

Repeatability Evaluation Report

Veterinary Lactate Monitoring System
Repeatability Evaluation Testing

Contents:

1. L-Pet Veterinary Lactate System

Approved By:



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Repeatability Evaluation

Protocol / Report of the L-Pet Veterinary Lactate System

Scope and Objective

The Metertech SP8001 UV/Vis Spectrophotometer (Pathtech, Preston, Australia) and L-Lactate (PAP) Kit (RANDOX, United Kingdom) will be used as the predicate device to perform a repeatability evaluation.

Tests will be performed using venous heparinised whole blood. The whole blood will be spiked to provide samples at three different lactate concentrations. The repeatability evaluation will consist of four replicates from four L-Pet Meters of each of the three spiked whole blood lactate levels. The within-run tests will be performed in one day and will consist of four replicates at the three blood lactate concentrations. Each sample will be tested on L-Pet Meters with the same lot of L-Pet Test Strips. The L-Lactate (PAP) Kit will be used to assist in attaining target blood lactate concentrations.

The accuracy of the L-Pet Meters will be verified prior to the start of each test set. The mean (mg/dL), standard deviation (SD, mg/dL) and coefficient of variation (CV, %) were also calculated for each test set.

Materials and Equipment

- L-Pet Meters
- L-Pet Test Strips (1 Lot)
- Metertech SP8001 UV/Vis Spectrophotometer (Pathtech, Preston, Australia)
- L-Lactate (PAP) Kit (RANDOX, United Kingdom)
- Laboratory PC

Test Protocol

1. Sample Preparation – Venous heparinised whole blood samples are required at the following range of the three lactate levels (21.0 mg/dL, 38.1 mg/dL and 110.3 mg/dL).
 - 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. The test conditions will be as follows:
 - Operating Temperature: 10 – 40°C
 - Relative Humidity: 30-85%
 - d. All test results will be recorded on the laboratory PC.
 - e. After each test, remove the test strip and discard.
2. This repeatability evaluation will consist of four tests at the three different lactate levels using the L-Pet Meters.
 - 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. The meter will power on automatically. Place a drop of the blood sample with the lowest lactate concentration on the test area of the strip and wait for the test result.
 - d. Repeat section 2c three times.
 - e. The plasma of the sample is separated by centrifugation. Add the plasma into the L-Lactate (PAP) Kit reagent to determine the lactate concentration.
 - f. Repeat sections 2c-2e for blood samples with another two different lactate concentrations.

Acceptance Criteria

Mean CV% of the Repeatability Evaluation shall be $\leq 5\%$.

Results

Exhibit 1 of this report contains the results for this repeatability testing. A summary table is shown in Exhibit 2. From all of the data taken together, estimates of system repeatability for the L-Pet Veterinary Lactate System were less than 5%.

Conclusion

Repeatability testing of the L-Pet Veterinary Lactate System are well below the 5% coefficient of variation that is accepted in the industry.

Exhibit 1

Table 1. Repeatability Evaluation (Level 1 Lactate Range)

Serial Number of the L-Pet Meters: PL100000002 – PL100000005				
Lot No. of the L-Pet Test Strips: LS001B-I				
Biokit Readings: 21 mg/dL		Blood HCT: 42%		24.1°C ; 51%
Meter (mg/dL)	1	2	3	4
PL100000002	21	20	22	20
PL100000003	21	21	20	21
PL100000004	21	20	22	22
PL100000005	22	21	22	20
Mean	21.3	20.5	21.5	20.8
SD	0.0	0.6	1.2	1.0
CV%	0.0	2.8	5.4	4.8

Table 2. Repeatability Evaluation (Level 2 Lactate Range)

Serial Number of the L-Pet Meters: PL100000002 – PL100000005				
Lot No. of the L-Pet Test Strips: LS001B-I				
Biokit Readings: 38.1 mg/dL		Blood HCT: 42%		24.1°C ; 51%
Meter (mg/dL)	1	2	3	4
PL100000002	40	37	36	36
PL100000003	35	39	35	37
PL100000004	36	39	37	38
PL100000005	38	37	37	38
Mean	37.3	38.0	36.3	37.3
SD	2.2	1.2	1.0	1.0
CV%	6.0	3.0	2.6	2.6

Table 3. Repeatability Evaluation (Level 3 Lactate Range)

Serial Number of the L-Pet Meters: PL100000002 – PL100000005				
Lot No. of the L-Pet Test Strips: LS001B-I				
Biokit Readings: 110.3 mg/dL		Blood HCT: 42%		24.1°C ; 51%
Meter (mg/dL)	1	2	3	4
PL100000002	105	106	107	110
PL100000003	108	102	106	105
PL100000004	105	103	108	108
PL100000005	100	106	102	105
Mean	106.0	103.7	107.0	107.7
SD	1.7	2.1	1.0	2.5
CV%	1.6	2.0	0.9	2.3

Exhibit 2

Table 4. Repeatability Evaluation (Summary)

4 Meters*4 Times (Total 16)	Level 1 (21 mg/dL)	Level 2 (38.1 mg/dL)	Level 3 (110.3 mg/dL)
Mean	21.0	37.2	105.4
SD	0.8	1.4	2.6
mCV%	3.9	3.8	2.5



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