



VENOSAFETM

**Polyolefin gel with heparin
for plasma yield**

Setting the standard for plasma chemistry

- **Extremely stable**
- **No oil drop formation**
- **No reported interference with clinical chemistry analytes and hormones**
- **Excellent plasma quality**
- **Wall-coated, easily soluble high quality heparin shows hardly any trace element contamination**
- **TERUMO PET gas barrier guarantees the exact blood/additive ratio over the whole shelf-life**

Clinical chemistry

Clinical chemistry test results

Compares

- Glass serum tube without gel, within 2 hours after sampling (VT-SP)

with

- PET plasma tube with gel and heparin within 2 hours after sampling (VF-SAHLW)
- PET plasma tube with gel and heparin after 24 hours storage at 4°C (VF-SAHLW, ± 24 hrs)

Table shows mean (SD of the results) and p-value for t-test comparing VT-SP with VF-SAHLW (2 hours after sampling) and VF-SAHLW (2 hours after sampling) with VF-SAHLW (24 hours after sampling).

Clinical significance has been judged by comparing the bias and 95% interval on the bias with the acceptable

performance criteria defined in the CLIA '88 Focus on Clinic and Office Laboratories U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Public Health Program Office - Publication date: 01/01/1988.

Parameter	n	Values					Clinically significant difference
		VT-SP	VF-SAHLW		VF-SAHLW (+24 hours)		
		\bar{X} (SD)	\bar{X} (SD)	p-value	\bar{X} (SD)	p-value	
Sodium	32	139.7 (1.4)	139.7 (1.4)	1.000	138.0 (1.6)	<0.0001	No
Potassium	32	4.25 (0.27)	3.93 (0.25)	<0.0001	3.95 (0.27)	0.720	No*
Chloride	32	104.5 (1.83)	105.1 (1.7)	<0.0001	103.7 (1.3)	<0.0001	No
Magnesium	32	2.08 (0.15)	2.15 (0.15)	0.0029	2.156 (0.17)	0.8788	No
Cholesterol	32	190 (33)	188 (33)	0.1153	192 (33)	0.0004	No
HDL Chol.	32	61.4 (17)	61.7 (17)	0.2645	61.6 (17)	0.7769	No
CRP	32	0.154 (0.14)	0.158 (0.15)	0.2311	0.158 (0.15)	0.9050	No
Orosomuroid	32	63.7 (14)	63.4 (14)	0.1775	64.1 (14)	0.1175	No
ApolipoB	31	95.3 (25)	94.4 (25)	0.0367	100.1 (25)	<0.0001	No ****
Triglycerides	31	103 (52)	102 (51)	0.0008	104.2 (51)	0.0128	No
IgG	32	1,077 (216)	1,068 (205)	0.2182	1,101 (220)	0.0057	No
IgM	32	130 (145)	130 (152)	0.8719	126 (146)	0.0022	No
IgA	32	227 (105)	225 (105)	0.1403	227 (106)	0.2638	No
Prolactin	32	200 (84)	202 (85)	0.0025	214 (85)	0.0041	No
FSH	29	9.14 (21)	9.13 (21)	1.000	9.00 (21)	0.1033	No
FT3	31	3.02 (0.54)	3.03 (53)	0.6837	3.05 (0.55)	0.5774	No
FT4	31	1.30 (0.16)	1.30 (0.15)	1.000	1.297 (0.14)	0.5722	No
PTH	32	30.0 (9.7)	32.8 (10.4)	0.0004			No **
LH	27	6.33 (8.5)	6.74 (8.6)	0.0003	6.37 (8.5)	0.0006	No
Cortisol	32	120 (66)	118 (65)	0.1618	119 (67)	0.6357	No
Testosterone	35	2.72 (1.9)	2.77 (1.9)	0.1550	2.83 (2.1)	0.3667	No
Vit B12	32	375 (142)	376 (145)	0.6259	381 (139)	0.1051	No
CEA	22	3.18 (2.2)	3.25 (2.3)	0.4341	3.16 (2.1)	0.5101	No ***
CA125	8	115 (230)	118 (241)	0.5063	114 (127)	0.4532	No ****
PSA	26	3.02 (4.1)	3.03 (4.3)	0.7962	3.02 (4.5)	0.9340	No

* Potassium: difference between serum and plasma value is described in various publications ^{(7) (8)}.

** PTH : The difference observed for PTH between the 2 tubes might be explained by the adherence of PTH to glass. This phenomenon was described in publications ⁽¹⁾.

*** CEA: No difference between the tubes was observed for low values, from detection limit up to 10 ng/ml (normal values 0-5 ng/ml) 2 highly evaluated values (± 900 ng/ml) showed up to 20% difference between the 2 tubes.

**** CA125 Only 8 patients had values above the detection limit. Considering these 8 cases the tubes seem to be equivalent as concerns CA125.

***** ApolipoB shows a consistent increase after storage. The same increase is also observed with serum stored not in contact with a gel barrier.

Example of therapeutic drug monitoring results

Compares serum tubes without gel with PET plasma tube with gel and heparin at different time intervals after sampling. Some statistical differences were indicated by the t-test ($p < 0.05$).

Further analysis did not reveal clinically significant differences

between the results with the different tubes or different storage time.

Level 1, level 2, level 3 are related to low, medium and high therapeutic levels used at the Erasmus University Hospital, Brussels, Belgium.

	Tube	VT-050SP			VF-054SAHLW		
	Time	0 h	4 h	24 h	0 h	4 h	24 h
Amikacin							
Level 1	Mean	2.73	2.69	2.71	2.66	2.76	2.72
	SD	0.14	0.12	0.18	0.18	0.14	0.13
level 2	Mean	8.69	8.63	8.53	8.85	9.00	9.01
	SD	0.22	0.23	0.29	0.33	0.38	0.40
Level 3	Mean	18.39	18.37	18.38	19.12	19.34	19.01
	SD	0.83	1.14	0.55	0.89	0.64	0.75
Digoxin							
Level 1	Mean	0.89	0.90	0.90	0.91	0.87	0.88
	SD	0.12	0.08	0.08	0.12	0.13	0.09
Level 2	Mean	1.395	1.392	1.390	1.416	1.409	1.450
	SD	0.04	0.03	0.04	0.03	0.02	0.03
Level 3	Mean	Concentration too high. no clinical application. risks of errors due to serial dilutions					
	SD						
Lidocain							
Level 1	Mean	1.212	1.212	1.221	1.130	1.147	1.152
	SD	0.03	0.04	0.03	0.05	0.03	0.03
Level 2	Mean	2.69	2.74	2.72	2.54	2.53	2.51
	SD	0.09	0.13	0.09	0.12	0.13	0.09
Level 3	Mean	10.71	11.05	11.20	10.37	10.27	10.62
	SD	0.23	0.18	0.22	0.22	0.26	0.37
Carbamazepin							
Level 1	Mean	3.4	3.51	3.54	3.27	3.43	3.49
	SD	0.09	0.16	0.21	0.16	0.05	0.07
Level 2	Mean	7.30	7.37	7.35	7.16	7.15	7.3
	SD	0.34	0.37	0.38	0.38	0.29	0.36
Level 3	Mean	10.47	10.49	10.39	10.26	10.17	10.21
	SD	0.21	0.25	0.28	0.20	0.23	0.28
Gentamycin							
Level 1	Mean	8.30	8.17	8.18	8.87	8.43	8.58
	SD	0.38	0.47	0.42	0.47	0.18	0.41
Level 2	Mean	14.74	14.74	14.87	14.87	14.79	14.88
	SD	0.17	0.30	0.20	0.28	0.25	0.25
Level 3	Mean	20.01	20.25	20.01	20.39	20.40	20.51
	SD	0.71	0.59	0.50	0.57	0.59	0.67
Phenobarbital							
Level 1	Mean	9.38	9.04	9.10	9.35	9.34	9.18
	SD	0.42	0.35	0.24	0.51	0.50	0.52
Level 2	Mean	15.24	15.46	15.28	15.59	15.27	15.31
	SD	1.04	0.84	0.90	0.81	0.94	0.66
Level 3	Mean	20.83	20.63	20.78	20.44	20.45	20.36
	SD	0.70	0.67	1.02	0.96	0.78	0.63
Phenytoin							
Level 1	Mean	4.70	6.54	7.25	4.56	7.37	7.07
	SD	0.16	0.18	0.39	0.20	0.21	0.24
Level 2	Mean	10.49	11.48	12.49	10.06	10.73	11.77
	SD	0.46	0.56	0.57	0.42	0.59	0.67
Level 3	Mean	16.19	17.77	18.89	15.87	16.99	17.95
	SD	0.30	0.48	0.47	0.38	0.64	0.50
Theophylline							
Level 1	Mean	12.07	11.93	11.98	12.25	12.17	12.20
	SD	0.21	0.38	0.49	0.32	0.35	0.23
Level 2	Mean	20.96	20.9	20.87	21.24	21.3	20.95
	SD	0.74	0.68	0.61	0.48	0.54	0.63
Level 3	Mean	27.94	28.17	27.65	28.14	28.45	28.19
	SD	0.54	0.91	0.55	0.61	0.47	0.21
Valproic Acid							
Level 1	Mean	57.2	55.4	54.4	58.7	57.6	57.3
	SD	2.20	2.67	2.22	1.49	1.07	1.49
Level 2	Mean	104.8	104.7	103.9	105.9	106.0	104.3
	SD	2.04	2.71	2.29	1.73	1.27	1.57
Level 3	Mean	131.3	132.5	131.4	133.6	134.8	134.4
	SD	3.71	3.39	3.03	4.40	5.00	4.32
Vancomycin							
Level 1	Mean	22.1	21.45	20.88	21.85	22.07	22.19
	SD	0.90	1.17	1.21	0.75	0.41	0.90
Level 2	Mean	33.89	33.85	32.3	34.23	34.62	32.51
	SD	1.64	1.56	1.50	1.20	1.47	1.22
Level 3	Mean	47.99	47.73	45.00	47.02	47.67	43.99
	SD	1.55	1.02	0.98	1.57	1.11	1.07

	Tube	VT-050SP			VF-054SAHLW		
		0 h	4 h	24 h	0 h	4 h	24 h
Methotrexate							
Level 1	Mean	1.24	1.26	1.27	1.29	1.29	1.29
	SD	0.10	0.10	0.12	0.11	0.11	0.10
Level 2	Mean	1.61	1.64	1.65	1.66	1.65	1.66
	SD	0.05	0.04	0.04	0.02	0.05	0.04
Level 3	Mean	2.98	3.07	3.10	3.15	3.09	3.09
	SD	0.17	0.12	0.13	0.14	0.14	0.17
Paracetamol							
Level 1	Mean	6.32	6.35	6.55	6.18	6.12	6.55
	SD	0.49	0.25	0.48	0.61	0.31	0.46
Level 2	Mean	7.47	6.99	7.37	7.50	7.43	7.23
	SD	0.72	0.96	0.66	0.89	0.84	0.60
Level 3	Mean	12.74	12.74	12.73	12.67	12.50	12.44
	SD	0.79	0.79	0.73	0.81	0.38	0.75
S-Salicylate							
Level 1	Mean	35.61	35.62	35.91	36.67	36.33	36.67
	SD	0.57	0.61	0.67	1.29	0.25	0.21
Level 2	Mean	37.88	37.92	37.76	38.44	39.00	38.88
	SD	0.63	0.49	0.53	0.46	1.04	0.46
Level 3	Mean	303.3	320.6	323.8	309.7	316.6	319.7
	SD	36.50	29.53	26.25	30.29	33.78	26.94

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