Stability of glucose concentration using **VACUETTE®** GLUCOMEDICS blood collection tubes

Background:

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

VACUETTE® GLUCOMEDICS 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®** GLUCOMEDICS 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® GLUCOMEDICS blood collection tubes are suitable for stabilization of glucose concentration over time up to 48h after blood collection.

Study design and procedure:

Venous whole blood was collected from 25 presumably healthy donors by using a **VACUETTE®** SAFETY Blood Collection Set (Item #450085) into the following tubes:

Sample 1: S-Monovette® GlucoEXACT (Item 05.1074.001)
Sample 2: VACUETTE® GLUCOMEDICS (Prod. No. 454347)

All samples were centrifuged at 1800g for 10 min at 20℃ (centrifuge: Eppendorf 5810R). In order to te st the robustness of whole blood, three tubes of each sample were taken and centrifuged under three different centrifugation conditions:

(a) initially after blood collection
(b) 24h after blood collection and
(c) 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, 24h and 48h after blood collection on the Olympus AU640 analyzer. The sample tubes which were centrifuged 24h after blood collection were analyzed at 24h and 48h after blood collection and the samples stored as whole blood for 48h were then centrifuged and analyzed (see table 1). The samples from donors 6-10 and donors 11-15 for centrifugation time (c) were spiked by 50 mg/dl or 200mg/dl, respectively.

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

Table 1 Schedule of centrifugation and determination of glucose concentration

Between measurements, all samples were stored at room temperature.

Results obtained under different conditions were compared between the two different blood collection tubes used.

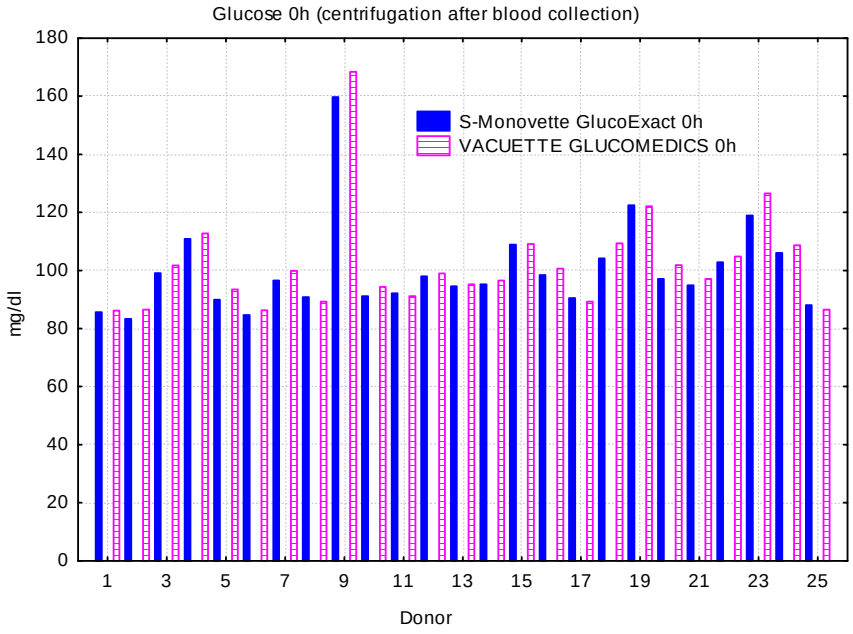
Results:

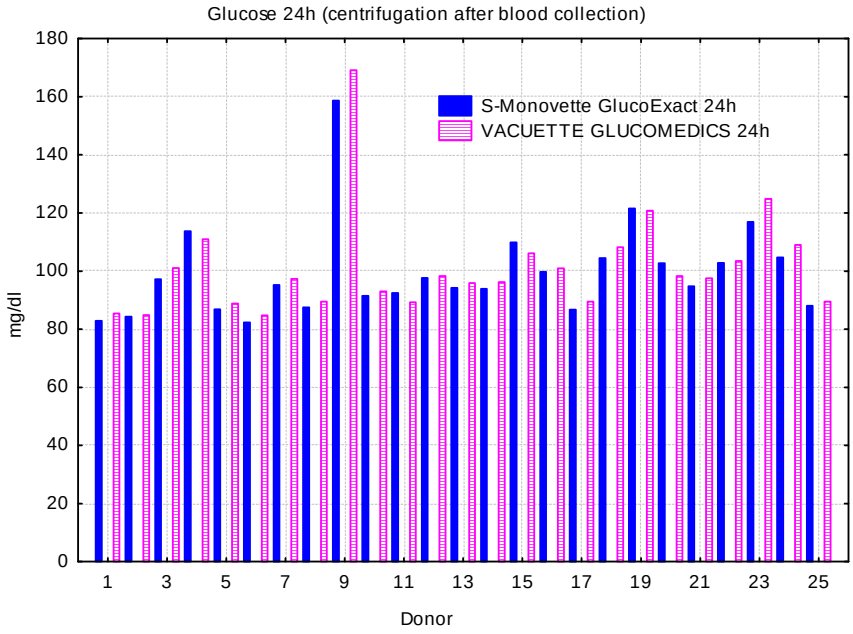
The results of glucose concentration have to be multiplied by a factor of 1.16 to compensate for dilution with the additive.

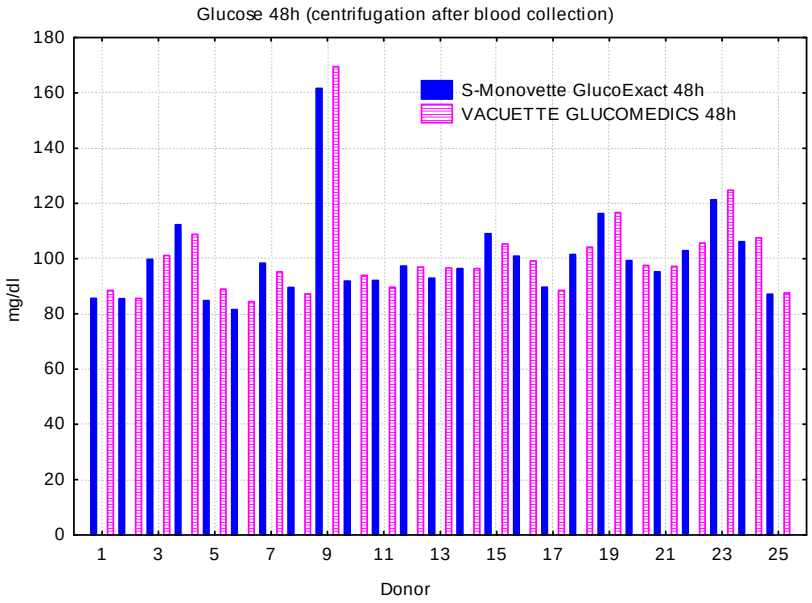
Comparison analysis was performed at all three time points of determination. Statistics was performed with the t-test (α = 0.05) using StatSoft Software, Version 9.

Clinical evaluation was based on the allowed recommendation by the German Medical Association (RILIBÄK). [4] No significant differences were observed between the both blood collection tubes S-Monovette® GlucoEXACT and **VACUETTE**® GLUCOMEDICS tubes regarding glucose concentration. No significant interfering influence could be observed for different centrifugation times and their relation to different times of analysis.

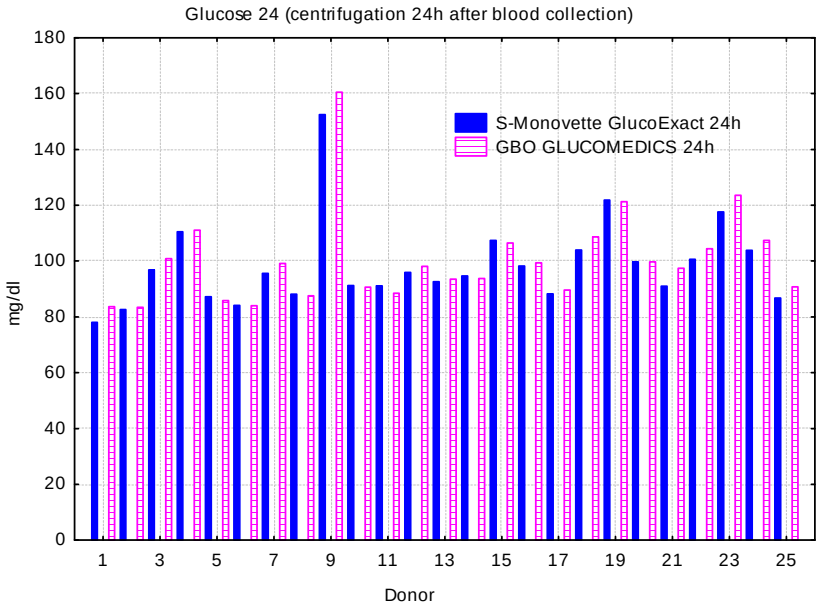
Centrifugation (a): initially after blood collection

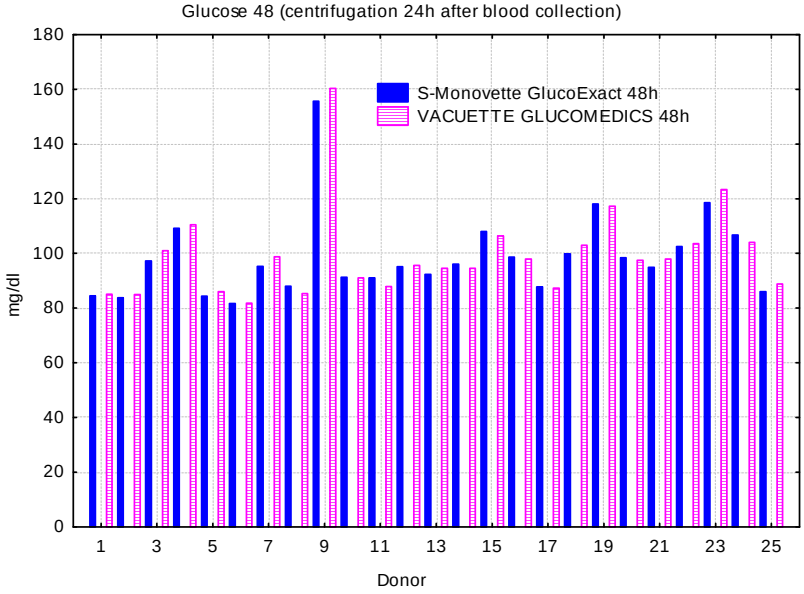




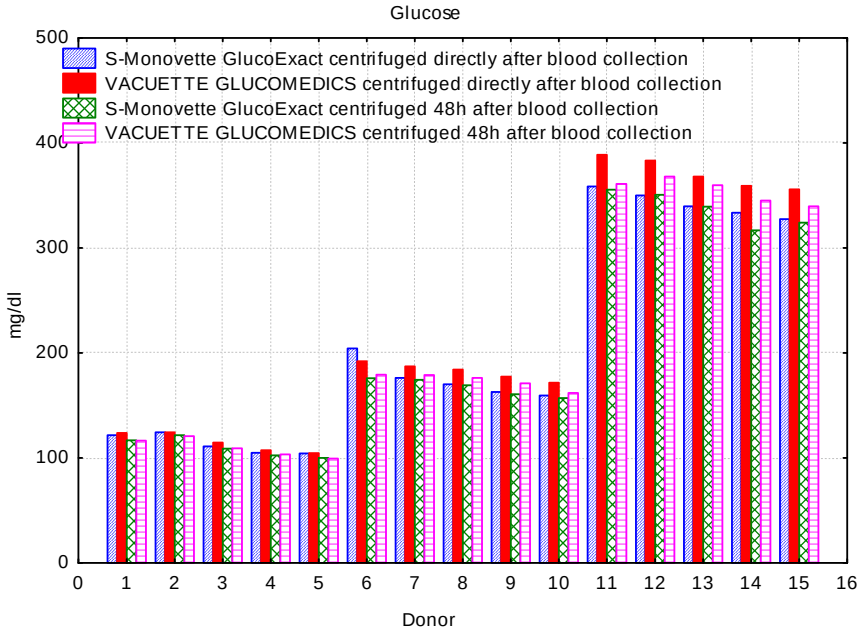


Centrifugation (b): 24 hours after blood collection





Centrifugation (c): 48 hours after blood collection



Conclusion:

Based on these results the sufficient stabilization of glucose concentration for both S-Monovette® GlucoEXACT and the **VACUETTE**® GLUCOMEDICS blood collection tubes was demonstrated for up to 48h at room temperature. No significant differences were observed between the two blood collection tubes regardless of delayed centrifugation time up to 48h after the blood collection. These results indicate the suitability of **VACUETTE**® GLUCOMEDICS 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.