

# Comparison of the Glucose Stability in Greiner VACUETTE® FX Sodium Fluoride/Potassium Oxalate Blood Collection Tubes and Terumo Venosafe™ FC-Mixture tubes

## **Background:**

Greiner-Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986. VACUETTE® FX NaF/Kox blood collection tubes are used for glucose determinations. The tubes contain sodium fluoride (NaF) as a stabilizer and Potassium Oxalate as an anticoagulant.

## **Study Objective:**

The aim of this study is to show equivalence in the performance of glucose stabilization with VACUETTE® FX NaF/KOx tubes and Terumo's FC-Mixture tube (NaF/ Na-Citrate/ EDTA-Na<sub>2</sub>).

Literature states that glucose is stable for up to 48 hours in NaF/KOx tubes. External tests confirmed this statement, however in those tests the tubes were centrifuged for the first measurement and then the glucose was measured from the plasma at different time points from the centrifuged primary tube. This test should investigate if there is a significant difference concerning glucose measurements from tubes which have been centrifuged directly after blood collection and then stored in an upright position.

## **Study design:**

Venous blood was collected from 20 blood donors. The samples were collected in random order to prevent systemic bias. (NOTE: the test was carried out in two donor groups. Donor No. 1-10 and the samples from donor No. 11-20 were collected another day)

The following tube types were used for blood collection:

- VACUETTE® FX, NaF/Kox (Sample A)
- Venosafe™, FC-Mixture (Sample B)

Directly after venipuncture, the tubes were carefully inverted 6- 8 times and approx. 30-60 minutes after blood collection, were centrifuged at 1800g for 10 minutes.

The measurement of glucose was performed at the following time points **0h** (directly after centrifugation), **3h, 24h and 48h** after blood collection. Tubes were stored in an upright position at room temperature.

The glucose analysis was performed on the Architect (Abbott) with the following methods:

Glucose determination: Hexokinase (Ref.: 3L82-20 by Abbott/ all data from package insert status June 2006)

Quantification limit: 5 mg/dL

Precision (Serum) ≤ 5,0 %

Accuracy (for serum): Systematic deviation is ≤ 6% and +/- 1mg/dL respectively. Cumulative failure is ≤ 16%.

## **Conclusion:**

There was no clinically significant higher glucose value measured from Terumo tubes compared to the VACUETTE® tubes, when comparing the Sample A and B at any of the investigated time points.

When comparing Sample A and B at the different time points: Sample B results showed statistically significant higher glucose values than Sample A at all investigated time points.

If the sample is centrifuged and kept in an upright position (comparing Sample A (0h) to Sample A (48h)/ Sample B (0h) to sample B (48h)), the occurring differences have no clinical relevance.

The result of glucose being stable in blood collection tubes centrifuged immediately after blood collection, stored in an upright position for 48 hour at room temperature, was again confirmed, for both Greiner VACUETTE® and Terumo Venosafe™ FC Mixture tubes.

## **References:**

- (1) NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition*. NCCLS document H1- A5 (ISBN 1-56238-519-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.
- (2) Gruber, H., *Product Manual: VACUETTE® Evacuated Blood Collection System- For In Vitro Diagnostic Use*. Rev.06. 2005, Kremsmünster, Austria: Greiner Bio-One GmbH.
- (3) *Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen*, Bundesärztekammer (Arbeitsgemeinschaft der deutschen Ärztekammer). 2001, Rev. 2003.
- (4) Thomas L., *Labor und Diagnose*. TH-Books, 6. Auflage (2005)

**Results:**

Glucose [mg/dl]:

Sample no.	Sample A VACUETTE®	Sample B Venosafe™	Sample A VACUETTE®	Sample B Venosafe™
	0h		3h	
1	89	89	88	91
2	105	102	103	104
3	97	98	94	98
4	89	92	89	93
5	83	80	80	82
6	92	92	93	93
7	85	86	83	87
8	90	93	91	94
9	80	82	81	83
10	92	99	95	99
11	108	109	107	111
12	103	109	101	110
13	106	107	104	107
14	92	97	94	98
15	93	89	91	88
16	103	109	105	113
17	88	91	90	92
18	68	70	68	71
19	112	113	117	118
20	101	107	102	112
MW	<b>93,8</b>	<b>95,7</b>	<b>93,8</b>	<b>97,2</b>

Sample no.	Sample A VACUETTE®	Sample B Venosafe™	Sample A VACUETTE®	Sample B Venosafe™
	24h		48h	
1	89	93	93	92
2	102	106	106	108
3	95	100	103	102
4	90	94	90	96
5	81	80	88	82
6	91	94	96	98
7	83	88	87	88
8	92	95	93	95
9	78	85	87	86
10	93	99	93	101
11	107	110	108	113
12	101	109	100	112
13	102	105	103	111
14	90	98	91	102
15	89	89	90	92
16	103	112	104	116
17	88	94	88	98
18	66	71	67	75
19	112	117	112	121
20	99	110	98	113
MW	<b>92,55</b>	<b>97,45</b>	<b>94,85</b>	<b>100,05</b>

**Glucose correlation at different points of time:**

