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# **COMPARISON OF VARIOUS BD VACUTAINER<sup>®</sup> GEL SEPARATOR TUBES PROCESSED WITH THE STATSPIN<sup>®</sup> EXPRESS 3, EXPRESS 4 AND A TRADITIONAL HORIZONTAL CENTRIFUGE**

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# Comparison of Various BD Vacutainer<sup>®</sup> Gel Separator Tubes Processed with the StatSpin<sup>®</sup> Express 3, Express 4 and a Traditional Horizontal Centrifuge

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## Purpose

The StatSpin<sup>®</sup> Express 3 and Express 4 are high-speed bench top centrifuges used to rapidly separate whole blood contained in original collection tubes. The Express 3 fixed angle rotor holds 8 tubes up to 10 mL. It has preset cycle times of 2, 3, and 5 minutes. The Express 4 horizontal rotor holds 8 tubes up to 10 mL and produces a flat gel separation in just 3 minutes. It has preset cycle times of 3, 5, and 10 minutes.

This study evaluated the Express 3 and Express 4, as compared to a traditional horizontal centrifuge, the LW Scientific EZ Swing 5K, in preparing serum and plasma from whole blood collected in various BD Vacutainer<sup>®</sup> gel separator tubes for analysis of potassium and lactate dehydrogenase (LDH), as indicators of hemolysis.

## Materials and Methods

Three BD SST<sup>™</sup> II *Advance* gel tubes (BD #367954, 13 x 100 mm, 5 mL, plastic), three BD PST<sup>™</sup> II gel tubes (BD #367377, lithium heparin, 16 x 100 mm, 8 mL, plastic), and three BD RST gel tubes (BD #368771, 13 x 100 mm, 4 mL, plastic) were collected from 30 donors. The BD SST<sup>™</sup> II *Advance* and BD RST tubes were allowed to clot for 30 and 5 minutes, respectively.

The tubes were centrifuged in the Express 3 (3 minutes, 7200 rpm, 4440 g), Express 4 (3 minutes, 5100 rpm, 4000 g), and EZ Swing 5K (10 minutes, 3000 rpm, 1460 g for BD SST<sup>™</sup> II *Advance* and BD PST<sup>™</sup> II; 10 minutes, 3100 rpm, 1558 g for BD RST). The serum/plasma was tested for potassium and LDH on the Beckman Coulter DXC 600 analyzer.

## Results

Tables 1 through 4 and Charts 1 through 4 present results of the statistical analysis and the original data. (For donor #20, results for the BD RST tube are not listed for EZ Swing 5K because blood flow ceased before the tube could be filled.)

## Data Analysis

The mean and standard deviation (SD) were calculated for each centrifuge, for each tube type, for potassium and LDH. For each tube type, results for Express 3 and Express 4 were compared to the EZ Swing 5K by calculating the mean bias and 95% confidence limits for the mean bias. The mean bias and 95% confidence limits were compared to the established clinical acceptance limit (CAL), an estimate of the maximum allowable difference in test results between the two centrifuges.

## Interpretation

BD SST<sup>™</sup> II *Advance*, BD PST<sup>™</sup> II, and BD RST gel tubes spun in Express 3 and Express 4 for only 3 minutes exhibited gel separation comparable to a 10 minute spin with the EZ Swing 5K. For both potassium and LDH, for each tube type, the means for Express 3 and Express 4 are in close agreement with the means for the EZ Swing 5K. For both potassium and LDH, for each tube type, the mean bias and 95% confidence limits are within  $\pm$  CAL.

## Discussion

The StatSpin<sup>®</sup> Express 3 and Express 4 high-speed centrifuges demonstrated clinically equivalent potassium and LDH results using BD Vacutainer<sup>®</sup> SST<sup>™</sup> II *Advance*, BD PST<sup>™</sup> II, and BD RST gel tubes, as compared to a traditional horizontal centrifuge, the LW Scientific EZ Swing 5K.

**Table 1**

<b>Potassium: BD SST™ II Advance</b>					
	<b>Study Range, mmol/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, mmol/L (95% Conf. Limits)</b>	<b>CAL, units</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	3.7 - 4.6	4.08 ± 0.24	----	----	----
<b>Express 3</b>	3.7 - 5.0	4.10 ± 0.28	0.02 (-0.07, 0.10)	0.3 mmol/L	YES
<b>Express 4</b>	3.7 - 5.1	4.12 ± 0.30	0.04 (-0.02, 0.11)	0.3 mmol/L	YES

<b>Potassium: BD PST™ II</b>					
	<b>Study Range, mmol/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, mmol/L (95% Conf. Limits)</b>	<b>CAL, units</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	3.5 - 4.4	3.81 ± 0.22	----	----	----
<b>Express 3</b>	3.5 - 4.6	3.84 ± 0.26	0.04 (-0.05, 0.13)	0.3 mmol/L	YES
<b>Express 4</b>	3.4 - 4.2	3.79 ± 0.21	-0.02 (-0.08, 0.04)	0.3 mmol/L	YES

<b>Potassium: BD RST</b>					
	<b>Study Range, mmol/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, mmol/L (95% Conf. Limits)</b>	<b>CAL, units</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	3.7 - 4.6	4.03 ± 0.26	----	----	----
<b>Express 3</b>	3.6 - 4.9	4.02 ± 0.29	-0.03 (-0.08, 0.03)	0.3 mmol/L	YES
<b>Express 4</b>	3.4 - 4.7	4.01 ± 0.29	-0.04 (-0.08, 0.01)	0.3 mmol/L	YES

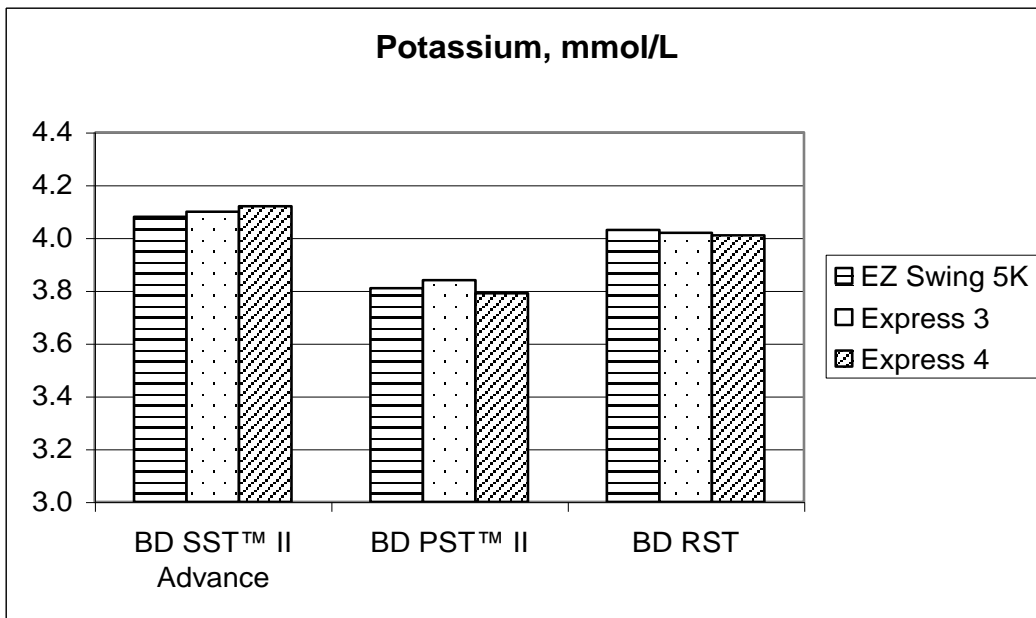
**Table 2**

<b>LDH: BD SST™ II Advance</b>					
	<b>Study Range, U/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, % (95% Conf. Limits)</b>	<b>CAL, %</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	100 - 195	141.1 ± 22.6	----	----	----
<b>Express 3</b>	99 - 195	138.5 ± 21.9	-1.8 (-2.6, -0.9)	20 %	YES
<b>Express 4</b>	103 - 196	143.0 ± 22.2	1.4 (0.2, 2.6)	20 %	YES

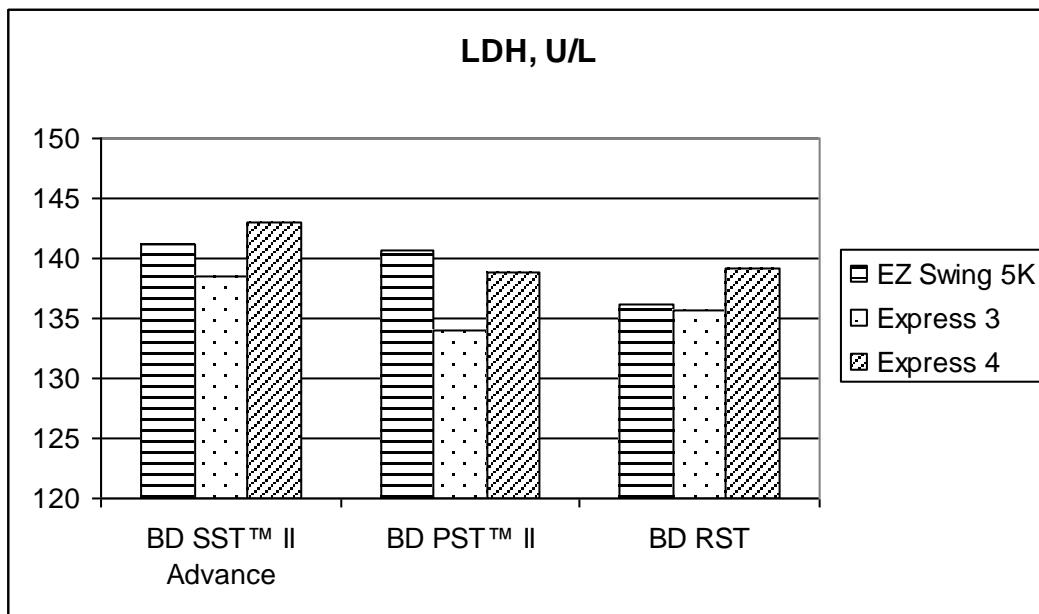
<b>LDH: BD PST™ II</b>					
	<b>Study Range, U/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, % (95% Conf. Limits)</b>	<b>CAL, %</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	106 - 197	140.7 ± 20.6	----	----	----
<b>Express 3</b>	96 - 183	134.0 ± 20.9	-4.9 (-6.1, -3.7)	20 %	YES
<b>Express 4</b>	104 - 193	138.9 ± 20.1	-1.3 (-2.5, 0.0)	20 %	YES

<b>LDH: BD RST</b>					
	<b>Study Range, U/L</b>	<b>Mean ± SD</b>	<b>Mean Bias, % (95% Conf. Limits)</b>	<b>CAL, %</b>	<b>Clinical Equivalence</b>
<b>EZ Swing 5K</b>	102 - 192	136.1 ± 21.6	----	----	----
<b>Express 3</b>	100 - 188	135.7 ± 21.1	-0.9 (-1.9, 0.2)	20 %	YES
<b>Express 4</b>	102 - 196	139.2 ± 22.3	1.6 (0.4, 2.9)	20 %	YES

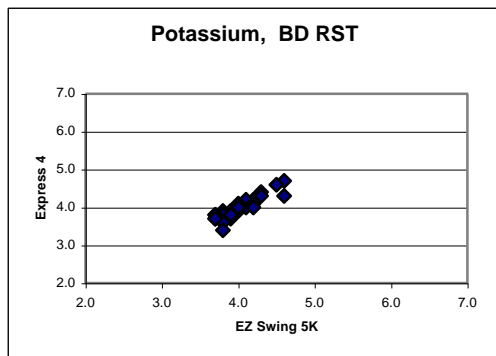
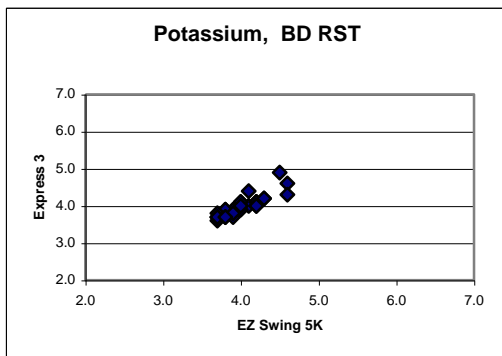
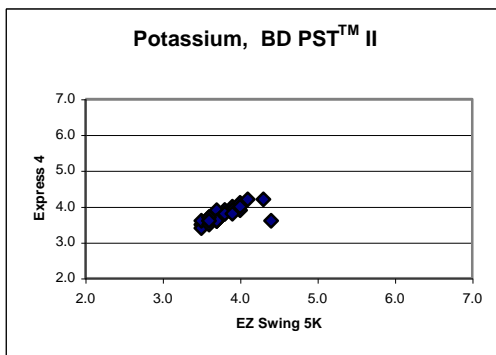
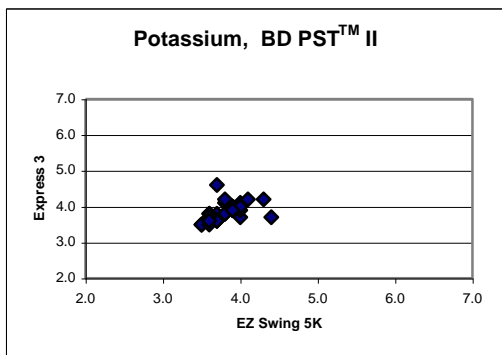
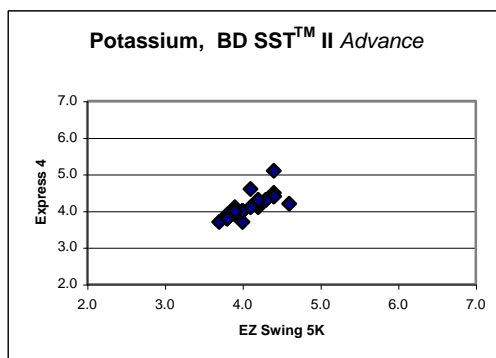
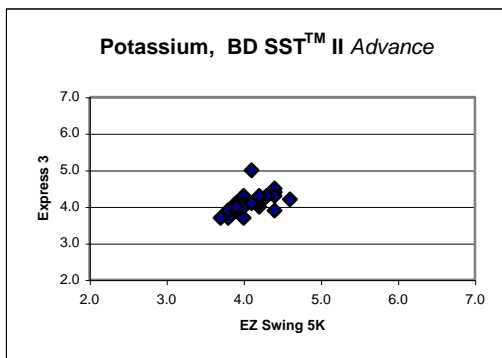
**Chart 1**



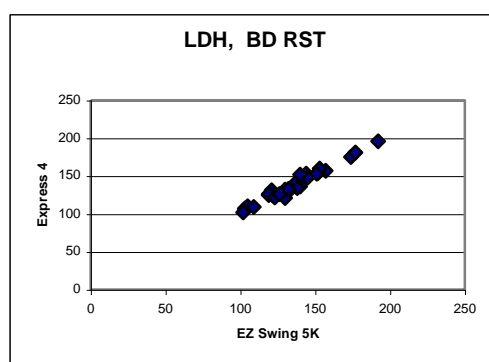
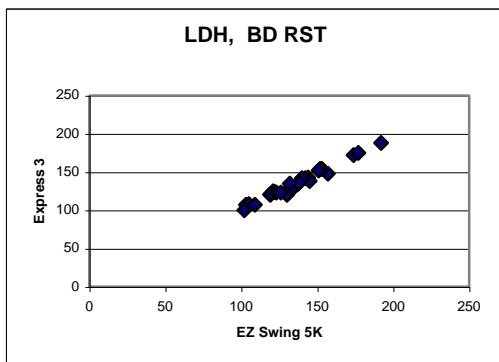
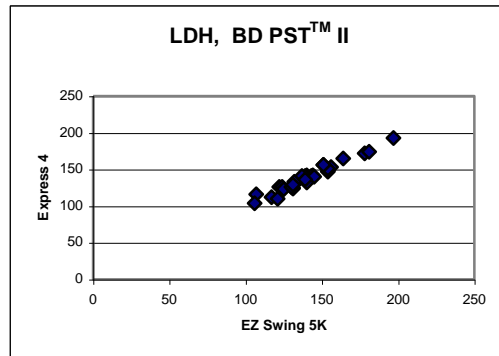
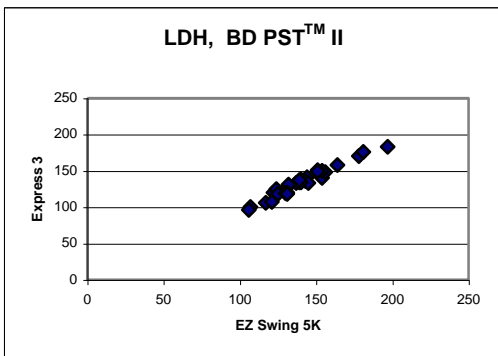
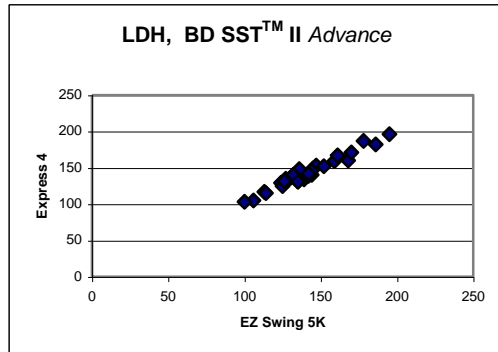
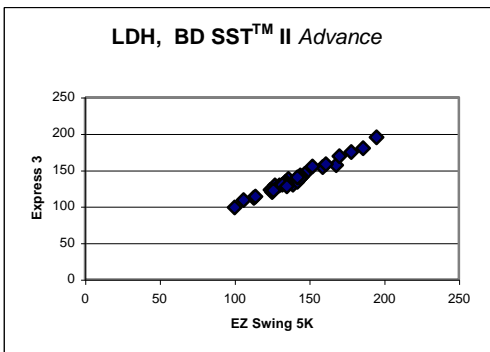
**Chart 2**



### Chart 3



### Chart 4



**Table 3**

Potassium, mmol/L									
Donor	BD SST™ II Advance			BD PST™ II			BD RST		
	Express 3	Express 4	EZ Swing	Express 3	Express 4	EZ Swing	Express 3	Express 4	EZ Swing
1	4.1	4.1	3.9	3.5	3.5	3.5	3.7	3.7	3.9
2	4.0	4.3	4.2	3.9	3.9	3.9	4.1	4.0	4.0
3	4.2	4.2	4.6	4.1	3.9	3.8	4.1	4.1	4.2
4	3.9	3.8	3.8	3.5	3.4	3.5	3.6	3.8	3.7
5	3.9	3.9	3.9	3.7	3.6	3.7	3.9	3.9	3.9
6	3.8	3.8	3.8	3.6	3.6	3.7	3.9	3.9	3.8
7	4.4	4.4	4.4	4.0	4.0	3.9	4.6	4.7	4.6
8	4.3	4.3	4.3	4.1	4.1	4.0	4.2	4.4	4.3
9	3.9	3.9	3.8	3.6	3.6	3.7	3.8	3.8	3.8
10	4.4	4.5	4.4	4.2	3.9	3.8	4.1	4.2	4.2
11	4.3	4.0	4.0	3.8	3.8	3.7	3.9	3.8	3.8
12	4.1	4.1	4.2	4.0	3.9	3.9	4.0	4.0	4.1
13	3.7	3.8	3.8	4.6	3.9	3.7	3.8	3.8	3.7
14	3.7	3.7	3.7	3.5	3.6	3.5	3.7	3.7	3.7
15	4.1	4.0	4.0	3.7	3.6	4.4	4.4	4.2	4.1
16	3.9	3.8	3.8	3.5	3.5	3.6	3.9	3.9	4.0
17	4.2	4.2	4.2	4.0	3.9	3.9	4.1	4.1	4.2
18	4.0	4.0	3.9	3.8	3.8	3.8	4.0	4.1	4.0
19	4.5	4.4	4.4	4.2	4.2	4.1	4.3	4.3	4.6
20	4.3	4.4	4.4	4.2	4.2	4.3	4.4	4.4	n/a
21	3.9	5.1	4.4	3.8	3.6	3.6	3.7	3.6	3.8
22	3.7	3.7	4.0	3.8	3.7	3.6	3.7	3.7	3.7
23	4.0	4.0	4.0	3.7	4.0	4.0	4.1	4.0	4.0
24	5.0	4.6	4.1	3.6	3.6	3.7	4.0	4.1	4.2
25	3.9	4.0	3.9	3.7	3.7	3.6	3.8	3.8	3.9
26	4.3	4.3	4.3	3.9	3.9	4.0	4.9	4.6	4.5
27	4.3	4.3	4.2	4.0	4.0	4.0	4.2	4.3	4.3
28	4.0	4.0	4.0	3.8	3.8	3.8	4.0	4.0	4.2
29	4.0	4.0	3.9	3.6	3.6	3.6	3.7	3.4	3.8
30	4.1	4.1	4.1	3.9	3.8	3.9	4.0	4.0	4.0

**Table 4**

LDH, U/L									
Donor	BD SST™ II Advance			BD PST™ II			BD RST		
	Express 3	Express 4	EZ Swing	Express 3	Express 4	EZ Swing	Express 3	Express 4	EZ Swing
1	141	149	145	138	142	140	142	136	140
2	138	148	136	141	142	144	142	144	142
3	130	134	139	129	130	132	127	128	131
4	145	153	147	140	147	154	143	153	144
5	154	159	159	148	153	156	148	157	157
6	122	130	125	120	126	122	125	131	121
7	143	140	144	136	141	143	138	148	145
8	112	117	113	106	112	117	107	107	103
9	134	139	142	134	141	139	134	141	137
10	134	135	134	125	126	124	124	124	122
11	175	187	178	170	172	178	172	175	174
12	129	135	127	119	125	131	122	121	130
13	195	196	195	183	193	197	188	196	192
14	139	146	144	133	141	137	141	152	140
15	109	105	106	100	116	107	108	110	105
16	157	160	168	150	151	154	154	154	152
17	140	142	142	133	140	145	136	134	138
18	123	129	124	118	123	125	120	125	119
19	129	136	130	134	132	140	120	132	130
20	169	171	170	158	165	164	162	164	n/a
21	180	182	186	176	174	181	175	181	177
22	132	131	135	131	133	132	127	131	133
23	120	125	125	120	124	131	121	126	119
24	122	132	126	119	126	130	123	122	123
25	130	140	132	137	136	139	135	133	132
26	99	103	100	96	104	106	100	102	102
27	114	115	114	107	110	121	107	109	109
28	158	167	161	151	156	151	154	160	153
29	128	131	135	118	129	131	123	126	126
30	155	152	152	149	156	151	152	153	151