

Comparison of VACUETTE® Serum Gel Z Tubes with VACUETTE® Serum Gel Tubes for Hormones

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 was to show equality of the performance of Gel Z and the current gel type (Gel P3) with regard to a variety of hormone parameters.

Study design:

Two tube types 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 20 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 Centaur by Bayer with the accompanying reagents by Bayer.

The following hormone parameters were compared:

Alpha-Fetoprotein (AFP)	IgE
Carcinoembryonic Antigen (CEA)	Progesterone
Cortisol	Prolactin
β-Estradiol	Prostate-specific Antigen (PSA)
Folic acid	Triiodothyronine (T3)
Free T3	Testosterone
Free Thyroxin (T4)	TSH
FSH	Vitamin B12

Results / Comments:

Statistical evaluation:

Student's T-test (α 0,05) was performed using Biosoft STAT200 software. No statistical significance was observed with any parameter tested.

Comments:

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

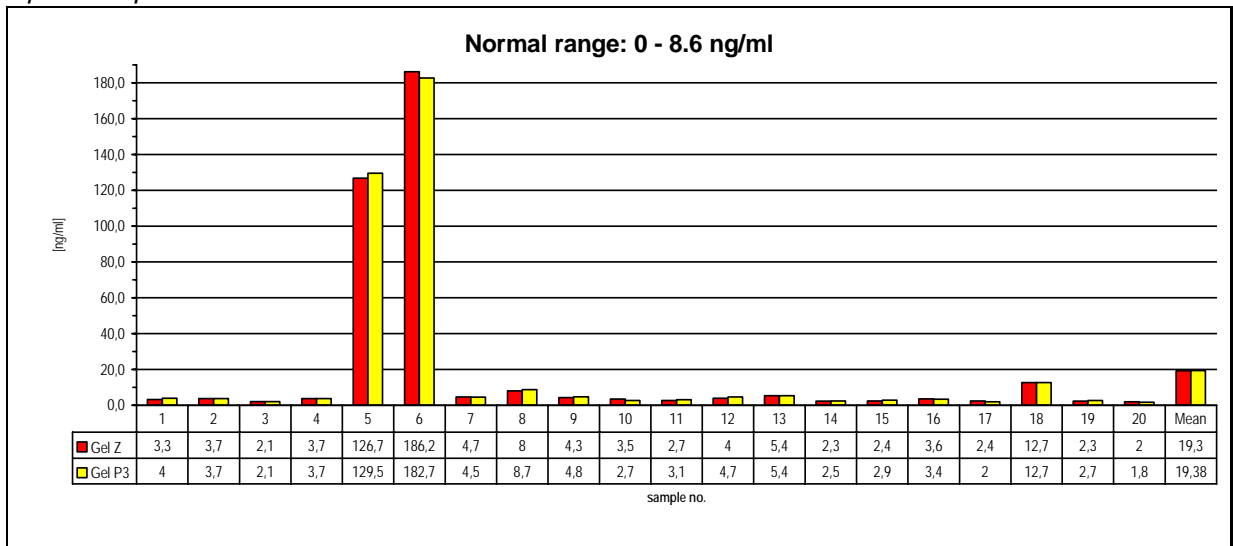
Conclusion:

This test examined the performance of Gel Z in comparison to the Gel P3 tubes. Therefore 16 common hormone parameters were tested. The Gel Z tubes gave equivalent results to the Gel P3 tubes for these parameters. This proves the equality of the performance of Gel Z and the current gel type (Gel P3), maintaining barrier integrity and stability post centrifugation.

References:

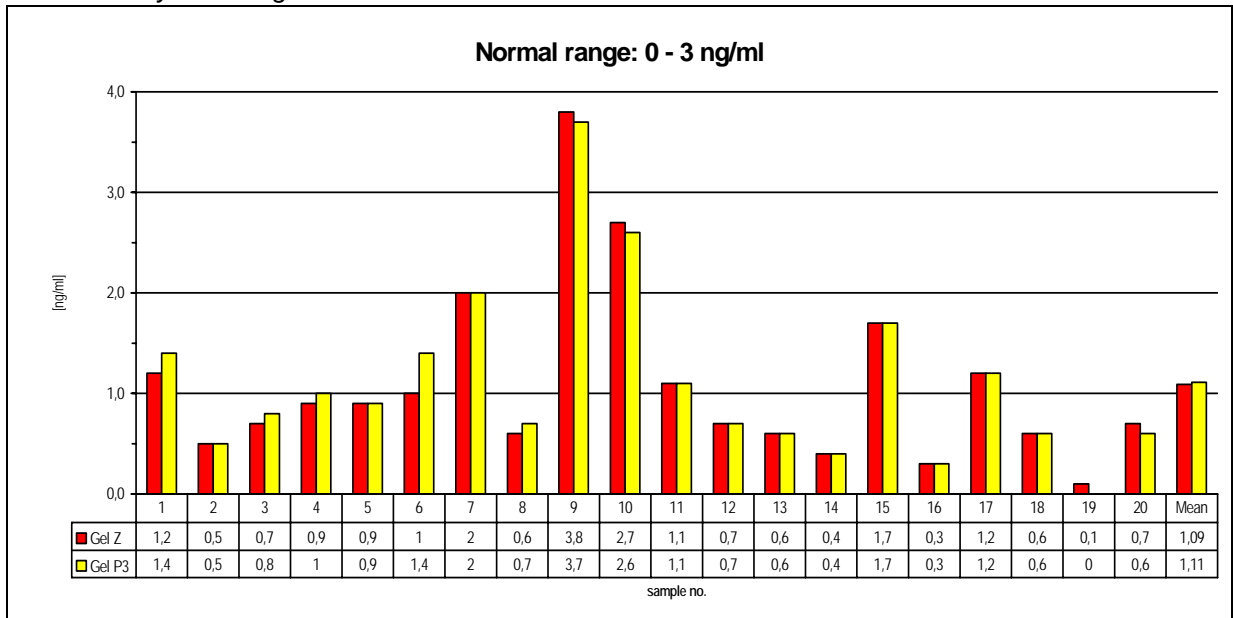
- (1) Thomas L., Labor und Diagnose. TH-Books, 5. Auflage (1998)
- (2) Tietz N.W., Clinical Guide to Laboratory Tests. W.B. Saunders Company, third edition (1995)
- (3) Guder W.G., Narayanan S., Wisser H., Zawta B., Samples: From the Patient to the Laboratory. GIT Verlag (1996)
- (4) NCCLS EP 9-A2, Method 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)
- (6) Meyer J.G., Bellwinkel S., Labormedizin – Klinische Chemie, Immunologie, Hämatologie, Mikrobiologie. Deutscher Ärzte Verlag, 4. Auflage; 170-171 (1990)

Alpha-Fetoprotein



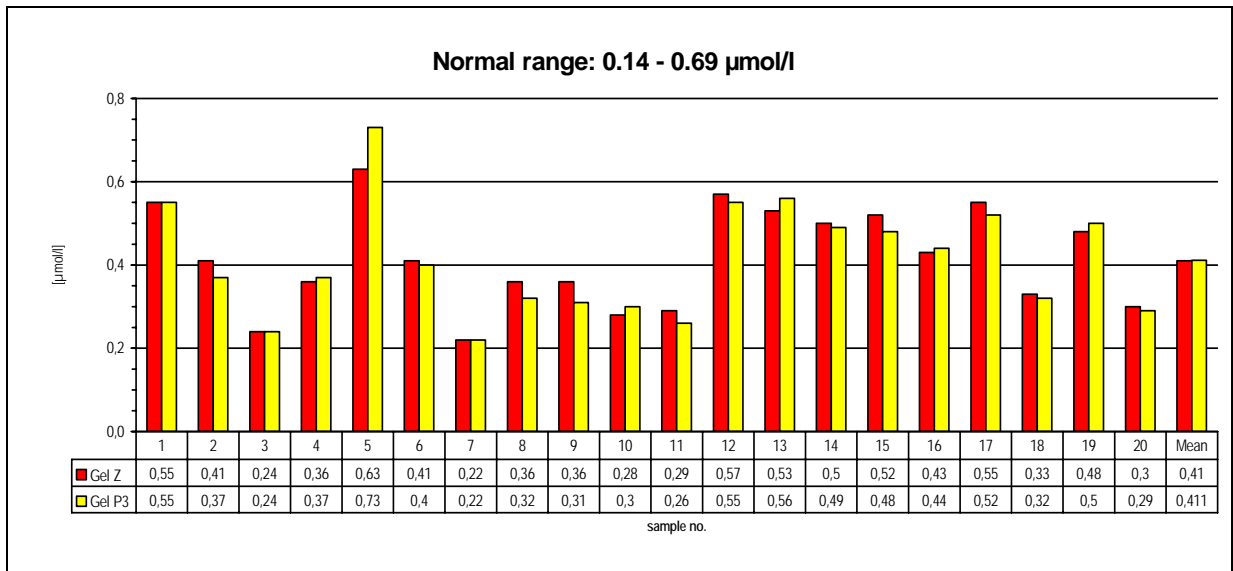
Student's t-test was performed at 5%: No statistical significance was observed.

Carcinoembryonic Antigen



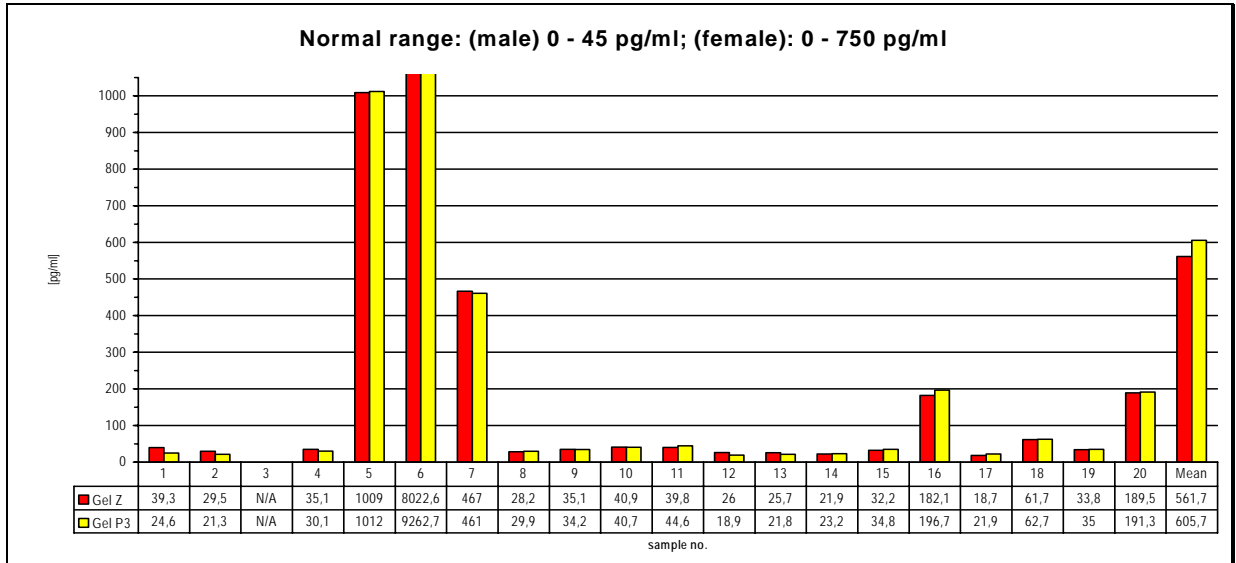
Student's t-test was performed at 5%: No statistical significance was observed.

Cortisol



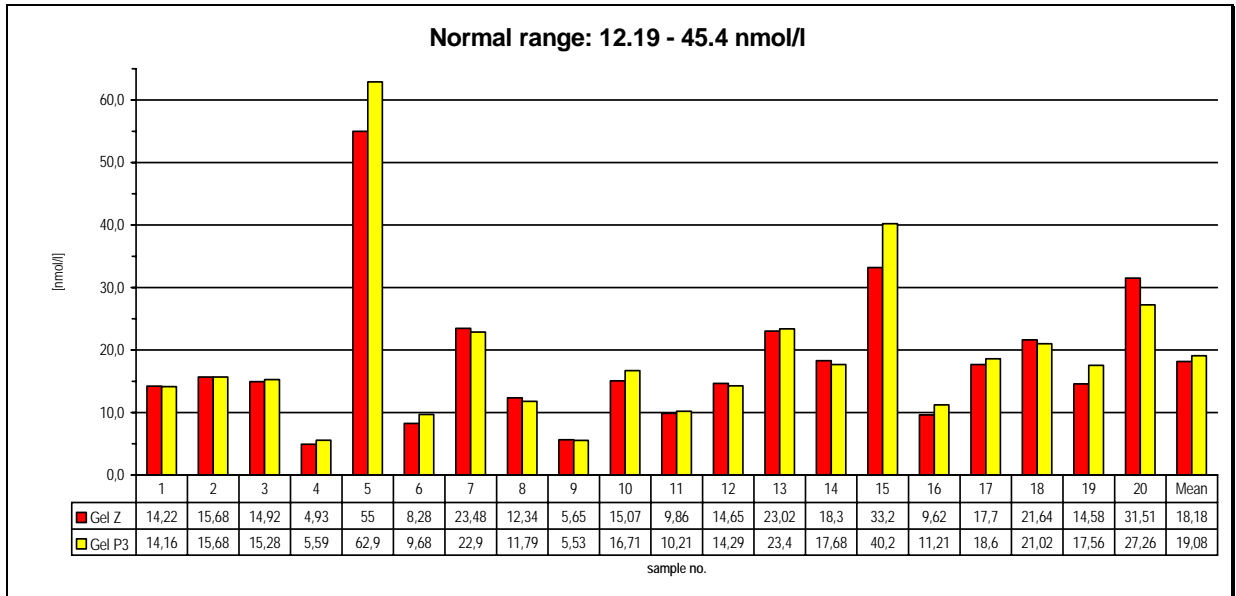
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Estradiol



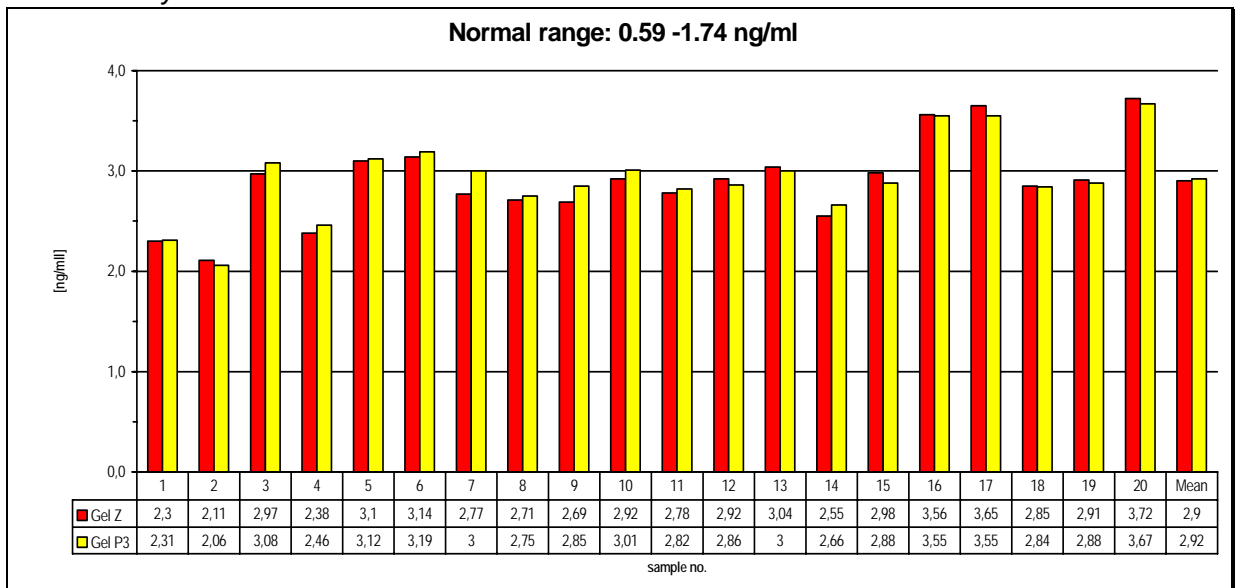
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Folic acid



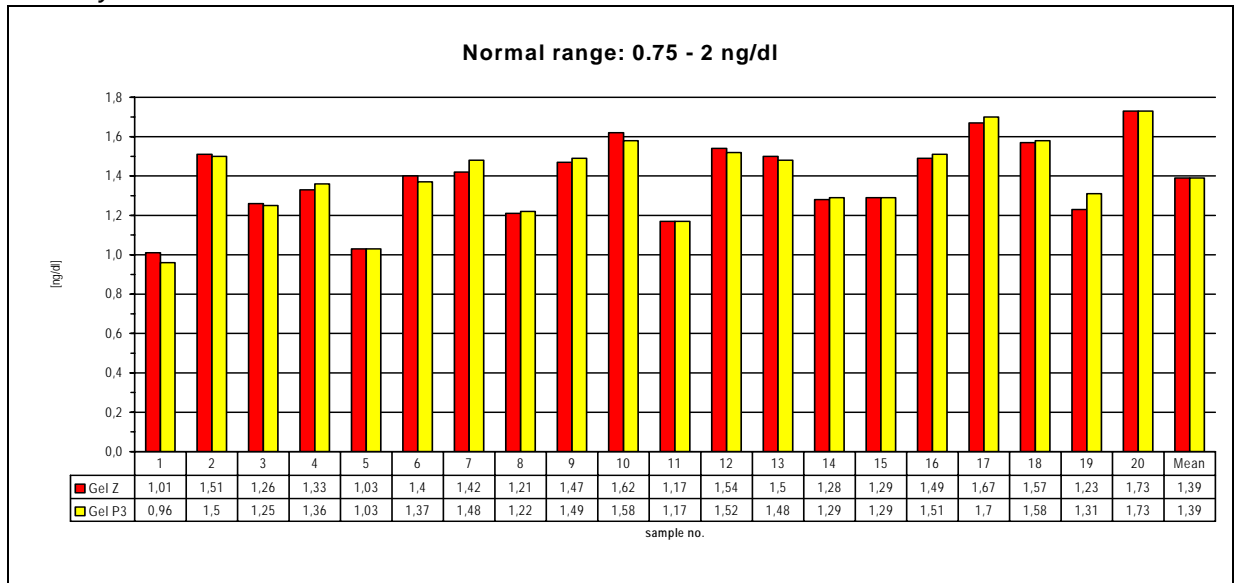
Student's t-test was performed at 5%: No statistical significance was observed.

free Triiodothyronine



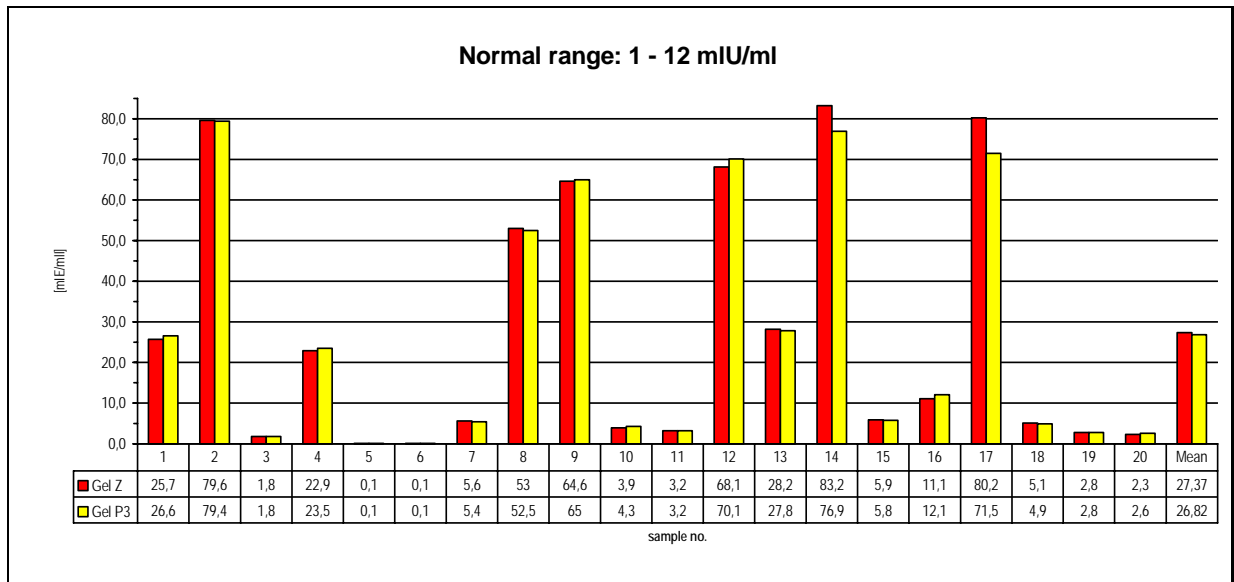
Student's t-test was performed at 5%: No statistical significance was observed.

Free Thyroxin



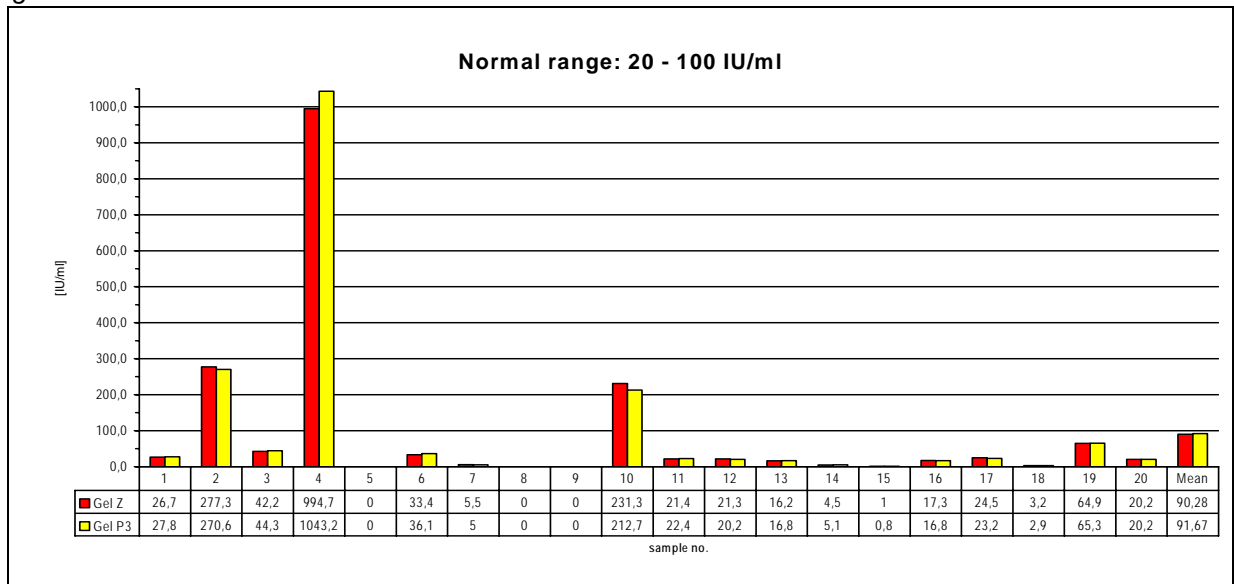
Student's t-test was performed at 5%: No statistical significance was observed.

FSH



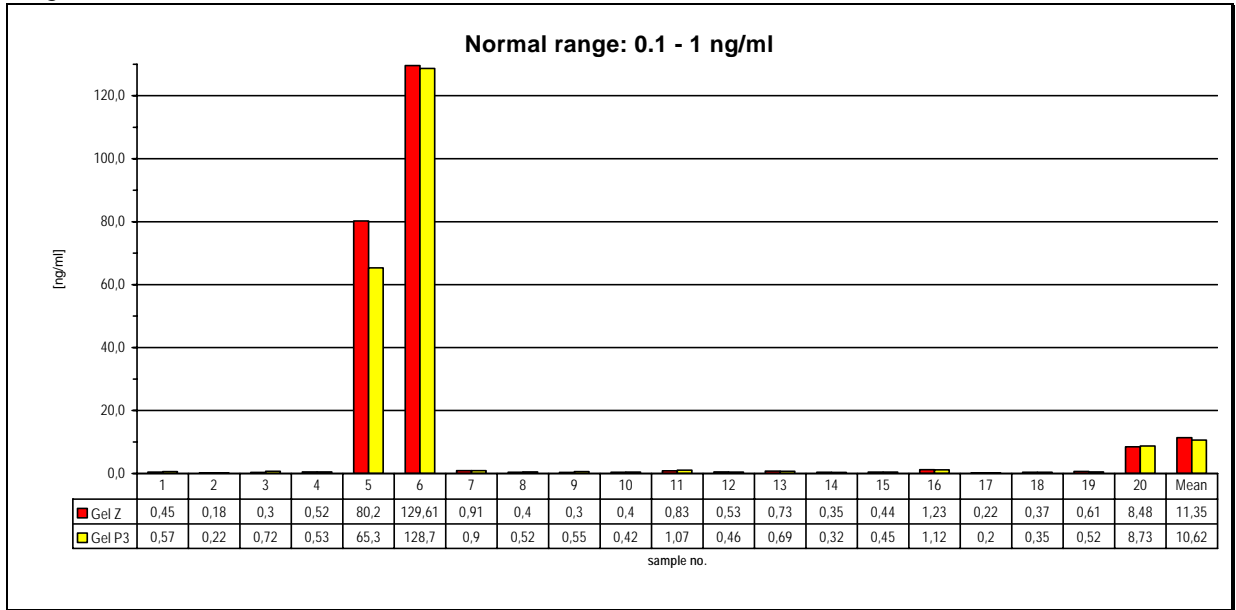
Student's t-test was performed at 5%: No statistical significance was observed.

IgE



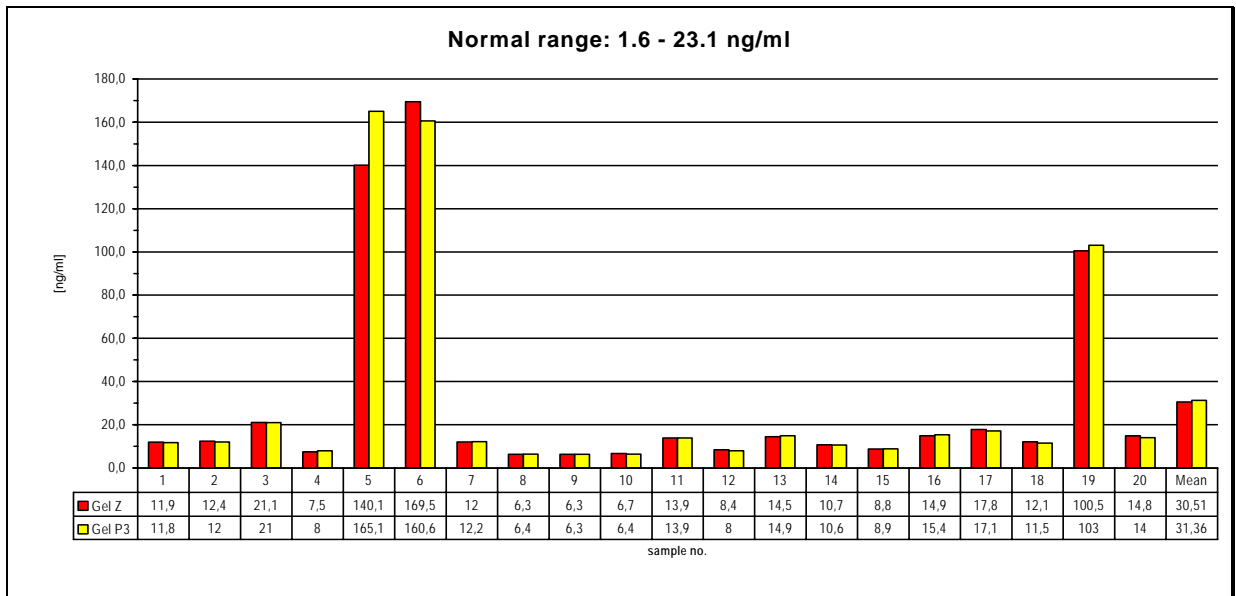
Student's t-test was performed at 5%: No statistical significance was observed.

Progesterone



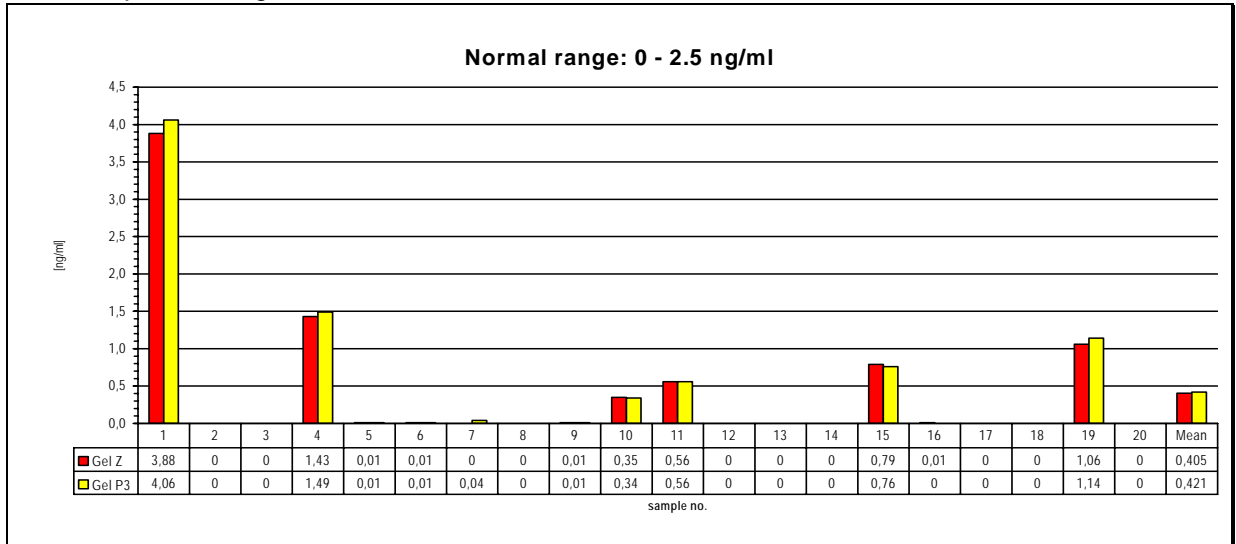
Student's t-test was performed at 5%: No statistical significance was observed.

Prolactin



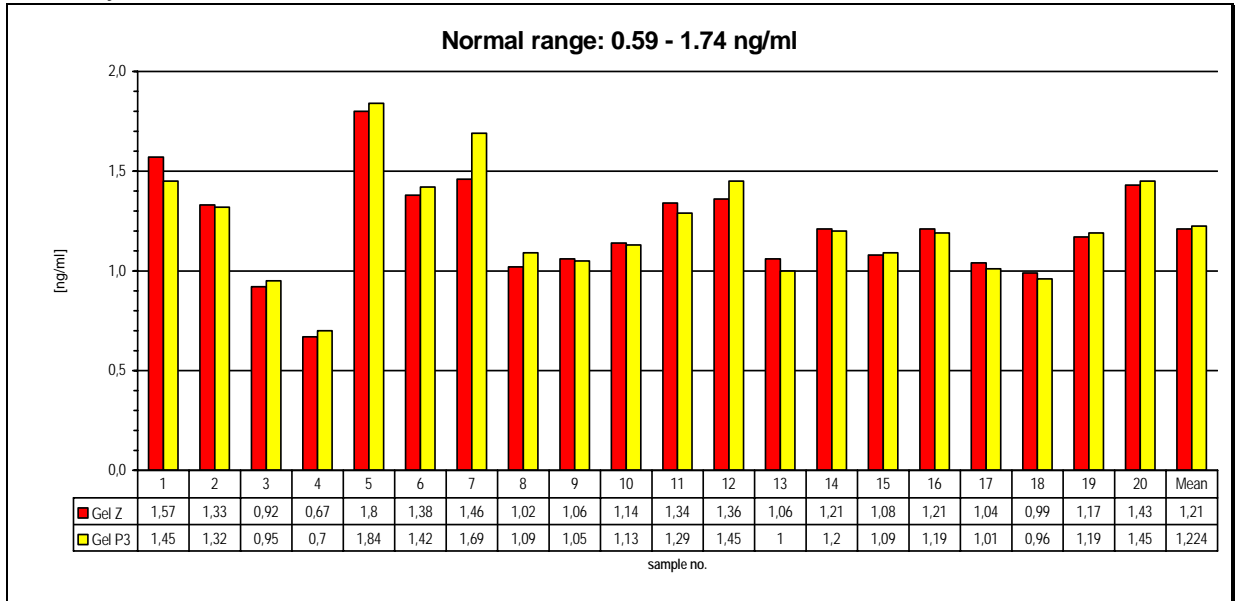
Student's t-test was performed at 5%: No statistical significance was observed.

Prostate-specific Antigen



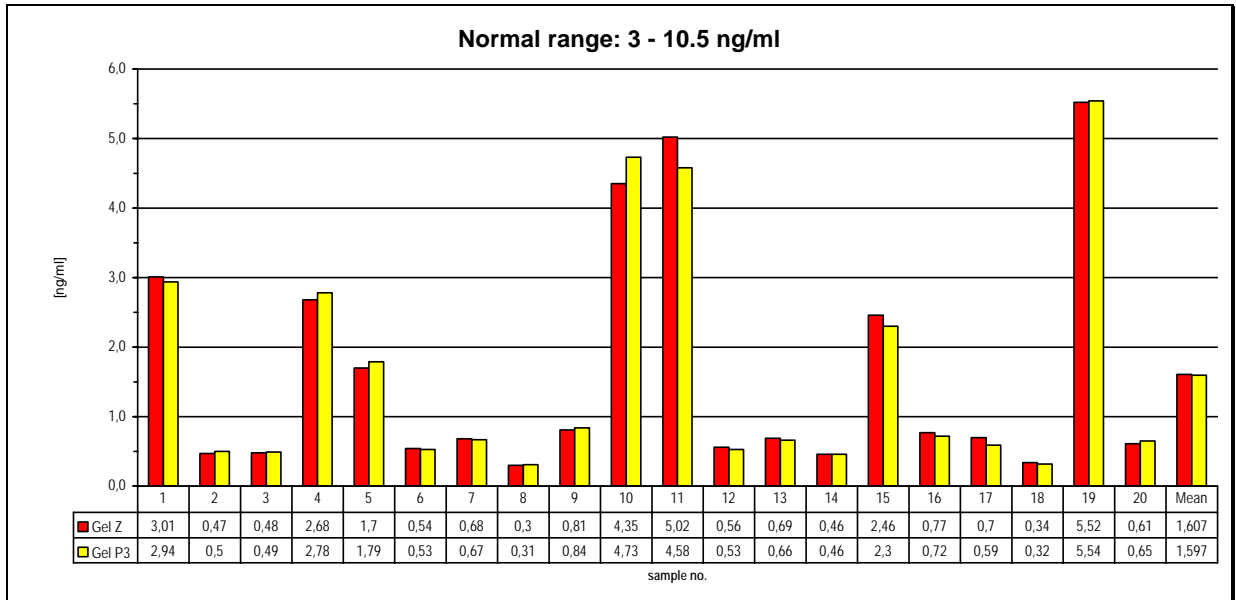
Student's t-test was performed at 5%: No statistical significance was observed.

Triiodothyronine total



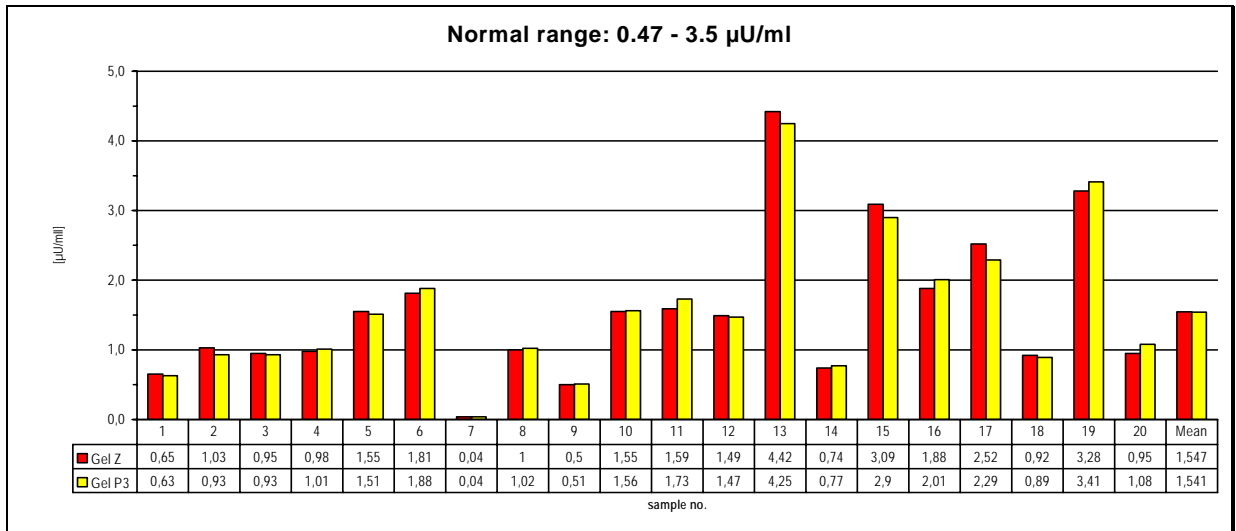
Student's t-test was performed at 5%: No statistical significance was observed.

Testosterone



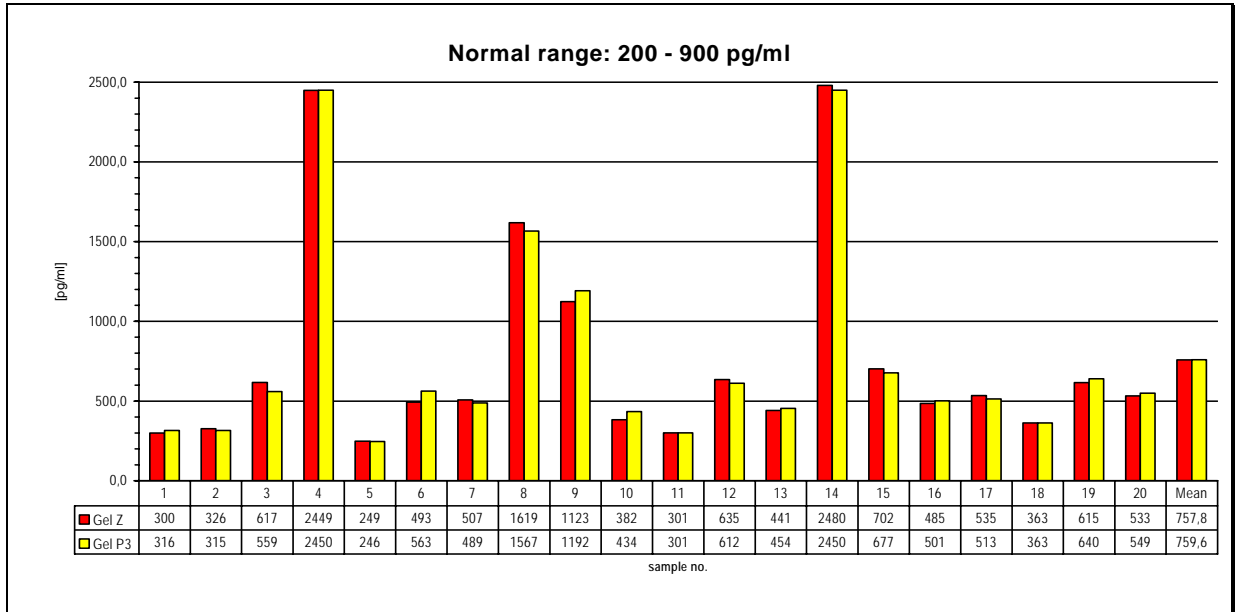
Student's t-test was performed at 5%: No statistical significance was observed.

TSH



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

Vitamin B12



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