

# Comparison of VACUETTE<sup>®</sup> Heparin Gel Z Tubes with VACUETTE<sup>®</sup> Heparin Gel Tubes for Hormone and Vitamin parameters

## **Background:**

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

VACUETTE<sup>®</sup> gel tubes contain an inert gel material with a specific gravity intermediate to plasma and clot. During centrifugation, the gel material forms an impermeable barrier between these two blood components.

Gel Z has been in development since 2001 and it has the same components as the current gel type (Gel P3N), the difference being the production process, which has been optimised. The gel might be slightly more yellowish in color, however provides better performance than gel P3N as well as 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 heparin tube comparison was to show equivalence of the analytical performance of Gel Z and the current gel type (Gel P3N) with regard to a variety of common hormone and vitamin parameters.

## **Study design:**

For this comparison, two types of VACUETTE<sup>®</sup> tubes were evaluated:

Sample	Description	Draw Volume	Size	Gel Type
1	VACUETTE <sup>®</sup> LH Lithium	8 ml	16x100 mm	Gel P3N
2	Heparin Sep.			Gel Z

Venous blood was drawn from 24 patients using the VACUETTE<sup>®</sup> Standard Tube Holder and VACUETTE<sup>®</sup> 21G Multi-Sample Needle. The two tubes were randomly collected from each patient (Sample 1 and Sample 2).

Directly after venipuncture, the tubes were carefully inverted 4-6 times according to the instructions given by the tube manufacturer. The samples were then centrifuged at 2200g for 15 minutes in a swing-out bucket centrifuge.

Determinations of all parameters were performed on Abbott analysers, using Abbott reagents. Evaluation of cortisol was done on an AxSYM analyzer, determination of IgE was done on an Imx, and evaluation of all other analytes was done on an Architect.

The following 14 parameters were tested:

No.	Parameter	Code	Normal Range
1	$\alpha$ -1-Fetoprotein	AFP	< 15 ng/ml
2	Carcinoembryonic Antigen	CEA	< 4,6 ng/ml
3	Cortisol, total	-	2-25 $\mu$ g/dl
4	Estradiol	E <sub>2</sub>	10-450 pg/ml (sex dependent)
5	Folic Acid	-	3-21 ng/ml
6	Follicle-stimulating Hormone	FSH	1-100 IU/l (sex and cycle dependent)
7	Immunoglobulin E	IgE	< 100 IU/ml
8	Progesterone	P <sub>4</sub>	0,1-4,2 ng/ml
9	Prolactin	PRL	< 30 ng/ml
10	Prostate-specific Antigen	PSA	0-10 ng/ml (sex and age dependent)
11	Testosterone, total	-	< 830 ng/dl (sex dependent)
12	Thyroid-stimulating Hormone	TSH	0,4-4 mU/l
13	Thyroxine, free	fT4	10-35 pmol/l
14	Vitamin B12	-	110-835 pg/ml

## **Conclusion:**

F-test ( $\alpha$  0,05) was performed and the correlation coefficient r was calculated using Biosoft STAT200 software.

Neither statistical significance nor clinical difference were observed for samples containing Gel Z compared to samples containing Gel P3N with any parameter tested.

This test examined the performance of Gel Z in comparison to Gel P3N for 14 common hormone and vitamin parameters. The Gel Z tubes gave equivalent results to the Gel P3N samples for these analytes.

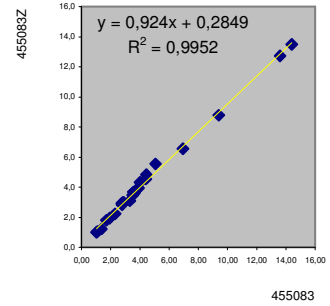
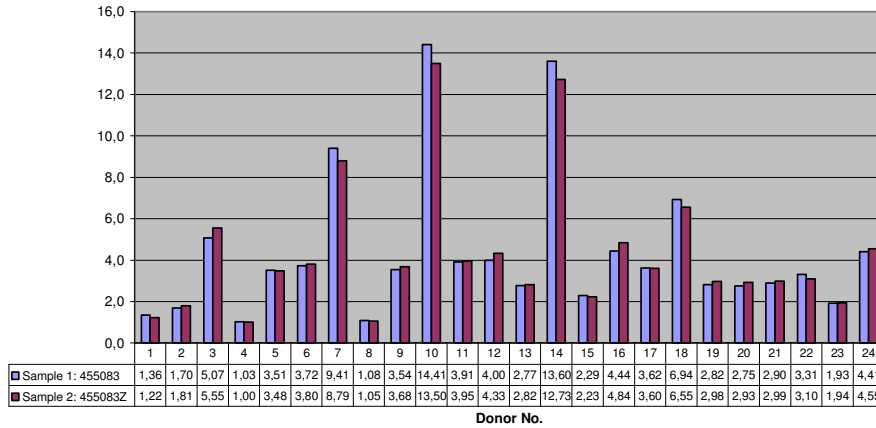
These results prove the equivalence of the performance of Gel Z and Gel P3N, maintaining barrier integrity and stability after centrifugation.

## **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)

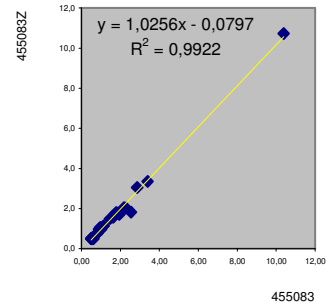
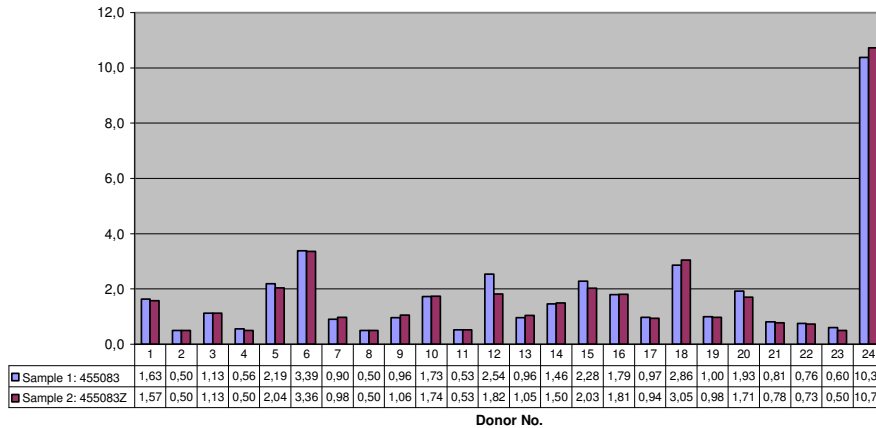
**Results / Comments:**

**α-1-Fetoprotein in [ng/ml]**  
normal range: < 15 ng/ml



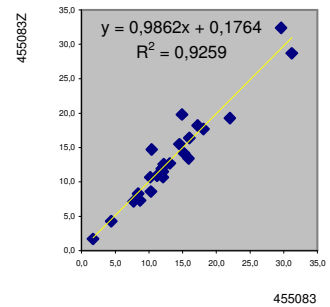
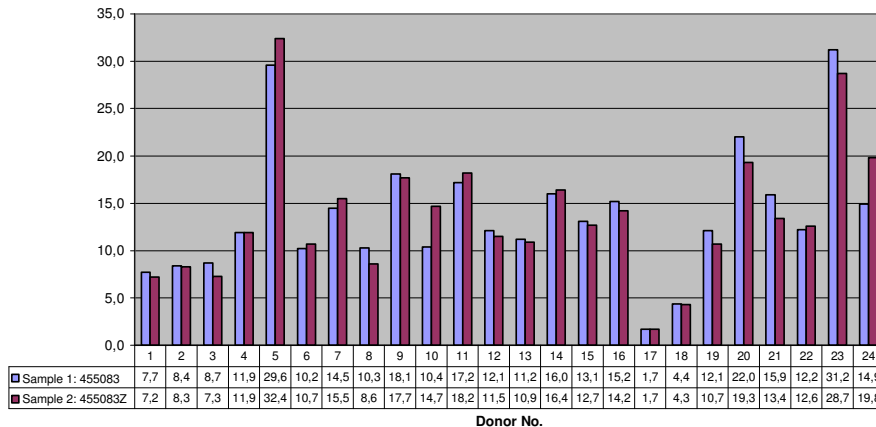
The correlation coefficient *r* between the two tubes for the parameter α-1-Fetoprotein is **0,999**. F-test was performed at 5% and **no statistical significance** was observed.

**Carcinoembryonic Antigen in [ng/ml]**  
normal range: < 4,6 ng/ml



The correlation coefficient *r* between the two tubes for the parameter carcinoembryonic antigen is **0,975**. F-test was performed at 5% and **no statistical significance** was observed.

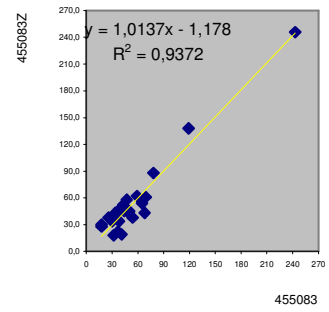
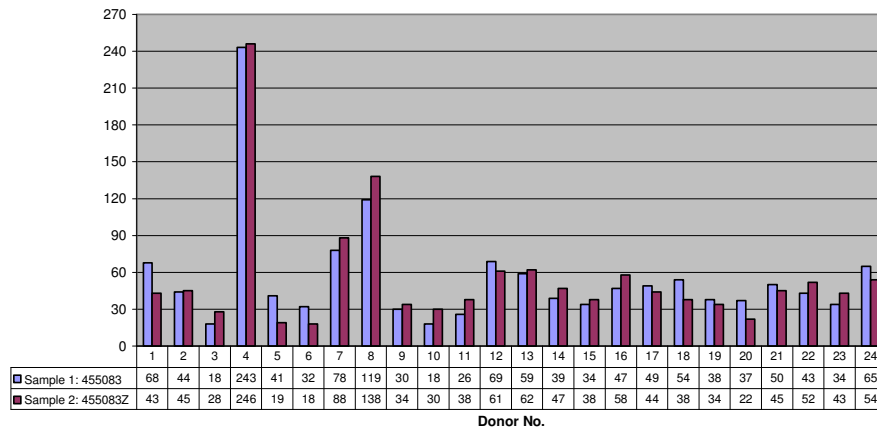
**Cortisol total in [µg/dl]**  
normal range: 2 – 25 µg/dl



The correlation coefficient *r* between the two tubes for the parameter cortisol total is **0,980**. F-test was performed at 5% and **no statistical significance** was observed.

### Estradiol in [pg/ml]

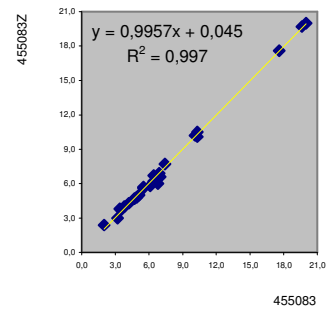
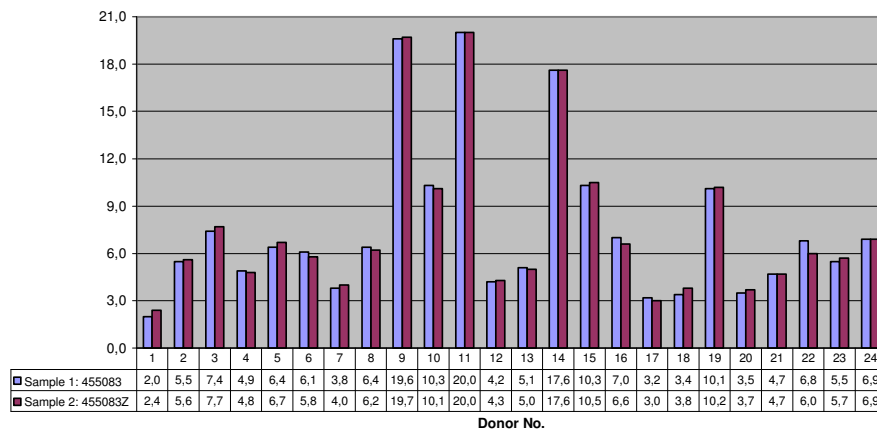
normal range: 10 – 450 pg/ml (sex-dependent)



The correlation coefficient  $r$  between the two tubes for the parameter estradiol is **0,970**.  
F-test was performed at 5% and **no statistical significance** was observed.

### Folic Acid in [ng/ml]

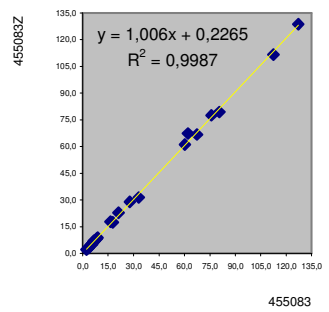
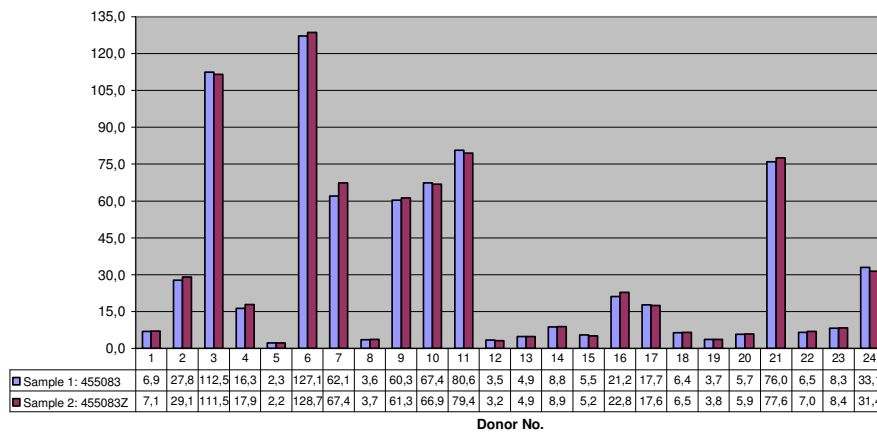
normal range: 3 – 21 ng/ml



The correlation coefficient  $r$  between the two tubes for the parameter folic acid is **0,997**.  
F-test was performed at 5% and **no statistical significance** was observed.

### Follicle-stimulating Hormone [IU/l]

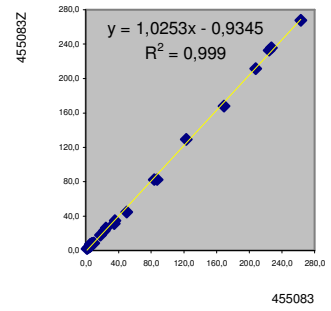
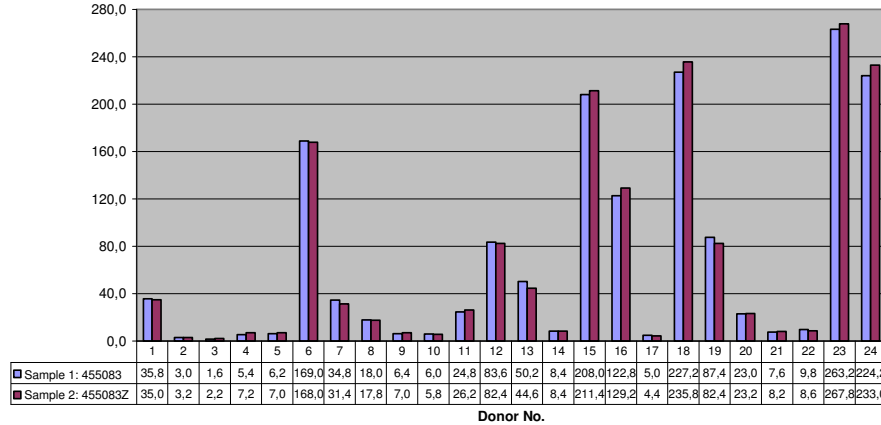
normal range: 1 – 100 IU/l (sex and cycle dependent)



The correlation coefficient  $r$  between the two tubes for the parameter follicle-stimulating hormone is **0,999**.  
F-test was performed at 5% and **no statistical significance** was observed.

### Immunoglobulin E in [U/ml]

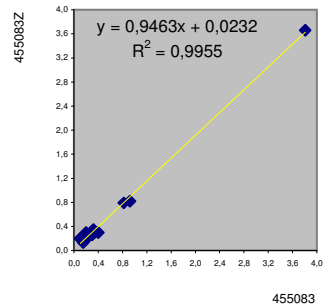
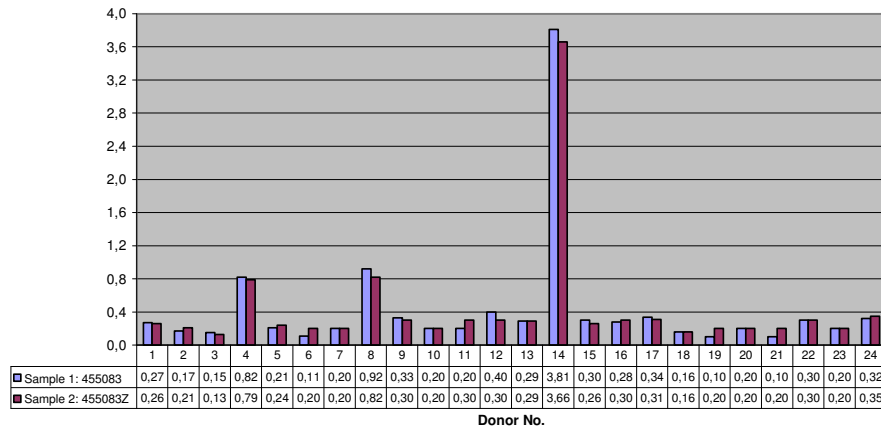
normal range: < 100 U/ml



The correlation coefficient  $r$  between the two tubes for the parameter immunoglobulin E is **0,999**. F-test was performed at 5% and **no statistical significance** was observed.

### Progesterone in [ng/ml]

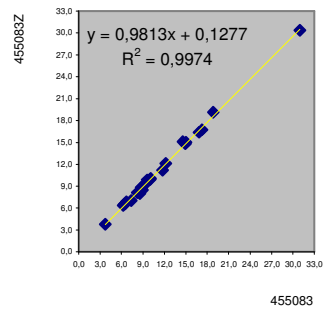
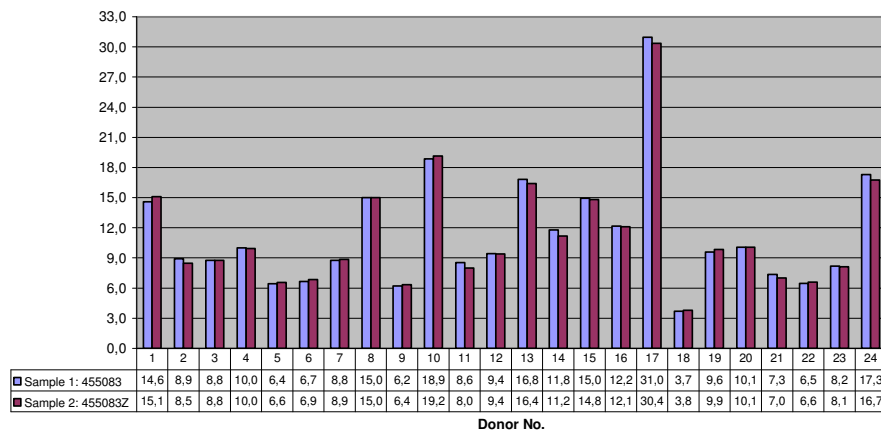
normal range: 0,1 – 4,2 ng/ml



The correlation coefficient  $r$  between the two tubes for the parameter progesterone is **1,000**. F-test was performed at 5% and **no statistical significance** was observed.

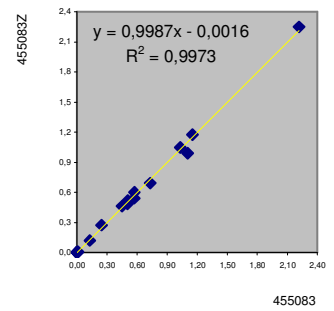
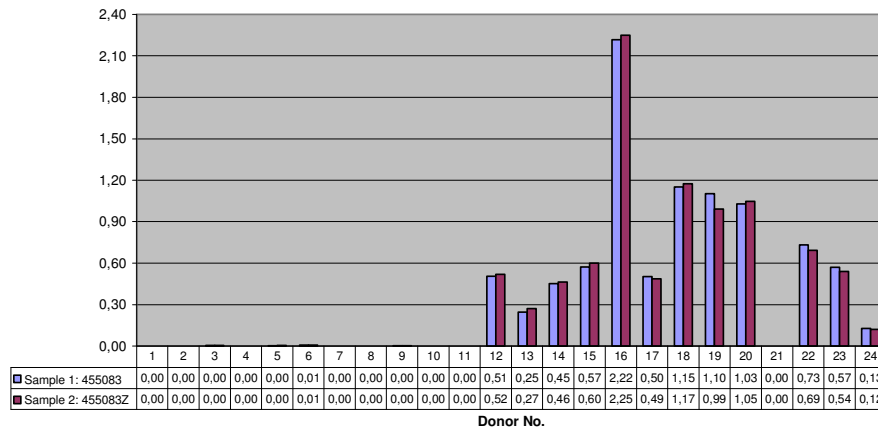
### Prolactin in [ng/ml]

normal range: < 30 ng/ml



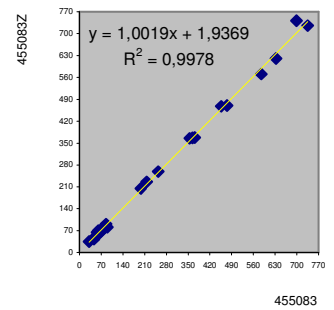
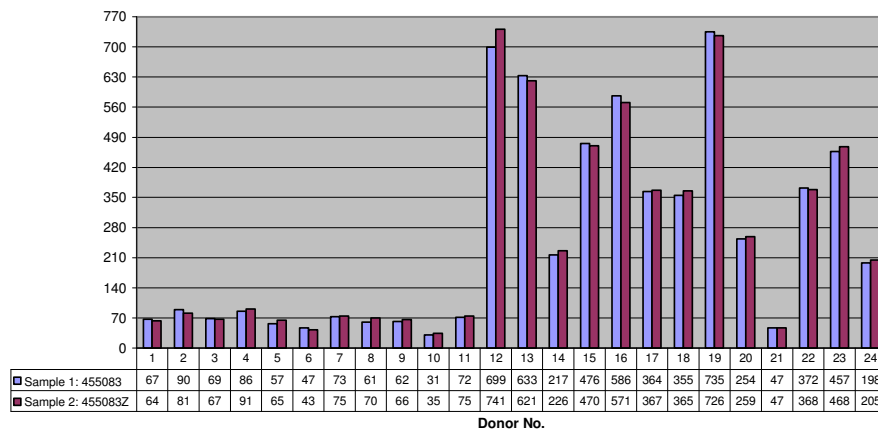
The correlation coefficient  $r$  between the two tubes for the parameter prolactin is **0,997**. F-test was performed at 5% and **no statistical significance** was observed.

**Prostate-specific Antigen in [ng/ml]**  
normal range: 0 – 10 ng/ml (sex dependent)



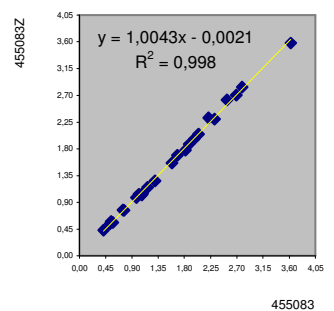
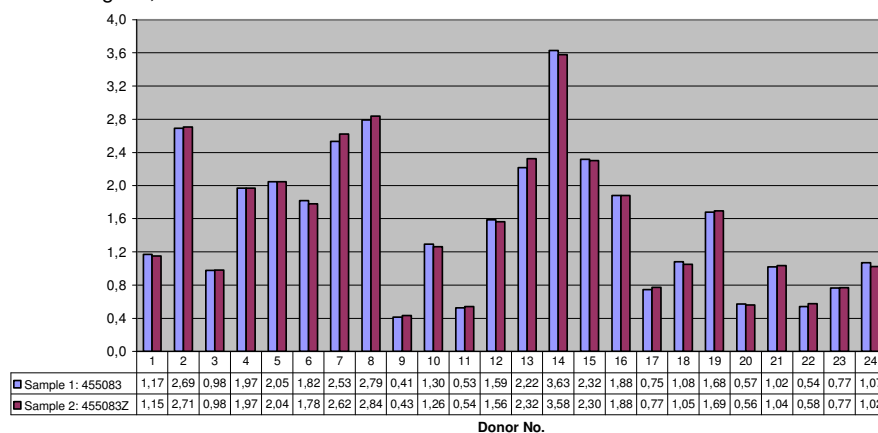
The correlation coefficient  $r$  between the two tubes for the parameter prostate-specific antigen is **0,917**. F-test was performed at 5% and **no statistical significance** was observed.

**Testosterone in [ng/dl]**  
normal range: < 830 ng/dl (sex dependent)



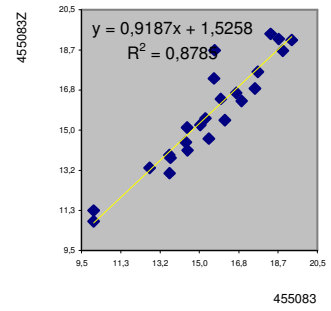
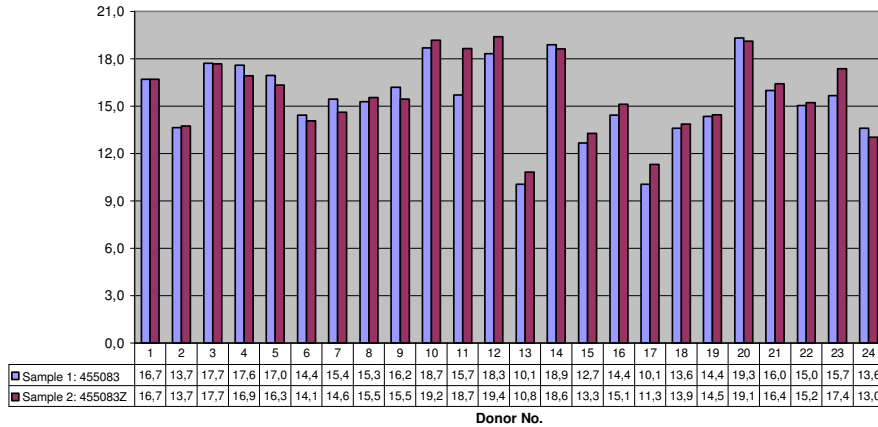
The correlation coefficient  $r$  between the two tubes for the parameter testosterone is **0,999**. F-test was performed at 5% and **no statistical significance** was observed.

**Thyroid-stimulating Hormone in [mU/l]**  
normal range: 0,4 – 4 mU/l



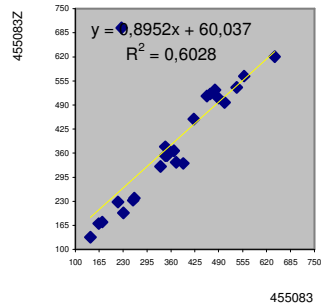
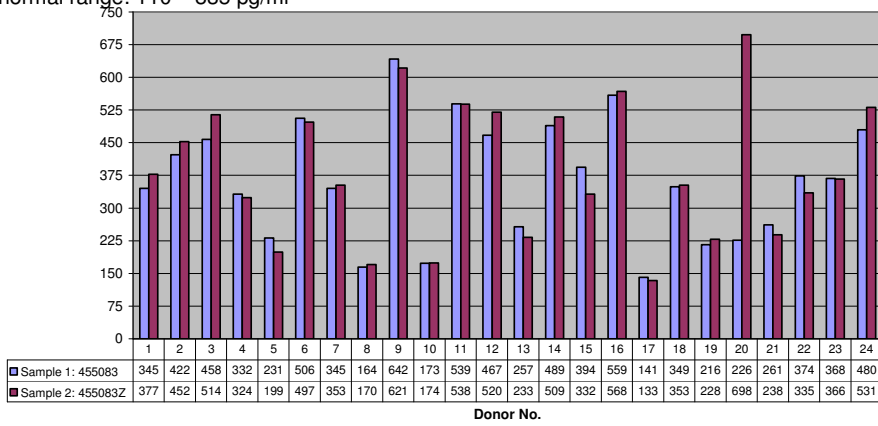
The correlation coefficient  $r$  between the two tubes for the parameter thyroid-stimulating hormone is **1,000**. F-test was performed at 5% and **no statistical significance** was observed.

**Thyroxine, free in [pmol/l]**  
normal range: 10 – 35 pmol/l



The correlation coefficient  $r$  between the two tubes for the parameter thyroxine, free is **0,940**.  
F-test was performed at 5% and **no statistical significance** was observed.

**Vitamin B12 in [pg/ml]**  
normal range: 110 – 835 pg/ml



The correlation coefficient  $r$  between the two tubes for the parameter vitamin B12 is **0,980**.  
F-test was performed at 5% and **no statistical significance** was observed.