

Veterinary Lactate Monitoring System
L-Pet Test Strip Use-Life Evaluation Testing Report

Contents:

1. L-Pet Blood Lactate Test Strip

Approved By:



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L-Pet Test Strip Use-life Evaluation

Protocol / Report of the L-Pet Veterinary Lactate System

Scope and Objective

The required specifications for the L-Pet Veterinary Lactate System require that the L-Pet Test Strip must be able to accurately detect the lactate level over its use-life. This study was conducted to demonstrate the precision and dependability of the L-Pet Test Strip over its use-life period. The test results were obtained using L-Pet Veterinary Lactate Meters.

This study consists of testing the L-Pet Test Strip in 'open bottle' and 'unopened bottle' conditions with control material (the sigma lactate standard solutions) using two different lactate levels. The 'open bottle' conditions mimic customer use conditions. The 'unopened bottle' conditions demonstrate the baseline performance of the L-Pet Test Strip. Compare the performance between the 'open bottle' and 'unopened bottle' conditions to evaluate the use-life of the L-Pet Test Strip.

All testing was conducted following the test method described in the package insert. Tests were performed in normal test mode. All the meter were checked using a Check Strip prior to testing.

Materials and Equipment

- L-Pet Meters
- L-Pet Test Strips (1 Lot)
- Lactate Control Solution (Trinity Biotech, Lactate Standard Set, Cat No. 735-11)
- R Check Strips
- Laboratory PC

Test Protocol

1. Sample Preparation

The lactate control solutions contain two levels at lactate concentrations. 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.

- a. The test conditions will be as follows:
 - **Operating Temperature** – $30 \pm 5^{\circ}\text{C}$, maintained within $\pm 2^{\circ}\text{C}$ of the starting temperature during the experiments
 - **Relative Humidity** – 30-50%
- b. All test results will be recorded on the laboratory PC.
- c. After each test, remove the test strip and discard.

2. The test strip use-life evaluation study will consist of six replicates testing both 'open bottle' and 'unopened bottle' conditions with one lot of L-Pet Test Strips, using L-Pet Meters. The test should be performed every two weeks after the first testing of two levels of lactate control concentrations over the use-life.
 - a. Obtain the required materials and equipment.
 - b. Record the serial number of the L-Pet Meters, the Lot No. of the L-Pet Test Strips and the Lot No. of the lactate control solutions.
 - c. Insert a test strip into each meter's strip port and the meter will power on automatically.
 - d. Add a drop of control solution onto the test area of the test strip and wait for the test result.
 - e. Repeat steps 2c-2d five times.
 - f. Repeat steps 2c-2e for another lactate control solution.

Acceptance Criteria

The Bias of 'open bottle' conditions compared to Day 0 'unopened bottle' conditions should fall within $\pm 20\%$.

Test Results

Table 1 shows the mean values of six 'open bottle' test strips and 'unopened bottle' test strips, respectively. Table 2 contains the bias calculation results of 'open bottle' and 'unopened bottle' conditions over the L-Pet Test Strip's use-life using two control solutions. Figure 1 shows the 'open bottle' and unopen bottle conditions of the L-Pet Test Strip with two levels of lactate control solutions.

Conclusion

The use-life of the L-Pet Test Strip is ≤ 10 weeks.

Exhibit 1

Table 1. L-Pet Test Strip use-life evaluation with the 'open bottle' vs 'unopened bottle' conditions

Test Strip Lot No.: LS001B-I	Meter S/N: PL100000002 - PL100000007					Control Solution Lot No.: N120902, N13007				
Date (Use-Life)	Lactate Level	Time (Week)								
Bottle Conditions		0	2	4	6	8	10	12	14	16
Unopened Bottle Condition	Low Level	33.5	36.5	34.2	34.2	36.6	31	33.3	35.6	32.6
Mean (mg/dL)	High Level	173.5	179.2	173.2	170	166.3	163	164.6	166	171.2
Open Bottle Condition	Low Level	33.5	33.3	33.7	33.3	26.8	29.7	32.6	35.2	28.7
Mean (mg/dL)	High Level	174	170	172	170	145	141	133.9	127	118

Exhibit 2

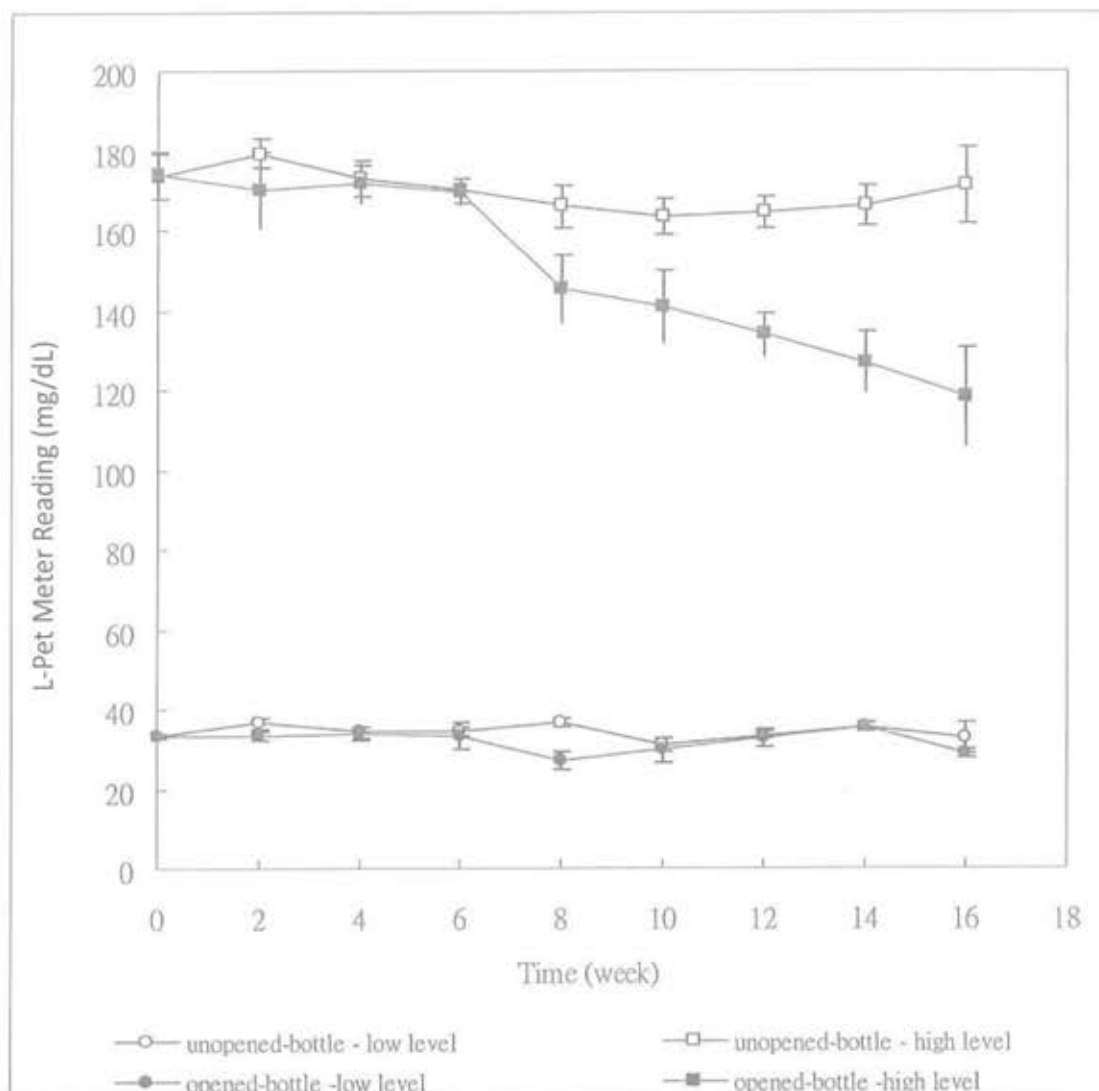
Table 2. Evaluation of the L-Pet Test Strip use-life testing

Test Strip Lot No.: LS001B-I		Meter S/N: PL100000002 - PL100000007				Control Solution Lot No.: N120902, N13007				
%Bias	Lactate Level	Time (Week)								
Bottle Conditions		0	2	4	6	8	10	12	14	16
Unopened Bottle	Low Level	0	9	2	2	9	-7	-1	6	-3
Condition	High Level	0	3	0	-2	-4	-6	-5	-4	-1
Open Bottle Condition	Low Level	0	-1	1	-1	-20	-11	-3	5	-14
Mean (mg/dL)	High Level	0	-2	-1	-2	-16	-19	-23	-27	-32

(Calculate %Bias using Day 0 'unopened bottle' as the basis)

Exhibit 3

Figure 1. The 'open bottle' and 'unopened bottle' conditions of the L-Pet Test Strip in the L-Pet Veterinary Lactate System





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