

## **Control Solution Qualification Report**

**L-Pet Lactate Screening System**

**Control Solution Qualification Test**

(Including Control Solution Concentration Verification)

Approved By:



Date: 23<sup>rd</sup> August 2019

## **Qualification of L-Pet Control Solutions**

### **For use with L-Pet Meter Test**

### **Protocol / Report**

#### **Scope and Objective**

L-Pet Control Solutions e.g. Level 1 and Level 2, are recommended to verify the performance of the L-Pet Veterinary Lactate System. The objective of this protocol is to verify the protocol to assign the concentration of each lot of control solution before release and qualify the L-Pet Control Solutions for use with the L-Pet Meter.

The requirement specifications for the L-Pet Meter require that test results using the lactate control solutions be within the specified range 95% of the time. The range for the lactate control solution is specified separately for each lot of test strips.

Lactate tests using one lot of the L-Pet Control Solutions were performed by the L-Pet Veterinary Lactate System. Three lots of L-Pet Test Strips and ten L-Pet Meters were used for all tests. Ten tests per day were performed using each of the control solutions. Testing was conducted over ten days with all test results recorded on a laboratory PC.

#### **Materials and Equipment**

- L-Pet Meters (Lot No. PL1000000010-40)
- L-Pet Test Strips (3 Lots)
- L-Pet Control Solutions Level 1 and Level 2 (1 Lot, individually)
- R Check Strip
- L-Lactate (PAP) Kit (RANDOX, United Kingdom)
- Metertech SP8001 UV/Vis Spectrophotometer (Pathtech, Preston, Australia)
- Laboratory PC

## Test Protocol

1. Verify the L-Pet Control Solution Concentration and Range Assignment
  - a. Formulate the L-Lactate (PAP) Kit into a Standard Set (Metertech SP8001 Analyser)  
L1:  $20 \pm 0.25$  mg/dL  
L2:  $50 \pm 0.25$  mg/dL
  - b. Test L-Pet Control Solution Level 1 and Level 2 with the Meter.  
The L-Lactate (PAP) Kit concentration of the L-Pet Control Solution must be within the Metertech SP8001 Spectrophotometer Analyser following range wavelength is set 550nm.  
L-Pet Lactate Control Solution Level 1: 16-49 mg/dL  
L-Pet Lactate Control Solution Level 2: 71-102 mg/dL
  - c. Perform 10 control tests with three lots of the L-Pet Test Strip on the L-Pet System with each of the Level 1 and Level 2 Control Solutions. Calculate the mean of 10 readings, the range was assigned as mean  $\pm 5\%$ .
2. L-Pet System Testing Setup
  - a. Obtain the required equipment and supplies
  - b. Record the serial numbers of the L-Pet Meters (LC9805031M, LC9805031H), the L-Pet Control Solutions and the Lot No. (LS001N) of the L-Pet Test Strips on the laboratory PC.
  - c. The test conditions will be as follows:
    - Temperature: 18-38°C
    - Humidity: 40-60%Check conditions prior to testing and every hour while testing. If test conditions are not within specification, stop testing until test conditions are within specification. In addition, repeat all testing since the last acceptable test condition check.
  - d. Verify that the meter is operating properly using the R Check Strip. If a meter fails, note the failure in the comments section of the log sheet and forward the meter(s) to service for repairs.
3. Testing
  - a. Match the code number on the meter to the test strip container. Insert the test strip.
  - b. Take the L-Pet Control Solution Level 1 and apply a drop of the solution to the test area of the L-Pet Test Strip.
  - c. In approximately 50 seconds, the lactate value will be displayed. Record the date, time and lactate reading on the PC next to the appropriate test number. Remove the strip from the meter and discard. Wait at least two minutes before starting another test.

- d. Repeat sections 3a-3c for Level 2 of the L-Pet Control Solution
- e. Repeat sections 3a-3d each day for a total of 10 days.

### **Acceptance Criteria**

95% of results shall be within the specified range.

### **Results**

The resulting lactate concentration by the L-Lactate (PAP) Kit of the L-Pet Control Solution Level 1 and Level 2 are 30 mg/dL and 85 mg/dL, respectively.

The ranges of Level 1 and Level 2 specified for the strip lot used in the L-Pet System are as follows:

| Lot    | Level 1 (mg/dL) | Level 2 (mg/dL) |
|--------|-----------------|-----------------|
| LS001L | 16-49           | 71-102          |
| LS001M | 16-49           | 71-102          |
| LS001N | 16-49           | 71-102          |

Table 1 contains a list of all test results of the L-Pet Control Solution on the L-Pet System. All test results fell within the specified ranges.

### **Conclusion**

The lactate concentration verification protocol by the L-Lactate (PAP) Kit is qualified in the L-Pet Control Solution release system.

The test results support the claim that L-Pet Control Solutions yield results that fall within their specified ranges (>95%). Since the L-Pet Control Solutions met their acceptance criteria, they are considered qualified for use with the L-Pet Meter.



Table 1. Qualification of the L-Pet Control Solutions with the L-Pet Lactate Screening System

| SN of the L-Pet Meter:<br>PL1000000010-40                                       | Specified Range (mg/dL)   |   |   |
|---|---|---|---|
| Lot of the L-Pet Control Solutions:<br>Level 1: LC980501M<br>Level 2: LC980501H | Lot of the L-Pet Strips:<br>LS001L<br>Level 1: 16-49 mg/dL<br>Level 2: 71-102 mg/dL | Lot of the L-Pet Strips:<br>LS001M<br>Level 1: 16-49 mg/dL<br>Level 2: 71-102 mg/dL | Lot of the L-Pet Strips:<br>LS001N<br>Level 1: 16-49 mg/dL<br>Level 2: 71-102 mg/dL |
| Date  | Average of Readings, mg/dL ; (Ratio of Results within Specified Ranges)             |   |   |
| 4/5/2009 (Day 1)  | L1: 32  | L1: 34  | L1: 36  |
|   | L2: 87  | L2: 90  | L2: 91  |
| 5/5/2009 (Day 2)  | L1: 34  | L1:31   | L1:34   |
|   | L2: 85  | L2: 85  | L2:92   |
| 6/5/2009 (Day 3)  | L1: 35  | L1: 32  | L1: 35  |
|   | L2: 85  | L2: 82  | L2: 85  |
| 7/5/2009 (Day 4)  | L1: 31  | L1: 35  | L1: 33  |
|   | L2: 83  | L2: 84  | L2: 84  |
| 8/5/2009 (Day 5)  | L1: 34  | L1: 31  | L1: 33  |
|   | L2: 83  | L2: 85  | L2: 83  |
| 9/5/2009 (Day 6)  | L1: 33  | L1: 33  | L1: 33  |
|   | L2: 86  | L2: 86  | L2: 86  |
| 10/5/2009 (Day 7)   | L1: 32  | L1: 33  | L1: 32  |
|   | L2: 90  | L2: 88  | L2: 86  |
| 11/5/2009 (Day 8)   | L1: 31  | L1: 34  | L1: 33  |
|   | L2: 86  | L2: 85  | L2: 84  |
| 12/5/2009 (Day 9)   | L1: 33  | L1: 34  | L1: 36  |
|   | L2: 85  | L2: 86  | L2: 82  |
| 13/5/2009 (Day 10)  | L1: 34  | L1: 32  | L1: 36  |
|   | L2: 84  | L2: 88  | L2: 83  |





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