

Veterinary Lactate Monitoring System
Accuracy Study Testing (In-House Clinical Study)

Contents:

1. L-Pet Veterinary Lactate System

Approved By: _____



Date: _____

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L-Pet Veterinary Lactate System
Accuracy Study (In-House Clinical Study)
Protocol / Report

Scope and Objective

The L-Pet Veterinary Lactate System consists of the L-Pet Meter and the L-Pet Test Strips for self-monitoring of blood lactate by veterinarians or pet owners. The meter and test strip utilise electrochemical technology based on enzymatic potassium ferricyanide oxidation-reduction reaction for determination of lactate levels in whole blood samples. The test strip requires approximately 5µl of blood which is drawn into the test chamber by capillary action to obtain a blood lactate reading. The range of lactate measured by the system is 6-200 mg/dL.

The in-house clinical trial included 75 capillary samples. The subjects' uric acid measured between at 3-8 mg/dL. Their haematocrits were within the range of 35-50%.

The primary objective of this study was to verify the performance of the system as compared to the L-Lactate (PAP) Kit (RANDOX, United Kingdom) as an accepted standard method for enzymatic determination of L-lactate.

All the data is the comparison of performance characteristics of the L-Pet Veterinary Lactate System and a standard laboratory method (using spectrophotometer) as performed.

Materials

- L-Pet Meters
- L-Pet Test Strips (3 Lots)
- R Check Strip
- Micro-haematocrit Centrifuge
- Capillary Tube with Sealing Cement
- L-Lactate (PAP) Kit (RANDOX, United Kingdom)
- Metertech SP8001 UV/Vis Spectrophotometer (Pathtech, Preston, Australia)
- Laboratory PC

Testing

1. Set up six L-Pet Meters and three lots of the L-Pet Test Strips (LS001A, LS001B and LS001B-I).
2. Insert a test strip into each meter's strip port and the meter will power on automatically.
3. Add blood samples on to the test zone and wait for the results. Record the readings.
4. Remove the test strips from the meters and discard. Wait two minutes before starting the next test.
5. Test the lactate level of the blood samples with the L-Lactate (PAP) Kit.
6. Repeat steps 2-5 for each blood sample.

Note Concerning Preparation of Capillary Puncture Site

Prior to performing a capillary puncture, the Clinical Study Investigator must first cleanse the puncture site. The preferred method is to wash with warm soapy water, rinse with warm water and then dry. If running water is not available where the test is being performed, the puncture site should be cleansed with an alcohol swab and be allowed to dry thoroughly prior to puncture.

Acceptance Criteria

80% of the individual results should fall within $\pm 20\%$ of the L-Lactate (PAP) Kit reference.

Results

The data of this study is shown in Exhibit 1. In the table, 22 readings are not within the $\pm 20\%$ limit of the reference in total 416 readings. The outside percentage is 5.3% (22/416).

Conclusion

The data of this study conforms to the Acceptance Criteria.

Exhibit 1

Table 1. Accuracy Study Testing (In-House Clinical Study) of the L-Pet Veterinary Lactate System – Raw Data

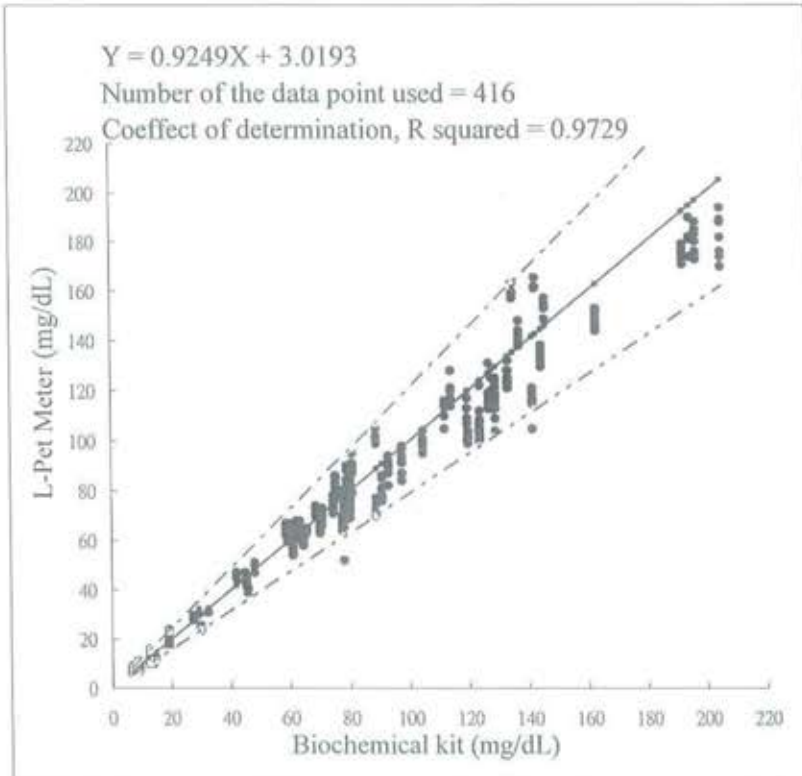
Reference	L-Pet							Graph			BIAS							HCT
	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	X = Y	-20%	+20%	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	
137.4	141	139	144	141	148	138	142	137	109	166	2.6	1.2	4.8	2.6	7.7	0.4	3.2	41
114.3	121	128	121	114	120	117	120	114	90	138	5.9	12	5.9	-0.3	5	2.4	5.1	41
8.6	9	8	9	9	9	9	9	9	7	10	4.7	-7	4.7	4.7	4.7	4.7	2.7	36
112.1	116	110	114	110	105	105	110	112	89	136	3.5	-1.9	1.7	-1.9	-6.3	-6.3	-1.9	44
128.0	125	113	120	114	114	116	117	128	101	155	-2.3	-11.7	-6.3	-10.9	-10.9	-9.4	-8.6	44
88.7	102	99	102	105		99	101	89	70	107	15	11.6	15	18.4		11.6	14.3	47
129.4	104	125	124	109	119	122	117	129	102	157	-19.6	-3.4	-4.2	-15.8	-8	-5.7	-9.5	47
194.8		181	182	181	174	190	182	195	154	236		-7.1	-6.6	-7.1	-10.7	-2.5	-6.8	44
205.4	194	176	189	174	188	170	182	205	162	249	-5.6	-14.3	-8	-15.3	-8.5	-17.2	-11.5	44
13.1	11	11	11	10	11	12	11	13	10	16	-16	-16	-16	-23.7	-16	-8.4	-16	46
129.4	116	121	119	115	118	113	117	129	102	157	-10.4	-6.5	-8	-11.1	-8.8	-12.7	-9.6	46
14.0	13	12	15	11	10	12	12	14	11	17	-7.1	-14.3	7.1	-21.4	-28.6	-14.3	-13.1	51
19.2	20	21	24	18	19	17	20	19	15	23	4.2	9.4	25	-6.3	-1	-11.5	3.3	41
119.8	117	113	107	109	109	100	109	120	95	145	-2.3	-5.7	-10.7	-9	-9	-16.5	-8.9	41
13.2	14	15	13	16	12	11	14	13	10	16	6.1	13.6	-1.5	21.2	-9.1	-16.7	2.3	42
75.3	86	85	78	80	83	78	82	75	59	91	14.2	12.9	3.6	6.2	10.2	3.6	8.5	42
77.6	70	67	65	68	80	64	69	78	61	94	-9.8	-13.7	-16.2	-12.4	3.1	-17.5	-11.1	42
80.2	84	84	77	82	78	79	81	80	63	97	4.7	4.7	-4	2.2	-2.7	-1.5	0.6	42
80	76	72	74	75	71	69	73	80	63	97	-5	-10	-7.5	-6.3	-11.3	-13.8	-9	42
12.8	10	11	12	13	13	12	12	13	10	15	-21.9	-14.1	-6.3	1.6	1.6	-6.3	-7.6	43
127.1	131	119	115	113	113	115	118	127	100	154	3.1	-6.4	-9.5	-11.1	-11.1	-9.5	-7.4	43
8.2	10		8	10	9	8	9	8	6	10	22		-2.4	22	9.8	-2.4	9.8	50
141.7	120	105	115	121	119	120	117	142	112	171	-15.3	-25.9	-18.8	-14.6	-16	-15.3	-17.7	50
123.8	100	103	107	105		104	104	124	98	150	-19.2	-16.8	-13.6	-15.2		-16	-16.2	50
192.5	173	179	175		171	177	175	193	152	233	-10.1	-7	-9.1		-11.2	-8.1	-9.1	43
196.9	175	173	183	188	185	176	180	197	156	238	-11.1	-12.1	-7.1	-4.5	-6	-10.6	-8.6	43
12.8	16	11	11	13	11	10	12	13	10	15	25	-14.1	-14.1	1.6	-14.1	-21.9	-6.3	42
124	122	103	112	101	108	105	109	124	98	150	-1.6	-16.9	-9.7	-18.5	-12.9	-15.3	-12.5	42
133.7	132	123	123	124	128	121	125	134	106	162	-1.3	-8	-8	-7.3	-4.3	-9.5	-6.4	42
90.8	86	81	78	77	85	76	81	91	72	110	-5.3	-10.8	-14.1	-15.2	-6.4	-16.3	-11.3	38
97.6	97	98	94	87	91	84	92	98	77	118	-0.6	0.4	-3.7	-10.9	-6.8	-13.9	-5.9	38
14.5	13	13	12	13	12	13	13	15	11	18	-10.3	-10.3	-17.2	-10.3	-17.2	-10.3	-12.6	36
104.7	100	104	98	101	95	101	100	105	83	127	-4.5	-0.7	-6.4	-3.5	-9.3	-3.5	-4.6	36
80.7	95	89	87	90	79	91	89	81	64	98	17.7	10.3	7.8	11.5	-2.1	12.8	9.7	36
9.2	7	8	9	9	8	7	8	9	7	11	-23.9	-13	-2.2	-2.2	-13	-23.9	-13	38

Table 1. (Continued)

Reference	L-Pet							Graph			BIAS							HCT
	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	X = Y	-20%	+20%	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	
70.1	66	64	64	63	64	64	64	70	55	85	-5.8	-8.7	-8.7	-10.1	-8.7	-8.7	-8.5	38
48.2	50	50	51	50	47	51	50	48	38	58	3.7	3.7	5.8	3.7	-2.5	5.8	3.4	38
8.7	10	11	8	7	8	8	9	9	7	11	14.9	26.4	-8	-19.5	-8	-8	-0.4	45
78.1	73	79	65	68	75	52	69	78	62	95	-6.5	1.2	-16.8	-12.9	-4	-33.4	-12.1	45
70.8	71	68	70	66	73	68	69	71	56	86	0.3	-4	-1.1	-6.8	3.1	-4	-2.1	40
79	90	82	88	80	81		84	79	62	96	13.9	3.8	11.4	1.3	2.5		6.6	41
88.7	77	74	70	73	70	72	73	89	70	107	-13.2	-16.6	-21.1	-17.7	-21.1	-18.8	-18.1	41
93	90	82	94	92	87	91	89	93	73	113	-3.2	-11.8	1.1	-1.1	-6.5	-2.2	-3.9	37
6.7	9	8	7	6	7	7	7	7	5	8	34.3	19.4	4.5	-10.4	4.5	4.5	9.5	43
61.1	65	65	64	66			65	61	48	74	6.4	6.4	4.7	8			6.4	47
61.1	66	63	64	64			64	61	48	74	8	3.1	4.7	4.7			5.2	47
61.2	65	65	67	63			65	61	48	74	6.2	6.2	9.5	2.9			6.2	47
61.6	63	60	61	61			61	62	49	75	2.3	-2.6	-1	-1			-0.6	47
62.3	66	63	65	68			66	62	49	75	5.9	1.1	4.3	9.1			5.1	47
61.0	57	55	60	54			57	61	48	74	-6.6	-9.8	-1.6	-11.5			-7.4	47
58.8	67	66	62	63			65	59	46	71	13.9	12.2	5.4	7.1			9.7	47
59.7	63	60	61	62			62	60	47	72	5.5	0.5	2.2	3.9			3	47
64.5	63	58	62	60			61	65	51	78	-2.3	-10.1	-3.9	-7			-5.8	47
63.1	68	65	62	66			65	63	50	76	7.8	3	-1.7	4.6			3.4	47
61.4	63	62	65	66			64	61	49	74	2.6	1	5.9	7.5			4.2	47
65.5	65	63	63	65			64	66	52	79	-0.8	-3.8	-3.8	-0.8			-2.3	47
68.7	73	71	74	70			72	69	54	83	6.3	3.3	7.7	1.9			4.8	47
74.6	74	74	71	73			73	75	59	90	-0.8	-0.8	-4.8	-2.1			-2.1	47
7.7	7	8	8	7	8	7	8	7.7	6	9	-9.1	3.9	3.9	-9.1	3.9	-9.1	-2.6	47.5
74.6	78	78	72	76	76		76	74.6	59	90	4.6	4.6	-3.5	1.9	1.9		1.9	43
45.3	42	45	42	42	43	42	43	45.3	36	55	-7.3	-0.7	-7.3	-7.3	-5.1	-7.3	-5.8	45
120	101	99	99	104	102	101	101	120	95	145	-15.8	-17.5	-17.5	-13.3	-15	-15.8	-15.8	45
32.5	31	31	31	31	31	31	31	33	26	39	-4.6	-4.6	-4.6	-4.6	-4.6	-4.6	-4.6	36
44.9	47	47	47	47	47	47	47	45	35	54	4.6	4.6	4.6	4.6	4.6	4.6	4.6	47
45.8	41	41	41	38	41	41	40	46	36	55	-11.5	-11.5	-11.5	-16.1	-11.5	-11.5	-12.3	49
41.9	45	45	47	45	45	45	45	42	33	51	6.8	6.8	11.9	6.8	6.8	6.8	7.7	46
28.9	32	30	30	30	30	30	30	29	23	35	11	3.6	3.6	3.6	3.6	3.6	4.9	41
30.1	26	26	26	26	24	24	25	30	24	36	-14.5	-14.5	-14.5	-14.5	-21.6	-21.6	-16.9	46
27.5	28	28	28	28	28	30	28	28	22	33	1.1	1.1	1.1	1.1	1.1	8.8	2.4	44

Table 1. (Continued)

Reference	L-Pet							Graph			BIAS							HCT
	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	X = Y	-20%	+20%	E. 1	E. 2	E. 3	E. 4	E. 5	E. 6	E. AVG	
142.7	165	161	161	161	161	161	162	143	113	173	15.9	13	13	13	13	13	13.5	36
135.3	159	163	163	157	157	159	160	135	107	164	17.6	20.7	20.7	16.1	16.1	17.6	18.1	36
163.0	149	153	153	151	153	153	152	163	129	197	-8.8	-6.2	-6.2	-7.5	-6.2	-6.2	-6.8	44
145.8	157	155	155	149	153	155	154	146	115	176	7.8	6.3	6.3	2	4.9	6.3	5.6	41
163.0	149	144	144	149	149	147	147	163	129	197	-8.6	-11.7	-11.4	-8.8	-8.8	-10.1	-9.9	44
144.6	130	132	136	138	134	134	134	145	114	175	-10.4	-8.9	-6	-4.5	-7.5	-7.5	-7.5	47





Old Station Park Buildings
St. John Street
Horwich
Bolton
BL6 7NY, UK

Tel: +44 (0) 1204 669033

Email: sales@woodleyequipment.com

Web: www.woodleyequipment.com