WOODLEY
EQUIPMENT COMPANY LTD.

L-Pet

Veterinary Lactate Monitoring System

Precision Evaluation Study

Contents:

Approved By: _____ **Date:** 23rd August 2019

Precision Evaluation Study Report of the L-Pet Veterinary Lactate Meter

Scope and Objective

The objective of this protocol is to detail the procedures required for within-run and between-run precision testing of the L-Pet Meter. The reference method used was the L-Lactate (PAP) Kit (RANDOX, United Kingdom) that is enzymatic determination of L-lactate.

In this study, within-run tests will be performed using venous heparinised whole blood. The whole blood will be spiked to provide samples at four different lactate concentrations. Between-run tests will be performed using two levels of lactate control solutions.

The precision assay should include within-run and between-run assay. The within-run precision assay contains ten replicates of each of the four spiked whole blood lactate levels. The between-run precision tests will consist of six replicates per day at the two lactate concentrations for six days. Each sample was tested on the L-Pet Meters with the same lot of L-Pet Test Strips. All lactate concentrations were determined by the L-Lactate (PAP) Kit.

The mean (mg/dL), standard deviation (SD, mg/dL) and coefficient of variation (CV, %) will be calculated for each test set.

Materials and Equipment

- L-Pet Meters
- L-Pet Test Strips (1 Lot)
- R Check Strip
- Metertech SP8001 UV/Vis Spectrophotometer (Pathtech, Preston, Australia)
- L-Lactate (PAP) Kit (RANDOX, United Kingdom)
- Lactate Control Solution (Trinity biotech, lactate standard set, cat no. 735-11)
- Laboratory PC

Protocol

1. Sample Preparation – Venous heparinised whole blood samples are required at four lactate concentrations.
   a. Using the L-Lactate (PAP) Kit, determine the blood lactate level of all samples.
   b. Prior to the start of each test set, verify that the meters are operating properly using the appropriate method per the appropriate operator's manual.
   c. Record all the time and lactate readings on the laboratory PC next to the appropriate test device, method and number.
   d. After each test, remove the test strip and discard.
2. Within-Run Precision Testing – This portion of the precision testing will consist of ten tests at the four different lactate levels using the L-Pet Meter. All test results were recorded on a laboratory PC.

a. Obtain the required materials and equipment.
b. Record the serial number of the L-Pet Meters and the Lot No. of the L-Pet Test Strips.
c. Insert an L-Pet Test Strip into the L-Pet Meter. Place a drop of the venous heparinised whole blood with the lowest lactate concentration on the test area of the strip and wait for the test result.
d. Repeat section 2c nine times.
e. The plasma of the sample is separated by centrifugation. Add the plasma into the biochemical kit reagent to determine the lactate concentration. Repeat sections 2c-2e for blood samples with another three different lactate concentrations.

3. Between-Run Precision Testing – This portion of the precision testing will consist of six tests at the two different lactate control solutions using the L-Pet Meter. All test results were recorded on a laboratory PC.
   a. Obtain the required materials and equipment.
   b. Record the serial number of the L-Pet Meters and the Lot No. of the L-Pet Test Strips.
   c. Insert an L-Pet Test Strip into the L-Pet Meter. Place a drop of the control solution with the low lactate concentration on the test area of the strip and wait for the test result.
   d. Repeat section 3c for control solution with high level lactate concentrations.
   e. Repeat sections 3a-3d for five days (total of six days).

Acceptance Criteria

Mean CV% of within-run and between-run components of precision shall be ≤5%.

Results

Exhibit 1 of this report contains the test results for the within-run precision tests. The between-run precision test results are presented in Exhibit 2 of this report. The mean coefficient of variation for within-run precision and between-run precision is 2.5% and 2.6%, respectively.

Conclusion

Both within-run and between-run components of precision are well below the 5% coefficient of variation that is accepted in the industry.

Exhibit 1

Table 1. Within-Run Precision Test

Temp: 23.0°C RH: 41.0%	Serial Number of Meters: PL100000002 – PL100000011 Lot No. of Strips: LS001B-I			
HCT: 45%	Blood	Blood	Blood	Blood
Reference Readings	Level 1 (44.9 mg/dL)	Level 2 (67.9 mg/dL)	Level 3 (106.3 mg/dL)	Level 4 (145.8 mg/dL)
Meter No. 1	21	70	102	157
Meter No. 2	19	68	100	155
Meter No. 3	19	68	102	155
Meter No. 4	19	68	100	149
Meter No. 5	19	68	100	153
Meter No. 6	19	68	100	155
Meter No. 7	19	70	100	155
Meter No. 8	21	70	102	157
Meter No. 9	19	70	104	153
Meter No. 10	21	70	102	153
Mean	20.0	69.2	101.2	154.2
SD	1.0	1.1	1.5	2.5
CV%	5.1	1.6	1.5	1.6
mCV%	2.5			

Exhibit 2

Table 2. Between-Run Precision Test

Temp: 23 ± 3°C RH: 30-50%	Date: 03/04/2006 ~ 11/04/2006 Serial Number of Meters: PL100000002 - PL100000007											
	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6	
Control Solution	Low Level	High Level	Low Level	High Level	Low Level	High Level	Low Level	High Level	Low Level	High Level	Low Level	High Level
PL100000002	37	181	33	167	33	168	32	169	34	167	37	166
PL100000003	34	177	35	168	35	168	35	170	35	172	38	179
PL100000004	33	170	34	169	34	169	36	171	36	169	36	169
PL100000005	34	170	33	167	35	172	33	168	33	165	36	172
PL100000006	33	177	34	160	33	169	35	166	34	166	38	180
PL100000007	34	166	33	177	33	170	34	168	33	172	35	182
Mean	34.2	173.5	33.7	168.0	33.8	169.3	34.2	168.7	34.2	168.5	36.7	174.7
SD	1.3	5.2	0.7	5.0	0.9	1.4	1.3	1.6	1.1	2.8	1.1	6.0
CV%	3.9	3.0	2.2	3.0	2.7	0.8	3.9	0.9	3.1	1.6	3.0	3.4
mCV%	2.6											

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