Stability of glucose concentration using VACUETTE® FC Mix blood collection tubes

Background:

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

VACUETTE® FC Mix blood collection tubes contain an additive mix of Na_2EDTA, sodium fluoride, citric acid and sodium citrate. This mixture inhibits glycolysis and prevents coagulation. [1,2]

The VACUETTE® FC Mix blood collection tubes are used to stabilize the *in-vivo* glucose level in whole blood or plasma for up to 48 hours at room temperature and enable prolonged sample processing time including both storage and/or transportation. [3]

Study Objective:

The study has been carried out to demonstrate that VACUETTE® FC Mix blood collection tubes are suitable for stabilization of glucose concentration for up to 48h after blood collection in comparison to Terumo VENOSAFE™ FC Mixture.

Study design and procedure:

Venous whole blood was collected from 20 presumably healthy donors by using a VACUETTE® SAFETY Blood Collection Set (Item #450085) into the following tubes:

Sample A: VENOSAFE™ FC Mixture® (Prod. No. VF-052SCF)
Sample B: VACUETTE® FC Mix (Prod. No. 454511)

All samples were centrifuged at 1800g for 10 min at 20°C (centrifuge: Eppendorf 5810R). In order to test the robustness of whole blood, two tubes of each sample were taken and centrifuged under two different time periods:

1) initially after blood collection and
2) 48h after blood collection

The sample tubes which were centrifuged initially after blood collection were analyzed for glucose at the initial time point within 2 hours after blood collection, 24 h and 48h after blood collection on the Beckman Coulter AU640 analyzer (glucose determination method: Hexokinase; total precision less than 3%). The sample tubes which were stored until 48h after blood collection at room temperature were then centrifuged and analyzed (see table 1).

Sample	Centrifugation		Determination of glucose concentration		
	Initially after blood collection	48 hours after blood collection	Within 2 hours after centrifugation	24 hours after centrifugation	48 hours after centrifugation
A	x		x	x	x
B 1	x		x	x	x
B 2		x			x

Table 1 Schedule of centrifugation and determination of glucose concentration

Between measurements, all samples were stored in an upright position at room temperature.

Results:

The mean values of the glucose concentration are shown in Table 1.

Comparison analysis was performed at all time points of determination. Statistics was performed with the t-test (α = 0.05) using StatSoft Software, Version 12.

Clinical evaluation was based on the allowed recommendation by the German Medical Association (RILIBÄK). [4].

Figure 1 illustrates the initial, 24h and 48h values for both samples centrifuged directly after blood collection. Although a slight decrease of glucose concentration over time has been found in samples A and B1, the stabilization of the glucose concentration has been demonstrated in both samples, no clinically or statistically significant deviations have been found comparing sample A to B1 at each point of time (highest single deviation: 9.09% after 48h) as well as sample A or B1 comparing their initial to 24h or 48h values, respectively (highest single deviation -8.05%) although the latter comparison means statistically significant deviations. On the basis of the healthy collective tested, the equivalence in the performance of the samples has been shown as both samples contain the additive composition of citrate, EDTA and sodium fluoride in order to prevent glycolysis.

The stability of the glucose concentration in sample B2 (48h in whole blood) has been demonstrated by Figure 2. The comparison between the initial values of sample B1 and the 48h values of sample B2 do not result in statistically or clinically significant differences due to sodium fluoride acting as an enolase inhibitor being responsible for the long term stabilization of the glucose concentration.

Table 1 Results of glucose concentration [mg/dl]

Sample	Valid N	Mean	±SD
A: **VENOSAFE™** FC Mixture initial	20	95.80	11.41
B1: **VACUETTE®** FC Mix initial	20	94.45	12.82
A: **VENOSAFE™** FC Mixture 24h	20	93.90	11,01
B1: **VACUETTE®** FC Mix 24h	20	92.65	12.63
A: **VENOSAFE™** FC Mixture 48h	20	93.75	11.45
B1: **VACUETTE®** FC Mix 48h	20	91.45	12.35
B2: **VACUETTE®** FC Mix 48h whole blood	20	92.94	12.98

Figure 1: Initial, 24h and 48h values

Centrifugation (a): initially after blood collection

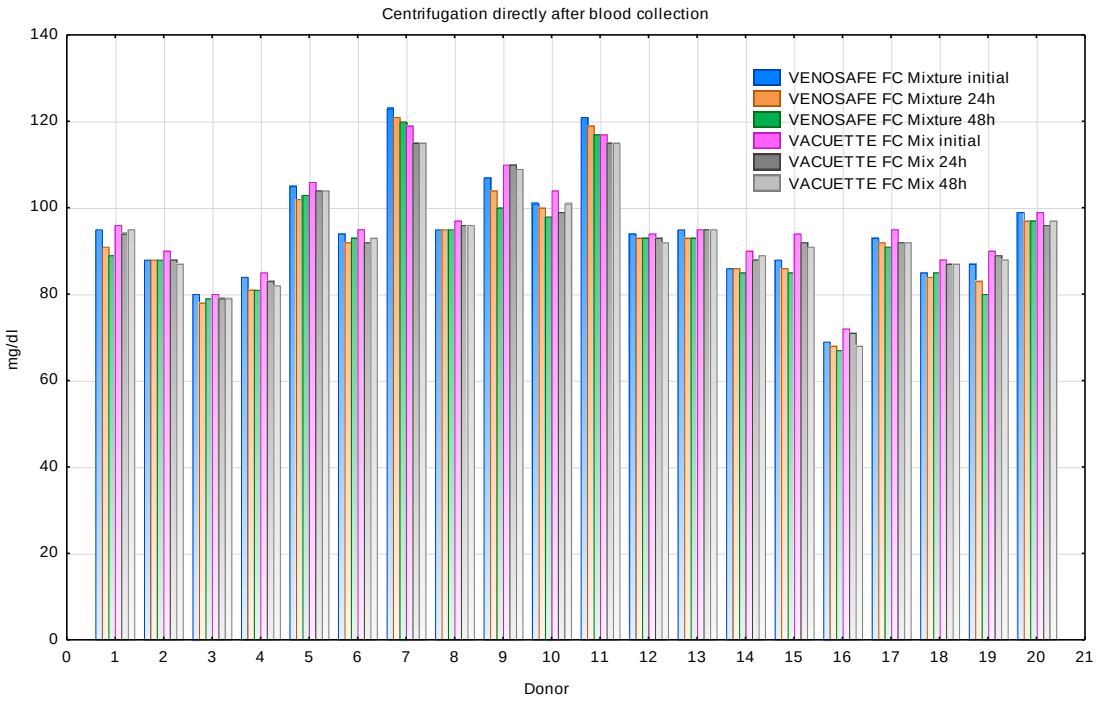
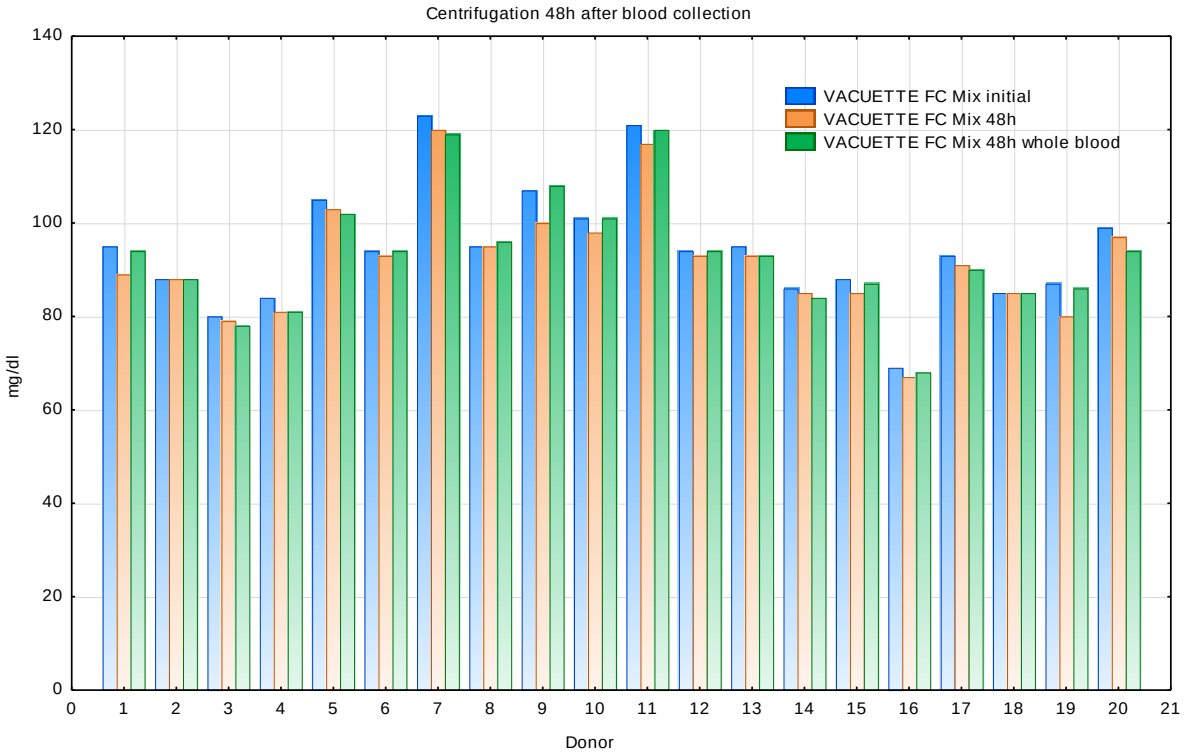


Figure 2: Storage as whole blood

Centrifugation (b): 48 hours after blood collection



Conclusion:

Based on these results the stabilization of glucose concentration in the **VACUETTE**® FC Mix blood collection tubes in comparison to VENOSAFE™ FC Mixture (Terumo) was demonstrated for up to 48h at room temperature. No clinically significant differences were observed between VENOSAFE™ FC Mixture and **VACUETTE**® FC Mix tube at any point of time when stored in an upright position. Furthermore, stability of glucose concentration was shown regardless of delayed centrifugation time up to 48h after the blood collection. These results indicate the suitability of **VACUETTE**® FC Mix blood collection tubes for reliable determination of glucose concentration if prolonged processing times including transport and/or storage times occur.

References:

[1] E. Yagmur, J. van Helden, A. Koch, J. Jadem, F. Tacke, Ch. Trautwein: Effektive Glykolyse-Inhibierung im Citrat-gepufferten venösen Vollblut und Plasma, J Lab Med 2012; 36 (3): 169-177.

[2] E. Yagmur, A. Koch, J. Jadem, F. Tacke: Effektive Glykolyse-Inhibierung in venösem Vollblut durch Azidifikation des Fluorid Additivs. Diabet. und Stoffwechsel 2012, 7-p_157.

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

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