



# WHITE PAPER

TECHNICAL NOTES & APPLICATIONS FOR LABORATORY WORK

## EVALUATION OF VACUETTE® CAT SERUM FAST SEPARATOR BLOOD COLLECTION TUBE FOR ROUTINE CHEMISTRY ANALYTES

### 1/ BACKGROUND

Greiner-Bio-One, Austria has been selling plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986. VACUETTE® CAT Serum Fast Separator blood collection tubes contain thrombin in addition to the blood clotting activator in order to accelerate the clotting process.

Due to the rapid clotting process within 5 minutes after blood collection and the following centrifugation, the VACUETTE® CAT Serum Fast Separator blood collection tubes enable faster turnaround times similar to plasma tubes. According to the available study results, the tubes are suitable for the usage for routine chemistry analyses. Patients who are on heparin or other thrombin inhibitor therapy were not included in this study design<sup>[1]</sup>.

The VACUETTE® CAT Serum Fast tube is offered as a gel separator tube. The gel has a specific gravity, forms a stable barrier between the blood cells and the serum during centrifugation and provides stability for most analytes up to 48h when measured out of the primary tube stored at 4-8°C.

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## 2/ STUDY OBJECTIVE

The study has been carried out to demonstrate that the modified VACUETTE® CAT Serum Fast Separator blood collection tubes are suitable for routine chemistry analysis for up to 48h. The comparison was conducted to the old design VACUETTE® CAT Serum Fast Separator blood collection tubes when stored at room temperature (RT) for 24h and following at 4-8°C in the refrigerator (at 4-8°C). The study also aimed to show the equivalence of representative analytes in aforementioned tubes when centrifuged at 1800g for 10 min as well as at 3000g for 5 min.

## 3/ STUDY DESIGN AND PROCEDURE

Venous blood was collected from 20 healthy donors aged 18-64 years by using a VACUETTE® Disposable Tourniquet (Item n° 840053), a VACUETTE® EVOPROTECT SAFETY Blood Collection Set + Holder (Item n° 450120) and a VACUETTE® No Additive tube as discard tube (Item n° 454001), into the tubes listed in the table below.

One tube of each sample was drawn from each donor. All samples were gently inverted 5 times. After a minimum of 5 min clotting time of the whole blood sample in an upright position, all samples were centrifuged within max. 2h according to the centrifugation setting in the

table above at 20°C (centrifuge: Hettich Rotanta 460R for Sample A and B; Hettich Rotanta 420R for Sample C and D).

After centrifugation, all samples were visually inspected if there were any floating clots in the serum. Initial analysis was done after centrifugation on an AU680 and Dxl800 from Beckman Coulter. Stability testing was performed after 24h storage at RT and following 24h in the refrigerator (4-8°C) on the same instrument. Free hemoglobin was determined according to Harboe for samples centrifuged at 1800g for 10min.

Sample	Tube description	Item N°	Volume [ml]	Centrifugation
A	VACUETTE® CAT Serum Fast Separator Tube	456310	5	1800g / 10 min / 20°C
B	VACUETTE® CAT Serum Fast Separator Tube	<b>456309*</b>	5	1800g / 10 min / 20°C
C	VACUETTE® CAT Serum Fast Separator Tube	456310	5	3000g / 5 min / 20°C
D	VACUETTE® CAT Serum Fast Separator Tube	<b>456309*</b>	5	3000g / 5 min / 20°C

Tubes used for the study.

\* modified VACUETTE CAT Serum Fast Separator tubes

## 4/ ANALYTES FOR STABILITY TESTING ON BECKMAN COULTER AU680 AND DXI800

Parameter	Abbreviation	Acceptance criteria CAL: <sup>2</sup> Rili-BÄK/ <sup>3</sup> CLIA / <sup>4</sup> BV
Alanine Transaminase	ALT	11.50 <sup>2</sup>
Complement 3	C3	8.40 <sup>4</sup>
Calcium	Ca	6.00 <sup>2</sup>
Cortisol	Cort	16.00 <sup>2</sup>
Creatine Kinase	CK	11.00 <sup>2</sup>
Chloride	Cl	4.50 <sup>2</sup>
C-reactive Protein	CRP	13.50 <sup>2</sup>
Creatinine	Crea	10.00 <sup>3</sup>
Follicle stimulation hormone	hFSH	18.00 <sup>3</sup>
Glucose	Gluc	8.00 <sup>3</sup>
High Density Lipoprotein	HDL	13.00 <sup>2</sup>

Parameter	Abbreviation	Acceptance criteria CAL: <sup>2</sup> Rili-BÄK/ <sup>3</sup> CLIA / <sup>4</sup> BV
Lactate-Dehydrogenase	LDH	9.00 <sup>2</sup>
Magnesium	Mg	15.00 <sup>3</sup>
Potassium	K	4.50 <sup>2</sup>
Sodium	Na	3.00 <sup>2</sup>
Thyroid-stimulating hormone	TSH	13.50 <sup>2</sup>
Total Bilirubin	TBil	20.00 <sup>3</sup>
Total Protein	TP	6.00 <sup>2</sup>
Cobalamine (Vitamin B <sub>12</sub> )	VitB <sub>12</sub>	25.00 <sup>3</sup>
LIH (Lipemia/Icterus/Hemolysis)	LIH	N.A.

For analyte stability the differences (bias) between the time points initial (0h) to 24h, 24h to 48h and 0h to 48h were calculated using GLIMS.

Acceptance criteria for bias estimation of analyte stability: the difference between tested time points for

each parameter was evaluated according to the Clinical Acceptance Limit (CAL). Clinical evaluation was based on the allowed recommendation by Rili-BÄK<sup>[2]</sup> guideline. If no acceptance criteria are listed in Rili-BÄK<sup>[2]</sup>, CLIA<sup>[3]</sup> or BV<sup>[4]</sup> guidelines were used.

## 5/ RESULTS

### 5.1/ CLOTTING TIME

Sample	Time [sec]			
	60	120	180	240
	Distribution clotting time [%]			
A	20	65	15	0
B	15	75	10	0
C	20	55	25	0
D	15	55	25	5

### 5.2/ DETERMINATION OF FREE HEMOGLOBIN

Sample	Median fHb
A	6.5 mg/dl
B	2.3 mg/dl
C	8.2 mg/dl
D	4.0 mg/dl

### 5.3/ DESCRIPTIVE STATISTICS

Analyte	Sample	Centrifugation	Mean 0h	SD 0h	Mean 24h	SD 24h	Mean 48h	SD 48h
ALT [U/l]	A	1800g/10 min	24.12	16.28	23.90	16.22	23.47	16.39
	B	1800g/10 min	24.20	16.38	23.90	15.94	23.63	16.02
	C	3000g/5 min	24.23	16.36	23.75	16.32	23.57	15.99
	D	3000g/5 min	24.35	16.83	23.98	16.72	23.90	16.36
C3 [mg/dl]	A	1800g/10 min	115.90	15.24	119.40	16.70	121.95	18.25
	B	1800g/10 min	117.70	15.10	120.78	15.16	123.03	16.23
	C	3000g/5 min	116.47	15.67	119.28	16.51	120.70	17.67
	D	3000g/5 min	117.75	14.65	120.97	15.28	122.40	17.23
Ca [mmol/l]	A	1800g/10 min	2.28	0.083	2.32	0.081	2.30	0.081
	B	1800g/10 min	2.29	0.094	2.33	0.080	2.28	0.081
	C	3000g/5 min	2.28	0.081	2.32	0.082	2.28	0.077
	D	3000g/5 min	2.31	0.079	2.33	0.081	2.30	0.093
CK [U/l]	A	1800g/10 min	122.65	67.98	123.97	67.63	113.39	40.88
	B	1800g/10 min	123.47	67.72	124.08	68.01	113.64	40.86
	C	3000g/5 min	123.58	69.64	124.08	68.22	133.82	76.35
	D	3000g/5 min	123.62	68.57	124.30	67.80	129.73	74.33
Cl [mmol/l]	A	1800g/10 min	105.05	2.06	103.88	2.16	103.92	2.44
	B	1800g/10 min	104.38	2.08	102.62	1.99	102.47	2.49
	C	3000g/5 min	105.05	2.09	103.67	2.01	103.67	2.43
	D	3000g/5 min	104.62	2.33	102.78	2.07	102.92	2.62
Cort [mg/dl]	A	1800g/10 min	8.46	2.93	8.57	3.04	8.40	3.00
	B	1800g/10 min	8.49	2.95	8.42	3.07	8.47	3.34
	C	3000g/5 min	8.40	3.00	8.49	3.03	8.53	3.26
	D	3000g/5 min	8.37	3.00	8.43	2.97	8.39	3.17
CRP [mg/l]	A	1800g/10 min	2.24	5.20	2.23	5.18	2.44	5.52
	B	1800g/10 min	2.20	4.96	2.32	5.22	2.87	6.07
	C	3000g/5 min	2.23	5.16	2.24	5.20	2.55	5.62
	D	3000g/5 min	2.24	5.12	2.21	5.08	2.46	5.34
Gluc [mg/dl]	A	1800g/10 min	96.40	21.71	96.03	21.08	95.14	20.94
	B	1800g/10 min	95.72	21.79	95.60	21.73	98.10	23.05
	C	3000g/5 min	96.22	22.02	95.42	21.15	91.97	16.51
	D	3000g/5 min	96.97	21.85	96.25	21.90	95.47	20.74
HDL [mg/dl]	A	1800g/10 min	59.55	10.70	58.14	10.43	57.67	10.49
	B	1800g/10 min	60.10	11.07	58.45	10.99	58.17	10.14
	C	3000g/5 min	59.97	10.90	58.41	10.61	58.17	10.62
	D	3000g/5 min	60.50	11.51	58.17	10.62	57.99	10.80
hFSH [mIU/ml]	A	1800g/10 min	17.63	23.95	17.05	22.84	17.61	23.54
	B	1800g/10 min	18.07	24.00	17.09	22.62	17.62	22.75
	C	3000g/5 min	17.54	23.63	17.02	22.58	17.61	23.54
	D	3000g/5 min	17.63	23.15	17.21	22.67	17.62	22.75

Analyte	Sample	Centrifugation	Mean 0h	SD 0h	Mean 24h	SD 24h	Mean 48h	SD 48h
K [mmol/l]	A	1800g/10 min	3.97	0.14	3.93	0.14	3.93	0.12
	B	1800g/10 min	4.00	0.15	3.95	0.15	3.95	0.14
	C	3000g/5 min	3.96	0.14	3.93	0.14	3.93	0.12
	D	3000g/5 min	4.00	0.15	3.95	0.15	3.94	0.14
Crea [mg/dl]	A	1800g/10 min	0.82	0.13	0.84	0.13	0.83	0.13
	B	1800g/10 min	0.83	0.13	0.83	0.13	0.78	0.22
	C	3000g/5 min	0.83	0.13	0.83	0.13	0.83	0.13
	D	3000g/5 min	0.84	0.13	0.84	0.13	0.82	0.12
LDH [U/l]	A	1800g/10 min	152.57	24.49	161.55	26.93	156.74	27.00
	B	1800g/10 min	152.95	24.16	160.85	26.66	155.24	25.96
	C	3000g/5 min	157.30	23.83	164.30	25.85	160.70	26.21
	D	3000g/5 min	155.82	24.86	162.05	26.05	157.82	25.11
Mg [mmol/l]	A	1800g/10 min	0.80	0.057	0.80	0.058	0.79	0.056
	B	1800g/10 min	0.81	0.058	0.80	0.055	0.79	0.059
	C	3000g/5 min	0.81	0.55	0.80	0.055	0.80	0.055
	D	3000g/5 min	0.81	0.056	0.80	0.57	0.79	0.055
Na [mmol/l]	A	1800g/10 min	138.90	1.71	137.88	1.38	137.68	1.86
	B	1800g/10 min	138.35	1.82	136.62	1.47	136.50	1.91
	C	3000g/5 min	139.10	1.78	137.80	1.57	137.57	2.17
	D	3000g/5 min	138.50	1.62	136.88	1.34	137.05	2.04
TBili [mg/dl]	A	1800g/10 min	0.71	0.33	0.67	0.33	0.61	0.29
	B	1800g/10 min	0.73	0.34	0.68	0.32	0.61	0.28
	C	3000g/5 min	0.72	0.34	0.67	0.32	0.64	0.32
	D	3000g/5 min	0.73	0.34	0.67	0.32	0.61	0.28
TP [g/l]	A	1800g/10 min	67.44	3.10	67.44	3.17	66.30	3.21
	B	1800g/10 min	69.00	3.17	68.42	3.15	66.16	3.24
	C	3000g/5 min	67.62	3.15	67.47	3.03	66.22	2.99
	D	3000g/5 min	69.24	3.23	68.72	3.15	67.02	2.93
TSH [μIU/ml]	A	1800g/10 min	1.52	0.73	1.50	0.71	1.48	0.71
	B	1800g/10 min	1.53	0.74	1.50	0.71	1.51	0.69
	C	3000g/5 min	1.53	0.76	1.51	0.73	1.50	0.71
	D	3000g/5 min	1.54	0.74	1.52	0.74	1.51	0.69
Vit B <sub>12</sub> [pg/ml]	A	1800g/10 min	272.10	89.62	263.10	82.90	263.05	81.42
	B	1800g/10 min	271.68	86.36	259.23	81.75	255.16	70.39
	C	3000g/5 min	276.45	93.86	261.35	87.13	256.17	80.95
	D	3000g/5 min	272.68	90.29	263.88	84.99	255.53	76.21

**Note:** For the parameter CK: donor 4-8 at time point T48 were excluded from calculation due to an incorrect reagents' preparation.

The results of comparing the timepoints are listed below for each parameter.  
All parameters tested meet the acceptance criteria of CAL.

**5.4/ BIAS METHOD COMPARISON AT INITIAL TIME POINT**

Analyt	Bias [%] Sample A to B (1800g/10 min)		Bias [%] Sample C to D (3000g /5 min)		Analyt	Bias [%] Sample A to B (1800g/10 min)		Bias [%] Sample C to D (3000g /5 min)	
	Initial time point [0h]		Initial time point [0h]			Initial time point [0h]		Initial time point [0h]	
ALT	1.91	2.07	2.07	2.07	hFSH	4.34	3.71	3.71	3.71
C3	2.04	1.79	1.79	1.79	K	1.83	1.47	1.47	1.47
Ca	1.30	1.22	1.22	1.22	Crea	2.17	1.66	1.66	1.66
CK	1.83	2.54	2.54	2.54	LDH	1.67	3.03	3.03	3.03
Cl	0.69	0.74	0.74	0.74	Mg	1.03	1.28	1.28	1.28
Cort	3.91	3.37	3.37	3.37	Na	0.47	0.43	0.43	0.43
CRP	2.81	2.54	2.54	2.54	TBili	2.48	2.28	2.28	2.28
Gluc	2.42	1.46	1.46	1.46	TP	2.41	2.56	2.56	2.56
HDL	1.58	2.20	2.20	2.20	TSH	2.21	2.64	2.64	2.64
					VitB <sub>12</sub>	3.26	4.21	4.21	4.21

**5.5/ BIAS STABILITY OVER 48H FOR SAMPLES A-D**

Analyt	Bias [%] Sample A (1800g/10 min)			Bias [%] Sample B (1800g /10min)			Bias [%] Sample C (3000g/5 min)			Bias [%] Sample D (3000g/5 min)		
	T0-T24	T0-T48	T24-T48	T0-T24	T0-T48	T24-T48	T0-T24	T0-T48	T24-T48	T0-T24	T0-T48	T24-T48
ALT	2.10	3.49	2.87	2.86	3.30	2.65	2.45	3.29	3.23	2.40	4.34	2.96
C3	2.95	3.90	1.52	2.65	3.41	1.24	2.37	3.51	1.43	2.73	3.81	1.78
Ca	1.75	1.37	1.32	1.68	1.38	1.30	1.61	1.08	1.08	1.16	1.09	1.54
CK	1.54	1.18	0.98	1.31	1.45	1.46	1.17	3.69	3.49	1.07	1.68	1.03
Cl	1.12	1.32	0.66	1.67	1.82	0.88	1.31	1.40	0.63	1.57	1.44	0.93
Cort	3.63	3.84	4.20	4.11	5.35	3.80	4.05	3.86	3.27	4.17	4.43	4.46
CRP	2.42	5.54	5.42	3.80	7.23	5.80	2.47	1.82	1.73	4.17	3.84	3.14
Gluc	1.05	2.16	1.80	1.15	1.80	1.93	1.23	1.59	1.65	1.30	2.37	2.11
HDL	2.36	3.94	1.75	2.87	4.45	1.83	2.67	4.29	1.69	3.00	5.36	2.48
hFSH	4.84	6.97	7.09	5.20	6.35	5.01	4.08	4.38	3.24	3.29	6.79	5.08
K	0.96	1.10	0.90	1.32	1.62	0.96	1.09	1.31	0.89	1.28	1.52	0.80
Crea	2.48	1.79	1.63	2.21	6.97	6.56	1.94	2.00	1.30	1.84	2.20	1.41
LDH	6.29	5.64	2.91	5.83	5.25	3.07	4.72	4.54	2.46	4.75	4.52	2.16
Mg	1.01	1.55	1.48	1.28	2.32	1.86	1.05	1.63	1.46	1.27	2.18	1.36
Na	0.81	1.09	0.55	1.24	1.44	0.68	0.97	1.20	0.57	1.17	1.22	0.68
TBili	7.96	12.19	4.32	7.49	12.66	4.82	7.51	11.18	3.55	8.79	13.24	4.52
TP	0.53	2.06	2.03	0.83	2.96	2.02	0.59	1.47	1.19	0.96	2.89	2.21
TSH	2.14	4.09	2.97	2.48	4.52	2.59	17.01	4.15	7.34	2.79	4.86	3.23
VitB <sub>12</sub>	4.86	5.42	4.31	4.99	5.10	5.12	5.67	6.17	4.80	5.10	3.75	5.32

All differences between the time points 0h/24h; 24h/48h and 0h/48h meet the acceptance criteria except the difference for TSH between 0h/24h in the old design VACUETTE® CAT Serum Fast Sep Clot Activator tube when centrifuged at 3000g for 5 min. The modified tube resulted in a difference of 2.79% within the CAL.

## 6/ RESULTS - SUMMARY

### 6.1/ METHOD COMPARISON

**Comparison of the old design VACUETTE® CAT Serum Fast Sep Clot Activator tubes with the modified VACUETTE® CAT Serum Fast Sep Clot Activator tubes at centrifugation setting 1800g/10 min and 3000g/5 min at the initial time point 0h.**

It has been demonstrated that comparing the old design VACUETTE® CAT Serum Fast Sep Clot Activator tubes (Samples A and C) with the **modified VACUETTE® CAT Serum Fast Sep Clot Activator tubes** (Samples B and D) shows clinically equivalent results for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

Comparison Sample A to B: **for all 19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBil, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

Comparison Sample C to D: **for all 19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBil, TP, TSH, VitB<sub>12</sub>).

### 6.2/ CLOTTING TIME

All samples completely clotted within 5 minutes.

### 6.3/ DETERMINATION OF FREE HEMOGLOBIN

The modified VACUETTE® CAT Serum Fast Sep Clot Activator tubes clearly showed an improvement of the serum quality regarding remaining erythrocytes in serum after centrifugation. The fHb concentration was halved in both centrifugation settings (1800g/10 min and 3000g/5 min).

### 6.4/ STABILITY

#### **ANALYTE STABILITY FOR 24H AND STORAGE AT RT**

No clinically significant deviations were found for the modified VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples B and D) when comparing the initial measurement (0h) to measurement 24 hours after centrifugation (24h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

No clinically significant deviations were found for the old design VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples A and C) when comparing the initial measurement (0h) to measurement 24 hours after centrifugation (24h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**18 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, VitB<sub>12</sub>).

### ANALYTE STABILITY AFTER 24H AT RT AND FOLLOWING 24H STORAGE AT 4-8°C IN THE REFRIGERATOR (24H-48H)

No clinically significant deviations were found for the modified VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples B and D) when comparing the measurement 24 hours after centrifugation (24h) to measurement 48 hours after centrifugation (48h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

No clinically significant deviations were found for the old design VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples A and C) when comparing the measurement 24 hours after centrifugation (24h) to measurement 48 hours after centrifugation (48h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

### ANALYTE STABILITY FOR 48H (24 HOURS STORAGE AT RT FOLLOWED BY 24H STORAGE IN REFRIGERATOR) (T0 – T48)

No clinically significant deviations were found for the modified VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples B and D) when comparing the initial measurement (0h) to measurement 48 hours after centrifugation (48h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

No clinically significant deviations were found for the old design VACUETTE® CAT Serum Fast Sep Clot Activator tube (Samples A and C) when comparing the initial measurement (0h) to measurement 48 hours after centrifugation (48h) out of the same tube (primary tube) for the following parameters:

#### **CENTRIFUGED AT 1800G, 10 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

#### **CENTRIFUGED AT 3000G, 5 MIN:**

**19 parameters** (of 19 tested) – (ALT, Ca, CK, Cl, C3, Cort, CRP, Gluc, hFSH, HDL, K, Crea, LDH, Mg, Na, TBili, TP, TSH, VitB<sub>12</sub>).

### LIH MEASUREMENTS

Hemolysis could not be detected. Slightly lipemic serum (L+) was found in two sample at all three time points. Icterus was not detected in any sample.



## 7/ CONCLUSION

The equivalent clinical performance of the modified VACUETTE® CAT Serum Fast Separator Blood Collection Tube in comparison to the old design VACUETTE® CAT Serum Separator Blood Collection Tube has been demonstrated for routine biochemical analytes on a Beckman Coulter analyzer at initial time point, after 24h storage at RT as well as after 24h more hours storage in the refrigerator (in total 48h stability) for donors who are not on an anticoagulant therapy.

By providing a clear serum after centrifugation, the utilization of the modified VACUETTE® CAT Serum Fast Separator tube enables a faster turnaround time in the laboratory due to the rapid clotting process minimizing the cell lysis in the tube within 5 minutes on the basis of the thrombin additive. Systematic differences to blood

collection tubes without a clotting accelerator such as thrombin were found in studies and discussed with regard to the benefit in emergency situations but need to be taken in consideration by clinicians <sup>[5/6/7]</sup>. One study investigated the risk of hyperkalaemia in a thrombin containing tube by measuring potassium values as well as LDH activity <sup>[8]</sup>. Another study presented stability data for a routine chemistry profile up to 4 days apart from bicarbonate, electrolytes and albumin <sup>[9]</sup>.



**CLINICALLY  
EQUIVALENT  
RESULTS HAVE BEEN  
DEMONSTRATED**

## 8/ REFERENCES

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- [2] Rili-BÄK: Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen, <https://www.bundesaerztekammer.de/aerzte/qualitaets-sicherung/richtlinien-leitlinien-empfehlungen-stellungnahmen/richtlinien-leitlinien-empfehlungen-zurqualitaets-sicherung/labor/> [14-FEB-2021; 14:31:00 UTC]
- [3] CLIA: CLIA: Clinical Laboratory Improvement Amendments (CLIA) <https://www.westgard.com/2019-clia-changes.htm> [24-JUN-2022]
- [4] BV: 2004 update of the Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) table of Desirable Quality Specifications based on Biological Variation
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- [6] M. Kojancic, J. Cargonja, A. Delic-Knezevic. Evaluation of the BD Vacutainer RST blood collection tube for routine chemistry analytes: clinical significances of differences and stability study Biochemica Medica 2014; 24: 368-75
- [7] Koch et al, BD rapid serum tubes reduce false positive plasma troponin T results on the Roche Cobas e411 analyzer. Clin Biochem 2012; 45: 842-44
- [8] Huyghe T et al. Studies on the use of BD Vacutainer SSTII and RST in general practice: investigation of artefactual hyperkalemia. Ann Clin Biochem 2014; 51: 30-37
- [9] W.-Y. Ng, C-P. Yeo, Thrombin-Accelerated Quick Clotting Serum Tubes: An Evaluation with 22 Common Biochemical Analytes. Advances in Hematology (Volume 2013), Advances in Hematology, Article ID 769479 <http://dx.doi.org/10.1155/2013/769479>

## PRODUCT & ORDERING INFORMATION

- / Only 5 minutes<sup>2</sup> waiting time before transport.
- / Reduced turnaround time.
- / Faster results.
- / Faster diagnosis.

Time is of the essence when it comes to accurate and fast test results for treating patients. Fast coagulation following blood collection allows crucial minutes to be saved.

Heparinized plasma is often used as an emergency tube as there is no need to wait for coagulation. Serum is sometimes indispensable in emergency departments and this is precisely where VACUETTE® CAT Serum Fast Tubes can save enormous amounts of time.<sup>1</sup>

The VACUETTE® CAT Serum Fast tube combines the speed of a plasma tube with the properties of serum. It allows coagulation in the whole blood sample to be completed in just 5 minutes,<sup>2</sup> thus considerably shortening the preanalytical process. This means targeted treatment can be initiated quicker. With a reduced centrifugation time of 5 minutes<sup>2</sup>, the time from collection to analysis is 10 minutes instead of 35 minutes<sup>3</sup>. This makes it easy to effectively reduce turnaround time (TAT) by 25 minutes per sample.<sup>1</sup>

### VACUETTE® CAT Serum Fast Separator Tube

Item No.	Nominal volume	Cap colour	Ring colour	Thread type	Tube size	Label	Barcode	Inner / Outer [Qty.]
454592	3.5 ml	orange	yellow	PREMIUM	13 x 75	Paper	no	50 / 1,200
454593	3.5 ml	orange	yellow	non-ridged	13 x 75	Paper	no	50 / 1,200
456309	5 ml	orange	yellow	PREMIUM	13 x 100	Paper	no	50 / 1,200
456313	5 ml	orange	yellow	non-ridged	13 x 100	Paper	no	50 / 1,200
486509	5 ml	orange	yellow	PREMIUM	13 x 100	Paper	yes	50 / 1,200

**References and information:**

1 Use of anticoagulants in diagnostic laboratory investigations. World Health Organization. WHO/DIL/LAB/99.1 Rev.2, 2002.

2 Serum Fast tubes are not intended for patients on thrombin inhibitor therapy or fibrinogen deficiency.

3 Depending on centrifugation conditions

