



**VENOSAFE**<sup>TM</sup>

**Polyolefin gel for serum yield**

## Setting the standard

- **Extremely stable**
- **No oil drop formation**
- **No reported interference with clinical chemistry analytes or hormones**

# Clinical chemistry

## Clinical chemistry test results

### Compares

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

### with

- PET serum tube with gel within 2 hours after sampling (VF-SASW))
- PET serum tube with gel after 24 hours storage at 4 °C (VF-SASW ± 24hrs)

Table shows mean (SD) and p-value for t-test comparing VT-SP with VF-SASW (2 hours after sampling) and VF-SASW (2 hours after sampling) with VF-SASW (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-SASW		VF-SASW (+24 hours)		
		$\bar{X}$ (SD)	$\bar{X}$ (SD)	p-value	$\bar{X}$ (SD)	p-value	
Sodium	32	139.7 (1.40)	139.3 (1.65)	0.0670	137.9 (1.56)	<0.0001	No
Potassium	32	4.25 (0.27)	4.29 (0.29)	0.1545	4.18 (0.25)	0.0023	No
Chloride	32	104.5 (1.83)	104.6 (1.75)	0.5000	103.6 (1.34)	0.0003	No
Magnesium	32	2.08 (0.15)	2.15 (0.14)	0.0005	2.16 (0.19)	0.7636	No
Cholesterol	32	190 (33)	194 (34)	<0.0001	197 (35)	0.0080	No
HDL Chol.	32	61.4 (17)	62.4 (18)	0.0002	62.3 (17)	0.3962	No
CRP	32	0.154 (0.14)	0.157 (0.15)	0.3621	0.161 (0.15)	0.1768	No
Orosomuroid	32	63.7 (14)	64.0 (14.4)	0.2768	65.6 (14)	0.0008	No
ApolipoB	31	95.3 (25)	95.5 (26)	0.4770	101.7 (26)	<0.0001	No ****
Triglycerides	31	103 (52)	105 (53)	<0.0001	108 (52)	0.0009	No
IgG	32	1,077 (216)	1,093 (212)	0.0129	1,099 (224)	0.4533	No
IgM	32	130 (145)	131 (148)	0.2194	130 (151)	0.1254	No
IgA	32	227 (105)	225 (104)	0.2465	231 (108)	0.0060	No
Prolactin	32	200 (84)	202 (85)	0.0003	215 (84)	0.0022	No
FSH	29	9.14 (21)	8.96 (22)	0.0433	9.07 (21)	0.2641	No
FT3	31	3.02 (0.54)	3.07 (53)	0.0976	3.04 (55)	0.4103	No
FT4	31	1.30 (0.16)	1.35 (0.17)	<0.0001	1.33 (0.14)	0.0463	No
PTH	32	30.0 (9.7)	37.1 (11.8)	<0.0001			Yes *
LH	27	6.33 (8.5)	6.55 (8.50)	0.0113	6.59 (8.63)	0.6632	No
Cortisol	32	120 (66)	120 (65)	0.1014	121 (64)	0.7671	No
Testosterone	35	2.72 (1.9)	2.61 (1.8)	0.0087	2.65 (1.9)	0.5322	No
Vit B12	32	375 (142)	392 (158)	0.0002	320 (151)	0.3836	No
CEA	22	3.18 (2.2)	3.29 (2.2)	0.0101	3.24 (2.2)	0.9830	No **
CA125	8	115 (230)	115 (231)	0.8656	109 (210)	0.4152	No ***
PSA	26	3.02 (4.15)	3.07 (4.32)	0.2892	3.18 (4.72)	0.2317	No

\* 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<sup>(1)</sup>.

\*\* 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 ( $\pm$  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 glass serum tubes without gel with PET serum tube with gel 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-054SASW		
		Time	0 h	4 h	24 h	0 h	4 h
<b>Amikacin</b>							
Level 1	Mean	2.73	2.69	2.71	2.68	2.65	2.68
	SD	0.14	0.12	0.18	0.13	0.13	0.16
level 2	Mean	8.69	8.63	8.53	8.76	8.69	8.79
	SD	0.22	0.23	0.29	0.37	0.25	0.26
Level 3	Mean	18.39	18.37	18.38	18.39	18.75	18.49
	SD	0.83	1.14	0.55	0.92	0.65	0.78
<b>Digoxin</b>							
Level 1	Mean	0.89	0.9	0.9	0.9	0.9	0.91
	SD	0.12	0.08	0.08	0.11	0.09	0.07
Level 2	Mean	1.395	1.392	1.390	1.399	1.394	1.419
	SD	0.04	0.03	0.04	0.04	0.04	0.03
Level 3	Mean	Concentration too high. no clinical application. risks of errors due to serial dilutions					
	SD						
<b>Lidocain</b>							
Level 1	Mean	1.212	1.212	1.221	1.149	1.164	1.194
	SD	0.03	0.04	0.03	0.03	0.03	0.04
Level 2	Mean	2.687	2.736	2.718	2.567	2.542	2.622
	SD	0.09	0.13	0.09	0.11	0.07	0.12
Level 3	Mean	10.71	11.05	11.20	10.62	10.56	10.76
	SD	0.23	0.18	0.22	0.33	0.24	0.31
<b>Carbamazepin</b>							
Level 1	Mean	3.40	3.51	3.54	3.40	3.46	3.57
	SD	0.09	0.16	0.21	0.08	0.08	0.07
Level 2	Mean	7.30	7.37	7.35	7.31	7.30	7.32
	SD	0.34	0.37	0.38	0.31	0.36	0.32
Level 3	Mean	10.47	10.49	10.39	10.28	10.32	10.38
	SD	0.21	0.25	0.28	0.21	0.19	0.15
<b>Gentamycin</b>							
Level 1	Mean	8.30	8.17	8.18	8.45	8.48	8.45
	SD	0.38	0.47	0.42	0.41	0.61	0.30
Level 2	Mean	14.74	14.74	14.87	15.00	14.87	14.97
	SD	0.17	0.30	0.20	0.29	0.23	0.28
Level 3	Mean	20.01	20.25	20.01	20.40	20.12	20.15
	SD	0.71	0.59	0.50	0.65	0.44	0.28
<b>Phenobarbital</b>							
Level 1	Mean	9.38	9.04	9.10	9.13	8.91	9.30
	SD	0.42	0.35	0.24	0.56	0.40	0.50
Level 2	Mean	15.24	15.46	15.28	15.34	15.05	15.30
	SD	1.04	0.84	0.90	0.99	0.95	0.79
Level 3	Mean	20.83	20.63	20.78	20.96	20.4	20.58
	SD	0.70	0.67	1.02	1.04	0.79	0.80
<b>Phenytoin</b>							
Level 1	Mean	4.70	6.54	7.25	5.04	7.26	7.90
	SD	0.16	0.18	0.39	0.26	0.28	0.12
Level 2	Mean	10.49	11.48	12.49	11.25	11.50	13.10
	SD	0.46	0.56	0.57	0.54	0.49	0.60
Level 3	Mean	16.19	17.77	18.89	16.78	17.99	19.53
	SD	0.30	0.48	0.47	0.60	0.41	0.32
<b>Theophylline</b>							
Level 1	Mean	12.07	11.93	11.98	12.04	12.13	12.24
	SD	0.21	0.38	0.49	0.37	0.33	0.28
Level 2	Mean	20.96	20.90	20.87	21.05	21.18	21.10
	SD	0.74	0.68	0.61	0.56	0.47	0.42
Level 3	Mean	27.94	28.17	27.65	28.05	27.65	28.04
	SD	0.54	0.91	0.55	0.78	0.42	0.62
<b>Valproic Acid</b>							
Level 1	Mean	57.2	55.4	54.4	56.4	55.6	56.2
	SD	2.20	2.67	2.22	0.84	3.17	2.57
Level 2	Mean	104.8	104.7	103.9	105.9	104.2	104.9
	SD	2.04	2.71	2.29	2.81	1.04	1.70
Level 3	Mean	131.3	132.5	131.4	136.5	134.5	133.3
	SD	3.71	3.39	3.03	5.25	5.30	3.99
<b>Vancomycin</b>							
Level 1	Mean	22.10	21.45	20.88	21.9	21.88	21.94
	SD	0.90	1.17	1.21	1.56	0.74	0.59
Level 2	Mean	33.89	33.85	32.30	33.44	32.96	32.51
	SD	1.64	1.56	1.50	1.32	1.36	1.11
Level 3	Mean	47.99	47.73	45.00	47.22	46.42	44.64
	SD	1.55	1.02	0.98	1.47	1.07	1.65

	Tube	VT-050SP			VF-054SASW		
		0 h	4 h	24 h	0 h	4 h	24 h
<b>Methotrexate</b>							
Level 1	Mean	1.24	1.26	1.27	1.30	1.30	1.30
	SD	0.10	0.10	0.12	0.10	0.10	0.10
Level 2	Mean	1.60	1.64	1.65	1.65	1.67	1.67
	SD	0.05	0.04	0.04	0.04	0.04	0.03
Level 3	Mean	2.98	3.07	3.10	3.10	3.12	3.14
	SD	0.17	0.12	0.13	0.18	0.15	0.18
<b>Paracetamol</b>							
Level 1	Mean	6.32	6.35	6.55	6.11	6.20	6.39
	SD	0.49	0.25	0.48	0.33	0.67	0.24
Level 2	Mean	7.47	6.99	7.38	7.39	7.03	7.26
	SD	0.72	0.96	0.66	0.84	0.85	0.89
Level 3	Mean	12.74	12.74	12.73	12.60	12.47	12.47
	SD	0.79	0.79	0.73	0.75	0.60	0.64
<b>S-Salicylate</b>							
Level 1	Mean	35.61	35.62	35.91	35.64	35.72	36.27
	SD	0.57	0.61	0.67	0.35	0.49	0.22
Level 2	Mean	37.88	37.92	37.76	38.10	38.18	38.56
	SD	0.63	0.49	0.53	0.45	0.50	0.40
Level 3	Mean	303.30	320.67	323.87	309.74	316.05	322.98
	SD	36.50	29.53	26.25	40.54	27.92	28.14

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