

Control Solution Stability Report (Use-Life and Shelf Life)

**Stability Study of the Control Solution of the
L-Pet Veterinary Lactate System**

Approved By:



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Stability Study of the Control Solution of the L-Pet Veterinary Lactate System

Scope and Objective

Woodley Equipment Company Ltd intends to determine the use-life and shelf life of the control solution of the L-Pet Veterinary Lactate System to be three months and 16 months respectively. The L-Pet Control Solution is designed to be stored at 2-8°C during the shelf life. There are two levels of control solution: Level 1 (Normal – 16-49 mg/dL) and Level 2 (High – 70-102 mg/dL). This protocol used real time stability to determine the shelf life of the Level 1 (Normal) control solution and used accelerated aging by comparison to the storage behaviour of Level 1 (Normal) to determine the shelf life of Level 2 (High).

This report will contain three sections: Use-Life Stability (Stability After First Opening), the Real Time Stability of Level 1 Control Solution and Accelerated Stability of Level 1 and Level 2.

1. Use-Life Stability (Stability After First Opening)

Method

1. Three control solution lots of Level 1 and Level 2 will be evaluated in the Use-Life Stability Study.
2. Select 25 bottles of one lactate test strip lot (#LS001N) and store at 5°C.
3. Lot numbers of control solution selected to be evaluated are:
Level 1 – LC980501M, LC980502M, LC980503M
Level 2 – LC980501H, LC980502H, LC980503H
4. Randomly select ten bottles of control solution from each lot. Divide them into two groups (opened and unopened) and store at 5°C.
5. Five bottles of control solution will be selected from the unopened group. This group of control solution will not be opened before testing.
6. The opened group will contain five bottles of control solution. Each bottle will be opened and dropped one drop of control solution every other day at room temperature.
7. One bottle of control solution will be selected from the opened and unopened group. Testing on lactate test strips and lactate concentration will be performed at the end of the 1st, 2nd and 3rd month.
8. The assay bias between the opened and unopened bottles will be evaluated.

Materials and Equipment

- L-Pet Meters (5)
- L-Pet Test Strips (1 Lot)
- L-Pet Control Solution (L1 and L2 – 3 Lots)
- L-Pet Plus Reagent (RANDOX)
- SP8001 UV Spectrophotometer
- Lactate Standard Solution (RANDOX LC2389)
- Check Strips

Test Protocol

1. Sample Preparation

Calibration of SP8001 UV Spectrophotometer

- a. Using the Lactate Standard Solution, RANDOX L-Lactate (PAP) Kit and the Lactate Plus Reagent (RANDOX) for preparation of a calibration curve as the reference method.

2. Testing

- a. Set up five L-Pet Meters
- b. Record the serial number of the L-Pet Meters, the SP8001 UV Spectrophotometer and the Lot No. of the test strips and control solution.
- c. The test conditions will be as follows:
 - **Temperature** – 18-30°C
 - **Humidity** – Less than 85%Check conditions prior to each test set. If conditions are within specification, continue testing. If test conditions are not within specification, stop testing and repeat all tests since last approved condition check.
- d. 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.
- e. Select two vials of the L-Pet Test Strip, Lot No. LS001N.
- f. Insert the Check Strip to enter control mode. Remove one strip from the assigned vial and insert it into the meter.
- g. Select one of the opened bottles of control solution from one lot. Apply a drop of control solution to the test area of the L-Pet Test Strip.
- h. In approximately 50 seconds, the lactate value will be displayed. Record the result. Remove the test strip and discard.
- i. Repeat steps 2f – 2h until one of the opened and unopened bottles from each lot has been tested.
- j. Evaluate the lactate concentration of each control solution bottle tested.
- k. Calculate the assay bias between the opened and unopened bottles of control solution.

Test Results

The test results and assay bias between the opened and unopened bottles of each of the L-Pet Control Solution lot are presented below.

Figure 1. L-Pet lactate readings of opened and unopened bottles of three L-Pet Control Solution Level 1 lots

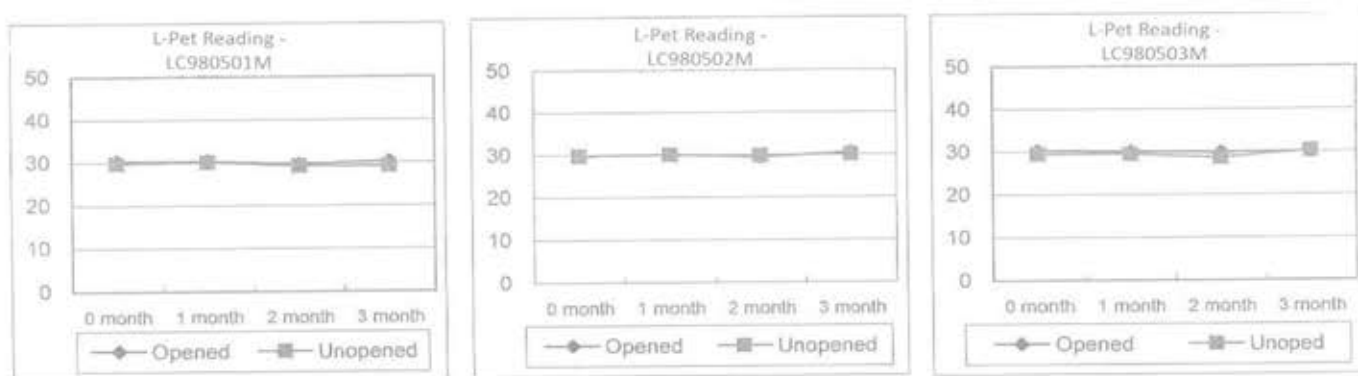


Figure 2. Lactate concentration of opened and unopened bottles determined by SP8001

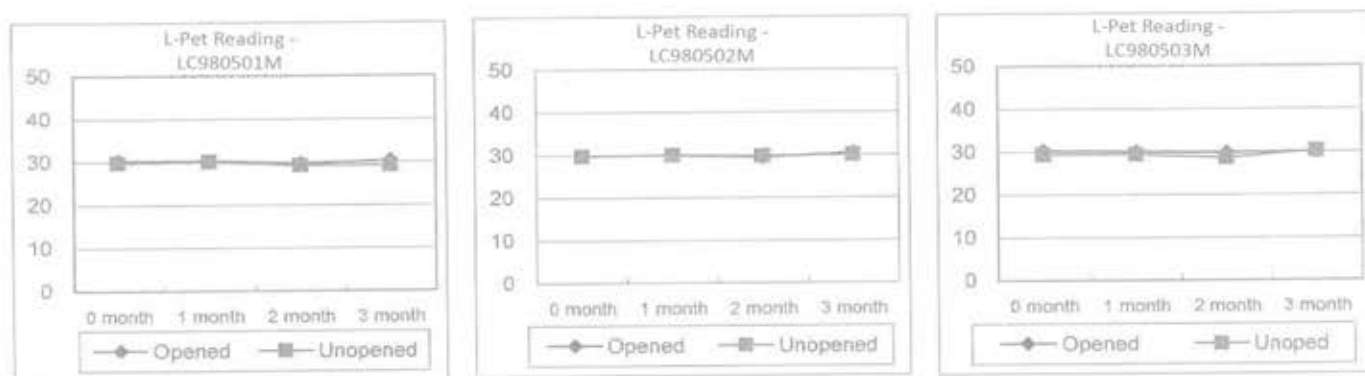


Figure 3. Lactate readings of opened and unopened bottles of three L-Pet Control Solution Level 2 lots

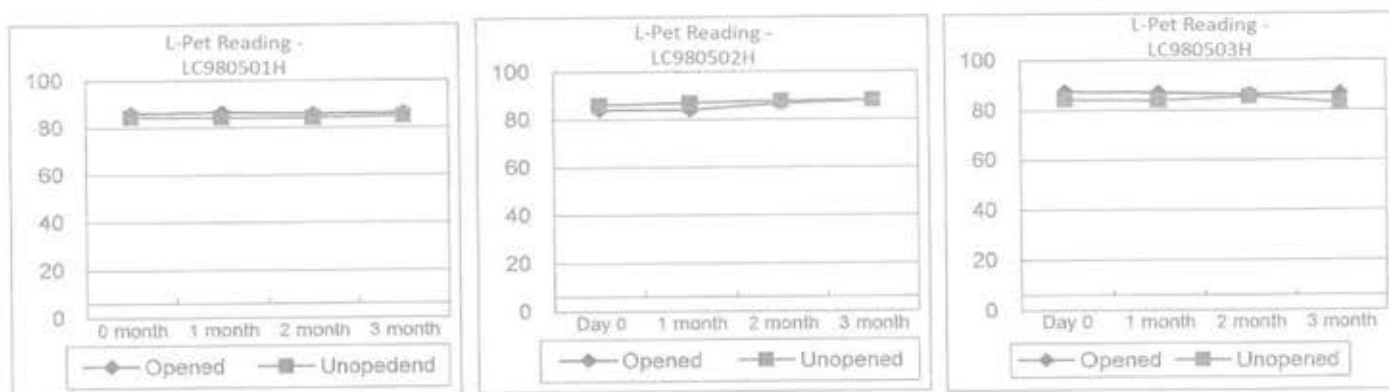
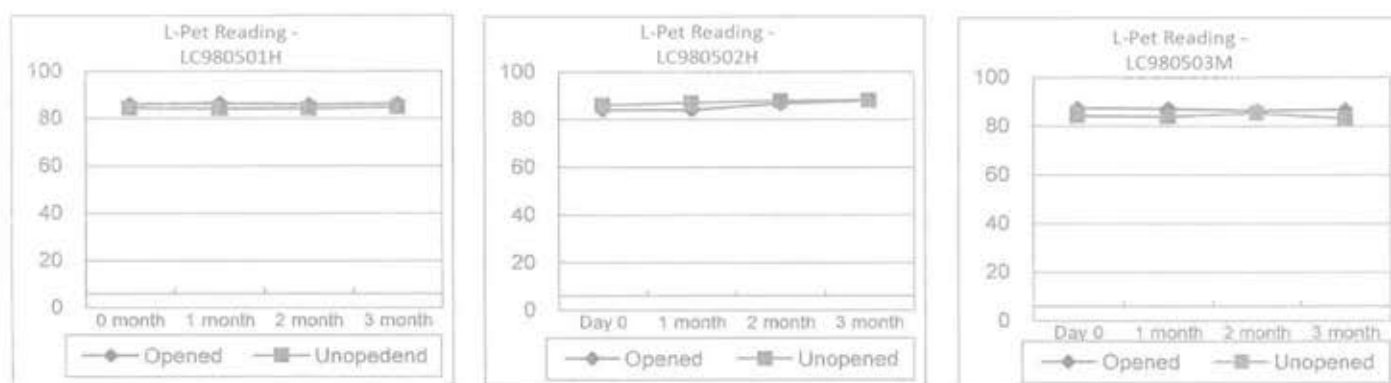


Figure 4. Lactate concentration of opened and unopened bottles determined by SP8001



Conclusion

The results show that there was no significant difference in the assay bias of unopened bottles or opened bottles stored at 5°C for up to three months. The lactate concentrations of each lot evaluated by the SP8001 Spectrophotometer have no change during the three months open period. This information supports the claim of a three months opened shelf life of control solution.

2. Real Time Stability

Method

1. Three lots of L-Pet Level 1 Control Solution, stored at 5°C, were evaluated in the Real Time Stability Study.
2. One lot of the L-Pet Test Strips were stored at 5°C to be used for evaluating the performance of the control solution.

3. Accelerated Stability

Method

1. Three lots of L-Pet Level 1 and Level 2 Control Solution were evaluated in the Accelerated Stability Study.
2. One lot of the L-Pet Test Strips were stored at 5°C, to be used for evaluating the performance of the control solution.
3. L-Pet Control Solution will be stored at 30°C for three months for the accelerated stability evaluation.
4. L-Pet Control Solution will also be stored at 5°C for the real time stability (at least 18 months) evaluation.

Materials and Equipment

- L-Pet Meters (5)
- L-Pet Test Strips (1 Lot)
- L-Pet Control Solution (L1 and L2 – 3 Lots)
- RANDOX-LAC L-Lactate (PAP) Kit
- SP8001 UV Spectrophotometer
- Check Strips

Test Protocol

1. Testing

- a. Set up five L-Pet Meters.
- b. Record the serial number of the L-Pet Meters and the Lot No. of the L-Pet Test Strips and Control Solution.
- c. The test conditions will be as follows:
 - **Temperature** – 18-30°C
 - **Humidity** – Less than 85%

Check conditions prior to each test set. If conditions are within specification, continue testing. If test conditions are not within specification, stop testing and repeat all tests since last approved condition check.

- d. 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.

- e. Insert the Check Strip to enter control mode. Remove one strip from the assigned vial and insert it into the meter.
- f. Select one bottle of control solution from one lot. Apply a drop of control solution to the test area of the L-Pet Test Strip.
- g. In approximately 50 seconds, the lactate value will be displayed. Record the result. Remove the test strip and discard.
- h. Repeat steps 1e-1g until one bottle from each lot has been tested.

2. Results Analysis

a. For Real Time Stability Test

Calculate the assay average of each storage period of each lot. Plot the real time stability graph.

b. For Accelerated Stability Test

Calculate the assay average at 5°C and 30°C of each lot. Plot the stability graph. The assay %Bias for L-Pet readings between the accelerated 30°C and the 5°C for the control solution will be calculated.

Acceptance Criteria

L-Pet Control Solution Level 1: Lactate Readings – 16-49 mg/dL

L-Pet Control Solution Level 2: Lactate Readings – 71-102 mg/dL

Test Results

1. Real Time Stability of the L-Pet Control Solution Level 1

Test results on the Real Time Stability of the L-Pet Control Solution Level 1 are presented in Exhibit 2.

Figure 5 presented the assay average of each storage period of the L-Pet Control Solution Level 1 up to 18 months. All the results were within 16-49 mg/dL reading range.

2. Accelerated Stability of the L-Pet Control Solution Level 1 and Level 2

Test results on the Accelerated Stability of L-Pet Control Solution Level 1 and Level 2 are presented in Exhibit 3.

Figure 6 presented the assay average at 5°C and 30°C of each storage period of L-Pet Control Solution Level 1. All the results were within 16-49 mg/dL reading range.

Figure 7 presented the assay average at 5°C and 30°C of each storage period of the L-Pet Control Solution Level 2. All the results were within 71-102 mg/dL reading range.

Figure 8 presented the assay %Bias between the accelerated 30°C and the 5°C of the L-Pet Control Solution Level 1 and Level 2.

3. Real Time Stability of the L-Pet Control Solution Level 1 and Level 2

Test results on the Real Time Stability of the L-Pet Control Solution Level 1 and Level 2 up to two months are presented in Exhibit 4.

Figure 9 presented the assay average of each storage period of the L-Pet Control Solution Level 1 and Level 2 up to three months. All the test results are within 16-49 mg/dL for Level 1 and within 71-102 mg/dL for Level 2.

Conclusion

The shelf life of the predicate L-Pet Control Solution Level 1 has a shelf life of 16 months. From the accelerated aging studies, the assay %Bias of control solution Level 1 is about -18%, for Level 2 it is about -18%. This concludes that the L-Pet Control Solution Level 2 has a shelf life of 16 months.

The Real Time Stability is carried out from 0 months and will be continued for up to 12 months.

Figure 5. The assay results of Real Time Stability of the L-Pet Control Solution Level 1 are shown below

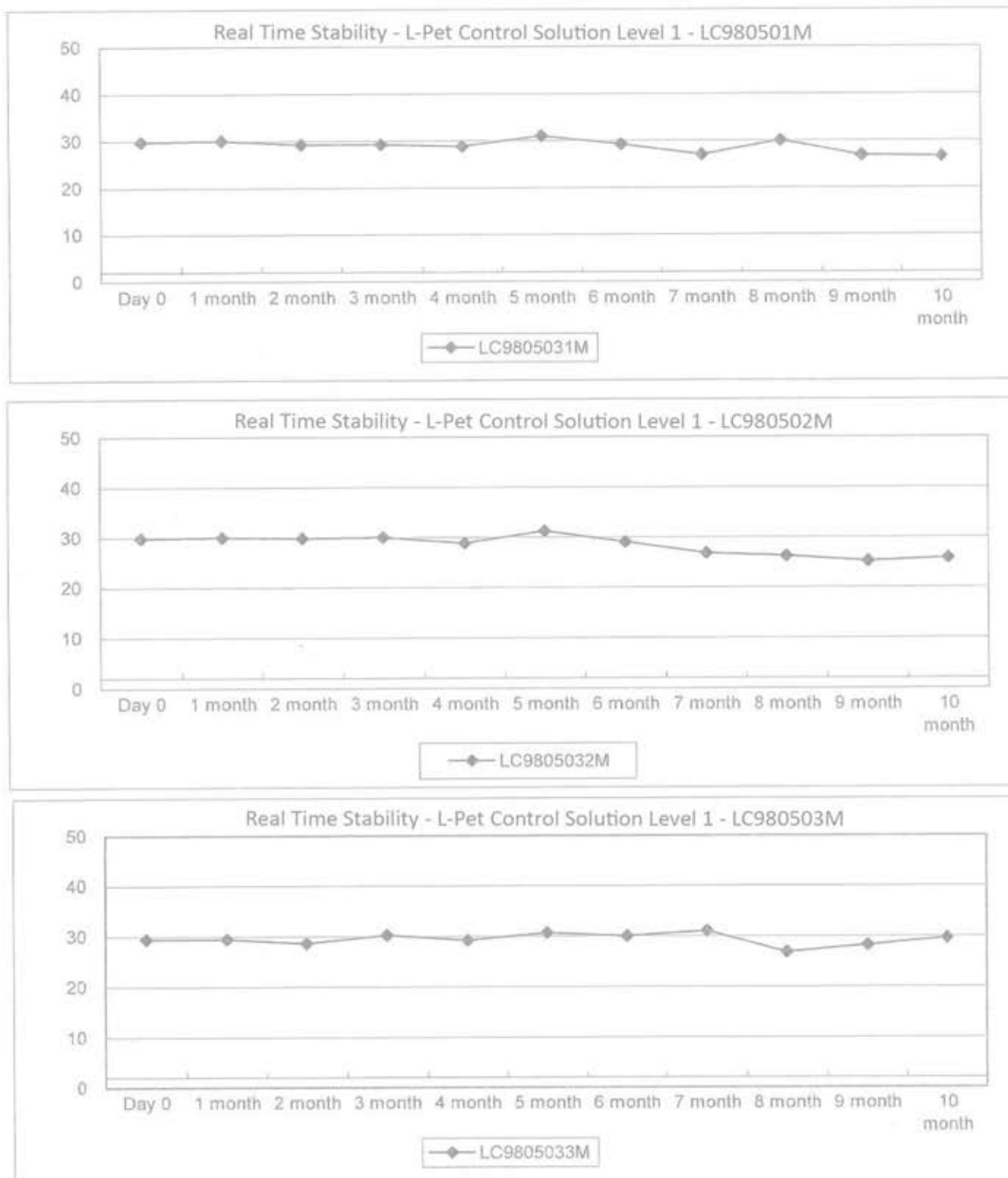


Figure 6. The assay results of Accelerated Stability of L-Pet Control Solution Level 1 are shown below

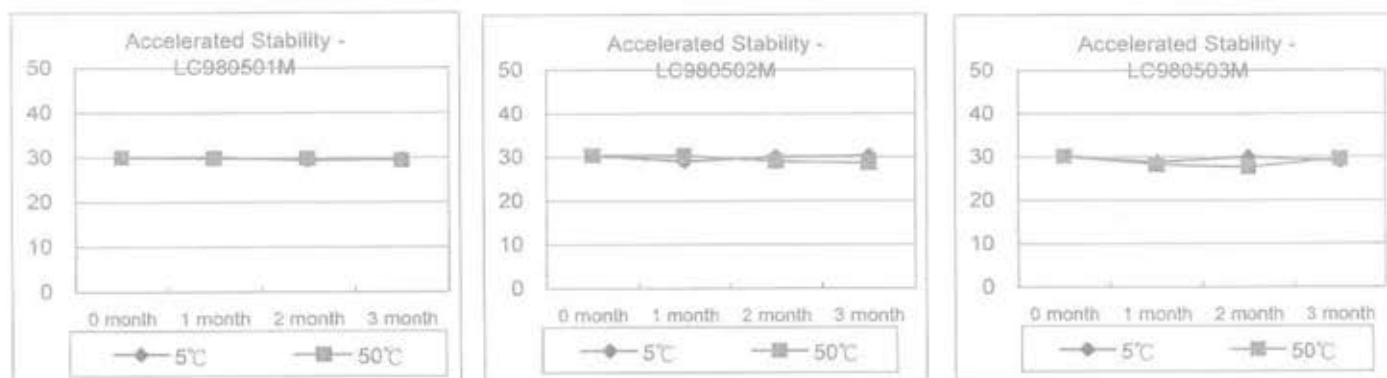


Figure 7. The assay results of Accelerated Stability of the L-Pet Control Solution Level 2 are shown below.

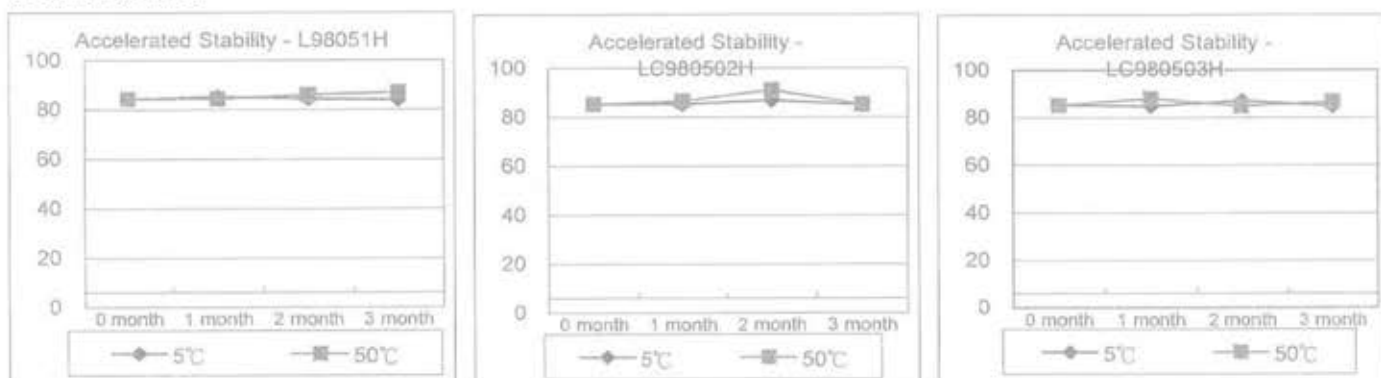
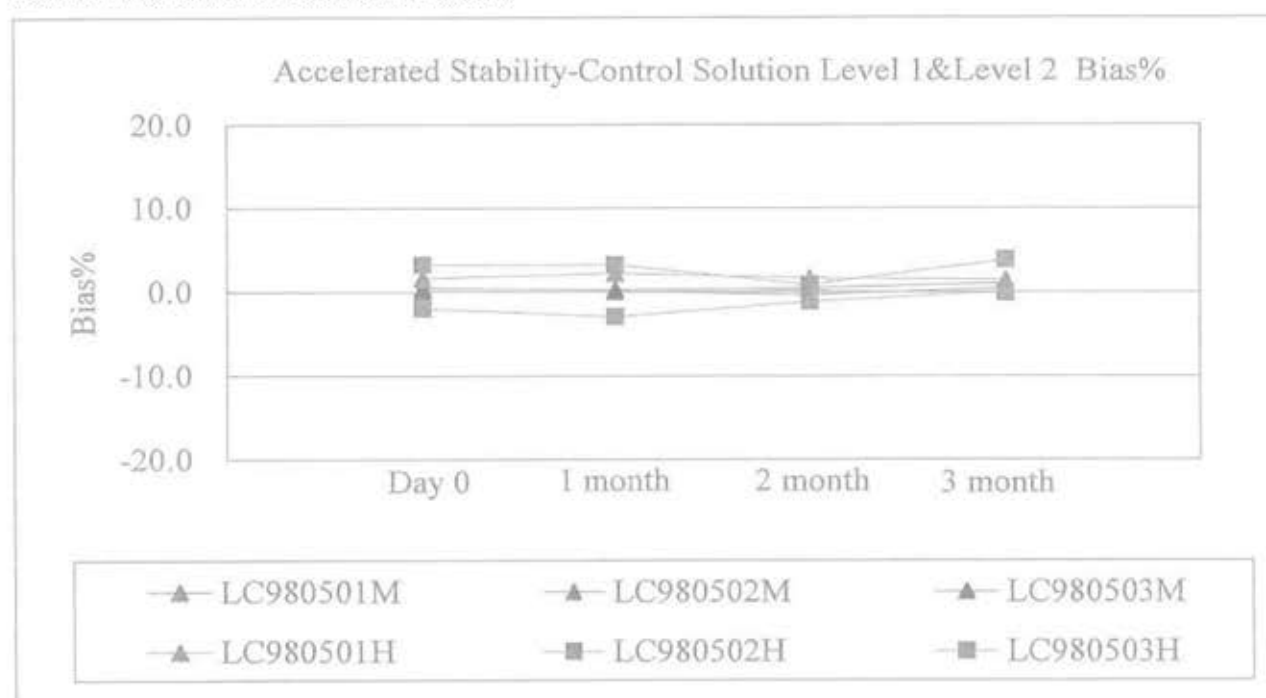


Figure 8. Assay %Bias between the accelerated 30°C and the 5°C of L-Pet Control Solution Level 1 and Level 2 are shown below



Data of Use-Life Stability

L-Pet Test Strip Lot No.: LS001N

L-Pet Meter 1 S/N: H000000091

L-Pet Meter 2 S/N: H000000092

L-Pet Meter 3 S/N: H000000093

L-Pet Meter 4 S/N: H000000094

L-Pet Meter 5 S/N: H000000095

Lot No.: LC980501M								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	30.0	30	29.0	30.0	30.0	30.0	30	29
Meter 2	30.0	31	29	30.0	30.0	30.0	28	28
Meter 3	30.0	30	30	30.0	30.0	29.0	28	30
Meter 4	30.0	30	30	30.0	29.0	31.0	30	29
Meter 5	31.0	30	30	31.0	30.0	30.0	30	30
Mean	30.2	30.2	29.6	30.2	29.8	30.0	29.2	29.2
SD	0.45	0.45	0.55	0.45	0.45	0.71	1.1	0.84
CV	1.5%	1.5%	1.9%	1.5%	1.5%	2.4%	3.8%	2.9%

Lot No.: LC980502M								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	30.0	30	30	31	30.0	30.0	29	30
Meter 2	30.0	29	29	30	30.0	31.0	30	30
Meter 3	31.0	30	28	30	31.0	30.0	29	31
Meter 4	30.0	31	30	31	30.0	29.0	30	29
Meter 5	28.0	30	30	30	28.0	30.0	31	30
Mean	29.8	30.0	29.4	30.4	29.8	30.0	29.8	30.0
SD	1.10	0.71	0.89	0.55	1.10	0.71	0.84	0.71
CV	3.7%	2.4%	3.0%	1.8%	3.7%	2.4%	2.8%	2.4%

Lot No.: LC980503M								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	30.0	30	31.0	30	30.0	30.0	28	29
Meter 2	30.0	29	29.0	30	30.0	28.0	28	31
Meter 3	31.0	29	30.0	31	30.0	30.0	29	30
Meter 4	30.0	30	29.0	29	28.0	30.0	28	31
Meter 5	30.0	31	30.0	30	29.0	29.0	30	30
Mean	30.2	30.0	29.8	30.0	29.4	29.4	28.6	30.2
SD	0.45	0.71	0.84	0.71	0.89	0.89	0.89	0.84
CV	1.5%	2.4%	2.8%	2.4%	3.0%	3.0%	3.1%	2.8%

Lot No.: LC980501H								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	85.0	85.0	88	87	87.0	85.0	86	87.0
Meter 2	86.0	86.0	85	85	85.0	85.0	83	85.0
Meter 3	88.0	86.0	85	90	84.0	83.0	84	83.0
Meter 4	85.0	87.0	86	84	84.0	85.0	85	84.0
Meter 5	86.0	88.0	85	85	82.0	83.0	83	85.0
Mean	86.0	86.4	85.8	86.2	84.4	84.2	84.2	84.8
SD	1.22	1.14	1.30	2.39	1.82	1.10	1.30	1.48
CV	1.4%	1.3%	1.5%	2.8%	2.2%	1.3%	1.5%	1.7%

Lot No.: LC980502H								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	85.0	83.0	87	88	87.0	86.0	87	89.0
Meter 2	82.0	85.0	87	85	92.0	87.0	87	92.0
Meter 3	84.0	84.0	86	86	88.0	86.0	88	88.0
Meter 4	83.0	85.0	87	88	84.0	86.0	89	85.0
Meter 5	86.0	83.0	86	84	85.0	86.0	88	86.0
Mean	84.0	84.0	86.6	88.0	86	87.0	87.8	88.0
SD	1.58	1.00	0.55	1.79	3.11	0.45	0.84	2.74
CV	1.9%	1.2%	0.6%	2.0%	3.6%	0.5%	1.0%	3.1%

Lot No.: LC980503H								
	Opened				Unopened			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	85.0	89.0	88	88	87.0	85.0	83	83.0
Meter 2	87.0	87.0	85	88	82.0	84.0	86	83.0
Meter 3	88.0	88.0	85	87	83.0	82.0	87	84.0
Meter 4	90.0	83.0	85	88	84.0	85.0	88	82.0
Meter 5	87.0	88.0	88	83	85.0	83.0	83	83.0
Mean	87.4	87.0	86.2	86.8	84.2	83.8	85.4	83.0
SD	1.82	2.35	1.64	2.17	1.92	1.30	2.30	0.71
CV	2.1%	2.7%	1.9%	2.5%	2.3%	1.6%	2.7%	0.9%

Bias Between Opened vs Unopened				
	0 month	1 month	2 month	3 month
	03/06/2009	03/07/2009	03/08/2009	04/09/2009
LC980501M	0.4	0.2	0.4	1.0
LC980502M	0.0	0.0	-0.4	0.4
LC980503M	0.0	0.0	0.1	-0.2
LC980501H	1.6	2.2	1.6	1.4
LC980502H	-2.0	-3.0	-1.2	0.0
LC980503H	3.2	3.2	0.8	3.8

Date of Accelerated Stability – L-Pet Control Solution Level 1 and Level 2

L-Pet Test Strip Lot No.: LS001L

L-Pet Meter 1 S/N: H000000096

L-Pet Meter 2 S/N: H000000097

L-Pet Meter 3 S/N: H000000098

L-Pet Meter 4 S/N: H000000099

L-Pet Meter 5 S/N: H000000100

Lot No.: LC980501M - L1								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	30.0	30.0	29.0	29.0	30.0	31.0	29.0	28.0
Meter 2	30.0	31.0	28.0	29.0	30.0	28.0	29.0	29.0
Meter 3	30.0	30.0	30.0	29.0	30.0	30.0	30.0	30.0
Meter 4	30.0	29.0	30.0	30.0	30.0	30.0	30.0	31.0
Meter 5	30.0	30.0	30.0	31.0	30.0	30.0	31.0	29.0
Mean	30.0	30.0	29.4	29.6	30.0	29.8	29.8	29.4
SD	0.00	0.71	0.89	0.89	0.00	1.10	0.84	1.14
CV	0.0%	2.4%	3.0%	3.0%	0.0%	3.7%	2.8%	3.9%

Lot No.: LC980502M - L1								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	31.0	30	30.0	31.0	31.0	31.0	29.0	28.0
Meter 2	31.0	28	31	31.0	31.0	30.0	28.0	30.0
Meter 3	31.0	29	30	29.0	31.0	30.0	26.0	27.0
Meter 4	29.0	29.0	30	30.0	29.0	30.0	28.0	30.0
Meter 5	30.0	28	29.0	30.0	30.0	31.0	28.0	28.0
Mean	30.4	29.0	30.0	30.2	30.4	30.4	29.0	28.6
SD	0.89	0.71	0.71	0.84	0.89	0.55	1.10	1.34
CV	2.9%	2.4%	2.4%	2.8%	2.9%	1.8%	3.8%	4.7%

Lot No.: LC980503M - L1								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	30.0	29.0	30.0	29.0	30.0	28.0	29.0	28.0
Meter 2	30.0	28.0	30	29.0	30.0	28.0	28.0	29.0
Meter 3	30.0	29.0	30	28.0	30.0	29.0	26.0	30.0
Meter 4	31.0	29.0	31	29.0	31.0	28.0	27.0	30.0
Meter 5	30.0	29.0	29.0	30.0	30.0	28.0	28.0	31.0
Mean	30.2	28.8	30.0	29.0	30.2	28.2	27.6	29.6
SD	0.45	0.45	0.71	0.71	0.45	0.45	1.14	1.14
CV	1.5%	1.6%	2.4%	2.4%	1.5%	1.6%	4.1%	3.9%

Lot No.: LC980501H - L2								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	85.0	86	85.0	85.0	85.0	87.0	86	90
Meter 2	84.0	83	84	84.0	84.0	85.0	85	85
Meter 3	84.0	87	85	85.0	84.0	84.0	88	86
Meter 4	85.0	85.0	85	83.0	85.0	83.0	85	88
Meter 5	83.0	85.0	83.0	83.0	83.0	83.0	86	86
Mean	84.2	85.2	84.4	84.0	84.2	84.4	86.0	87.0
SD	0.84	1.48	0.89	1.00	0.84	1.67	1.22	2.00
CV	1.0%	1.7%	1.1%	1.2%	1.0%	2.0%	1.4%	2.3%

Lot No.: LC980502H - L2								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	86.0	85.0	89.0	86.0	86.0	87.0	88.0	88.0
Meter 2	85.0	85.0	90.0	83.0	85.0	85.0	87.0	83.0
Meter 3	84.0	83.0	85.0	85.0	84.0	86.0	83.0	82.0
Meter 4	85.0	85.0	85.0	86.0	85.0	87.0	85.0	85.0
Meter 5	86.0	88.0	85.0	85.0	86.0	88.0	90.0	88.0
Mean	85.2	85.2	86.8	85.0	85.2	86.6	91.0	85.2
SD	0.84	1.79	2.49	1.22	0.84	1.14	2.70	2.77
CV	1.0%	2.1%	2.9%	1.4%	1.0%	1.3%	3.0%	3.3%

Lot No.: LC980503H - L2								
	5°C				50°C			
	0 month	1 month	2 month	3 month	0 month	1 month	2 month	3 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/09/2009	03/06/2009	03/07/2009	03/08/2009	04/09/2009
Meter 1	85.0	86.0	89.0	86.0	85.0	82.0	83.0	88.0
Meter 2	86.0	85.0	88.0	83.0	86.0	90.0	87.0	86.0
Meter 3	85.0	83.0	86.0	86.0	85.0	86.0	85.0	88.0
Meter 4	82.0	82.0	87.0	86.0	82.0	92.0	86.0	85.0
Meter 5	88.0	88.0	85.0	83.0	88.0	90.0	83.0	86.0
Mean	85.2	84.8	87.0	84.8	85.2	88.0	84.8	86.7
SD	2.17	2.39	1.58	1.64	2.17	4.00	1.79	1.34
CV	2.5%	2.8%	1.8%	1.9%	2.5%	4.5%	2.1%	1.5%

	Bias Between 5°C vs 50°C			
	0 month	1 month	2 month	3 month
	03/06/2009	03/07/2009	03/08/2009	04/09/2009
LC980501M - L1	0%	-1%	1%	-1%
LC980502M - L1	0%	5%	-3%	-5%
LC980503M - L1	0%	-2%	-8%	2%
LC980501H - L2	0%	-1%	2%	4%
LC980502H - L2	0%	2%	5%	0%
LC980503H - L2	0%	4%	-3%	2%

Date of Real Time Stability of Control Solution Level 1

L-Pet Meter 1 S/N: H000000091

L-Pet Meter 2 S/N: H000000092

L-Pet Meter 3 S/N: H000000093

L-Pet Meter 4 S/N: H000000094

L-Pet Meter 5 S/N: H000000095

Lot No.: LC9805031M		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	30.0	30.0	30.0	29.0	30.0	32.0	28.0	27.0	28.0	28.0	27.0
Meter 2	30.0	30.0	28.0	28.0	28.0	33.0	28.0	26.0	29.0	26.0	26.0
Meter 3	30.0	29.0	28.0	30.0	27.0	32.0	29.0	28.0	30.0	28.0	25.0
Meter 4	29.0	31.0	30.0	29.0	29.0	30.0	30.0	26.0	32.0	26.0	26.0
Meter 5	30.0	30.0	30.0	30.0	30.0	28.0	31.0	28.0	31.0	26.0	29.0
Mean	29.6	30	29.2	29.2	28.8	31	29.2	27	30	26.8	26.6
SD	0.45	0.71	1.10	0.84	1.30	2.0	1.3	1.0	1.6	1.1	1.5
CV	1.5%	2.4%	3.8%	2.9%	4.5%	0.1	0.0	0.0	0.1	0.0	0.1

Lot No.: LC9805032M		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	30.0	30.0	29.0	30.0	30.0	32.0	28.0	26.0	26.0	25.0	26.0
Meter 2	30.0	31.0	30.0	30.0	28.0	33.0	28.0	26.0	26.0	26.0	27.0
Meter 3	31.0	30.0	29.0	31.0	27.0	32.0	29.0	28.0	25.0	24.0	26.0
Meter 4	30.0	29.0	30.0	29.0	29.0	30.0	29.0	26.0	26.0	25.0	25.0
Meter 5	28.0	30.0	31.0	30.0	30.0	29.0	31.0	28.0	28.0	26.0	25.0
Mean	29.8	30.0	29.8	30.0	28.8	31.2	29.0	26.8	26.2	25.2	25.8
SD	1.10	0.71	0.84	0.71	1.30	1.64	1.22	1.10	1.10	0.84	0.84
CV	3.7%	2.4%	2.8%	2.4%	4.5%	5.3%	4.2%	4.1%	4.2%	3.3%	3.2%

Lot No.: LC9805033M		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	30.0	30.0	28.0	29.0	29.0	31.0	29.0	31.0	25.0	26.0	30.0
Meter 2	30.0	28.0	28.0	31.0	29.0	31.0	29.0	30.0	28.0	28.0	31.0
Meter 3	30.0	30.0	29.0	30.0	29.0	32.0	31.0	31.0	28.0	30.0	28.0
Meter 4	28.0	30.0	28.0	31.0	29.0	31.0	30.0	31.0	27.0	29.0	29.0
Meter 5	29.0	29.0	30.0	30.0	30.0	28.0	31.0	32.0	26.0	28.0	30.0
Mean	29.4	29.4	28.6	30.2	29.2	30.6	30.0	31.0	26.8	28.2	29.6
SD	0.89	0.89	0.89	0.84	0.45	1.52	1.00	0.71	1.30	1.48	1.14
CV	3.0%	3.0%	3.1%	2.8%	1.5%	5.0%	3.3%	2.3%	4.9%	5.3%	3.9%

Lot No.: LC980501H L2		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	87.0	83.0	85.0	83.0	90.0	88.0	82.0	86.0	85.0	88.0	91.0
Meter 2	85.0	85.0	84.0	85.0	88.0	86.0	85.0	85.0	86.0	86.0	90.0
Meter 3	86.0	83.0	85.0	86.0	91.0	85.0	86.0	86.0	89.0	90.0	83.0
Meter 4	85.0	85.0	84.0	89.0	88.0	84.0	88.0	84.0	90.0	92.0	85.0
Meter 5	87.0	86.0	85.0	88.0	86.0	83.0	87.0	88.0	92.0	92.0	90.0
Mean	86.0	84.4	84.6	86.2	88.6	85.2	85.6	85.8	88.4	89.6	87.8
SD	1.00	1.34	0.55	2.39	1.95	1.92	2.30	1.48	2.88	2.61	3.56
CV	1.2%	1.6%	0.6%	2.8%	2.2%	2.3%	2.7%	1.7%	3.3%	2.9%	4.1%

Lot No.: LC980502H L2		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	87.0	86.0	88.0	88.0	85.0	85.0	89.0	87.0	90.0	88.0	90.0
Meter 2	85.0	85.0	90.0	85.0	86.0	84.0	88.0	85.0	9.0	82.0	91.0
Meter 3	85.0	83.0	90.0	86.0	87.0	80.0	83.0	84.0	86.0	83.0	92.0
Meter 4	85.0	85.0	88.0	90.0	90.0	83.0	90.0	83.0	87.0	85.0	85.0
Meter 5	85.0	86.0	89.0	92.0	92.0	82.0	86.0	82.0	87.0	86.0	86.0
Mean	85.4	85.0	89.0	88.2	88.0	82.8	87.2	84.2	88.4	84.8	88.8
SD	0.89	1.22	1.00	2.86	2.92	1.92	2.77	1.92	2.51	2.39	3.11
CV	1.0%	1.4%	1.1%	3.2%	3.3%	2.3%	3.2%	2.3%	2.8%	2.8%	3.5%

Lot No.: LC980503H L2		L-Pet Test Strip Lot No.: LS001L									
	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month	8 month	9 month	10 month
Test Date	03/06/2009	03/07/2009	03/08/2009	04/10/2009	05/12/2009	06/09/2009	07/09/2009	08/09/2009	09/09/2009	10/09/2009	11/09/2009
Meter 1	84.0	88.0	86.0	84.0	86.0	83.0	88.0	88.0	90.0	88.0	88.0
Meter 2	83.0	86.0	88.0	85.0	87.0	85.0	89.0	90.0	85.0	89.0	83.0
Meter 3	85.0	89.0	86.0	83.0	88.0	85.0	86.0	91.0	91.0	93.0	86.0
Meter 4	86.0	88.0	85.0	85.0	85.0	85.0	85.0	84.0	89.0	85.0	91.0
Meter 5	87.0	87.0	86.0	85.0	86.0	90.0	90.0	90.0	90.0	92.0	90.0
Mean	85.0	87.6	86.2	84.4	86.4	85.6	87.6	88.6	89.0	89.4	87.6
SD	1.58	1.14	1.10	0.89	1.14	2.61	2.07	2.79	2.35	3.21	3.21
CV	1.9%	1.3%	1.3%	1.1%	1.3%	3.0%	2.4%	3.2%	2.6%	3.6%	3.7%



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