

Litton BIONETICS

SSIRN/Chelsea Lab
Kensington, Maryland
2079

MONS 016418

LBI PROJECT 20771

FINAL REPORT

APPENDIX VOLUME I

APPENDICES A-B-C-D-E

EFFECTS OF PCB ON THE REPRODUCTIVE PERFORMANCE OF THE RHESUS MONKEY (*Macaca mulatta*)

APRIL 4, 1977 - DECEMBER 11, 1978

SUBMITTED TO

MONSANTO COMPANY
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI

SUBMITTED BY

LITTON BIONETICS, INC.
5516 NICHOLSON LANE
KENSINGTON, MARYLAND

APRIL 30, 1981

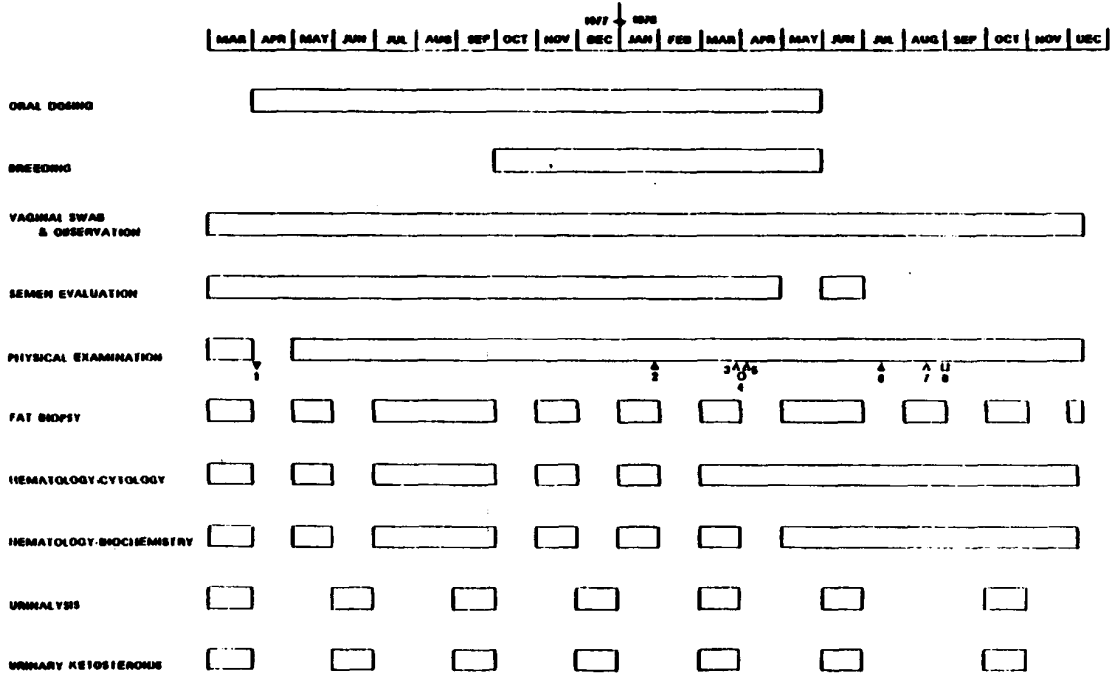
MONS 016419

Litton BIONETICS

APPENDIX A

TABLE 1

TESTING SCHEDULE AND DEATHS OF ADULT ANIMALS



○ - Control Dose Death
▼ - Low Dose Death
□ - Medium Dose Death
▲ - High Dose Death

1. 2081 ♀ 4/12/77*
2. 1637 ♀ 1/22/78
3. 4881 ♀ 3/22/78
4. 877 ♀ 3/31/78
5. 7701 ♀ 4/05/78
6. 7005 ♂ 7/10/78
7. 3881 ♀ 6/21/78
8. 8481 ♀ 6/30/78

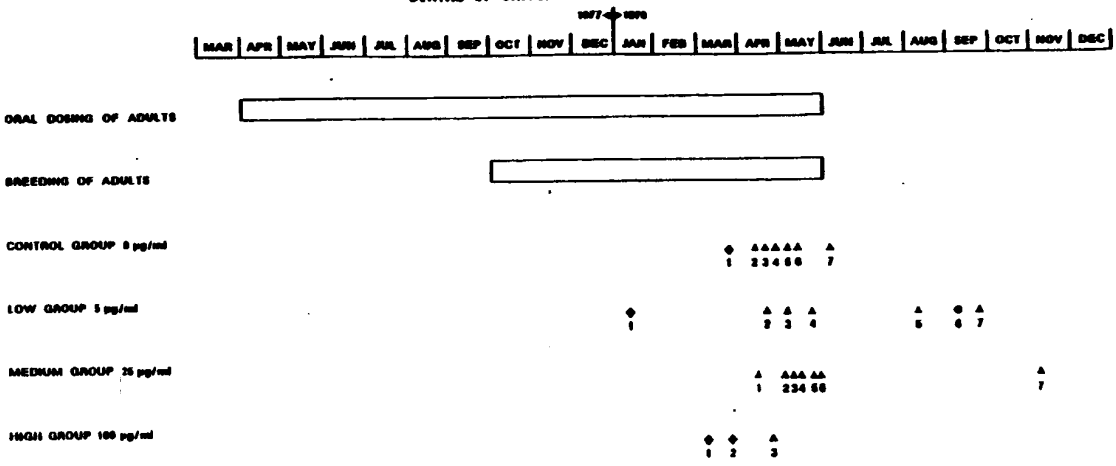
*Replaced by animal no. 4637

Note: All testing done in March 1977 was considered pre-drug.

MONS 016421

TABLE 2

BIRTHS OF INFANTS BY DOSE GROUPS



	Control	Low	Medium	High
▲ - Live Birth	1. B0403 3/20/76	1. Fetal Wastage 1/10/76 *	1. B0511 4/16/76	1. P0433 3/2/76
● - Still Birth	2. B0510 4/19/76	2. B0527 4/23/76	2. B0546 5/3/76	2. B0466 3/30/76
◆ - Fetal Wastage	3. B0532 4/25/76	3. B0562 5/9/76	3. B0569 5/9/76	3. B0542 4/30/76
	4. B0533 4/26/76	4. B0564 5/27/76	4. B0568 5/9/76	
	5. B0547 5/6/76	5. B0754 6/10/76	5. B0582 5/23/76	
	6. B0574 5/14/76	6. B0766 6/18/76	6. B0583 5/27/76	
	7. B0631 6/6/76	7. B0816 6/30/76	7. B0589 6/10/76	

*No number assigned since no evidence of fetal tissues or vaginal bleeding was observed.

MONS 016422

TABLE 3

TEST COMPOUND RECEIPT

Supply for Month of	April	May	June	July
Received at LBI	4/01/77	4/01/77	5/31/77	7/05/77
Returned to Monsanto	5/31/77	7/13/77	7/13/77	8/09/77
LBI Control No./Dose	1146/Control	1150/Control	1150A/Control	1608/Control
	1148/TI*	1149/TI	1376/TI	1609/TI
	1145/TII	1151/TII	1374/TII	1610/TII
	1147/TIII	1152/TIII	1375/TIII	1611/TIII

Supply for Month of	August	September	October	November
Received at LBI	8/02/77	8/04/77	8/29/77	9/28/77
Returned to Monsanto	9/07/77	11/08/77	11/08/77	1/16/78
LBI Control No./Dose	1613/Control	1626/Control	1706/Control	1813/Control
	1614/TI	1627/TI	1707/TI	1814/TI
	1615/TII	1628/TII	1708/TII	1811/TII
	1616/TIII	1629/TIII	1709/TIII	1812/TIII**

* Note: TI = 5 µg/kg or low dose; TII = 25 µg/kg or medium dose; TIII = 100 µg/kg or high dose.

** Cap broken during transport. No leakage.

TABLE 3.1

TEST COMPOUND RECEIPT

Supply for Month of	December	January	February	March
Received at LBI	11/07/77	11/29/77	12/28/77	1/30/78
Returned to Monsanto	1/16/78	2/13/78	3/13/78	4/18/78
LBI Control No./Dose	1959/Control	2050/Control	2213/Control	2389/Control
	1960/TI	2051/TI	2214/TI	2390/TI
	1961/TII	2052/TII	2215/TII	2391/TII
	1962/TIII	2053/TIII	2216/TIII	2392/TIII

Supply for Month of	April	April	May	Not Administered
Received at LBI	3/02/78	3/28/78	4/26/78	5/30/78
Returned to Monsanto	6/13/78	5/04/78	6/13/78	6/13/78
LBI Control No./Dose	2536/Control	2605/Control	2715/Control	2855/Control
	2534/TI	2602/TI	2713/TI	2856/TI
	2533/TII	2603/TII	2714/TII	2858/TII
	2535/TIII	2604/TIII	2716/TIII	2857/TIII

TABLE 4

SERUM LEVELS OF VITAMIN A
(mg/dl)

	Control			5 µg/kg	
Females:	764-E	73.0	Females:	646-E	17.0
	200-F	103.0		701-E	77.0
	274-F	12.0		605-F	56.0
	569-H	32.0		839-H	44.0
	578-H	76.0		284-I	28.0
	604-I	60.0		483-F	59.0
	618-I	32.0		309-I	24.0
				624-I	44.0
Mean		55.4	Mean		43.6
S.E.		11.95	S.E.		7.12
Number		7	Number		8
Males:	739-F	43.0	Males:	516-G	32.0
	227-G	69.0		119-H	61.0
	426-G	20.0		428-J	33.0
	418-J	70.0		432-J	25.0
Mean		50.5	Mean		37.8
S.E.		11.93	S.E.		7.95
Number		4	Number		4

	25 µg/kg			100 µg/kg	
Females:	762-E	14.0	Females:	226-F	31.0
	763-E	14.0		269-I	36.0
	281-G	25.0		287-I	47.0
	540-H	21.0		312-I	85.0
	273-I	20.0			
	307-I	15.0			
	757-I	28.0			
Mean		19.6*	Mean		49.8
S.E.		2.10	S.E.		12.21
Number		7	Number		4
Males:	20-I	25.0	Males:	600-I	19.0
	46-I	56.0		425-J	83.0
	595-I	42.0		427-J	40.0
	599-I	41.0			
Mean		41.0	Mean		47.3
S.E.		6.33	S.E.		18.84
Number		4	Number		3

* Significance at 95% level.

Note: Serum drawn just prior to necropsy, Month 21.

MONS 016425

TABLE 5

BODY WEIGHTS AND DISPOSITION OF INFANTS
(gm)

	Baby Number	Birth	1 Month	2 Months*
Control	B-8518	482.5	**	656.0
	B-8532	440.7	**	675.0
	B-8533	514.0	**	669.0
	B-8557	473.0	623.0	756.0
	B-8574	500.0	506.0	573.0
	B-8621	561.0	697.0	918.0
5 ug/kg	B-8527	470.0	**	748.0
	B-8562	600.0	680.0	863.0
	B-8604	471.0	613.0	671.0
	B-8754	593.0	753.0	858.0
	B-8796[1]	460.0	N/A	N/A
	B-8815	349.0	438.0	592.0[2]
25 ug/kg	B-8511	328.0	326.0	397.7
	B-8546	326.0	406.0	473.0[3]
	B-8559	603.5	639.0	789.0
	B-8560	394.0	426.0	452.0[4]
	B-8592	442.0	513.0	690.0
	B-8603	396.0	420.0	485.0
	B-8860	467.0	493.0[5]	N/A[6]
100 ug/kg	B-8542	365.0	391.0	425.0[7]

* Infants left to nurse on mother and killed at 2 mos of age unless otherwise noted.

** Somatic measurements and body weights were not required by protocol when these first four animals to be born were 1 mo old (Protocol Change #20771-12).

[1]Stillbirth.

[2]Taken to Nursery (Nur) at 9 days of age; killed 71 days of age at termination of study.

[3]Taken to Nur at 68 days of age; died 86 days of age.

[4]Taken to Nur at 69 days of age; killed 211 days of age at termination of study; 3-mo wt 587 g, 4-mo wt 639 g; 5-mo wt 723 g; 6-mo wt 973 g; 7 mo wt 1267 g.

[5]Seventeen days of age.

[6]Killed at 31 days of age at termination of study.

[7]Taken to Nur at 78 days of age; died 97 days of age; 3-mo wt 400 gm.

TABLE 6

OFFSPRING
HEMATOLOGY - CYTOLOGY

Control at Birth

Animal Number	RBC ($mm^3 x 10^6$)	Cell Vol (%)	Hgb (gm%)	Platelet ($mm^3 x 10^3$)	WBC (mm^3)	Retic (%)	Differential* (%) Mye	Juv	Ban	Seg	Lym	Mon	Eos	Bas	Other
B-8518	4.83	39.5	13.6	--[1]	16,700	0	0	0	0	52	47	1	0	0	0
B-8532	5.72	46.0	15.9	Adeq	18,300	0	0	0	0	39	59	2	0	0	0
B-8533	7.39	55.0	20.0	Adeq	18,300	0	0	0	0	83	16	1	0	0	0
B-8557	8.85	56.0	19.8	--[1]	11,100	0	0	0	0	73	26	1	0	0	0
B-8621	6.40	63.0	22.7	Adeq	9,900	1.9	0	0	2	73	23	1	1	0	0
5 µg/kg at Birth															
B-8527	4.81	42.0	15.3	Adeq	7,700	0	0	0	0	25	73	2	0	0	0
B-8562	5.84	51.0	17.7	Adeq	9,900	0	0	0	0	63	36	1	0	0	0
B-8604	7.27	56.0	19.9	Adeq	5,900	0	0	0	0	29	70	1	0	0	0
B-8754	4.65	44.0	14.9	297	1,400	3.8	0	0	0	79	14	6	1	0	0
B-8815	5.46	49.0	17.3	383	11,100	2.0	0	0	0	80	19	1	0	0	0
25 µg/kg at Birth															
B-8511[2]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-
B-8546	5.93	50.5	17.9	Adeq	8,800	0	0	0	0	36	63	1	0	0	0
B-8559	6.18	51.0	17.5	Adeq	10,800	0	0	0	0	69	31	0	0	0	0
B-8560[2]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-
B-8592	6.59	56.0	18.9	Adeq	19,200	0	0	0	0	87	12	1	0	0	0
B-8601	5.59	50.0	16.9	Adeq	5,100	0	0	0	0	15	84	0	1	0	0
B-8860	6.68	59.0	20.8	327	11,200	0	0	0	1	74	18	7	0	0	0
100 µg/kg at Birth															
B-8542	6.30	47.0	16.3	--[1]	10,800	0	0	0	0	49	50	1	0	0	0

[1]Not required by protocol at time of birth.
[2]Blood not drawn.

* Mye = myelocytes; Juv = juveniles; Ban = bands; Seg = segmented neutrophils; Lym = lymphocytes; Mon = monocytes; Eos = eosinophils; Bas = basophils.

MONS 016427

TABLE 6.1

OFFSPRING
HEMATOLOGY - CYTOLOGY

Control at 1 Month

Animal Number	RBC ($mm^3 \times 10^6$)	Cell Vol (%)	Hgb (gm%)	Platelet ($mm^3 \times 10^3$)	WBC (mm^3)	Retic (%)	Differential* (%)								
							Mye	Juv	Ban	Seg	Lym	Mon	Eos	Bas	Other
B-8518	3.45	33.0	11.0	Adeq	5,800	0	0	0	0	29	70	1	0	0	0
B-8532	5.16	37.0	12.9	Adeq	7,400	0	0	0	0	22	75	0	3	0	0
B-8533	4.87	38.0	14.0	Adeq	4,900	0	0	0	0	24	76	0	0	0	0
B-8557	4.70	37.0	13.2	335	7,400	0.5	0	0	0	20	79	1	0	0	0
B-8574	6.32	43.0	15.3	442	7,000	0.4	0	0	0	48	47	1	2	2	0
B-8621[2]	4.64	37.5	13.1	350	12,000	0	0	0	0	57	32	8	2	1	0
5 µg/kg at 1 Month															
B-8527	3.64	35.5	11.6	Adeq	6,700	0	0	0	0	21	78	1	0	0	0
B-8562	5.66	44.0	15.1	470	8,200	0.6	0	0	0	28	71	0	1	0	0
B-8604	4.66	37.0	13.1	515	6,500	1.0	0	0	0	37	59	2	2	0	0
B-8754	4.80	37.0	12.5	467	6,000	0.4	0	0	0	11	83	1	5	0	0
B-8815	5.09	41.0	13.3	414	8,000	5.8	0	0	0	53	45	1	1	0	0
25 µg/kg at 1 Month															
B-8511[1]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-
B-8546	4.14	37.5	12.8	374	7,300	1.9	0	0	0	20	79	1	0	0	0
B-8559	4.42	34.0	11.5	529	4,900	0.9	0	0	0	16	67	5	11	1	0
B-8560	5.60	39.0	13.2	239	9,000	1.0	0	0	0	29	64	4	2	1	0
B-8592	5.70	42.0	14.0	282	7,000	1.0	0	0	0	19	80	0	1	0	0
B-8603	4.53	36.0	14.2	767	11,300	3.1	0	0	0	52	45	3	0	0	0
B-8860	5.08	41.0	14.3	394	3,900	0.7	0	0	3	24	70	1	2	0	0
100 µg/kg at 1 Month															
B-8542[1]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-

[1]Blood not drawn.
[2]Repeat value.
* Mye = myelocytes; Juv = juveniles; Ban = bands; Seg = segmented neutrophils; Lym = lymphocytes; Mon = monocytes; Eos = eosinophils; Bas = basophils.

TABLE 6.2

OFFSPRING
HEMATOLOGY - CYTOLOGY

Control at 2 Months

Animal Number	RBC ($mm^3 x 10^6$)	Cell Vol (%)	Hgb (gm%)	Platelet ($mm^3 x 10^3$)	WBC (mm^3)	Retic (%)	Differential* (%)								
							Mye	Juv	Ban	Seg	Lym	Mon	Eos	Bas	Other
B-8518	5.38	36.0	11.6	35	9,500	0.3	0	0	0	16	83	1	0	0	0
B-8532[1]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-
B-8533	4.75	36.0	12.3	699	4,900	0.6	0	0	0	18	79	2	1	0	0
B-8557	5.03	40.0	12.5	463	12,700	0.3	0	0	0	14	85	1	0	0	0
B-8574	5.26	38.0	12.8	430	8,400	0.2	0	0	0	17	64	5	13	1	0
B-8621	5.94	43.0	14.1	445	10,600	0.2	0	0	0	34	64	2	0	0	0
5 µg/kg at 2 Months															
B-8527[2]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-
B-8562	5.02	38.0	12.3	570	5,500	1.1	0	0	0	16	77	3	4	0	0
B-8604	4.75	36.0	11.2	404	7,500	0.2	0	0	0	32	65	1	2	0	0
B-8754	4.67	38.0	12.5	304	9,700	0.4	0	0	1	16	80	1	2	0	0
B-8815	4.65	34.0	11.6	414	4,800	5.0	0	0	1	43	50	4	2	0	0
25 µg/kg at 2 Months															
B-8511	4.70	35.5	12.6	400	8,200	0	0	0	0	22	77	0	1	0	0
B-8546	5.41	32.0	10.5	512	5,500	2.1	0	0	0	19	71	8	2	0	0
B-8559	4.30	33.0	10.4	484	5,200	1.2	0	0	0	23	67	3	7	0	0
B-8560	4.27	28.5	9.6	490	8,900	5.5	0	0	0	24	64	2	10	0	0
B-8592	5.20	36.0	12.4	383	9,500	0.8	0	0	0	25	71	1	2	1	0
B-8603	4.59	38.0	11.5	165	12,600	0.5	0	0	0	49	51	0	0	0	0
100 µg/kg at 2 Months															
B-8542[1]	--	--	--	--	--	--	-	-	-	-	-	-	-	-	-

[1]Blood not drawn.
[2]Sacrificed June 23, 1978.

* Mye = myelocytes; Juv = juveniles; Ban = bands; Seg = segmented neutrophils; Lym = lymphocytes; Mon = monocytes; Eos = eosinophils; Bas = basophils.

MONS 016429

TABLE 6.3

OFFSPRING
HEMATOLOGY - CYTOLOGY

Animal Number	RBC ($mm^3 x 10^6$)	Cell Vol (%)	Hgb (gm%)	Platelet ($mm^3 x 10^3$)	WBC (mm^3)	Retic (%)	Differential*(%)								
							Mye	Juv	Ban	Seg	Lym	Mon	Eos	Bas	Other
25 µg/kg at 3 Months															
B-8560	4.42	32.0	10.8	825	12,200	1.6	0	0	1	65	32	2	0	0	0
100 µg/kg at 3 Months															
B-8542	4.57	35.0	11.9	570	7,800	0.9	0	0	0	77	19	4	0	0	0
25 µg/kg at 4 Months															
B-8560	4.71	35.0	11.3	364	9,500	0.8	0	0	0	53	42	2	3	0	0
25 µg/kg at 5 Months															
B-8560	4.49	31.0	10.3	Adeq	13,400	2.0	0	0	0	47	49	0	4	0	0
25 µg/kg at 6 Months															
B-8560	5.09	39.0	12.8	318	8,200	1.6	0	0	0	18	80	0	2	0	0
25 µg/kg at 7 Months															
B-8560	5.13	39.5	12.8	498	8,200	0.9	0	0	0	25	75	0	0	0	0
5 µg/kg at 21 Months**															
B-8815	4.72	38.0	12.2	590	6,100	1.8	0	0	2	35	57	5	1	0	0

* Mye = myelocytes; Juv = juveniles; Ban = bands; Seg = segmented neutrophils; Lym = lymphocytes; Mon = monocytes; Eos = eosinophils; Bas = basophils.

** Terminal sample (12/6/78).

MONS 016430

TABLE 7

SERUM LEVELS OF VITAMIN A - INFANTS
(mg/dl)

Female	B-8815	90.0
Female	B-8560	89.0
Male	B-8860	25.0

APPENDIX B

Monsanto

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone (314) 694-1000

March 8, 1979

Dr. David P. Martin
Director, Laboratory Animal
Medicine & Science
Litton Bionetics
5516 Nicholson Lane
Kensington, MD 20795

Dear David:

Enclosed please find three interim reports of the analytical results of levels of PCB's (AROCLOR 1254) found in monkey samples from Litton. These analyses were performed at Monsanto Research Corporation, Dayton, Ohio. The analyst (Beverly Warner) informs me that the final samples from the terminal necroscopy have still not been received. Would you please look into this situation. Please also send periodic samples of the monkey chow used in the study for analysis for possible PCB contents. These samples can be sent direct to Dayton as you have been doing with the tissues. I am informed that the analyses of tissues should be complete by mid-April, 1979. If you have any questions on the analytical data, you may contact Beverly Warner direct; I believe that she has already been in contact with Linda Adamo concerning shipment. The analytical data generated at Dayton have already been audited and no discrepancies that would invalidate the study were found.

With regard to your letter of January 19, 1979, this letter will confirm that according to paragraph 58:31 section D of the GLP regulations, the AROCLOR 1254 which was used in the primate study was "appropriately tested for identity, strength, purity, stability, and uniformity, as applicable". A memorandum dated March 18, 1977, is available in our internal file to confirm this fact and would serve as verification if needed.

I have just received the October 1 to December 31, 1978, draft report on the PCB study and will be in contact with you after I have read it.

Sincerely,

Peter F. Berteau, PhD
Senior Toxicology Specialist

PFB:alw
cc: Linda Adamo, Litton
Beverly Warner, Dayton, Ohio

MAR 12 1979

MONS 016433

B-1

LITTON BIONETICS, INC.

INTEROFFICE MEMORANDUM June 21, 1978

TO: Dr. David Martin

FROM: Steve Johnson

SUBJECT: LBI Project No. 20771

The following tissues have been added to the list of those harvested at necropsy: spleen, skeletal muscle, sciatic nerve, spinal cord and bone marrow smear.

Histopathologic processing and evaluation will be performed pending the approval of the principal investigator and the client.

SLJ/sf

cc: Dr. Seibold
D. Herndon
Contracts

JUN 26 1978

MONS 016434

LITTON BIONETICS, INC.
Inter-Office Memorandum

April 13, 1978

To: Mr. M. Abbaticchio

From: Dr. D. P. Martin

Subject: Protocol for Project 20771

Although we expect to receive authorization and final instructions shortly for the continuing protocol of Project 20771, please proceed with the following until a protocol change sheet is issued:

1. Perform a CBC with platelet and reticulocyte counts on each animal monthly.

2. Take and record weights and somatic measurements on all offspring born of both study males and females.

3. Offspring of study males may be considered Project 20020 property for normal disposition.

4. Offspring of study females are to remain on the mother. As soon as practicable after the birth of one of these infants, a milk/colostrum sample should be obtained from the mother and frozen for shipment to Monsanto Company. If the health of the infant so warrants it, a skin/fat sample biopsy of the infant should be taken.

5. Because the decision as to whether or not to continue to take fat biopsies from the adults has not yet been made, please inform me if the next scheduled sampling time arrives before a protocol change has been issued.

6. At this time, Monsanto Company is considering dropping further biochemistry, urinalysis (including 17-ketosteroids), and semen analysis testing. Should this change, I will notify you.

DPM:jl

cc: Dr. J. Cicmanec

MONS 016435

LITTON BIONETICS, INC.
Inter-Office Memorandum

June 7, 1978

To: Mr. Steve Johnson

From: Dr. D. P. Martin

Subject: Necropsy Dates for Infants on Project 20771

As you are aware, the revised protocol for Project 20771 states that infants are to be killed two months after birth unless signs of PCB toxicity are noted. The attached schedule has been set up to comply with this, taking weekends into account.

Each infant will be examined 3 to 5 days prior to the scheduled necropsy date, and a "go-no go" decision made at that time. The necropsy protocol will be that of the adults. Please contact me to arrange a revised schedule if any of these dates cause a problem.

Four more infants remain to be born, and a schedule for these will be provided as the dates become available.

DPM:la
Attachment

cc: Dr. J. Cicmanec
Mr. M. Abbaticchio
Mr. D. Herndon

MONS 016436

8-4

LITTON BIONETICS, INC.
Inter-Office Memorandum

January [illegible], 1978

To: Dr. J. L. Cicmanec

From: Dr. D. P. Martin

Subject: Conversation with Dr. Paul Wright, Monsanto Company (MC)

In the absence of the MC Project Officer for Project 20771, I spoke with Dr. Paul Wright on January 23, 1978. The following subjects were discussed:

1. Regarding the death of No. 152-F: We are to prepare a clinical information sheet and submit it with a gross and micro necropsy report as soon as these are available.

2. Sample diet submission to MC: Because we did not submit a sample of the Purina diet for PCB analysis at 6 months as required by the protocol, we should submit one with a letter of explanation at our earliest convenience.

3. 17 ketosteroid testing: For all future tests the "window" for obtaining urine will be 22 to 26 days of the cycle, as specified in the final protocol.

4. Observations of lesions: Because the lesions, if any, which may appear in the animals at the diet levels we are using may be minimal (for example, swollen lids, reddened lids, etc.), we should make every effort to include these in the observations and physical sheet even if they are "normal" for that particular animal.

   If the condition persists, the notation, "this lesion remains unchanged and will no longer be recorded unless a change warrants it," should be noted. A change, of course, may be an increase or a decrease in the intensity of the lesion.

5. While no changes should be made in existing records, any lesions which are noted must be accounted for; that is, they can get worse, stay the same, or go away, but they cannot just be forgotten.

DPM:la

cc: Messrs. M. Ahbaticchio
R. Acuff
M. George

C/R Prot. (Proj) Change #20771-13
20771 memos ✓

LITTON BIONETICS, INC.
Inter-Office Memorandum

July 18, 1978

To: Project 20771 File

From: Dr. D. P. Martin

Subject: Error in Following of Protocol on Project 20771

I discovered on July 14, 1978, that three Project 20771 infants which had not been euthanatized due to their showing signs of PCB toxicity had inadvertently been left nursing on the mother beyond the 2-month period called for in Protocol Change No. 20771-13.

One of these infants, No. B-8546 from Monkey No. 757-I, medium dose, had been transferred to the Nursery for health reasons on July 10, 1978, rather than on July 3, 1978, as called for in the protocol.

The other two infants, No. B-8542 from Monkey No. 312-I, high dose, and No. B-8560 from Monkey No. 540-H, medium dose, had been scheduled to move to the Nursery on July 2, 1978, and July 9, 1978, respectively. These were moved on July 17, 1978.

DPM:jl

7/19/78 cc: Mr. M. Abbaticchio
Dr. J. Cicmanec
Dr. E. Gard
Mr. M. George
Monkey No. B-8542's File
Monkey No. B-8546's File
Monkey No. B-8560's File

MONS 016438

LITTON BIONETICS, INC.
Inter-Office Memorandum

December 7, 1978

To: Project 20771 File

From: Dr. D. P. Martin

Subject: Discrepancy in Protocol Regarding Animal No. 226-F, Female, High Dose

At the time of the final blood sampling for the animals on this program, Animal No. 226-F was easily stressed, and the blood samples were not readily obtained. Rather than further stress the animal, we decided to wait until the time of necropsy to obtain the final blood.

A protocol change (#20771-22) instituted on December 4 called for obtaining a final serum sample from each animal for Vitamin A level determination and for storage.

Mike George, the technician working most closely with the animals, was aware that the blood for hematology and biochemistry testing was to be obtained from this animal before necropsy, but he was under the impression, due to a euthanasia schedule that I had provided, that 226-F would be killed late in the day. In fact, at the request of Dr. William Ribelin from the Monsanto Company and agreed to by all present at the pre-necropsy meeting on December 4, 1978, the high dose animals were euthanatized immediately after the control animals were done; therefore, at the time that the serum for the Vitamin A determination was obtained, Mike was busy in another area, and the technician obtaining the blood for the Vitamin A level determination took only a 15-ml sample of whole blood. The biochemistry values were obtained from this, but no hematology values could be read.

DPM:jl

APPENDIX C

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-1

Test Compound AROCLOR Date November 2, 1977

Sponsor:

Monsanto Company
St. Louis, Missouri
(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

David P. Martin, V.M.D.

Individual Initiating Change:

David P. Martin, V.M.D.

Effective Date of Change:

November 2, 1977

Reason for Change: To facilitate timely compilation of data and to expidite reporting of results to sponsor.

Change to be Initiated: The technician assigned to the project will provide the Study Director with the results tables for hematology, biochemistry, and urinalysis (if performed) by the fifteenth day of the following month.

Study Dir.
Initials of Individual Preparing Change Sheet

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LBMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-2

Test Compound AROCLOR 1254 Date November 2, 1977

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

David P. Martin, V.M.D.

Individual Initiating Change:

David P. Martin, V.M.D.

Effective Date of Change:

November 2, 1977

Reason for Change: To insure prompt reporting of test results when results are missing or spurious.

Change to be Initiated: The Project Veterinarian will provide the Project Technician with a list of animals and tests which need to be repeated due to their being missing or spurious within three days of his receipt of the test results from the Clinical Laboratory.

The Project Technician will then take the appropriate blood samples for the necessary test repeats. The report submitted to the sponsor should show the original test result with the repeated result footnoted.

_____ Study Dir.

Initials of Individual Preparing Change Sheet

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

MONS 016442

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-3

Test Compound AROCLOR 1254 Date January 26, 1978

Sponsor:
Monsanto Company
St. Louis, Missouri
(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:
Dr. David P. Martin

Individual Initiating Change:
Dr. John L. Cicmanec

Effective Date of Change:
January 27, 1978

Reason for Change: Preliminary information of Necropsy #78/1033 for rhesus monkey 152-F indicates disease of possible viral etiology.

Change to be Initiated: (1) All animal care personnel and veterinarians entering Rooms 7 and 10 of Ward 8 are to wear a separate laboratory coat when in these areas, and these coats are to be left in the room.

(2) Animal handlers' leather gloves are to be sprayed after handling the monkeys, and examination gloves are to be worn by all others handling these monkeys.

(3) In addition, their footwear is to be sprayed with Zep Check® disinfectant before leaving these areas.

(4) The monkeys of this study are not to be taken from these rooms for weighing, treatments, or for other reasons until further notice.

JLC 1/26/78
Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Invest., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

JAN 30

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-4

Test Compound AROCLOR 1254 Date January 27, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

Dr. James Laveglia

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Effective Date of Change:

January 27, 1978

Reason for Change: Death of Animal No. 152-F.

Change to be Initiated:

Draw blood (10 cc red top), spin, and freeze for submission for virus titer analysis.

Five animals, one time only: Nos. 762-F, 225-F, 646-F, 764-F, 770-I, and 618-I.

(Confirmed as ok by telephone conversation with Dr. Paul Wright, Monsanto, on 1/27/78.)

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Invgs., (2) LBNS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-5

Test Compound AROCHLOR 1254 Date January 31, 1979

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

Dr. David P. Martin

Individual Initiating Change:

Dr. John L. Cicmanec

Effective Date of Change:

January 31, 1979

Reason for Change: Death of 152-F does not appear to be due to contagious disease.

Change to be Initiated: The monkeys of this study may be moved to other rooms of Ward B to be bred, and females not on this study may be brought to the males' cages of Room 10.

This change supercedes Item 4 of Project (Protocol) Change Sheet Change #20771-1.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LBMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-6

Test Compound AROCHLOR 1254 Date February 22, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

Dr. David P. Martin

Individual Initiating Change:

Dr. John L. Cicmanec

Effective Date of Change:

February 22, 1978

Reason for Change: Death of Monkey No. 152-F does not appear to be due to contagious disease.

Change to be Initiated: The monkeys of this study may be moved freely to other rooms. Special sanitation procedures, such as spraying feet and wearing special laboratory coats, may be ceased.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAHS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-7

Test Compound AROCHLOR 1254 Date March 29, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

Dr. David P. Martin

Individual Initiating Change:

Dr. John L. Cicmanec

Effective Date of Change:

March 30, 1978

Reason for Change: Recent occurrence of anemia thrombocytopenia and leucopenia in some females of Group IV.

Change to be Initiated: All animals of the control group (Group I) and the high dose group (Group IV) are to have CBC's, total platelet count, and reticulocyte count performed once every month rather than once every two months.

The next CBC blood sample should be collected from these monkeys during the first full week in April.

MONS 016447

JLC

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

cc: LAMS Veterinarians

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-8

Test Compound AROCHLOR 1254 Date April 17, 1973

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. P. Barteau, Project Officer, Monsanto Company

Effective Date of Change:

April 17, 1973

Reason for Change: Requested by Project Officer.

Change to be Initiated: In spite of hemorrhagic crisis or other indication, no blood transfusions are to be given to any animal on Project No. 20771. The animal may be given other fluids, but any clinical problem involving the blood elements is to be allowed to run a natural course.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

MONS 016448

C-8

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-9

Test Compound AROCLOR 1254 Date April 24, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. James Laveglia)

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. P. Martin

Effective Date of Change:

April 24, 1978

Reason for Change: To determine exact food consumption of each animal.

Change to be Initiated: For one week, please count exact consumption of biscuits per animal.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-10

Test Compound AROCLOR 1254 Date April 26, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. J. Laveglia)

LSI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. J. L. Cicmanec

Effective Date of Change:

April 27, 1978

Reason for Change: To avoid interference with late gestation and early postnatal period.

Change to be Initiated: In all of the drug dosage groups, fat biopsies are not to be performed on females that are more than 100 days of gestation of a pregnancy nor are fat biopsies to be performed on mothers that are rearing their infants during the first month of the infant's life.

JLC

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-11

Test Compound AROCLOR 1254 Date May 2, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

(Dr. J. Laveglia)

LSI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. P. Martin

Effective Date of Change:

May 2, 1978

Reason for Change: Authorization from Monsanto Company. Supersedes memorandum to Mr. M. Abbaticchio of April 13, 1978.

Change to be Initiated: 1. Perform a CBC with platelet and reticulocyte counts on each animal monthly.

2. Take and record weights and somatic measurements on all offspring born of both study males and females.

3. Offspring of study males may be considered Project 20020 property for normal distribution.

4. Offspring of study females are to remain on the mother. As soon as practicable after the birth of one of these infants, a milk/colostrum sample should be obtained from the mother and frozen for shipment to Monsanto Company. If the health of the infant so warrants it, a skin/fat sample biopsy of the infant should be taken.

5. Current authorization extends only through May 31, 1978. Thus no further fat biopsies are currently scheduled. If any future fat biopsies are done, pregnant and post-partum mothers will be scheduled according to Protocol Change No. 20771-10.

6. No further semen analyses are to be done. All other testing will occur at same intervals, if applicable.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

MONS 016451

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-12

Test Compound AROCLOR 1254 Date May 25, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. O. P. Martin

Effective Date of Change:

May 26, 1978

Reason for Change: To provide additional information on the toxicity of PCB's.

Change to be Initiated: In addition to the body weight and somatic measurements obtained at the time of birth on offspring of females assigned to this study, body weights and somatic measurements are to be obtained at one month and at two months at the time that blood is obtained. Infants which have passed their one-month anniversary at the time of this change should have these measurements taken as soon as possible and then again at the two-month anniversary.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-13

Test Compound AROCLOR 1254 Date May 31, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

Individual Initiating Change:

Dr. P. E. Berteau, Monsanto Company

LSI Prin. Investigator/Study Director:

Dr. D. P. Martin

Effective Date of Change:

May 31, 1978

Reason for Change: To adjust the protocol to provide for a conclusion to the study.

Change to be initiated: SEE ATTACHED.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

PROTOCOL CHANGE NO. 20771-13

CHANGE TO BE INITIATED

1. Feeding of test compound and vehicle will be discontinued after May 31, 1978.

2. All breeding of animals will be discontinued after May 31, 1978. (Animals which are in breeding as of May 31, 1978, will complete that breeding cycle.)

3. The testing schedule for adults will be as follows:

Hematology (including platelet and reticulocyte count):	Monthly
Biochemistry (SMAC):	Monthly
Fat Biopsies:	Every two months beginning in June (with the exception of animals noted in Protocol Change No. 20771-10. Female animals rescheduled due to pregnancy will be biopsied at the next scheduled biopsy time if it is less than 30 days away.)
Semen Analysis:	Do in June and then discontinue.
Urinalysis and 17-Ketosteroid Analysis:	Every three months beginning in June.
Body Weight:	Biweekly
Physical Examination:	Monthly

4. Adult animals are to be held for six months after discontinuance of PCB's and killed in December 1978 after final testing has been completed.

5. Infants are to be left with the mother to nurse when possible and have somatic measurements, body weight, hematology (including platelet and reticulocyte count), a skin biopsy, and a physical examination taken at birth, one month, and two months (when deemed safe by the attending veterinarian). Any signs of PCB toxicity in infants will be recorded.

6. Infants will be killed two months after birth unless evidence of PCB toxicity has developed in which case the infant is to be weaned from the mother and observed for reversal of signs.

cc: Dr. P. Bertsau

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-14

Test Compound AROCLOR 1254 Date June 5, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. P. Martin

Effective Date of Change:

June 5, 1978

Reason for Change: To account for recent pregnancy in the testing for urinary levels of 17-ketosteroids.

Change to be Initiated: Animals which have given birth are not to be tested for urinary levels of 17-ketosteroids until the second cycle following birth. If this cycle falls within 60 days of the next regularly scheduled determination, then testing should be postponed until the scheduled month.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Invest., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-15

Test Compound AROCLOR 1254 Date July 17, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LSI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. P. Martin

Effective Date of Change:

July 17, 1978

Reason for Change: To more closely follow changes in the status of the offspring on Project 20771.

Change to be Initiated: A complete physical examination should be done on the offspring of Project 20771 females with a separate physical examination sheet filled out at birth and at the time of the 1- and 2-month examinations after birth. Should any signs of toxicity be observed, a complete physical should be performed at 2-week intervals with observations recorded as necessary between these. This procedure should continue in any of the infants transferred to the Nursery at two months.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LSMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

cc: Dr. P. Berteau

LITTON BIONETICS, INC.
Inter-Office Memorandum

July 18, 1978

To: Project 20771 File

From: Dr. O. P. Martin

Subject: Error in Following of Protocol on Project 20771

I discovered on July 14, 1978, that three Project 20771 infants which had not been euthanatized due to their showing signs of PCB toxicity had inadvertently been left nursing on the mother beyond the 2-month period called for in Protocol Change No. 20771-13.

One of these infants, No. B-8546 from Monkey No. 757-I, medium dose, had been transferred to the Nursery for health reasons on July 10, 1978, rather than on July 3, 1978, as called for in the protocol.

The other two infants, No. B-8542 from Monkey No. 312-I, high dose, and No. B-8560 from Monkey No. 540-H, medium dose, had been scheduled to move to the Nursery on July 2, 1978, and July 9, 1978, respectively. These were moved on July 17, 1978.

DPM:jl

cc: Mr. M. Abbaticchio
Dr. J. Cicmanec
Dr. E. Gard
Mr. M. George
Monkey No. B-8542's File
Monkey No. B-8546's File
Monkey No. B-8560's File

MONS 016457

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-16

Test Compound AROCLOR 1254 Date July 26, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. O. P. Martin

Effective Date of Change:

July 26, 1978

Reason for Change: To provide maximum information for sponsor.

Change to be Initiated: Those infants which have been separated from the mother due to their showing toxic signs and which are being raised in the Nursery to observe for the reversal of these signs are to have the same testing procedures continued monthly at three months and older as they had at birth, one, and two months, specifically: 1. CBC with reticulocyte and platelet counts,

2. body weight,

3. somatic measurements,

4. fat (skin) biopsy.

As indicated in Protocol Change No. 20771-15, these infants are to be given a physical examination every two weeks.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

cc: Dr. P. Bertsau

9/30/78 (cc) Dr. P. Berteau
Dr. J. Laveglia

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-17

Test Compound AROCLOR 1254 Date August 30, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. Martin/Dr. J. Laveglia

Effective Date of Change:

September 1, 1978

Reason for Change: To eliminate conflict in present schedule which calls for urine collections in September 1978 and December 1978 (which would run into January 1979) and for necropsy in December.

Change to be Initiated: Cancel urine collections in September and December and replace with one collection beginning October 1, 1978.

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

MONS 016459

cc: Dr. P. Berteau

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-18

Test Compound AROCLOR 1254 Date September 29, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LSI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. P. Berteau, Monsanto Company

Effective Date of Change:

September 29, 1978

Reason for Change: To reduce the number of variables in the study and, specifically, not to interfere with the action of PCB's which may be contributing to intercurrent disease by immune suppression.

Change to be Initiated: No adults on the study are to receive antibiotics. Infants may receive antibiotics only with prior sponsor approval.

Comment: The use of antibiotics had not been discussed with Dr. Berteau since he became associated with the study. Their use is theoretically possible when the treatment is for a condition clearly not related to the PCB administration; however, because so few conditions can be separated from the PCB administration and its possible effects on immune suppression, antibiotic use has been suspended.

MONS 016460

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

cc: Dr. P. Berteau

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-19

Test Compound AROCLOR 1254 Date October 3, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. O. P. Martin

Individual Initiating Change:

Dr. P. Berteau, Monsanto Company

Effective Date of Change:

October 3, 1978

Reason for Change: A. Condition of Monkey No. 600-I.

B. Quality assurance of PCB's (if any) in monkey diet.

Change to be Initiated: A. The fat biopsy scheduled to occur in Monkey No. 600-I this week should be postponed pending a return to a stable condition of the animal (discretion of veterinarian).

B. One pound of Purina monkey chow from a bag used to feed the animals on Project 20771 should be placed in a plastic bag; marked with the project number, date, and contents; and then frozen in a Revco freezer until called for by Monsanto Company (Mike George).

MONS 016461

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Invest., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

cc: Dr. P. Berteau

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-20

Test Compound AROCLOR 1254 Date October 18, 1978

Sponsor:

Monsanto Company (MC)

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. Martin/Dr. P. Berteau (MC)

Effective Date of Change:

October 18, 1978

Reason for Change: Diarrhea in Monkey No. 9-8815.

Change to be Initiated: If condition of animal and/or results of bacterial swabs so indicate, this animal can be placed on antibiotic treatment.

MONS 016462

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

QA Inter-Office Memos (20771)
Project (Protocol) Change ✓

10/26/78 (cc:) Dr. P. Berteau

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-21

Test Compound AROCLOR 1254 Date October 25, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change:

Dr. D. Martin as result of Bionetics Medical Laboratories' action

Effective Date of Change:

Immediate

Reason for Change: Deletion of CPK from SMAC 1000 test series by Bionetics Medical Laboratories.

Change to be Initiated: The CPK results will not appear in the October biochemistry results for the animals on this project. This is a result of this test having been deleted from the SMAC 1000 series by the Bionetics Medical Laboratories. For the November and December biochemistry series, the CPK test should be requested as a separate test in addition to the SMAC 1000 series.

MONS 016463

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

Amended 12/12/78

cc: Dr. P. Berteau, MC
Dr. J. Cicmanec
Mr. D. Hermoon
Mr. S. Johnson
Dr. H. Seibold

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-22 (page 1 of 2)

Test Compound AROCLOR 1254 Date December 7, 1978

Sponsor:

Monsanto Company

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change: (Agreed to by discussion with Drs. P. Berteau & W. Ribelan of MC, Drs. D. Martin, J. Cicmanec, & H. Seibold, and Ms. B. Sheetz and M. George of LBI.

Effective Date of Change: December 4, 1978

Reason for Change: To assure that maximal information is gained from Project 20771.

Change to be Initiated:

(1) The protocol has been changed to add the sections from the tissues, which are herewith listed on page 2, to be taken at necropsy and put in formalin until a decision is made as to whether or not histologic sections will be made.

(2) 30 cc of clotted blood are to be obtained from each adult and as much as possible from each infant just prior to euthanasia. This is to be wrapped to minimize exposure to light and spun down to obtain serum. Three ml of serum are to be submitted to the Bionetics Medical Lab for determination of Vitamin A levels. DO NOT EXPOSE BLOOD OR SERUM TO LIGHT! The remaining serum is to be frozen at -70°C.

(3) A 5-gm sample of liver is to be obtained at necropsy and frozen in a plastic bag for future use in determining Vitamin A levels.

(4) The remaining infants, 3-8560, 5-3815, and 9-3860, are to have blood taken for determination of hematology values just prior to euthanasia regardless of when the most recent test was performed.

MONS 016464

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

PROJECT (PROTOCOL) CHANGE SHEET Change #20771-22 (page 2 of 2)

Effective Date of Change: December 4, 1978

Refer to (1) on page 1 of 2: Additional sections from tissues to be taken at necropsy and put in formalin.

Parathyroids, if present

Stomach; add one section to include both pyloric and fundic regions

Spleen

Extrahepatic bile duct

Prostate

Cecum

Left Nipple

Foreskin

Labium

Skeletal muscle

Sciatic nerve

Distal tibial nerve

Spinal cord, lumbar region

Skin, left hip

Skin, left thigh

Bone marrow, smear-femur

Fat biopsy to be sent to MC

MONS 016465

cc: Dr. P. Berteau, MC
Dr. J. Cicmanec
Mr. O. Herndon
Mr. S. Jonnson
Dr. H. Seibold

PROJECT (PROTOCOL) CHANGE SHEET

LBI Project # 20771 Change # 20771-23 (page 1 of 2)

Test Compound AROCLOR 1254 Date December 12, 1978

Sponsor:

Monsanto Company (MC)

St. Louis, Missouri

LBI Prin. Investigator/Study Director:

Dr. D. P. Martin

Individual Initiating Change: Agreed to by discussion with Drs. P. Berteau & W. Ribelin of MC, Drs. D. Martin, J. Cicmanec, & H. Seibold, and Mr. B. Sheetz and Mr. M. George of LBI.

Effective Date of Change: December 12, 1978

Reason for Change: To assure that maximal information is gained from Project 20771.

Change to be Initiated: On the following page is a clarification of the sections from tissues to be taken at necropsy excluding those listed on Protocol Change #20771-22.

MONS 016466

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LBI Regulatory Affairs Officer.

Effective Date of Change: December 12, 1978

Brain (3 sections)
Pituitary (1)
Eyelids (2)
Lips (2)
Mandible (1)
Salivary glands (2), parotid with duct (1) and submaxillary (1)
Thyroids (2)
Lymph nodes (2), axillary (1) and mesenteric (1)
Heart (3)
Thymus (1), if present
Lungs (4), right and left of both apical and diaphragmatic
Tongue (1)
Esophagus
Duodenum (1)
Liver (1)
Gall bladder (1)
Pancreas with duct
Jejunum (1)
Ileum (1)
Colon (1)
Kidneys (2)
Adrenals (2)
Urinary bladder
Ovaries
Uterus
Vagina (1)
Cervix (1)
Testes (2)
Epididymis (2)
Lesions (1)
Bone marrow, sternum and femur

cc: Dr. P. Barteau, MC
Dr. J. Cicmanec
Mr. D. Herndon
Mr. S. Jonnson
Dr. H. Seibold

PROJECT (PROTOCOL) CHANGE SHEET

LSI Project # 20771 Change # 20771-24 (page 1 of 2)

Test Compound AROCLOR 1254 Date December 15, 1978

Sponsor:
Monsanto Company (MC)
St. Louis, Missouri

LSI Prin. Investigator/Study Director:
Dr. D. P. Martin

Individual Initiating Change:
Dr. P. Barteau of MC (by telephone on 12/14/78 - to be followed by letter)

Effective Date of Change:
December 15, 1978

Reason for Change: To institute the final Pathology protocol and to combine Protocol Changes #20771-22 and #20771-23 in one place.

Change to be Initiated: The Monsanto Company has authorized all tissues taken at necropsy to be trimmed, stained, and read. The final listing, therefore, is as follows: SEE ATTACHED

MONS 016468

Initials of Individual Preparing Change Sheet

Initials of Study Director

Copies of this sheet must be sent to: (1) Prin. Inves., (2) LAMS Dept. Dir., (3) Project Tech., (4) Project Vet., and (5) LSI Regulatory Affairs Officer.

Effective Date of Change: December 15, 1978

Parathyroids, if present
Stomach; add one section to include both pyloric and fundic regions
Spleen
Extrahepatic bile duct
Prostate
Cecum
Left nipple
Foreskin
Labium
Skeletal muscle
Sciatic nerve
Distal tibial nerve
Spinal cord, lumbar region
Skin, left hip
Skin, left thigh
Bone marrow, smear-femur
Fat biopsy to be sent to MC
Brain (3 sections)
Pituitary (1)
Eyelids (2)
Lips (2)
Mandible (1)
Salivary glands (2), parotid with duct (1) and submaxillary (1)
Thyroids (2)
Lymph nodes (2), axillary (1) and mesenteric (1)
Heart (3)
Thymus (1), if present
Lungs (4), right and left of both apical and diaphragmatic
Tongue (1)
Esophagus
Duodenum (1)
Liver (1)
Gall bladder (1)
Pancreas with duct
Jejunum (1)
Ileum (1)
Colon (1)
Kidneys (2)
Adrenals (2)
Urinary bladder
Ovaries
Uterus
Vagina (1)
Cervix (1)
Testes (2)
Epididymis (2)
Lesions (1)
Bone marrow, sternum and femur

MONS 016469

APPENDIX D

APPENDIX D

The following appendix contains all urinalyses performed and is arranged chronologically within dose levels. Urinalyses were performed pre-drug and at Months 3, 6, 9, 12, 15, and 19.

	Page
Control	D-1
5 µg/kg	D-22
25 µg/kg	D-43
100 µg/kg	D-64

Key

Δ Repeat value.

URINALYSIS

Control - Pre-Drug

	Females			
	764-F	87-F	200-F	274-F
Total Volume (ml)	92.0	129.0	90.0	168.0
Color	none	straw	yellow	yellow
Appearance	clear	hazy	cloudy	hazy
Specific Gravity	1.004	1.010	1.033	1.018
pH	7.0	8.0	6.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	3+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.0	2.0	1.3	1.5
Urobilinogen, Random	neg	neg	1.0	neg
WBC	---	2-3	---	---
RBC.	---	10-12	---	---
Epithelial Cells	trace	6-10	1-5	3-5
Amorphous Sediment	trace	1+	trace	---
Triple Phosphate Crystals	---	trace	---	---
Calcium Oxalate Crystals	---	---	---	4+
Mucous Threads	---	1+	trace	---
Casts	2-3	---	---	---
Bacteria	---	1+	---	trace
Other	---	---	---	---

URINALYSIS

Control - Pre-Drug

	Females			
	569-H	578-H	604-I	618-I
Total Volume (ml)	85.0	140.0	265.0	185.0
Color	yellow	yellow	yellow	yellow
Appearance	turbid	cloudy	cloudy	hazy
Specific Gravity	1.025	1.026	1.017	1.022
pH	9.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	1+	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.2	1.9	0.8	2.0
Urobilinogen, Random	trace	neg	0.1	neg
WBC	---	---	0-3	occ
RBC	---	---	---	---
Epithelial Cells	---	3-5	5-7	3-5
Amorphous Sediment	3+	3+	1+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	3+	3+	---	1+
Mucous Threads	---	---	---	1+
Casts	---	---	---	---
Bacteria	---	---	---	trace
Other	---	---	---	---

URINALYSIS

Control - Pre-Drug

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	105.0	260.0	175.0	160.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	clear	cloudy
Specific Gravity	1.032	1.025	1.011	1.034
pH	6.0	7.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.5	2.7	1.1	2.1
Urobilinogen, Random	trace	neg	neg	neg
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	2-3	6-8
Amorphous Sediment	4+	4+	1+	3+
Triple Phosphate Crystals	4+	---	4+	---
Calcium Oxalate Crystals	---	---	---	1+
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	1+
Other	---	---	---	---

MONS 016474

URINALYSIS

Control - Month 3

	Females			
	764-E	87-F	200-F	274-F
Total Volume (ml)	360.0	220.0	180.0	350.0
Color	straw	straw	straw	straw
Appearance	hazy	cloudy	cloudy	hazy
Specific Gravity	1.011	1.017	1.015	1.011
pH	7.0	7.0	5.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	1+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	08.0	08.0	09.0	07.0
Urobilinogen, Random	neg	trace	1.0	neg
WBC	0-3	0-3	---	0-3
RBC	0-1	2-5	---	---
Epithelial Cells	2-5	---	7-10	---
Amorphous Sediment	1+	trace	1+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	1+	---
Casts	Na	---	---	---
Bacteria	---	trace	---	---
Other	---	---	---	---

URINALYSIS

Control - Month 3

	Females			
	569-H	578-H	604-I	618-I
Total Volume (ml)	90.0	400.0	170.0	180.0
Color	yellow	straw	yellow	yellow
Appearance	hazy	cloudy	hazy	turbid
Specific Gravity	1.050	1.011	1.014	1.025
pH	5.0	8.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	1+	neg	neg	neg
Ketone	3+	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.8	1.0	0.6	1.7
Urobilinogen, Random	1+	neg	neg	1.0
WBC	---	5-7	---	5-7
RBC.	---	0-1	---	---
Epithelial Cells	5-7	---	5-7	---
Amorphous Sediment	1+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	trace
Other	---	---	---	---

MONS 016476

URINALYSIS

Control - Month 3

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	100.0	155.0	165.0	115.0
Color	straw	yellow	yellow	yellow
Appearance	clear	clear	clear	hazy
Specific Gravity	1.036	1.030	1.029	1.042
pH	6.0	6.0	8.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.4	1.8	1.6	2.1
Urobilinogen, Random	1+	trace	1+	1+
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	1+	1+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	trace
Other	---	sperm trace	sperm trace	sperm trace

MONS 016477

URINALYSIS

Control - Month 6

	Females			
	764-E	87-F	200-F	274-F
Total Volume (ml)	480.0	250.0	390.0	410.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	clear	clear
Specific Gravity	1.013	1.015	1.011	1.010
pH	8.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	3+	neg	trace
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.5	0.9	1.3	1.0
Urobilinogen, Random (E unit/dl)	trace	trace	1+	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	7-8	2-7	2-5	0-2
Amorphous Sediment	---	2+	trace	trace
Triple Phosphate Crystals	2+	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	---	---	---	---

URINALYSIS

Control - Month 6

	Females			
	569-H	578-H	504-I	518-I
Total Volume (ml)	320.0	240.0	1,020.0	425.0
Color	yellow	straw	yellow	yellow
Appearance	cloudy	hazy	clear	hazy
Specific Gravity	1.022	1.010	1.006	1.012
pH	7.0	6.0	7.0	8.0
Protein	neg	trace	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	3+	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.1	1.8	2.7	2.7
Urobilinogen, Random (E unit/dl)	trace	trace	trace	trace
WBC	1-2	---	---	6-8
RBC	---	3-4	---	---
Epithelial Cells	3-5	2-3	5-8	---
Amorphous Sediment	1+	1+	1+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	trace	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	bacteria trace	bacteria 2+	bacteria trace	bacteria 4+

URINALYSIS

Control - Month 6

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	160.0	335.0	335.0	335.0
Color	yellow	yellow	yellow	yellow
Appearance	clear	clear	hazy	hazy
Specific Gravity	1.011	1.015	1.018	1.017
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.1	1.6	1.5	2.0
Urobilinogen, Random (E unit/dl)	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	0-2
Amorphous Sediment	1+	trace	2+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Treads	---	---	---	trace
Casts	---	---	---	---
Other	---	---	---	bacteria 2+ budding yst 1+ sperm 1+

MONS 016480

URINALYSIS

Control - Month 9

	Females			
	764-F	87-F	200-F	274-F
Total Volume (ml)	190.0	340.0	110.0	570.0
Color	yellow	yellow	straw	yellow
Appearance	hazy	cloudy	turbid	cloudy
Specific Gravity	1.025	1.014	1.039	1.010
pH	7.0	7.0	6.0	8.0
Protein	neg	neg	neg	trace
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	trace
17-Ketosteroids (mg/24 hr)	lab acc	2.4	2.1	pregnant
Urobilinogen, Random	1+	1+	1+	trace
WBC	0-1	---	---	0-1
RBC	---	---	---	---
Epithelial Cells	0-3	---	1-7	0-1
Amorphous Sediment	2+	2+	2+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	trace	---
Other	---	---	---	---

MONS 016481

URINALYSIS

Control - Month 9

	Females			
	569-H	578-H	604-I	618-I
Total Volume (ml)	180.0	380.0	640.0	240.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	cloudy	hazy	cloudy
Specific Gravity	1.023	1.010	1.007	1.019
pH	7.0	7.0	8.0	7.0
Protein	neg	neg	1+	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	0.7	pregnant	pregnant	pregnant
Urobilinogen, Random	1+	1+	0.1	1+
WBC	0-1	---	0-2	---
RBC	---	---	---	---
Epithelial Cells	2-4	0-1	0-1	4-6
Amorphous Sediment	2+	2+	trace	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	trace	---	---
Other	---	---	---	---

URINALYSIS

Control - Month 9

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	180.0	180.0	630.0	370.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	hazy	hazy
Specific Gravity	1.021	1.025	1.017	1.010
pH	8.0	8.0	8.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.4	1.2	4.1	1.1
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	sperm trace	---	---

MONS 016483

URINALYSIS

Control - Month 12

	Females			
	764-E	87-F	200-F	274-F
Total Volume (ml)	---	---	---	---
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	clear	clear
Specific Gravity	1.008	1.013	1.031	1.020
pH	7.0	6.0	6.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	4+	4+	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	trace	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	pregnant	pregnant
Urobilinogen, Random	1+	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	0-3	0-3	---
Amorphous Sediment	2+	3+	1+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	1+	---
Other	---	---	---	---

MONS 016484

URINALYSIS

Control - Month 12

	Females			
	569-H	578-H	604-I	618-I
Total Volume (ml)	210.0	---	---	---
Color	yellow	yellow	straw	straw
Appearance	hazy	clear	cloudy	cloudy
Specific Gravity	1.022	1.015	1.009	1.016
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	pregnant	pregnant	pregnant
Urobilinogen, Random	1+	neg	trace	neg
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	3-7	---	---	---
Amorphous Sediment	2+	1+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016485

URINALYSIS

Control - Month 12

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	150.0	400.0	200.0	600.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	cloudy	cloudy
Specific Gravity	1.030	1.018	1.029	1.017
pH	7.0	8.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	5.8	2.8	3.1	1.0
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016486

URINALYSIS

Control - Month 15

	Females		
	764-F*	200-F	274-F
Total Volume (ml)	---	300	700
Color	---	straw	straw
Appearance	---	hazy	hazy
Specific Gravity	---	1.019	1.010
pH	---	7.0	8.0
Protein	---	neg	neg
Glucose	---	neg	neg
Katone	---	neg	neg
Bilirubin	---	neg	neg
Blood	---	neg	neg
Bilirubin, qual.	---	neg	neg
17-Katosteroids (mg/24 hr)	---	3.0	9.6
Urobilinogen, Random (E unit/dl)	---	neg	neg
WBC	---	---	---
RBC	---	---	---
Epithelial Cells	---	---	2-3
Amorphous Sediment	---	2+	trace
Triple Phosphate Crystals	---	---	---
Calcium Oxalate Crystals	---	---	---
Mucous Threads	---	---	---
Casts	---	---	---
Bacteria	---	---	trace
Other	---	---	---

* Urine not collected; animal had not begun second cycle after giving birth.

MONS 016487

URINALYSIS

Control - Month 15

	Females			
	569-H	578-H	604-I	618-I*
Total Volume (ml)	310	700	860	---
Color	yellow	yellow	colorless	---
Appearance	hazy	clear	hazy	---
Specific Gravity	1.014	1.022	1.006	---
pH	7.0	7.0	7.0	---
Protein	neg	neg	neg	---
Glucose	neg	neg	neg	---
Ketone	neg	neg	neg	---
Bilirubin	neg	neg	neg	---
Blood	neg	neg	neg	---
Bilirubin, qual.	neg	neg	neg	---
17-Ketosteroids (mg/24 hr)	1.9	8.4	2.8	---
Urobilinogen, Random (E unit/dl)	trace	neg	neg	---
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	0-3	1-2	15-20	---
Amorphous Sediment	2+	---	1+	---
Triple Phosphate Crystals	---	4+	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	trace	---
Other	---	---	---	---

* Urine not collected; animal had not begun second cycle after giving birth.

MONS 016488

URINALYSIS

Control - Month 15

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	300	350	540	270
Color	yellow	yellow	yellow	straw
Appearance	clear	clear	clear	cloudy
Specific Gravity	1.015	1.014	1.010	1.023
pH	7.0	8.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	3+
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	0.7	0.2	1.1	2.2
Urobilinogen, Random (E unit/dl)	trace	trace	trace	1+
WBC	---	---	---	0-2
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	2+	trace	trace	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	sperm trace	---

MONS 016489

URINALYSIS

Control - Month 19

	Females		
	764-E	200-F	274-F
Total Volume (ml)	680.0	340.0	920.0
Color	yellow	straw	yellow
Appearance	hazy	cloudy	clear
Specific Gravity	1.009	1.016	1.005
pH	8.0	7.0	7.0
Protein	neg	neg	neg
Glucose	neg	neg	neg
Ketone	neg	neg	neg
Bilirubin	neg	neg	neg
Blood	neg	neg	neg
Bilirubin, qual.	neg	neg	neg
17-Ketosteroids (mg/24 hr)	4.3	2.5	2.9
Urobilinogen, Random	1.0	1+	trace
WBC	---	1-2	0-3
RBC	---	---	---
Epithelial Cells	3-8	6-8	0-4
Amorphous Sediment	2+	4+	1+
Triple Phosphate Crystals	1+	4+	---
Calcium Oxalate Crystals	---	---	---
Mucous Threads	---	---	---
Casts	---	---	---
Bacteria	---	---	1+
Other	---	---	---

URINALYSIS

Control - Month 19

	Females			
	569-H	578-H	604-I	618-I*
Total Volume (ml)	240.0	255.0	800.0	---
Color	yellow	straw	yellow	---
Appearance	hazy	cloudy	hazy	---
Specific Gravity	1.022	1.017	1.004	---
pH	7.0	7.0	7.0	---
Protein	neg	neg	neg	---
Glucose	neg	neg	neg	---
Ketone	neg	neg	neg	---
Bilirubin	neg	neg	neg	---
Blood	neg	neg	neg	---
Bilirubin, qual.	neg	neg	neg	---
17-Ketosteroids (mg/24 hr)	2.6	2.1	3.2	---
Urobilinogen, Random	4.0	trace	0.0	---
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	0-3	7-10	0-3	---
Amorphous Sediment	2+	2+	2+	---
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	trace	2+	---
Other	---	hippuric acid crystals 1+	---	---

* Urine not collected; animal has not cycled normally.

MONS 016491

URINALYSIS

Control - Month 19

	Males			
	739-F	227-G	426-G	418-J
Total Volume (ml)	140.0	380.0	520.0	650.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	clear	clear	clear
Specific Gravity	1.025	1.014	1.010	1.012
pH	7.0	8.0	8.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.4	1.1	2.0	3.3
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	NNA	---	---	---
Amorphous Sediment	2+	trace	trace	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	2+	---	---	---
Casts	---	---	---	---
Bacteria	trace	---	---	trace
Other	---	---	---	---

URINALYSIS

5 ug/kg - Pre-Drug

	Females			
	646-E	701-E	605-F	839-H
Total Volume (ml)	90.0	185.0	186.0	90.0
Color	yellow	yellow	straw	yellow
Appearance	cloudy	cloudy	hazy	cloudy
Specific Gravity	1.056	1.021	1.012	1.040
pH	6.0	7.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	1+
Bilirubin	neg	neg	neg	1+
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	---
17-Ketosteroids (mg/24 hr)	1.8	1.0	1.1	2.0
Urobilinogen, Random	neg	trace	0.1	neg
WBC	1-2	occ	---	---
RBC	---	---	---	---
Epithelial Cells	8-10	3-5	5-8	3-5
Amorphous Sediment	---	trace	---	2+
Triple Phosphate Crystals	---	---	---	occ
Calcium Oxalate Crystals	2+	---	3+	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	trace
Other	---	---	---	---

MONS 016493

URINALYSIS

5 ug/kg - Pre-Drug

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	350.0	*	130.0	110.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	cloudy	cloudy
Specific Gravity	1.011	1.028	1.027	1.026
pH	7.0	6.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	1+
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	1+
17-Ketosteroids (mg/24 hr)	1.5	*	1.3	2.9
Urobilinogen, Random	neg	neg	neg	neg
WBC	1-2	2-5	---	---
RBC	---	rare	---	0-2
Epithelial Cells	5-7	2-3	2+	5-7
Amorphous Sediment	---	1+	---	2+
Triple Phosphate Crystals	---	---	---	occ
Calcium Oxalate Crystals	trace	---	2+	---
Mucous Threads	---	---	---	1+
Casts	---	---	15-18	---
Bacteria	---	---	---	2+
Other	---	---	---	---

* Through laboratory error, the volume of urine submitted was lost; however, the value for 1 ml was 0.010. This is within normal limits for this test.

MONS 016494

URINALYSIS

5 µg/kg - Pre-Drug

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	170.0	160.0	195.0	190.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	cloudy	cloudy
Specific Gravity	1.017	1.023	1.031	1.021
pH	6.0	6.0	7.0	7.0
Protain	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	1.5	2.1	1.3
Urobilinogen, Random	neg	neg	neg	neg
WBC	1-2	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	1-2	---
Amorphous Sediment	2+	4+	3+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	2+
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	---
Other	---	---	---	---

URINALYSIS

5 µg/kg - Month 3

	Females			
	646-E	701-E	605-E	839-H
Total Volume (ml)	55.0	290.0	170.0	170.0
Color	yellow	yellow	yellow	yellow
Appearance	turbid	cloudy	clear	hazy
Specific Gravity	1.038	1.016	1.008	1.005
pH	6.0	7.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	1+	2+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.3	0.8	0.4	1.1
Urobilinogen, Random	1+	neg	neg	neg
WBC	5-7	---	---	---
RBC	5-7	---	---	---
Epithelial Cells	7-10	---	1-2	0-2
Amorphous Sediment	2+	3+	3+	---
Triple Phosphate Crystals	---	---	---	2+
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	1+	---
Other	---	---	---	---

URINALYSIS

5 µg/kg - Month 3

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	260.0	150.0	183.0	93.0
Color	straw	straw	yellow	yellow
Appearance	cloudy	cloudy	turbid	turbid
Specific Gravity	1.010	1.016	1.026	1.028
pH	8.0	7.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.3	0.9	1.4	2.2
Urobilinogen, Random	1+	neg	0.1	trace
WBC	---	0-3	---	5-7
RBC	---	---	---	---
Epithelial Cells	occ	2-5	---	---
Amorphous Sediment	trace	trace	2+	1+
Triple Phosphate Crystals	1+	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	trace	trace	trace
Other	---	---	---	---

URINALYSIS

5 µg/kg - Month 3

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	190.0	140.0	175.0	140.0
Color	yellow	yellow	yellow	yellow
Appearance	clear	clear	clear	cloudy
Specific Gravity	1.021	1.028	1.028	1.031
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	2+	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	0.7	0.8	1.7	2.0
Urobilinogen, Random	1+	trace	trace	2+
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	trace	trace	1+
Triple Phosphate Crystals	---	---	---	trace
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	trace	trace	---	---
Other	---	---	---	---

URINALYSIS

5 ug/kg - Month 6

	Females			
	646-E	701-E	605-E	839-H
Total Volume (ml)	120.0	255.0	240.0	260.0
Color	straw	straw	straw	yellow
Appearance	hazy	cloudy	hazy	cloudy
Specific Gravity	1.026	1.016	1.011	1.013
pH	6.0	7.0	6.0	8.0
Protein	neg	neg	trace	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	trace	2+	3+
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.5	1.6	1.8	1.3
Urobilinogen, Random (E unit/dl)	1+	trace	trace	1+
WBC	---	15-20	3-4	7-9
RBC	---	5-6	5-6	30-40
Epithelial Cells	5-7	7-9	10-15	5-7
Amorphous Sediment	2+	trace	---	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Treads	---	---	---	---
Casts	---	---	---	---
Other	---	bacteria trace	bacteria trace	bacteria trace

MONS 016499

URINALYSIS

5 µg/kg - Month 6

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	110.0	29.0	480.0	120.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	turbid	turbid	turbid
Specific Gravity	1.023	1.044	1.025	1.020
pH	5.0	5.0	6.0	5.0
Protein	neg	neg	trace	1+
Glucose	neg	neg	2+	neg
Ketone	neg	neg	1+	trace
Bilirubin	neg	neg	neg	neg
Blood	2+	3+	neg	3+
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	1.3	1.2	1.7
Urobilinogen, Random (E unit/dl)	trace	2+	trace	trace
WBC	occ	---	0-2	5-6
RBC	3-4	10-12	---	6-10
Epithelial Cells	---	3-4	2-3	10-12
Amorphous Sediment	---	1+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	trace	2+	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	bacteria trace	bacteria 2+	bacteria 1+	bacteria 2+

URINALYSIS

5 ug/kg - Month 6

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	335.0	50.0	425.0	250.0
Color	yellow	yellow	straw	straw
Appearance	hazy	clear	clear	cloudy
Specific Gravity	1.015	1.019	1.010	1.021
pH	7.0	6.0	8.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Katone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.1	0.4	2.5	2.8
Urobilinogen, Random (E unit/dl)	trace	trace	trace	trace
WBC	---	0-4	0-2	---
RBC	---	0-2	---	---
Epithelial Cells	---	---	0-2	---
Amorphous Sediment	2+	trace	trace	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	---	bacteria trace	---	---

MONS 016501

URINALYSIS

5 µg/kg - Month 9

	Females			
	646-E	701-E	605-F	839-H
Total Volume (ml)	115.0	320.0	160.0	270.0
Color	straw	yellow	straw	straw
Appearance	cloudy	hazy	cloudy	cloudy
Specific Gravity	1.040	1.014	1.031	1.020
pH	6.0	7.0	6.0	7.0
Protein	neg	neg	3+	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	2+	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	pregnant	2.6
Urobilinogen, Random	1+	trace	1+	1+
WBC	---	---	2-4	---
RBC	---	---	7-15	---
Epithelial Cells	1-4	0-4	2-5	4-7
Amorphous Sediment	3+	2+	3+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

5 µg/kg - Month 9

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	630.0	340.0	190.0	114.0
Color	yellow	yellow	straw	straw
Appearance	cloudy	cloudy	cloudy	turbid
Specific Gravity	1.009	1.010	1.028	1.028
pH	8.0	7.0	7.0	7.0
Protein	neg	neg	neg	trace
Glucose	neg	neg	2+	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	3+
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.3	1.2	2.0	pregnant
Urobilinogen, Random	2+	1+	1+	0.1
WBC	0-1	0-2	---	0-2
RBC	---	---	---	7-15
Epithelial Cells	0-1	0-4	7-10	1-5
Amorphous Sediment	2+	1+	2+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	trace	---	2+
Other	---	---	---	---

URINALYSIS

5 ug/kg - Month 9

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	200.0	170.0	160.0	300.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	hazy	hazy
Specific Gravity	1.026	1.023	1.027	1.022
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.8	1.3	1.5	2.7
Urobilinogen, Random	trace	trace	1+	1+
WBC	0-2	0-1	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	2+	2+	2+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other			sperm trace	

URINALYSIS

5 µg/kg - Month 12

	Females			
	646-E	701-E	605-F	839-H
Total Volume (ml)	140.0	---	---	270.0
Color	yellow	straw	brown	yellow
Appearance	cloudy	cloudy	cloudy	cloudy
Specific Gravity	1.031	1.023	1.026	1.021
pH	6.0	7.0	7.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	trace	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	trace
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.3	pregnant	pregnant	0.5
Urobilinogen, Random	1+	neg	neg	1+
WBC	0-1	---	0-1	0-2
RBC	---	---	---	0-4
Epithelial Cells	3-6	0-1	0-2	1-7
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	1+	---	---	---
Casts	---	---	---	---
Bacteria	trace	---	---	1+
Other	---	---	---	---

MONS 016505

URINALYSIS

5 µg/kg - Month 12

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	300.0	205.0	190.0	---
Color	yellow	yellow	yellow	straw
Appearance	cloudy	cloudy	cloudy	cloudy
Specific Gravity	1.015	1.015	1.019	1.034
pH	6.0	7.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	1+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.3	0.7	0.7	pregnant
Urobilinogen, Random	1+	trace	1+	neg
WBC	---	---	---	---
RBC	---	4-7	---	---
Epithelial Cells	0-2	2-5	1-3	---
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	trace	---	---
Other	---	---	---	---

URINALYSIS

5 ug/kg - Month 12

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	300.0	300.0	800.0	320.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	cloudy	clear
Specific Gravity	1.022	1.019	1.011	1.009
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.3	2.9	3.6	1.0
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	0-2	---	---
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016507

URINALYSIS

5 µg/kg - Month 15

	Females			
	646-E	701-E*	605-F	839-H
Total Volume (ml)	133	---	610	140
Color	yellow	---	yellow	yellow
Appearance	cloudy	---	hazy	hazy
Specific Gravity	1.028	---	1.006	1.020
pH	7.0	---	7.0	7.0
Protein	neg	---	neg	neg
Glucose	neg	---	neg	neg
Ketone	neg	---	neg	1+
Bilirubin	neg	---	neg	neg
Blood	neg	---	neg	neg
Bilirubin, qual.	neg	---	neg	neg
17-Ketosteroids (mg/24 hr)	1.7	---	2.3	1.6
Urobilinogen, Random (E unit/dl)	trace	---	neg	1+
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	4-6	---	2-4	---
Amorphous Sediment	2+	---	3+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	2+	---	---	trace
Other	---	---	---	---

* Urine not collected; animal had not begun second cycle after giving birth.

MONS 016508

URINALYSIS

5 ug/kg - Month 15

	Females			
	284-I	483-F	309-I	624-I
Total Volume (ml)	---	---	---	145
Color	yellow	yellow	yellow	brown
Appearance	clear	hazy	hazy	turbid
Specific Gravity	1.008	1.012	1.021	1.029
pH	8.0	7.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	trace	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	trace
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	---	---	---	3.4
Urobilinogen, Random (E unit/dl)	trace	trace	trace	1+
WBC	---	---	---	0-3
RBC	---	---	---	0-4
Epithelial Cells	1-2	0-2	---	---
Amorphous Sediment	2+	1+	1+	3+
Triple Phosphate Crystals	3+	---	1+	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	1+
Casts	---	---	---	---
Bacteria	---	---	---	2+
Other	---	---	---	---

MONS 016509

URINALYSIS

5 µg/kg - Month 15

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	430	600	700	160
Color	yellow	yellow	yellow	straw
Appearance	hazy	hazy	clear	hazy
Specific Gravity	1.010	1.011	1.007	1.026
pH	7.0	8.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	0.7	1.4	0.9	1.8
Urobilinogan, Random (E unit/dl)	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	2+	2+	1+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016510

URINALYSIS

5 ug/kg - Month 19

	Females			
	646-E	701-E	605-F	839-H
Total Volume (ml)	195.0	260.0	540.0	100.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	cloudy	cloudy
Specific Gravity	1.020	1.013	1.010	1.028
pH	7.0	8.0	7.0	5.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	2+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.4	1.1	3.6	1.5
Urobilinogen, Random	trace	1+	trace	1+
WBC	---	---	---	---
RBC	---	150-200	---	---
Epithelial Cells	5-7	15-20	6-10	7-10
Amorphous Sediment	1+	1+	1+	2+
Triple Phosphate Crystals	---	---	trace	---
Calcium Oxalate Crystals	trace	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	trace	3+	2+	trace
Other	---	---	---	hippuric acid crystals 1+

MONS 016511

URINALYSIS

5 µg/kg - Month 19

	Females			
	284-I	483-F*	309-I**	624-I
Total Volume (ml)	415.0	---	---	190.0
Color	yellow	---	---	green
Appearance	hazy	---	---	turbid
Specific Gravity	1.010	---	---	1.021
pH	7.0	---	---	7.0
Protein	neg	---	---	neg
Glucose	neg	---	---	neg
Ketone	neg	---	---	neg
Bilirubin	neg	---	---	neg
Blood	trace	---	---	trace
Bilirubin, qual.	neg	---	---	neg
17-Ketosteroids (mg/24 hr)	1.8	---	---	2.9
Urobilinogen, Random	trace	---	---	trace
WBC	0-3	---	---	0-6
RBC	occ	---	---	15-20
Epithelial Cells	2-8	---	---	0-6
Amorphous Sediment	---	---	---	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	2+	---	---	4+
Other	---	---	---	---

* Urine not collected; gave birth at time of collection.

** Urine not collected; animal has not cycled normally.

MONS 016512

URINALYSIS

5 µg/kg - Month 19

	Males			
	516-G	119-H	428-J	432-J
Total Volume (ml)	400.0	600.0	330.0	230.0
Color	yellow	yellow	yellow	yellow
Appearance	clear	clear	clear	clear
Specific Gravity	1.013	1.007	1.017	1.022
pH	8.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	1+	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.7	2.3	2.1	2.1
Urobilinogen, Random	1+	trace	trace	trace
WBC	---	0-1	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	trace	trace	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016513

URINALYSIS

25 µg/kg - Pre-Drug

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	152.0	132.0	165.0	258.0
Color	yellow	straw	yellow	yellow
Appearance	cloudy	hazy	hazy	cloudy
Specific Gravity	1.030	1.006	1.022	1.019
pH	7.0	8.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	3+	neg	3+
Bilirubin, qual.	1+	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.0	1.1	0.9	0.8
Urobilinogen, Random	1+	neg	trace	neg
WBC	1-2	---	occ	---
RBC	---	3-5	---	0-3
Epithelial Cells	3-5	8-12	3-5	10-12
Amorphous Sediment	2+	2+	1+	---
Triple Phosphate Crystals	1+	---	---	---
Calcium Oxalate Crystals	---	---	1+	---
Mucous Threads	---	---	---	2+
Casts	---	---	---	---
Bacteria	trace	1+	trace	---
Other	---	---	---	---

MONS 016514

URINALYSIS

25 µg/kg - Pre-Drug

	Females			
	841-H	273-I	307-I	757-I
Total Volume (ml)	310.0	172.0	90.0	174.0
Color	yellow	yellow	yellow	straw
Appearance	hazy	hazy	cloudy	cloudy
Specific Gravity	1.012	1.026	1.040	1.020
pH	7.0	7.0	6.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	1+	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.0	1.5	1.6	1.0
Urobilinogen, Random	0.1	0.1	1+	neg
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	5-7	5-7	rare	0-2
Amorphous Sediment	trace	4+	1+	---
Triple Phosphate Crystals	---	---	---	1+
Calcium Oxalate Crystals	2+	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	trace
Other	---	---	---	---

URINALYSIS

25 µg/kg - Pre-Drug

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	210.0	110.0	360.0	190.0
Color	yellow	yellow	straw	yellow
Appearance	cloudy	hazy	cloudy	hazy
Specific Gravity	1.032	1.040	1.017	1.013
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	3.0	1.0	7.4	2.3
Urobilinogen, Random	neg	trace	neg	neg
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	2-3	---	---	---
Amorphous Sediment	4+	---	2+	4+
Triple Phosphate Crystals	---	2+	---	1+
Calcium Oxalate Crystals	4+	2+	---	3+
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	1+	2+	trace	trace
Other	---	---	---	---

MONS 016516

URINALYSIS

25 µg/kg - Month 3

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	65.0	170.0	200.0	170.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	hazy	hazy
Specific Gravity	1.045	1.014	1.020	1.025
pH	6.0	8.0	7.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.1	0.6	0.7	1.2
Urobilinogen, Random	trace	neg	1+	neg
WBC	---	2-3	occ	---
RBC	---	---	---	---
Epithelial Cells	3-5	0-2	0-1	---
Amorphous Sediment	trace	trace	2+	2+
Triple Phosphate Crystals	---	2+	---	occ
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	trace	trace
Casts	---	---	---	---
Bacteria	---	---	1+	---
Other	---	---	---	---

MONS 016517

URINALYSIS

25 µg/kg - Month 3

	Females			
	841-H	273-I	307-I	757-I
Total Volume (ml)	600.0	115.0	80.0	115.0
Color	none	yellow	yellow	yellow
Appearance	clear	turbid	hazy	hazy
Specific Gravity	1.007	1.032	1.036	1.027
pH	7.0	7.0	6.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.2	1.6	12.1	0.8
Urobilinogen, Random	0.1	1+	1+	neg
WBC	---	---	---	2-7
RBC	---	---	---	---
Epithelial Cells	5-7	2-3	---	3-5
Amorphous Sediment	---	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	trace	---	---
Mucous Threads	trace	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

MONS 016518

URINALYSIS

25 µg/kg - Month 3

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	175.0	190.0	165.0	140.0
Color	straw	straw	yellow	yellow
Appearance	hazy	hazy	clear	hazy
Specific Gravity	1.031	1.026	1.026	1.029
pH	6.0	7.0	6.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.0	0.7	0.8	1.6
Urobilinogen, Random	1+	1+	1+	trace
WBC	---	0-1	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	0-3
Amorphous Sediment	1+	trace	trace	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	sperm 1+	sperm trace	sperm trace

URINALYSIS

25 µg/kg - Month 6

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	100.0	420.0	1,000.0	278.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	hazy	cloudy	cloudy
Specific Gravity	1.028	1.016	1.006	1.020
pH	5.0	8.0	7.0	9.0
Protein	trace	neg	neg	neg
Glucose	---	neg	neg	neg
Ketone	trace	neg	neg	neg
Bilirubin	---	neg	neg	neg
Blood	3+	neg	neg	trace
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	3.1	3.6	1.2
Urobilinogen, Random (E unit/dl)	trace	trace	trace	1+
WBC	---	8-10	---	---
RBC	7-8	---	---	3-5
Epithelial Cells	3-5	5-7	---	2-3
Amorphous Sediment	2+	---	1+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	2+	---	---	---
Casts	---	---	---	---
Other	bacteria 1+	---	---	bacteria 1+

MONS 016520

URINALYSIS

25 ug/kg - Month 6

	Females			
	841-H	273-I	307-I	757-I
Total Volume (ml)	400.0	345.0	30.0	270.0
Color	yellow	straw	yellow	straw
Appearance	hazy	hazy	turbid	hazy
Specific Gravity	1.008	1.013	1.024	1.010
pH	7.0	8.0	5.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	3+	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.2	1.5	0.5	1.3
Urobilinogen, Random (E unit/dl)	trace	trace	1+	trace
WBC	---	0-1	2-3	---
RBC	0-2	---	5-6	---
Epithelial Cells	2-5	0-3	8-10	10-15
Amorphous Sediment	1+	2+	2+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	1+	trace
Casts	---	---	---	---
Other	---	---	bacteria 2+	bacteria trace

MONS 016521

URINALYSIS

25 µg/kg - Month 6

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	430.0	280.0	850.0	160.0
Color	straw	straw	straw	straw
Appearance	hazy	hazy	clear	hazy
Specific Gravity	1.013	1.018	1.007	1.018
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteriods (mg/24 hr)	3.1	1.7	2.6	2.2
Urobilinogen, Random (E unit/dl)	trace	1+	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	1+	1+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	---	sperm trace	---	bacteria trace

MONS 016522

URINALYSIS

25 ug/kg - Month 9

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	120.0	385.0	540.0	173.0
Color	yellow	straw	yellow	yellow
Appearance	cloudy	hazy	hazy	cloudy
Specific Gravity	1.028	1.016	1.011	1.027
pH	7.0	8.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	1+
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	1.2	pregnant
Urobilinogen, Random	trace	0.1	trace	trace
WBC	---	0-1	0-1	---
RBC	---	---	---	---
Epithelial Cells	2-5	0-3	4-6	5-7
Amorphous Sediment	3+	2+	1+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	1+	trace
Other	---	---	---	---

MONS 016523

URINALYSIS

25 ug/kg - Month 9

	Females			
	841-H	273-I	307-I	757-I
Total Volume (ml)	560.0	290.0	*	300.0
Color	yellow	straw	brown	yellow
Appearance	hazy	cloudy	turbid	cloudy
Specific Gravity	1.006	1.024	1.066	1.015
pH	7.0	8.0	5.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	*	pregnant
Urobilinogen, Random	trace	1+	1+	1+
WBC	0-2	---	---	---
RBC	---	---	---	---
Epithelial Cells	0-1	2-6	2-5	0-4
Amorphous Sediment	2+	3+	3+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	trace
Mucous Threads	---	---	2+	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

* Lab accident.

URINALYSIS

25 ug/kg - Month 9

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	190.0	170.0	360.0	180.0
Color	orange	yellow	yellow	yellow
Appearance	clear	hazy	hazy	clear
Specific Gravity	1.031	1.030	1.015	1.016
pH	8.0	6.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	1+	neg	neg	neg
17-Ketosteroids (mg/24 hr)	4.1	2.5	2.9	3.5
Urobilinogen, Random	trace	1+	1+	1+
WBC	---	---	---	1-2
RBC	---	---	---	---
Epithelial Cells	---	---	---	1-5
Amorphous Sediment	trace	2+	1+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	trace	1+	1+	---
Other	---	---	---	---

URINALYSIS

25 µg/kg - Month 12

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	---	---	360.0	---
Color	yellow	yellow	yellow	straw
Appearance	hazy	clear	hazy	hazy
Specific Gravity	1.027	1.019	1.009	1.028
pH	6.0	6.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	1+	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	1.1	pregnant
Urobilinogen, Random	neg	neg	trace	neg
WBC	---	---	---	---
RBC	2-5	---	---	---
Epithelial Cells	0-3	---	0-3	---
Amorphous Sediment	2+	1+	2+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	trace	---	---	1+
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

25 µg/kg - Month 12

	Females			
	841-H	273-I	307-I	757-I
Total Volume (ml)	---	---	120.0	---
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	cloudy	clear
Specific Gravity	1.011	1.018	1.030	1.014
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	pregnant	pregnant	1.1	pregnant
Urobilinogen, Random	neg	neg	trace	neg
WBC	0-1	---	---	---
RBC	---	---	2-3	---
Epithelial Cells	0-3	0-2	1-4	---
Amorphous Sediment	2+	2+	3+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	trace	---	2+	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

25 µg/kg - Month 12

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	555.0	220.0	200.0	360.0
Color	yellow	yellow	straw	yellow
Appearance	hazy	cloudy	hazy	cloudy
Specific Gravity	1.013	1.029	1.026	1.019
pH	8.0	7.0	8.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.7	4.1	1.3	5.3
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	0-1	---
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

25 ug/kg - Month 15

	Females			
	762-E*	763-E*	281-G	540-H
Total Volume (ml)	---	---	370	160
Color	---	---	straw	yellow
Appearance	---	---	clear	turbid
Specific Gravity	---	---	1.011	1.025
pH	---	---	8.0	7.0
Protein	---	---	neg	neg
Glucose	---	---	neg	neg
Ketone	---	---	neg	neg
Bilirubin	---	---	neg	neg
Blood	---	---	neg	neg
Bilirubin, qual.	---	---	neg	neg
17-Ketosteroids (mg/24 hr)	---	---	2.0	1.9
Urobilinogen, Random (E unit/dl)	---	---	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	---	---	trace	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	trace	trace
Other	---	---	---	crystals; ur acid 1+

* Urine not collected; animal had not begun second cycle after giving birth.

MONS 016529

URINALYSIS

25 ug/kg - Month 15

	Females			
	841-H	273-I	307-I	757-I*
Total Volume (ml)	600	320	80	---
Color	straw	yellow	yellow	---
Appearance	clear	hazy	clear	---
Specific Gravity	1.006	1.015	1.037	---
pH	7.0	7.0	6.0	---
Protein	neg	neg	neg	---
Glucose	neg	neg	neg	---
Ketone	neg	neg	neg	---
Bilirubin	neg	neg	neg	---
Blood	neg	neg	neg	---
Bilirubin, qual.	neg	neg	neg	---
17-Ketosteroids (mg/24 hr)	4.2	1.6	1.2	---
Urobilinogen, Random (E unit/dl)	neg	neg	1+	---
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	3-5	2-4	---	---
Amorphous Sediment	trace	2+	trace	---
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	1+	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	trace	---	trace	---
Other	---	---	---	---

* Urine not collected; animal had not begun second cycle after giving birth.

MONS 016530

URINALYSIS

25 µg/kg - Month 15

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	750	260	750	250
Color	yellow	straw	yellow	yellow
Appearance	clear	cloudy	clear	clear
Specific Gravity	1.007	1.027	1.008	1.021
pH	7.0	8.0	8.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	4.2	1.3	1.7	1.9
Urobilinogen, Random (E units/dl)	1+	trace	trace	trace
WBC	---	0-2	---	---
RBC	---	---	---	---
Epithelial Cells	0-3	---	---	---
Amorphous Sediment	trace	1+	1+	2+
Triple Phosphate Crystals	---	1+	1+	2+
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

25 µg/kg - Month 19

	Females			
	762-E	763-E	281-G	540-H
Total Volume (ml)	415.0	380.0	---	220.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	clear	hazy
Specific Gravity	1.010	1.014	1.007	1.022
pH	8.0	8.0	7.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.1	2.4	pregnant	1.2
Urobilinogen, Random	trace	trace	1.0	1.0
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	6-11	3-6	---	0-4
Amorphous Sediment	1+	trace	2+	2+
Triple Phosphate Crystals	1+	1+	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	3+	---	---	---
Other	---	---	---	---

MONS 016532

URINALYSIS

25 µg/kg - Month 19

	Females			
	841-H*	273-I	307-I**	757-I
Total Volume (ml)	---	540.0	---	260.0
Color	---	yellow	---	yellow
Appearance	---	hazy	---	hazy
Specific Gravity	---	1.012	---	1.015
pH	---	8.0	---	8.0
Protein	---	neg	---	neg
Glucose	---	neg	---	neg
Ketone	---	neg	---	neg
Bilirubin	---	neg	---	neg
Blood	---	neg	---	neg
Bilirubin, qual.	---	neg	---	neg
17-Ketosteroids (mg/24 hr)	---	2.2	---	2.0
Urobilinogen, Random	---	trace	---	0.1
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	0-2	---	7-10
Amorphous Sediment	---	2+	---	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

* No data; animal died 8/30/78.

** Urine not collected; animal has not cycled normally.

MONS 016533

URINALYSIS

25 µg/kg - Month 19

	Males			
	20-I	46-I	595-I	599-I
Total Volume (ml)	235.0	225.0	490.0	760.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	hazy	clear	clear
Specific Gravity	1.026	1.025	1.013	1.007
pH	8.0	8.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.5	1.4	2.6	3.5
Urobilinogen, Random	1.0	0.1	0.1	1.0
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	trace	1+	trace	1+
Triple Phosphate Crystals	3+	2+	trace	trace
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	0-3	---	---
Bacteria	---	---	---	trace
Other	---	---	---	---

MONS 016534

URINALYSIS

100 µg/kg - Pre-Drug

	Females			
	152-F	226-F	486-H	269-I
Total Volume (ml)	58.0	63.0	174.0	175.0
Color	straw	straw	straw	yellow
Appearance	hazy	hazy	hazy	cloudy
Specific Gravity	1.009	1.007	1.017	1.019
pH	9.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	3+	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	3.8	1.1	1.3	0.7
Urobilinogen, Random	neg	neg	0.1	neg
WBC	---	---	0-3	---
RBC	18-20	---	---	---
Epithelial Cells	8-10	0-4	3-5	---
Amorphous Sediment	1+	---	1+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	2+	1+	1+	---
Mucous Threads	---	---	---	2+
Casts	---	---	---	---
Bacteria	---	1+	trace	---
Other	---	---	---	---

URINALYSIS

100 µg/kg - Pre-Drug

	Females			
	287-I	312-I	338-I	770-I
Total Volume (ml)	168.0	168.0	390.0	120.0
Color	straw	yellow	straw	yellow
Appearance	cloudy	hazy	hazy	cloudy
Specific Gravity	1.012	1.024	1.010	1.031
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	1+
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	1+
17-Ketosteroids (mg/24 hr)	1.0	1.7	2.2	1.7
Urobilinogen, Random	neg	neg	neg	neg
WBC	15-25	---	---	---
RBC.	---	---	---	---
Epithelial Cells	0-2	5-7	---	8-10
Amorphous Sediment	trace	3+	trace	2+
Triple Phosphate Crystals	---	---	---	occ
Calcium Oxalate Crystals	---	---	2+	---
Mucous Threads	1+	---	---	---
Casts	---	---	---	---
Bacteria	1+	trace	trace	trace
Other	---	---	---	---

URINALYSIS

100 µg/kg - Pre-Drug

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	130.0	140.0	207.0	170.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	cloudy	hazy	cloudy
Specific Gravity	1.037	1.035	1.022	1.033
pH	6.0	6.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.0	1.6	1.6	1.7
Urobilinogen, Random	neg	neg	neg	neg
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	15-20	---	---
Amorphous Sediment	4+	3+	3+	2+
Triple Phosphate Crystals	4+	---	---	---
Calcium Oxalate Crystals	---	4+	---	4+
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	---
Other	---	---	---	---

MONS 016537

URINALYSIS

100 µg/kg - Month 3

	Females			
	152-F	226-F	486-H	269-I
Total Volume (ml)	170.0	155.0	160.0	200.0
Color	yellow	yellow	yellow	straw
Appearance	hazy	turbid	hazy	cloudy
Specific Gravity	1.022	1.026	1.015	1.016
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	1.5	0.7	1.6
Urobilinogen, Random	neg	1.0	1+	neg
WBC	---	---	occ	---
RBC.	---	---	---	---
Epithelial Cells	---	---	2-4	8-10
Amorphous Sediment	2+	2+	3+	---
Triple Phosphate Crystals	4+	---	---	1+
Calcium Oxalate Crystals	---	---	trace	---
Mucous Threads	---	---	---	trace
Casts	---	---	---	---
Bacteria	---	trace	1+	---
Other	---	---	---	---

URINALYSIS

100 µg/kg - Month 3

	Females			
	287-I	312-I	338-I	770-I
Total Volume (ml)	340.0	170.0	190.0	122.0
Color	straw	yellow	yellow	yellow
Appearance	clear	cloudy	turbid	turbid
Specific Gravity	1.006	1.020	1.028	1.031
pH	7.0	8.0	6.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	3+	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.1	1.1	0.9	1.6
Urobilinogen, Random	0.1	neg	1+	1.0
WBC	---	---	---	---
RBC.	---	---	---	---
Epithelial Cells	0-4	1-2	---	---
Amorphous Sediment	trace	2+	4+	3+
Triple Phosphate Crystals	1+	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	trace	---	---	---
Casts	---	---	---	---
Bacteria	---	---	3+	---
Other	---	---	---	---

URINALYSIS

100 ug/kg - Month 3

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	110.0	155.0	90.0	165.0
Color	yellow	straw	straw	yellow
Appearance	clear	clear	hazy	cloudy
Specific Gravity	1.036	1.034	1.040	1.028
pH	6.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	3+	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.1	1.3	1.3	1.9
Urobilinogen, Random	1+	1+	1+	2+
WBC	0.2	---	---	---
RBC	---	---	---	---
Epithelial Cells	trace	---	---	---
Amorphous Sediment	---	trace	trace	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	Sperm 2+	---	---	---

URINALYSIS

100 ug/kg - Month 6

	Females			
	287-I	312-I	338-I	770-I
Total Volume (ml)	600.0	400.0	110.0	230.0
Color	straw	yellow	yellow	yellow
Appearance	hazy	clear	turbid	clear
Specific Gravity	1.008	1.012	1.036	1.012
pH	7.0	7.0	7.0	7.0
Protein	neg	neg	1+	neg
Glucose	neg	neg	3+	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	trace	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.5	0.9	0.6	0.9
Urobilinogen, Random (E unit/dl)	trace	neg	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	1-2	0-3	tntc	0-2
Amorphous Sediment	2+	trace	2+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	trace	---	---	---
Casts	---	---	---	---
Other	bacteria trace	---	---	---

URINALYSIS

100 ug/kg - Month 6

	Females			
	152-F	225-F	486-H	269-I
Total Volume (ml)	620.0	120.0	240.0	540.0
Color	yellow	yellow	yellow	yellow
Appearance	hazy	turbid	cloudy	clear
Specific Gravity	1.007	1.036	1.020	1.009
pH	7.0	6.0	7.0	8.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Katone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	3+	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Katosteriods (mg/24 hr)	1.9	1.9	1.7	2.9
Urobilinogen, Random (E unit/dl)	trace	neg	1+	trace
WBC	---	---	10-15	---
RBC	2-3	---	40-50	---
Epithelial Cells	1-2	---	7-9	0-3
Amorphous Sediment	---	2+	trace	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	hyaline 0-1	---	---	---
Other				

URINALYSIS

100 µg/kg - Month 6

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	260.0	275.0	520.0	325.0
Color	straw	straw	yellow	yellow
Appearance	hazy	hazy	clear	hazy
Specific Gravity	1.020	1.017	1.008	1.018
pH	8.0	7.0	7.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	neg	trace
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.6	1.5	1.9	2.9
Urobilinogen, Random (E unit/dl)	trace	1+	trace	trace
WBC	---	---	---	---
RBC	---	---	---	2-5
Epithelial Cells	---	---	0-2	0-3
Amorphous Sediment	2+	trace	trace	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Other	sperm trace	---	bacteria trace	sperm trace

URINALYSIS

100 ug/kg - Month 9

	Females			
	287-1	312-1	338-1	770-1
Total Volume (ml)	530.0	380.0	320.0	90.0
Color	yellow	straw	yellow	yellow
Appearance	cloudy	cloudy	turbid	cloudy
Specific Gravity	1.008	1.015	1.026	1.029
pH	7.0	7.0	6.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	3+	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.8	pregnant	pregnant	2.0
Urobilinogen, Random	trace	2+	1+	1+
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	2-5	---	3-5
Amorphous Sediment	2+	2+	4+	3+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

100 ug/kg - Month 9

	Females			
	152-F	226-F	486-H	269-I
Total Volume (ml)	129.0	182.0	340.0	550.0
Color	straw	yellow	yellow	yellow
Appearance	hazy	hazy	cloudy	clear
Specific Gravity	1.031	1.021	1.014	1.010
pH	6.0	7.0	8.0	7.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	trace
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	trace
Bilirubin, qual.	neg	neg	neg	trace
17-Ketosteroids (mg/24 hr)	1.9	1.7	2.4	2.6
Urobilinogen, Random	1.0	trace	1+	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	0-2	3-5	0-2	1-2
Amorphous Sediment	2+	trace	2+	trace
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	---
Other	---	---	---	---

URINALYSIS

100 ug/kg - Month 9

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	490.0	170.0	370.0	100.0
Color	yellow	yellow	straw	orange
Appearance	clear	hazy	hazy	clear
Specific Gravity	1.015	1.030	1.012	1.040
pH	8.0	6.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	trace	neg	neg	1+
17-Ketosteroids (mg/24 hr)	3.5	3.6	2.2	2.7
Urobilinogen, Random	trace	1+	1+	1+
WBC	---	0-2	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	1+	1+	1+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	1+	---	trace
Other	---	---	---	---

URINALYSIS

100 µg/kg - Month 12

	Females			
	287-I	312-I	338-I	770-I
Total Volume (ml)	480.0	---	---	76.0
Color	yellow	straw	yellow	straw
Appearance	cloudy	hazy	turbid	cloudy
Specific Gravity	1.009	1.022	1.025	1.034
pH	7.0	7.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	trace	1+
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	pregnant	pregnant	0.9
Urobilinogen, Random	trace	neg	neg	1+
WBC	---	---	---	---
RBC	---	---	0-4	5-6
Epithelial Cells	0-1	0-1	0-4	1-5
Amorphous Sediment	2+	2+	3+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	trace	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

100 ug/kg - Month 12

	Females			
	152-F*	226-F	486-H	269-I
Total Volume (ml)	---	---	200.0	640.0
Color	---	yellow	yellow	yellow
Appearance	---	cloudy	cloudy	cloudy
Specific Gravity	---	1.030	1.021	1.009
pH	---	6.0	6.0	7.0
Protein	---	neg	neg	neg
Glucose	---	neg	neg	neg
Ketone	---	neg	neg	neg
Bilirubin	---	neg	neg	neg
Blood	---	trace	1+	neg
Bilirubin, qual.	---	neg	neg	neg
17-Ketosteroids (mg/24 hr)	---	pregnant	2.1	13.6
Urobilinogen, Random	---	1+	neg	neg
WBC	---	---	---	---
RBC	---	---	7-10	---
Epithelial Cells	---	0-3	5-10	0-1
Amorphous Sediment	---	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

* Died 1/22/78.

URINALYSIS

100 µg/kg - Month 12

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	420.0	550.0	600.0	120.0
Color	yellow	yellow	yellow	yellow
Appearance	cloudy	cloudy	cloudy	hazy
Specific Gravity	1.021	1.018	1.010	1.027
pH	8.0	8.0	7.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	neg	neg	neg	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	5.7	3.1	3.3	1.0
Urobilinogen, Random	trace	trace	trace	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	---	0-2
Amorphous Sediment	2+	2+	2+	2+
Triple Phosphate Crystals	---	---	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

100 ug/kg - Month 15

	Females		
	287-1	312-1*	338-1
Total Volume (ml)	690	---	280
Color	yellow	---	straw
Appearance	clear	---	hazy
Specific Gravity	1.006	---	1.013
pH	7.0	---	7.0
Protein	neg	---	neg
Glucose	neg	---	neg
Ketone	neg	---	neg
Bilirubin	neg	---	neg
Blood	neg	---	neg
Bilirubin, qual.	neg	---	neg
17-Ketosteroids (mg/24 hr)	2.6	---	1.4
Urobilinogen, Random (E unit/dl)	trace	---	neg
WBC	0-1	---	---
RBC	---	---	---
Epithelial Cells	0-2	---	0-3
Amorphous Sediment	1+	---	2+
Triple Phosphate Crystals	---	---	---
Calcium Oxalate Crystals	---	---	---
Mucous Threads	---	---	---
Casts	---	---	---
Bacteria	---	---	1+
Other	---	---	---

* Urine not collected; animal had not begun second cycle after giving birth.

URINALYSIS

100 ug/kg - Month 15

	Females	
	226-F	269-F
Total Volume (ml)	150	590
Color	yellow	yellow
Appearance	hazy	hazy
Specific Gravity	1.027	1.008
pH	6.0	7.0
Protein	neg	neg
Glucose	neg	neg
Ketone	neg	neg
Bilirubin	neg	neg
Blood	neg	neg
Bilirubin, qual.	neg	neg
17-Ketosteroids (mg/24 hr)	1.8	3.2
Urobilinogen, Random (E unit/dl)	neg	trace
WBC	3-5	---
RBC	---	---
Epithelial Cells	6-8	0-3
Amorphous Sediment	1+	2+
Triple Phosphate Crystals	---	---
Calcium Oxalate Crystals	---	---
Mucous Threads	---	---
Casts	---	---
Bacteria	---	---
Other	---	---

URINALYSIS

100 ug/kg - Month 15

	Males			
	706-E	600-I	425-J	427-J
Total Volume (ml)	400	640	130	210
Color	yellow	yellow	colorless	yellow
Appearance	cloudy	hazy	clear	hazy
Specific Gravity	1.014	1.028	1.012	1.026
pH	7.0	5.0	5.0	6.0
Protein	neg	neg	neg	neg
Glucose	neg	neg	neg	neg
Ketone	neg	neg	neg	neg
Bilirubin	neg	neg	neg	neg
Blood	trace	neg	trace	neg
Bilirubin, qual.	neg	neg	neg	neg
17-Ketosteroids (mg/24 hr)	2.2	2.0	1.8	2.1
Urobilinogen, Random (E unit/dl)	trace	neg	neg	neg
WBC	---	---	---	---
RBC	0-4	---	---	---
Epithelial Cells	---	---	---	---
Amorphous Sediment	1+	2+	trace	trace
Triple Phosphate Crystals	1+	---	---	---
Calcium Oxalate Crystals	---	trace	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

URINALYSIS

100 µg/kg - Month 19

	Females		
	287-I	312-I	338-I*
Total Volume (ml)	1,360.0	420.0	---
Color	yellow	yellow	---
Appearance	clear	hazy	---
Specific Gravity	1.004	1.011	---
pH	7.0	8.0	---
Protein	neg	neg	---
Glucose	neg	neg	---
Ketone	neg	neg	---
Bilirubin	neg	neg	---
Blood	neg	neg	---
Bilirubin, qual.	neg	neg	---
17-Ketosteroids (mg/24 hr)	4.1	2.1	---
Urobilinogen, Random	neg	0.0	---
WBC	0-1	1-4	---
RBC	---	---	---
Epithelial Cells	---	3-8	---
Amorphous Sediment	trace	trace	---
Triple Phosphate Crystals	---	---	---
Calcium Oxalate Crystals	---	---	---
Mucous Threads	---	---	---
Casts	---	---	---
Bacteria	1+	---	---
Other	---	calcium carbonate crystals 2+	---

* No data; animal died 8/21/78.

URINALYSIS

100 µg/kg - Month 19

	Females	
	226-F	269-I
Total Volume (ml)	240.0	400.0
Color	yellow	yellow
Appearance	hazy	cloudy
Specific Gravity	1.019	1.009
pH	8.0	7.0
Protein	neg	neg
Glucose	neg	neg
Ketone	neg	neg
Bilirubin	neg	neg
Blood	neg	neg
Bilirubin, qual.	neg	neg
17-Ketosteroids (mg/24 hr)	1.6	1.7
Urobilinogen, Random	1+	trace
WBC	---	---
RBC	---	---
Epithelial Cells	2-3	3-6
Amorphous Sediment	trace	1+
Triple Phosphate Crystals	2+	1+
Calcium Oxalate Crystals	---	---
Mucous Threads	---	trace
Casts	---	---
Bacteria	---	trace
Other	---	---

URINALYSIS

100 µg/kg - Month 19

	Males			
	706-E*	600-I	425-J	427-J
Total Volume (ml)	---	215.0	510.0	320.0
Color	---	yellow	yellow	yellow
Appearance	---	hazy	clear	clear
Specific Gravity	---	1.024	1.009	1.018
pH	---	7.0	8.0	7.0
Protein	---	neg	neg	neg
Glucose	---	neg	neg	neg
Ketone	---	neg	neg	neg
Bilirubin	---	neg	neg	neg
Blood	---	neg	neg	neg
Bilirubin, qual.	---	neg	neg	neg
17-Ketosteroids (mg/24 hr)	---	1.2	2.6	2.7
Urobilinogen, Random	---	trace	0.0	trace
WBC	---	---	---	---
RBC	---	---	---	---
Epithelial Cells	---	---	0-2	---
Amorphous Sediment	---	trace	1+	trace
Triple Phosphate Crystals	---	2+	---	---
Calcium Oxalate Crystals	---	---	---	---
Mucous Threads	---	---	---	---
Casts	---	---	---	---
Bacteria	---	---	---	---
Other	---	---	---	---

* No data; animal died 7/19/78.

MONS 016555

APPENDIX E

APPENDIX E

The following appendix contains all semen analyses performed and is arranged chronologically within dose levels. Analyses were performed pre-drug and at Months 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 15.

	Page
Control	E-1
5 µg/kg	E-6
25 µg/kg	E-11
100 µg/kg	E-16

SEMEN ANALYSIS*

Control

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Pre-Drug									
739-F	0.60	2.6	3.20	65	39.0	80/80/70	16	10	---
227-G	0.70	1.6	2.30	355	248.5	80/80/70	8	25	---
426-G	0.25	0.3	0.55	370	92.5	70/60/50	21	15	---
418-J	0.45	0.4	0.85	35	16.0	60/50/50	20	17	---
Month 1									
739-F	0.30	0.4	0.70	90	27.0	80/80/70	17	9	Slight clump.
227-G	0.40	0.5	0.90	585	234.0	80/80/70	8	21	---
426-G	0.10	0.1	0.20	420	42.0	60/60/50	25	26	A lot of clump.
418-J	0.20	0.2	0.40	55	11.0	70/60/60	15	27	---
Month 2									
739-F	0.10	0.1	0.20	65	6.5	80/80/70	14	20	A lot of clump.
227-G	0.15	0.1	0.25	455	68.0	80/80/70	10	28	---
426-G	0.10	0.0	0.10	305	30.5	40/30/20	33	28	---
418-J	0.20	0.2	0.40	20	4.0	70/70/60	32	32	Vibratory motility.
Month 3									
739-F	0.10	0.2	0.30	70	7.0	70/70/60	23	18	Clump.
227-G	0.80	0.1	0.90	370	296.0	80/80/70	21	24	Slight clump.
426-G	0.10	0.0	0.10	370	37.0	40/30/20	33	35	---
418-J	0.20	0.4	0.60	30	6.0	80/70/70	9	11	Vibratory motility.

* All semen collections were obtained at 40 volts for 30 milliseconds unless otherwise noted.

MONS 016558

SEMEN ANALYSIS

Control

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 4									
739-F	0.10	0.2	0.30	110	11.0	80/80/70	28	15	Slight clump.
227-G	0.25	0.1	0.35	375	94.0	80/80/70	22	37	Clump.
426-G	0.10	0.0	0.10	235	23.5	60/50/40	34	16	Clump.
418-J	0.10	0.0	0.10	10	1.0	40/30/20	51	23	Vibratory motility.
Month 5									
739-F	0.10	0.2	0.30	185	18.5	80/70/70	26	31	Clump.
227-G	0.40	0.1	0.50	735	294.0	80/70/70	13	35	A lot of clump; milky semen.
426-G[1]	0.10	0.0	0.10	210	21.0	5/00/0	18	47	Clump.
418-J[2]	0.10	0.0	0.10	90	9.0	50/10/0	69	27	Extrem. lazy motility; clump.
Month 6									
739-F	0.95	1.3	2.25	120	114.0	80/80/70	32	16	Some clump.
227-G	0.70	0.1	0.80	275	192.5	80/80/70	14	21	Slight clump; some circular motility.
426-G	0.10	0.2	0.30	215	21.5	70/60/50	26	44	Clump.
418-J	0.10	0.0	0.10	325	32.5	60/50/40	34	25	Clump.
Repeat Values									
[1]426-G	0.10	0.0	0.10	280	28.0	60/50/40	30	16	---
[2]418-J	0.10	0.0	0.10	195	19.5	40/30/20	56	25	---

MONS 016559

SEMEN ANALYSIS

Control

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 7				
739-F	0.55	3.0	3.55	50.0	27.5	80/80/70	26	10	Circular motility.
227-G	0.60	0.3	0.90	430.0	258.0	80/70/70	22	13	Clump.
426-G	0.50	0.5	1.00	310.0	155.0	80/70/70	19	8	Slight clump.
418-J	0.30	1.4	1.70	280.0	84.0	50/40/30	41	30	Vibratory cells; slight clump.
					Month 8				
739-F	1.20	2.2	2.40	120.0	144.0	80/70/60	11	20	---
227-G	0.60	1.5	2.10	200.0	120.0	80/80/70	7	14	Clump.
426-G	0.65	1.1	1.75	285.0	185.0	80/70/60	29	10	---
418-J	1.45	2.5	3.95	360.0	522.0	80/80/70	14	7	Clump.
					Month 9				
739-F	0.60	4.0	4.60	135.0	81.0	80/70/60	17	6	Circular motility.
227-G	0.40	0.7	1.10	555.0	222.0	70/60/50	36	25	Clump.
426-G	0.70	0.8	1.50	320.0	224.0	80/70/60	19	12	Clump.
418-J	1.25	1.9	3.15	395.0	494.0	80/80/70	15	5	Slight clump.

MONS 016560

SEMEN ANALYSIS

Control

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 10									
739-F	0.40	1.3	1.70	260.0	104.0	80/70/70	26	16	---
227-G	0.95	0.4	1.35	380.0	361.0	60/50/40	38	16	A lot of clump.
426-G	0.70	0.7	1.40	390.0	273.0	80/70/60	27	7	Slight clump.
418-J	1.20	1.6	2.80	115.0	138.0	80/70/60	13	16	Slight clump.
Month 11									
739-F	0.95	2.1	3.05	160.0	152.0	80/80/70	12	19	Clump.
227-G	0.65	1.0	1.65	790.0	514.0	80/70/60	12	27	A lot of clump.
426-G	1.10	2.0	3.10	145.0	160.0	80/70/70	21	17	Circular motility.
418-J	1.10	1.6	2.70	125.0	138.0	80/80/70	25	18	Slight clump; vibratory motility.
Month 12									
739-F	0.90	1.9	2.80	200.0	180.0	80/80/70	12	15	Slight clump.
227-G	0.90	1.1	2.00	455.0	410.0	70/60/50	42	12	A lot of clump.
426-G	1.20	1.6	2.80	210.0	252.0	80/70/70	25	13	Circular motility.
418-J*	---	---	---	---	---	---	---	---	---

* No semen obtained.

MONS 016961

SEMEN ANALYSIS

Control

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 13				
739-F	0.90	0.5	1.40	125.0	113.0	80/70/60	22	14	---
227-G	0.65	0.6	1.25	405.0	263.0	80/70/60	34	27	Clump.
426-G	0.75	1.1	1.85	175.0	131.0	80/80/70	18	11	Slight clump.
418-J*	---	---	---	---	---	---	---	---	---
					Month 15				
739-F	0.30	0.7	1.00	40.0	12.0	80/70/70	10	25	---
227-G	0.45	0.3	0.75	365.0	164.0	80/80/70	8	27	A lot of clump.
426-G	0.20	0.3	0.50	90.0	18.0	70/70/60	23	42	Clump.
418-J	0.10	0.0	0.10	25.0	2.5	60/40/20	41	21	Watery semen; vibratory motility.

* No semen obtained.

MONS 016562

SEMEN ANALYSIS

5 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Pre-Drug									
516-G	0.10	0.1	0.20	245	24.5	80/80/70	18	28	---
119-H*	---	---	---	---	---	---	---	---	---
428-J	1.00	1.2	2.20	125	125.0	80/80/70	8	4	---
432-J	0.70	1.1	1.80	85	59.5	80/80/70	11	24	---
Month 1									
516-G	0.10	0.1	0.20	200	20.0	80/70/60	19	20	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.55	0.8	1.35	40	22.0	80/70/70	27	14	Vibratory motility.
432-J	0.10	0.0	0.10	705	70.5	60/50/40	42	25	Heavy clump.
Month 2									
516-G	0.10	0.1	0.20	120	12.0	60/50/40	23	20	Slight clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J*	---	---	---	---	---	---	---	---	---
432-J*	---	---	---	---	---	---	---	---	---
Month 3									
516-G	0.50	0.4	0.90	20	4.0	60/50/50	32	15	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.20	0.3	0.50	55	11.0	70/60/60	27	26	Vibratory motility.
432-J[1]	0.10	0.0	0.10	20	2.0	20/00/0	60	31	---

*No semen obtained.

Repeat Values

[1]432-J	0.10	0.0	0.10	120	12.0	30/00/0	78	20	---

MONS 016563

SEMEN ANALYSIS

5 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 4				
516-G	0.10	0.0	0.10	145	14.5	40/30/20	21	24	---
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.70	0.8	1.50	95	66.5	80/80/70	26	67	---
432-J	0.10	0.0	0.10	420	42.0	50/40/40	64	31	---
					Month 5				
516-G	0.20	0.1	0.30	940	188.0	80/70/60	36	41	---
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.55	0.5	1.05	200	110.0	80/80/70	27	44	Some backward motility due to bent mid-pieces; slight clump.
432-J	0.10	0.0	0.10	830	83.0	70/60/50	61	23	Clump.
					Month 6				
516-G	1.15	0.2	1.35	40	46.0	60/40/20	74	12	Extrem. heavy clump; many immature, abn. sperm cells; esp. hooktails; great motility.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.60	0.6	1.20	140	84.0	80/80/70	11	14	Slight circular motility.
432-J	0.10	0.1	0.20	190	19.0	60/50/40	25	21	Clump.

*No semen obtained.

MONS 016569

SEMEN ANALYSIS

5 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 7									
516-G	0.40	0.2	0.60	180.0	72.0	60/50/40	22	12	Clump; immature cells present.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.90	1.0	1.90	160.0	144.0	80/80/70	9	15	Clump.
432-J	0.80	2.2	3.00	95.0	76.0	80/80/70	18	9	Clump.
Month 8									
516-G	1.15	1.2	2.35	255.0	293.0	80/80/70	13	34	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J	1.10	1.2	2.30	160.0	176.0	80/70/60	17	4	Slight clump.
432-J	1.30	3.0	3.30	210.0	273.0	80/80/70	14	15	A lot of clump.
Month 9									
516-G	1.80	0.6	2.40	365.0	657.0	80/70/70	37	13	Heavy clump; vibratory motility.
119-H*	---	---	---	---	---	---	---	---	---
428-J*	---	---	---	---	---	---	---	---	No pulses.
432-J	1.00	2.0	3.00	95.0	95.0	80/80/70	22	24	Clump; circular motility.

* No semen obtained.

MONS 016965

SEMEN ANALYSIS

5 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 10				
516-G	0.10	0.1	0.20	250.0	25.0	80/70/70	16	20	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J*	---	---	---	---	---	---	---	---	---
432-J	0.90	2.2	3.10	185.0	167.0	80/80/70	11	19	Clump.
					Month 11				
516-G	0.50	0.3	0.80	215.0	108.0	80/80/70	15	29	Heavy clump; vibratory motility.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.90	1.9	2.80	100.0	90.0	80/80/70	8	17	Circular motility.
432-J	0.85	1.5	2.35	240.0	204.0	80/80/70	13	17	Slight clump.
					Month 12				
516-G	0.40	0.1	0.50	140.0	56.0	80/70/70	35	25	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J*	---	---	---	---	---	---	---	---	---
432-J	1.00	1.0	2.00	155.0	155.0	80/80/70	9	31	Clump.

* No semen obtained.

MONS 016566

SEMEN ANALYSIS

5 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 13				
516-G	0.10	0.2	0.30	75.0	7.5	80/80/70	36	15	Clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.60	0.8	1.40	125.0	75.0	80/80/70	7	13	---
432-J	0.70	0.7	1.40	100.0	70.0	80/80/70	32	20	Clump.
					Month 15				
516-G	0.20	0.2	0.40	35.0	7.0	70/60/50	18	38	Vibratory motility; clump.
119-H*	---	---	---	---	---	---	---	---	---
428-J	0.90	1.2	2.10	90.0	81.0	70/60/50	26	15	Circular motility.
432-J	0.70	0.2	0.90	30.0	21.0	70/60/50	68	56	Slight clump.

* No semen obtained.

MONS 016597

SEMEN ANALYSIS

25 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Pre-Drug				
20-I	0.60	0.9	1.50	245	147.0	70/70/60	8	22	---
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.70	1.1	1.80	215	150.5	80/70/70	12	19	---
599-I*	---	---	---	---	---	---	---	---	---
					Month 1				
20-I	0.60	1.1	1.70	250	150.0	80/80/70	16	12	Heavy clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.10	0.0	0.10	665	66.5	80/70/60	41	32	A lot of clump and neutrophils; very milky.
599-I*	---	---	---	---	---	---	---	---	---
					Month 2				
20-I	0.55	1.0	1.55	325	179.0	80/70/70	8	24	Slight clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.10	0.0	0.10	285	28.5	70/70/60	22	18	---
599-I*	---	---	---	---	---	---	---	---	---
					Month 3				
20-I	0.30	1.0	1.30	265	79.5	80/70/70	14	25	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.10	0.0	0.10	235	23.5	50/30/10	47	15	---
599-I*	---	---	---	---	---	---	---	---	---

*No semen obtained.

MONS 016568

SEMEN ANALYSIS

25 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
					Month 4				
20-I	0.30	0.3	0.60	130	39.0	80/80/70	48	27	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I[1]	0.10	0.0	0.10	50	5.0	5/00/0	48	26	---
599-I*	---	---	---	---	---	---	---	---	---
					Month 5				
20-I	0.55	0.6	1.15	215	118.0	80/70/70	31	22	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I[2]	0.10	0.0	0.10	260	26.0	30/05/0	51	27	---
599-I*	---	---	---	---	---	---	---	---	---
					Month 6				
20-I	0.85	1.4	2.25	45	38.0	70/70/60	24	6	---
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.10	0.0	0.10	415	41.5	60/40/20	22	17	Bent mid-pieces; protoplasmic droplets.
599-I*	---	---	---	---	---	---	---	---	---

*No semen obtained.

Repeat Values

[1]595-I	0.10	0.0	0.10	380	38.0	80/70/60	22	29	---
[2]595-I	0.10	0.0	0.10	280	28.0	70/60/60	24	29	---

MONS 016569

SEMEN ANALYSIS

25 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 7									
20-I	0.80	2.6	3.40	40.0	32.0	80/70/60	16	15	Circular motility.
46-I*	---	---	---	---	---	---	---	---	---
595-I	1.10	2.3	3.40	85.0	93.5	80/70/70	11	10	---
599-I*	---	---	---	---	---	---	---	---	---
Month 8									
20-I	0.90	1.8	2.70	130.0	117.0	70/60/50	16	4	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.80	1.0	1.80	200.0	160.0	80/80/70	12	35	Clump.
599-I*	---	---	---	---	---	---	---	---	---
Month 9									
20-I	0.60	3.2	3.80	260.0	156.0	80/70/60	20	11	Slight clump; circular motility.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.50	0.7	1.20	495.0	248.0	80/80/70	28	10	Clump.
599-I*	---	---	---	---	---	---	---	---	---

* No semen obtained.

MONS 016570

SEMEN ANALYSIS

25 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
				Month 10					
20-I	0.90	2.0	2.90	280.0	252.0	80/80/70	7	21	A lot of clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.90	1.4	2.30	435.0	392.0	80/70/60	28	21	---
599-I*	---	---	---	---	---	---	---	---	---
				Month 11					
20-I	0.80	3.1	3.90	365.0	292.0	60/50/40	16	11	Heavy clump; vibratory motility.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.30	0.4	0.70	265.0	80.0	80/80/70	9	16	---
599-I*	---	---	---	---	---	---	---	---	---
				Month 12					
20-I	0.90	2.2	3.10	120.0	108.0	80/80/70	15	11	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.70	1.2	1.90	495.0	347.0	80/70/70	15	22	Slight clump.
599-I*	---	---	---	---	---	---	---	---	---

* No semen obtained.

MONS 016571

SEMEN ANALYSIS

25 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 13									
20-I	0.60	1.3	1.90	350.0	210.0	80/80/70	8	16	Clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.70	1.0	1.70	385.0	270.0	80/80/70	8	20	Slight clump.
599-I*	---	---	---	---	---	---	---	---	---
Month 15									
20-I	0.50	0.2	0.70	410.0	205.0	80/70/60	32	41	A lot of clump.
46-I*	---	---	---	---	---	---	---	---	---
595-I	0.10	0.0	0.10	465.0	47.0	60/50/40	44	32	Little clump.
599-I*	---	---	---	---	---	---	---	---	---

* No semen obtained.

MONS 016572

SEMEN ANALYSIS

100 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Pre-Drug									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.70	1.0	1.70	220	154.0	80/70/70	9	25	---
425-J	0.30	0.3	0.60	95	28.5	60/60/50	43	29	---
427-J	0.30	3.0	3.30	30	9.0	70/60/50	13	4	---
Month 1									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.45	0.6	1.05	160	72.0	80/80/70	15	23	Some clump.
425-J	0.20	0.1	0.30	165	33.0	80/70/60	38	19	Slight clump.
427-J	0.10	0.2	0.30	15	1.5	80/70/60	47	11	Vibratory flagellation.
Month 2									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.50	0.6	1.10	130	65.0	80/80/70	13	17	---
425-J[1]	0.10	0.0	0.10	55	5.5	30/00/0	45	24	Vibratory motility; watery semen.
427-J	0.10	0.1	0.20	10	1.0	70/60/50	50	15	Vibratory motility.
Month 3									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.70	1.1	1.80	50	35.0	80/80/70	7	18	Slight clump.
425-J	0.10	0.1	0.20	235	23.5	60/60/50	34	29	Vibratory motility; heavy clump.
427-J	0.15	0.2	0.35	15	2.0	60/60/50	27	21	---

*No semen obtained.

Repeat Values

[1]425-J	0.10	0.0	0.10	20	2.0	60/40/20	25	6	Clump.

MONS 016573

SEMEN ANALYSIS

100 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x)10^6	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 4									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.45	0.5	0.95	70	31.5	80/70/70	17	19	Circular motility.
425-J	0.10	0.0	0.10	235	23.5	50/40/30	31	38	---
427-J	0.50	0.4	0.90	60	30.0	80/80/70	8	13	---
Month 5									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.45	0.5	0.95	70	31.5	80/80/70	15	8	---
425-J	0.20	0.1	0.30	340	68.0	70/70/60	57	22	Numerous hooktails; vibratory motility; heavy clump.
427-J	0.55	0.7	1.25	75	41.0	80/80/70	5	14	Slight clump.
Month 6									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.55	1.0	1.55	205	113.0	80/80/70	18	15	Slight clump; slight circular motility.
425-J	0.40	0.5	0.90	120	48.0	80/70/70	22	29	---
427-J	0.55	0.9	1.45	60	33.0	80/80/70	12	29	Very slight clump.

*No semen obtained.

MONS 016574

SEMEN ANALYSIS

100 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm (x10^6)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 7									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.70	1.1	1.80	30.0	21.0	80/80/70	19	10	---
425-J	0.50	0.9	1.40	185.0	92.5	80/80/70	16	25	Clump.
427-J	1.30	2.5	3.80	155.0	201.5	80/70/70	6	8	Clump.
Month 8									
706-E*	---	---	---	---	---	---	---	---	---
600-I	1.00	1.3	2.30	170.0	170.0	80/80/70	21	29	Slight clump.
425-J	0.70	1.4	2.10	285.0	199.5	80/70/70	17	19	Slight clump.
427-J	1.20	2.3	3.50	140.0	168.0	80/80/70	19	24	Clump.
Month 9									
706-E*	---	---	---	---	---	---	---	---	---
600-I	1.10	2.3	3.40	400.0	440.0	80/80/70	14	23	Slight clump.
425-J	0.55	1.1	1.65	305.0	168.0	80/70/70	12	24	Slight clump.
427-J	1.05	2.6	3.65	145.0	152.0	80/80/70	15	11	Slight clump.

* No semen obtained.

MONS 016575

SEMEN ANALYSIS

100 µg/kg

Animal Number	Liquid Vol(ml)	Plug Vol(ml)	Total Vol(ml)	Conc (ml x 10^6)	Total Sperm ($x10^6$)	Motility (%)	Abnorm (%)	Dead (%)	Remarks
Month 10									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.80	1.2	2.00	235.0	188.0	80/80/70	13	27	Slight clump.
425-J	0.50	0.6	1.10	310.0	155.0	80/80/70	16	24	Clump.
427-J	1.10	1.7	2.80	225.0	248.0	80/70/70	25	22	A lot of clump; slight vibratory motility.
Month 11									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.85	3.2	4.05	135.0	115.0	80/80/70	31	20	Slight clump.
425-J	0.40	0.6	1.00	135.0	54.0	70/70/60	32	18	Clump.
427-J	0.90	1.4	2.30	90.0	81.0	80/80/70	13	4	Clump; slight circular motility.
Month 12									
706-E*	---	---	---	---	---	---	---	---	---
600-I	0.60	0.7	1.30	230.0	138.0	80/80/70	10	9	---
425-J	0.30	0.3	0.60	195.0	59.0	80/70/60	23	8	Clump.
427-J	0.95	1.5	2.45	100.0	95.0	80/80/70	11	6	Slight clump; some circular motility.

* No semen obtained.

MONS 016576