

Comparison of VACUETTE® Serum Gel Z Tubes with VACUETTE® Serum Gel Tubes for Common Chemistry Analytes

Background:

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

VACUETTE® Gel Tubes incorporate an inert gel material into the blood collection tube. These gels have a controlled viscosity and a specific gravity intermediate to serum and clot. During centrifugation, the gel material forms an impermeable barrier between the serum and clot.

Gel Z has been in development since 2001 and has the same components as the last gel type (Gel P3), the difference being the production process, which has been optimised. The gel might be slightly more yellow in colour however provides the better performance than the last gel type as well as providing the advantage of a more stable barrier, which is particularly beneficial during transport.

Preanalytical handling remains the same and does not require any changes (i.e. centrifugation conditions, storage, transport, etc).

Study Objective:

The aim of this tube comparison was to show equality of the analytical performance of Gel Z and the current type gel (Gel P3) with regard to a variety of biochemical parameters.

Study design:

Two types of tubes were evaluated in this study:

- 16/100mm Serum Gel Z Tube with 8ml draw (item # 455071Z)
- 16/100mm Serum Gel P3 Tube with 8ml draw (item # 455071)

Venous blood was collected from 26 patients using the VACUETTE® Standard Tube Holder and 21G Needle. Two tubes were collected from each patient (one 455071Z and one 455071). Directly after venipuncture, the tubes were carefully inverted 8 times according to the instructions given by the tube manufacturer. The samples were left at RT for 30 minutes to let them clot completely. The clotted samples were centrifuged at 1800g for 10 minutes in a swing out centrifuge.

The analysis was performed on an Integra 700 by Roche Boehringer with the accompanying reagents.

The following parameters were compared:

Albumin	HDL
Alkaline Phosphatase	Iron
Alaninaminotransferase	Lactatedehydrogenase
Aspartataminotransferase	LDL
Blood Urea Nitrogen	Magnesium
Calcium	Phosphate
Chloride	Potassium
Cholesterol	Sodium
Creatinine	Total Bilirubin
Creatinine Kinase	Total Protein
Ferritin	Triglycerides
Gamma Glutamyl Transferase	Uric acid
Glucose	

Results / Comments:

Statistical evaluation:

Student's T-test (α 0,05) was performed using Biosoft STAT200 software.

No statistical significance was found for tubes containing Gel Z compared to samples with Gel P3 with any parameter tested.

Comments:

No statistical difference and no clinical significance was observed with any parameter tested.

Conclusion:

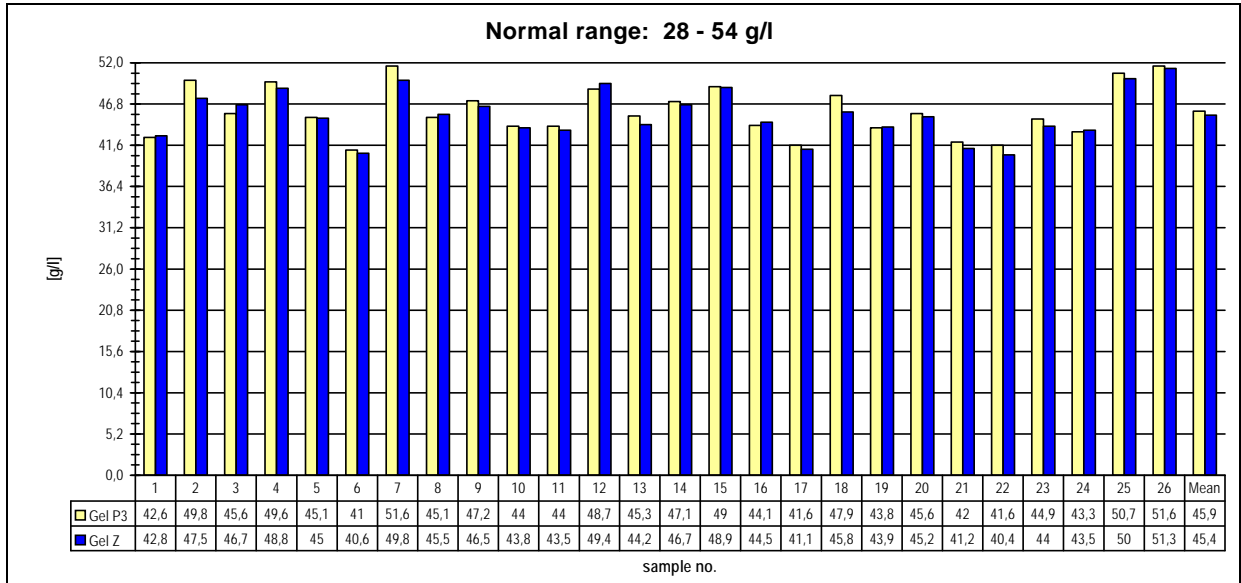
The actual study examined the analytical performance of Gel Z in comparison to the Gel P3 tubes. Therefore 25 common chemistry analytes were tested. The Gel Z tubes gave equivalent results to the Gel P3 tubes for these biochemical parameters.

The results prove the equality of the performance of Gel Z and the current gel type (P3), maintaining barrier integrity and stability post centrifugation.

References:

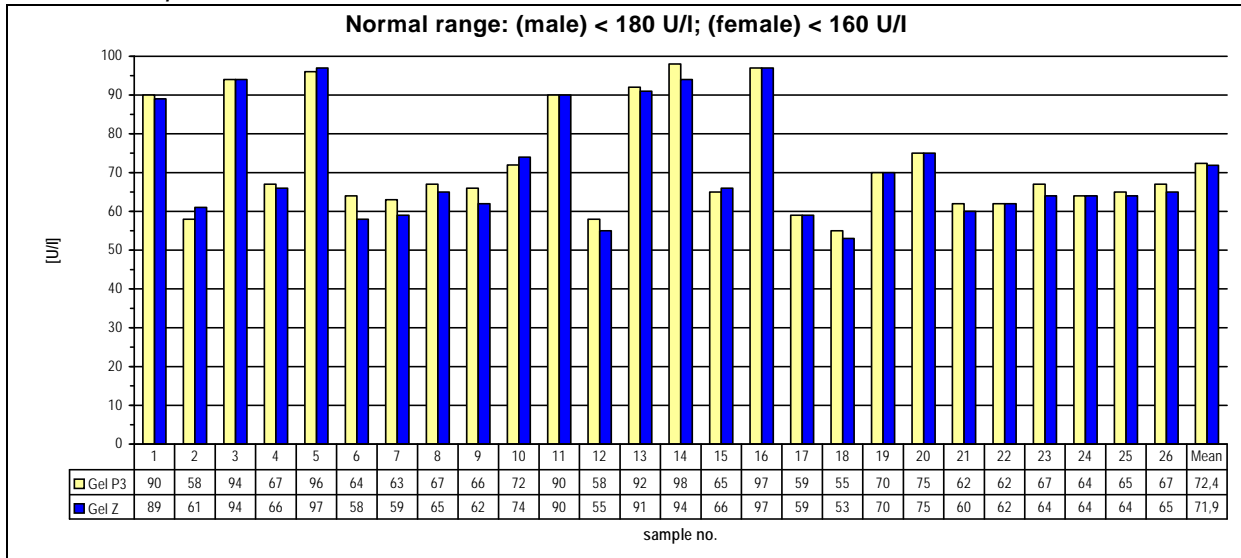
- (1) Thomas L., Labor und Diagnose. TH-Books, 5. Auflage (1998)
- (2) Tietz N.W., Clinical Guide to Laboratory Tests. W.B. Saunders Company, third edition (1995)
- (3) Guder W.G., Narayanan S., Wisser H., Zawta B., Samples: From the Patient to the Laboratory. GIT Verlag (1996)
- (4) NCCLS EP 9-A2, Method comparison and Bias Estimation using patient samples; Approved Guideline
- (5) Heil W., Schuckließ F., Zawta B., Referenzbereiche für Kinder und Erwachsene - Präanalytik. 4. Auflage (1996)

Albumin



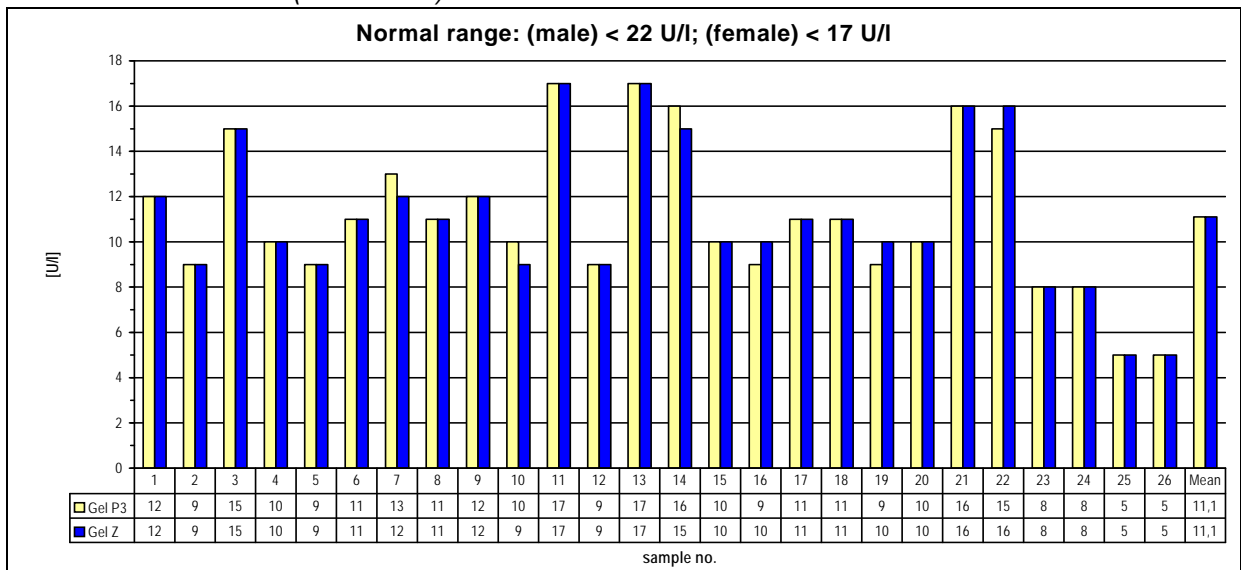
Student's t-test was performed at 5%: No statistical significance was observed.

Alkaline Phosphatase



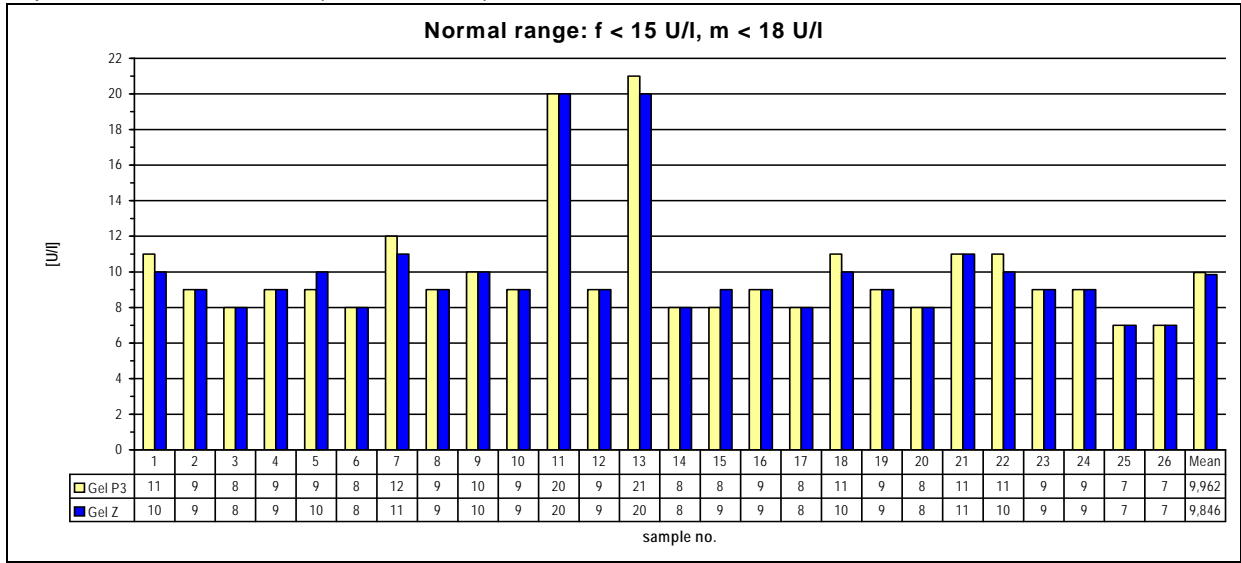
Student's t-test was performed at 5%: No statistical significance was observed.

Alaninaminotransferase (ALT = GPT)



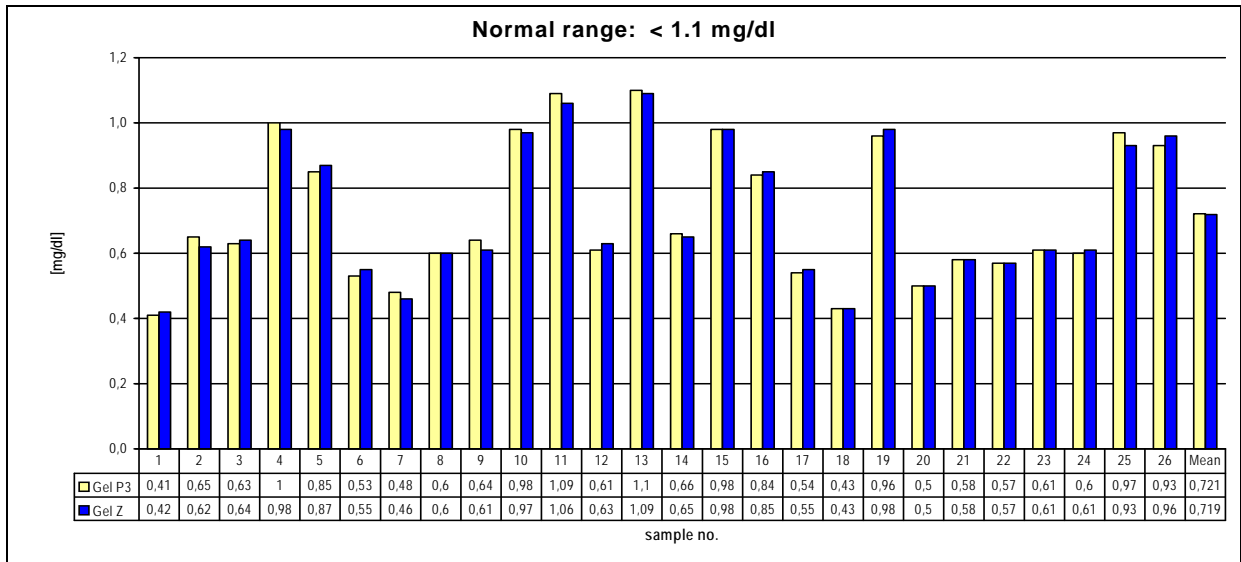
Student's t-test was performed at 5%: No statistical significance was observed.

Aspartataminotransferase (AST = SGOT)



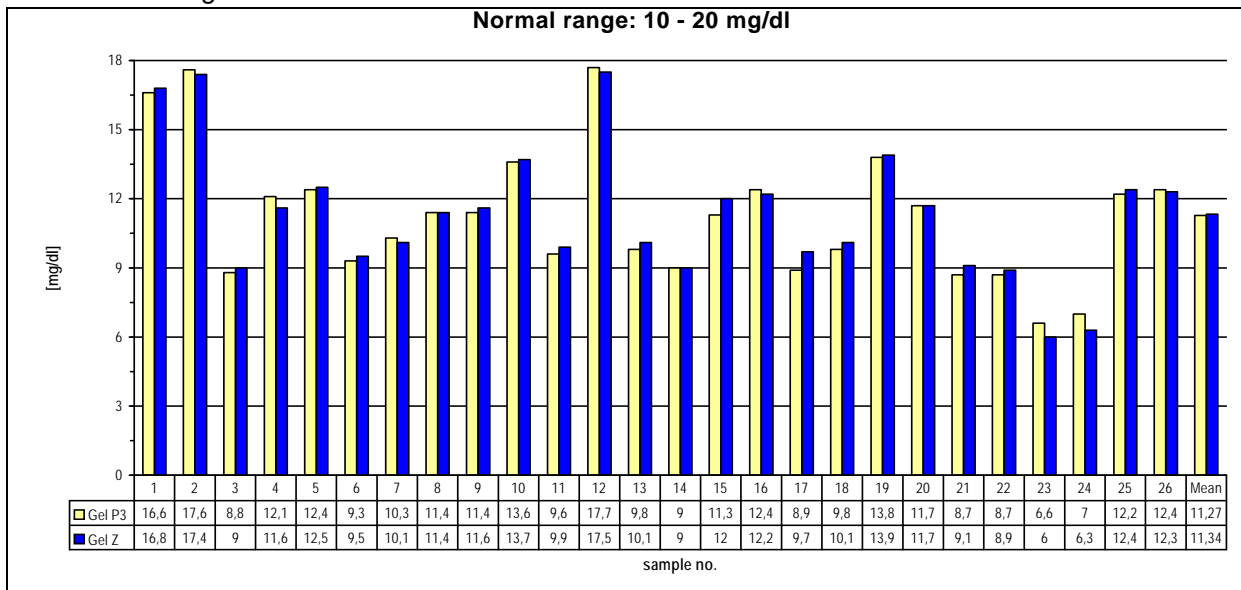
Student's t-test was performed at 5%: No statistical significance was observed.

Bilirubin



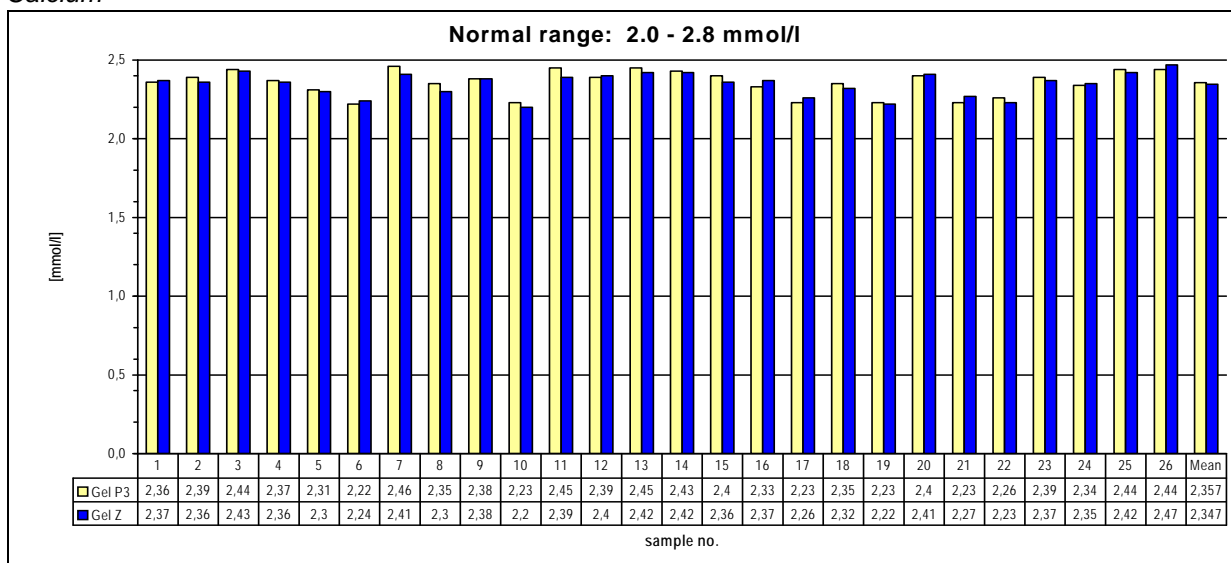
Student's t-test was performed at 5%: No statistical significance was observed.

Blood Urea Nitrogen



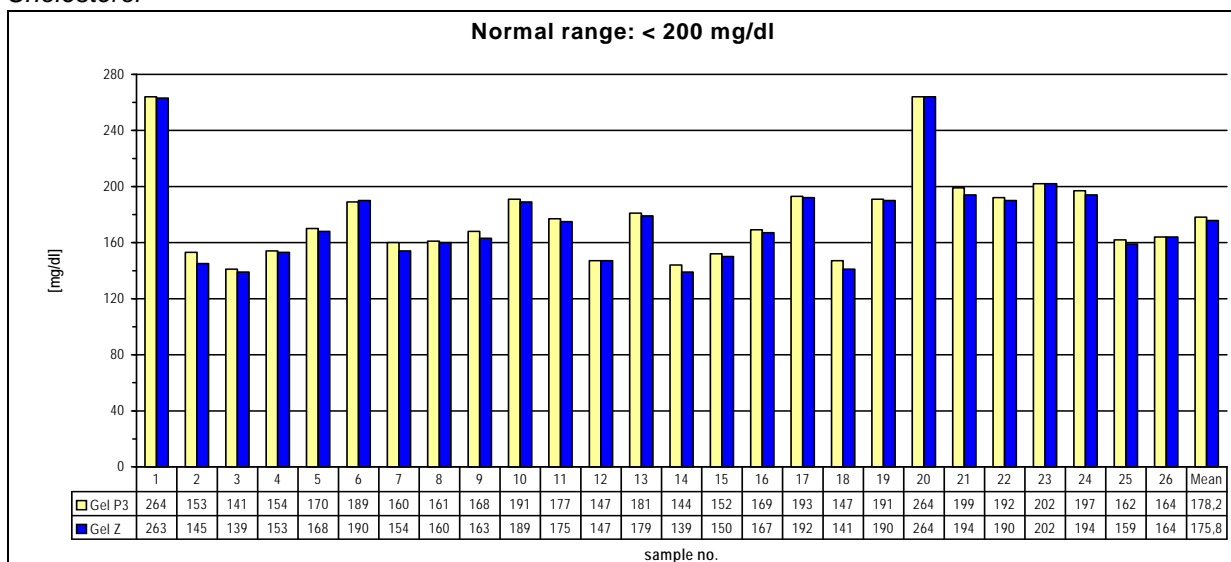
Student's t-test was performed at 5%: No statistical significance was observed.

Calcium



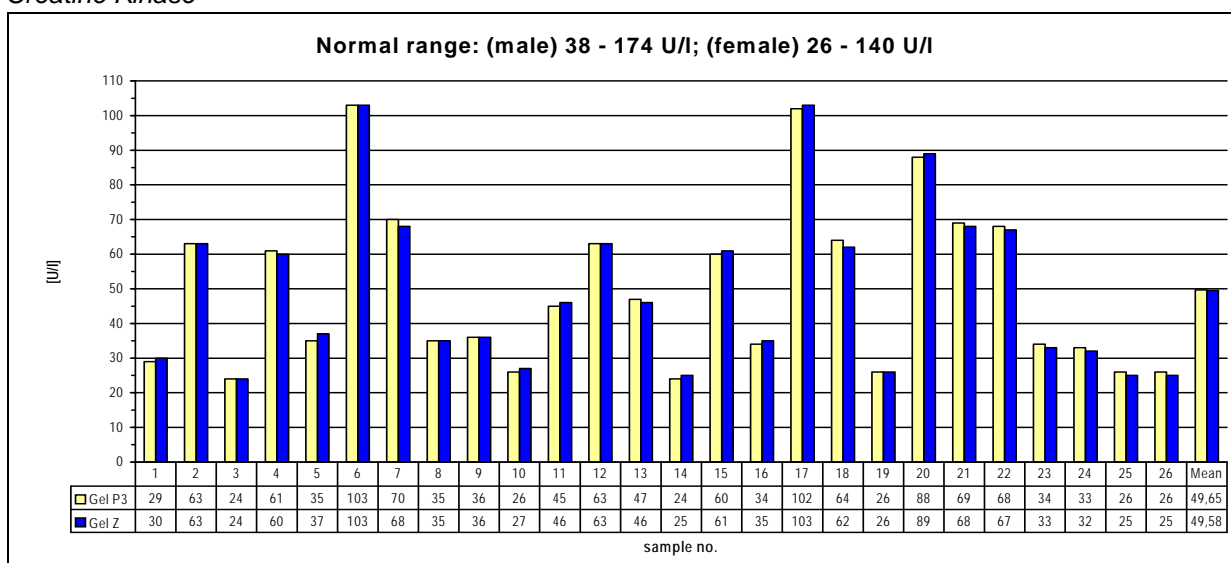
Student's t-test was performed at 5%: No statistical significance was observed.

Cholesterol



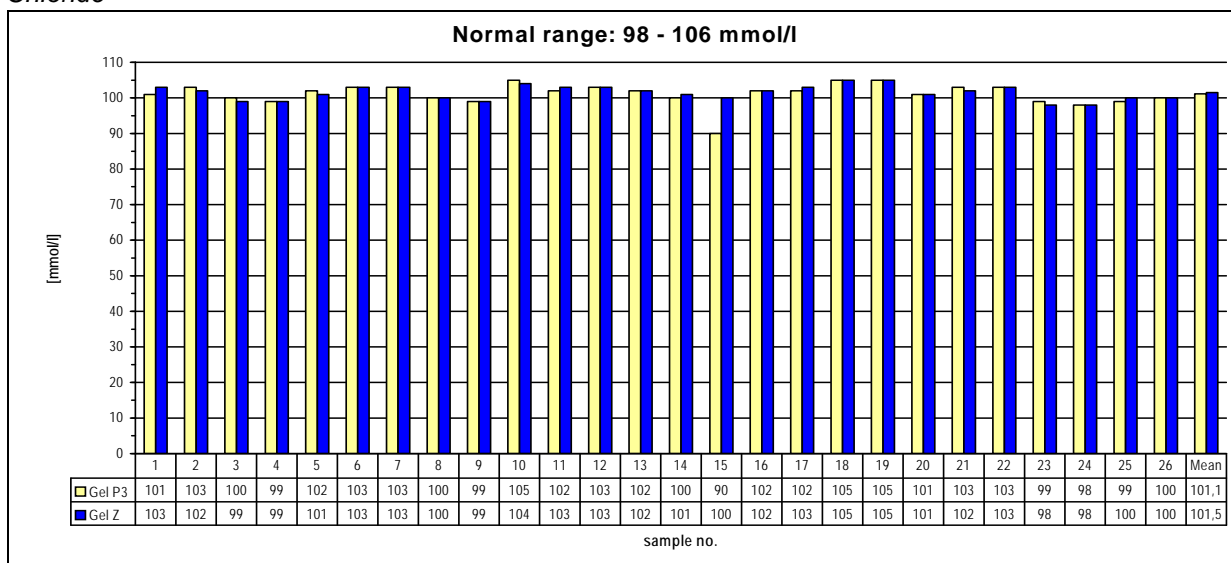
Student's t-test was performed at 5%: No statistical significance was observed.

Creatine Kinase



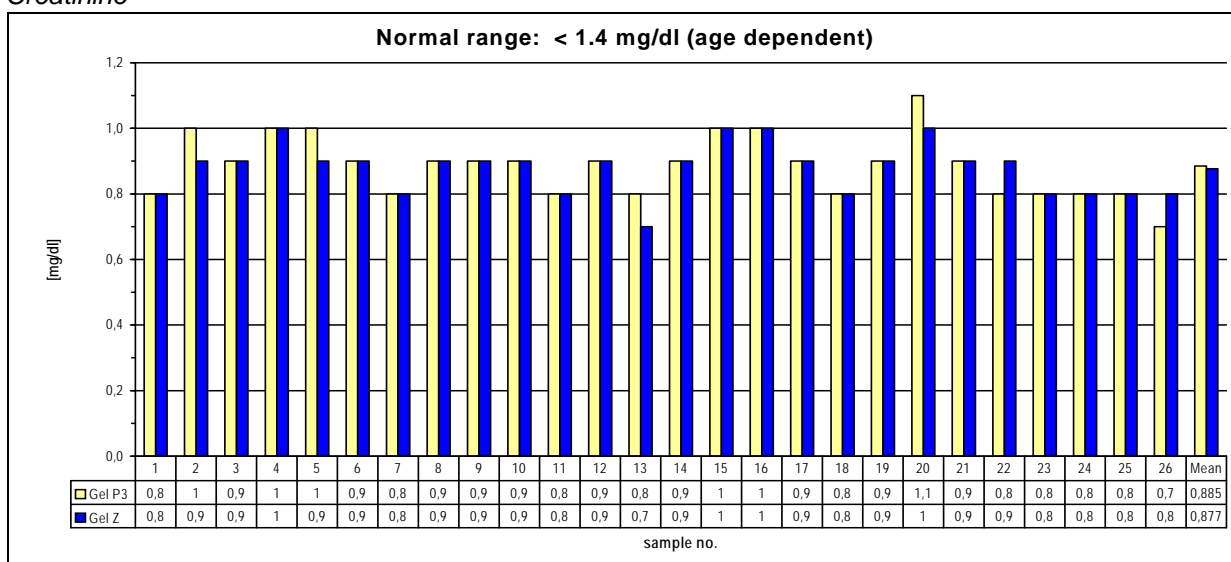
Student's t-test was performed at 5%: No statistical significance was observed.

Chloride



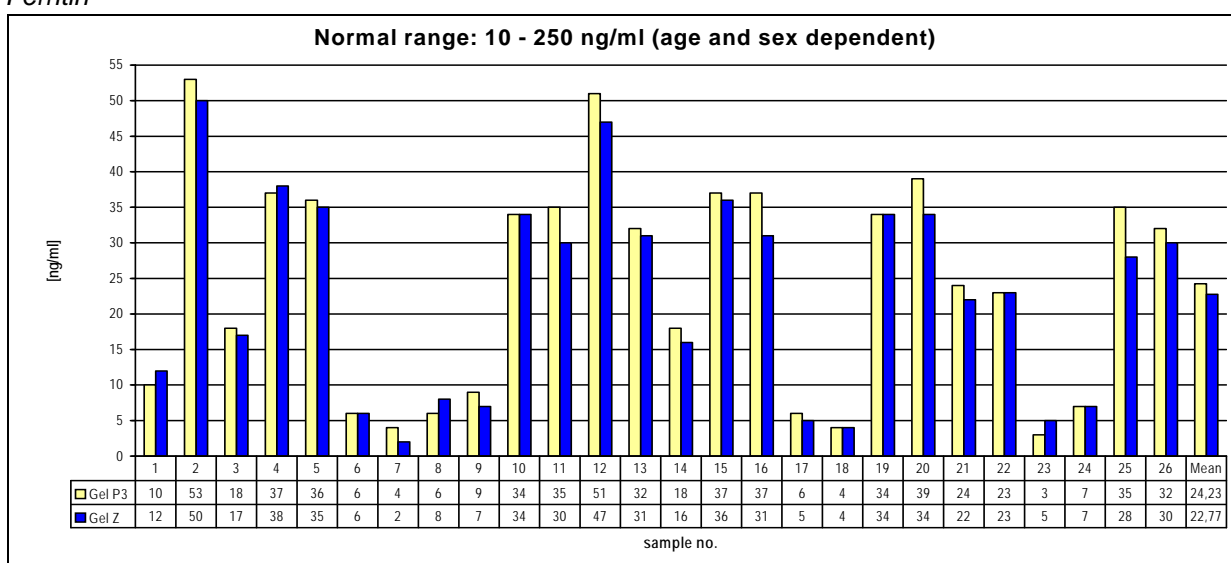
Student's t-test was performed at 5%: No statistical significance was observed.

Creatinine



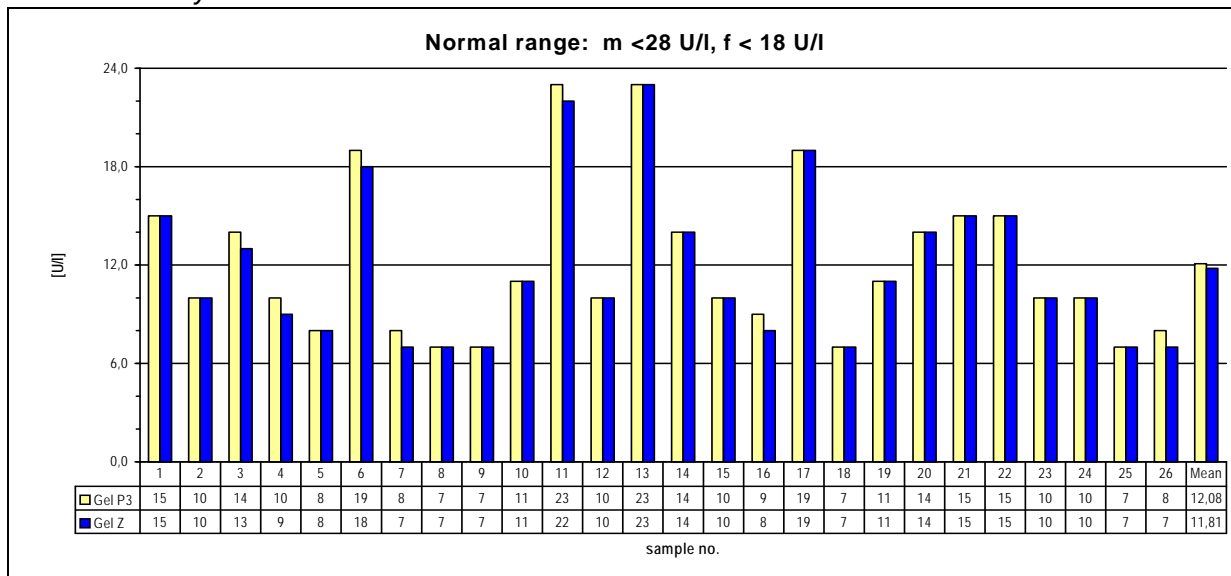
Student's t-test was performed at 5%: No statistical significance was observed.

Ferritin



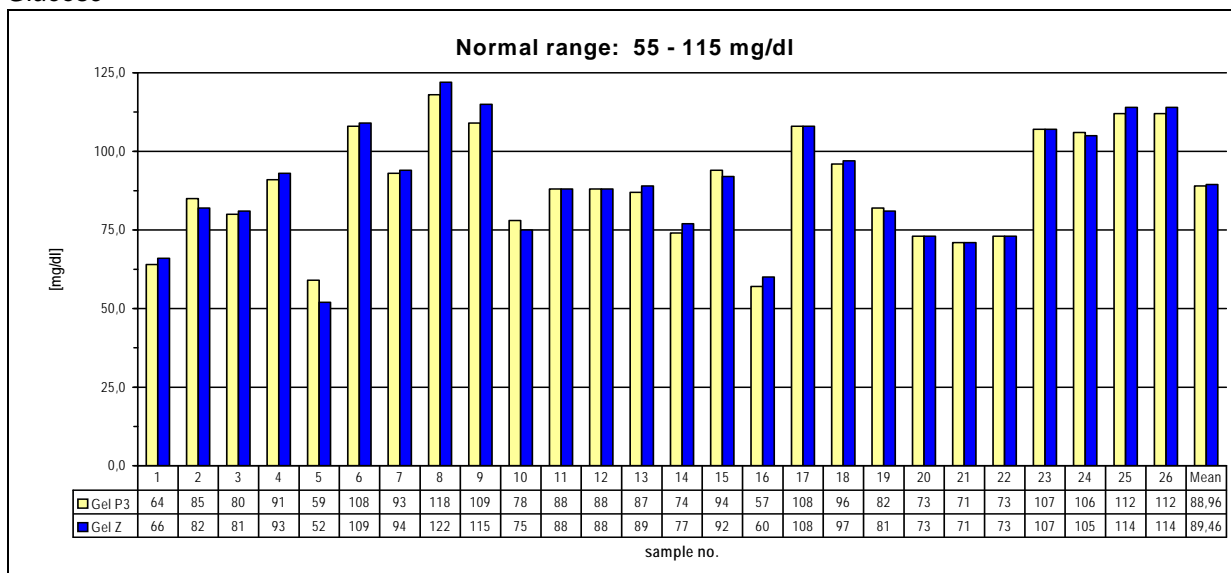
Student's t-test was performed at 5%: No statistical significance was observed.

Gamma Glutamyl Transferase



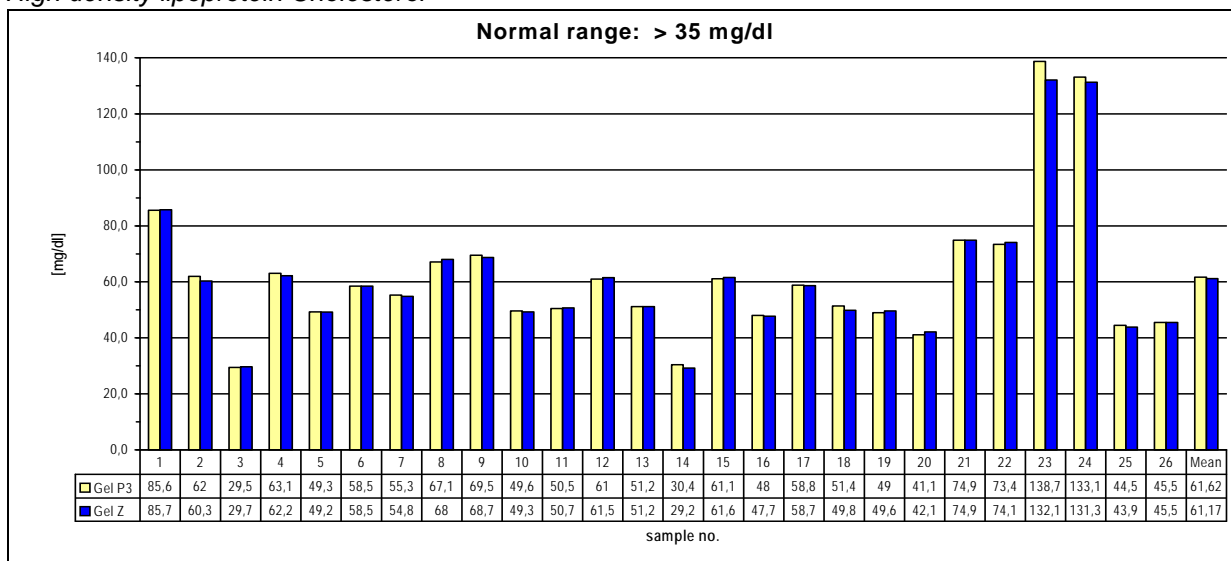
Student's t-test was performed at 5%: No statistical significance was observed.

Glucose



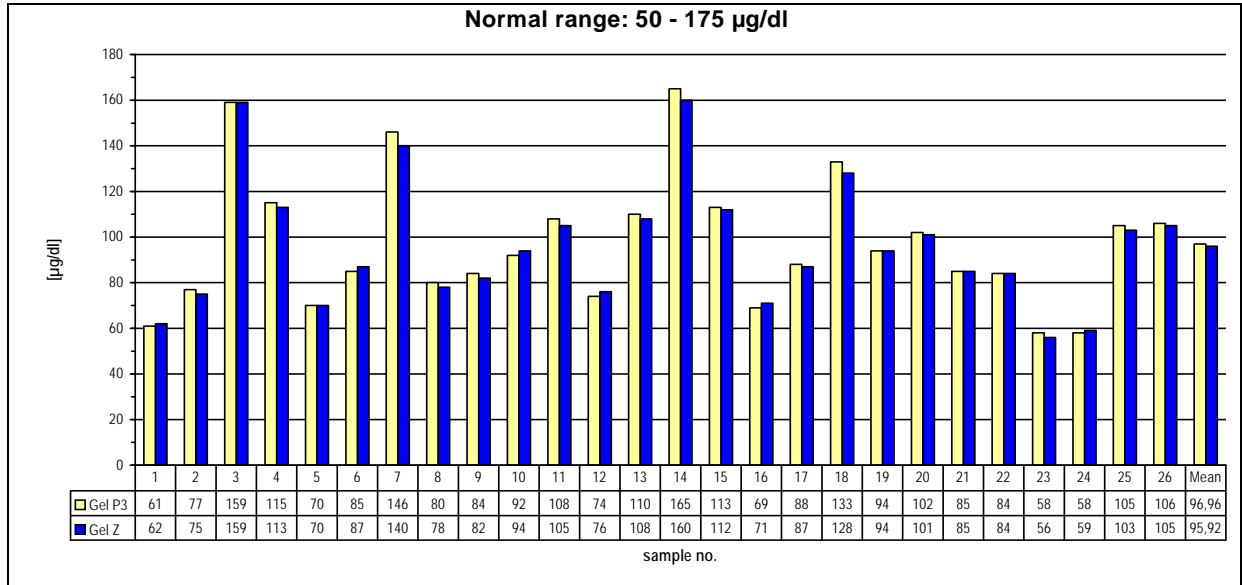
Student's t-test was performed at 5%: No statistical significance was observed.

High density lipoprotein Cholesterol



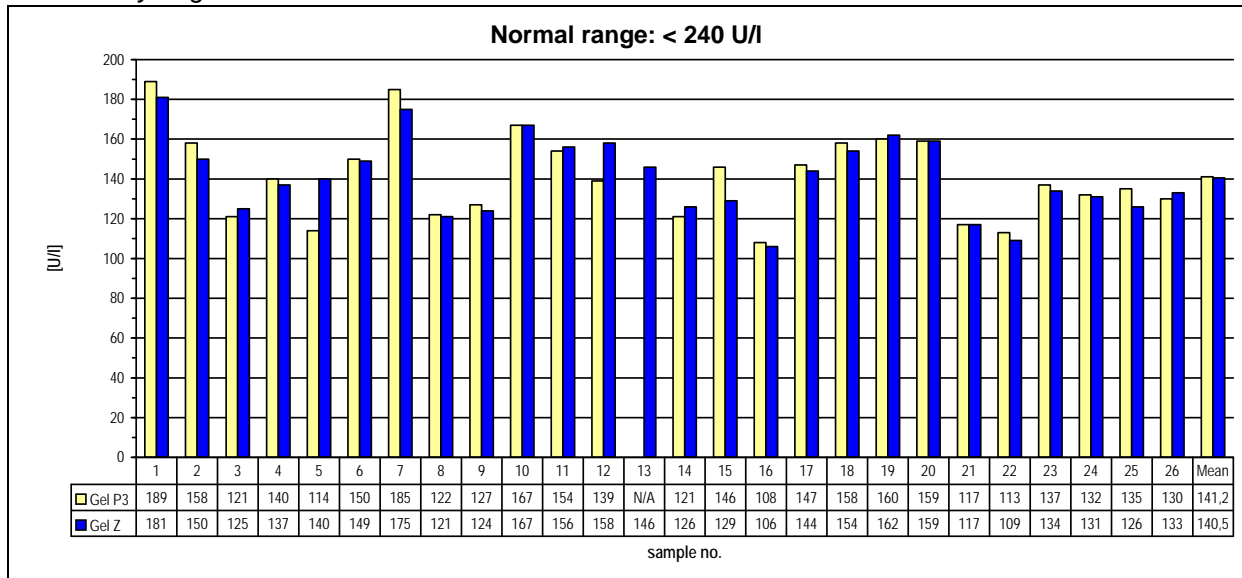
Student's t-test was performed at 5%: No statistical significance was observed.

Iron



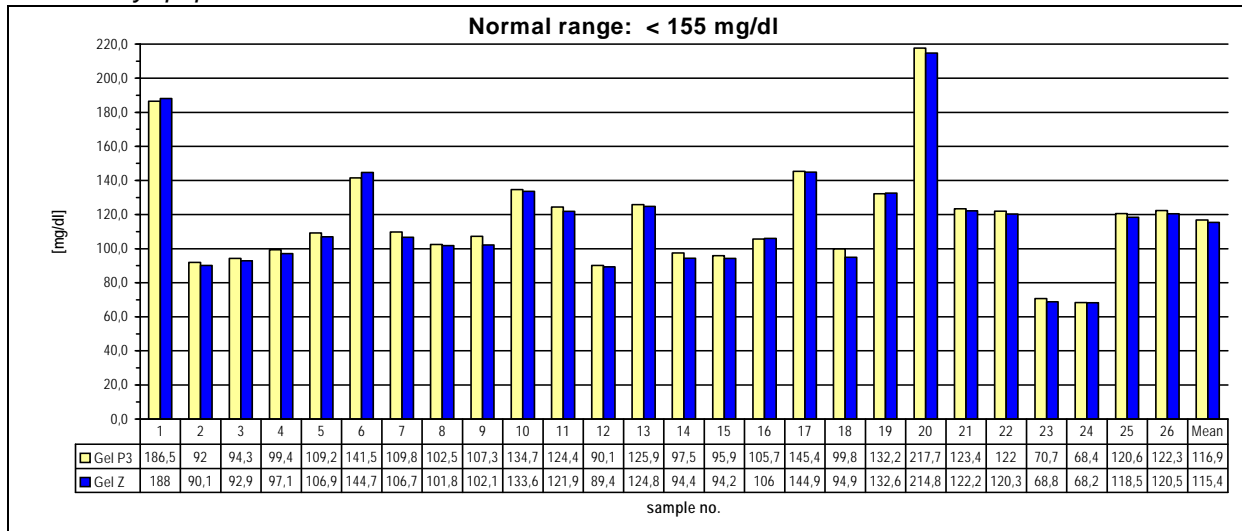
Student's t-test was performed at 5%: No statistical significance was observed.

Lactatedehydrogenase



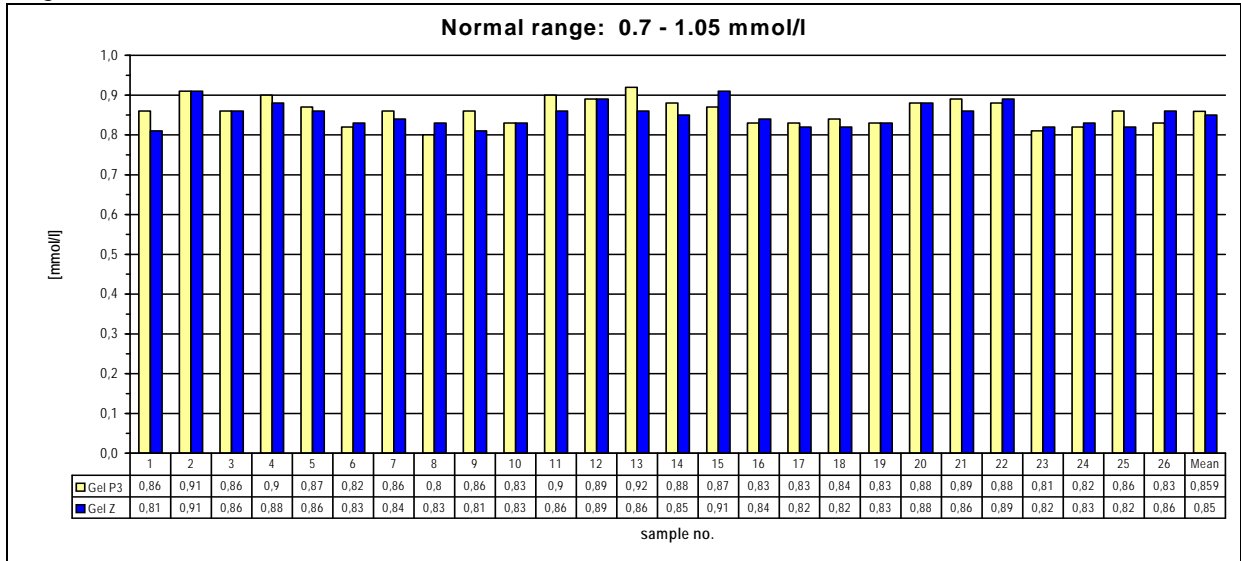
Student's t-test was performed at 5%: No statistical significance was observed.

Low density lipoprotein Cholesterol



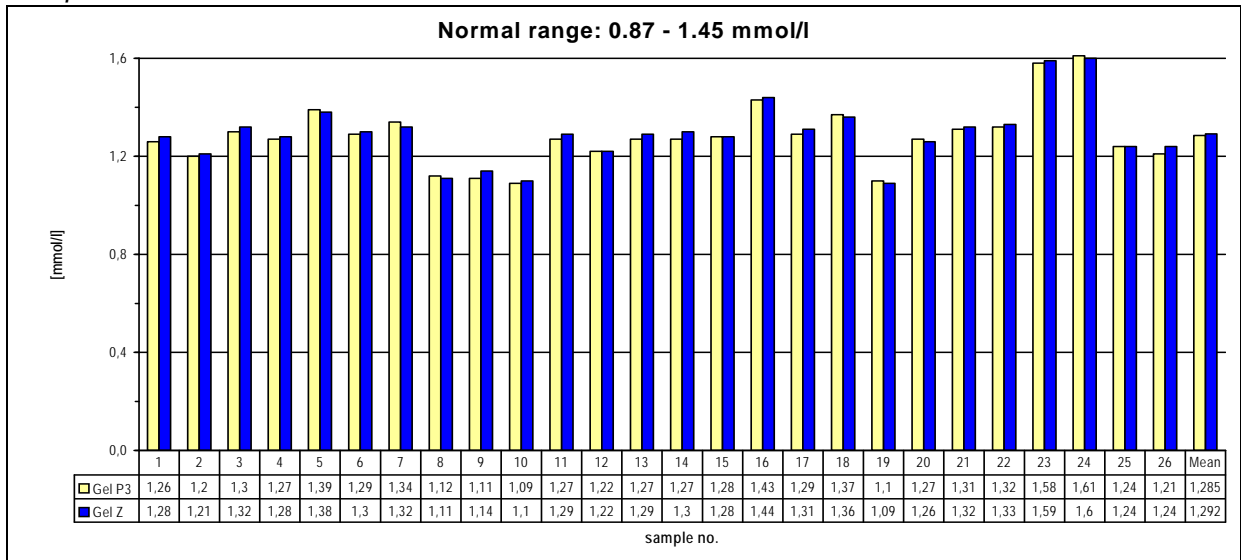
Student's t-test was performed at 5%: No statistical significance was observed.

Magnesium



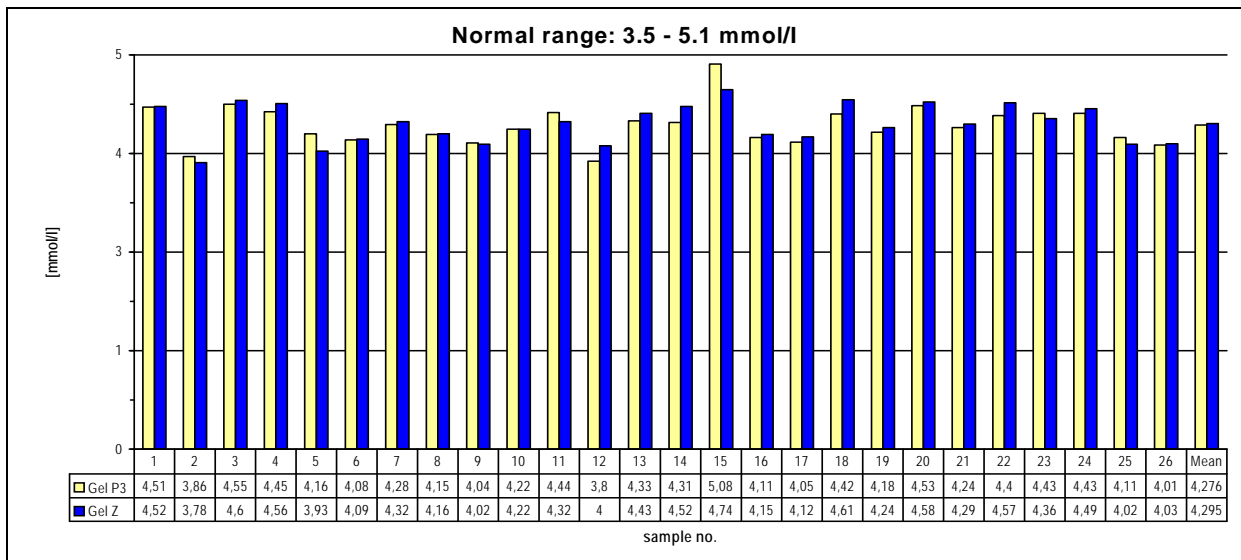
Student's t-test was performed at 5%: No statistical significance was observed.

Phosphate



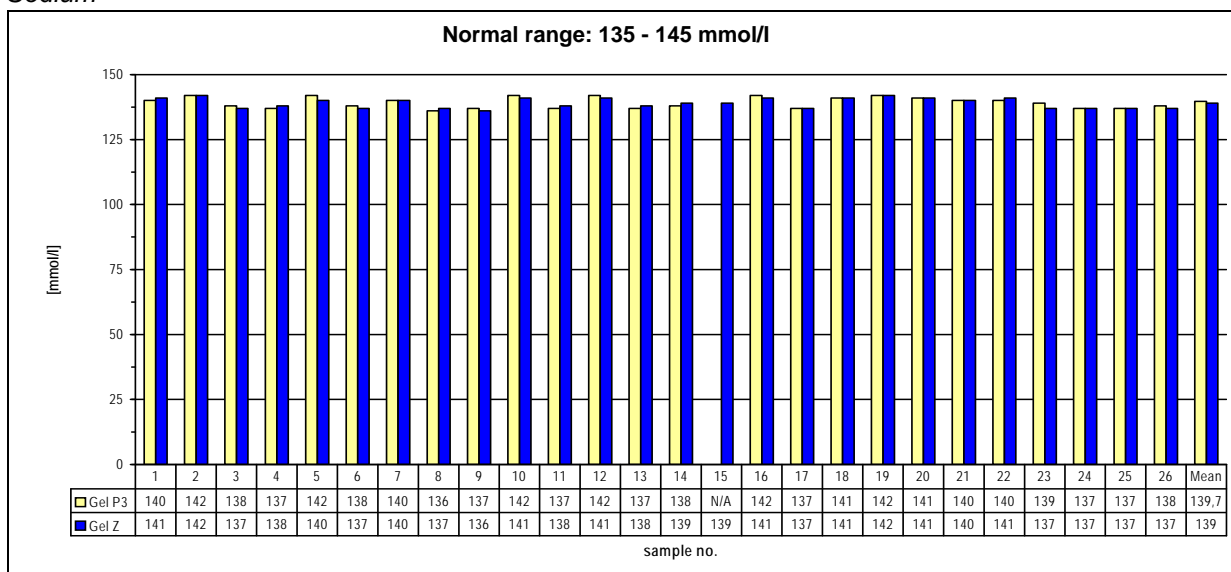
Student's t-test was performed at 5%: No statistical significance was observed.

Potassium



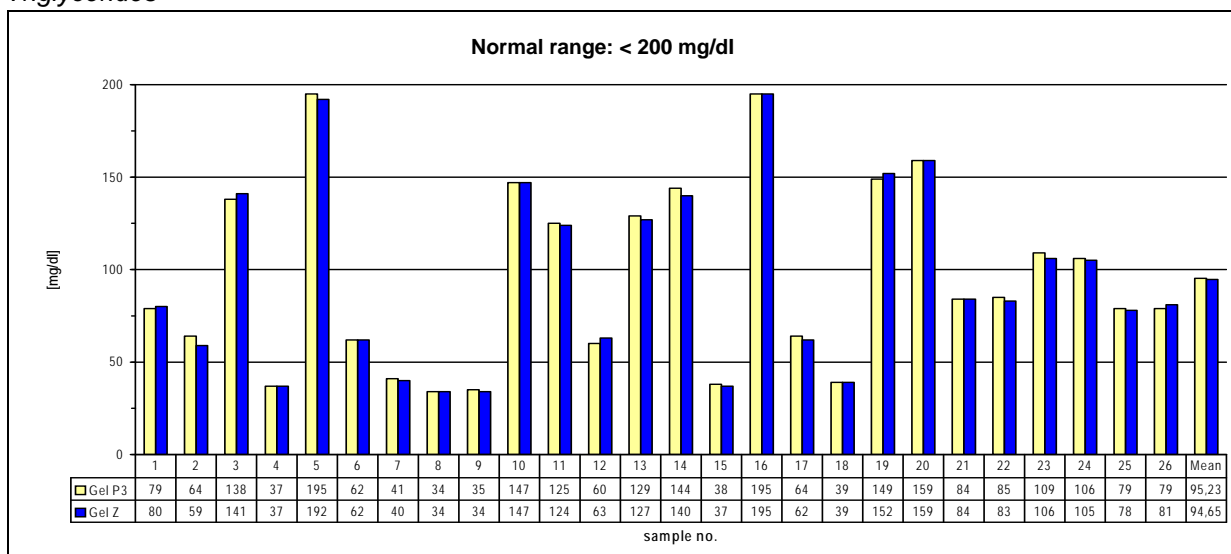
Student's t-test was performed at 5%: No statistical significance was observed.

Sodium



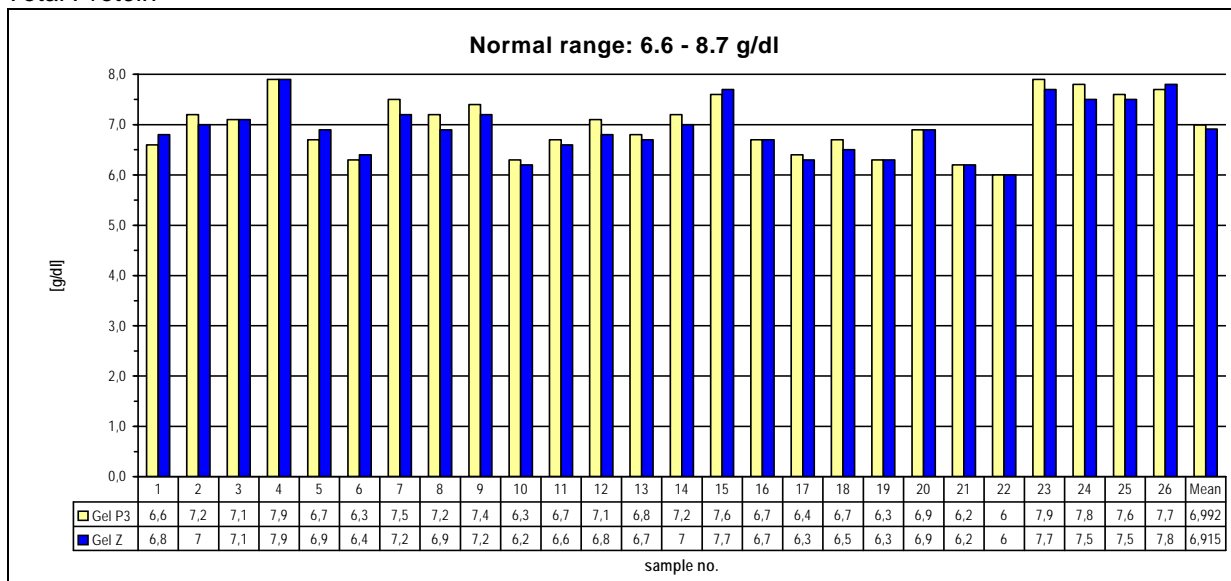
Student's t-test was performed at 5%: No statistical significance was observed.

Triglycerides



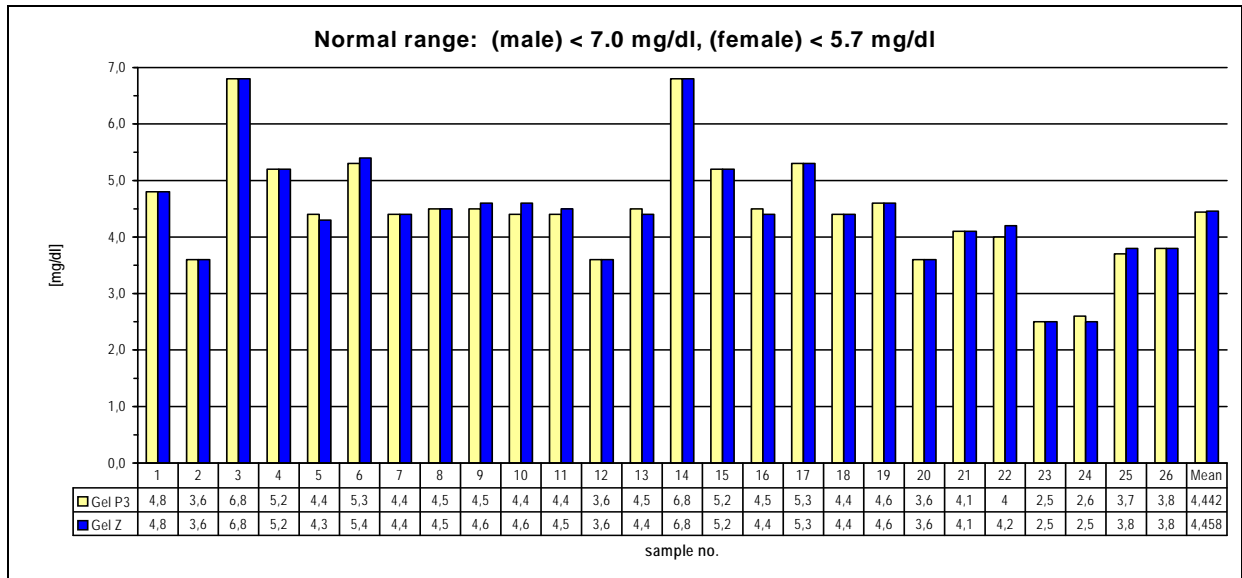
Student's t-test was performed at 5%: No statistical significance was observed.

Total Protein



Student's t-test was performed at 5%: No statistical significance was observed.

Uric Acid



Student's t-test was performed at 5%: No statistical significance was observed.