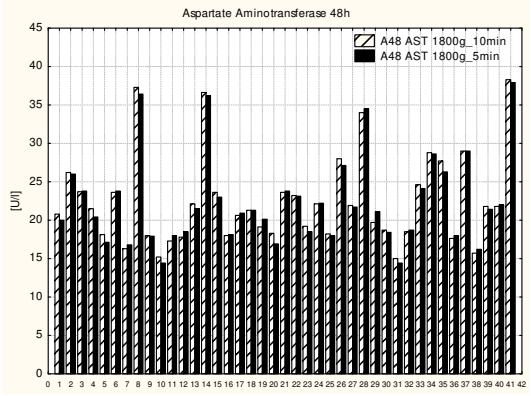
Aspartate aminotransferase (AST, GOT)

Reference range male: <45 U/l
Reference range female: < 34 U/l [5]

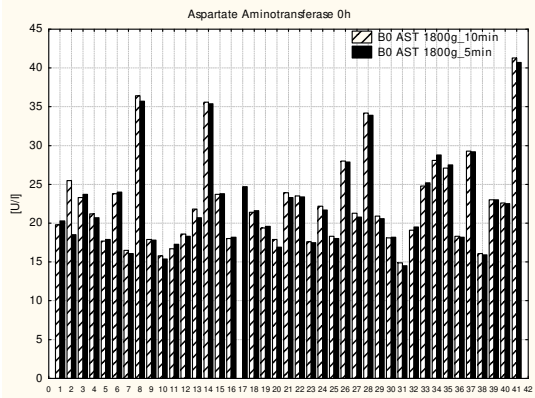
Sample A 0h



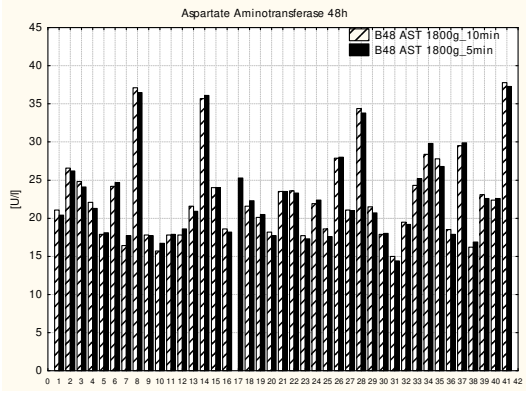
Sample A 48h



Sample B 0h



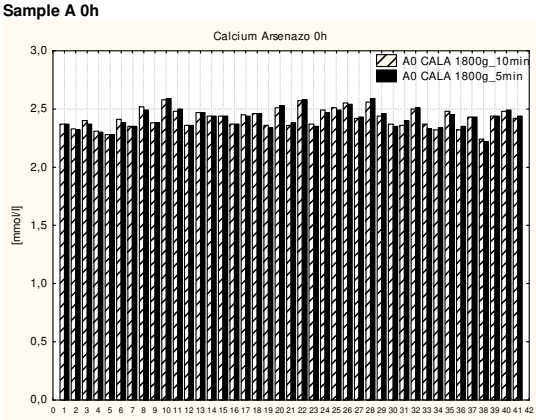
Sample B 48h



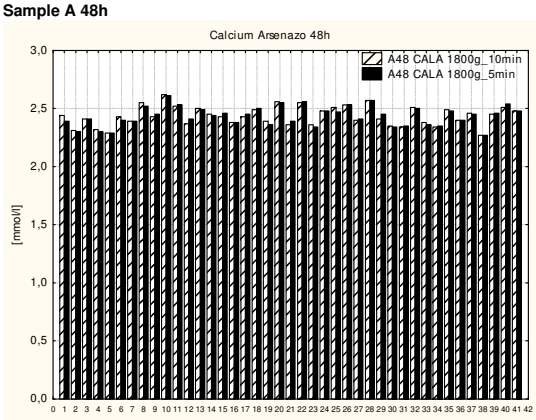
Calcium (Arsenazo)

Reference range: 2.20-2.65 mmol/l [5]

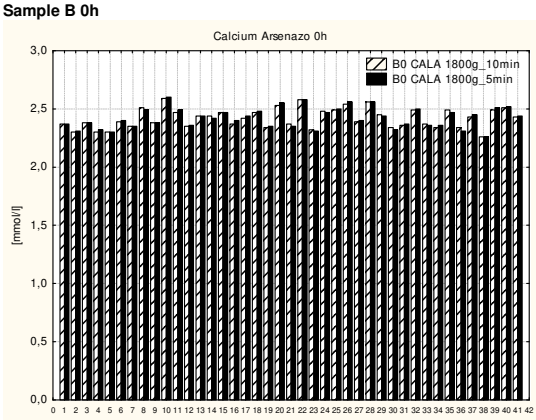
Sample A 0h



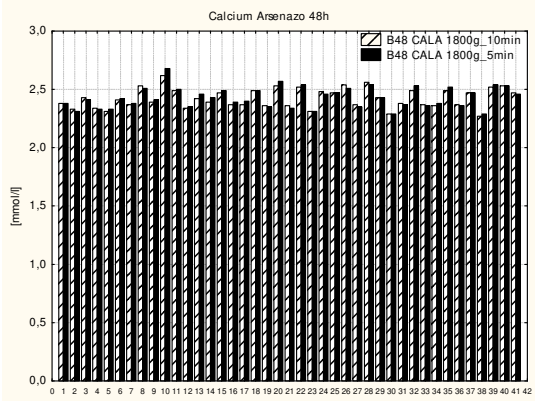
Sample A 48h



Sample B 0h



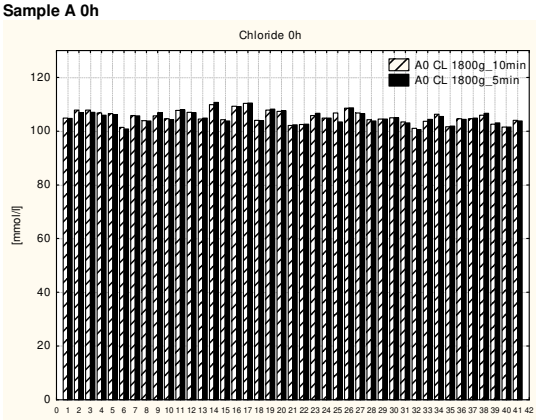
Sample B 48h



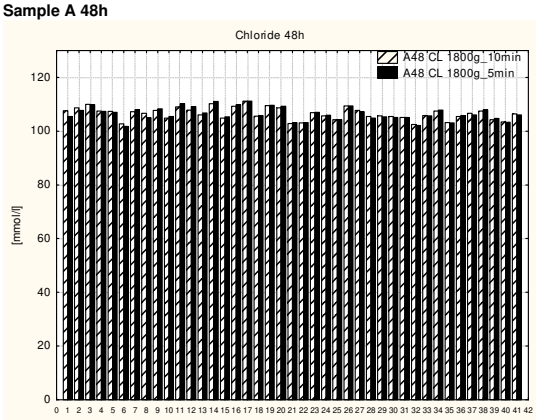
Chloride

Reference range: 95-105 mmol/l [5]

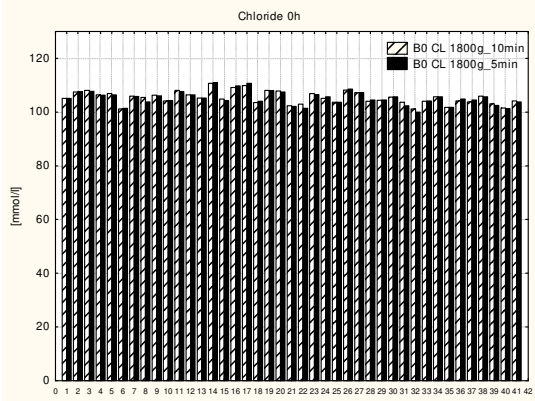
Sample A 0h



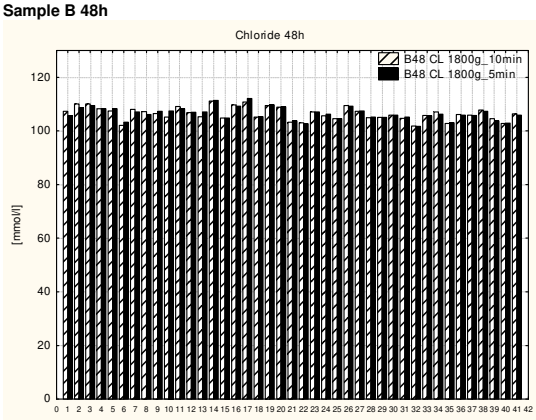
Sample A 48h



Sample B 0h



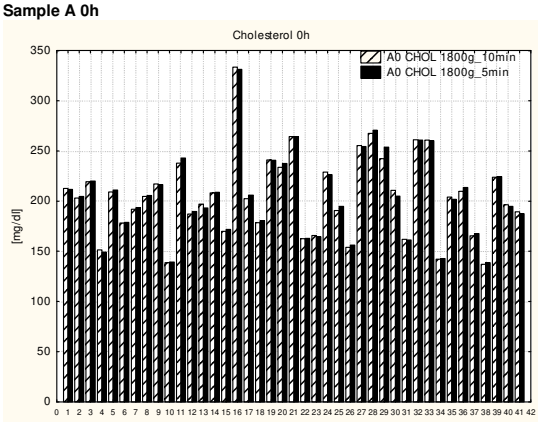
Sample B 48h



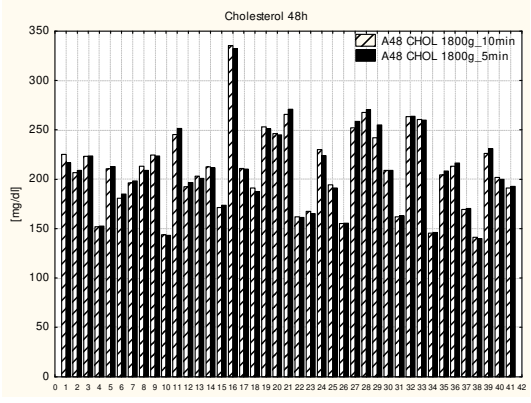
Cholesterol

Reference range: <200 mg/dl [5]

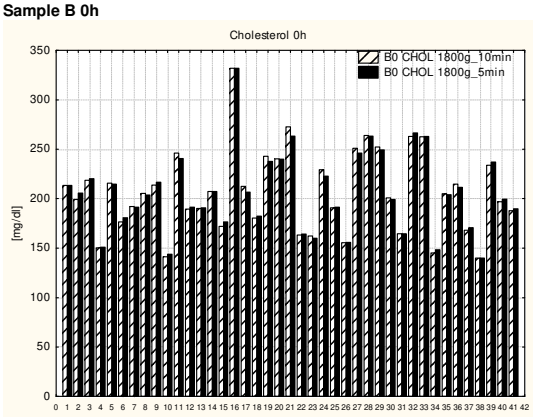
Sample A 0h



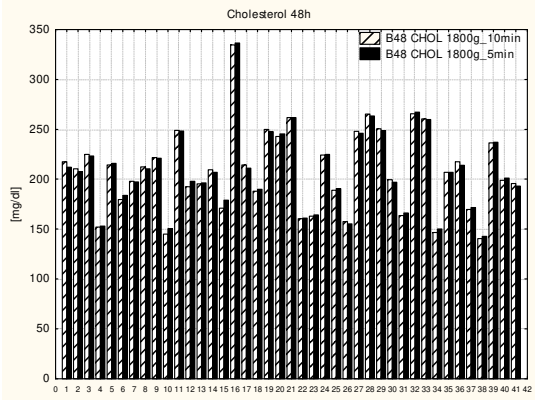
Sample A 48h



Sample B 0h



Sample B 48h

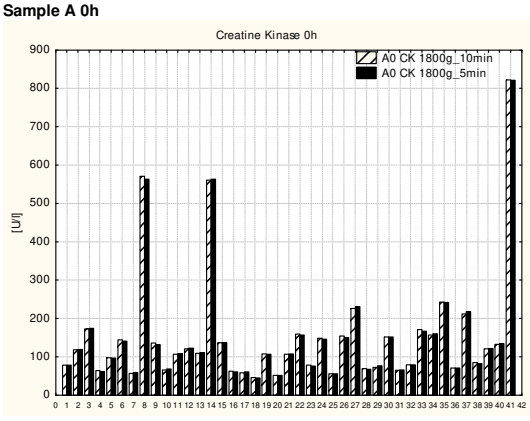


Creatine Kinase (CK)

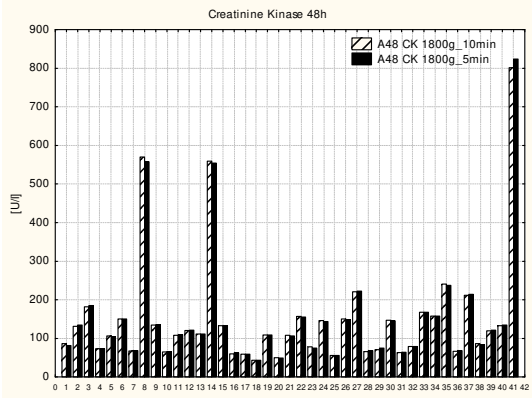
Reference range male: < 190 U/l

Reference range female: <167 U/l [5]

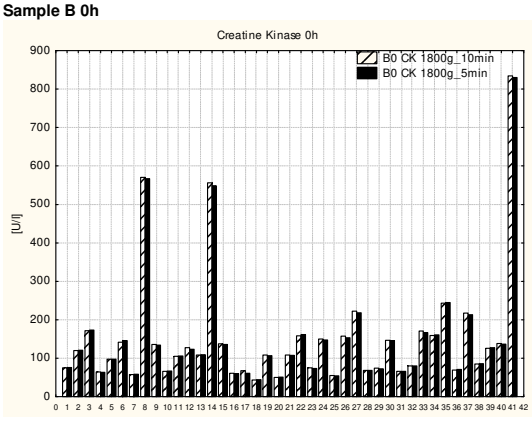
Sample A 0h



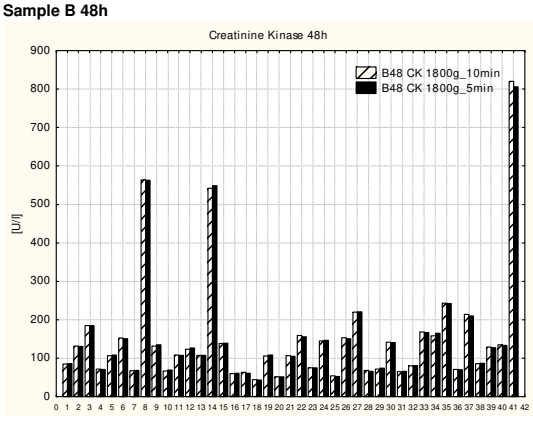
Sample A 48h



Sample B 0h



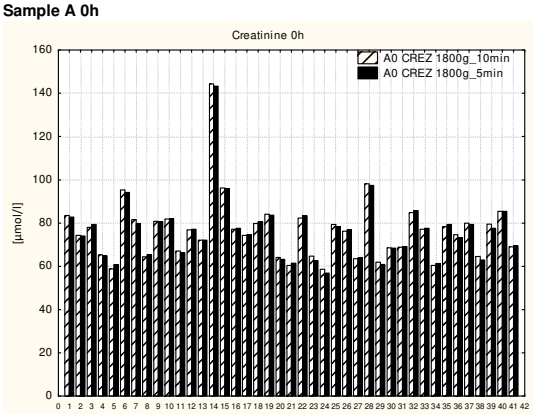
Sample B 48h



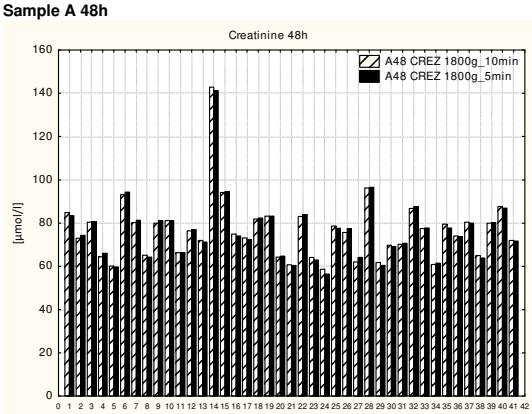
Creatinine

Reference range male: 49-97 µmol/l
Reference range female: 42-80 µmol/l [5]

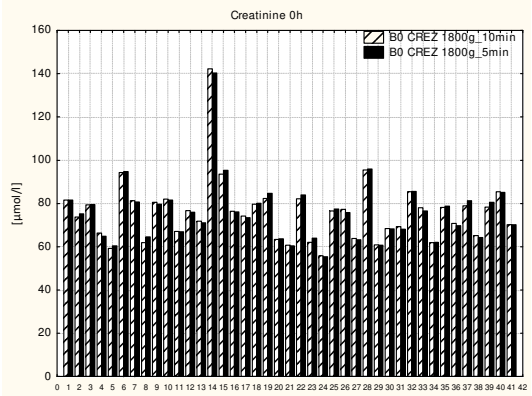
Sample A 0h



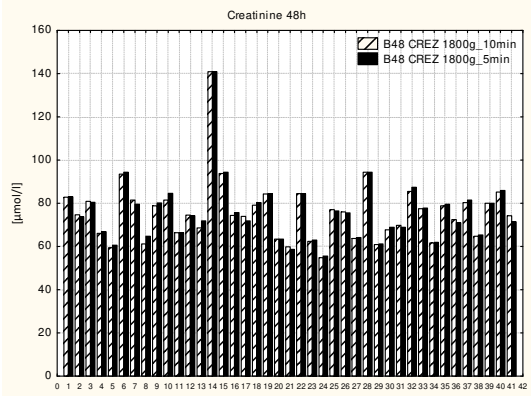
Sample A 48h



Sample B 0h



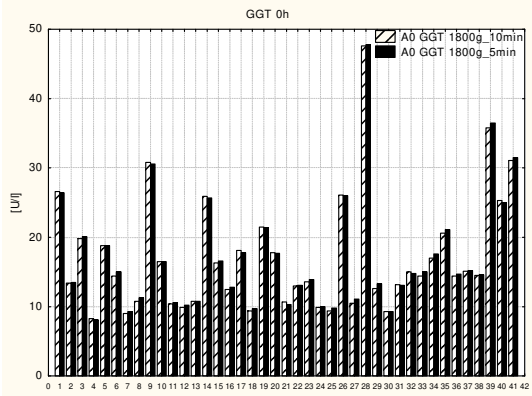
Sample B 48h



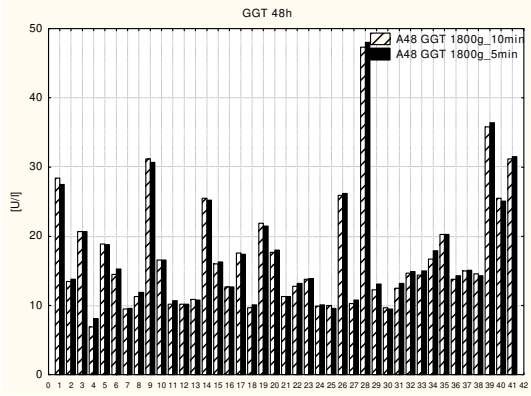
Gamma Glutamyltransferase (GGT)

Reference range male: < 55 U/l
Reference range female: <38 U/l [5]

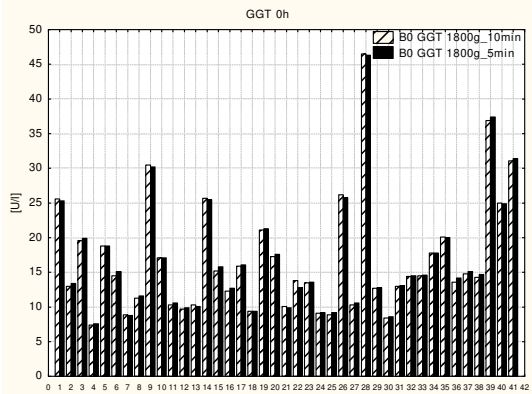
Sample A 0h



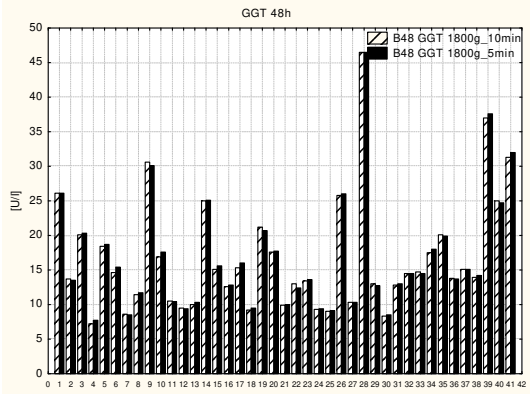
Sample A 48h



Sample B 0h



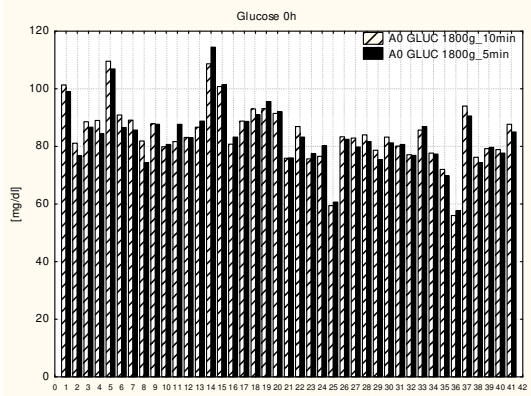
Sample B 48h



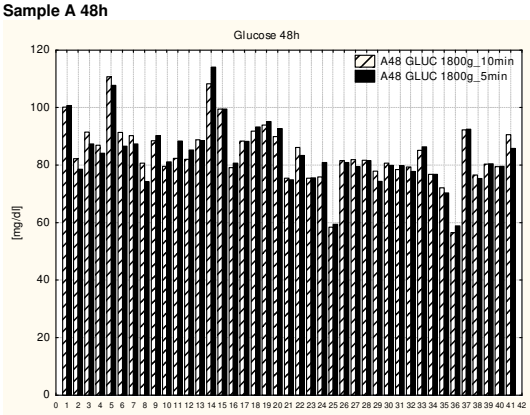
Glucose

Reference range: 74-109 mg/dl [5]

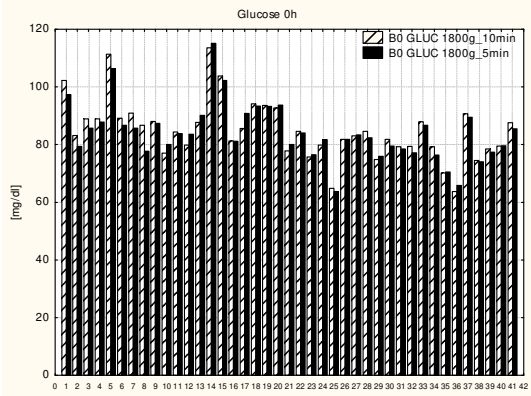
Sample A 0h



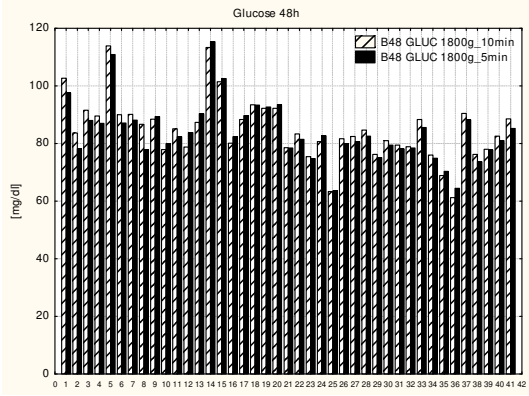
Sample A 48h



Sample B 0h



Sample B 48h

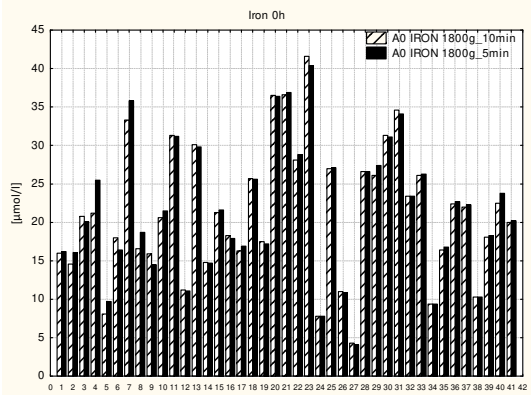


Iron

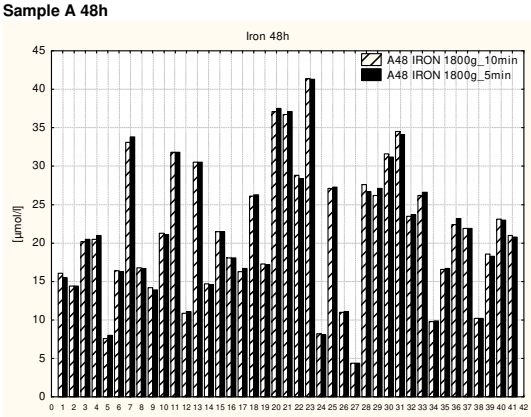
Reference range male: 6.3-30.7 µmol/l

Reference range female: 4.1-29.5 µmol/l [5]

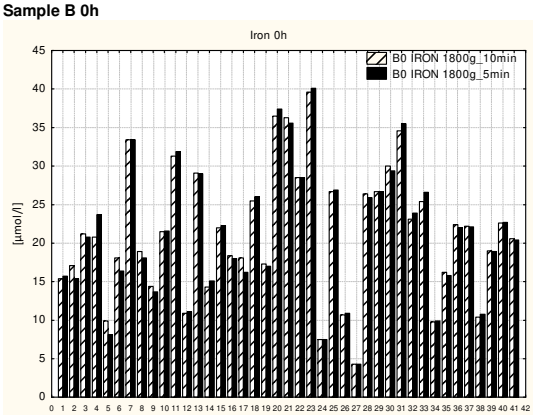
Sample A 0h



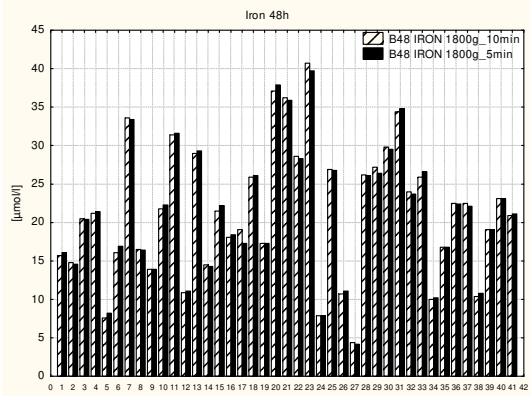
Sample A 48h



Sample B 0h



Sample B 48h

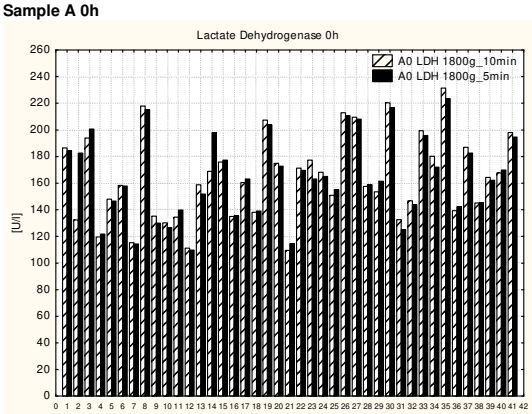


Lactate Dehydrogenase (LDH)

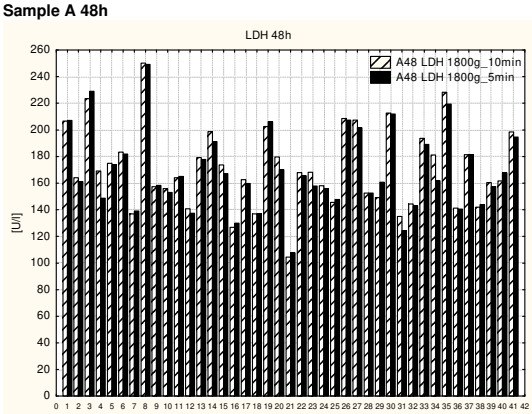
Reference range male: <248 U/l

Reference range female:<247 U/l [5]

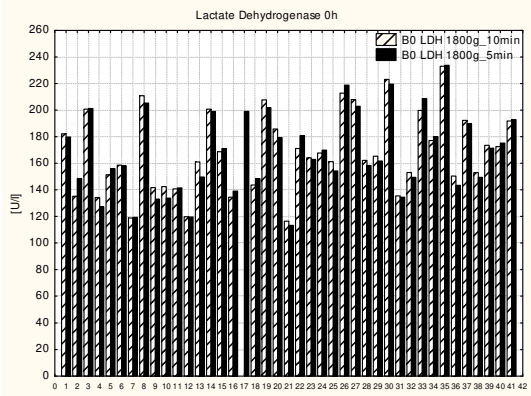
Sample A 0h



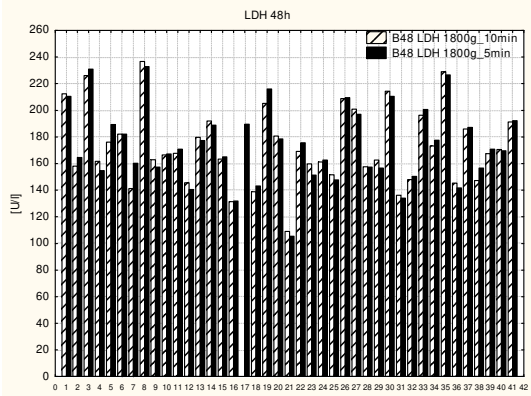
Sample A 48h



Sample B 0h



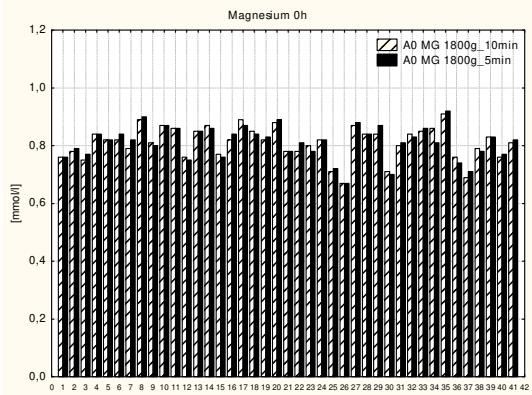
Sample B 48h



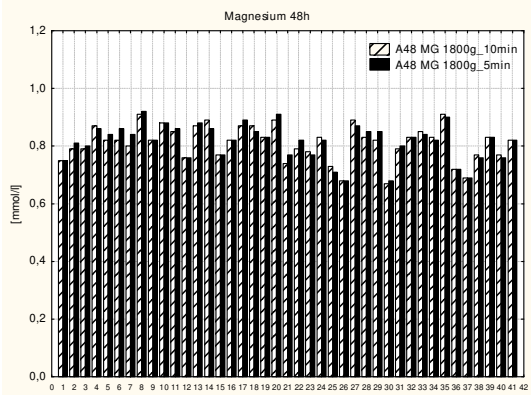
Magnesium

Reference range: 0.75-1.10 mmol/l [5]

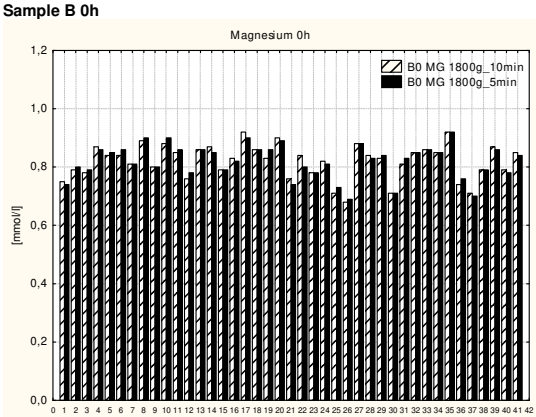
Sample A 0h



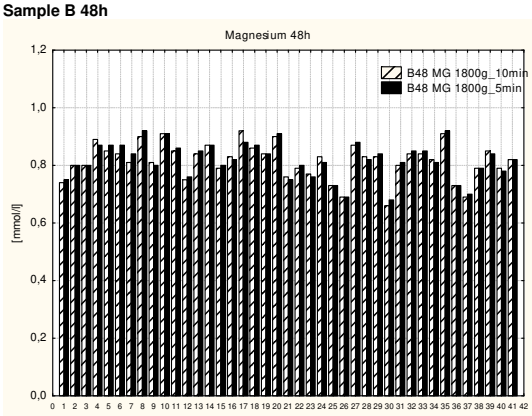
Sample A 48h



Sample B 0h



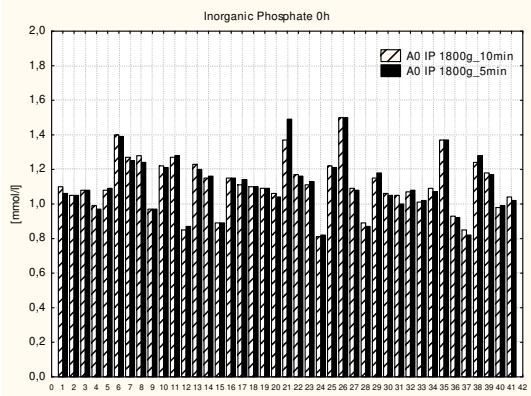
Sample B 48h



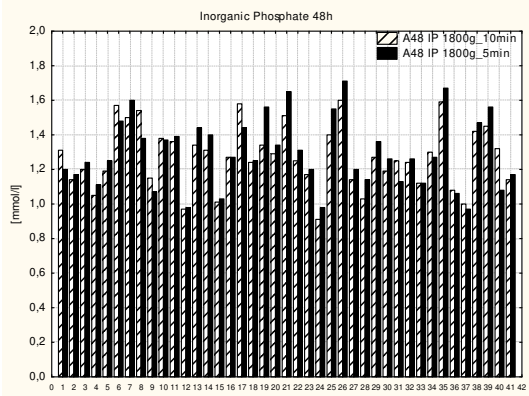
Phosphate, inorganic

Reference range: 0.84-1.45 mmol/l [5]

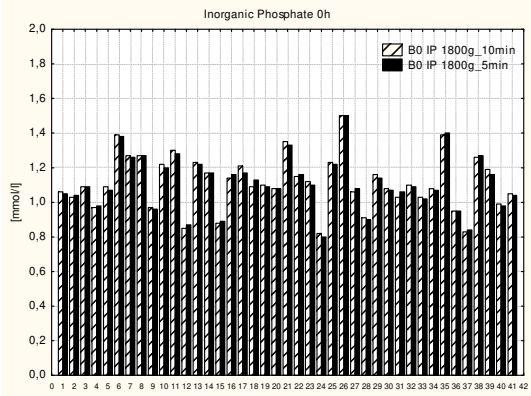
Sample A 0h



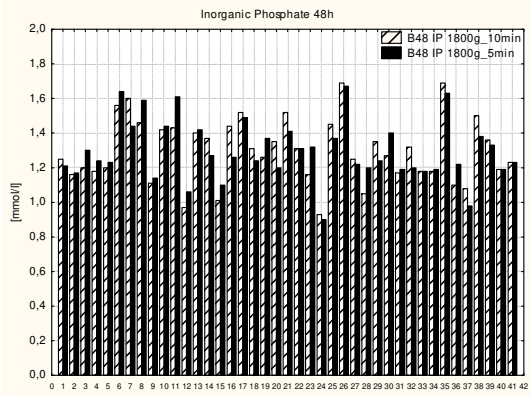
Sample A 48h



Sample B 0h



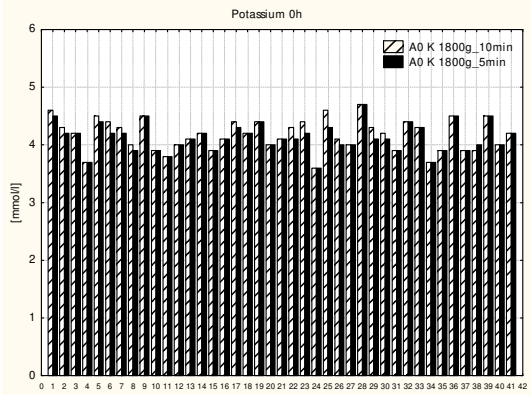
Sample B 48h



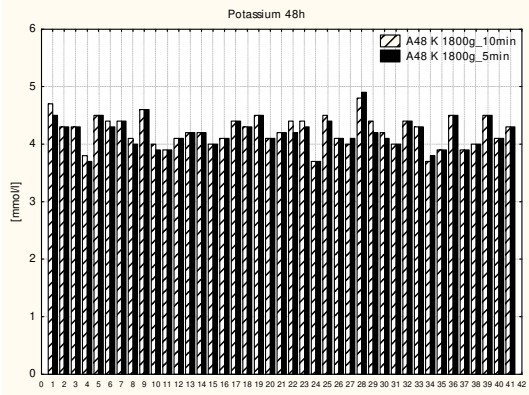
Potassium

Reference range: 3.6-4.8 mmol/l [5]

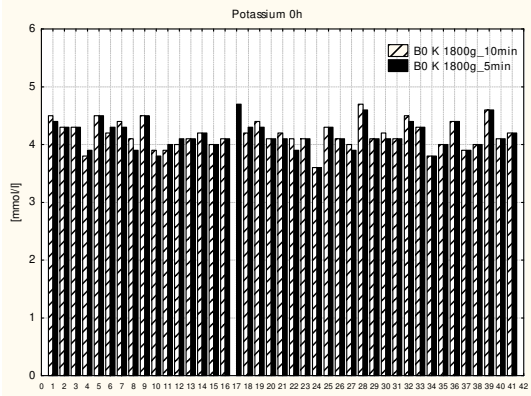
Sample A 0h



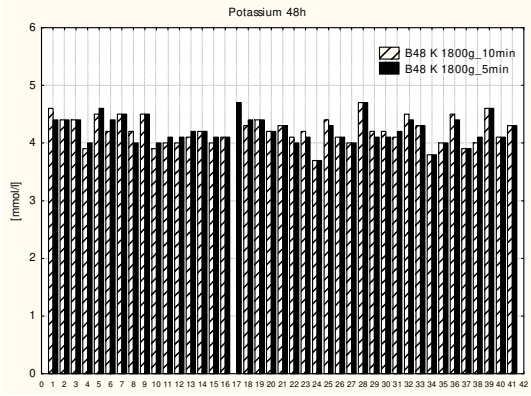
Sample A 48h



Sample B 0h



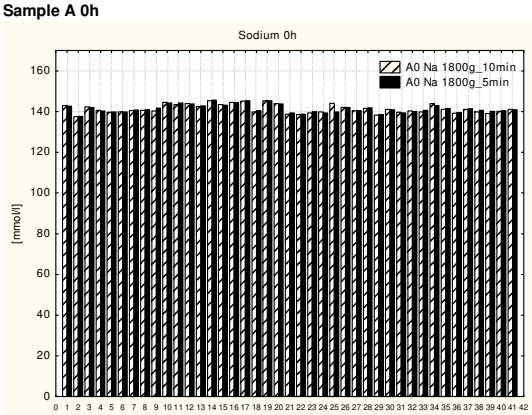
Sample B 48h



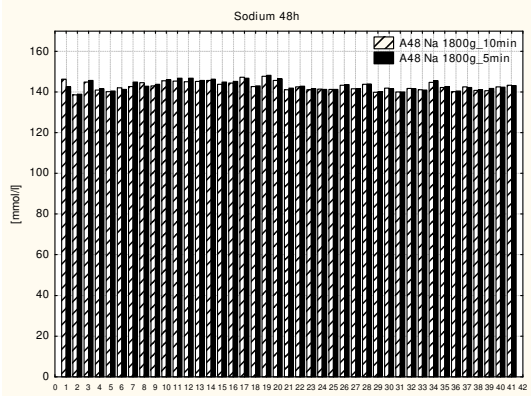
Sodium

Reference range: 135-145 mmol/l [5]

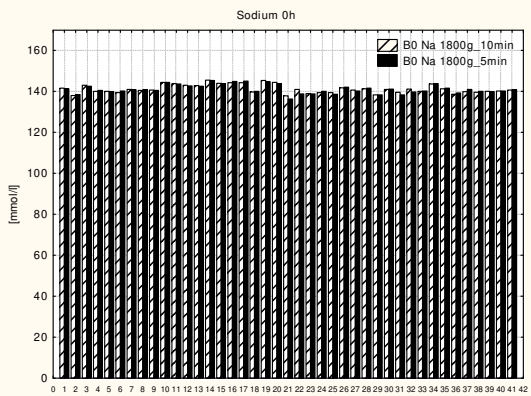
Sample A 0h



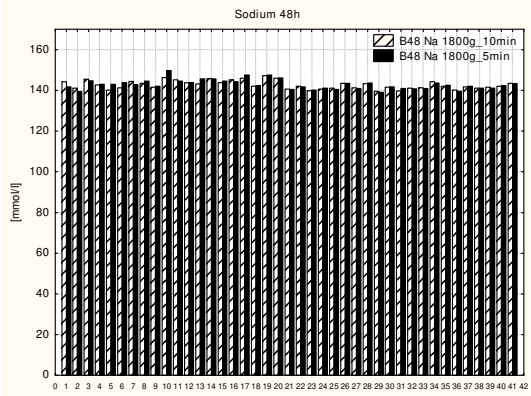
Sample A 48h



Sample B 0h



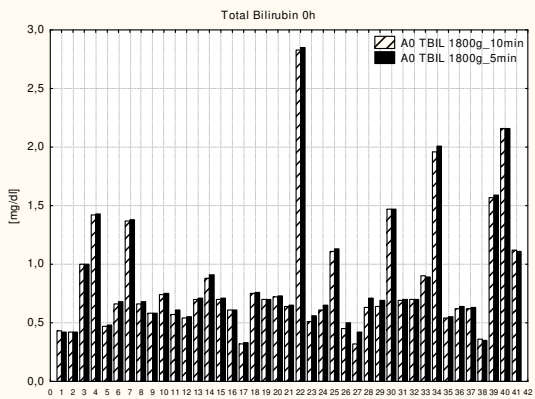
Sample B 48h



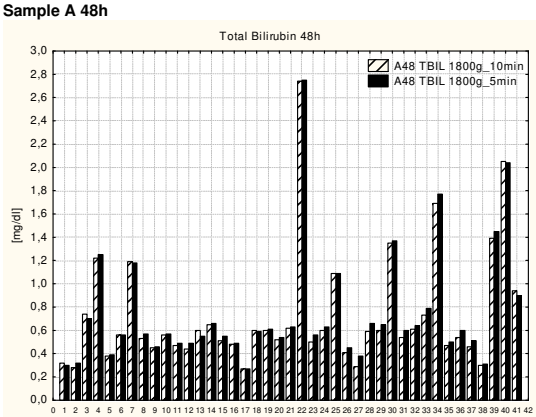
Total Bilirubin

Reference range: 0.1-1.2 mg/dl [5]

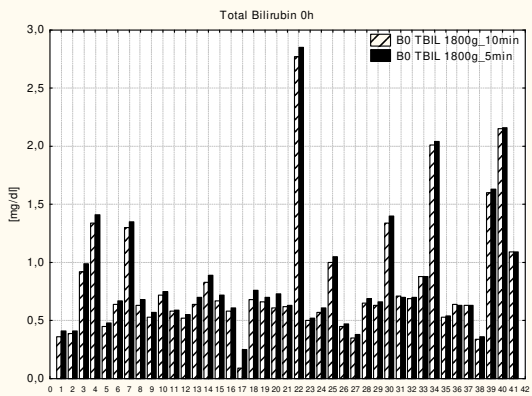
Sample A 0h



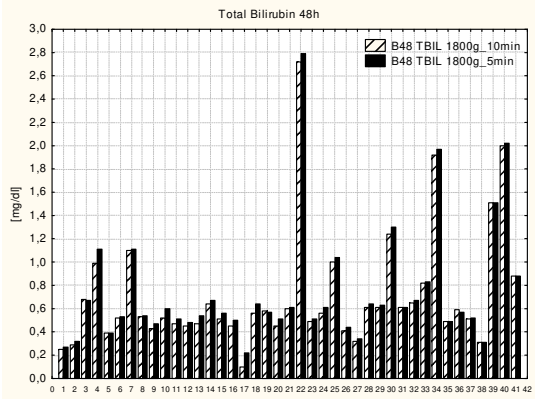
Sample A 48h



Sample B 0h



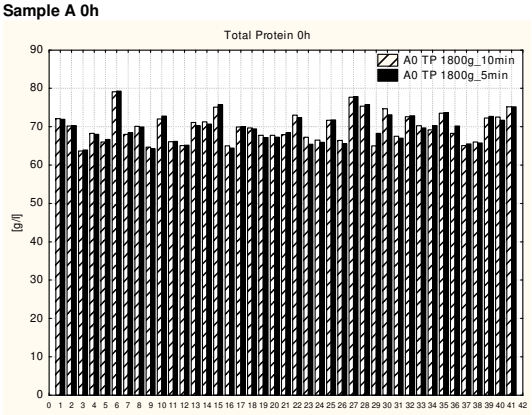
Sample B 48h



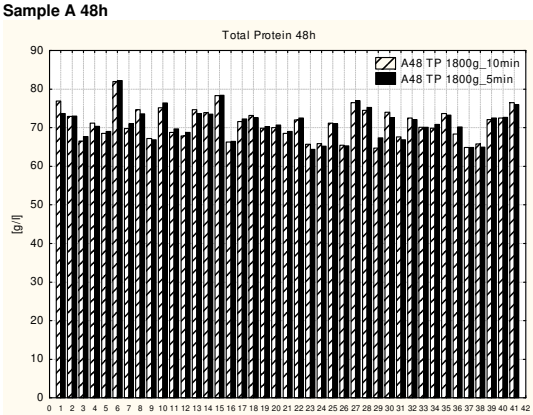
Total Protein

Reference range: 66-83 g/l [5]

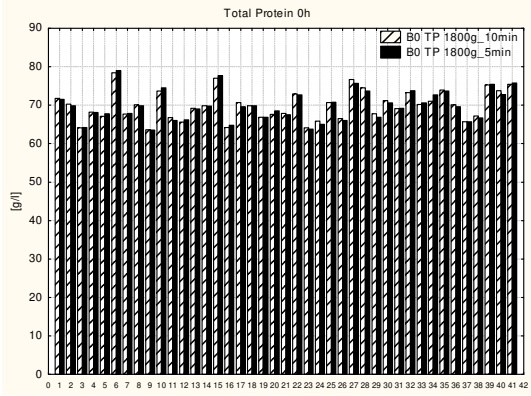
Sample A 0h



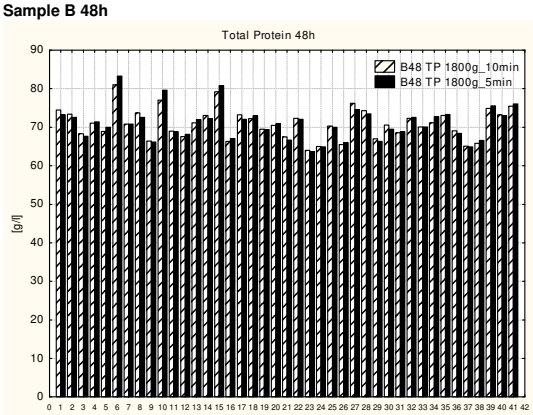
Sample A 48h



Sample B 0h



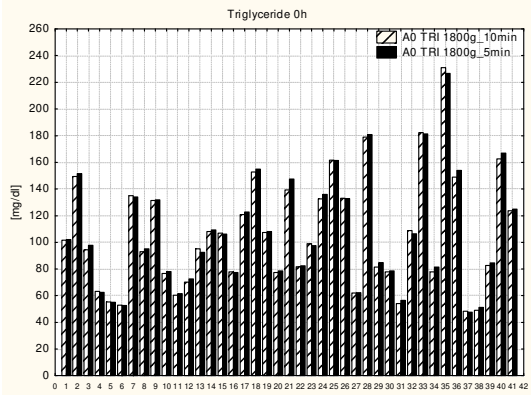
Sample B 48h



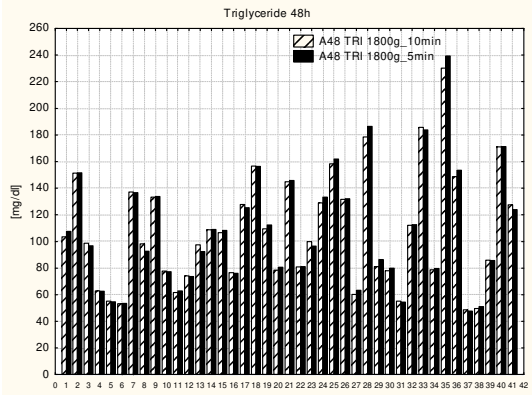
Triglyceride

Reference range: <150 mg/dl [5]

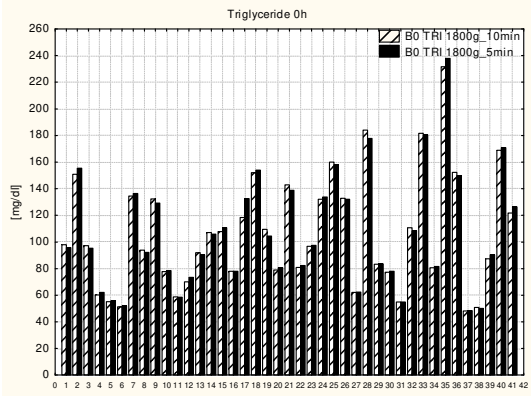
Sample A 0h



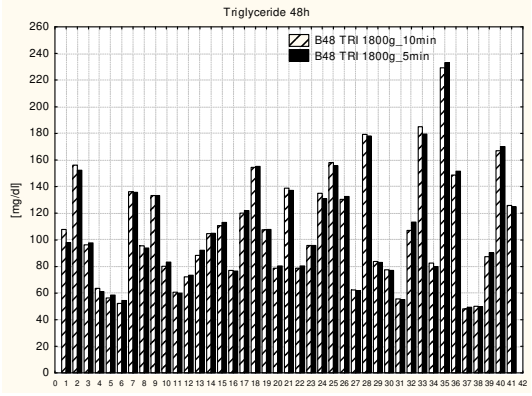
Sample A 48h



Sample B 0h



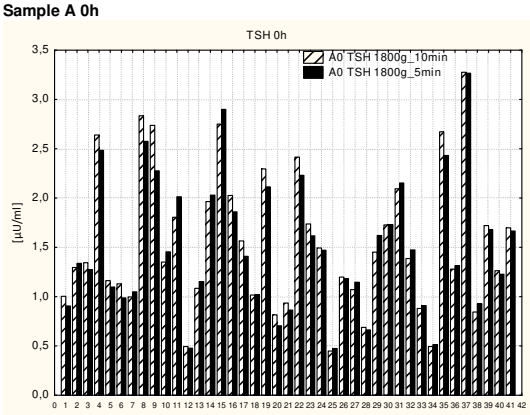
Sample B 48h



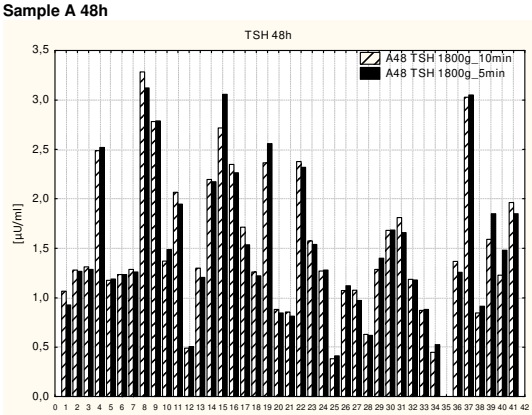
Thyroid stimulating hormone (TSH)

Reference range: 0.49-4.67 µU/ml [6]

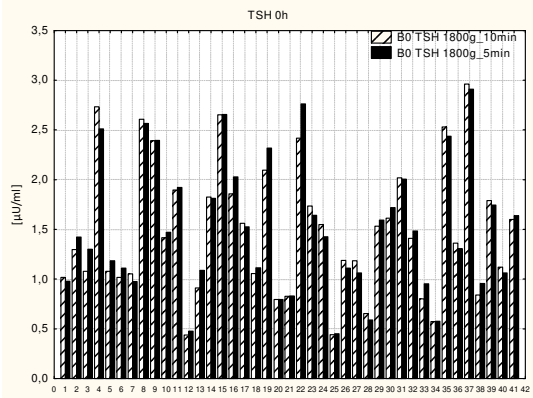
Sample A 0h



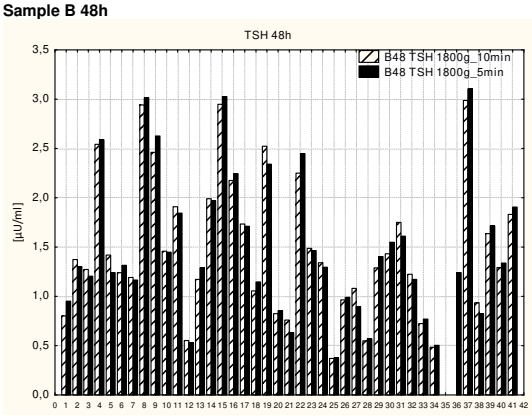
Sample A 48h



Sample B 0h



Sample B 48h

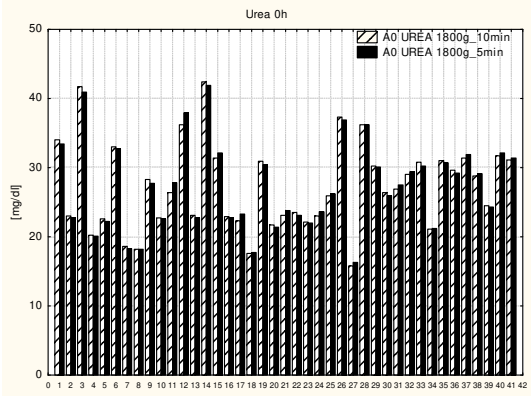


Urea

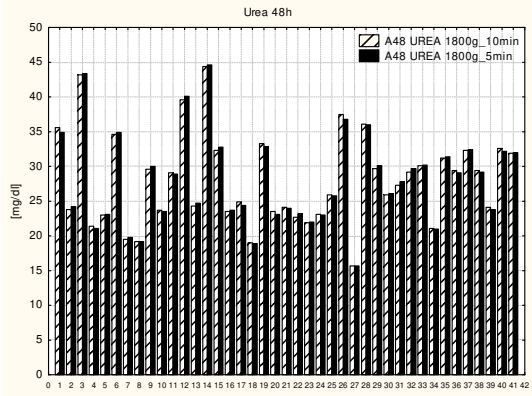
Reference range male: 18-55 mg/dl

Reference range female: 15-43 mg/dl [5]

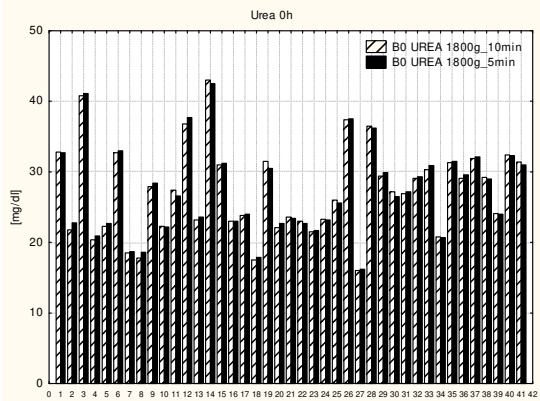
Sample A 0h



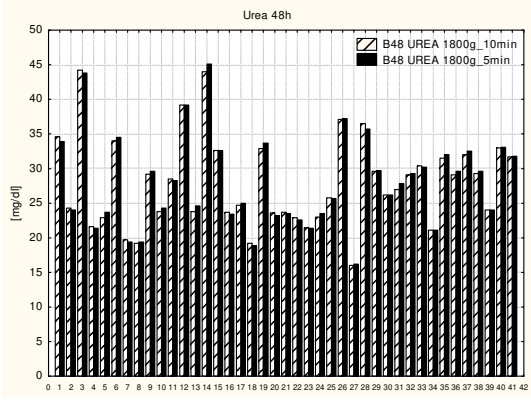
Sample A 48h



Sample B 0h



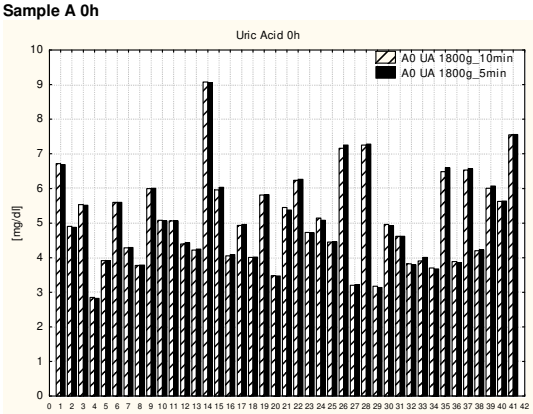
Sample B 48h



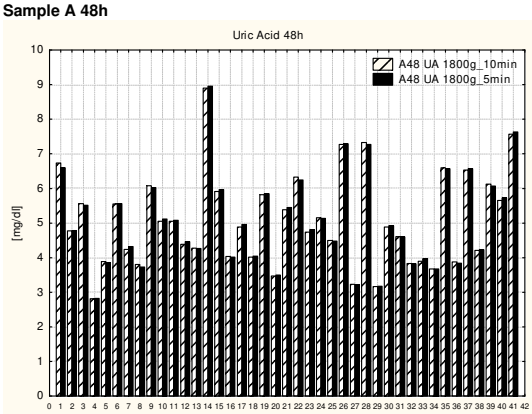
Uric acid

Reference range male: 3.6-7.0 mg/dl
Reference range female: 2.3-6.1 mg/dl [5]

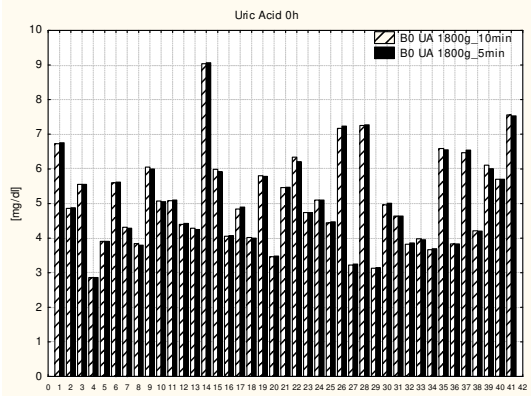
Sample A 0h



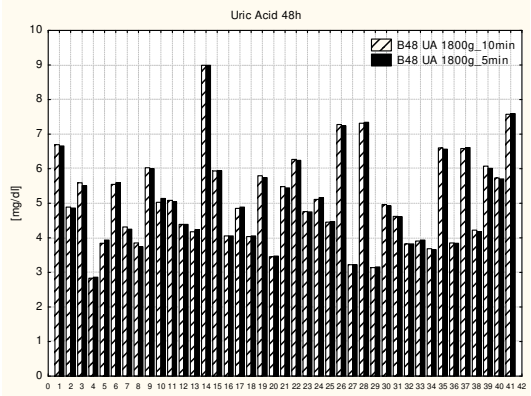
Sample A 48h



Sample B 0h



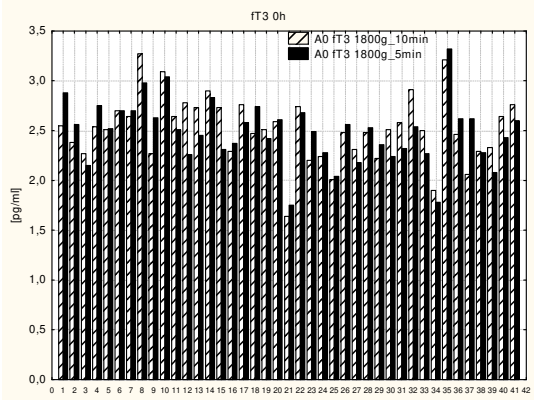
Sample B 48h



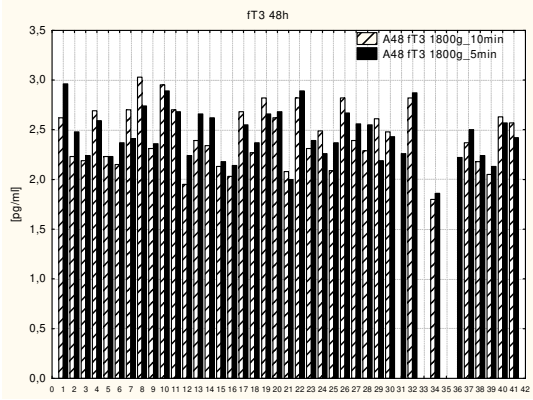
Free Triiodthyronin (fT_3)

Reference range: 1.45-3.48 pg/ml [6]

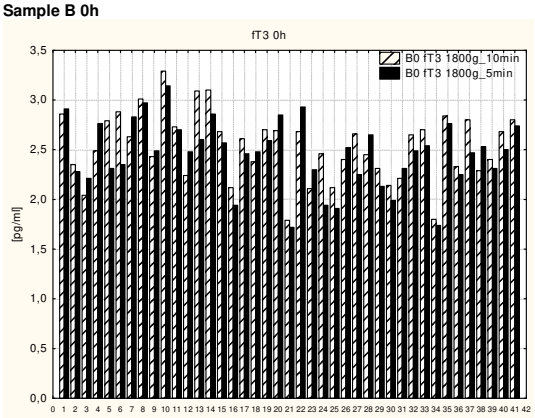
Sample A 0h



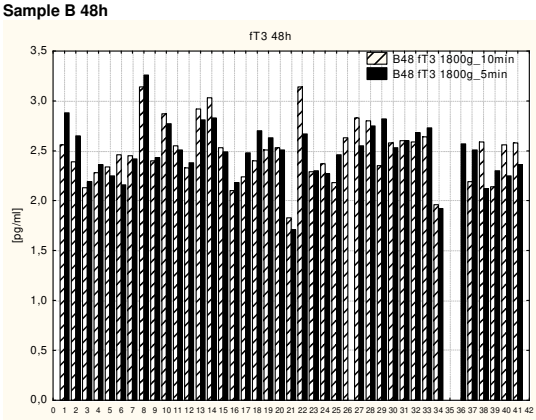
Sample A 48h



Sample B 0h



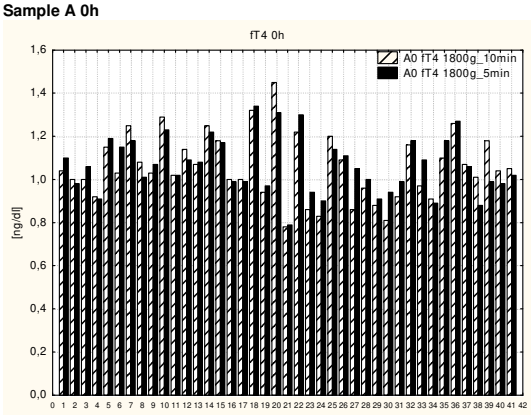
Sample B 48h



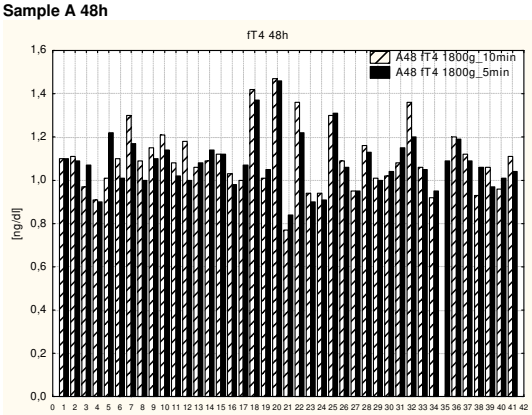
Free Thyroxin (fT_4)

Reference range: 0.71-1.85 ng/dl [6]

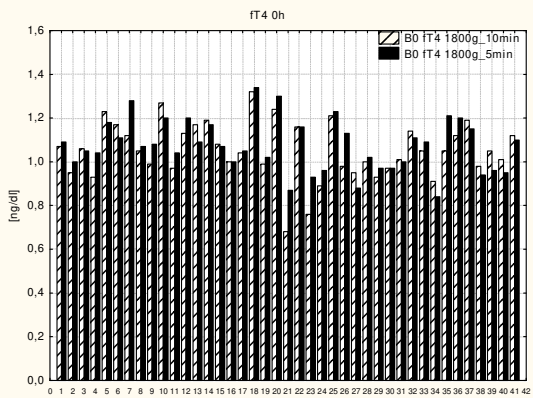
Sample A 0h



Sample A 48h



Sample B 0h



Sample B 48h