

October 17, 2006

Mr. Dennis Lawyer
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

RE: NRC License Number 37-30229-01
Docket Number: 03033881
Control Number: 138463

Dear Dennis:

As you requested, we have completed both one hundred percent scanning and wipe testing of our Radioisotope Laboratory and the Tissue Culture Laboratory. The testing did not indicate any level of contamination in either laboratory.

The scanning test was completed with 2 Ludlum Model 3 Detectors. Calibration information for each instrument is included in Attachment 1.

A description of the scanning procedure and the results are outlined in "Survey of Radiation Lab", Attachment 2.

A total of 18 wipe tests were completed for the lab areas. The sampling description, area sampled and area map indicating the location of each sample is included in "Radiological Survey Data Sheet – Removable Contamination," Attachment 3.

The wipe samples were sent to Eberline Services of Richmond, California, for analysis. The results of the analysis are included in "Eberline Services Analysis Results," Attachment 4.

I believe this completes all of the requirements for testing and the submission of records for the decommissioning of our laboratory. Please call me if you need additional information.

Respectfully,



Paul G. Diorio
Director – Safety, Health and Security
West Pharmaceutical Services

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West Pharmaceutical Services
NRC License Number 37-30229-01
Docket Number: 03033881
Control Number: 138463

ATTACHMENT 1

LUDLUM MODEL 3 CALIBRATION INFORMATION



Designer and Manufacturer
of
Scientific and Industrial
Instruments

CERTIFICATE OF CALIBRATION

LUDLUM MEASUREMENTS, INC.

POST OFFICE BOX 810 PH. 325-235-5494
501 OAK STREET FAX NO. 325-235-4672
SWEETWATER, TEXAS 79556, U.S.A.

TOMER WEST PHARMACEUTICAL SERVICES

ORDER NO. 259885 / 304228

Ludlum Measurements, Inc. Model 3 Serial No. 120200
Ludlum Measurements, Inc. Model 44-9 Serial No. PR-122408

Date 26-Jul-06 Cal Due Date 26-Jul-07 Cal. Interval 1 Year Meterface 202-608

mark ☒ applies to applicable instr. and/or detector IAW mfg. spec. T. 72 °F RH 44 % Alt 702.8 mm Hg

New Instrument Instrument Received ☐ Within Toler. +10% ☐ 10-20% ☐ Out of Tol. ☒ Requiring Repair ☐ Other-See comments

Mechanical ck. ☒ Meter Zeroed ☐ Background Subtract ☐ Input Sens. Linearity
F/S Resp. ck. ☒ Reset ck. ☐ Window Operation ☒ Geotropism
Audio ck. ☐ Alarm Setting ck. ☒ Batt. ck. (Min. Volt) 2.2 VDC

Calibrated in accordance with LMI SOP 14.8 rev 12/05/89. ☒ Calibrated in accordance with LMI SOP 14.9 rev 02/07/97.

Instrument Volt Set 900 V Input Sens. 33 mV Det. Oper. 900 V at 33 mV Threshold mV
Dial Ratio =

☐ HV Readout (2 points) Ref./Inst. / V Ref./Inst. / V

REMARKS:

37 ~ 1 µCi check source SN 2507 reads ~ 11 mR/hr when protective screen of 44-9 is
placed flat against open source holder. (1.1 mR/hr at x 10)

37 ~ 1 µCi check source SN 2507 reads ~ 49 K cpm when crystal end of 44-3 is placed
against open source holder. (4900 cpm at x 10)

AS FOUND READING TAKEN, REPAIR.

Calibration: GM detectors positioned perpendicular to source except for M 44-9 in which the front of probe faces source.

RANGE/MULTIPLIER	REFERENCE CAL. POINT	INSTRUMENT REC'D "AS FOUND READING"	INSTRUMENT METER READING*
X 100	150 mR/hr	<u>11</u>	<u>1.5</u>
X 100	50 mR/hr	<u>3.3</u>	<u>0.5</u>
X 10	15 mR/hr	<u>1.1</u>	<u>1.5</u>
X 10	5 mR/hr	<u>0.33</u>	<u>0.5</u>
X 1	1.5 mR/hr = <u>4850 cpm</u>	<u>1.5</u>	<u>1.5</u>
X 1	1.0 mR/hr	<u>1.0</u>	<u>1.0</u>
X 0.1	<u>485</u> cpm	<u>0.15</u>	<u>1.5</u>
X 0.1	<u>162</u> cpm	<u>0.05</u>	<u>0.5</u>

*Uncertainty within ± 10% C.F. within ± 20%

X 0.1 Range(s) Calibrated Electronically

REFERENCE CAL. POINT	INSTRUMENT RECEIVED	INSTRUMENT METER READING*	Log Scale	REFERENCE CAL. POINT	INSTRUMENT RECEIVED	INSTRUMENT METER READING*
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Measurements, Inc. certifies that the above instrument has been calibrated by standards traceable to the National Institute of Standards and Technology, or to the calibration facilities of International Standards Organization members, or have been derived from accepted values of natural physical constants or have been derived by the ratio type of calibration techniques. Calibration system conforms to the requirements of ANSI/NCCL Z540-1-1994 and ANSI N323-1978 State of Texas Calibration License No. LO-1963

Reference Instruments and/or Sources: ☐ S-394 ☐ 1122 ☐ 781

7 Gamma S/N ☒ 1162 ☐ G112 ☐ M565 ☐ 5105 ☐ T1008 ☐ T879 ☒ E552 ☐ E551 ☐ 720 ☐ 734 ☐ 1616 ☐ Neutron Am-241 Be S/N T-304

Alpha S/N ☐ Beta S/N ☒ Other I¹²⁹ SN 1058-60

mm 500 S/N 189506 ☐ Oscilloscope S/N ☒ Multimeter S/N 57390613

Calibrated By: William Tinsley Date 26-July-06

Reviewed By: W. Tinsley Date 26 July 06

Designer and Manufacturer
of
Scientific and Industrial
Instruments

LUDLUM MEASUREMENTS, INC.
POST OFFICE BOX 810 PH. 325-235-5494
501 OAK STREET FAX NO. 325-235-4672
SWEETWATER, TEXAS 79556, U.S.A.

Bench Test Data For Detector

Detector 44-3 Serial No. PR-123252

Customer WEST PHARMACEUTICAL SERVICES

Order #. 259885 / 304228

Counter 3 Serial No. 120200

Counter Input Sensitivity: 33 mV

Count Time 6m

Distance Source to Detector Surface

Other _____

[illegible]

Signature William Tinsley

Date 26-July-06



Designer and Manufacturer
of
Scientific and Industrial
Instruments

CERTIFICATE OF CALIBRATION

LUDLUM MEASUREMENTS, INC.
POST OFFICE BOX 810 PH. 325-235-5494
501 OAK STREET FAX NO. 325-235-4672
SWEETWATER, TEXAS 79556, U.S.A.

CUSTOMER WEST PHARMACEUTICAL SERVICES ORDER NO. 257955 / 303659
Mfg. Ludlum Measurements, Inc. Model 3 Serial No. 120333
Mfg. Ludlum Measurements, Inc. Model 44-9 Serial No. PR-122412
Cal. Date 3-Jul-06 Cal Due Date 3-Jul-07 Cal. Interval 1 Year Meterface 202-608

Check mark ☒ applies to applicable instr. and/or detector IAW mfg. spec. T. 72 °F RH 45 % Alt 702.8 mm Hg

- ☐ New Instrument ☐ Instrument Received ☐ Within Toler. $\pm 10\%$ ☐ 10-20% ☐ Out of Tol. ☒ Requiring Repair ☐ Other-See comments
- ☒ Mechanical ck. ☒ Meter Zeroed ☐ Background Subtract ☐ Input Sens. Linearity
☒ F/S Resp. ck. ☒ Reset ck. ☐ Window Operation ☒ Geotropism
☐ Audio ck. ☐ Alarm Setting ck. ☒ Batt. ck. (Min. Volt) 2.2 VDC
☐ Calibrated in accordance with LMI SOP 14.8 rev 12/05/89. ☒ Calibrated in accordance with LMI SOP 14.9 rev 02/07/97.

Instrument Volt Set 900 V Input Sens. 31 mV Det. Oper. 900 V at 31 mV Threshold mV
Dial Ratio =
☐ HV Readout (2 points) Ref./Inst. / V Ref./Inst. / V

COMMENTS:

Cs-137 ≈ 1 μ Ci check source SN 2305 reads \approx 8 mR/hr when protective screen of 44-9 is placed flat against open source holder.
(0.8 mR/hr at X10)

NO AS FOUND READING TAKEN, REPAIR.

Gamma Calibration: GM detectors positioned perpendicular to source except for M 44-9 in which the front of probe faces source.

RANGE/MULTIPLIER	REFERENCE CAL. POINT	INSTRUMENT REC'D "AS FOUND READING"	INSTRUMENT METER READING*
X 100	150 mR/hr		<u>1.5</u>
X 100	50 mR/hr		<u>0.5</u>
X 10	15 mR/hr		<u>1.5</u>
X 10	5 mR/hr		<u>0.5</u>
X 1	1.5 mR/hr = <u>4850 cpm</u>		<u>1.5</u>
X 1	1.0 mR/hr		<u>1.0</u>
X 0.1	<u>485 cpm</u>		<u>1.5</u>
X 0.1	<u>162 cpm</u>		<u>0.5</u>

*Uncertainty within $\pm 10\%$ C.F. within $\pm 20\%$

X 0.1 Range(s) Calibrated Electronically

REFERENCE CAL. POINT	INSTRUMENT RECEIVED	INSTRUMENT METER READING*	REFERENCE CAL. POINT	INSTRUMENT RECEIVED	INSTRUMENT METER READING*
Digital Readout			Log Scale		

Ludlum Measurements, Inc. certifies that the above instrument has been calibrated by standards traceable to the National Institute of Standards and Technology, or to the calibration facilities of other International Standards Organization members, or have been derived from accepted values of natural physical constants or have been derived by the ratio type of calibration techniques. The calibration system conforms to the requirements of ANSI/NCSL Z540-1-1994 and ANSI N323-1978. State of Texas Calibration License No. LO-1963

Reference Instruments and/or Sources:

Cs-137 Gamma S/N ☒ 1162 ☐ G112 ☐ M565 ☐ 5105 ☐ T1008 ☐ T879 ☒ E552 ☐ E551 ☐ 720 ☐ 734 ☐ 1616 ☐ Neutron Am-241 Be S/N T-304
☐ Alpha S/N ☐ Beta S/N ☐ Other
☒ m 500 S/N 189506 ☐ Oscilloscope S/N ☒ Multimeter S/N 57390613

Calibrated By: William Tinsley Date 3 July 06

Reviewed By: W. R. B. B. B. Date 3 July 06

West Pharmaceutical Services
NRC License Number 37-30229-01
Docket Number: 03033881
Control Number: 138463

ATTACHMENT 2

SURVEY OF RADIATION LAB

From Page No. Begin

Purpose: To screen (survey) the surfaces of the Radiation lab for total beta contamination.

Method: One hundred percent scanning per the "Simplified Survey Procedures" on page 8-2 of NUREG-1757, Vol. 1, Rev. 1

Equipment Used:

- Ludlum Model 3: SN 120333, calibrated 07/13/06, due 07/03/07
 - Ludlum 44-A probe: SN 122417
 - Batt ^{TE} 09/06/06 Check Source: ^{TE} 1uCi Cs-137: SN: 2505
 - Battery test: OK
 - check source Reading: 28,000 CPM
 - Bkgd reading: 40 CPM
- Ludlum Model 3: SN 120200, calibrated 07/26/06, due 07/26/07
 - Ludlum 44-A probe: SN 122408
 - Check source: 1uCi Cs-137: SN 2507
 - Battery test: OK
 - check source reading: 36,000 CPM
 - Bkgd reading: 40 CPM

Reagents: N/A

Samples: N/A

Procedure/Results

Joe Runkly scanned and Dustin Walker scanned exposed surfaces in the Radiation Laboratory (including cell culture laboratory) for total beta contamination. Scanned surfaces included all counters, drawers, shelves, instrumentation, hoods, cabinets, refrigerators/freezers, incubators, floors, walls adjacent to work surfaces, and glassware known to have been in contact with radioactive material. The only items to read above background were a development container and a microscope slide which read 100 CPM (60 CPM above Bkgd). All other scanned surfaces read background.

To Page No. 58

Witnessed & Understood by me,

Paul G. DiStasio

Date

9/6/06

Invented by

Recorded by A. Walker

Date

09/06/06

9/6/06

From Page No. 57Conclusion

Results will be submitted to the NRC

09/06/06

To Page No. End

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by

09/06/06

9/6/06

West Pharmaceutical Services
NRC License Number 37-30229-01
Docket Number: 03033881
Control Number: 138463

ATTACHMENT 3

RADIOLOGICAL SURVEY DATA SHEET REMOVABLE CONTAMINATION

RADIOLOGICAL SURVEY DATA SHEET – REMOVABLE CONTAMINATION

Survey Date: 09/06/06

Performed By: Name Dustin A. Walker Signature Dustin A. Walker

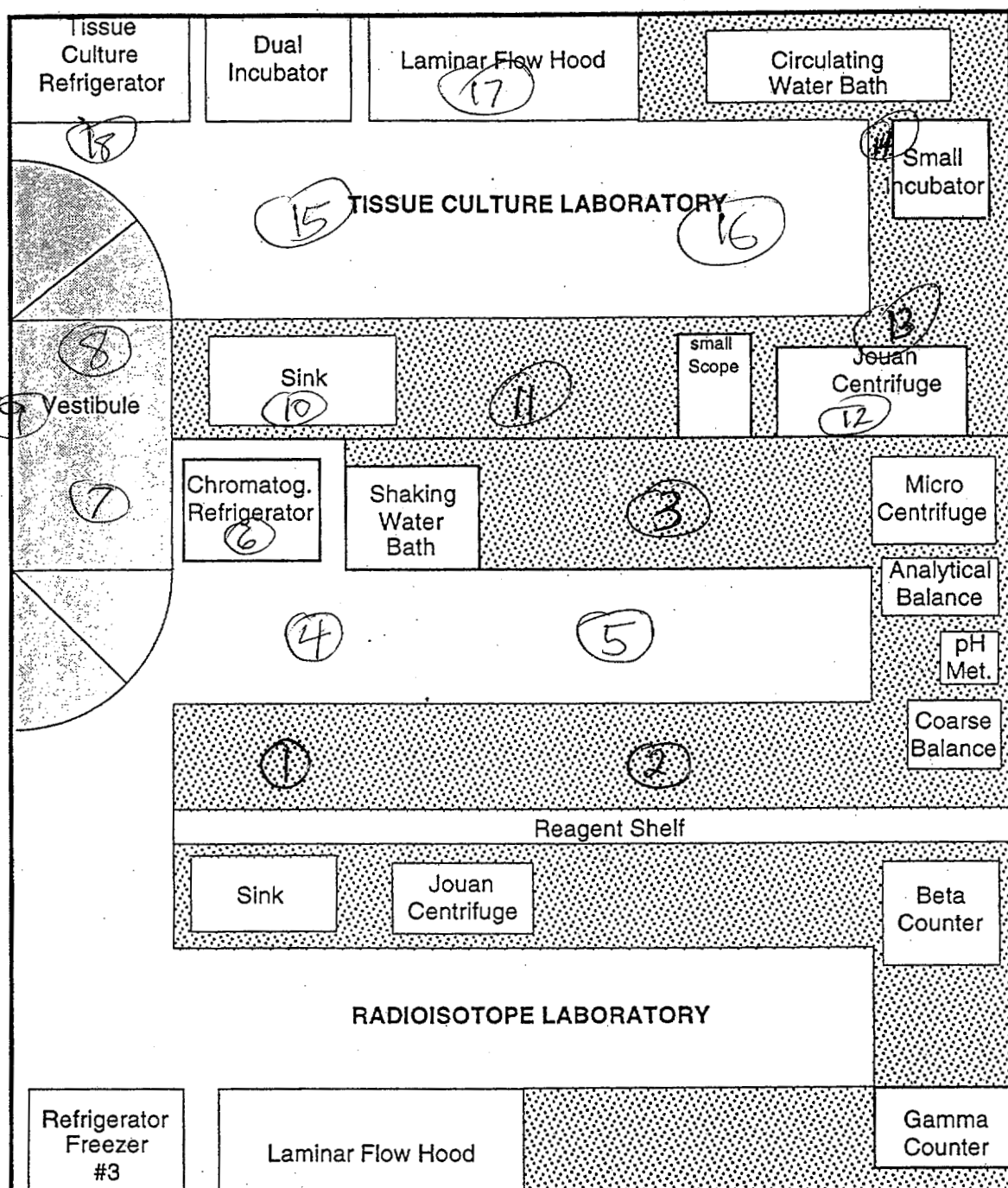
Sampling Media / Sampling Description:

Gellman Sciences wipes were dampened with DI water. 100 cm² wipe samples were taken as indicated below. The wipe samples were placed into liquid scintillation vials that were individually numbered to correspond to the wipe numbers below.

Wipe Number	Sample Description	Sample Area (cm ²)
1	Counter	100
2	Counter	100
3	Counter	100
4	Floor	100
5	Floor	100
6	Inner Base of Refrigerator (SN: 013E-1989360F)	100
7	Floor	100
8	Floor	100
9	Door Push Strip	100
10	Base of Sink by Drain	100
11	Counter	100
12	Inner Base of Jouan Centrifuge (SN: 49502042)	100
13	Counter	100
14	Counter	100
15	Floor	100
16	Floor	100
17	Working Surface of Laminar Flow Hood	100
18	Floor	100
19	Blank	100

Comments: N/A

Reviewed By: Name PAUL G. DIORIO Signature/Date Paul G. Diorio 9/6/06



COHN LABORATORY

West Pharmaceutical Services
NRC License Number 37-30229-01
Docket Number: 03033881
Control Number: 138463

ATTACHMENT 4

EBERLINE SERVICES ANALYSIS RESULTS

Eberline Services

ANALYSIS RESULTS

SDG <u>8326</u> Work Order <u>R609050-01</u> Received Date <u>09/07/06</u>	Client <u>WEST PHARMAC</u> Contract _____ Matrix <u>WIPE</u>
--	--

Client	Lab	Collected	Analyzed	Nuclide	Results $\pm 2\sigma$	Units	MDA
Sample ID	Sample ID						
1 Counter	8326-001	09/06/06	09/17/06	Tritium	-0.402 \pm 0.94	pCi/Smpl	1.62
2 Counter	8326-002	09/06/06	09/17/06	Tritium	1.10 \pm 1.1	pCi/Smpl	1.56
3 Counter	8326-003	09/06/06	09/17/06	Tritium	0.471 \pm 0.85	pCi/Smpl	1.41
4 Floor	8326-004	09/06/06	09/17/06	Tritium	0.497 \pm 0.92	pCi/Smpl	1.54
5 Floor	8326-005	09/06/06	09/17/06	Tritium	0.698 \pm 0.98	pCi/Smpl	1.62
6 Base of refrigerator	8326-006	09/06/06	09/17/06	Tritium	0.350 \pm 1.1	pCi/Smpl	1.60
7 Floor	8326-007	09/06/06	09/17/06	Tritium	0.467 \pm 1.0	pCi/Smpl	1.72
8 Floor	8326-008	09/06/06	09/17/06	Tritium	0.396 \pm 1.0	pCi/Smpl	1.69
9 Door push strip	8326-009	09/06/06	09/17/06	Tritium	-0.007 \pm 0.81	pCi/Smpl	1.36
10 Base of sink	8326-010	09/06/06	09/17/06	Tritium	-0.251 \pm 1.1	pCi/Smpl	1.85
11 Counter	8326-011	09/06/06	09/17/06	Tritium	-0.122 \pm 1.0	pCi/Smpl	1.71
12 base of centrifuge	8326-012	09/06/06	09/17/06	Tritium	0.334 \pm 0.86	pCi/Smpl	1.44
13 Counter	8326-013	09/06/06	09/17/06	Tritium	-0.307 \pm 1.1	pCi/Smpl	1.67
14 Counter	8326-014	09/06/06	09/17/06	Tritium	-0.248 \pm 1.0	pCi/Smpl	1.70
15 Floor	8326-015	09/06/06	09/17/06	Tritium	0.199 \pm 0.87	pCi/Smpl	1.46
16 Floor	8326-016	09/06/06	09/17/06	Tritium	-0.558 \pm 0.99	pCi/Smpl	1.37
17 Laminar flow hood	8326-017	09/06/06	09/17/06	Tritium	0.441 \pm 1.1	pCi/Smpl	2.18
18 Floor	8326-018	09/06/06	09/17/06	Tritium	-0.321 \pm 0.94	pCi/Smpl	1.60
19 Blank	8326-019	09/06/06	09/17/06	Tritium	0.136 \pm 0.80	pCi/Smpl	1.34

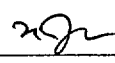
Certified by 22
 Report Date 10/06/06
 Page 1

Eberline Services

QC RESULTS

SDG <u>8326</u>	Client <u>WEST PHARMAC</u>
Work Order <u>R609050-01</u>	Contract _____
Received Date <u>09/07/06</u>	Matrix <u>WIPE</u>

Lab						
<u>Sample ID</u>	<u>Nuclide</u>	<u>Results</u>	<u>Units</u>	<u>Amount Added</u>	<u>MDA</u>	<u>Evaluation</u>
<u>LCS</u>						
8326-020	H-3	244 ± 3.8	pCi/Smpl	238	1.24	103% recovery
<u>BLANK</u>						
8326-021	H-3	-0.738 ± 0.73	pCi/Smpl	NA	1.28	<MDA

Certified by 
Report Date <u>10/06/06</u>
Page 2

Eberline Services – Richmond

Chain of Custody

CLIENT: <u>West Pharmaceutical Services</u> ADDRESS: <u>101 Gordon Drive</u> <u>Licenceville, PA 19341</u> PROJECT: <u>Rad Lab</u>				PURCHASE ORDER NO. <u>call for credit card info.</u>												DATE <u>09/06/06</u> PAGE <u>1</u> OF <u>2</u> TAT (IN DAYS) <u>30</u> OBSERVATIONS, COMMENTS, VOLUMES, SPECIAL OR ADDITIONAL TEST <div style="text-align: center; font-size: 1.5em;">8326</div>				
SAMPLERS SIGNATURE: <u>[Signature]</u>				PARAMETERS												# CONTAINERS				
SAMPLE NO.	DATE	TIME	LOCATION	Tritium Analysis	CH-DIR															SAMPLE TYPE OR MATRIX
1	09/06/06	1059	counter	X															wipe	1
2		1100	counter	X																1
3		1101	counter	X																1
4		1102	floor	X																1
5		1102	floor	X																1
6		1103	base of refrigerator	X																1
7		1104	floor	X																1
8		1104	floor	X																1
9		1105	door push strip	X																1
10		1106	base of sink	X																1
11		1107	counter	X																1
12		1109	base of centrifuge	X																1
1) RELINQUISHED BY / DATE: <u>[Signature] / 09/06/06</u> COMPANY: <u>WPS</u>				2) RECEIVED BY / DATE: <u>[Signature] 09/07/06</u> COMPANY: <u>EBERLINE</u>				3) RELINQUISHED BY / DATE: COMPANY:				4) RECEIVED BY / DATE: COMPANY:				TOTAL NO. OF CONTAINERS: <u>19</u>				
5) RELINQUISHED BY / DATE: COMPANY:				6) RECEIVED BY / DATE: COMPANY:				7) RELINQUISHED BY / DATE: COMPANY:				8) RECEIVED BY / DATE: COMPANY:				METHOD OF SHIPMENT: <u>UPS</u>				
SPECIAL SHIPMENT-HANDLING, STORAGE REQUIREMENTS, OR POSSIBLE HAZARDS																				

Eberline Services – Richmond

Chain of Custody

SAMPLE NO.	DATE	TIME	LOCATION
13	09/06/06	1110	Counter
14		1111	counter
15		1112	Floor
16		1112	Floor
17		1113	laminar flow hood
18		1113	floo r
19	T	1114	blank
_____ 09/06/06 _____			

1) RELINQUISHED BY / DATE:
[Signature] / 09/06/06
 COMPANY: WPS

2) RECEIVED BY / DATE:
Mfy 09/07/06
 COMPANY: BDERLINE

3) RELINQUISHED BY / DATE:

4) RECEIVED BY / DATE:

5) RELINQUISHED BY / DATE:

6) RECEIVED BY / DATE:

7) RELINQUISHED BY / DATE:

8) RECEIVED BY / DATE:

CONTAINERS TAT (IN DAYS)

OBSERVATIONS, COMMENTS,
VOLUMES,SPECIAL OR ADDITIONAL TEST

TOTAL NO. OF CONTAINERS: see pg. 1

METHOD OF SHIPMENT: UPS

SPECIAL SHIPMENT-HANDLING,
STORAGE REQUIREMENTS, OR POSSIBLE HAZARDS



RICHMOND, CA LABORATORY
SAMPLE RECEIPT CHECKLIST

Client: WEST PHARM'L SERVICES City LIONVILLE State PA

Date/Time received 09/07/06 CoC No. PROJ. RAD LAB

Container I.D. No. PROJ Requested TAT (Days) 30 P.O. Received Yes [] No []

INSPECTION

1. Custody seals on shipping container intact? Yes [] No [] N/A [X]
2. Custody seals on shipping container dated & signed? Yes [] No [] N/A [X]
3. Custody seals on sample containers intact? Yes [] No [] N/A [X]
4. Custody seals on sample containers dated & signed? Yes [] No [] N/A [X]
5. Packing material is: Wet [] Dry [X]
6. Number of samples in shipping container: 19 Sample Matrix E-SMERA
7. Number of containers per sample: 1 (Or see CoC)
8. Samples are in correct container Yes [X] No []
9. Paperwork agrees with samples? Yes [X] No []
10. Samples have: Tape [] Hazard labels [] Rad labels [] Appropriate sample labels [X]
11. Samples are: In good condition [X] Leaking [] Broken Container [] Missing []
12. Samples are: Preserved [] Not preserved [] pH Preservative
13. Describe any anomalies:

14. Was P.M. notified of any anomalies? Yes [] No [] Date

15. Inspected by [Signature] Date: 09/07/06 Time: 11:00

Customer Sample No.	cpm	mR/hr	Wipe	Customer Sample No.	cpm	mR/hr	wipe

Ion Chamber Ser. No.

Calibration date

Alpha Meter Ser. No.

Calibration date

Beta/Gamma Meter Ser. No.

Calibration date