

Comparison of VACUETTE® Serum Separator Tubes with Vacutainer® SST™ Tubes for Protein and Hormone Analytes

Background:

Greiner-Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986. VACUETTE® Serum Separator tubes incorporate an inert gel material into the blood collection tube.

The gel has 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 separating the serum from fibrin and cells.

Study Objective:

The aim of this study is to show equivalence in the performance of VACUETTE® Serum Separator tubes and Vacutainer® SST™ tubes on various protein and hormone analytes.

Study design:

Venous blood was collected from up to 40 hospital inpatients using the VACUETTE® Standard Tube Holder and VACUETTE® 21G Multi-Sample Needle. The samples were collected in random order to prevent systemic bias.

The following tube types were used in blood collection:

- VACUETTE® Serum Separator
- Vacutainer® SST™ (glass)

Directly after venipuncture, the tubes were carefully inverted and centrifuged according to the instructions given by the tube manufacturer.

The analysis of the following parameters was performed:

Analytes	
α-1-antitrypsin	IgA
α-1-acid-glycoprotein (Orosomuroid)	IgM
Haptoglobin	Growth Hormone
Ceruloplasmin	β-hCG
C3	AFP
C4	Insulin
IgG	PSA

Proteins were analysed on Hitachi 917 (Roche Diagnostics) with the instrument's accompanying reagents.

Hormones were analysed on AutoDelfia (PerkinElmer) with the instrument's accompanying reagents.

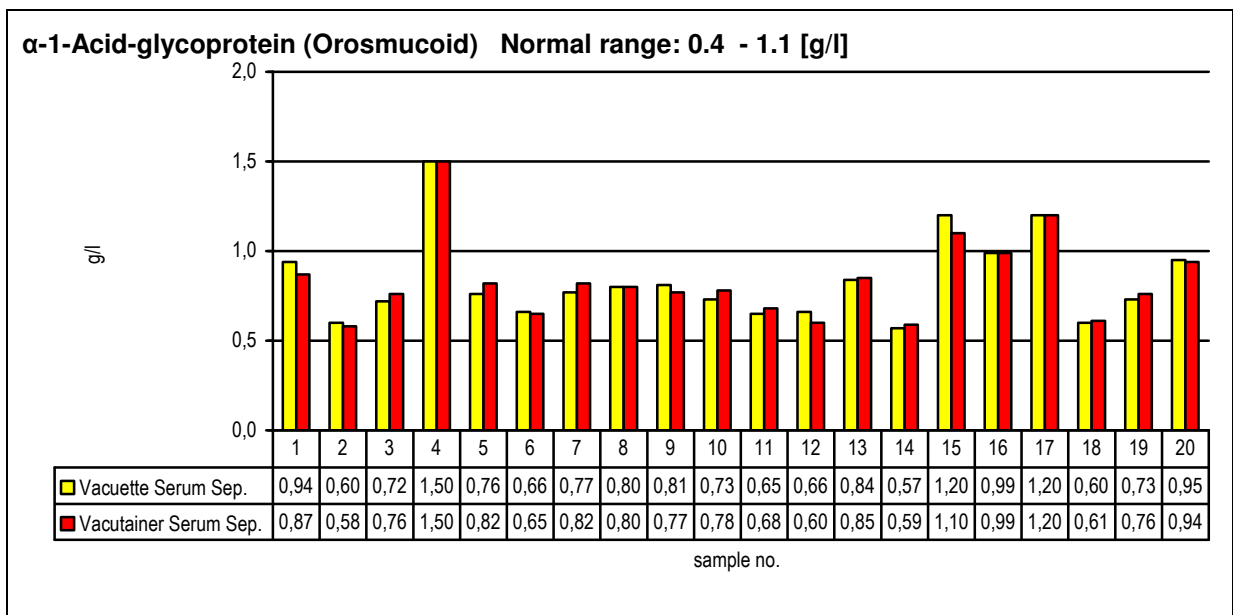
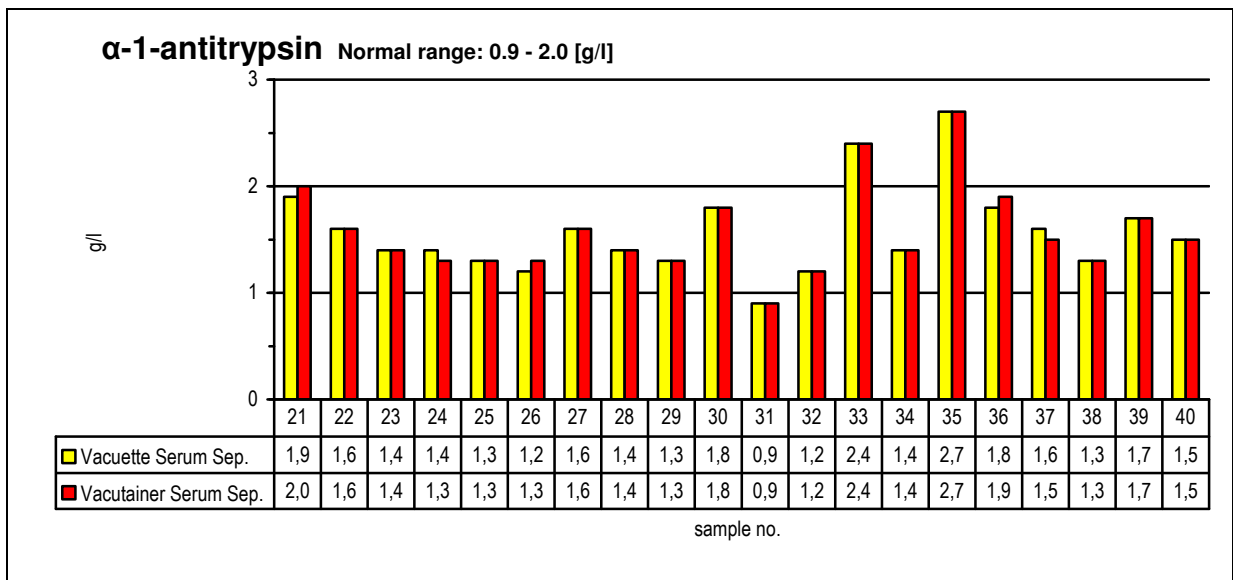
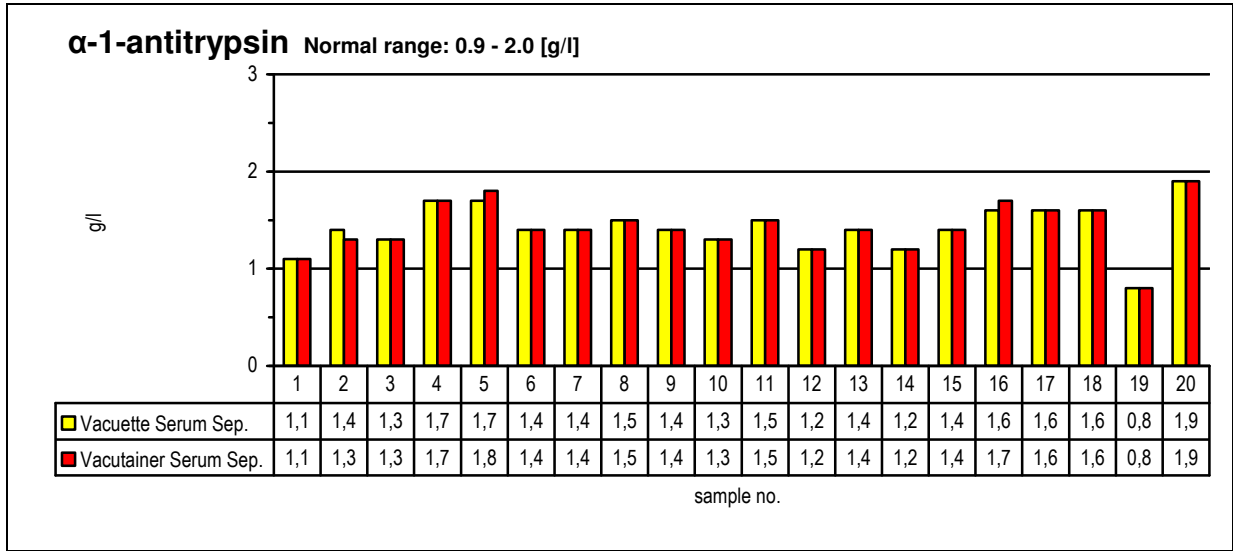
Conclusion:

Neither statistical significance using Student's T-Test at p(0.05) level, nor clinical relevance could be found when comparing VACUETTE® Serum Separator tubes and Vacutainer® SST™ tubes for the 7 analytes tested in this study.

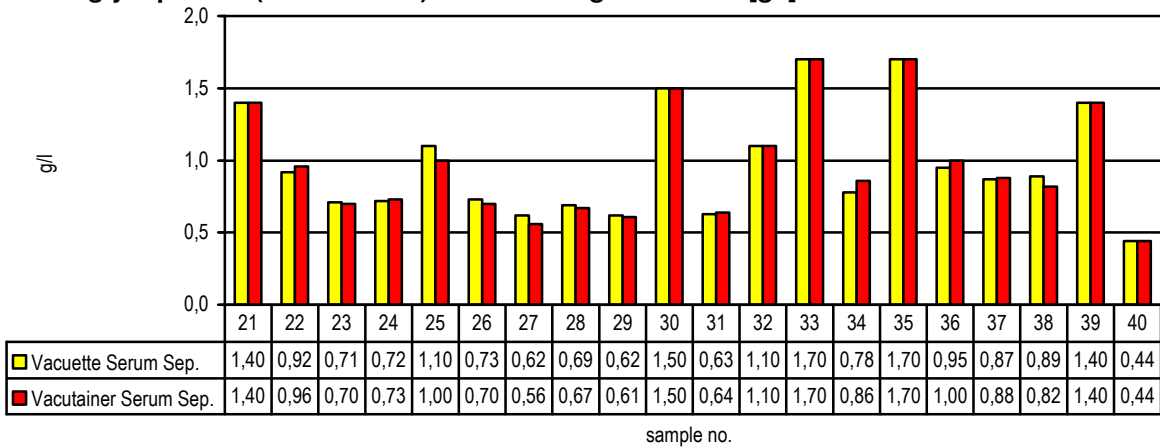
References:

- (1) Guder W.G., Narayanan S., Wisser H., Zawta B., Samples: From the Patient to the Laboratory. Wiley-VCH, 3rd edition (2003)
- (2) Thomas L., Labor und Diagnose. TH-Books, 5. Auflage (1998)
- (3) Tietz N.W., Clinical Guide to Laboratory Tests. W.B. Saunders Company, third edition (1995)

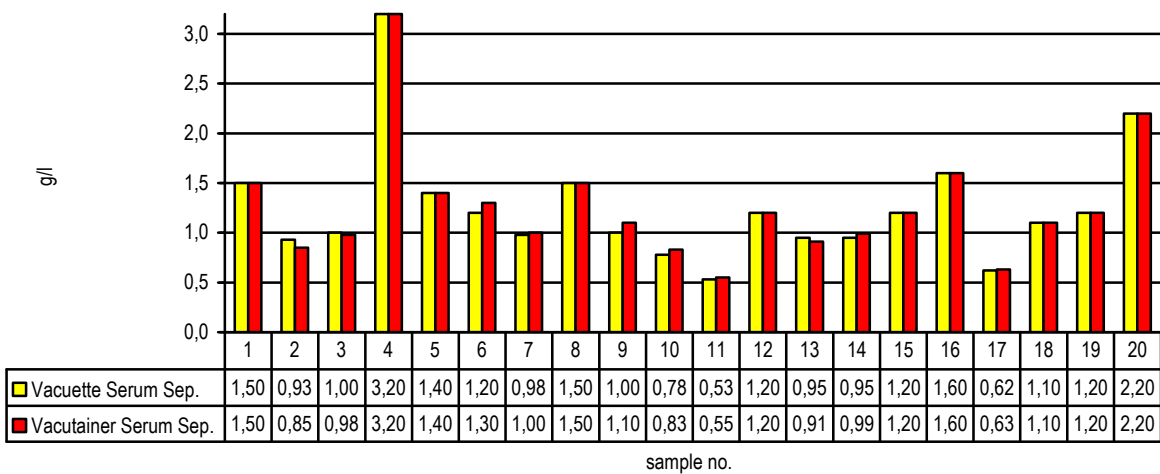
Results:



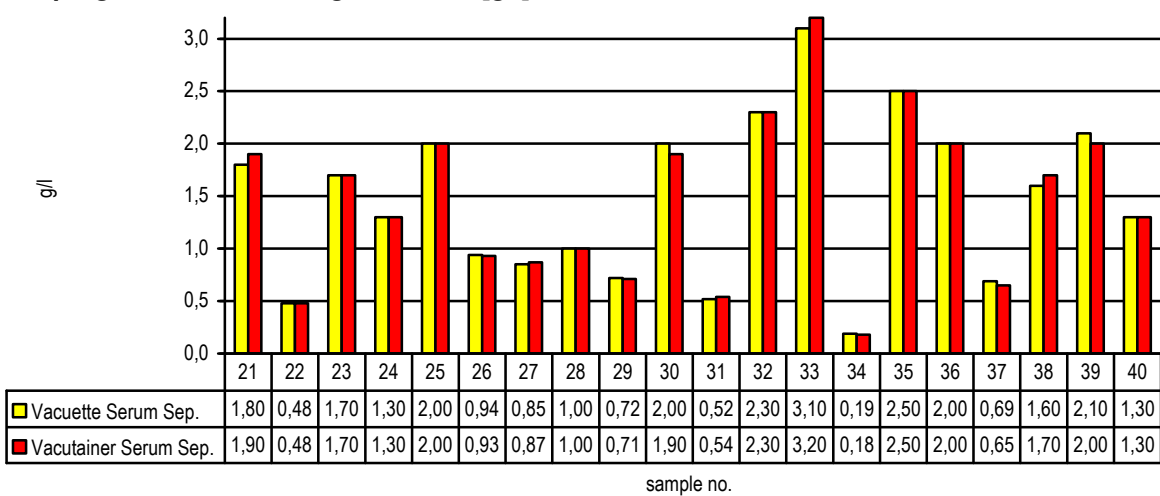
α-1-Acid-glycoprotein (Orosmuroid) Normal range: 0.4 - 1.1 [g/l]



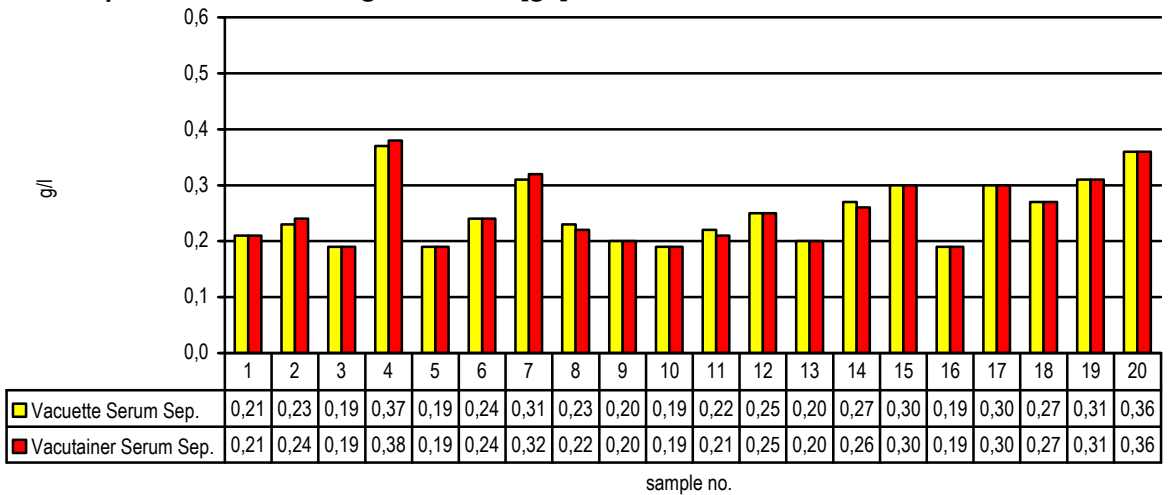
Haptoglobin Normal range: 0.3 - 2.0 [g/l]



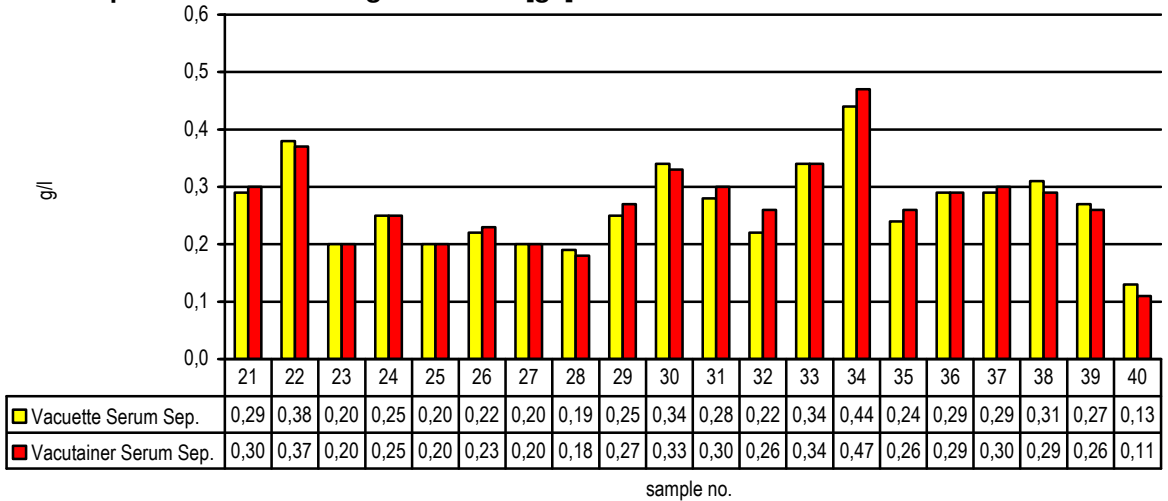
Haptoglobin Normal range: 0.3 - 2.0 [g/l]



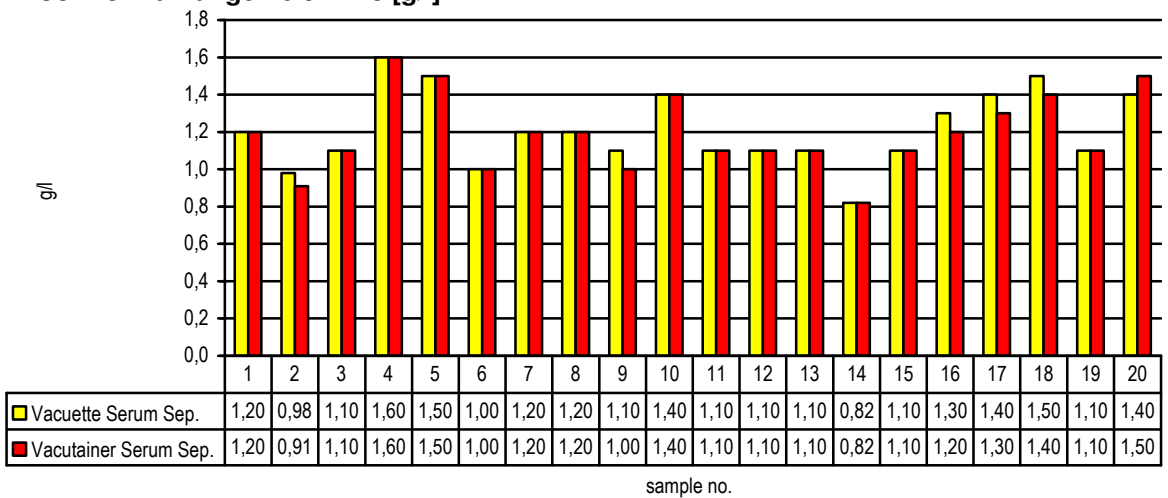
Ceruloplasmin Normal range: 0.2 - 0.6 [g/l]



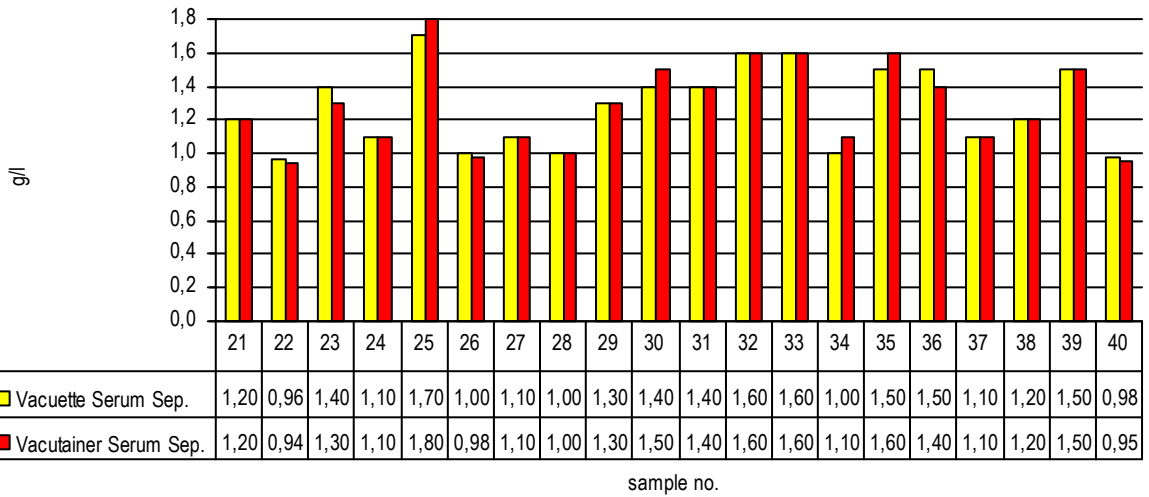
Ceruloplasmin Normal range: 0.2 - 0.6 [g/l]



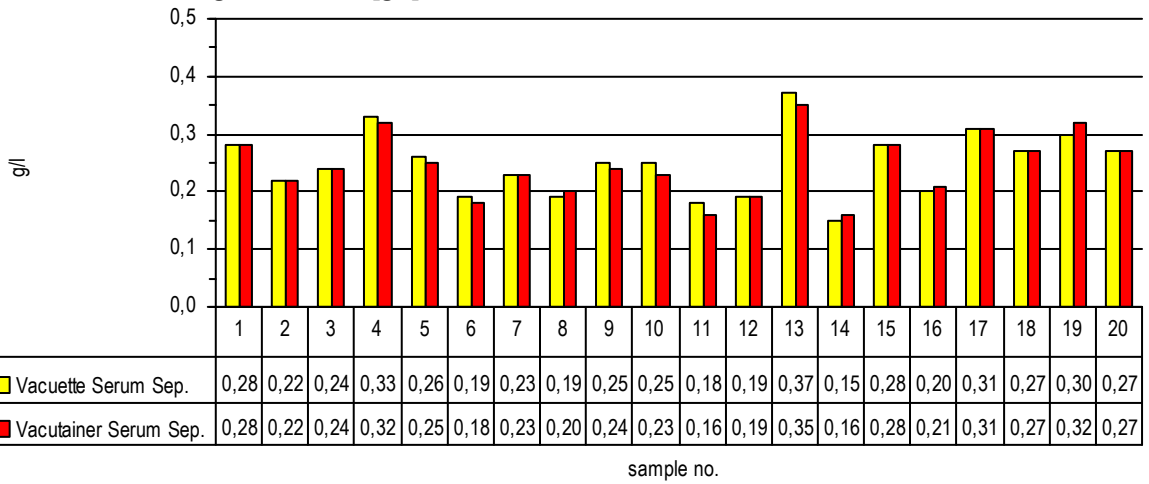
C3 Normal range: 0.9 - 1.8 [g/l]



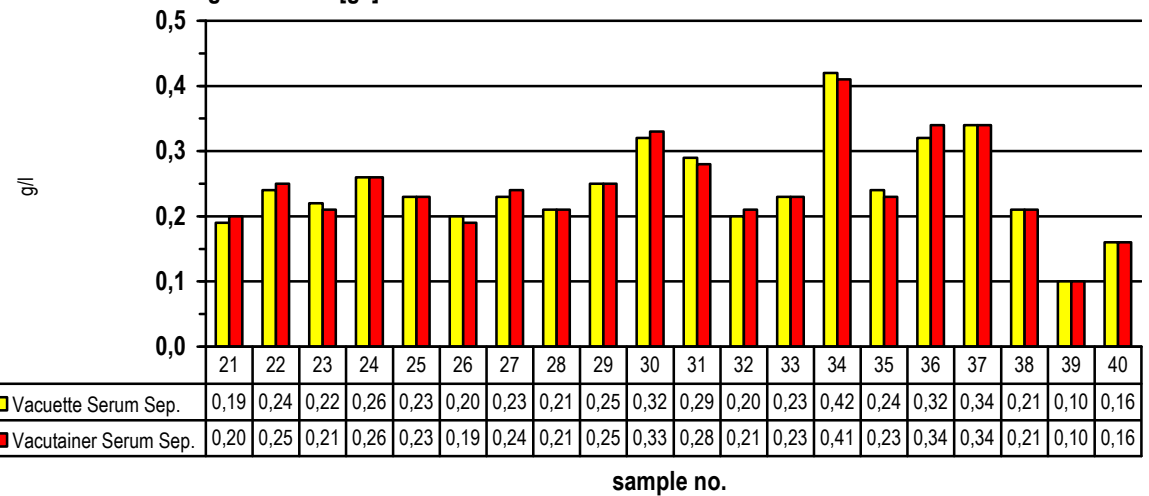
C3 Normal range: 0.9 - 1.8 [g/l]



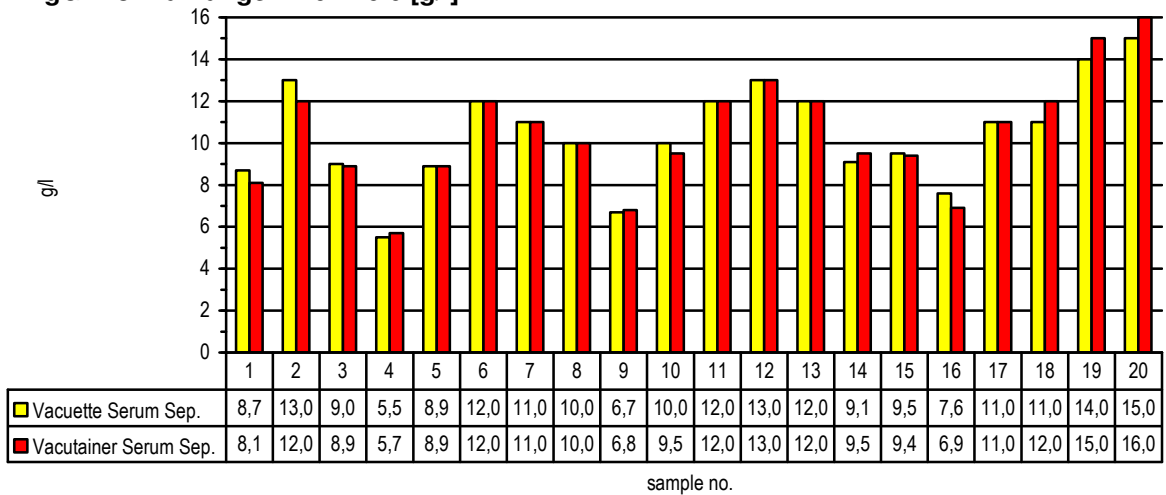
C4 Normal range: 0.1 - 0.4 [g/l]



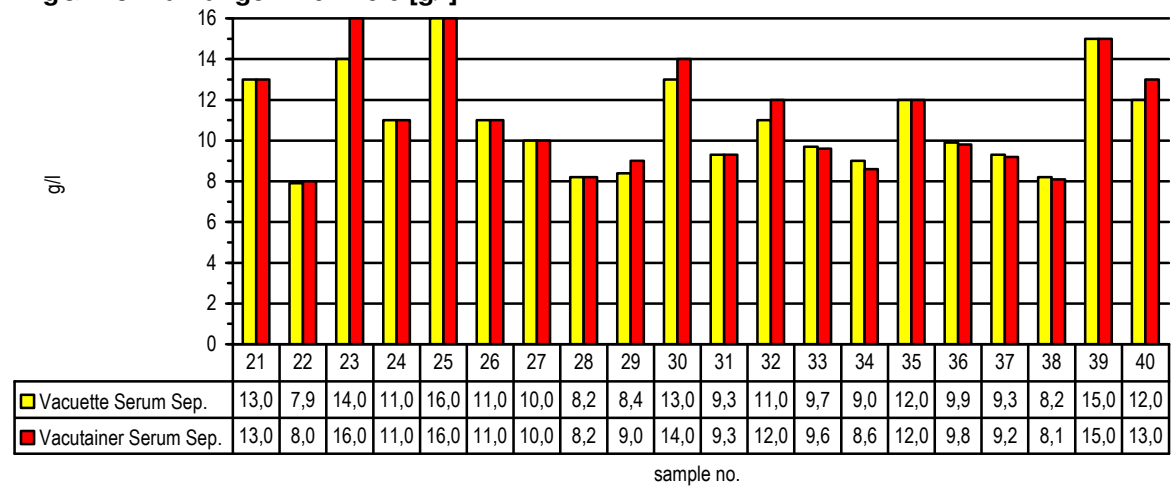
C4 Normal range: 0.1 - 0.4 [g/l]



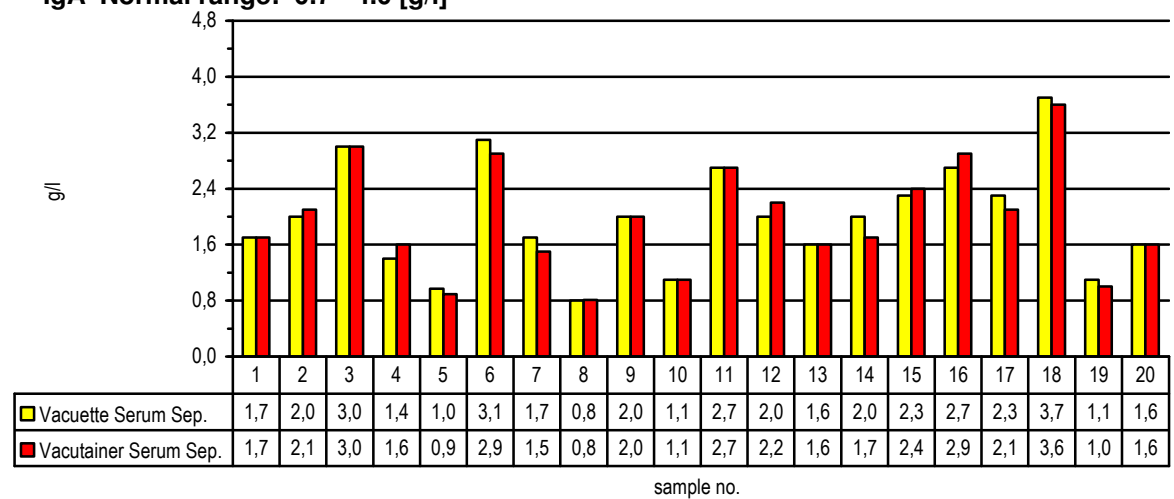
IgG Normal range: 7.0 - 16.0 [g/l]



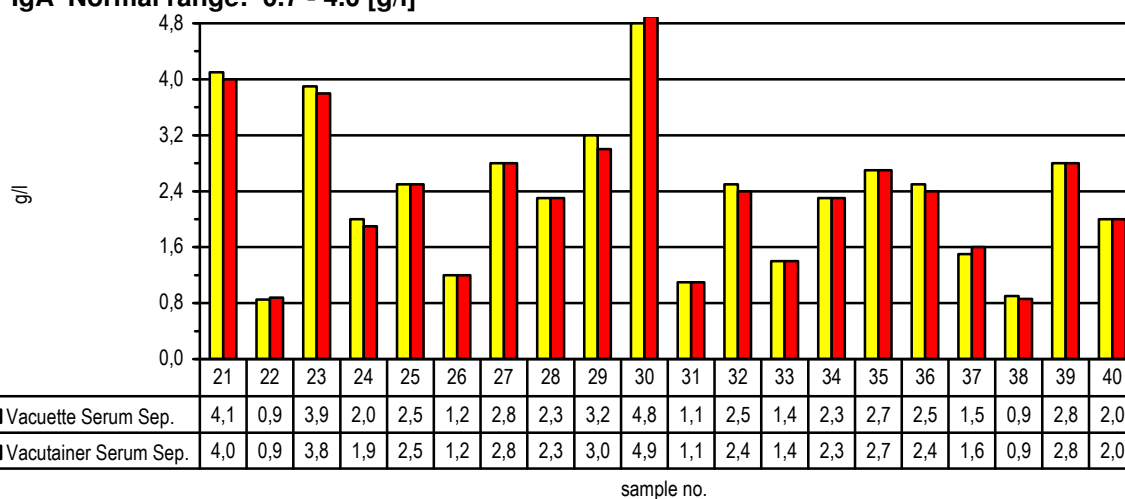
IgG Normal range: 7.0 - 16.0 [g/l]



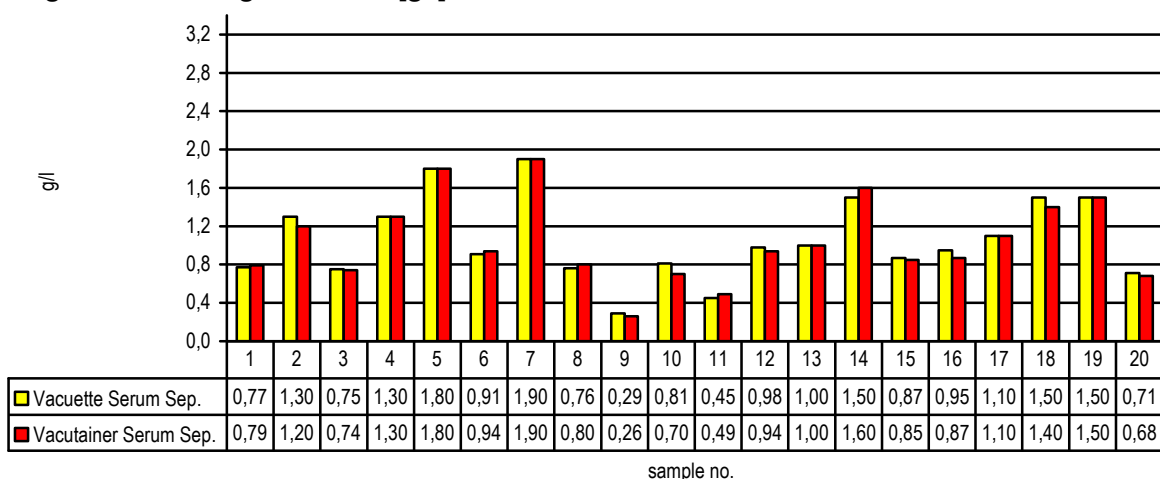
IgA Normal range: 0.7 - 4.0 [g/l]



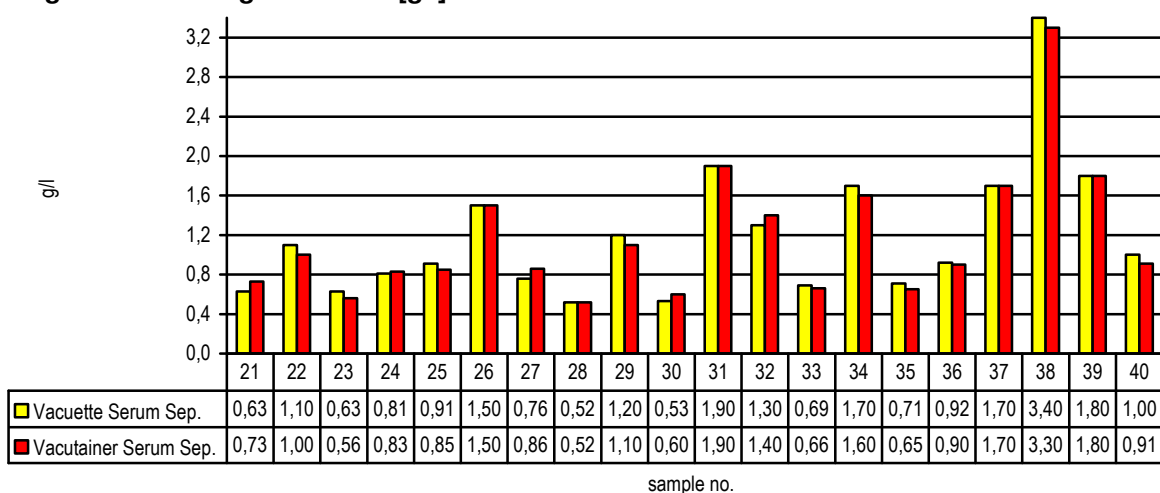
IgA Normal range: 0.7 - 4.0 [g/l]



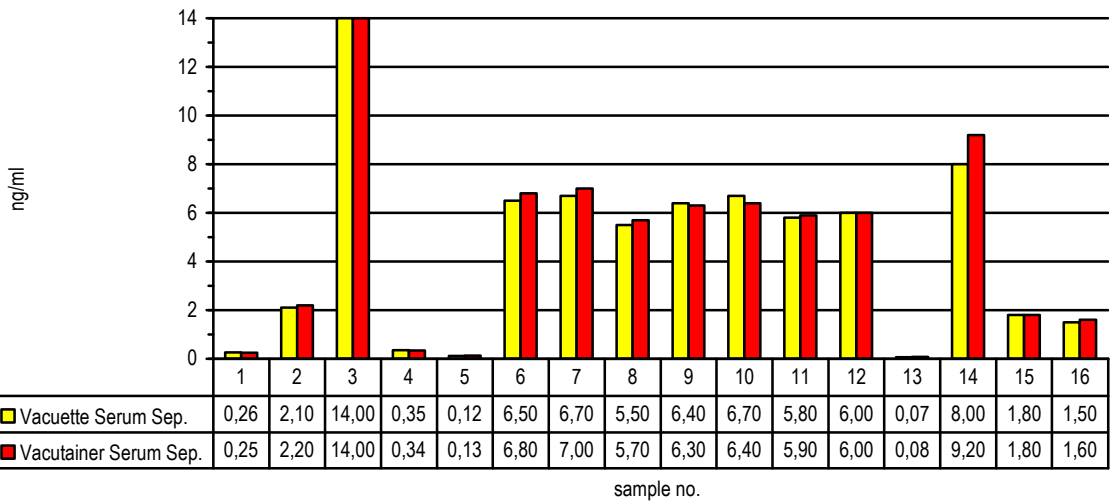
IgM Normal range: 0.4 - 2.3 [g/l]



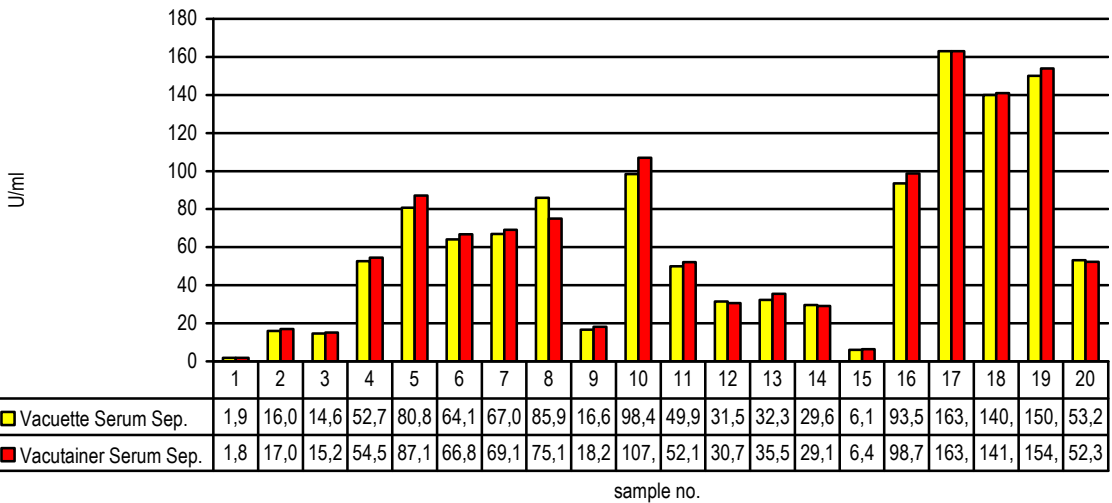
IgM Normal range: 0.4 - 2.3 [g/l]



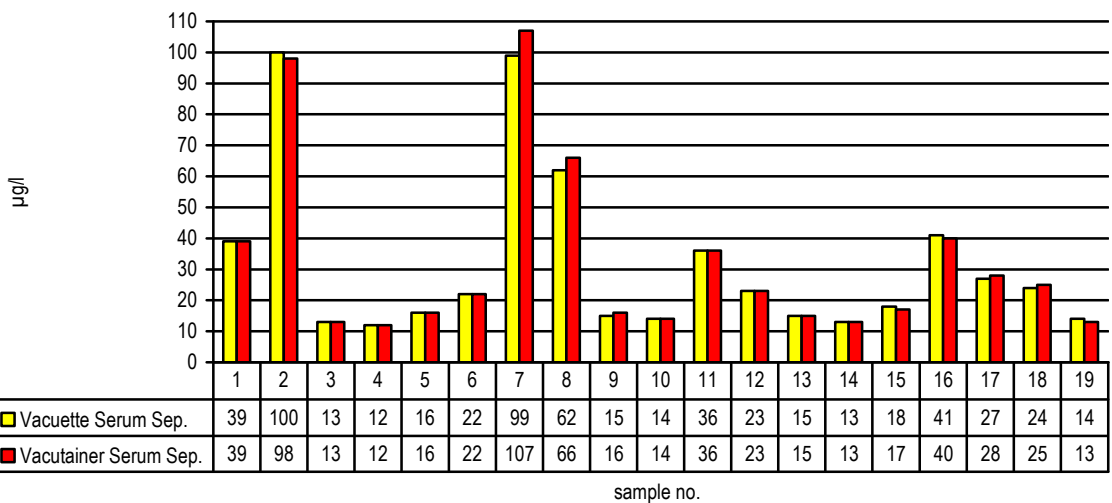
Growth Hormone Normal range: 0 - 4 [ng/ml]



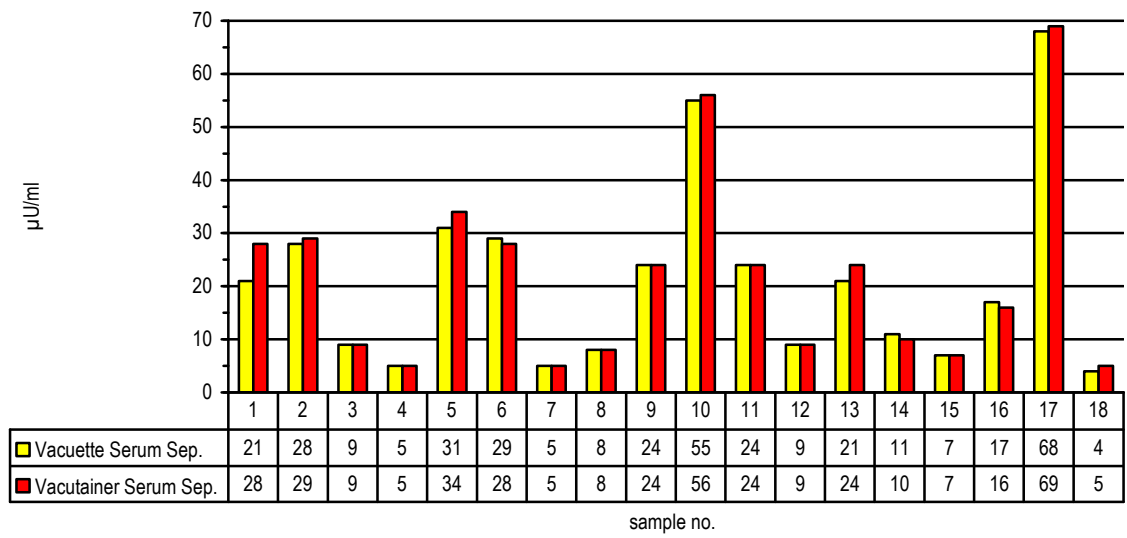
β-hcG Normal range: < 5 [U/l]



α-Fetoprotein Normal range: < 20 [µg/l]



Insulin Normal range: < 35 [μ U/ml]



PSA Normal range: < 4 [ng/ml]

