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# 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 <sup>(7) (8)</sup>.

\*\* 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 (± 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.

	Tube	VT-050SP			VF-054SAHLW		
	Time	0 h	4 h	24 h	0 h	4 h	24 h
<b>Amikacin</b>							
Level 1	Mean	2.73	2.694	2.711	2.664	2.757	2.719
	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	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
<b>Digoxin</b>							
Level 1	Mean	0.89	0.9	0.9	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	1.39	1.416	1.409	1.45
	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						
<b>Lidocain</b>							
Level 1	Mean	1.212	1.212	1.221	1.13	1.147	1.152
	SD	0.03	0.04	0.03	0.05	0.03	0.03
Level 2	Mean	2.687	2.736	2.718	2.543	2.53	2.513
	SD	0.09	0.13	0.09	0.12	0.13	0.09
Level 3	Mean	10.714	11.052	11.204	10.374	10.268	10.622
	SD	0.23	0.18	0.22	0.22	0.26	0.37
<b>Carbamazepin</b>							
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	7.3	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
<b>Gentamycin</b>							
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
<b>Phenobarbital</b>							
Level 1	Mean	9.38	9.04	9.1	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
<b>Phenytoin</b>							
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
<b>Theophylline</b>							
Level 1	Mean	12.07	11.93	11.98	12.25	12.17	12.2
	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
<b>Valproic Acid</b>							
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	104.81	104.71	103.91	105.94	106.05	104.38
	SD	2.04	2.71	2.29	1.73	1.27	1.57
Level 3	Mean	131.37	132.52	131.42	133.6	134.8444	134.4
	SD	3.71	3.39	3.03	4.40	5.00	4.32
<b>Vancomycin</b>							
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
<b>Methotrexate</b>							
Level 1	Mean	1.24	1.265	1.272	1.29	1.295	1.29
	SD	0.10	0.10	0.12	0.11	0.11	0.10
Level 2	Mean	1.607	1.643	1.65	1.66	1.654	1.664
	SD	0.05	0.04	0.04	0.02	0.05	0.04
Level 3	Mean	2.978	3.074	3.102	3.154	3.09	3.088
	SD	0.17	0.12	0.13	0.14	0.14	0.17
<b>Paracetamol</b>							
Level 1	Mean	6.325	6.356	6.552	6.185	6.199	6.551
	SD	0.49	0.25	0.48	0.61	0.31	0.46
Level 2	Mean	7.471	6.994	7.386	7.497	7.433	7.228
	SD	0.72	0.96	0.66	0.89	0.84	0.60
Level 3	Mean	12.743	12.742	12.734	12.673	12.497	12.44
	SD	0.79	0.79	0.73	0.81	0.38	0.75
<b>S-Salicylate</b>							
Level 1	Mean	35.608	35.622	35.907	36.675	36.334	36.667
	SD	0.57	0.61	0.67	1.29	0.25	0.21
Level 2	Mean	37.884	37.919	37.758	38.439	39.002	38.882
	SD	0.63	0.49	0.53	0.46	1.04	0.46
Level 3	Mean	303.305	320.671	323.875	309.7	316.624	319.746
	SD	36.50	29.53	26.25	30.29	33.78	26.94

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