

## ORIGINAL ARTICLE

# Could S-Monovette Serum Gel Tubes be Used for Clinical Chemistry Analysis Instead of Serum Separator Tube II Advance?

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### SUMMARY

**Background:** We aimed to compare the Sarstedt S-Monovette serum gel tube and the BD (Becton, Dickinson and Company) Serum Separator Tube II (SST II) Advance based on technical specifications and tests results.

**Methods:** One hundred and twenty volunteers were included in the technical evaluation and 42 of 120 volunteers in the clinical evaluation. Blood was collected into S-Monovette, and SST II. Twelve quality indicators (QI) were determined for technical evaluation. For clinical evaluation, 29 clinical chemistry analytes were analysed simultaneously on a Roche Cobas 6000 c501 (Roche Diagnostics, Mannheim, Germany). Calculations were made using the formula suggested by the EFLM according to the QIs. If the difference between S-Monovette and SST II was < 1%, S-Monovette was considered sufficient for relevant QI. For clinical evaluation, Passing Bablok regression analysis and Bland-Altman plots were used. Desirable bias values for comparison with mean percentage difference (MPD) were obtained from biological variation databases.

**Results:** S-Monovette tubes were found to be suitable for all QIs (difference < 1%). No significant differences were observed in analytes except lactate dehydrogenase (LDH). LDH results (U/L) obtained from the SST II were statistically significantly higher (SST II:  $201 \pm 42$ , S-Monovette:  $195 \pm 35$ , regression equation was  $y = 31.4 + 0.8x$ ). The MPD of LDH (2.4%) remained within the desirable bias (3.4%); however, the 95% CI of the MPD of LDH (0.5% - 4.4%) exceeded the desirable bias.

**Conclusions:** S-Monovette has been deemed appropriate for use in clinical chemistry analysis, as the MPD of LDH and other analytes remained within the bias limits. The LDH was considered sensitive to microhemolysis as a possible reason for the difference in LDH results.

(Clin. Lab. 2022;68:1-3. DOI: 10.7754/Clin.Lab.2021.210841)

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## Supplementary Tables and Figures

Supplemental Table S1. Comparison of twenty-nine analyte results between SST II Advance and S-Monovette serum gel tubes.

Analytes (units)	BD Serum Separator Tube II (SST II) Advance	Sarstedt S-Monovette serum gel tube	Intercept (95% CI) *	Slope (95% CI) *	Mean percentage difference (95% CI) ‡	Desirable bias (%) §	CV (%)
Alb g/L	46 ± 3	46 ± 3	0.000 (-2.859 - 3.429)	1.000 (0.929 - 1.062)	-0.294 (-0.726 - 0.138)	1.4	3.9
ALP U/L	64 (59 - 78)	65 (58 - 78)	0.000 (0.000 - 0.000)	1.000 (1.000 - 1.000)	-0.044 (-0.495 - 0.406)	6.2	4.7
ALT U/L	19 (13 - 34)	19 (13 - 34)	0.211 (-0.121 - 0.632)	0.995 (0.979 - 1.011)	-0.779 (-1.731 - 0.172)	7.7	4.3
Amy U/L	75 ± 25	76 ± 25	0.000 (-0.884 - 0.000)	1.000 (1.000 - 1.018)	-0.664 (-1.169 to -0.160)	7.7	4.1
AST U/L	19 (15 - 23)	18 (15 - 24)	0.771 (-0.306 - 1.840)	0.955 (0.900 - 1.013)	1.292 (-0.695 - 3.279)	5.7	4.5
BUN mmol/L	8.57 (7.5 - 10.7)	8.57 (7.5 - 10.35)	0.501 (-0.050 - 0.966)	0.982 (0.961 - 1.000)	-0.076 (-0.581 - 0.429)	6.3	3.1
Ca mmol/L	2.39 ± 0.1	2.39 ± 0.1	0.359 (-0.525 - 1.430)	0.964 (0.851 - 1.059)	-0.267 (-0.630 - 0.095)	0.82	3.1
Chol mmol/L	4.84 ± 1.06	4.86 ± 1.03	0.622 (-3.309 - 3.854)	0.996 (0.976 - 1.016)	-0.121 (-0.599 - 0.356)	4.3	3.8
CK U/L	94 (67 - 125)	94 (67 - 127)	0.000 (-2.104 - 0.000)	1.000 (1.000 - 1.022)	0.669 (-0.286 - 1.625)	10.2	3.4
Cl mmol/L	102 ± 2	102 ± 2	9.423 (-0.150 - 20.650)	0.909 (0.800 - 1.000)	-0.162 (-0.357 - 0.034)	0.4	5.0
Crea µmol/L	0.06 (0.05 - 0.07)	0.06 (0.05 - 0.08)	0.000 (-0.051 - 0.010)	1.000 (0.989 - 1.077)	-0.401 (-1.465 - 0.664)	3.7	4.8
CRP mg/L	13 (9 - 42)	13 (9 - 41)	-0.012 (-0.029 - 0.007)	1.004 (0.997 - 1.010)	0.762 (-0.323 - 1.847)	22.6	4.2
D. Bil µmol/L	3.42 (1.71 - 5.13)	3.42 (1.71 - 5.13)	0.002 (-0.004 - 0.013)	0.976 (0.925 - 1.011)	-1.342 (-4.649 - 1.966)	14.2	4.1
Fe µg/L	90 ± 36	90 ± 36	-0.333 (-2.243 - 1.230)	1.002 (0.984 - 1.025)	0.088 (-0.730 - 0.905)	8.8	4.5
GGT U/L	18 (10 - 21)	18 (11 - 24)	0.000 (0.000 - 0.586)	1.000 (0.971 - 1.000)	-2.933 (-5.269 to -0.596)	11.4	3.3
Glu mmol/L	5.38 (4.94 - 5.99)	5.33 (5 - 5.99)	1.130 (-2.520 - 4.123)	0.989 (0.959 - 1.027)	0.201 (-0.376 - 0.777)	2.4	3.2
HDL-C mmol/L	1.22 (1.03 - 1.53)	1.24 (1.03 - 1.53)	0.200 (-0.368 - 0.903)	1.000 (0.984 - 1.014)	-0.484 (-0.843 to -0.126)	6.3	3.5
K mmol/L	4.4 ± 0.3	4.4 ± 0.3	0.185 (-0.143 - 0.422)	0.966 (0.910 - 1.040)	-0.397 (-0.870 - 0.077)	1.5	5.9
LDH U/L	201 ± 42	195 ± 35	<u>0.816</u> (0.723 - 0.919)	<u>31.401</u> (12.905 - 48.170)	<u>2.440</u> (0.486 - 4.393)	3.4	4.7
LDL-C mmol/L	3.26 ± 0.91	3.26 ± 0.91	-0.839 (-2.358 - 0.525)	1.009 (0.998 - 1.022)	-0.212 (-0.690 - 0.266)	6.8	4.0
Lip U/L	35 ± 12	36 ± 12	1.091 (-1.518 - 4.140)	0.975 (0.888 - 1.059)	-1.850 (-5.358 - 1.657)	6.6	5.4
Mg mmol/L	0.82 ± 0.04	0.82 ± 0.04	0.005 (-0.197 - 0.116)	1.000 (0.947 - 1.100)	-0.091 (-0.513 - 0.332)	1.8	4.5
Na mmol/L	138 (137 - 140)	139 (138 - 140)	0.000 (0.000 - 0.000)	1.000 (1.000 - 1.000)	-0.120 (-0.324 - 0.085)	0.3	4.3
P mmol/L	1.13 (1.06 - 1.19)	1.13 (1.06 - 1.19)	0.115 (-0.005 - 0.197)	0.967 (0.944 - 1.000)	-0.392 (-0.847 - 0.062)	3.38	3.0

## S-Monovette Serum Gel Tubes for Clinical Chemistry

Analytes (units)	BD Serum Separator Tube II (SST II) Advance	Sarstedt S-Monovette serum gel tube	Intercept (95% CI) *	Slope (95% CI) *	Mean percentage difference (95% CI) ‡	Desirable bias (%) §	CV (%)
<b>T.Bil</b> μmol/L	<b>7.7</b> (5.82 - 14.37)	<b>7.53</b> (6.16 - 14.02)	<b>0.001</b> (-0.004 - 0.010)	<b>1.000</b> (0.984 - 1.016)	<b>-0.414</b> (-1.547 - 0.719)	<b>8.95</b>	<b>4.7</b>
<b>TG</b> mmol/L	<b>1.4</b> (0.95 - 3.15)	<b>1.43</b> (0.95 - 3.1)	<b>0.132</b> (-1.127 - 2.061)	<b>1.001</b> (0.990 - 1.010)	<b>-0.351</b> (-0.943 - 0.241)	<b>10.5</b>	<b>3.5</b>
<b>TP</b> g/L	<b>72 ± 4</b>	<b>72 ± 4</b>	<b>-0.487</b> (-5.649 - 4.086)	<b>1.011</b> (0.946 - 1.082)	<b>-0.294</b> (-0.664 - 0.076)	<b>1.3</b>	<b>2.2</b>
<b>UA</b> mmol/L	<b>0.29 ± 0.07</b>	<b>0.29 ± 0.07</b>	<b>0.000</b> (0.000 - 0.001)	<b>1.000</b> (1.000 - 1.000)	<b>0.310</b> (-0.138 - 0.757)	<b>4.87</b>	<b>3.0</b>
<b>UIBC</b> μg/L	<b>258 ± 74</b>	<b>260 ± 74</b>	<b>-0.806</b> (-8.176 - 6.341)	<b>1.008</b> (0.980 - 1.037)	<b>-0.517</b> (-1.353 - 0.320)	<b>10<sup>l</sup></b>	<b>6.7</b>

Analytes with a statistical difference are highlighted - underlined.

Results were presented as Mean ± SD or Median (IQR) depending on relevance for the normal distribution.

\* Slope and intercept values were obtained by Passing-Bablok regression analysis.

† Mean percentage differences were computed via Bland-Altman plots.

‡ Values were obtained from EFLM and Westgard BV databases.

§ Due to the lack of information in the databases for the UIBC, the desirable bias value was accepted as 10%.

CI: Confidence interval, CV: Coefficient of variation.

Analytes; Alb: Albumin, ALP: Alkaline phosphatase, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, BUN: Blood urea nitrogen, Ca: Calcium, Chol: Total cholesterol, CK: Creatine kinase, Cl: chloride, CRP: C-reactive protein, Crea: Creatinine, D.Bil: Direct bilirubin, Fe: Iron, GGT: Gamma-glutamyl transferase, Glu: Glucose, HDL-C: HDL cholesterol, K: Potassium, LDH: Lactate dehydrogenase, LDL-C: LDL cholesterol, Lip: Lipase, Mg: Magnesium, Na: Sodium, P: Phosphorus, T.Bil: Total bilirubin, TP: Total protein, TG: Triglycerides, UA: uric acid, UIBC: Unsaturated iron binding capacity.