



Report OCL-500-PRE-002.2

**OCCLUSIN® 503 ARTIFICIAL
EMBOLIZATION DEVICE**

**A PRECLINICAL STUDY OF THE SAFETY
AND EFFICACY OF OCCLUSIN® 503
ARTIFICIAL EMBOLIZATION DEVICE
IN SHEEP**

Final Study Report

15 December 2011

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Preclinical Study Report Approval

PRECLINICAL STUDY REPORT OCL-500-PRE-002.2

Report Title: A Preclinical Study of the Safety and Efficacy of Occlusin® 503
Artificial Embolization Device in Sheep

Report Number: R-OCL-500-PRE-002.2

Start Date: 22 March 2007

Completion Date: 27 June 2008

Study Director: Irwin Griffith

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Version: Version 2.2

Date of Report: 2 September 2008

Date of Revision: 15 December 2011

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1. Abbreviations

AED	Artificial Embolization Device
A/G Ratio	Albumin/Globulin Ratio
AST (Sgot)	Aspartate aminotransferase (Serum glutamic oxaloacetic transaminase)
ALT (Sgpt)	Alanine aminotransferase (Serum glutamic-pyruvic transaminase)
BUN/Cr	Blood urea nitrogen/creatinine
CBC	Complete blood cell count
CCAC	Canadian Council on Animal Care
CFR	Code of Federal Regulations
FDPs	Fibrin degradation products
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
IACUC	Institutional Animal Care and Use Committee
ISO	International Standards Organization
IU	International Unit
OCL 500	Occlusin® Artificial Embolization Device
OCL 503	OCL 500 with a size range of 150 – 212 µm.
PBS	Phosphate Buffered Saline
PLGA	Poly(DL lactic-co-glycolic acid)
PTT	Partial thromboplastin time
PVA	Polyvinyl alcohol
RBC	Red blood cell
RDW	Red Cell Distribution Width
PT	Prothrombin time
SD	Standard Deviation
µg	Microgram
µm	Micrometer
mL	Milliliter
vWF	von Willebrand Factor
WBC	White blood cell

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2. Summary

The purpose of this preclinical study was to evaluate the safety, effectiveness, and biocompatibility of Occlusin® 503 Artificial Embolization Device (OCL 503). This study also examined other important device-related issues including the ease of injection, extent of target vessel occlusion, rate of resorption, migration to non-target tissues, recanalization of the target vessel and local tissue reaction.

The effectiveness of OCL 503 as an artificial embolizing device (AED) was evaluated in sheep by implanting the device in either the left or right uterine artery. OCL 503 was implanted by transcatheter arterial administration and the target vessels were occluded to effective stasis. Procedural data and follow up clinical and hematological data were recorded. Test animals were sacrificed one, three, six and twelve months after embolization. The tissue responses to OCL 503 were examined histologically. Embosphere® Microspheres, a commercially available artificial embolization device, was implanted and followed as a control group.

One month post implantation, there was evidence of OCL 503 remodelling consistent with the microspheres beginning to biodegrade. Three months post implantation, the OCL 503 had undergone significant structural changes and degradation and by six months post implantation the OCL 503 microspheres had completely degraded. All OCL 503-treated arteries were completely occluded at one, three and six months post treatment. Twelve months post implantation, OCL 503-treated uterine arteries had fully recanalized in three of four treated sheep; the uterine artery of the fourth animal was in the process of recanalizing.

OCL 503 microspheres were only found in the uterine vasculature. Embosphere® Microspheres were found in the uterine, vaginal, ovarian and urinary bladder vasculatures.

No device related issues or adverse events were recorded. OCL 503 was an effective and safe embolic agent when used to occlude uterine arteries in sheep

3. Introduction

3.1 Product Overview

OCL 503 is an embolotherapeutic agent consisting of poly(DL lactic-co-glycolic acid) (PLGA) microspheres that are coated with type I bovine fibrillar collagen. OCL 503 was manufactured with a size range of 150 to 212 µm.

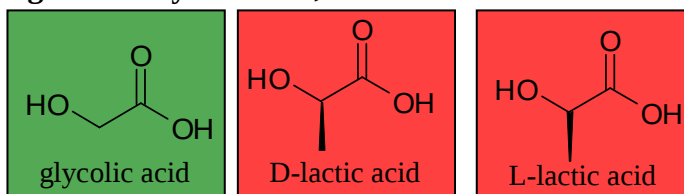
3.2 Intended Use/Indication for Use

OCL 503 is intended to be used as an artificial embolization device in the treatment of hypervascularized tumors. These tumors often arise in the liver, kidneys, and the uterus.

3.3 Characterization of the OCL 503 Microsphere Components

PLGA has long been used as suture material and more recently as a sustained-release drug delivery vehicle. PLGA is synthesized as a copolymer of glycolide and DL-lactide (Figure 1) with the ratio of the monomers governing the rate of biodegradation.

Figure 1. Glycolic acid, D-lactic acid and L-lactic acid monomers



Collagen is a family of closely related extracellular proteins that form major constituents of connective tissue of animals, giving the tissues strength and flexibility. At least 14 different types exist, each composed of tropocollagen. Tropocollagens have a common triple-helical structure but vary somewhat in composition between the separate collagen types that are localized in different tissues. Type I collagen is the most common type of collagen.

3.4 Mechanism of Action

OCL 503 acts as an embolization agent based on physical blockade of the target blood vessel(s), leading to blood stasis and subsequent clot formation. In addition, OCL 503 can promote vascular occlusion by activating platelets and consolidating clot formation.

OCL 503 uses two distinct pathways to capture and activate platelets *in vivo*. In the first pathway, collagen-specific receptors on platelets can recognize and directly bind to the collagen on the surface of the OCL 503 microspheres. Binding to the collagen activates the platelets. Platelet activation causes a complex cascade of events that result in a tight clot formation. These events include the release of chemokines, the recruitment of other platelets from the blood and platelet aggregation. In the second pathway, von Willebrand Factor (vWF) in the blood can bind to the collagen on the surface of the OCL 503 microsphere. Specific receptors on the platelets then bind to the vWF-collagen complex. Binding of the platelets to the vWF-collagen complex leads to platelet activation and clot formation as noted above.

3.5 Justification for Species Selection

The uterine organ system, vascular network, and hemostatic system of the sheep closely resemble that of humans (1). Therefore, sheep are often the species of choice for studying safety and efficacy of embolotherapeutic agents for the potential treatment of uterine fibroids (2-5).

One year old female Suffolk cross sheep were used in this study.

3.6 Justification for Study Design

Sheep were treated with OCL 503 or Embosphere® Microspheres as detailed in Table 1. Animals from each group were scheduled to be sacrificed one, three, six and 12 months post implantation. This schedule permitted an analysis of the effectiveness of OCL 503 in embolizing the targeted vasculature at various time points, a determination of when the OCL 503 microspheres biodegraded and whether the treated vasculature recanalized.

Table 1: Study Design

Study Type	Sacrificed	Test Procedure	Test Article	Number of Animals	Sheep Number
One Month	4 Weeks Post Embolization	Uterine Artery Embolization	OCL 503	4	Y26, Y30, Y187, Y790
			Embosphere® Microspheres	4	Y28, Y33, Y110, Y184
Three Months	12 Weeks Post Embolization	Uterine Artery Embolization	OCL 503	4	G57, G186 ¹ , G194, G261,
			Embosphere® Microspheres	4	G188, G196, G253, G410
Six Months	24 Weeks Post Embolization	Uterine Artery Embolization	OCL 503	4	R56 ² , R179, R193, R198
			Embosphere® Microspheres	4	R27, R32, R184, R199
Twelve Months	52 Weeks Post Embolization	Uterine Artery Embolization	OCL 503	4	B53, B182, B183, B346
			Embosphere® Microspheres	4	B29, B34, B54, B197

¹Animal G186 had a spinal abscess and was sacrificed 7 weeks post embolization.

²Animal R56 was sacrificed 3 months post embolization rather than at 6 months as originally scheduled.

3.7 Justification for Number of Animals Tested

Thirty-two sheep were treated with OCL 503 or Embosphere® Microspheres as detailed in Table 1. Eight animals (four treated with OCL 503 and four treated with Embosphere® Microsphere) were scheduled to be sacrificed one, three, six and twelve months after implantation. Four animals per group provided sufficient experience to evaluate the properties of OCL 503 and Embosphere® Microspheres at each time point while minimizing the total number of animals used in the study.

3.8 Justification for Selecting the Sex of Animals Tested

Uterine artery embolization was studied in female sheep.

3.9 Study Compliance

This study was conducted at the Metabolic Unit and Ellerslie Research Facility at the University of Alberta in compliance with the Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies (21 CFR Part 58) and applicable University of Alberta SOPs. ViRexx Medical Corp.'s Quality Assurance Unit performed quality assurance auditing and inspecting activities of procedures and analyses and reporting of findings.

The test article was manufactured in compliance with current Good Manufacturing Practices (cGMP) regulations.

The University of Alberta is accredited by both the Canadian Council on Animal Care and the Association for Assessment and Accreditation of Laboratory Animal Care and has received Animal Welfare Assurance number A5070-01 issued by the American National Institutes of Health's Office of Laboratory Animal Welfare. The University has an Institutional Animal Care and Use Committee responsible for compliance with applicable laws and regulations concerning the humane care and use of laboratory animals.

4. Study Objectives

The primary objective of this preclinical study was:

- (a) To evaluate the efficacy and safety of OCL 503 as an artificial embolization agent.

The secondary objectives of this preclinical study were:

- (a) To determine the integrity of OCL 503 in the arterial vessel one, three, six and twelve months after implantation.
- (b) To detect any toxicity associated with the implantation of OCL 503.
- (c) To determine the nature and extent of local tissue reaction to the implantation of OCL 503.
- (d) To determine the extent of recanalization of the target blood vessels.
- (e) To determine the ease of use of OCL 503 as an embolic device.
- (f) To compare the safety and efficacy of OCL 503 with that of Embosphere® Microspheres.

5. Materials and Methods

5.1 Animals

Thirty-two one year old female Suffolk cross sheep were used in the study. All animals were approximately one year old when they entered the study. Animals were weighed and paired by weight. Each pair of animals was then randomly assigned to one of four treatment groups (one month, three months, six months or twelve months). Each treatment group was assigned a unique ear tag color (one month group = yellow, three month group = green; six month group = red and 12 month group = blue). Sheep then received ear tags with a unique combination of numbers and colors to identify individual animals. One animal in each original pair was selected to be implanted with OCL 503 while the other was implanted with Embosphere® Microspheres.

5.2 Animal Care

Animals were housed at the University of Alberta under conditions consistent with all mandated provincial and national regulations. All animals received water and food *ad libitum* by qualified animal care providers. Animals received a 50% mixture of barley and alfalfa pellets when they were housed inside and timothy hay during the winter when they were housed outside. The Director of Animal Care for the Faculty of Agriculture, Forestry and Home Economics monitored animal health and veterinary care was provided as necessary.

All animals were physically examined and their vital signs recorded according to the schedule given in Appendix A. Individual animal weights are recorded in Appendix B. All animals were dewormed with Ivomec Injection (Merial Canada Ltd., Baie D'urfe, QC) and vaccinated with Tasvax 8 (Schering-Plough Animal Health, Pointe Claire, QC) annually per manufacturer's instructions.

All animals were kept in a flock on an outside pasture. One week prior to surgery, animals were brought into the barn, sheared, and housed in individual pens within sight of other sheep. Animals were kept inside until their coat was long enough or the outside temperature was warm enough for them to be released back into the outside flock. All animals were kept in the barn at least one week post surgery.

Animals were transported to and from the Metabolic Unit and the Ellerslie Research Facility for surgery in an approved animal trailer under the care of qualified animal care providers. All animals were transported to the Ellerslie Research Facility the day before surgery and returned to the Metabolic Unit the day after surgery.

All animals had a jugular cannula inserted the day prior to surgery for administration of an intravenous saline drip while anesthetized. The cannula was removed immediately following surgery.

All animals received intramuscular injections of Metacam® (0.2 mg/kg; Boehringer Ingelheim Vetmedica; Burlington, ON), a non-steroidal anti-inflammatory analgesic, on the day of surgery, the day after surgery and then as needed. The first six treated animals (Y28, Y30, Y110, Y184, Y187, and Y790) received 1 g of Ampicillin Sodium 1000 mg (Novopharm, Toronto, ON) in their intravenous drip during surgery and two intramuscular injections of 500 mg each on the day following surgery. The remaining 26 animals received Excenel® RTU Sterile Suspension (ceftiofur hydrochloride; 2 mg/kg; Pharmacia & Upjohn; Orangeville, ON) intramuscularly on the day of surgery and on the following day.

Animal G186 received intramuscular injections of Oxytetra LA (20 mg/10 kg, Citadel Animal Health, Cambridge, ON) for two days to treat an infection.

5.3 Study Design

The study design is summarized in Table I.

5.4 Hormone Induction

Veramix® sponges (Pharmacia and Upjohn) impregnated with medroxyprogesterone acetate were inserted into the vagina of each animal 13-15 days prior to surgery. The sponges were removed one day prior to surgery.

Animals received 400 international units of pregnant mare serum gonadotropin (Folligon® Injection; Intervet Canada Ltd, Whitby, ON) through an intramuscular injection one day prior to surgery.

5.5 Anesthesia and Euthanasia

5.5.1 Anesthesia. All animals were anesthetized with 5% isoflurane and maintained on ventilation at approximately 2% (+/- 0.5%) isoflurane as needed for the duration of the embolization procedure. Following the completion of surgery, the isoflurane was reduced to 0% and ventilation continued until the animals recovered from anesthesia.

5.5.2 Euthanasia. All animals were euthanized with 120 mg/kg sodium pentobarbital (Euthanyl®, Bimeda-MTC Animal Health Inc., Cambridge, ON) administered intravenously in accordance with manufacturer's instructions.

5.6 Embolic Device

5.6.1 OCL 503. OCL 503 microspheres (150 – 212 µm) were manufactured at Brookwood Pharmaceuticals (Birmingham, AL) in compliance with cGMP regulations. The OCL 503 used in this study was from Lot number FL289. The contents of a vial (400 mg/vial) were suspended in 5 – 10 mL of Sodium Chloride

for Injection 0.9% USP (Appendix C lists the individual volumes). Omnipaque™ 300 (Amersham Health) or Omnipaque™ 240 (Amersham Health) was used as contrast agent. Omnipaque 300 was added to the suspended particles in a 3-to-1 ratio of Omnipaque 300 to Sodium Chloride for Injection ratio. The volume of Omnipaque 240 required was calculated using the following formula:

$$\text{Volume Omnipaque 240 (mL)} = \text{Volume of saline (mL)} \times 3.75.$$

5.6.2 Embosphere® Microspheres. Embosphere® Microspheres lot 286LB6 (Inter Medical Inc., Montreal, QC) with a nominal size range of 300 – 500 µm were used according to manufacturer's instructions.

5.7 Embolization Procedure

Embolization procedures were carried out under general anesthesia with femoral artery cannulation. All animals were treated by a single interventional radiologist in a similar manner with standard angiographic equipment. A 2.3F Rapid Transit Microcatheter (Cordis Corporation, Markham, ON; 29/32 sheep), a 2.3F Prowler Select Plus Microcatheter (Cordis Corporation, Markham, ON; 1/32 sheep) or a 5F Beacon Tip Torcon Advantage Catheter (Cook Incorporated, Bloomington, IN; 2/32 sheep) was directed to the uterine artery under fluoroscopic guidance. Once the position of the catheter was confirmed, either OCL 503 or Embosphere® Microspheres suspended to neutral buoyancy was injected into the target artery at the discretion of the interventional radiologist. Small increments of the embolic agent were administered until the radiologist determined that effective stasis had been achieved. Procedural data were recorded.

The interventional radiologist unilaterally treated the left (25 sheep) or right (7 sheep) uterine artery based on the architecture of each animal's arterial blood supply. Target arteries were clearly identified in all 32 animals. Embolization to effective stasis was achieved in all cases. The post procedure course was uneventful for all animals and there were no post operative complications.

5.8 Clinical Laboratory Data

Table 2 shows the parameters that were measured at baseline and at the intervals listed in the protocol study schedule (Appendix A). Three 5 mL blood samples were drawn from each animal at the specified times. All clinical laboratory analyses were conducted at Central Laboratory for Veterinarians, Ltd. (Edmonton, Canada). A qualified veterinary pathologist reviewed the data.

Table 2. Clinical Laboratory Parameters

Chemistry Albumin Albumin/Globulin Ratio Alkaline Phosphatase Anion Gap Blood Urea Nitrogen (BUN) BUN/Creatinine (Cr) Ratio Calcium Calculated Osmolality Carbon Dioxide Chloride Creatinine Creatine Phosphokinase Gamma -GT Globulin Glucose Phosphorus Potassium AST (Sgot) ALT (Sgpt) Sodium Sodium/Potassium Ratio Sorbital Dehydrogenase - AO Total Bilirubin Total Protein Uric Acid	Hematology WBC and Differential Count RBC Count Hematocrit Hemoglobin Mean Corpuscular Volume Mean Corpuscular Hemoglobin Mean Corpuscular Hemoglobin Concentration Red Cell Distribution Width Platelet Count Mean Platelet Volume
	Coagulation Partial Thromboplastin Time Prothrombin Time Fibrinogen Degradation Products
	Morphology Platelet Morphology Fibrinogen Semi Quantitative RBC Morphology

5.9 Postmortem Examination

Animals were euthanized as described in Section 5.5.2. A gross examination of the target and non-target uterine arteries was performed after they were surgically exposed. A standard postmortem examination was then performed and tissues specified in Table 3 were collected for histologic examination. Tissue samples were processed and histological sections prepared by Histobest Inc. (Edmonton, AB) using standard procedures.

All carcasses were incinerated following post mortem examination and tissue collection.

Table 3. Tissues collected for histologic examination

Abomasum	Liver
Adrenals	Lungs
Bladder	Ovarian Arteries
Brain	Ovaries
Diaphragm	Pancreas
Duodenum	Quadriceps Muscle
Eyes	Small Intestine
Gall Bladder	Spleen
Gluteal Muscles	Uterine Arteries
Heart	Uterus
Kidneys	Vagina
Large Intestine (with Rectum)	Vaginal Arteries
Any abnormal tissues observed at the gross necropsy	

5.10 Statistical Analysis

An appropriate analysis of the safety and biological data developed in this preclinical study was performed. Safety analyses were based on the clinical and laboratory effects observed in treated animals. The statistical analysis was primarily descriptive. Statistical significance for the surgical time for implantation, fluorographic time and vials required for effective stasis was determined with the one-tailed Student's t-test.

5.11 Key Personnel

Dr. Richard Owen, M.D., F.R.C.P.(C), an interventional radiologist at the University of Alberta Hospital, performed all device implantation procedures and made the determination that effective stasis of blood flow to the target organ had been achieved. Dr. P. N. Nation, D.V.M., Ph.D., a board certified veterinary pathologist, performed all necropsies and interpreted all Clinical Laboratory data, gross pathologies and histological analyses. The resumes for Drs. Owen and Nation are included in Appendix X.

6. Results

6.1 Embolization

All animals were healthy at the time of embolization and were examined, weighed, and blood samples drawn in accordance with the Study Schedule (Appendix A). Individual and group mean weights are recorded in Appendix B. Data recorded during the embolization procedure are listed in Appendix C.

The left or right uterine artery was embolized with OCL 503 or Embosphere® Microspheres using a femoral approach. The devices were administered through standard microcatheters.

Although it took significantly longer to surgically implant (time from insertion of the catheter to its removal) OCL 503 than Embosphere® Microspheres (Table 4; $p=0.0002$), the fluorographic time required to achieve effective stasis was not significantly different for sheep implanted with either device (Table 5, $p=0.32$). The mean number of vials and the range of vials required to reach effective stasis in both treatment groups were not significantly different (Table 6, $p=0.31$).

Table 4. Total surgical time to implant each device

Treatment Group	Number of sheep	Minutes (Mean $\pm$ 1 SD)
OCL 503	n = 14	18.4** $\pm$ 5.7
Embosphere® Microspheres	n = 14	9.6 $\pm$ 3.2

**Significantly different: $p=0.0002$, single tailed Student's t-test

Note that the fluorographic time was only recorded in 88% of the treated sheep (28/32 of total sheep; 14/16 in each treatment group).

Table 5. Fluorographic time to achieve effective stasis in each group of sheep

Treatment Group	Number of sheep	Minutes (Mean $\pm$ 1 SD)
OCL 503	n = 8	8.9 $\pm$ 2.7
Embosphere® Microspheres	n = 8	8.1 $\pm$ 3.6

Not significantly different: $p=0.32$, single-tailed Student's t-test

Note that the fluorographic time was only recorded in 50% of the treated sheep (16/32 of total sheep; 8/16 in each treatment group).

Table 6. Number of vials required to achieve effective stasis

Treatment Group	Number of sheep	Vials (Mean $\pm$ 1 SD)	Vials (Range)
OCL 503	n = 16	0.8 $\pm$ 0.3	0.4 – 1.3
Embosphere® Microspheres	n = 16	0.9 $\pm$ 0.3	0.3 – 1.6

Not significantly different: $p=0.31$, single-tailed Student's t-test

6.2 Animal Health

Sheep G186 developed an infection in the neck one day after surgery at the site of the jugular cannula used for an intravenous drip. The animal was treated with hot compresses, Excenel (six days), and Oxytetra LA for two days. In addition, an abscess in the neck was lanced and flushed with betadine. The infection appeared to resolve within 8 days. Three weeks after surgery, G186 began to exhibit signs of walking stiffly. Clinical signs became more pronounced over time and the sheep had limited mobility and eating. Although scheduled to be sacrificed 3 months after treatment, the study veterinarian put G186 down 7 weeks after surgery to minimize its suffering. Post-mortem examination showed that this animal had a spinal

abscess that caused the clinical signs. This was interpreted to have arisen by extension from the infection at the site of cannulation. The abscess was unrelated to implantation of OCL 503.

All other sheep were in good health and were euthanized as scheduled.

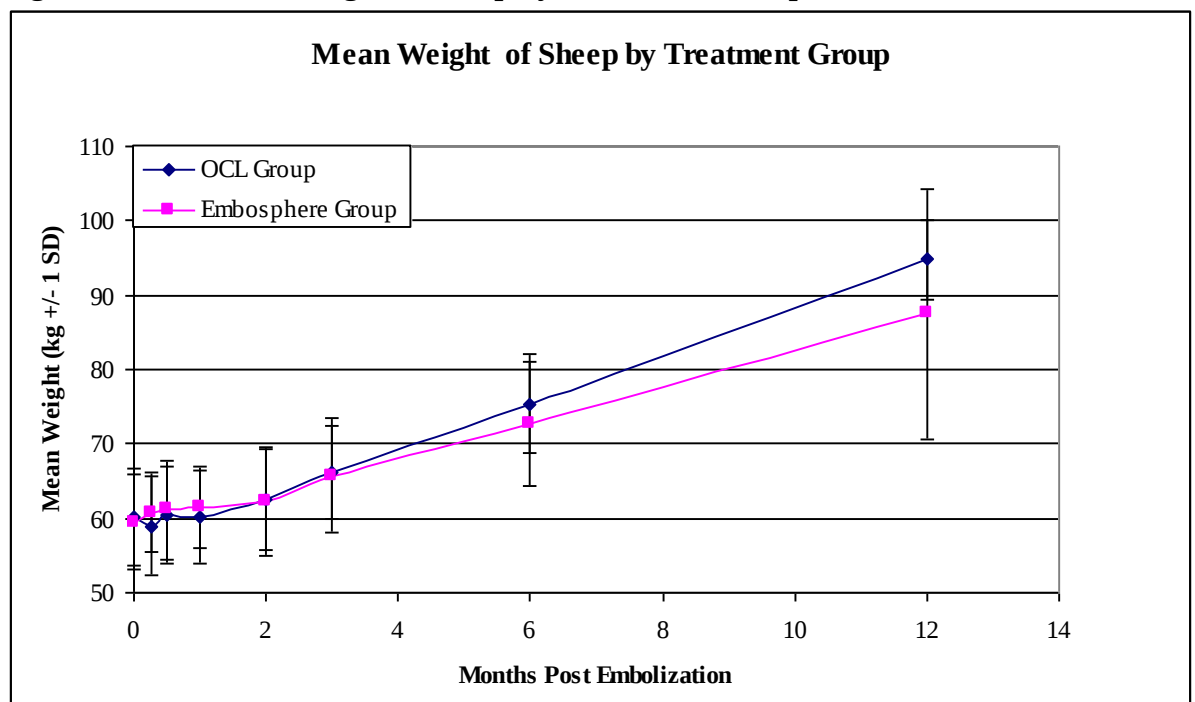
6.3 Animal Weights

The sheep with the spinal abscess (sheep number G186), lost 10 kg in weight over the last three weeks of its life due to its decreased mobility and lack of food consumption. This weight loss was unrelated to treatment with OCL 503. The weight of each sheep over the course of the study is presented in Appendix B.

There was some fluctuation in weight of individual animals between their pre-treatment weight and their weights at one week and two weeks post surgery and again at 1 month post implantation (Appendix B). This variability is due in part to their response to the surgery and in part to being fed *ad libitum* in the barn and then being moved back to the pasture to graze.

The mean weight of sheep in each treatment group is shown in Figure 2. Both of the groups gained weight with time and the rate of weight gain was similar. The sheep implanted with Embosphere® Microspheres appear to gain weight more slowly than sheep treated with OCL 503 from six to twelve months after

Figure 2. The Mean Weight of Sheep by Treatment Group



Note: The error bars represent one standard deviation (SD).

implantation. This lower weight gain is due primarily to the loss of 3 kg in weight by sheep number B29 while all other sheep gained between 12 and 26 kg during this period (Appendix B). Sheep B29 was in good health at the time of sacrifice and no physiological reason was identified for its failure to gain weight.

6.4 Clinical Laboratory Data

Blood samples were collected the day before surgery and again 1 day, 7 days, 14 days, 1 month, 2 months, 3 months, 6 months and 12 months after embolization. The clinical laboratory units and standard reference range used by Central Laboratory for Veterinarians, Ltd. are provided in Appendix D. An Internal Reference Range, the range of clinical laboratory data on day -1 for the thirty-two sheep used in this study, is also provided in Appendix D. This internal reference range is the most appropriate to use in assessing individual variations in hematology and clinical chemistry values.

Graphs of the means of the clinical laboratory data for each group of animals (sheep implanted with OCL 503 and sheep implanted with Embosphere® Microspheres) are presented in Appendices K to P.

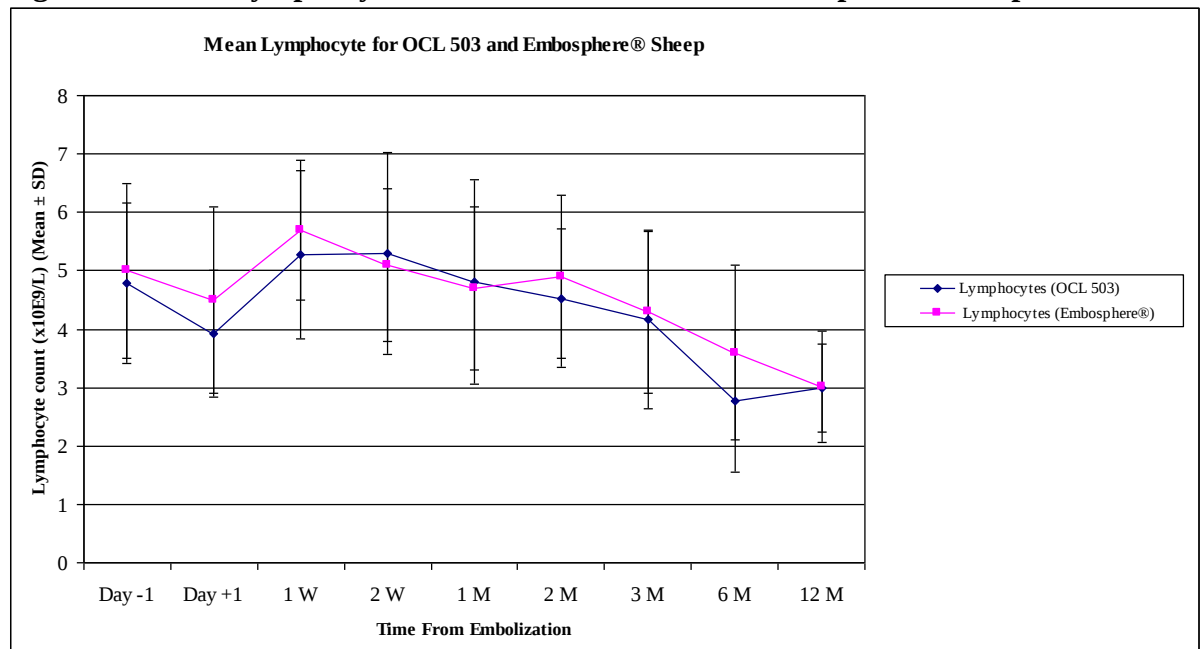
The laboratory parameters means that changed following implantation are discussed below.

6.4.1. Hematology. The mean lymphocyte count decreased one day after implantation, rebounded slightly above pre-implantation values one week after implantation and then gradually decreased with time (Figure 3). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar and fell within the pre-treatment internal standard reference range (Appendix D).

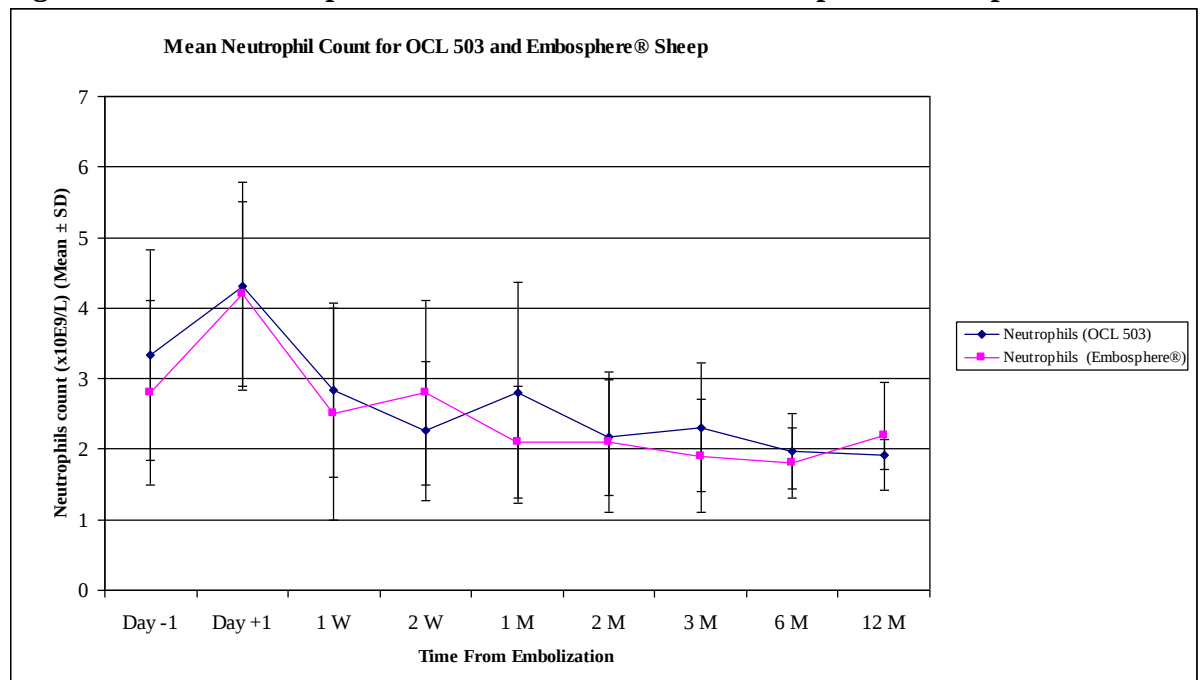
The mean number of neutrophils increased one day after implantation, decreased to slightly below pre-implantation values one week after implantation and then decreased with age (Figure 4). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar and fell within the pre-treatment internal standard reference range (Appendix D).

6.4.2 Chemistry. The mean blood urea nitrogen/creatinine (BUN/Cr) ratio decreased one day after implantation, rebounded above pre-implantation values by one week after implantation and remained elevated in both groups thereafter (Figure 5). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar and fell within the pre-treatment internal standard reference range (Appendix D).

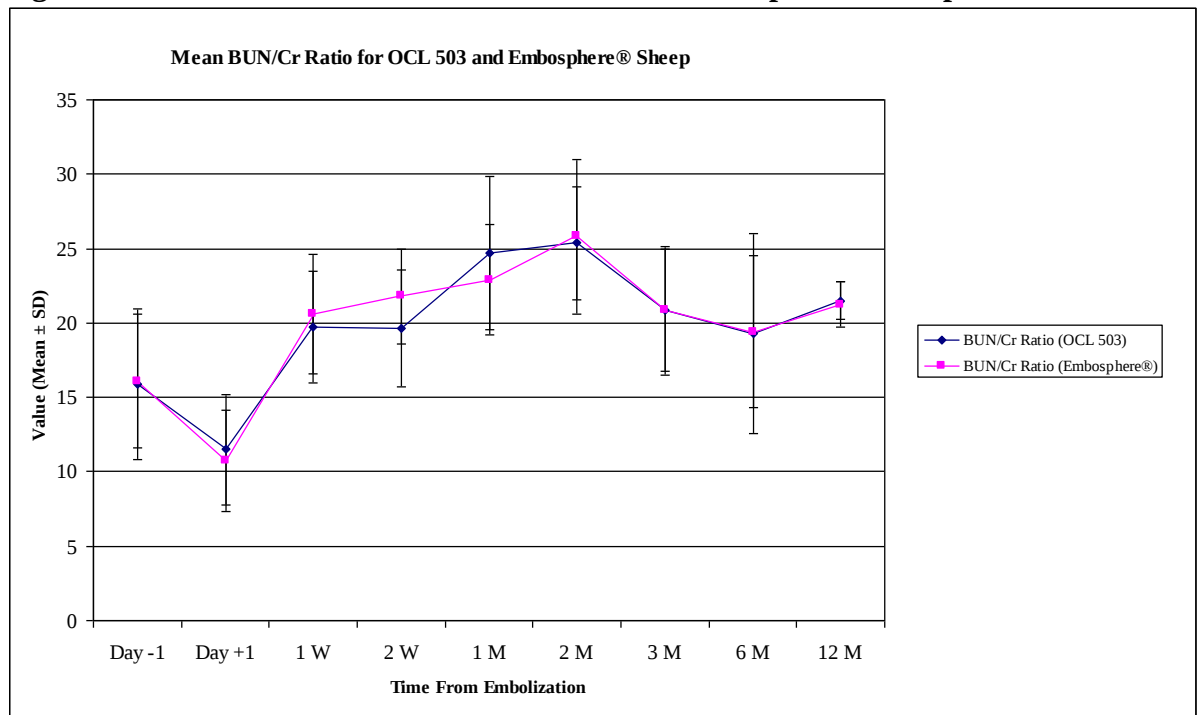
The mean sorbital dehydrogenase-AO levels increased sharply one day after implantation but returned to normal by one week post implantation (Figure 6). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar. The values for individual animals implanted with OCL 503 and Embosphere®

Figure 3. Mean Lymphocyte Count for OCL 503 and Embosphere® Sheep

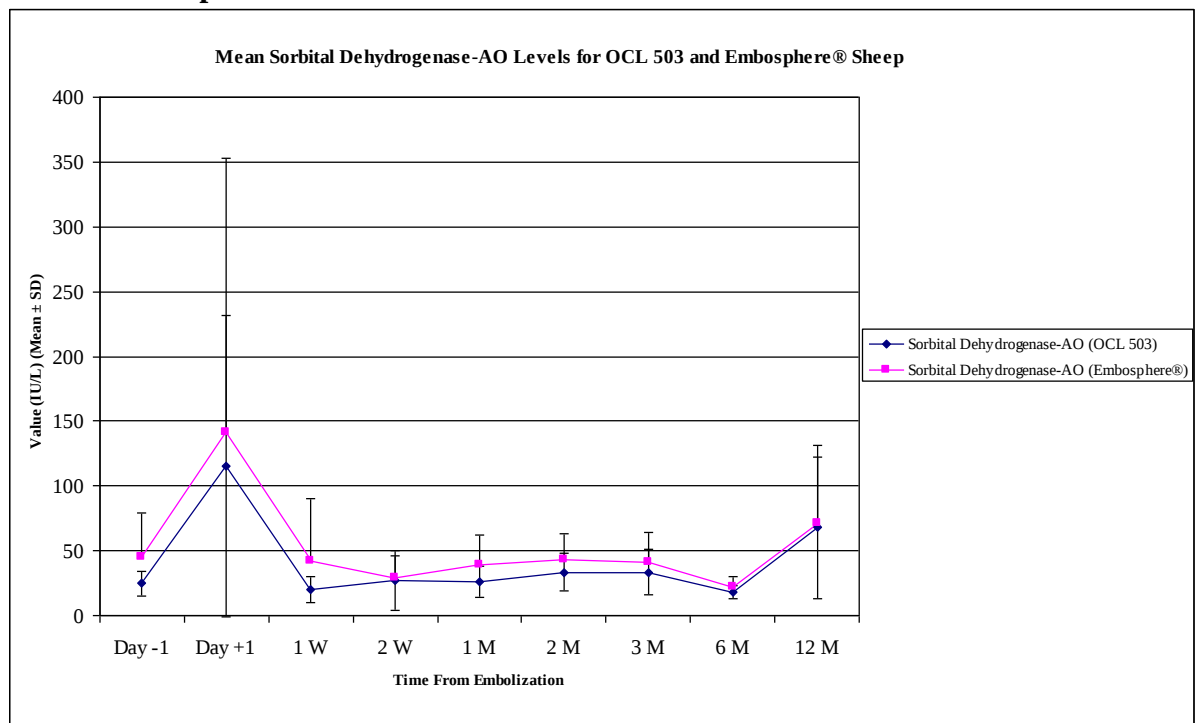
Source: Appendix L, panels a and b

Figure 4. Mean Neutrophil Count for OCL 503 and Embosphere® Sheep

Source: Appendix L, panels a and b

Figure 5. Mean BUN/Cr Ratio for OCL 503 and Embosphere® Sheep

Source: Appendix O, panels a and b

Figure 6. Mean Sorbital Dehydrogenase-AO Levels for OCL 503 and Embosphere® Sheep

Source: Appendix O, panels a and b

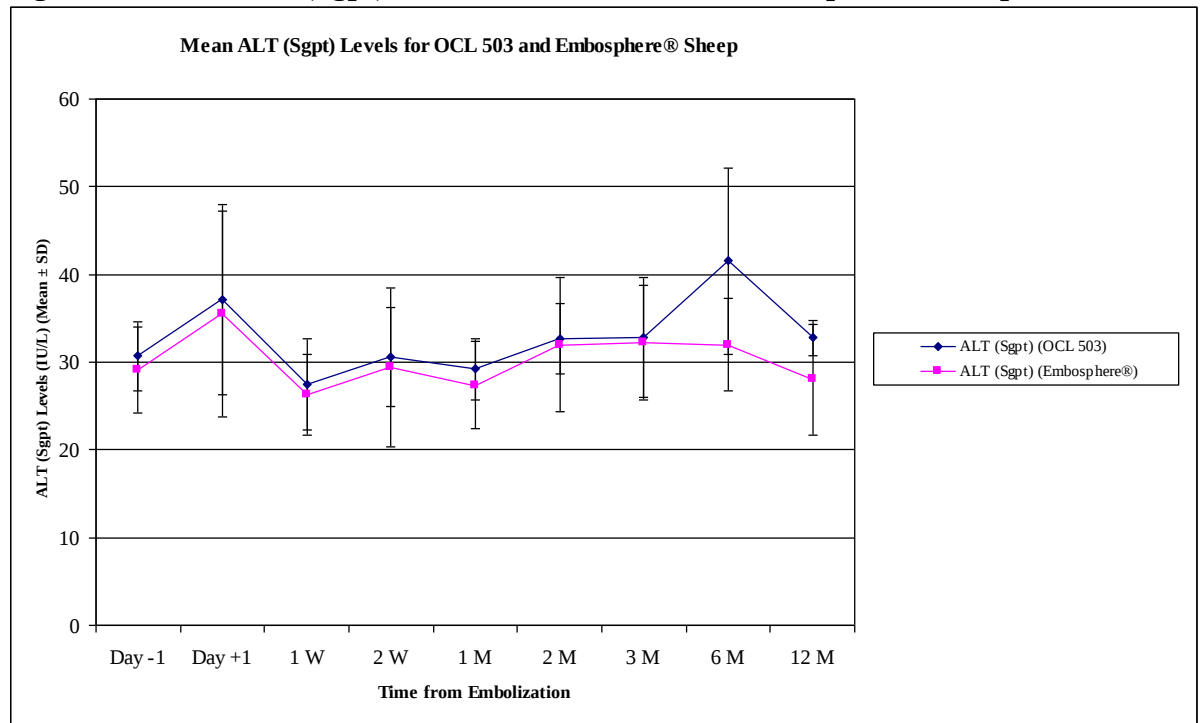
Microspheres are shown in Appendix Q. Seven of sixteen OCL 503-implanted sheep showed an increase in sorbital dehydrogenase one day after implantation while the remaining nine of sixteen animals had relatively minor increases (Appendix Q, panel a). Fifteen of sixteen Embosphere® Microspheres-implanted sheep had modest increases in Sorbital Dehydrogenase while one of sixteen had a substantial increase (Appendix Q, panel b).

The mean ALT (Sgpt) levels increased one day after implantation, decreased to or below pre-implantation values by one week post-implantation (Figures 7). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar. The values for individual animals implanted with OCL 503 and Embosphere® Microspheres are shown Appendix R.

The trends for the OCL 503 and Embosphere® Microspheres Sheep were similar. Each individual change had resolved itself by the next laboratory examination. All changes were within the pre-treatment internal standard reference range (Appendix D).

The mean AST (Sgot) levels increased one day after implantation, decreased to or below pre-implantation values by one week post-implantation (Figures 8). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar. All means fell within the pre-treatment internal standard reference range (Appendix D). The values for individual animals implanted with OCL 503 and Embosphere®

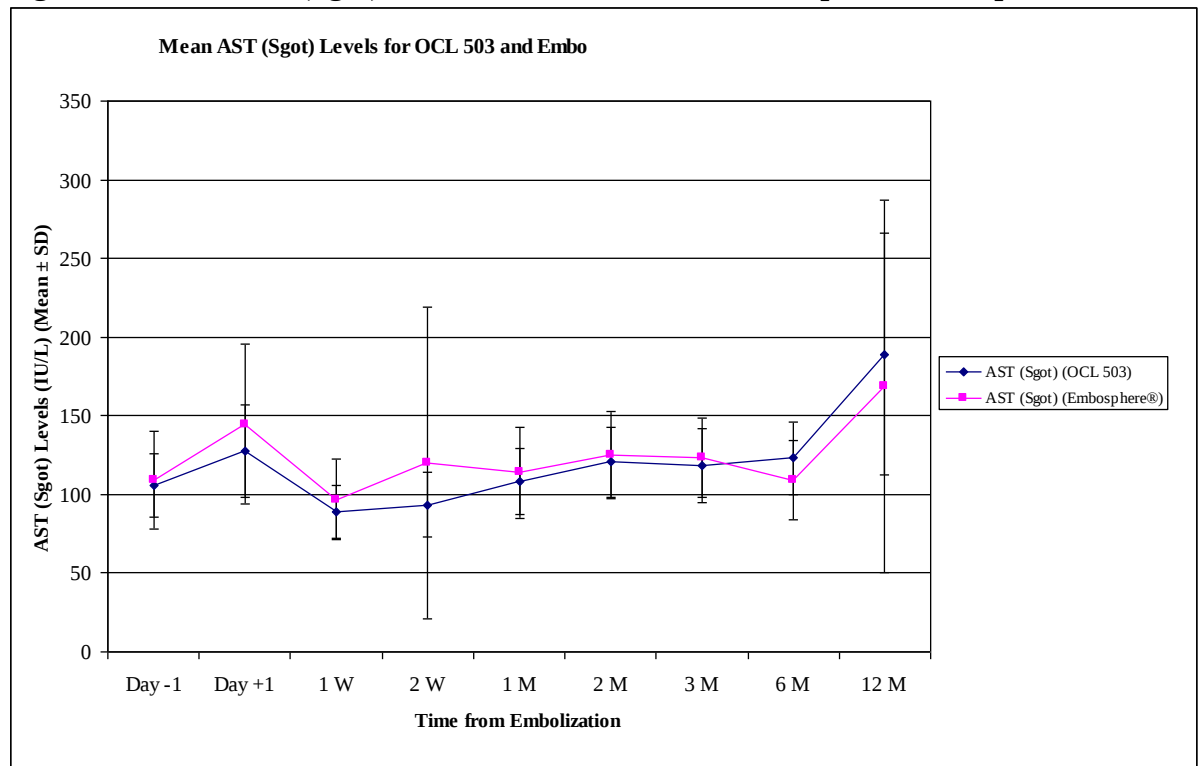
Figure 7. Mean ALT (Sgpt) Levels for OCL 503 and Embosphere® Sheep



Source: Appendix O, cont., panels c and d

Microspheres are shown in Appendix S. The trends for the OCL 503- and Embosphere® Microspheres-treated sheep were similar. The AST (Sgot) level increased from 130 IU/L one week post implantation to 438 IU/L two weeks after implantation in Embosphere® Microspheres-treated sheep number B34 (Appendix H14, Appendix S). The cause of this increase in sheep B34 is unknown. The values returned to 140 IU/L one month post implantation (Appendix H14).

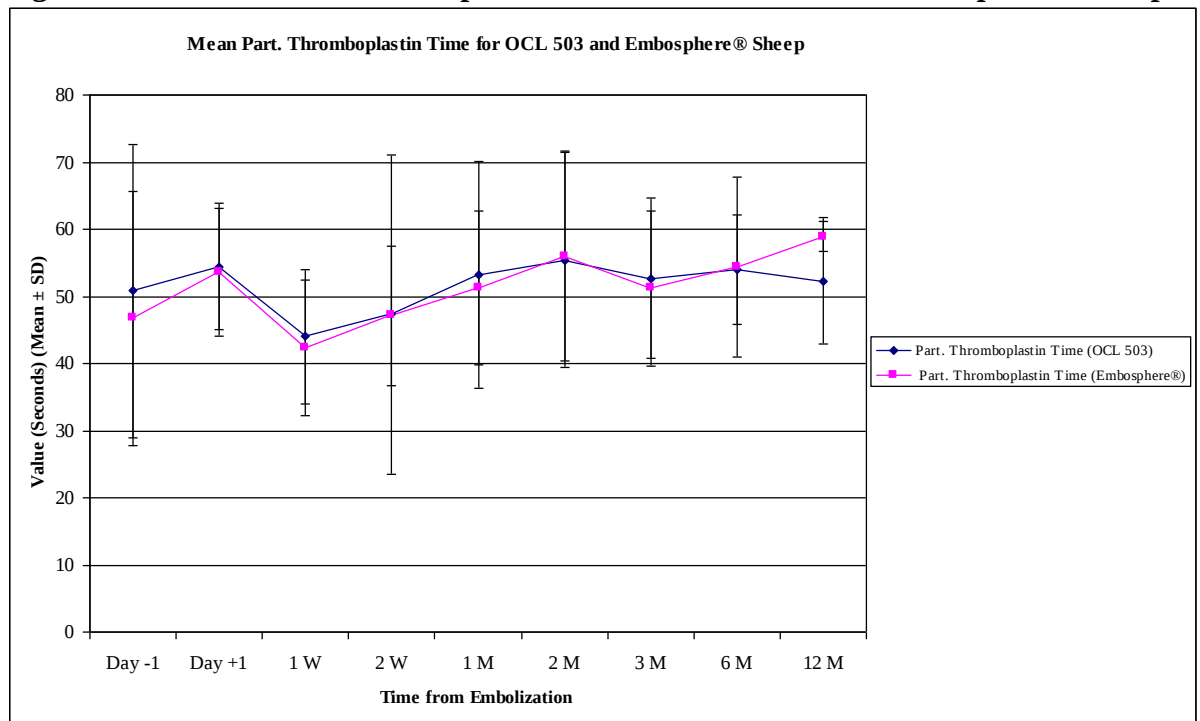
Figure 8. Mean AST (Sgot) Levels for OCL 503 and Embosphere® Sheep



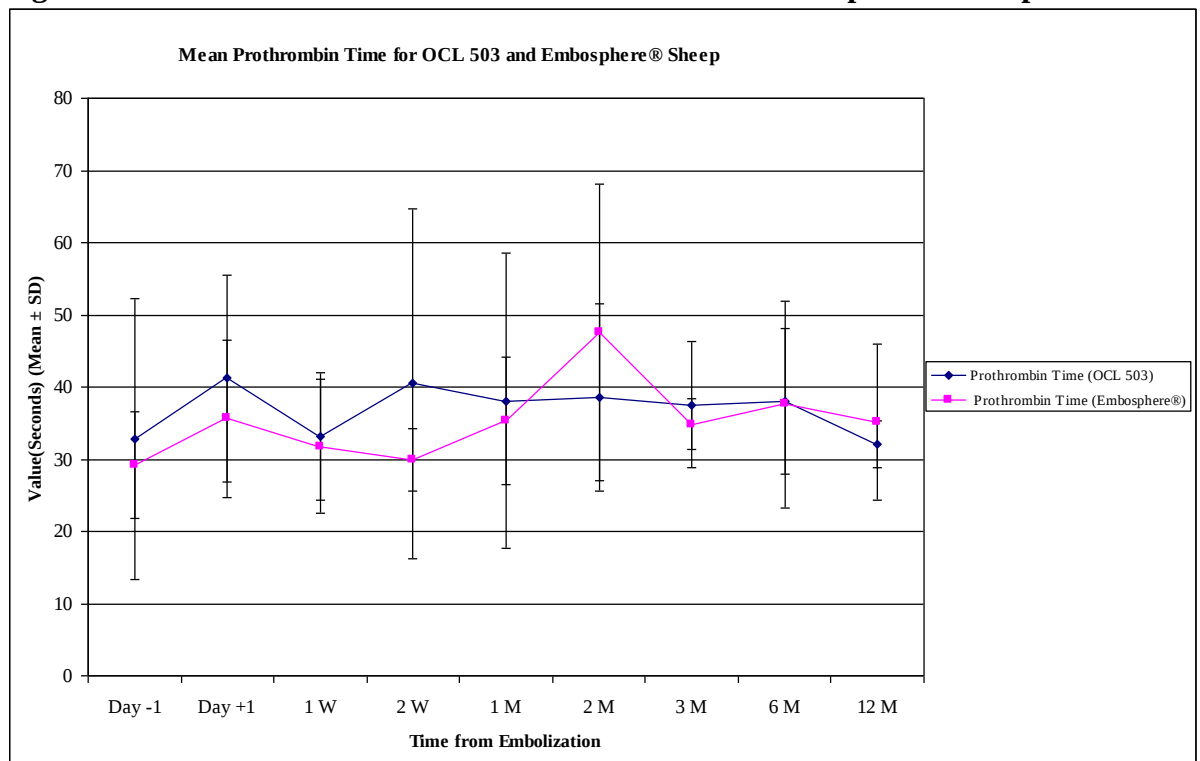
Source: Appendix O, cont., panels c and d

6.4.3 Coagulation. The mean partial thromboplastin time increased one day after implantation, decreased to or below pre-implantation values by one week post-implantation and then increased gradually with time (Figure 9). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar. All means fall within the pre-treatment internal standard reference range (Appendix D). Due to the large error bars, the values for individual animals implanted with OCL 503 and Embosphere® Microspheres are shown in Appendix T. Although there is significant variation in Partial Thromboplastin time during the study in individual animals, all values fell within the pre-treatment reference range established in this study (Appendix D).

The prothrombin time increased one day after implantation but fell to or below pre-implantation values by one week post-implantation (Figure 10). The mean values for the OCL 503 and Embosphere® Microspheres groups were similar. All means fall within the pre-treatment internal standard reference range (Appendix D). Due

Figure 9. Mean Partial Thromboplastin Time for OCL 503 and Embosphere® Sheep

Source: Appendix O, panels c and d

Figure 10. Mean Prothrombin Time for OCL 503 and Embosphere® Sheep

Source: Appendix O, panels c and d

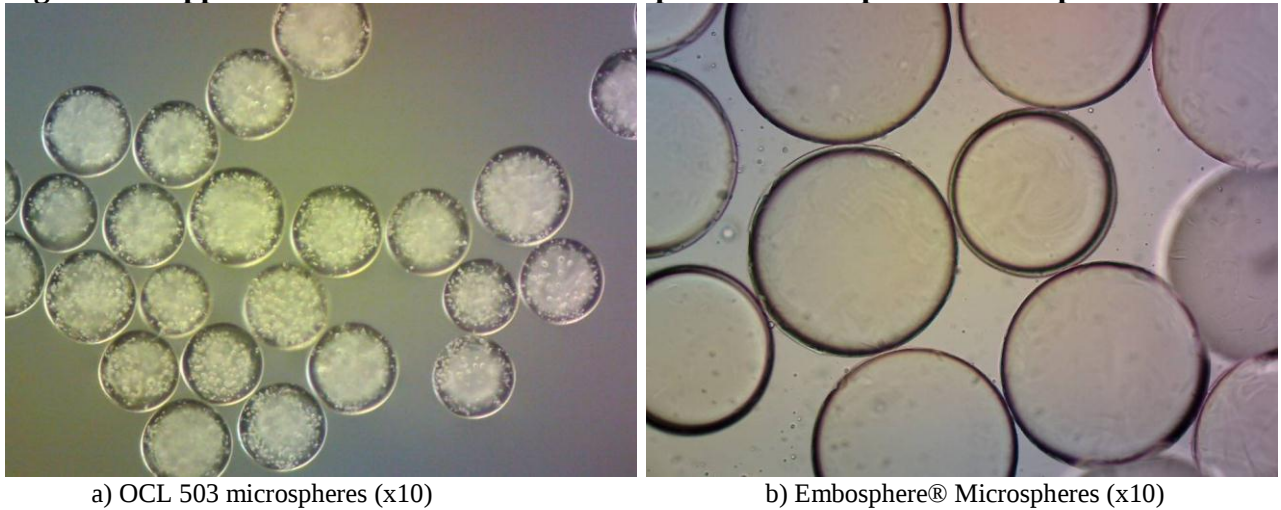
to the large error bars, the values for individual animals implanted with OCL 503 and Embosphere® Microspheres are shown in Appendix U. Although there is significant variation in prothrombin time through the study, all values fell within the pre-treatment reference range established in this study (Appendix D).

6.4.4. Raw Clinical Laboratory Data. The clinical laboratory data for each sheep implanted with OCL 503 for all sample days are listed in Appendix E. The summary clinical laboratory data for all sheep implanted with OCL 503 are provided for each sampling day (Day -1, Day +1, 1 Week, 2 Weeks, 1 Month, 2 Months, 3 Months, 6 Months and 12 Months) in Appendix F. The mean and standard deviations for the clinical laboratory data for all days for sheep implanted with OCL 503 are given in Appendix G. The corresponding clinical laboratory data for the sheep implanted with Embosphere® Microspheres are provided in Appendices H, I and J, respectively. Data outside the normal reference range used by Central Laboratory for Veterinarians are shown in the tables in bold. It should be noted that the Internal Reference range for sheep in this study is broader than the reference range used by Central Laboratory for Veterinarians. This may be due to a more limited number of sheep in the Central Laboratory for Veterinarians database or that the sheep are housed under different conditions. Most of the values that exceed the Central Laboratory for Veterinarians reference range fall within the normal internal reference range for the sheep in this study.

6.5 Histopathological Findings

Implantation of OCL 503 and Embosphere® Microspheres caused complete occlusion of the treated artery. One month after implantation, all treated arteries stood out as a thick, rope-like, cords that were hard to the touch. Three and six months post implantation, the arteries treated with OCL 503 were still firm and distended and could be clearly distinguished from the contralateral untreated arteries, although the differences were less at six months than at three months post treatment. By twelve months post implantation, the uterine arteries treated with OCL 503 were visually indistinguishable from the untreated contralateral arteries. The Embosphere® Microspheres-treated arteries remained unchanged throughout the study.

A photomicrograph of the OCL 503 microspheres and Embosphere® Microspheres pre-implantation is shown in Figure 11. Photomicrographs of cross-sections of the treated uterine arteries at one, three, six and twelve months post-implantation with OCL 503 or Embosphere® Microspheres are presented in Figures 12 to 15. As can be seen in Figure 12a, the initially spherical OCL 503 microspheres showed profound shape changes one month after implantation as they were compressed in the artery and began to biodegrade. Figures 12a and 13a reveal that fibrous connective tissue formed around and between OCL 503 microspheres and held them in place as the microspheres underwent biodegradation. Figure 14a shows that the fibrous connective tissue appears to have replaced the inner luminal wall of the artery, which remained completely occluded six months post implantation, even

Figure 11. Appearance of OCL 503 and Embosphere® Microspheres Pre-Implantation

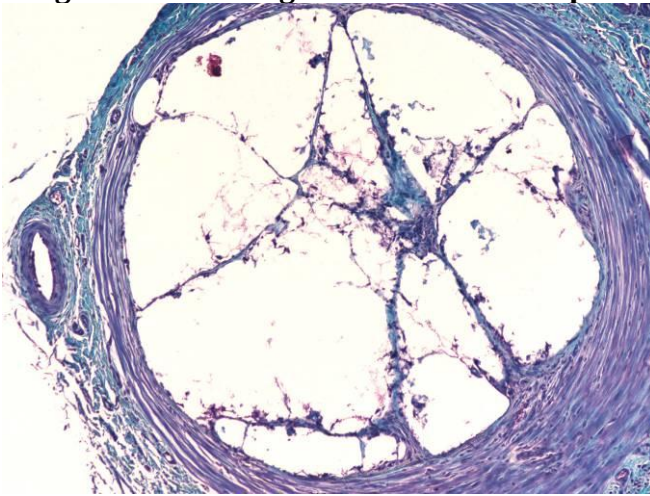
This phase contrast photomicrograph is representative of the microspheres implanted in this study. Note the size variation in both devices.

though the OCL 503 microspheres have completely degraded. Figure 15a and Figure 16 demonstrate that the treated uterine arteries had either fully recanalized or were in the process of being recanalized twelve months after implantation with OCL 503. The histological appearance of the Embosphere® Microspheres-treated arteries remained unchanged throughout the twelve month observation period (Figures 12b to 15b).

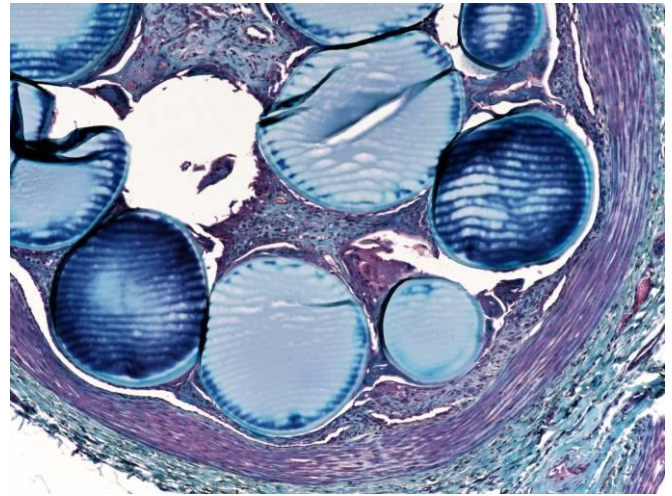
OCL 503 microspheres were found in the lumen of the treated artery (Figure 12a) as well as the branches of the treated uterine artery as distal as the wall of the uterus along the mesenteric attachment. As detailed in Appendix V and summarized in Figure 17, OCL 503 microspheres were also found occluding the untreated contralateral uterine arterioles.

Embosphere® Microspheres had a similar qualitative distribution in the uterine vasculature to that of the OCL 503 microspheres. Embosphere® Microspheres were also detected in the contralateral untreated uterine, vaginal, ovarian and urinary bladder vasculatures (see Figure 17). The presence of Embosphere® Microspheres is denoted as “yes” or “few.” In general, “yes” indicates that Embosphere® Microspheres were readily apparent and were numerous enough to have occluded the main artery or larger arterioles of the affected organ while “few” indicate that a smaller number of Embosphere® Microspheres were occluding smaller arterioles. This was not a quantitative analysis and only a few sections were examined in each organ system

Figure 17 graphically presents the percentage of treated sheep in which occluded arteries were identified by histopathological examination. Both OCL 503 (12/12) and Embosphere® Microspheres (16/16) completely occluded the artery in which

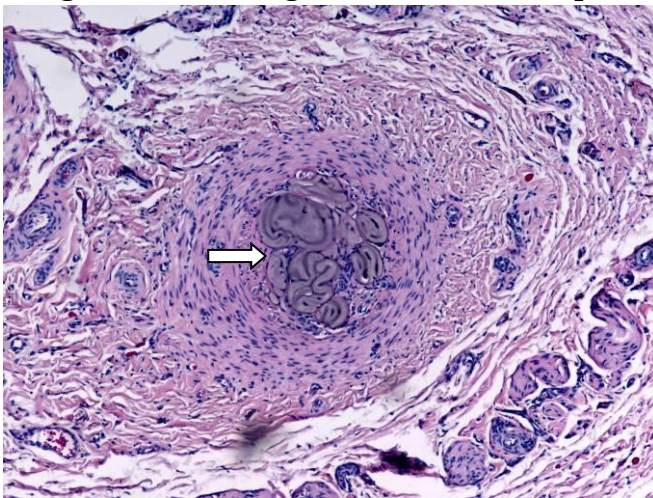
Figure 12. Histological Sections of Sheep Uterine Arteries One Month after Treatment

12a) Implanted OCL 503 Microspheres (x100)

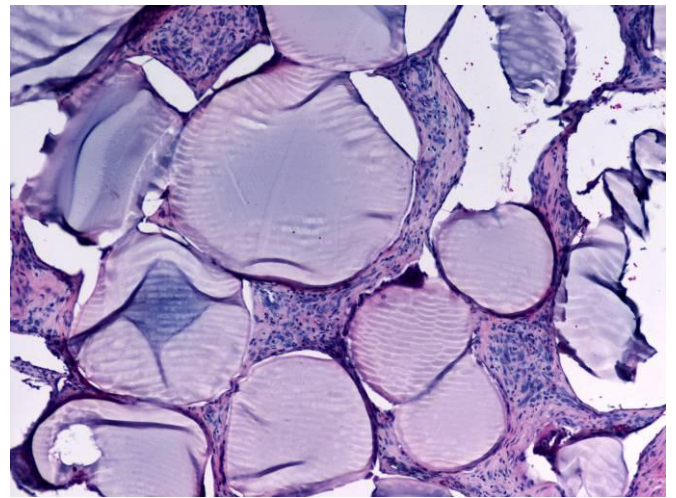


12b) Implanted Embosphere® Microspheres (x100)

One month after implantation, uterine arteries treated with Occlusin® 503 AED or Embosphere® Microspheres were fully occluded. The initially spherical OCL 503 microspheres showed profound shape changes as they were compressed in the artery and began to biodegrade. The OCL 503 microspheres did not stain and appear as white, irregular, shapes. In contrast, the Embosphere® Microspheres retained their spherical shapes and stain blue. Note: the folding and rippling appearance of the surface of the Embosphere® Microspheres are artifacts of the tissue sectioning.

Figure 13. Histological Sections of Sheep Uterine Arteries Three Month after Treatment

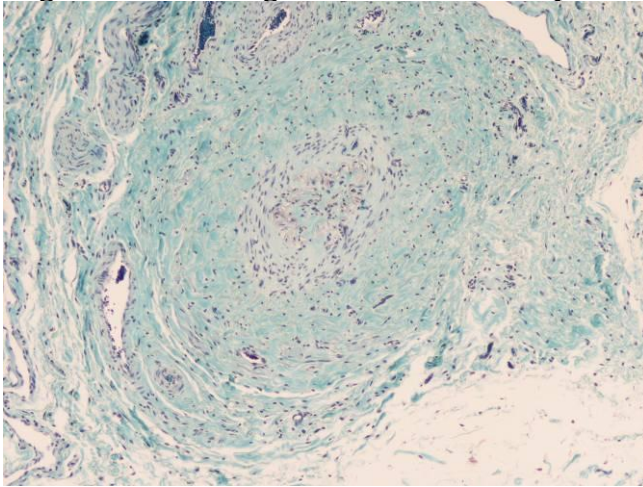
13a) Implanted OCL 503 microspheres (x100)



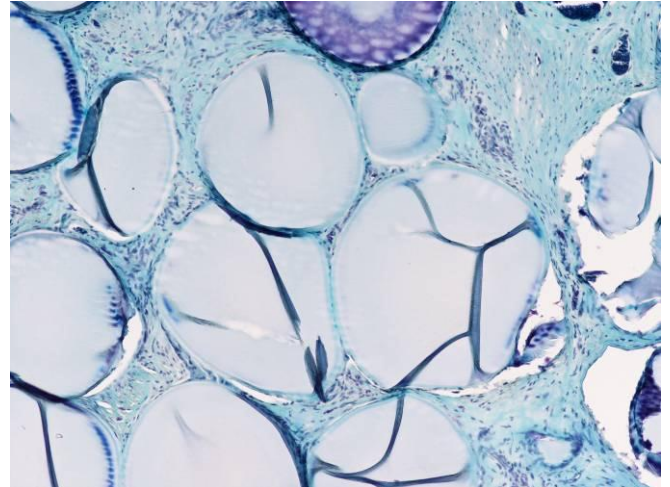
13b) Implanted Embosphere® Microspheres (x100)

Three months after implantation, uterine arteries treated with Occlusin® 503 AED or Embosphere® Microspheres remained fully occluded. There were no identifiable intact OCL 503 microspheres. The residual material was highly deformed and compressed in the center of the artery as it continued to degrade (arrow). In other sections, even less OCL 503 microsphere material was visible. In contrast, the Embosphere® Microspheres retained their round shapes and the artery remained highly distended.

Note: the folding and rippling of the surface of the Embosphere® Microspheres are artifacts of the tissue sectioning.

Figure 14. Histological Sections of Sheep Uterine Arteries Six Months after Treatment

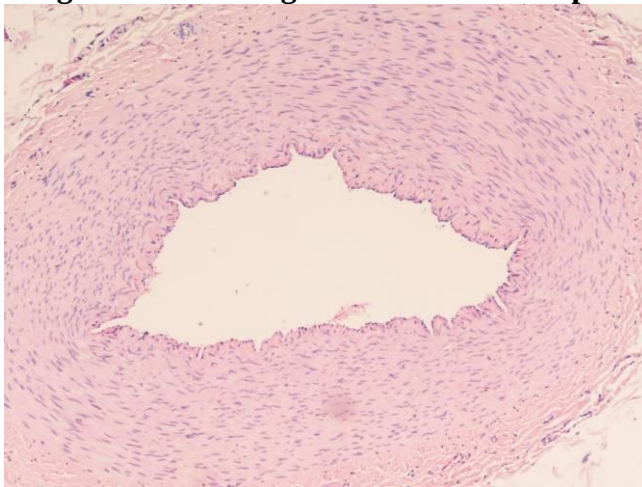
14a) Implanted OCL 503 microspheres (x100)



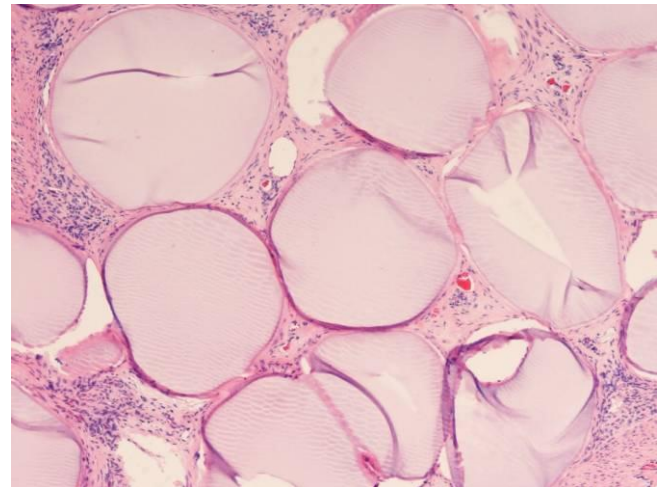
14b) Implanted Embosphere® Microspheres (x100)

Six months after implantation, uterine arteries treated with Occlusin® 503 AED or Embosphere® Microspheres remained fully occluded. The inner luminal wall of the artery treated with OCL 503 microspheres was replaced by fibrous connective tissue. No residual OCL 503 microspheres were observed six months after implantation. In contrast, the Embosphere® Microspheres retained their round shapes and the artery remained highly distended. Connective tissue was present between the Embosphere® Microspheres.

Note: the folding and rippling of the surface of the Embosphere® Microspheres are artifacts of the tissue sectioning.

Figure 15. Histological Sections of Sheep Uterine Arteries Twelve Months after Treatment

15a) Implanted OCL 503 microspheres (x100)



15b) Implanted Embosphere® Microspheres (x100)

Twelve months after implantation into the sheep uterine artery, the lumen of the uterine artery treated with OCL 503 microspheres was fully recanalized in 3 of 4 sheep. In contrast, the artery treated with Embosphere® Microspheres remained fully occluded.

Note: the folding and rippling of the surface of the Embosphere® Microspheres are artifacts of the tissue sectioning.

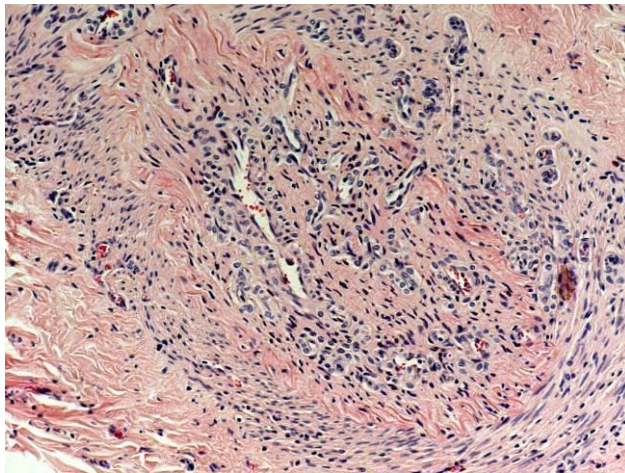
Figure 16. Histological Sections of Sheep B183 Left Uterine Artery Twelve Months after Treatment

a)



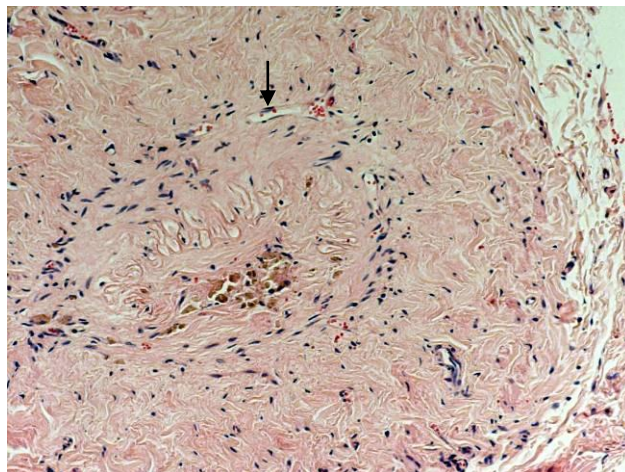
Panel a shows a section of the left uterine artery of sheep B183. The artery has been recanalized and contained blood as confirmed by the presence of red blood cells and precipitated serum proteins (arrow). Although patent, the arterial lumen was smaller than that seen in recanalized arteries in other animals (Figure 15a). The precipitated serum proteins are an artifact of tissue processing.

b)



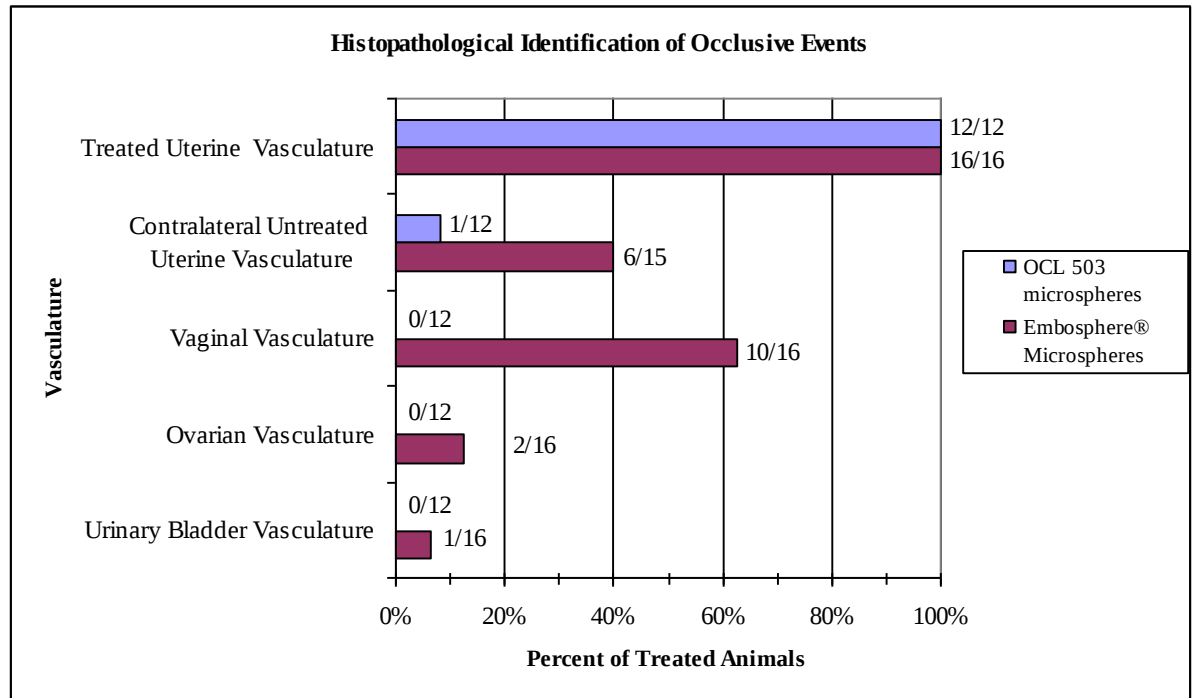
Panel b is a more distal section of the left uterine artery of sheep B183. Although the arterial wall is more irregular in organization and the lumen is smaller than in Panel 16a, the presence of red blood cells indicates that there was blood flow through this portion of the artery.

c)



Panel c is a more distal section yet of the left uterine artery of sheep B183. The arterial wall is even more irregular in organization than in Panel 16b and the artery was occluded in this micrograph with no evidence of red blood cells to indicate blood flow. Note that there are small arterioles (arrow) around the occluded artery that supplied blood to the surrounding tissue. Fibrous connective tissue was not observed in any OCL 503-treated artery twelve months after implantation.

Sheep 183 treated left uterine artery (x200)

Figure 17. Histopathological Identification of Occlusive Events

they were implanted. OCL 503 microspheres were also found in the untreated contralateral uterine vasculature (1/12 = 8%). Embosphere® Microspheres were detected in a larger percentage of treated sheep in the contralateral uterine vasculature (6/15 = 40%). In addition, Embosphere® Microspheres were identified in the vaginal (10/16 = 63%), ovarian (2/16 = 13%) and urinary bladder (1/16 = 6%) arteries. Results are only shown for the twelve OCL 503-treated sheep sacrificed by six months post implantation. The OCL 503 material was directly observed *in situ* through three months post implantation while treated blood vessels remained completely occluded six months after implantation. Data for the OCL 503-treated sheep sacrificed twelve months post implantation were excluded from this analysis since the treated arteries had either fully recanalized or were in the process of recanalizing.

It should be noted that a large number of Embosphere® Microspheres were found occluding the vaginal artery of sheep number Y184, while only a few were found within the uterine vasculature. This suggests that microspheres were originally implanted in the vaginal artery rather than the uterine artery in this animal.

A summary report for the gross post-mortem and histopathological findings for OCL 503 and Embosphere® Microspheres treatment groups is provided in Appendix W.

7. Discussion

This preclinical study examined the safety and efficacy of OCL 503 implanted in the uterine arteries of female Suffolk cross sheep. Embosphere® Microspheres, a commercially available artificial embolization device, was used as the control agent.

OCL 503 microspheres were suspended in saline and contrast medium (Appendix C1) and the resulting suspension of microspheres was delivered to the target vasculature through standard microcatheters. Any blockages of the microcatheters were easily cleared by simple flushing. Embosphere® Microspheres were resuspended per manufacturer's instructions and delivered to the target vasculature through standard microcatheters. Figure 11 shows the appearance of the microspheres pre-implantation.

An interventional radiologist implanted the OCL 503 and Embosphere® Microspheres artificial embolic devices in all thirty-two sheep in this study. The radiologist noted that the OCL 503 microspheres were more reliably and consistently suspended in saline and contrast medium than Embosphere® Microspheres and that the OCL 503 microspheres were very easy to administer.

It took significantly longer to surgically implant (time from insertion of the catheter to its removal) OCL 503 than Embosphere® Microspheres (18.4 ± 2.7 versus 9.6 ± 3.2 minutes; $p=0.0002$; Table 4). However, this is misleading as much of this difference is due to time taken suspending and testing OCL 503 in different total volumes (at the same 3:1 ratio of saline and contrast agent). Time was also taken to determine how to best administer OCL 503. This is supported by the determination that there was no statistically significant difference in the fluorographic time required to achieve effective stasis for either OCL 503 or Embosphere® Microspheres (8.9 ± 2.7 versus 8.1 ± 3.6 minutes; $p=0.32$; Table 5). Interestingly, there was no statistically significant difference in the number of vials of OCL 503 and the number of syringes of Embosphere® Microspheres required to achieve effective stasis (0.8 ± 0.3 versus 0.9 ± 0.3 vials; $p=0.31$; Table 6)

There were no indications of local or systemic toxicities. Changes observed in hematology (lymphocyte and neutrophil numbers [Figures 3 and 4]), clinical chemistry (BUN/Cr ratio, sorbital dehydrogenase-AO, ALT and AST [Figures 5 to 8]) and coagulation parameters (partial thromboplastin and prothrombin times [Figures 9 and 10]) were detected one day following surgery and generally resolved by seven days post surgery. Further, the changes were observed in both treatment groups, indicating that the changes were due to the anesthesia and stress of surgery rather than the implantation of either device. Fluctuations in laboratory parameters remained within the pre-treatment reference range established for the thirty-two sheep in this study. Fluctuations were generally not observed for the same parameter on consecutive sampling days.

Implanted OCL 503 microspheres underwent profound shape changes by one month post implantation (Figure 12a) as they were compressed and began to undergo biodegradation. Three months after implantation, the residual OCL 503 material was highly deformed and

compressed in the center of the artery (Figure 13a). There was no detectable OCL 503 material present by 6 months post implantation (Figure 14a).

Fibrous connective tissue formed around and between the OCL 503 microspheres. The connective tissue formed a matrix that helped hold the microspheres in place as they degraded (Figures 12a [one month post implantation] and 13a [three months post implantation]). The fibrous connective tissue replaced the inner luminal wall of the artery and maintained a complete occlusion of the treated artery despite the complete disappearance of the OCL 503 microspheres (Figure 14a [six months post implantation]).

Arteries treated with OCL 503 microspheres were either fully recanalized (Figure 15a) or were in the process of recanalizing (Figure 16) one year after implantation. The fibrous connective tissue observed earlier had completely resolved and the treated arteries either had normal morphology or were undergoing final tissue reorganization as they recanalized. In contrast, arteries treated with Embosphere® Microspheres were still fully occluded one year after implantation (Figure 15b).

OCL 503 microspheres were found in the lumen of the treated uterine artery and the branches of the artery as distal as the wall of the uterus along the mesenteric attachment (Figure 17). The OCL 503 microspheres were also found in the untreated contralateral uterine vasculature in one animal (1/12 treated sheep = 8%; Figure 17). The presence of OCL 503 microspheres in the untreated contralateral uterine vasculature most likely represents transit of the OCL 503 microspheres through an arterial anastomosis.

Embosphere® Microspheres had a similar qualitative distribution to OCL 503 in the treated uterine vasculature (Figure 17). Embosphere® Microspheres were detected in the contralateral uterine vasculature in 40% of treated animals (Figure 17). The high incidence of Embosphere® Microspheres in the untreated contralateral uterine vasculature supports the hypothesis of the embolic agents transiting through an anastomosis. Furthermore, Embosphere® Microspheres were detected in the vaginal (63%), ovarian (13%) and urinary bladder (6%) vasculatures (Figure 17). This suggests that Embosphere® Microspheres were more buoyant than the OCL 500 microspheres and migrated more readily to the other vasculatures.

Occlusin® 503 AED was found to be safe and effective as an embolotherapeutic agent as tested. Additional work is warranted with this device.

8. Conclusions

Primary Objective:

- (a) OCL 503 was safe and effective for use as an artificial embolization device as tested.

Secondary Objectives:

- (a) OCL 503 microspheres showed signs of particle remodelling one month after implantation. The remodelling was the result of the OCL 503 microspheres undergoing biodegradation and reabsorption. The OCL 503 microspheres continued to biodegrade with time. There was no evidence of residual OCL 503 material 6 months after implantation.
- (b) No significant systemic toxicity was observed in any treated animal. Transient changes in hematology, clinical chemistry and coagulation parameters were due to anesthesia and surgery rather than implantation of OCL 503. Fibrous connective tissue that formed around the implanted OCL 503 microspheres had completely resolved by one year after implantation.
- (c) Implantation of OCL 503 caused no detectable infarction to the uterus of any treated animal.
- (d) Uterine arteries treated with OCL 503 remained completely occluded six months after implantation. Recanalization of arteries in OCL 503-treated sheep was observed by twelve months after device implantation. The arteries of sheep treated with Embosphere® Microspheres did not recanalize.
- (e) OCL 503 was readily and consistently suspended to neutral buoyancy in contrast media and Sodium Chloride for Injection USP. The resuspended device was found to be easily administered through standard microcatheters.

9. References

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5. Laurent, A, Wassef, M, Namur, J, Martal, J, Labarre, D, and Pelage, J-P. 2009. Recanalization and particle exclusion after embolization of uterine arteries in sheep: a long-term study. *Fertil. Steril*. 91:884-892.

Appendix A. Study Timeline and Flow Chart

	DAYS											WEEKS				MONTHS											
	-14	-7	-1	1	2	3	4	5	6	7	2	3	4	2	3	4	5	6	7	8	9	10	11	12			
All Live Animals																											
Daily Observation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Physical Exam	X		X	X ¹	X					X	X		X	X	X			X						X			
Body Weight	X		X							X	X		X	X	X			X						X			
Vital Signs	X		X	X ¹	X					X	X		X	X	X			X						X			
Bleed & Lab Tests			X		X					X	X		X	X	X			X						X			
Sponge Insertion	X																										
Acclimatization		X																									
Sponge Removal			X																								
Folligon Injection			X																								
Angiography				X																							
Embolization				X																							
Excenel				X	X																						
Metacam				X	X																						
One Month Sacrifice																											
Gross Evaluation													X														
Necropsy													X														
Histology													X														
Three Month Sacrifice																											
Gross Evaluation														X													
Necropsy															X												
Histology															X												
Six Month Sacrifice																											
Gross Evaluation																		X									
Necropsy																		X									
Histology																		X									
Twelve Month Sacrifice																											
Gross Evaluation																								X			
Necropsy																								X			
Histology																								X			

¹One hour post-embolization

Appendix B. Individual Sheep Weights

Treatment	Sheep	Time Post Embolization								
Group	Number	D -1 ¹	W1	W2	M1	W7	M2	M3	M6	M12
OCL 503	Y26	53 ²	51	55	57	---	---	---	---	---
OCL 503	Y30	64	62	66	65	---	---	---	---	---
OCL 503	Y187	61	58	60	62	---	---	---	---	---
OCL 503	Y790	62	58	60	65	---	---	---	---	---
OCL 503	G57	44	43	46	46	---	52	60	---	---
OCL 503	G186	63	56	56	65	55 ⁴	---	---	---	---
OCL 503	G194	64	61	61	61	---	69	74	---	---
OCL 503	G261	64	62	64	62	---	65	72	---	---
OCL 503	R56	49	51	52	52	---	58	62	---	---
OCL 503	R179	57	58	53	51	---	54	57	64	---
OCL 503	R193	63	65	61	59	---	59	66	75	---
OCL 503	R198	69	65	70	70	---	74	73	84	---
OCL 503	B53	59	59	64	59	---	60	65	76	95
OCL 503	B182	63	63	64	62	---	64	67	75	93
OCL 503	B183	61	59	64	59	---	62	58	72	89
OCL 503	B346	67	72	70	67	---	71	73	82	102
OCL 503	Mean	60.2	58.9	60.4	60.1	55	62.5	66.1	75.4	94.8
	1 SD	6.6	6.7	6.6	6.3	---	6.9	6.3	6.6	5.4
Embosphere	Y28	64	64	67	70	---	---	---	---	---
Embosphere	Y33	57	58	60	61	---	---	---	---	---
Embosphere	Y110	59	59	60	64	---	---	---	---	---
Embosphere	Y184	54	54	52	60	---	---	---	---	---
Embosphere	G188	61	63	64	65	---	71	80	---	---
Embosphere	G196	50	53	52	59	---	53	59	---	---
Embosphere	G253	46	51	52	49	---	53	60	---	---
Embosphere	G410	64	66	70	67	---	71	77	---	---
Embosphere	R27	67	63	64	61	---	63	69	77	---
Embosphere	R32	55	60	54	60	---	57	60	69	---
Embosphere	R184	60	63	58	54	---	55	56	60	---
Embosphere	R199	65	68	63	62	---	68	72	74	---
Embosphere	B29	60	59	62	58	---	64	59	66	63
Embosphere	B34	70	70	74	70	---	72	69	88	100
Embosphere	B54	55	57	59	58	---	57	61	71	97
Embosphere	B197	65	64	67	65	---	62	67	77	90
Embosphere	Mean	59.5	60.8	61.1	61.4	---	62.2	65.8	72.8	87.5
	1 SD	6.4	5.4	6.6	5.5	---	7.2	7.8	8.4	16.9

¹D -1 = Day -1, Wn = Week n, Mn = Month n.

²Weight of the individual animals in kilograms on the specified time post embolization.

³Data Not Available

⁴Animal G186 was sacrificed 7 weeks post embolization due to a cervical lesion unrelated to treatment with OCL 503

Appendix C. Embolization Information

C1. Embolization Information for Sheep Implanted with OCL 503

C2. Embolization Information for Sheep Implanted with Embosphere® Microspheres

Appendix C1. Embolization Information for All Sheep Injected with OCL-503**(Device: OCL-503, Target Artery: Uterine)**

Animal ID	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Order of Surgery	9	5	6	4	12	15	10	11	17	32	31	27	20	25	26	22
Date of Surgery	25-Apr 2007	11-Apr 2007	11-Apr 2007	11-Apr 2007	2-May 2007	9-May 2007	25-Apr 2007	2-May 2007	9-May 2007	11-Jul 2007	11-Jul 2007	4-Jul 2007	27-Jun 2007	4-Jul 2007	4-Jul 2007	27-Jun 2007
Artery Embolized	Left	Left	Left	Left	Left	Left	Left	Left	Left	Left	Left	Left	Left	Right	Left	Left
Volume for Effective Stasis (mL)	60	55	21	57	38.5	27	17.25	54	14	39.5	28	39.5	24.2	59	31.5	37
Total Volume of Agent (mL)	60	60	40	80	56	40	51.25	56	40	40	40	40	40	70	40	40
Total Vials	1	0.92	0.53	0.71	0.69	0.68	0.34	0.96	0.35	1.23	0.70	0.99	0.61	1.3	0.79	0.93
Time to Embolize (min)	16	29	16	19	15	DNR ¹	10	18	DNR	26	16	26	16	22	10	18
Fluorographic time (min)	DNR	DNR	DNR	DNR	DNR	5.6	DNR	DNR	5.6	8.7	11.4	7.7	13	11	8	DNR
Hands On	12:30	11:20	13:59	9:27	11:18	9:34	14:10	9:30	13:15	2:57	1:45	14:57	11:00	11:39	13:45	14:50
Hands Off	13:10	12:00	14:56	10:21	11:53	10:12	15:08	10:39	13:53	3:39	2:38	15:39	12:01	12:31	14:20	15:37
Total Surgery Time (h)	0:40	0:40	0:57	0:54	0:35	0:38	0:58	1:09	0:38	0:42	0:53	0:42	1:01	0:52	0:35	0:47
Start Anesthesia	12:00	10:50	13:30	8:58	10:43	8:56	13:35	8:55	13:02	14:43	13:35	14:43	10:43	11:14	13:25	14:30
End Anesthesia	13:15	12:05	14:56	10:36	11:53	10:27	15:08	10:40	14:05	15:43	14:39	15:43	12:03	12:30	14:20	15:37
Total Procedure Time (h)	1:15	1:15	1:26	1:38	1:10	1:31	1:33	1:45	1:03	1:00	1:04	1:00	1:20	1:16	0:55	1:07

¹ Did Not Record

**Appendix C2. Embolization Information for All Sheep Injected with Embosphere® Microspheres
(Device: Embosphere® Microspheres, Target Artery: Uterine)**

Animal ID	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B346
Order of Surgery	2	7	3	1	8	16	14	13	28	18	29	30	23	24	19	22
Date of Surgery	4-Apr 2007	25-Apr 2007	4-Apr 2007	4-Apr 2007	25-Apr 2007	9-May 2007	2-May 2007	2-May 2007	11-Jul 2007	9-May 2007	11-Jul 2007	11-Jul 2007	4-Jul 2007	4-Jul 2007	27-Jun 2007	27-Jun 2007
Artery Embolized	Right	Left	Left	Left	Left	Left	Left	Left	Right	Right	Right	Left	Left	Left	Left	Left
Volume for Effective Stasis (mL)	13.5	13	14	5	13.5	18	19.5	28	21	24	18.5	31	15	17	4	37
Total Volume of Agent (mL)	14	20	17	12	16	22	22	28	24	44	20.5	40	19	18	14	40
Total Vials	0.96	0.65	0.82	0.42	0.84	0.82	0.89	1	0.88	1.09	0.90	1.55	0.79	0.94	0.29	0.93
Time to Embolize (min)	7	10	2	9	8	DNR ¹	12	15	10		9	13	10	10	13	18
Fluorographic time (min)	DNR	DNR	DNR	DNR	DNR	5.6	DNR	DNR	8	14.4	5.3	9.7	6	4.1	12	DNR
Hands On	11:45	9:30	13:25	9:10	10:57	11:04	14:44	12:53	9:13	15:07	10:25	11:45	9:20	10:35	9:40	14:50
Hands Off	13:05	10:25	14:16	10:59	11:32	11:47	15:25	13:42	9:59	15:51	11:07	12:33	10:10	11:08	10:29	15:37
Total Surgery Time (h)	1:20	0:55	0:51	1:49	0:35	0:43	0:41	0:49	0:46	0:44	0:42	0:48	0:50	0:33	0:49	0:47
Start Anesthesia	11:06	8:55	13:13	8:55	10:35	10:50	14:08	12:33	8:55	14:40	10:05	11:10	8:45	10:16	9:10	14:30
End Anesthesia	13:05	9:25	14:10	11:05	11:30	11:50	15:32	13:54	9:59	16:01	11:08	12:35	10:10	11:09	10:30	15:37
Total Procedure Time (h)	1:59	0:30	0:57	2:10	0:55	1:00	1:24	1:21	1:04	1:21	1:03	1:25	1:25	0:53	1:20	1:07

¹ Did Not Record

Appendix D. Clinical Laboratory Data Standard Reference Ranges

	Units	Reference Range (Central Laboratory)	Reference Range (Internal Study, n = 32)
Hematology			
White Cell Count	x10E9/L	1.8-9.2	4.9 - 12.8
Red Cell Count	x10E12/L	7.8 - 11.9	8.1 - 13.8
Hemoglobin	g/L	92 - 140	95 - 156
Hematocrit	L/L	0.3 - 0.4	0.3 - 0.4
Mean Corp Vol	fl	28 - 42	25 - 34
Mean Corp Hemoglobin	pg	9.5 - 14 .0	9.7 - 12.5
Mean Corp Hemoglobin Conc	g/L	305 - 364	351 - 396
RDW	%CV	19.0 - 29.0	17 - 28
Platelet CNT	x10E9/L	300 - 780	64 – 1,478
Mean Platelet Volume	fl	4 - 8	
Differential Cell Count			
% Neutrophils	%	Reported Value	14 - 63
% Lymphocytes	%	Reported Value	31 - 78
% Monocytes	%	Reported Value	1 - 18
% Eosinophils	%	Reported Value	0 - 10
% Basophils	%	Reported Value	1 - 2
Absolute Differential Values			
Neutrophils	x10E9/L	0.8 - 3.6	1.1 - 7.3
Lymphocytes	x10E9/L	1.0 - 4.5	2.9 - 8.6
Monocytes	x10E9/L	0.0 - 0.8	0.1 - 2.3
Eosinophils	x10E9/L	0.0 - 1.1	0 - 0.8
Basophils	x10E9/L	0.0 - 0.3	0.1 - 0.2
Chemistry			
Glucose	mmol/L	2.0 - 6.1	2.9 - 5
Blood Urea Nitrogen	mmol/L	3.0 - 14.3	2.1 - 7.3
Creatinine	µmol/L	72 - 155	61 - 106
BUN/Cr Ratio	Ratio	Reported Value	6 - 26
Sodium	mmol/L	134 - 153	140 - 151
Potassium	mmol/L	3.7 - 6.0	3.7 - 6.3
Na/K Ratio	Ratio	Reported Value	23 - 33
Chloride	mmol/L	100 - 113	106 - 119
Carbon Dioxide	mmol/L	15 - 34	20 - 29
Anion Gap	mEq/L	8 - 21	9 - 23
Calcium	mmol/L	2.2 - 3.0	2.2 - 2.8
Phosphorus	mmol/L	1.0 - 2.6	1.6 - 2.7
Total Protein	g/L	58 - 83	63 - 81
Albumin	g/L	30 - 41	26 - 34
Globulin	g/L	20 - 49	33 - 50
A/G Ratio	Ratio	0.4 - 1.3	0.5 - 0.9
Total Bilirubin	µmol/L	0 - 11	3 - 10
Alkaline Phosphatase	IU/L	30 - 340	151 - 333
ALT (Sgpt)	IU/L	Reported Value	21 - 41
Gamma gt	IU/L	25 - 100	16 - 104
Creatine Phosphokinase	IU/L	35 - 490	49 - 177
Calculated Osmolality	mmol/kg	272 - 310	280 - 297
AST (Sgot)	IU/L	70 - 210	67 - 187
Sorbital Dehydrogenase-AO	IU/L	6 - 60	15 - 155
Uric Acid	µmol/L	Reported Value	0 - 8

Appendix D. Clinical Laboratory Data Standard Reference Ranges, cont.

	Units	Reference Range (Central Laboratory)	Reference Range (Internal Study, n = 32)
Morphology and Coagulation Parameters			
Platelets	Reported Value	Adequate	Reported Value
RBC Morph	Reported Value	Normal	Reported Value
Aniso	Reported Value	0 – 4+	0 – 2+
Poik	Reported Value	0 – 4+	0 – 1+
Fibrinogen Degradation Products	Observation	Negative	Negative
Fibrinogen Semi Quantitative	g/L	1 - 4	1 - 4
Part. Thromboplastin Time	second	28 - 55	28 - 100
Prothrombin Time	second	13 - 25	20 - 100

Appendix E. Clinical Laboratory Data for Individual Sheep Implanted with OCL 503

- E1. Clinical Laboratory Data for Sheep Y26
- E2. Clinical Laboratory Data for Sheep Y30
- E3. Clinical Laboratory Data for Sheep Y187
- E4. Clinical Laboratory Data for Sheep Y790
- E5. Clinical Laboratory Data for Sheep G57
- E6. Clinical Laboratory Data for Sheep G186
- E7. Clinical Laboratory Data for Sheep G194
- E8. Clinical Laboratory Data for Sheep G261
- E9. Clinical Laboratory Data for Sheep R56
- E10. Clinical Laboratory Data for Sheep R179
- E11. Clinical Laboratory Data for Sheep R193
- E12. Clinical Laboratory Data for Sheep R198
- E13. Clinical Laboratory Data for Sheep B53
- E14. Clinical Laboratory Data for Sheep B182
- E15. Clinical Laboratory Data for Sheep B183
- E16. Clinical Laboratory Data for Sheep B346

Appendix E1. Clinical Laboratory Data for Sheep Y26 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	11.61¹	10.8	7.71	8.04	7.24
Red Cell Count	13.1	10.5	11.4	11.7	10.4
Hemoglobin	156	128	138	138	131
Hematocrit	0.445	0.358	0.385	0.395	0.36
Mean Corp Vol	34.1	34	33.8	33.7	34.6
Mean Corp Hemoglobin	12	12.2	12.1	11.8	12.6
Mean Corp Hemoglobin Conc	351	358	359	350	364
RDW	28	23.3	26.1	24.3	25.2
Platelet CNT	463	435	753	523	485
Mean Platelet Volume	NR ²	NR	8.47	NR	NR
Differential Cell Count					
% Neutrophils	63	45	24	27	29
% Lymphocytes	31	50	73	69	63
% Monocytes	4	4	3	3	6
% Eosinophils	2	1	0	0	1
% Basophils	NR	1	0	1	0
Absolute Differential Values					
Neutrophils	7.32	4.89	1.82	2.17	2.13
Lymphocytes	3.6	5.39	5.6	5.58	4.57
Monocytes	0.46	0.392	0.242	0.225	0.417
Eosinophils	0.23	0.057	0.009	0.016	0.105
Basophils	NR	0.057	0.029	0.042	0.01
Chemistry					
Glucose	4.5	4.8	3.4	3.5	3.4
Blood Urea Nitrogen	2.1	2.5	5.1	8.1	8.2
Creatinine	92.3	82.4	82	80.9	94.8
BUN/Cr Ratio	6	8	16	25	22
Sodium	147	150	150	142	144
Potassium	6.3	5	5.2	5.2	4.2
Na/K Ratio	23	30	29	27	34
Chloride	110	114	114	106	111
Carbon Dioxide	28.2	25.9	31.2	29.4	22.7
Anion Gap	15	15	10	12	15
Calcium	2.64	2.51	2.61	2.54	2.49
Phosphorus	2.51	2.01	2.11	2.11	1.62
Total Protein	74	77	73	72	71
Albumin	29.24	32.15	28.18	29.29	31.39
Globulin	45	45	45	43	40
A/G Ratio	0.7	0.7	0.6	0.7	0.8
Total Bilirubin	6	4	5	6	5
Alkaline Phosphatase	206	194	141	202	170
ALT (Sgpt)	31	40	28	32	34
Gamma gt	76	86	78	83	64
Creatine Phosphokinase	84	122	193	89	1,249
Calculated Osmolality	292	296	297	285	287
AST (Sgot)	90	127	85	81	97
Sorbital Dehydrogenase-AO	31.1	210.1	27.9	31.2	20.9
Uric Acid	0	9	5	8	2
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07

Appendix E1. Clinical Laboratory Data for Sheep Y26 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Adequate	Increased	Adequate	Increased
RBC Morph	See Below	See Below	See Below	See Below	See Below
Aniso	NR	1+	NR	NR	NR
Poik	1+	1+	1+	1+	1+
Fibrinogen Degradation Products	Negative	Positive	Negative	Negative	Negative
Fibrinogen Semi Quantitative	4	4	4	1	2
Part. Thromboplastin Time	37.8	>60	48	35.1	42.2
Prothrombin Time	22.2	>60	32.3	23.7	23.7
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E2.Clinical Laboratory Data for Sheep Y30 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	6.41	6.62	6.18	6.66	7.25
Red Cell Count	9.87	11.4	12.6¹	11.8	12.3
Hemoglobin	109	120	131	126	133
Hematocrit	0.282	0.32	0.356	0.338	0.359
Mean Corp Vol	28.6	28	28.2	28.6	29.1
Mean Corp Hemoglobin	11	10.5	10.4	10.7	10.8
Mean Corp Hemoglobin Conc	386	373	369	373	372
RDW	21.6	22.3	22.9	22.3	23.2
Platelet CNT	357	587	363	394	445
Mean Platelet Volume	NR ²	NR	NR	NR	NR
Differential Cell Count					
% Neutrophils	38	58	31	23	25
% Lymphocytes	56	36	59	72	71
% Monocytes	6	2	8	4	2
% Eosinophils	NR	4	2	1	1
% Basophils	NR	NR	1	NR	1
Absolute Differential Values					
Neutrophils	2.44	3.85	1.91	1.52	1.79
Lymphocytes	3.59	2.38	3.62	4.8	5.18
Monocytes	0.38	0.13	0.473	0.27	0.153
Eosinophils	NR	0.26	0.119	0.07	0.06
Basophils	NR	NR	0.053	NR	0.062
Chemistry					
Glucose	5.1	4.5	4	4	3.5
Blood Urea Nitrogen	5.4	2.2	7	5.9	8
Creatinine	100	93.4	85.5	85.5	89.8
BUN/Cr Ratio	14	6	21	17	22
Sodium	145	150	154	150	145
Potassium	4.5	4.9	5.5	5.5	5.7
Na/K Ratio	32	31	28	27	25
Chloride	109	115	117	113	108
Carbon Dioxide	23.7	28.8	25.6	30.5	29.2
Anion Gap	17	11	17	12	14
Calcium	2.47	2.45	2.62	2.57	2.55
Phosphorus	2.63	2.48	2.67	2.26	2.65
Total Protein	63	69	71	71	68
Albumin	27.69	30.71	29.92	29.9	30.54
Globulin	35	38	41	41	37
A/G Ratio	0.8	0.8	0.7	0.7	0.8
Total Bilirubin	6	5	4	5	5
Alkaline Phosphatase	219	228	190	207	223
ALT (Sgpt)	40	42	30	29	33
Gamma gt	20	22	20	22	24
Creatine Phosphokinase	177	83	82	76	80
Calculated Osmolality	289	295	308	299	292
AST (Sgot)	146	138	82	98	90
Sorbital Dehydrogenase-AO	23.2	19.5	17.2	24.8	17.5
Uric Acid	0	4	0	9	5
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

Appendix E2.Clinical Laboratory Data for Sheep Y30 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Adequate	Adequate	Increased	Adequate	Adequate
RBC Morph	See Below	See Below	Normal	See Below	Normal
Aniso	1+	1+	NR	1+	NR
Poik	1+	NR	NR	NR	NR
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	3	3	2	2
Part. Thromboplastin Time	32.5	33.1	68	25.5	37
Prothrombin Time	23	29.3	34	21.5	25.8
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E3.Clinical Laboratory Data for Sheep Y187 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	9.33¹	7.08	7.89	8.54	9.91
Red Cell Count	10.7	10.8	11.7	10.6	11.1
Hemoglobin	127	130	140	124	131
Hematocrit	0.341	0.344	0.375	0.342	0.355
Mean Corp Vol	31.9	31.7	31.9	32.2	31.9
Mean Corp Hemoglobin	11.9	12	12	11.7	11.8
Mean Corp Hemoglobin Conc	373	378	375	363	370
RDW	21.8	23.7	22	21.5	23
Platelet CNT	135	144	289	122	142
Mean Platelet Volume	NR ²	NR	NR	NR	NR
Differential Cell Count					
% Neutrophils	33	38	37	19	20
% Lymphocytes	56	58	53	71	76
% Monocytes	7	2	4	8	3
% Eosinophils	4	1	6	2	1
% Basophils	NR	1	NR	1	NR
Absolute Differential Values					
Neutrophils	3.09	2.69	2.92	1.58	1.98
Lymphocytes	5.22	4.11	4.18	6.08	7.53
Monocytes	0.65	0.14	0.32	0.656	0.3
Eosinophils	0.37	0.07	0.47	0.16	0.1
Basophils	NR	0.07	NR	0.058	NR
Chemistry					
Glucose	4.5	4.9	3.8	4.1	3.4
Blood Urea Nitrogen	6.2	2.4	6.6	5.6	8.9
Creatinine	89.2	81.1	81.7	83.3	81.8
BUN/Cr Ratio	17	7	20	17	27
Sodium	147	150	152	151	143
Potassium	4.3	4.4	6.1	5.8	5.2
Na/K Ratio	34	34	25	26	28
Chloride	114	114	115	113	111
Carbon Dioxide	25.7	25.5	28.2	31.1	25
Anion Gap	12	15	15	13	12
Calcium	2.44	2.53	2.42	2.6	2.38
Phosphorus	2.34	2.14	2.5	2.11	2.43
Total Protein	68	73	71	72	72
Albumin	29.63	32.19	30.14	29.57	31.81
Globulin	38	41	41	42	40
A/G Ratio	0.8	0.8	0.7	0.7	0.8
Total Bilirubin	7	6	5	5	5
Alkaline Phosphatase	275	275	249	214	253
ALT (Sgpt)	24	26	22	25	26
Gamma gt	25	30	29	36	41
Creatine Phosphokinase	116	91	103	97	93
Calculated Osmolality	292	294	304	301	288
AST (Sgot)	103	113	107	101	108
Sorbital Dehydrogenase-AO	25	39.2	30.5	32.1	21.2
Uric Acid	0	1	0	3	12
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

Appendix E3.Clinical Laboratory Data for Sheep Y187 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	NR	1+	NR
Poik	1+	1+	1+	2+	2+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	2	2	2	1
Part. Thromboplastin Time	56.7	39.8	41.7	34.5	36
Prothrombin Time	22.5	25.2	28.7	24.8	21.6
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E4.Clinical Laboratory Data for Sheep Y790 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	8.78	9.44¹	8.11	10.5	9.41
Red Cell Count	9.02	8.81	10.3	9.98	10.9
Hemoglobin	113	109	126	123	131
Hematocrit	0.301	0.293	0.342	0.333	0.359
Mean Corp Vol	33.4	33.2	33.1	33.4	32.9
Mean Corp Hemoglobin	12.5	12.3	12.2	12.4	12
Mean Corp Hemoglobin Conc	374	371	368	370	366
RDW	21.9	22.6	23.3	22.6	21.6
Platelet CNT	551	558	652	188	107
Mean Platelet Volume	9.75	11.1	NR ²	NR	NR
Differential Cell Count					
% Neutrophils	30	56	23	29	28
% Lymphocytes	60	40	56	61	66
% Monocytes	2	2	16	3	2
% Eosinophils	8	2	4	6	3
% Basophils	NR	NR	1	1	1
Absolute Differential Values					
Neutrophils	2.63	5.28	1.89	3.07	2.64
Lymphocytes	5.27	3.78	4.52	6.45	6.21
Monocytes	0.18	0.19	1.29	0.265	0.19
Eosinophils	0.7	0.19	0.299	0.617	0.28
Basophils	NR	NR	0.102	0.089	0.09
Chemistry					
Glucose	3.8	4.2	3.5	3.7	3.3
Blood Urea Nitrogen	5.4	1.5	5.7	5.3	8.6
Creatinine	77.4	80.7	69.4	69.2	85.1
BUN/Cr Ratio	18	5	21	19	25
Sodium	148	151	149	148	145
Potassium	4.9	4.7	5.1	4.9	5.5
Na/K Ratio	30	32	29	30	26
Chloride	113	116	111	111	108
Carbon Dioxide	26	29.1	32.1	27	27.7
Anion Gap	14	11	11	15	15
Calcium	2.69	2.59	2.75	2.69	2.65
Phosphorus	2.07	1.7	2.24	1.83	2.27
Total Protein	68	69	70	75	71
Albumin	28.87	29.96	29.16	30.89	31.32
Globulin	39	39	41	44	40
A/G Ratio	0.7	0.8	0.7	0.7	0.8
Total Bilirubin	8	5	6	6	6
Alkaline Phosphatase	307	307	245	312	374
ALT (Sgpt)	27	42	23	31	31
Gamma gt	104	103	96	110	105
Creatine Phosphokinase	83	97	111	63	97
Calculated Osmolality	294	295	296	293	292
AST (Sgot)	141	171	102	145	168
Sorbital Dehydrogenase-AO	53.7	267.2	38.7	101.8	46.8
Uric Acid	0	2	0	2	3
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

Appendix E4.Clinical Laboratory Data for Sheep Y790 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Adequate	Increased	Adequate	Adequate
RBC Morph	See below	See below	See below	See below	See Below
Aniso	1+	1+	NR	1+	NR
Poik	1+	NR	2+	2+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	2	2	2	1
Part. Thromboplastin Time	31.8	38	48.3	33.1	31.4
Prothrombin Time	23	26.5	28.8	22.7	22.4
Date of Bleed	10-Apr-07	12-Apr-07	18-Apr-07	25-Apr-07	9-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E5. Clinical Laboratory Data for Sheep G57 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	12.046¹	11.5	10.6	13.5	12.5	9.19	12.21
Red Cell Count	10.9	10.2	10	10.7	10.3	9.78	10.7
Hemoglobin	126	120	112	124	117	112	123
Hematocrit	0.334	0.318	0.313	0.324	0.322	0.306	0.33
Mean Corp Vol	30.6	31.1	31.2	30.3	31.4	31.3	31
Mean Corp Hemoglobin	11.5	11.8	11.2	11.6	11.4	11.4	11.6
Mean Corp Hemoglobin Conc	376	378	359	383	362	365	373
RDW	21	23.8	22.5	22.5	23.5	22.4	20.3
Platelet CNT	410	399	407	446	291	61.2	364
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR
Differential Cell Count							
% Neutrophils	33	42	22	26	28	25	33
% Lymphocytes	47	51	73	71	69	68	65
% Monocytes	18	5	4	3	2	5	2
% Eosinophils	0	2	1	NR	1	2	NR
% Basophils	2	NR	NR	NR	NR	NR	NR
Absolute Differential Values							
Neutrophils	4.03	4.82	2.33	3.5	3.49	2.4	4.03
Lymphocytes	5.62	5.87	7.74	9.59	8.63	6.25	7.94
Monocytes	2.18	0.58	0.42	0.41	0.25	0.46	0.24
Eosinophils	0.002	0.23	0.11	NR	0.13	0.18	NR
Basophils	0.214	NR	NR	NR	NR	NR	NR
Chemistry							
Glucose	4	4.4	3.6	3.5	3.7	3.8	3.1
Blood Urea Nitrogen	3.8	4.3	4.6	6.7	8	9.5	8.8
Creatinine	84.3	76.6	69.4	91.2	74.6	71.8	77.9
BUN/Cr Ratio	11	14	17	18	27	33	28
Sodium	149	149	145	147	145	144	141
Potassium	4.9	4.8	5.2	5.2	5	5.1	4.8
Na/K Ratio	30	31	28	28	29	28	29
Chloride	115	114	113	113	111	109	105
Carbon Dioxide	25.8	25	27.9	25.8	26.8	26.5	28
Anion Gap	13	15	9	13	12	14	13
Calcium	2.75	2.68	2.53	2.75	2.6	2.6	2.65
Phosphorus	2.28	2.35	2.56	2.39	2.14	2.17	2.1
Total Protein	69	72	66	71	68	68	71
Albumin	29.49	29.58	26.25	29.15	29.78	30.63	31.13
Globulin	40	42	40	42	38	37	40
A/G Ratio	0.7	0.7	0.7	0.7	0.8	0.8	0.8
Total Bilirubin	7	7	5	6	6	5	5
Alkaline Phosphatase	264	239	144	188	260	270	222
ALT (Sgpt)	33	70	31	30	26	29	27
Gamma gt	52	54	53	58	45	54	54
Creatine Phosphokinase	127	197	136	163	182	134	447
Calculated Osmolality	294	295	288	293	291	291	283
AST (Sgot)	92	152	87	95	93	103	115
Sorbital Dehydrogenase-AO	14.6	245.3	12	14.6	20.7	25.3	24
Uric Acid	3	3	4	5	0	0	0
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

Appendix E5. Clinical Laboratory Data for Sheep G57 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	Normal	See Below
Aniso	NR	NR	NR	1+	1+	NR	2+
Poik	NR	1+	1+	NR	1+	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative
Fibrinogen Semi Quantitative	2	1	1	1	2	1	2
Part. Thromboplastin Time	34.2	>60	38.9	33.6	47.8	34.5	69.5
Prothrombin Time	24.3	30.7	26	29.3	38.4	32.8	38.3
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E6. Clinical Laboratory Data for Sheep G186 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	7 W
Hematology						
White Cell Count	9.97¹	12.005	11.5	7.17	10.2	6.93
Red Cell Count	9.95	9.25	9.27	9.66	9.47	10.4
Hemoglobin	108	98.6	101	107	99.8	107
Hematocrit	0.286	0.261	0.263	0.275	0.265	0.276
Mean Corp Vol	28.7	28.2	28.4	28.5	27.9	26.5
Mean Corp Hemoglobin	10.8	10.7	10.8	11.1	10.5	10.3
Mean Corp Hemoglobin Conc	378	378	382	389	377	389
RDW	23	22.7	22.3	25.1	23.6	26.5
Platelet CNT	473	332	1,075	1,014	1,403	1,242
Mean Platelet Volume	NR ²	NR	9.64	NR	NR	NR
Differential Cell Count						
% Neutrophils	45	60	43	22	61	38
% Lymphocytes	41	21	54	56	24	51
% Monocytes	7	15	3	21	14	9
% Eosinophils	7	0	NR	0	0	2
% Basophils	NR	2	NR	1	1	NR
Absolute Differential Values						
Neutrophils	4.48	7.17	4.94	1.61	6.2	2.64
Lymphocytes	4.09	2.47	6.21	4	2.46	3.53
Monocytes	0.7	1.83	0.35	1.5	1.39	0.62
Eosinophils	0.7	0.03	NR	0.008	0.002	0.14
Basophils	NR	0.235	NR	0.046	0.1	NR
Chemistry						
Glucose	3.8	4.1	4.2	3.9	3.7	4
Blood Urea Nitrogen	7	4	4.7	4.3	4.8	5.1
Creatinine	68.2	70.4	65.9	73.3	82.5	80.9
BUN/Cr Ratio	26	14	18	15	15	16
Sodium	143	144	146	145	145	143
Potassium	5.1	4.1	4.6	5.6	4.5	4.8
Na/K Ratio	28	35	32	26	32	30
Chloride	111	116	111	111	112	111
Carbon Dioxide	25.3	21.9	29.6	26.1	24.1	23.7
Anion Gap	12	10	10	14	13	13
Calcium	2.62	2.46	2.6	2.6	2.55	2.35
Phosphorus	2.55	1.96	2.16	2.38	2.65	2.05
Total Protein	70	79	83	81	104	105
Albumin	30.24	29.86	26.59	26.74	26.94	24.74
Globulin	40	49	56	54	77	80
A/G Ratio	0.8	0.6	0.5	0.5	0.3	0.3
Total Bilirubin	6	3	5	7	8	7
Alkaline Phosphatase	233	98	53	139	74	72
ALT (Sgpt)	33	29	20	22	23	19
Gamma gt	19	17	74	73	87	78
Creatine Phosphokinase	108	55	66	184	332	269
Calculated Osmolality	286	284	289	288	287	284
AST (Sgot)	88	86	68	60	92	50
Sorbital Dehydrogenase-AO	20.5	42.3	8.4	11.9	8.1	10
Uric Acid	8	12	8	10	0	2
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	25-Jun-07

Appendix E6. Clinical Laboratory Data for Sheep G186 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	7 W
Morphology and Coagulation Parameters						
Platelets	Increased	Adequate	Increased	Increased	Increased	Increased
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	NR	1+	NR	NR	NR
Poik	1+	1+	NR	1+	1+	1+
Fibrinogen Degradation Products	Negative	Positive @ 1:2	Positive @ 1:2	Negative	Negative	Positive
Fibrinogen Semi Quantitative	1	6	8	2	4	5
Part. Thromboplastin Time	40.8	>60	34	35.7	75.7	1.6
Prothrombin Time	22.6	30.5	36.6	25.2	38.8	29
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	25-Jun-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E7. Clinical Laboratory Data for Sheep G194 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	7.92	7.45	7.98	6.75	7.49	5.87	7.26
Red Cell Count	10.8	10.2	9.93	10	10.5	11.3	11.3
Hemoglobin	131	124	121	121	128	136	139
Hematocrit	0.355	0.34	0.328	0.336	0.352	0.384	0.38
Mean Corp Vol	32.9	33.4	33.1	33.6	33.7	33.9	33.6
Mean Corp Hemoglobin	12.1	12.1	12.2	12.1	12.3	12	12.3
Mean Corp Hemoglobin Conc	369¹	363	370	360	364	353	366
RDW	23.7	23.6	21.3	24.2	22.4	23	22.9
Platelet CNT	522	622	563	345	512	566	506
Mean Platelet Volume	NR ²	NR	8.49	NR	NR	8.21	NR
Differential Cell Count							
% Neutrophils	34	42	32	13	23	39	36
% Lymphocytes	52	50	57	78	69	53	46
% Monocytes	10	5	6	4	3	1	3
% Eosinophils	4	3	3	5	4	7	14
% Basophils	1	NR	1	NR	0	NR	1
Absolute Differential Values							
Neutrophils	2.67	3.13	2.57	0.87	1.71	2.29	2.61
Lymphocytes	4.08	3.73	4.58	5.27	5.18	3.11	3.34
Monocytes	0.78	0.37	0.505	0.27	0.262	0.06	0.22
Eosinophils	0.297	0.22	0.258	0.34	0.315	0.41	1.02
Basophils	0.086	NR	0.06	NR	0.021	NR	0.07
Chemistry							
Glucose	3.5	4.2	3.2	3.4	4	2.9	2.8
Blood Urea Nitrogen	2.6	5	6.7	8.6	10	9.1	9.4
Creatinine	85.6	95.5	90	88.9	79.8	82.1	95.9
BUN/Cr Ratio	8	13	19	24	31	28	25
Sodium	147	151	150	144	146	145	148
Potassium	4.5	4.6	5.1	5.5	5.2	5.1	4.4
Na/K Ratio	33	33	29	26	28	28	34
Chloride	108	116	113	107	111	110	110
Carbon Dioxide	28.9	23.1	31.6	32.4	25.6	22.2	26.7
Anion Gap	15	17	11	10	15	18	16
Calcium	2.59	2.66	2.56	2.55	2.7	2.61	2.68
Phosphorus	2.71	1.79	2.27	2.32	1.79	2.17	1.96
Total Protein	70	80	68	69	71	74	78
Albumin	31.27	36.5	30.43	32.12	33.96	34.23	33.96
Globulin	39	44	38	37	37	40	44
A/G Ratio	0.8	0.8	0.8	0.9	0.9	0.9	0.8
Total Bilirubin	6	7	5	6	5	4	4
Alkaline Phosphatase	218	240	186	241	265	284	213
ALT (Sgpt)	30	45	28	30	30	37	33
Gamma gt	25	27	21	30	23	66	58
Creatine Phosphokinase	83	891	68	85	121	1,525	117
Calculated Osmolality	288	299	298	290	295	291	296
AST (Sgot)	106	182	90	107	122	152	170
Sorbital Dehydrogenase-AO	25.1	255.6	23	54.3	32.3	38.5	38.6
Uric Acid	5	1	5	16	8	0	13
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07	19-Jun-07	18-Jul-07

Appendix E7. Clinical Laboratory Data for Sheep G194 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Increased	Increased	Increased	Adequate	Increased	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	NR	NR	NR	1+	1+	1+
Poik	NR	1+	1+	2+	2+	1+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Positive	Negative
Fibrinogen Semi Quantitative	2	3	3	2	1	1	1
Part. Thromboplastin Time	35.3	52.6	51	NR	43.4	76.8	>60
Prothrombin Time	20.3	24.5	26.7	NR	21.7	39.1	>60
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07	19-Jun-07	18-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E8. Clinical Laboratory Data for Sheep G261 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	9.06	7.66	8.33	10.4¹	9.32	8.47	8.08
Red Cell Count	10.4	8.85	8.82	10.4	10.2	9.53	9.93
Hemoglobin	125	108	105	125	121	113	119
Hematocrit	0.338	0.287	0.288	0.335	0.329	0.304	0.317
Mean Corp Vol	32.6	32.4	32.6	32.3	32.4	31.9	31.9
Mean Corp Hemoglobin	12.1	12.2	11.9	12	11.9	118	12
Mean Corp Hemoglobin Conc	370	377	366	372	369	370	375
RDW	24.4	21.9	21.5	21	22.8	20.4	21.3
Platelet CNT	542	548	537	649	636	452	376
Mean Platelet Volume	NR ²	NR	NR	NR	9.9	8.67	NR
Differential Cell Count							
% Neutrophils	32	30	20	28	37	32	25
% Lymphocytes	52	61	76	62	60	63	65
% Monocytes	12	4	2	4	3	2	1
% Eosinophils	1	5	2	6	NR	3	9
% Basophils	2	NR	NR	NR	NR	NR	NR
Absolute Differential Values							
Neutrophils	2.93	2.3	1.66	2.91	3.45	2.71	2.02
Lymphocytes	4.69	4.67	6.33	6.45	5.59	5.34	5.25
Monocytes	1.11	0.31	0.17	0.42	0.28	0.17	0.08
Eosinophils	0.135	0.38	0.17	0.62	NR	0.25	0.73
Basophils	0.187	NR	NR	NR	NR	NR	NR
Chemistry							
Glucose	3.8	4.2	3.8	3.8	3.6	3.6	3.1
Blood Urea Nitrogen	4.4	2.7	6.6	6.6	7.5	8.2	7.8
Creatinine	81.7	73	66.4	88.6	84.8	69.8	87
BUN/Cr Ratio	14	9	25	19	22	30	23
Sodium	146	147	149	151	146	146	145
Potassium	4.8	4.4	5	4.6	4.5	4.6	4.8
Na/K Ratio	30	33	30	33	32	32	30
Chloride	111	116	114	114	110	111	108
Carbon Dioxide	27.1	27.3	29.1	25.6	25.8	26.8	27.6
Anion Gap	13	8	11	16	15	13	14
Calcium	2.7	2.55	2.57	2.67	2.56	2.58	2.73
Phosphorus	2.34	2.64	2.68	2.8	2.53	2.55	2.21
Total Protein	75	75	67	79	72	68	74
Albumin	34.15	33.11	30.64	35.53	33.8	32.2	34.26
Globulin	41	42	36	43	38	36	40
A/G Ratio	0.8	0.8	0.8	0.8	0.9	0.9	0.9
Total Bilirubin	7	6	6	6	6	5	5
Alkaline Phosphatase	258	255	276	254	300	252	239
ALT (Sgpt)	26	27	24	23	24	26	25
Gamma gt	44	33	39	37	27	26	35
Creatine Phosphokinase	62	106	89	60	94	84	81
Calculated Osmolality	289	289	297	300	291	292	290
AST (Sgot)	76	82	73	71	96	91	91
Sorbital Dehydrogenase-AO	17	22.2	15.8	1.4	26.2	24.8	20.1
Uric Acid	5	12	8	4	0	3	0
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

Appendix E8. Clinical Laboratory Data for Sheep G261 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Increased	Increased	Adequate	Increased	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	Normal	See Below
Aniso	NR	2+	NR	1+	1+	NR	1+
Poik	NR	NR	1+	NR	1+	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Positive	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	3	2	1	3	1	1	1
Part. Thromboplastin Time	39.7	>60	36.8	54.6	58.2	89.4	66
Prothrombin Time	24.7	33.8	24.3	40	55.5	75.5	37.1
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E9. Clinical Laboratory Data for Sheep R56 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	8.22	8.96	13.4¹	8.58	6.1	5.55	5.24
Red Cell Count	9.8	9.4	9.59	9.44	9.71	8.82	9.96
Hemoglobin	105	100	101	101	114	103	114
Hematocrit	0.282	0.269	0.271	0.27	0.293	0.292	0.322
Mean Corp Vol	28.8	28.7	28.2	28.6	30.2	33.1	32.4
Mean Corp Hemoglobin	10.8	10.7	10.5	10.7	11.7	11.7	11.5
Mean Corp Hemoglobin Conc	374	373	373	372	388	354	355
RDW	20.7	21.7	22.3	21	22	22.7	21.8
Platelet CNT	175	154	371	315	115	318	203
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR
Differential Cell Count							
% Neutrophils	40	32	46	29	34	17	29
% Lymphocytes	53	58	46	64	59	77	63
% Monocytes	4	5	5	6	5	2	5
% Eosinophils	3	4	3	0	2	4	3
% Basophils	NR	1	NR	1	NR	NR	NR
Absolute Differential Values							
Neutrophils	3.28	2.86	6.17	2.5	2.07	0.95	1.52
Lymphocytes	4.36	5.2	6.16	5.5	3.6	4.27	3.3
Monocytes	0.33	0.45	0.67	0.507	0.31	0.11	0.26
Eosinophils	0.25	0.36	0.4	0.008	0.12	0.22	0.16
Basophils	NR	0.09	NR	0.057	NR	NR	NR
Chemistry							
Glucose	4	4.6	3.8	4.2	0.5	3.4	0.8
Blood Urea Nitrogen	5.3	4.3	5.5	4.9	7.7	7.5	8.3
Creatinine	78.5	77.2	80.9	77.7	76.5	69.4	83.7
BUN/Cr Ratio	17	14	17	16	25	27	25
Sodium	150	149	146	143	146	144	142
Potassium	5	4.5	4.6	4.8	5.8	4.9	4.8
Na/K Ratio	30	33	32	30	25	29	30
Chloride	115	116	110	111	108	110	107
Carbon Dioxide	28.3	24.6	30.6	25.2	23.5	24.3	21.7
Anion Gap	12	13	10	12	20	15	18
Calcium	2.69	2.57	2.51	2.65	2.74	2.68	2.66
Phosphorus	3.13	2.5	2.06	2.16	2.61	2.08	1.8
Total Protein	69	71	69	65	75	71	70
Albumin	30.55	31.21	28.1	29.11	33.38	33.47	34.47
Globulin	38	40	41	36	42	38	36
A/G Ratio	0.8	0.8	0.7	0.8	0.8	0.9	1
Total Bilirubin	7	6	5	7	HEM	6	4
Alkaline Phosphatase	219	193	90	148	117	136	94
ALT (Sgpt)	31	33	25	26	29	33	27
Gamma gt	71	62	62	71	69	57	60
Creatine Phosphokinase	123	175	116	86	148	291	157
Calculated Osmolality	298	294	289	284	291	288	282
AST (Sgot)	116	122	83	92	110	137	131
Sorbital Dehydrogenase-AO	17.8	21.1	9.1	13.5	18.4	20.8	18.9
Uric Acid	2	2	6	8	4	1	0
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	4-Jul-07	1-Aug-07

Appendix E9. Clinical Laboratory Data for Sheep R56 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Adequate	Adequate	Increased	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	Normal	See Below	See Below	See Below	See Below	See Below
Aniso	NR	NR	1+	NR	NR	1+	1+
Poik	NR	NR	NR	1+	1+	NR	2+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive @ 1:2	Positive @ 1:2, 1:8	Negative
Fibrinogen Semi Quantitative	1	3	4	3	1	1	1
Part. Thromboplastin Time	35.3	>60	40.5	39.1	46.2	41	52.4
Prothrombin Time	25.3	30.5	32.3	26.2	31.1	37.7	43
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	4-Jul-07	1-Aug-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix E10. Clinical Laboratory Data for Sheep R179 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	6.01	6.39	4.98	2.66	4.33	4.45	5.86	3.36
Red Cell Count	10.2	11.5	11.1	10	9.39	8.87	9.18	9.81
Hemoglobin	111	124	123	124	105	99.5	101	122
Hematocrit	0.304	0.34	0.336	0.324	0.311	0.286	0.298	0.335
Mean Corp Vol	29.9	29.7	30.4	32.3	33.1	32.2	32.5	34.2
Mean Corp Hemoglobin	11	10.8	11.2	12.3	11.2	11.2	11	12.4
Mean Corp Hemoglobin Conc	366¹	366	367	382	339	348	340	363
RDW	18.6	22.4	20.3	19.8	21	20	21.6	32.5
Platelet CNT	64.4	64.1	146	78.9	41.5	48.6	59.4	109
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv
Differential Cell Count								
% Neutrophils	43	58	48	31	22	24	41	49
% Lymphocytes	46	39	46	61	62	70	52	30
% Monocytes	2	2	5	4	4	2	5	19
% Eosinophils	9	1	1	4	12	4	1	1
% Basophils	NR	NR	NR	NR	NR	NR	1	1
Absolute Differential Values								
Neutrophils	2.59	3.71	2.39	0.82	0.96	1.06	2.4	1.64
Lymphocytes	2.76	2.49	2.29	1.62	2.68	3.12	3.05	1
Monocytes	0.12	0.13	0.25	0.11	0.17	0.09	0.29	0.638
Eosinophils	0.54	0.06	0.05	0.11	0.52	0.18	0.06	0.046
Basophils	NR	NR	NR	NR	NR	NR	0.06	0.029
Chemistry								
Glucose	3.7	6	2.9	0.3	2.8	3.3	4.3	4.2
Blood Urea Nitrogen	5.6	5.6	6.8	7	8.4	7.1	6.6	4.8
Creatinine	81	83.1	86.4	84	85.4	81.1	81.9	83
BUN/Cr Ratio	17	17	20	21	25	22	20	15
Sodium	143	147	148	147	146	145	145	144
Potassium	4.6	3.9	4.2	5.2	4.1	4.5	4.3	4.7
Na/K Ratio	31	38	35	28	36	32	34	31
Chloride	108	113	112	108	111	110	107	110
Carbon Dioxide	25	21.3	25.4	24.7	24.3	27.2	28.3	29.5
Anion Gap	15	17	15	20	15	12	14	9
Calcium	2.72	2.71	2.5	2.85	2.86	2.64	2.69	2.72
Phosphorus	1.75	1.6	2.13	2.09	1.72	1.76	2.12	1.61
Total Protein	72	77	70	75	79	73	74	74
Albumin	33.91	36.69	32.5	34.85	34.7	32.39	34.45	34.09
Globulin	38	40	38	40	44	41	40	40
A/G Ratio	0.9	0.9	0.9	0.9	0.8	0.8	0.9	0.9
Total Bilirubin	5	5	4	6	3	4	5	3
Alkaline Phosphatase	220	189	193	155	162	111	138	157
ALT (Sgpt)	32	35	35	41	32	29	49	38
Gamma gt	25	35	23	30	22	28	24	26
Creatine Phosphokinase	116	410	193	689	151	244	308	691
Calculated Osmolality	284	292	293	290	290	288	289	286
AST (Sgot)	105	119	110	115	99	137	124	117
Sorbital Dehydrogenase-AO	21.8	22.1	27	23.3	28.4	60.8	39.5	20.4
Uric Acid	1	3	1	0	0	0	9	0
Date of Bleed ³	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

Appendix E10. Clinical Laboratory Data for Sheep R179 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	1+	2+	1+	NR	1+	NR
Poik	1+	1+	1+	3+	2+	1+	NR	3+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive	Negative	Negative	Positive
Fibrinogen Semi Quantitative	1	2	2	2	2	3	1	1
Part. Thromboplastin Time	36	> 60	34.4	> 100	45.3	48.6	33.1	50.5
Prothrombin Time	29	> 60	30	> 100	25.5	27.8	26.7	31.3
Date of Bleed	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E11. Clinical Laboratory Data for Sheep R193 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	7.24	7.73	8.59	7.15	3.75	6.76	4.02	4.64
Red Cell Count	10.4	10.5	10.3	10.9	11	9.29	10.1	10.8
Hemoglobin	117	117	116	124	124	107	117	127
Hematocrit	0.31	0.315	0.31	0.332	0.345	0.312	0.33	0.358
Mean Corp Vol	29.7	30.1	30.2	30.5	31.4	33.5	32.6	33.2
Mean Corp Hemoglobin	11.2	11.2	11.3	11.4	11.3	11.5	11.5	11.7
Mean Corp Hemoglobin Conc.	377¹	371	374	373	359	342	353	354
RDW	21	21.7	21	22.9	21.3	23.2	22.9	22.9
Platelet CNT	273	262	470	374	111	281	348	239
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	11.6	inv
Differential Cell Count								
% Neutrophils	22	60	22	31	30	38	20	47
% Lymphocytes	74	38	73	66	59	51	70	46
% Monocytes	1	1	2	1	7	6	7	7
% Eosinophils	3	1	3	2	4	3	3	NR
% Basophils	NR	NR	NR	NR	NR	2	NR	NR
Absolute Differential Values								
Neutrophils	1.59	4.63	1.89	2.22	1.13	2.56	0.81	2.19
Lymphocytes	5.36	2.94	6.27	4.72	2.21	3.45	2.81	2.13
Monocytes	0.07	0.08	0.17	0.07	0.26	0.41	0.28	0.32
Eosinophils	0.22	0.08	0.26	0.14	0.15	0.2	0.12	NR
Basophils	NR	NR	NR	NR	NR	0.14	NR	NR
Chemistry								
Glucose	2.9	5.8	2.7	3	0.6	3.4	4	4.8
Blood Urea Nitrogen	6.1	3.7	8.1	7.8	9	7.2	6.8	7.3
Creatinine	78.8	64.2	77.3	75.3	60	81.7	77.7	87
BUN/Cr Ratio	19	14	26	26	38	22	22	21
Sodium	146	146	147	144	146	142	146	145
Potassium	4.6	3.9	4.3	4.7	4.6	4.8	4.1	5.3
Na/K Ratio	32	37	34	31	32	30	36	27
Chloride	113	114	113	108	109	108	109	111
Carbon Dioxide	25.5	23.2	25.3	25.4	23.1	27.1	27.8	27.6
Anion Gap	12	13	13	15	19	12	13	12
Calcium	2.65	2.42	2.42	2.61	2.64	2.51	2.58	2.56
Phosphorus	1.69	1.3	1.97	1.83	1.93	1.76	1.38	1.54
Total Protein	72	73	70	74	79	78	75	76
Albumin	32.08	32.73	30.56	32.81	33.68	33.01	33.95	34.95
Globulin	40	40	39	41	45	45	41	41
A/G Ratio	0.8	0.8	0.8	0.8	0.7	0.7	0.8	0.9
Total Bilirubin	4	4	4	4	2	5	2	3
Alkaline Phosphatase	300	306	233	227	163	160	170	99
ALT (Sgpt)	32	31	29	38	30	29	30	37
Gamma gt	21	24	17	24	26	31	32	46
Creatine Phosphokinase	104	195	95	244	91	147	55	156
Calculated Osmolality	289	288	292	287	290	284	290	292
AST (Sgot)	129	122	100	108	100	102	120	132
Sorbital Dehydrogenase-AO	35	21.5	22.5	26	16.9	23.3	56.3	15.2
Uric Acid	0	0	4	3	0	0	0	5
Date of Bleed ³	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

Appendix E11. Clinical Laboratory Data for Sheep R193 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	Normal	See Below	Normal	See Below	See Below
Aniso	1+	1+	1+	1+	1+	1+	1+	NR
Poik	NR	1+	NR	NR	3+	NR	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	2	3	2	1	2	2	1	1
Part. Thromboplastin Time	>60	>60	51.3	>100	48.6	43.4	36	>60
Prothrombin Time	32.5	42.8	41.5	83.1	31	32.3	30.3	31.8
Date of Bleed	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E12. Clinical Laboratory Data for Sheep R198 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	8	6.93	9.73¹	7.54	8.97	8.25	6.01	5.54
Red Cell Count	10.8	10.1	10.9	11.4	12	12.4	11.8	12.7
Hemoglobin	126	119	128	134	133	135	127	146
Hematocrit	0.338	0.318	0.343	0.357	0.369	0.372	0.353	0.417
Mean Corp Vol	31.3	31.5	31.3	31.4	30.8	29.9	29.9	32.8
Mean Corp Hemoglobin	11.7	11.8	11.7	11.8	11.1	10.9	10.7	11.5
Mean Corp Hemoglobin Conc	374	374	372	375	359	363	359	352
RDW	19.6	22.8	20.5	22.4	21.3	23.5	21.4	26.2
Platelet CNT	687	748	646	707	541	605	648	667
Mean Platelet Volume	NR ²	7.83	6.53	NR	NR	NR	NR	inv
Differential Cell Count								
% Neutrophils	21	44	38	39	27	36	29	33
% Lymphocytes	64	51	59	50	62	47	64	59
% Monocytes	4	1	2	6	2	2	3	4
% Eosinophils	10	4	1	5	8	15	4	4
% Basophils	1	NR	NR	NR	1	NR	NR	NR
Absolute Differential Values								
Neutrophils	1.68	3.05	3.7	2.94	2.42	2.96	1.74	1.83
Lymphocytes	5.12	3.53	5.74	3.77	5.56	3.88	3.85	3.27
Monocytes	0.32	0.07	0.19	0.45	0.18	0.17	0.18	0.22
Eosinophils	0.8	0.28	0.1	0.38	0.72	1.24	0.24	0.22
Basophils	0.08	NR	NR	NR	0.09	NR	NR	NR
Chemistry								
Glucose	3.5	4.4	3.5	3.2	3.4	3.2	3.4	4
Blood Urea Nitrogen	6.3	5.9	6.2	5.3	8	6.6	6.6	5.8
Creatinine	83	87.8	70	86	77.5	74.7	81.4	95.8
BUN/Cr Ratio	19	17	22	15	26	22	20	15
Sodium	147	151	144	146	140	141	145	145
Potassium	4.5	4.6	4.5	4.8	4.2	4.4	4.5	5.2
Na/K Ratio	33	33	32	30	33	32	32	28
Chloride	110	120	111	112	108	108	111	110
Carbon Dioxide	25.1	22.6	25.2	22.1	23.1	25.2	26.5	26.6
Anion Gap	16	13	12	17	13	12	12	14
Calcium	2.6	2.48	2.46	2.61	2.6	2.59	2.53	2.72
Phosphorus	2.04	1.09	2.29	1.91	2.19	1.83	2.1	2.36
Total Protein	75	79	69	76	77	78	77	79
Albumin	31.49	33.96	30.35	32.45	31.15	31.94	31.18	35.39
Globulin	44	45	39	44	46	46	46	44
A/G Ratio	0.7	0.8	0.8	0.7	0.7	0.7	0.7	0.8
Total Bilirubin	10	6	5	5	3	3	3	4
Alkaline Phosphatase	177	161	172	233	244	294	233	224
ALT (Sgpt)	30	46	26	32	29	36	37	39
Gamma gt	30	42	42	38	45	31	25	46
Creatine Phosphokinase	66	236	60	111	104	174	260	103
Calculated Osmolality	292	300	286	289	280	280	288	289
AST (Sgot)	76	139	69	81	90	112	105	91
Sorbital Dehydrogenase-AO	15.6	332.9	10	24.2	21.6	26.6	21.2	12.6
Uric Acid	3	5	0	3	0	0	1	0
Date of Bleed ³	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec

Appendix E12. Clinical Laboratory Data for Sheep R198 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	1+	1+	1+	1+	1+	NR
Poik	NR	1+	1+	1+	2+	1+	1+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	2	1	2	1	1	1	2	1
Part. Thromboplastin Time	58.5	47.5	>60	>60	>60	55	62.8	55.8
Prothrombin Time	34.5	44.5	>60	>60	30.8	28.8	34.8	35.3
Date of Bleed	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E13. Clinical Laboratory Data for Sheep B53 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	8.26	9.32¹	8.12	7.01	7.02	7.59	6.2	5.08	5.08
Red Cell Count	10.2	10.4	10.4	9.37	11	11.1	9.45	8.82	10.6
Hemoglobin	108	114	111	102	119	114	101	102	116
Hematocrit	0.292	0.294	0.295	0.267	0.314	0.312	0.277	0.296	0.324
Mean Corp Vol	28.5	28.2	28.4	28.5	28.4	28	29.3	33.6	30.6
Mean Corp Hemoglobin	10.5	11	10.7	10.9	10.8	10.3	10.7	11.6	11
Mean Corp Hemoglobin Conc	369	388	376	381	380	366	365	345	358
RDW	21.2	22.1	20.8	19.9	22.1	22.3	20.5	23.2	22.7
Platelet CNT	326	434	477	373	454	191	465	482	498
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	12.4	NR
Differential Cell Count									
% Neutrophils	46	59	38	43	45	28	37	51	40
% Lymphocytes	49	35	54	52	50	55	53	41	38
% Monocytes	1	2	2	4	1	6	3	5	19
% Eosinophils	4	4	6	1	4	11	6	3	1
% Basophils	NR	NR	NR	NR	NR	NR	1	NR	1
Absolute Differential Values									
Neutrophils	3.8	5.5	3.09	3.01	3.16	2.13	2.29	2.6	2.03
Lymphocytes	4.05	3.26	4.38	3.65	3.51	4.17	3.29	2.08	1.94
Monocytes	0.08	0.19	0.16	0.28	0.07	0.46	0.19	0.25	0.979
Eosinophils	0.33	0.37	0.49	0.07	0.28	0.83	0.37	0.15	0.055
Basophils	NR	NR	NR	NR	NR	NR	0.06	NR	0.075
Chemistry									
Glucose	3.4	3.7	3.5	3.5	3.2	3.4	3.3	3.7	3.2
Blood Urea Nitrogen	7	3.8	4.4	7.3	6.8	7.6	5.5	9.5	7.7
Creatinine	76.4	99	91.5	77	84.4	86.2	93.4	82.6	84.7
BUN/Cr Ratio	23	10	12	24	20	22	15	29	23
Sodium	144	148	145	144	143	145	142	143	147
Potassium	4.7	4.2	4.3	4.6	4.4	4.3	4.6	4.9	4.2
Na/K Ratio	31	35	34	31	33	34	31	29	35
Chloride	112	110	111	111	110	110	109	108	112
Carbon Dioxide	23.8	27	23.9	25.8	26.6	27.4	27.3	26.5	24.6
Anion Gap	13	15	14	12	11	12	10	13	15
Calcium	2.63	2.6	2.78	2.61	2.66	2.62	2.6	2.62	2.72
Phosphorus	1.72	1.87	1.34	1.88	1.4	1.84	1.46	1.94	1.33
Total Protein	72	75	74	69	72	77	79	75	76
Albumin	31.14	31.94	30.64	30.36	31.06	30.65	28.64	33.67	33.73
Globulin	41	43	43	39	41	46	50	41	42
A/G Ratio	0.8	0.7	0.7	0.8	0.8	0.7	0.6	0.8	0.8
Total Bilirubin	5	4	5	5	4	3	5	5	2
Alkaline Phosphatase	203	192	130	166	191	209	144	195	191
ALT (Sgpt)	35	33	31	35	26	32	31	65	30
Gamma gt	16	12	15	17	17	17	19	21	63
Creatine Phosphokinase	107	179	401	683	104	111	119	523	170
Calculated Osmolality	287	291	286	287	284	289	281	288	292
AST (Sgot)	113	110	101	101	131	127	106	162	190
Sorbital Dehydrogenase-AO	22	24.9	17.7	19.2	22.1	18.4	17.8	15	31.4
Uric Acid	4	5	5	0	0	0	1	12	10
Date of Bleed ³	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

Appendix E13. Clinical Laboratory Data for Sheep B53 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	1+	1+	2+	1+	NR	NR	1+	NR
Poik	NR	NR	1+	NR	2+	1+	1+	2+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	1	1	2	1	2	2	1	1
Part. Thromboplastin Time	>100	>60	36	59.8	59.8	45.8	43.2	37.4	48.2
Prothrombin Time	49.8	>60	37.2	>60	50.2	36.3	40.2	34.7	30.5
Date of Bleed	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E14. Clinical Laboratory Data for Sheep B182 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	8.53	9.3¹	6.73	9.2	8.49	8.3	8.34	5.24	6.37
Red Cell Count	12.7	13.1	11.2	12.1	11.8	12	11.8	12.5	12
Hemoglobin	135	139	119	129	121	120	120	138	132
Hematocrit	0.346	0.356	0.31	0.332	0.327	0.328	0.323	0.369	0.375
Mean Corp Vol	27.2	27.2	27.7	27.5	27.8	27.3	27.3	29.5	31.4
Mean Corp Hemoglobin	10.6	10.6	10.7	10.6	10.3	9.97	10.2	11	11.1
Mean Corp Hemoglobin Conc	390	390	385	387	372	365	372	373	352
RDW	22	22	23.3	23.6	21.8	23.6	21.8	27	22.5
Platelet CNT	829	791	1,097	1,029	622	632	719	855	534
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv	NR
Differential Cell Count									
% Neutrophils	43	59	34	44	39	29	43	28	33
% Lymphocytes	44	38	59	52	45	55	46	64	51
% Monocytes	2	1	1	2	1	1	3	4	3
% Eosinophils	1	1	6	2	15	15	8	4	13
% Basophils	NR	1	NR	NR	NR	NR	NR	NR	---
Absolute Differential Values									
Neutrophils	3.67	5.5	2.29	4.06	3.32	2.4	3.58	1.47	2.1
Lymphocytes	3.75	3.53	3.97	4.78	3.82	4.57	3.84	3.35	3.25
Monocytes	0.17	0.09	0.07	0.18	0.08	0.08	0.25	0.21	0.19
Eosinophils	0.94	0.09	0.4	0.18	1.27	1.25	0.67	0.21	0.83
Basophils	NR	0.09	NR	NR	NR	NR	NR	NR	NR
Chemistry									
Glucose	3.4	4.2	3.8	2.9	3.2	3.2	3.2	3.2	3.2
Blood Urea Nitrogen	4.8	3.9	6	5.9	8.5	8.3	6.7	5.4	7
Creatinine	91.1	88.2	61.2	84.9	79.4	80.6	86.5	92	79.5
BUN/Cr Ratio	13	11	25	17	27	26	19	15	22
Sodium	146	151	146	146	140	143	142	143	145
Potassium	4.7	4.3	4.5	4.4	4.1	4.2	4.2	4.8	4.8
Na/K Ratio	31	35	32	33	34	34	34	30	30
Chloride	107	119	112	109	107	110	108	108	110
Carbon Dioxide	29.4	24.2	27.3	30.6	25.8	25.5	27.3	29.1	24.1
Anion Gap	14	12	11	11	11	12	11	11	16
Calcium	2.61	2.5	2.54	2.5	2.64	2.66	2.69	2.76	2.64
Phosphorus	2.33	1.52	1.97	2.31	2.11	1.8	2.02	2.04	1.93
Total Protein	68	73	63	66	68	74	73	73	74
Albumin	30.85	32.42	25.78	28.13	28.11	32.53	37.14	35.01	33.51
Globulin	37	41	37	38	39	41	36	38	40
A/G Ratio	0.8	0.8	0.7	0.7	0.7	0.8	1	0.9	0.8
Total Bilirubin	9	4	4	5	3	4	3	4	2
Alkaline Phosphatase	151	144	81	127	150	144	117	109	123
ALT (Sgpt)	32	32	22	27	29	34	38	33	33
Gamma gt	46	49	61	70	44	27	22	65	27
Creatine Phosphokinase	69	108	67	72	77	105	72	136	162
Calculated Osmolality	289	297	290	289	280	285	282	284	289
AST (Sgot)	107	110	71	79	110	119	109	102	133
Sorbital Dehydrogenase-AO	26.2	23.8	12	14.6	27.3	31.2	22.5	15.3	35
Uric Acid	5	0	2	2	2	0	2	3	6
Date of Bleed ³	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

Appendix E14. Clinical Laboratory Data for Sheep B182 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Increased	Increased	Adequate	Adequate	Adequate	Adequate	Adequate	Increased	Adequate
RBC Morph	See Below	See Below	See Below	See Below	Normal	See Below	See Below	See Below	Normal
Aniso	1+	1+	2+	1+	2+	1+	1+	NR	NR
Poik	NR	NR	1+	NR	NR	NR	NR	1+	NR
Fibrinogen Degradation Products	Negative	Positive @ 1:2, 1:8	Negative	Negative	Negative	Negative	Positive @ 1:2	Negative	Negative
Fibrinogen Semi Quantitative	1	3	4	2	2	2	1	1	1
Part. Thromboplastin Time	58.5	>60	45	33.3	>60	>60	48.7	54.5	41
Prothrombin Time	36.8	59.8	36.8	33.5	32.6	40.6	35.7	33.5	30.9
Date of Bleed	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E15. Clinical Laboratory Data for Sheep B183 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	8.92	8.15	9.28¹	6.89	7.89	6.51	5.73	4.76	5.37
Red Cell Count	13.8	12.8	12.6	11.1	12.1	12.9	12.6	11.7	13.6
Hemoglobin	134	125	124	113	119	124	123	136	134
Hematocrit	0.346	0.323	0.33	0.308	0.34	0.347	0.329	0.369	0.377
Mean Corp Vol	25.1	25.2	26.1	27.7	28.1	26.9	26.1	31.6	27.8
Mean Corp Hemoglobin	9.68	9.73	9.82	10.2	9.86	9.61	9.72	11.7	9.86
Mean Corp Hemoglobin Conc	386	386	376	366	351	357	372	369	355
RDW	27.2	24.2	24.8	22.5	24.2	22	23.9	29	24
Platelet CNT	1,344	1,141	637	355	773	258	1,073	345	943
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv	NR
Differential Cell Count									
% Neutrophils	20	35	26	11	25	15	32	36	30
% Lymphocytes	73	61	57	84	67	77	62	57	57
% Monocytes	3	1	15	2	5	2	4	6	7
% Eosinophils	4	3	0	2	3	6	2	1	5
% Basophils	NR	NR	1	1	NR	NR	NR	NR	1
Absolute Differential Values									
Neutrophils	1.78	2.86	2.4	0.75	1.97	0.98	1.84	1.71	1.62
Lymphocytes	6.51	4.97	5.32	5.79	5.29	5.01	3.55	2.71	3.07
Monocytes	0.27	0.08	1.43	0.14	0.39	0.13	0.23	0.29	0.396
Eosinophils	0.36	0.24	0.038	0.14	0.24	0.39	0.11	0.05	0.243
Basophils	NR	NR	0.089	0.07	NR	NR	NR	NR	0.035
Chemistry									
Glucose	3.4	3.6	0.8	2.7	3.4	2.9	3	3.1	3.7
Blood Urea Nitrogen	6	5.8	7.6	6.8	7.4	7.3	6.6	5.6	7.5
Creatinine	100.9	103.6	89	104.1	90.2	74	91.2	85.6	90.5
BUN/Cr Ratio	15	14	21	16	21	25	18	16	21
Sodium	147	150	147	147	140	140	144	144	146
Potassium	4.7	4.7	5	4.7	4.5	5.2	5.6	5.3	5.3
Na/K Ratio	31	32	29	31	31	27	26	27	28
Chloride	109	117	110	110	107	106	111	110	110
Carbon Dioxide	24.9	23.1	28.1	28.5	19.7	26.4	28.3	27.3	25.6
Anion Gap	18	15	14	13	18	13	10	12	16
Calcium	2.46	2.41	2.46	2.52	2.53	2.48	2.59	2.55	2.5
Phosphorus	2.02	1.78	1.87	1.72	1.96	1.91	1.89	1.97	1.79
Total Protein	71	74	71	78	76	71	71	75	71
Albumin	28.44	29.92	27.74	26.12	28.17	30.11	29.7	32.87	31.21
Globulin	43	44	43	52	48	41	41	42	40
A/G Ratio	0.7	0.7	0.6	0.5	0.6	0.7	0.7	0.8	0.8
Total Bilirubin	10	5	5	4	3	2	5	3	3
Alkaline Phosphatase	171	152	117	150	125	162	121	113	145
ALT (Sgpt)	25	28	25	29	30	35	29	38	33
Gamma gt	55	52	45	31	38	41	32	55	71
Creatine Phosphokinase	76	120	71	41	154	510	167	3,307	116
Calculated Osmolality	292	297	291	292	280	280	288	286	293
AST (Sgot)	101	99	72	72	94	92	90	133	136
Sorbital Dehydrogenase-AO	26.2	65.6	12.4	17.1	32.9	36.1	36.6	23.7	56.1
Uric Acid	0	0	1	7	0	0	0	1	13
Date of Bleed ³	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

Appendix E15. Clinical Laboratory Data for Sheep B183 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Increased	Increased	Adequate	Adequate	Adequate	Adequate	Increased	Adequate	Increased
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	1+	1+	1+	1+	1+	1+	NR
Poik	NR	1+	1+	NR	1+	NR	NR	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative	Negative	Positive	Negative
Fibrinogen Semi Quantitative	1	3	2	1	1	1	3	1	1
Part. Thromboplastin Time	55.5	>60	35	31.4	>60	>60	57.8	>60	>60
Prothrombin Time	33.7	40.9	23.2	27.5	>60	39	34.3	39.3	30
Date of Bleed	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix E16. Clinical Laboratory Data for Sheep B346 (OCL 503)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	14.8¹	12.7	11.7	9.8	12	10.9	9.24	7.59	6.85
Red Cell Count	11.1	9.7	10.4	10.3	10.6	11.6	10.4	11.5	10.5
Hemoglobin	122	112	118	118	123	128	112	125	122
Hematocrit	0.347	0.306	0.328	0.323	0.341	0.362	0.323	0.374	0.357
Mean Corp Vol	31.2	31.5	31.5	31.3	32.1	31.3	31.2	32.6	33.9
Mean Corp Hemoglobin	11	11.6	11.3	11.4	11.6	11	10.8	10.9	11.6
Mean Corp Hemoglobin Conc	352	366	359	364	362	352	347	334	342
RDW	22.5	21.2	22.1	21.2	21.8	21.9	21.2	25.1	23.5
Platelet CNT	217	250	501	473	428	325	247	250	123
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	9.32	NR	NR
Differential Cell Count									
% Neutrophils	37	53	30	26	53	31	28	31	28
% Lymphocytes	58	35	63	67	41	61	60	65	54
% Monocytes	2	5	1	3	3	2	3	2	15
% Eosinophils	3	7	6	3	3	6	9	1	1
% Basophils	NR	NR	NR	1	NR	NR	NR	1	1
Absolute Differential Values									
Neutrophils	5.48	6.72	3.51	2.55	6.36	3.38	2.59	2.35	1.95
Lymphocytes	8.58	4.45	7.37	6.57	4.92	6.65	5.54	4.93	3.73
Monocytes	0.3	0.64	0.12	0.29	0.36	0.22	0.28	0.15	1.06
Eosinophils	0.44	0.89	0.7	0.29	0.36	0.65	0.83	0.08	0.041
Basophils	NR	NR	NR	0.1	NR	NR	NR	0.08	0.066
Chemistry									
Glucose	3.3	3	3.2	3.3	3.2	3.4	3.3	3.8	3.5
Blood Urea Nitrogen	6.1	4.6	5.6	7.7	9	7.8	5.9	9.7	7.6
Creatinine	89.9	108.9	85.7	77.3	104.6	89.6	104.3	100.3	94.7
BUN/Cr Ratio	17	11	16	25	22	22	14	24	20
Sodium	145	151	149	145	146	146	141	143	146
Potassium	4.9	4.6	5	4.5	4.8	4.7	5	4.8	5
Na/K Ratio	30	33	30	32	30	31	28	30	29
Chloride	110	115	112	111	113	113	109	109	114
Carbon Dioxide	23	25.3	24	26.5	24.8	23.1	25.3	23.2	17.8
Anion Gap	17	15	18	12	13	15	12	16	19
Calcium	2.32	2.4	2.57	2.43	2.57	2.49	2.52	2.49	2.44
Phosphorus	2.52	1.95	1.82	1.96	1.9	1.73	1.84	2.08	1.86
Total Protein	68	74	72	66	73	72	70	71	70
Albumin	28.75	29.96	30.74	29.51	31.19	31.68	30.11	34.32	32.66
Globulin	39	44	41	36	42	40	40	37	37
A/G Ratio	0.7	0.7	0.7	0.8	0.7	0.8	0.8	0.9	0.9
Total Bilirubin	4	3	4	4	4	2	3	4	2
Alkaline Phosphatase	239	203	269	262	276	330	291	225	303
ALT (Sgpt)	30	35	40	40	35	39	35	41	35
Gamma gt	61	59	67	52	39	42	39	38	35
Creatine Phosphokinase	63	181	230	124	167	157	188	386	87
Calculated Osmolality	288	297	295	289	293	292	281	288	292
AST (Sgot)	106	168	124	90	132	153	142	125	298
Sorbital Dehydrogenase-AO	20.5	227.4	36.5	26.3	55.6	58.7	72.2	24.9	148.3
Uric Acid	8	5	10	1	0	0	0	3	5
Date of Bleed ³	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

Appendix E16. Clinical Laboratory Data for Sheep B346 (OCL 503), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below	Normal
Aniso	NR	1+	1+	1+	2+	NR	NR	1+	NR
Poik	1+	1+	1+	2+	1+	1+	1+	1+	NR
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	4	2	2	2	1	1	2	1	1
Part. Thromboplastin Time	>100	>60	35	34.3	>100	55	50.2	>60	>60
Prothrombin Time	>100	>60	32.3	29.7	>100	34.3	32.7	>60	36.8
Date of Bleed	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix F. Summary Clinical Laboratory Data for Sheep Implanted with OCL 503

- F1. Summary Clinical Laboratory Data for Sheep on Day -1
- F2. Summary Clinical Laboratory Data for Sheep on Day +1
- F3. Summary Clinical Laboratory Data for Sheep at 1 Week
- F4. Summary Clinical Laboratory Data for Sheep at 2 Weeks
- F5. Summary Clinical Laboratory Data for Sheep at 1 Month
- F6. Summary Clinical Laboratory Data for Sheep at 2 Months
- F7. Summary Clinical Laboratory Data for Sheep at 3 Months
- F8. Summary Clinical Laboratory Data for Sheep at 6 Months
- F9. Summary Clinical Laboratory Data for Sheep at 12 Months

Appendix F1. Summary Clinical Laboratory Data for Sheep on Day -1 (OCL 503)

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1
Hematology																
White Cell Count	11.6	6.4	9.3	8.8	12.1	10.0	7.9	9.1	8.2	6.0	7.2	8.0	8.3	8.5	8.9	14.8
Red Cell Count	13.1	9.9	10.7	9.0	10.9	10.0	10.8	10.4	9.8	10.2	10.4	10.8	10.2	12.7	13.8	11.1
Hemoglobin	156	109	127	113	126	108	131	125	105	111	117	126	108	135	134	122
Hematocrit	0.4	0.3	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Mean Corp Vol	34.1	28.6	31.9	33.4	30.6	28.7	32.9	32.6	28.8	29.9	29.7	31.3	28.5	27.2	25.1	31.2
Mean Corp Hemoglobin	12.0	11.0	11.9	12.5	11.5	10.8	12.1	12.1	10.8	11.0	11.2	11.7	10.5	10.6	9.7	11.0
Mean Corp Hemoglobin Conc	351	386	373	374	376	378	369	370	374	366	377	374	369	390	386	352
RDW	28.0	21.6	21.8	21.9	21.0	23.0	23.7	24.4	20.7	18.6	21.0	19.6	21.2	22.0	27.2	22.5
Platelet CNT	463	357	135	551	410	473	522	542	175	64	273	687	326	829	1344	217
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	63	38	33	30	33	45	34	32	40	43	22	21	46	43	20	37
% Lymphocytes	31	56	56	60	47	41	52	52	53	46	74	64	49	44	73	58
% Monocytes	4	6	7	2	18	7	10	12	4	2	1	4	1	2	3	2
% Eosinophils	2		4	8	0	7	4	1	3	9	3	10	4	1	4	3
% Basophils	NR	NR	NR	NR	2	NR	1	2	NR	NR	NR	1	NR	NR	NR	NR
Absolute Differential Values																
Neutrophils	7.3	2.4	3.1	2.6	4.0	4.5	2.7	2.9	3.3	2.6	1.6	1.7	3.8	3.7	1.8	5.5
Lymphocytes	3.6	3.6	5.2	5.3	5.6	4.1	4.1	4.7	4.4	2.8	5.4	5.1	4.1	3.8	6.5	8.6
Monocytes	0.5	0.4	0.7	0.2	2.2	0.7	0.8	1.1	0.3	0.1	0.1	0.3	0.1	0.2	0.3	0.3
Eosinophils	0.2		0.4	0.7	0.0	0.7	0.3	0.1	0.3	0.5	0.2	0.8	0.3	0.9	0.4	0.4
Basophils	NR	NR	NR	NR	0.2	NR	0.09	0.2	NR	NR	NR	0.1	NR	NR	NR	NR
Chemistry																
Glucose	4.5	5.1	4.5	3.8	4.0	3.8	3.5	3.8	4.0	3.7	2.9	3.5	3.4	3.4	3.4	3.3
Blood Urea Nitrogen (BUN)	2.1	5.4	6.2	5.4	3.8	7.0	2.6	4.4	5.3	5.6	6.1	6.3	7.0	4.8	6.0	6.1
Creatinine	92.3	100.0	89.2	77.4	84.3	68.2	85.6	81.7	78.5	81.0	78.8	83.0	76.4	91.1	100.9	89.9
BUN/Cr Ratio	6	14	17	18	11	26	8	14	17	17	19	19	23	13	15	17
Sodium	147	145	147	148	149	143	147	146	150	143	146	147	144	146	147	145
Potassium	6.3	4.5	4.3	4.9	4.9	5.1	4.5	4.8	5.0	4.6	4.6	4.5	4.7	4.7	4.7	4.9
Na/K Ratio	23	32	34	30	30	28	33	30	30	31	32	33	31	31	31	30
Chloride	110	109	114	113	115	111	108	111	115	108	113	110	112	107	109	110
Carbon Dioxide	28.2	23.7	25.7	26.0	25.8	25.3	28.9	27.1	28.3	25.0	25.5	25.1	23.8	29.4	24.9	23.0

Appendix F1. Summary Clinical Laboratory Data for Sheep on Day -1 (OCL 503), cont.

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1
Anion Gap	15	17	12	14	13	12	15	13	12	15	12	16	13	14	18	17
Calcium	2.6	2.5	2.4	2.7	2.8	2.6	2.6	2.7	2.7	2.7	2.7	2.6	2.6	2.6	2.5	2.3
Phosphorus	2.5	2.6	2.3	2.1	2.3	2.6	2.7	2.3	3.1	1.8	1.7	2.0	1.7	2.3	2.0	2.5
Total Protein	74	63	68	68	69	70	70	75	69	72	72	75	72	68	71	68
Albumin	29.2	27.7	29.6	28.9	29.5	30.2	31.3	34.2	30.6	33.9	32.1	31.5	31.1	30.9	28.4	28.8
Globulin	45	35	38	39	40	40	39	41	38	38	40	44	41	37	43	39
A/G Ratio	0.7	0.8	0.8	0.7	0.7	0.8	0.8	0.8	0.8	0.9	0.8	0.7	0.8	0.8	0.7	0.7
Total Bilirubin	6	6	7	8	7	6	6	7	7	5	4	10	5	9	10	4
Alkaline Phosphatase	206	219	275	307	264	233	218	258	219	220	300	177	203	151	171	239
ALT (Sgpt)	31	40	24	27	33	33	30	26	31	32	32	30	35	32	25	30
Gamma gt	76	20	25	104	52	19	25	44	71	25	21	30	16	46	55	61
Creatine Phosphokinase	84	177	116	83	127	108	83	62	123	116	104	66	107	69	76	63
Calculated Osmolality	292	289	292	294	294	286	288	289	298	284	289	292	287	289	292	288
AST (Sgot)	90	146	103	141	92	88	106	76	116	105	129	76	113	107	101	106
Sorbital Dehydrogenase-AO	31.1	23.2	25.0	53.7	14.6	20.5	25.1	17.0	17.8	21.8	35.0	15.6	22.0	26.2	26.2	20.5
Uric Acid	0	0	0	0	3	8	5	5	2	1	0	3	4	5	0	8
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	4	1	1	1	2	1	2	3	1	1	2	2	1	1	1	4
Part. Thromboplastin Time	37.8	32.5	56.7	31.8	34.2	40.8	35.3	39.7	35.3	36.0	60³	58.5	100	58.5	55.5	100
Prothrombin Time	22.2	23.0	22.5	23.0	24.3	22.6	20.3	24.7	25.3	29.0	32.5	34.5	49.8	36.8	33.7	100

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F2. Summary Clinical Laboratory Data for Sheep on Day +1 (OCL 503)

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1
Hematology																
White Cell Count	10.8	6.6	7.1	9.4	11.5	12.0	7.5	7.7	9.0	6.4	7.7	6.9	9.3	9.3	8.2	12.7
Red Cell Count	10.5	11.4	10.8	8.8	10.2	9.3	10.2	8.9	9.4	11.5	10.5	10.1	10.4	13.1	12.8	9.7
Hemoglobin	128	120	130	109	120	99	124	108	100	124	117	119	114	139	125	112
Hematocrit	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.3	0.3
Mean Corp Vol	34.0	28.0	31.7	33.2	31.1	28.2	33.4	32.4	28.7	29.7	30.1	31.5	28.2	27.2	25.2	31.5
Mean Corp Hemoglobin	12.2	10.5	12.0	12.3	11.8	10.7	12.1	12.2	10.7	10.8	11.2	11.8	11.0	10.6	9.7	11.6
Mean Corp Hemoglobin Conc	358	373	378	371	378	378	363	377	373	366	371	374	388	390	386	366
RDW	23.3	22.3	23.7	22.6	23.8	22.7	23.6	21.9	21.7	22.4	21.7	22.8	22.1	22.0	24.2	21.2
Platelet CNT	435	587	144	558	399	332	622	548	154	64	262	748	434	791	1141	250
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.8	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	45	58	38	56	42	60	42	30	32	58	60	44	59	59	35	53
% Lymphocytes	50	36	58	40	51	21	50	61	58	39	38	51	35	38	61	35
% Monocytes	4	2	2	2	5	15	5	4	5	2	1	1	2	1	1	5
% Eosinophils	1	4	1	2	2	0	3	5	4	1	1	4	4	1	3	7
% Basophils	NR	NR	NR	NR	NR	2	NR	NR	1	NR	NR	NR	NR	1	NR	NR
Absolute Differential Values																
Neutrophils	4.9	3.9	2.7	5.3	4.8	7.2	3.1	2.3	2.9	3.7	4.6	3.1	5.5	5.5	2.9	6.7
Lymphocytes	5.4	2.4	4.1	3.8	5.9	2.5	3.7	4.7	5.2	2.5	2.9	3.5	3.3	3.5	5.0	4.5
Monocytes	0.4	0.1	0.1	0.2	0.6	1.8	0.4	0.3	0.5	0.1	0.1	0.1	0.2	0.1	0.1	0.6
Eosinophils	0.1	0.3	0.1	0.2	0.2	0.0	0.2	0.4	0.4	0.1	0.1	0.3	0.4	0.1	0.2	0.9
Basophils	0.06		0.07			0.24			0.09					0.09		
Chemistry																
Glucose	4.8	4.5	4.9	4.2	4.4	4.1	4.2	4.2	4.6	6	5.8	4.4	3.7	4.2	3.6	3
Blood Urea Nitrogen (BUN)	2.5	2.2	2.4	1.5	4.3	4	5	2.7	4.3	5.6	3.7	5.9	3.8	3.9	5.8	4.6
Creatinine	82.4	93.4	81.1	80.7	76.6	70.4	95.5	73	77.2	83.1	64.2	87.8	99	88.2	103.6	108.9
BUN/Cr Ratio	8	6	7	5	14	14	13	9	14	17	14	17	10	11	14	11
Sodium	150	150	150	151	149	144	151	147	149	147	146	151	148	151	150	151
Potassium	5	4.9	4.4	4.7	4.8	4.1	4.6	4.4	4.5	3.9	3.9	4.6	4.2	4.3	4.7	4.6
Na/K Ratio	30	31	34	32	31	35	33	33	33	38	37	33	35	35	32	33
Chloride	114	115	114	116	114	116	116	116	116	113	114	120	110	119	117	115
Carbon Dioxide	25.9	28.8	25.5	29.1	25	21.9	23.1	27.3	24.6	21.3	23.2	22.6	27	24.2	23.1	25.3

Appendix F2. Summary Clinical Laboratory Data for Sheep on Day +1 (OCL 503), cont.

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1	Day +1
Anion Gap	15	11	15	11	15	10	17	8	13	17	13	13	15	12	15	15
Calcium	2.5	2.5	2.5	2.6	2.7	2.5	2.7	2.6	2.6	2.7	2.4	2.5	2.6	2.5	2.4	2.4
Phosphorus	2.0	2.5	2.1	1.7	2.4	2.0	1.8	2.6	2.5	1.6	1.3	1.1	1.9	1.5	1.8	2.0
Total Protein	77	69	73	69	72	79	80	75	71	77	73	79	75	73	74	74
Albumin	32.2	30.7	32.2	30.0	29.6	29.9	36.5	33.1	31.2	36.7	32.7	34.0	31.9	32.4	29.9	30.0
Globulin	45	38	41	39	42	49	44	42	40	40	40	45	43	41	44	44
A/G Ratio	0.7	0.8	0.8	0.8	0.7	0.6	0.8	0.8	0.8	0.9	0.8	0.8	0.7	0.8	0.7	0.7
Total Bilirubin	4	5	6	5	7	3	7	6	6	5	4	6	4	4	5	3
Alkaline Phosphatase	194	228	275	307	239	98	240	255	193	189	306	161	192	144	152	203
ALT (Sgpt)	40	42	26	42	70	29	45	27	33	35	31	46	33	32	28	35
Gamma gt	86	22	30	103	54	17	27	33	62	35	24	42	12	49	52	59
Creatine Phosphokinase	122	83	91	97	197	55	891	106	175	410	195	236	179	108	120	181
Calculated Osmolality	296	295	294	295	295	284	299	289	294	292	288	300	291	297	297	297
AST (Sgot)	127	138	113	171	152	86	182	82	122	119	122	139	110	110	99	168
Sorbital Dehydrogenase-AO	210	20	39	267	245	42	256	22	21	22	22	333	25	24	66	227
Uric Acid	9	4	1	2	3	12	1	12	2	3	0	5	5	0	0	5
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	4	3	2	2	1	6	3	2	3	2	3	1	1	3	3	2
Part. Thromboplastin Time	603	33.1	39.8	38	60	60	52.6	60	60	60	60	47.5	60	60	60	60
Prothrombin Time	60	29.3	25.2	26.5	30.7	30.5	24.5	33.8	30.5	60	42.8	44.5	60	59.8	40.9	60

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F3. Summary Clinical Laboratory Data for Sheep at 1 Week (OCL 503)

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W
Hematology																
White Cell Count	7.7	6.2	7.9	8.1	10.6	11.5	8.0	8.3	13.4	5.0	8.6	9.7	8.1	6.7	9.3	11.7
Red Cell Count	11.4	12.6	11.7	10.3	10.0	9.3	9.9	8.8	9.6	11.1	10.3	10.9	10.4	11.2	12.6	10.4
Hemoglobin	138	131	140	126	112	101	121	105	101	123	116	128	111	119	124	118
Hematocrit	0.4	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Mean Corp Vol	33.8	28.2	31.9	33.1	31.2	28.4	33.1	32.6	28.2	30.4	30.2	31.3	28.4	27.7	26.1	31.5
Mean Corp Hemoglobin	12.1	10.4	12.0	12.2	11.2	10.8	12.2	11.9	10.5	11.2	11.3	11.7	10.7	10.7	9.8	11.3
Mean Corp Hemoglobin Conc	359	369	375	368	359	382	370	366	373	367	374	372	376	385	376	359
RDW	26.1	22.9	22.0	23.3	22.5	22.3	21.3	21.5	22.3	20.3	21.0	20.5	20.8	23.3	24.8	22.1
Platelet CNT	753	363	289	652	407	1075	563	537	371	146	470	646	477	1097	637	501
Mean Platelet Volume		NR ¹	NR	NR	NR	9.6	8.5	NR	NR	NR	NR	6.5	NR	NR	6.5	
Differential Cell Count																
% Neutrophils	24	31	37	23	22	43	32	20	46	48	22	38	38	34	26	30
% Lymphocytes	73	59	53	56	73	54	57	76	46	46	73	59	54	59	57	63
% Monocytes	3	8	4	16	4	3	6	2	5	5	2	2	2	1	15	1
% Eosinophils	0	2	6	4	1		3	2	3	1	3	1	6	6	0	6
% Basophils	NR	NR	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	1	NR
Absolute Differential Values																
Neutrophils	1.8	1.9	2.9	1.9	2.3	4.9	2.6	1.7	6.2	2.4	1.9	3.7	3.1	2.3	2.4	3.51
Lymphocytes	5.6	3.6	4.2	4.5	7.7	6.2	4.6	6.3	6.2	2.3	6.3	5.7	4.4	4.0	5.32	7.37
Monocytes	0.2	0.5	0.3	1.3	0.4	0.4	0.5	0.2	0.7	0.3	0.2	0.2	0.2	0.1	1.43	0.12
Eosinophils	0.0	0.1	0.5	0.3	0.1		0.3	0.2	0.4	0.1	0.3	0.1	0.5	0.4	0.04	0.7
Basophils	0.03	0.05	NR	0.1	NR	NR	0.06	NR	NR	NR	NR	NR	NR	NR	0.09	NR
Chemistry																
Glucose	3.4	4.0	3.8	3.5	3.6	4.2	3.2	3.8	3.8	2.9	2.7	3.5	3.5	3.8	0.8	3.2
Blood Urea Nitrogen (BUN)	5.1	7.0	6.6	5.7	4.6	4.7	6.7	6.6	5.5	6.8	8.1	6.2	4.4	6.0	7.6	5.6
Creatinine	82.0	85.5	81.7	69.4	69.4	65.9	90.0	66.4	80.9	86.4	77.3	70.0	91.5	61.2	89.0	85.7
BUN/Cr Ratio	16	21	20	21	17	18	19	25	17	20	26	22	12	25	21	16
Sodium	150	154	152	149	145	146	150	149	146	148	147	144	145	146	147	149
Potassium	5.2	5.5	6.1	5.1	5.2	4.6	5.1	5.0	4.6	4.2	4.3	4.5	4.3	4.5	5.0	5.0
Na/K Ratio	29	28	25	29	28	32	29	30	32	35	34	32	34	32	29	30
Chloride	114	117	115	111	113	111	113	114	110	112	113	111	111	112	110	112
Carbon Dioxide	31.2	25.6	28.2	32.1	27.9	29.6	31.6	29.1	30.6	25.4	25.3	25.2	23.9	27.3	28.1	24.0

Appendix F3. Summary Clinical Laboratory Data for Sheep at 1 Week (OCL 503), cont.

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W
Anion Gap	10	17	15	11	9	10	11	11	10	15	13	12	14	11	14	18
Calcium	2.6	2.6	2.4	2.8	2.5	2.6	2.6	2.6	2.5	2.5	2.4	2.5	2.8	2.5	2.5	2.6
Phosphorus	2.1	2.7	2.5	2.2	2.6	2.2	2.3	2.7	2.1	2.1	2.0	2.3	1.3	2.0	1.9	1.8
Total Protein	73	71	71	70	66	83	68	67	69	70	70	69	74	63	71	72
Albumin	28.2	29.9	30.1	29.2	26.3	26.6	30.4	30.6	28.1	32.5	30.6	30.4	30.6	25.8	27.7	30.7
Globulin	45	41	41	41	40	56	38	36	41	38	39	39	43	37	43	41
A/G Ratio	0.6	0.7	0.7	0.7	0.7	0.5	0.8	0.8	0.7	0.9	0.8	0.8	0.7	0.7	0.6	0.7
Total Bilirubin	5	4	5	6	5	5	5	6	5	4	4	5	5	4	5	4
Alkaline Phosphatase	141	190	249	245	144	53	186	276	90	193	233	172	130	81	117	269
ALT (Sgpt)	28	30	22	23	31	20	28	24	25	35	29	26	31	22	25	40
Gamma gt	78	20	29	96	53	74	21	39	62	23	17	42	15	61	45	67
Creatine Phosphokinase	193	82	103	111	136	66	68	89	116	193	95	60	401	67	71	230
Calculated Osmolality	297	308	304	296	288	289	298	297	289	293	292	286	286	290	291	295
AST (Sgot)	85	82	107	102	87	68	90	73	83	110	100	69	101	71	72	124
Sorbital Dehydrogenase-AO	27.9	17.2	30.5	38.7	12.0	8.4	23.0	15.8	9.1	27.0	22.5	10.0	17.7	12.0	12.4	36.5
Uric Acid	5	0	0	0	4	8	5	8	6	1	4	0	5	2	1	10
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	4	3	2	2	1	8	3	1	4	2	2	2	1	4	2	2
Part. Thromboplastin Time	48	68	41.7	48.3	38.9	34	51	36.8	40.5	34.4	51.3	60 ³	36	45	35	35
Prothrombin Time	32.3	34	28.7	28.8	26	36.6	26.7	24.3	32.3	30	41.5	60	37.2	36.8	23.2	32.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F4. Summary Clinical Laboratory Data for Sheep at 2 Weeks (OCL 503)

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W
Hematology																
White Cell Count	8.0	6.7	8.5	10.5	13.5	7.2	6.8	10.4	8.6	2.7	7.2	7.5	7.0	9.2	6.9	9.8
Red Cell Count	11.7	11.8	10.6	10.0	10.7	9.7	10.0	10.4	9.4	10.0	10.9	11.4	9.4	12.1	11.1	10.3
Hemoglobin	138	126	124	123	124	107	121	125	101	124	124	134	102	129	113	118
Hematocrit	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3
Mean Corp Vol	33.7	28.6	32.2	33.4	30.3	28.5	33.6	32.3	28.6	32.3	30.5	31.4	28.5	27.5	27.7	31.3
Mean Corp Hemoglobin	11.8	10.7	11.7	12.4	11.6	11.1	12.1	12	10.7	12.3	11.4	11.8	10.9	10.6	10.2	11.4
Mean Corp Hemoglobin Conc	350	373	363	370	383	389	360	372	372	382	373	375	381	387	366	364
RDW	24.3	22.3	21.5	22.6	22.5	25.1	24.2	21	21	19.8	22.9	22.4	19.9	23.6	22.5	21.2
Platelet CNT	523	394	122	188	446	1014	345	649	315	78.9	374	707	373	1029	355	473
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Differential Cell Count																
% Neutrophils	27	23	19	29	26	22	13	28	29	31	31	39	43	44	11	26
% Lymphocytes	69	72	71	61	71	56	78	62	64	61	66	50	52	52	84	67
% Monocytes	3	4	8	3	3	21	4	4	6	4	1	6	4	2	2	3
% Eosinophils	0	1	2	6		0	5	6	0	4	2	5	1	2	2	3
% Basophils	NR	NR	NR	NR	NR	1	NR	NR	1	NR	NR	NR	NR	NR	1	1
Absolute Differential Values																
Neutrophils	2.2	1.5	1.6	3.1	3.5	1.6	0.9	2.9	2.5	0.8	2.2	2.9	3.0	4.1	0.8	2.6
Lymphocytes	5.6	4.8	6.1	6.5	9.6	4.0	5.3	6.5	5.5	1.6	4.7	3.8	3.7	4.8	5.8	6.6
Monocytes	0.2	0.3	0.7	0.3	0.4	1.5	0.3	0.4	0.5	0.1	0.1	0.5	0.3	0.2	0.1	0.3
Eosinophils	0.0	0.1	0.2	0.6	NR	0.0	0.3	0.6	0.0	0.1	0.1	0.4	0.1	0.2	0.1	0.3
Basophils	0.04	NR	0.06	0.09	NR	0.05	NR	NR	0.06	NR	NR	NR	NR	NR	0.07	0.1
Chemistry																
Glucose	3.5	4	4.1	3.7	3.5	3.9	3.4	3.8	4.2	0.3	3	3.2	3.5	2.9	2.7	3.3
Blood Urea Nitrogen (BUN)	8.1	5.9	5.6	5.3	6.7	4.3	8.6	6.6	4.9	7	7.8	5.3	7.3	5.9	6.8	7.7
Creatinine	80.9	85.5	83.3	69.2	91.2	73.3	88.9	88.6	77.7	84	75.3	86	77	84.9	104.1	77.3
BUN/Cr Ratio	25	17	17	19	18	15	24	19	16	21	26	15	24	17	16	25
Sodium	142	150	151	148	147	145	144	151	143	147	144	146	144	146	147	145
Potassium	5.2	5.5	5.8	4.9	5.2	5.6	5.5	4.6	4.8	5.2	4.7	4.8	4.6	4.4	4.7	4.5
Na/K Ratio	27	27	26	30	28	26	26	33	30	28	31	30	31	33	31	32
Chloride	106	113	113	111	113	111	107	114	111	108	108	112	111	109	110	111
Carbon Dioxide	29.4	30.5	31.1	27	25.8	26.1	32.4	25.6	25.2	24.7	25.4	22.1	25.8	30.6	28.5	26.5

Appendix F4. Summary Clinical Laboratory Data for Sheep at 2 Weeks (OCL 503), cont.

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W
Anion Gap	12	12	13	15	13	14	10	16	12	20	15	17	12	11	13	12
Calcium	2.5	2.6	2.6	2.7	2.8	2.6	2.6	2.7	2.7	2.9	2.6	2.6	2.6	2.5	2.5	2.4
Phosphorus	2.1	2.3	2.1	1.8	2.4	2.4	2.3	2.8	2.2	2.1	1.8	1.9	1.9	2.3	1.7	2.0
Total Protein	72	71	72	75	71	81	69	79	65	75	74	76	69	66	78	66
Albumin	29.3	29.9	29.6	30.9	29.2	26.7	32.1	35.5	29.1	34.9	32.8	32.5	30.4	28.1	26.1	29.5
Globulin	43	41	42	44	42	54	37	43	36	40	41	44	39	38	52	36
A/G Ratio	0.7	0.7	0.7	0.7	0.7	0.5	0.9	0.8	0.8	0.9	0.8	0.7	0.8	0.7	0.5	0.8
Total Bilirubin	6	5	5	6	6	7	6	6	7	6	4	5	5	5	4	4
Alkaline Phosphatase	202	207	214	312	188	139	241	254	148	155	227	233	166	127	150	262
ALT (Sgpt)	32	29	25	31	30	22	30	23	26	41	38	32	35	27	29	40
Gamma gt	83	22	36	110	58	73	30	37	71	30	24	38	17	70	31	52
Creatine Phosphokinase	89	76	97	63	163	184	85	60	86	689	244	111	683	72	41	124
Calculated Osmolality	285	299	301	293	293	288	290	300	284	290	287	289	287	289	292	289
AST (Sgot)	81	98	101	145	95	60	107	71	92	115	108	81	101	79	72	90
Sorbital Dehydrogenase-AO	31.2	24.8	32.1	101.8	14.6	11.9	54.3	1.4	13.5	23.3	26.0	24.2	19.2	14.6	17.1	26.3
Uric Acid	8	9	3	2	5	10	16	4	8	0	3	3	0	2	7	1
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	2	2	2	1	2	2	3	3	2	1	1	2	2	1	2
Part. Thromboplastin Time	35.1	25.5	34.5	33.1	33.6	35.7		54.6	39.1	100	100	60 ³	59.8	33.3	31.4	34.3
Prothrombin Time	23.7	21.5	24.8	22.7	29.3	25.2		40	26.2	100	83.1	60	60	33.5	27.5	29.7

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F5. Summary Clinical Laboratory Data for Sheep at 1 Month (OCL 503)

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M
Hematology																
White Cell Count	7.2	7.3	9.9	9.4	12.5	10.2	7.5	9.3	6.1	4.3	3.8	9.0	7.0	8.5	7.9	12.0
Red Cell Count	10.4	12.3	11.1	10.9	10.3	9.5	10.5	10.2	9.7	9.4	11.0	12.0	11.0	11.8	12.1	10.6
Hemoglobin	131	133	131	131	117	100	128	121	114	105	124	133	119	121	119	123
Hematocrit	0.4	0.4	0.4	0.4	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3
Mean Corp Vol	34.6	29.1	31.9	32.9	31.4	27.9	33.7	32.4	30.2	33.1	31.4	30.8	28.4	27.8	28.1	32.1
Mean Corp Hemoglobin	12.6	10.8	11.8	12.0	11.4	10.5	12.3	11.9	11.7	11.2	11.3	11.1	10.8	10.3	9.9	11.6
Mean Corp Hemoglobin Conc	364	372	370	366	362	377	364	369	388	339	359	359	380	372	351	362
RDW	25.2	23.2	23.0	21.6	23.5	23.6	22.4	22.8	22.0	21.0	21.3	21.3	22.1	21.8	24.2	21.8
Platelet CNT	485	445	142	107	291	1403	512	636	115	42	111	541	454	622	773	428
Mean Platelet Volume								9.9								
Differential Cell Count																
% Neutrophils	29	25	20	28	28	61	23	37	34	22	30	27	45	39	25	53
% Lymphocytes	63	71	76	66	69	24	69	60	59	62	59	62	50	45	67	41
% Monocytes	6	2	3	2	2	14	3	3	5	4	7	2	1	1	5	3
% Eosinophils	1	1	1	3	1	0	4		2	12	4	8	4	15	3	3
% Basophils	NR ¹	NR	NR	NR	NR	1	0	NR	NR	NR	NR	1	NR	NR	NR	NR
Absolute Differential Values																
Neutrophils	2.1	1.8	2.0	2.6	3.5	6.2	1.7	3.5	2.1	1.0	1.1	2.4	3.2	3.3	2.0	6.4
Lymphocytes	4.6	5.2	7.5	6.2	8.6	2.5	5.2	5.6	3.6	2.7	2.2	5.6	3.5	3.8	5.3	4.9
Monocytes	0.4	0.2	0.3	0.2	0.3	1.4	0.3	0.3	0.3	0.2	0.3	0.2	0.1	0.1	0.4	0.4
Eosinophils	0.1	0.1	0.1	0.3	0.1	0.0	0.3		0.1	0.5	0.2	0.7	0.3	1.3	0.2	0.4
Basophils	0.01	0.06	NR	0.09	NR	0.1	0.02	NR	NR	NR	NR	0.09	NR	NR	NR	NR
Chemistry																
Glucose	3.4	3.5	3.4	3.3	3.7	3.7	4	3.6	0.5	2.8	0.6	3.4	3.2	3.2	3.4	3.2
Blood Urea Nitrogen (BUN)	8.2	8	8.9	8.6	8	4.8	10	7.5	7.7	8.4	9	8	6.8	8.5	7.4	9
Creatinine	94.8	89.8	81.8	85.1	74.6	82.5	79.8	84.8	76.5	85.4	60	77.5	84.4	79.4	90.2	104.6
BUN/Cr Ratio	22	22	27	25	27	15	31	22	25	25	38	26	20	27	21	22
Sodium	144	145	143	145	145	145	146	146	146	146	146	140	143	140	140	146
Potassium	4.2	5.7	5.2	5.5	5	4.5	5.2	4.5	5.8	4.1	4.6	4.2	4.4	4.1	4.5	4.8
Na/K Ratio	34	25	28	26	29	32	28	32	25	36	32	33	33	34	31	30
Chloride	111	108	111	108	111	112	111	110	108	111	109	108	110	107	107	113
Carbon Dioxide	22.7	29.2	25	27.7	26.8	24.1	25.6	25.8	23.5	24.3	23.1	23.1	26.6	25.8	19.7	24.8

Appendix F5. Summary Clinical Laboratory Data for Sheep at 1 Month (OCL 503), cont.

Animal Number:	Y26	Y30	Y187	Y790	G57	G186	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M
Anion Gap	15	14	12	15	12	13	15	15	20	15	19	13	11	11	18	13
Calcium	2.5	2.6	2.4	2.7	2.6	2.6	2.7	2.6	2.7	2.9	2.6	2.6	2.7	2.6	2.5	2.6
Phosphorus	1.6	2.7	2.4	2.3	2.1	2.7	1.8	2.5	2.6	1.7	1.9	2.2	1.4	2.1	2.0	1.9
Total Protein	71	68	72	71	68	104	71	72	75	79	79	77	72	68	76	73
Albumin	31.4	30.5	31.8	31.3	29.8	26.9	34.0	33.8	33.4	34.7	33.7	31.2	31.1	28.1	28.2	31.2
Globulin	40	37	40	40	38	77	37	38	42	44	45	46	41	39	48	42
A/G Ratio	0.8	0.8	0.8	0.8	0.8	0.3	0.9	0.9	0.8	0.8	0.7	0.7	0.8	0.7	0.6	0.7
Total Bilirubin	5	5	5	6	6	8	5	6		3	2	3	4	3	3	4
Alkaline Phosphatase	170	223	253	374	260	74	265	300	117	162	163	244	191	150	125	276
ALT (Sgpt)	34	33	26	31	26	23	30	24	29	32	30	29	26	29	30	35
Gamma gt	64	24	41	105	45	87	23	27	69	22	26	45	17	44	38	39
Creatine Phosphokinase	1249	80	93	97	182	332	121	94	148	151	91	104	104	77	154	167
Calculated Osmolality	287	292	288	292	291	287	295	291	291	290	290	280	284	280	280	293
AST (Sgot)	97	90	108	168	93	92	122	96	110	99	100	90	131	110	94	132
Sorbital Dehydrogenase-AO	20.9	17.5	21.2	46.8	20.7	8.1	32.3	26.2	18.4	28.4	16.9	21.6	22.1	27.3	32.9	55.6
Uric Acid	2	5	12	3	0	0	8	0	4	0	0	0	0	2	0	0
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	2	1	1	2	4	1	1	1	2	2	1	1	2	1	1
Part. Thromboplastin Time	42.2	37	36	31.4	47.8	75.7	43.4	58.2	46.2	45.3	48.6	60³	59.8	60	60	100
Prothrombin Time	23.7	25.8	21.6	22.4	38.4	38.8	21.7	55.5	31.1	25.5	31	30.8	50.2	32.6	60	100

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as “60” for the purposes of calculating mean and standard deviation.

Appendix F6. Summary Clinical Laboratory Data for Sheep at 2 Months (OCL 503)

Animal Number:	G57	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M
Hematology											
White Cell Count	9.2	5.9	8.5	5.6	4.5	6.8	8.3	7.6	8.3	6.5	10.9
Red Cell Count	9.8	11.3	9.5	8.8	8.9	9.3	12.4	11.1	12.0	12.9	11.6
Hemoglobin	112	136	113	103	100	107	135	114	120	124	128
Hematocrit	0.31	0.38	0.30	0.29	0.29	0.31	0.37	0.31	0.33	0.35	0.36
Mean Corp Vol	31.3	33.9	31.9	33.1	32.2	33.5	29.9	28.0	27.3	26.9	31.3
Mean Corp Hemoglobin	11.4	12.0	118.0	11.7	11.2	11.5	10.9	10.3	10.0	9.6	11.0
Mean Corp Hemoglobin Conc	365	353	370	354	348	342	363	366	365	357	352
RDW	22.4	23.0	20.4	22.7	20.0	23.2	23.5	22.3	23.6	22.0	21.9
Platelet CNT	61	566	452	318	49	281	605	191	632	258	325
Mean Platelet Volume		8.21	8.67	NR	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count											
% Neutrophils	25	39	32	17	24	38	36	28	29	15	31
% Lymphocytes	68	53	63	77	70	51	47	55	55	77	61
% Monocytes	5	1	2	2	2	6	2	6	1	2	2
% Eosinophils	2	7	3	4	4	3	15	11	15	6	6
% Basophils	NR ¹	NR	NR	NR	NR	2	NR	NR	NR	NR	NR
Absolute Differential Values											
Neutrophils	2.4	2.3	2.7	1.0	1.1	2.6	3.0	2.1	2.4	1.0	3.4
Lymphocytes	6.3	3.1	5.3	4.3	3.1	3.5	3.9	4.2	4.6	5.0	6.7
Monocytes	0.5	0.1	0.2	0.1	0.1	0.4	0.2	0.5	0.1	0.1	0.2
Eosinophils	0.2	0.4	0.3	0.2	0.2	0.2	1.2	0.8	1.3	0.4	0.7
Basophils	NR	NR	NR	NR	NR	0.14	NR	NR	NR	NR	NR
Chemistry											
Glucose	3.8	2.9	3.6	3.4	3.3	3.4	3.2	3.4	3.2	2.9	3.4
Blood Urea Nitrogen (BUN)	9.5	9.1	8.2	7.5	7.1	7.2	6.6	7.6	8.3	7.3	7.8
Creatinine	71.8	82.1	69.8	69.4	81.1	81.7	74.7	86.2	80.6	74	89.6
BUN/Cr Ratio	33	28	30	27	22	22	22	22	26	25	22
Sodium	144	145	146	144	145	142	141	145	143	140	146
Potassium	5.1	5.1	4.6	4.9	4.5	4.8	4.4	4.3	4.2	5.2	4.7
Na/K Ratio	28	28	32	29	32	30	32	34	34	27	31
Chloride	109	110	111	110	110	108	108	110	110	106	113
Carbon Dioxide	26.5	22.2	26.8	24.3	27.2	27.1	25.2	27.4	25.5	26.4	23.1

Appendix F6. Summary Clinical Laboratory Data for Sheep at 2 Months (OCL 503), cont.

Animal Number:	G57	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M
Anion Gap	14	18	13	15	12	12	12	12	12	13	15
Calcium	2.6	2.6	2.6	2.7	2.6	2.5	2.6	2.6	2.7	2.5	2.5
Phosphorus	2.2	2.2	2.6	2.1	1.8	1.8	1.8	1.8	1.8	1.9	1.7
Total Protein	68	74	68	71	73	78	78	77	74	71	72
Albumin	30.6	34.2	32.2	33.5	32.4	33.0	31.9	30.7	32.5	30.1	31.7
Globulin	37	40	36	38	41	45	46	46	41	41	40
A/G Ratio	0.8	0.9	0.9	0.9	0.8	0.7	0.7	0.7	0.8	0.7	0.8
Total Bilirubin	5	4	5	6	4	5	3	3	4	2	2
Alkaline Phosphatase	270	284	252	136	111	160	294	209	144	162	330
ALT (Sgpt)	29	37	26	33	29	29	36	32	34	35	39
Gamma gt	54	66	26	57	28	31	31	17	27	41	42
Creatine Phosphokinase	134	1525	84	291	244	147	174	111	105	510	157
Calculated Osmolality	291	291	292	288	288	284	280	289	285	280	292
AST (Sgot)	103	152	91	137	137	102	112	127	119	92	153
Sorbital Dehydrogenase-AO	25.3	38.5	24.8	20.8	60.8	23.3	26.6	18.4	31.2	36.1	58.7
Uric Acid	0	0	3	1	0	0	0	0	0	0	0

Morphology and Coagulation Parameters

Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	1	1	3	2	1	2	2	1	1
Part. Thromboplastin Time	34.5	76.8	89.4	41	48.6	43.4	55	45.8	60³	60	55
Prothrombin Time	32.8	39.1	75.5	37.7	27.8	32.3	28.8	36.3	40.6	39	34.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F7. Summary Clinical Laboratory Data for Sheep at 3 Months (OCL 503)

Animal Number:	G57	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M
Hematology											
White Cell Count	12.2	7.3	8.1	5.2	5.9	4.0	6.0	6.2	8.3	5.7	9.2
Red Cell Count	10.7	11.3	9.9	10.0	9.2	10.1	11.8	9.5	11.8	12.6	10.4
Hemoglobin	123	139	119	114	101	117	127	101	120	123	112
Hematocrit	0.3	0.4	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3
Mean Corp Vol	31.0	33.6	31.9	32.4	32.5	32.6	29.9	29.3	27.3	26.1	31.2
Mean Corp Hemoglobin	11.6	12.3	12.0	11.5	11.0	11.5	10.7	10.7	10.2	9.7	10.8
Mean Corp Hemoglobin Conc	373	366	375	355	340	353	359	365	372	372	347.0
RDW	20.3	22.9	21.3	21.8	21.6	22.9	21.4	20.5	21.8	23.9	21.2
Platelet CNT	364	506	376	203	59	348	648	465	719	1073	247
Mean Platelet Volume		NR	NR	NR	NR	11.6	NR	NR	NR	NR	NR
Differential Cell Count											
% Neutrophils	33	36	25	29	41	20	29	37	43	32	28
% Lymphocytes	65	46	65	63	52	70	64	53	46	62	60
% Monocytes	2	3	1	5	5	7	3	3	3	4	3
% Eosinophils		14	9	3	1	3	4	6	8	2	9
% Basophils	NR ¹	1	NR	NR	1	NR	NR	1	NR	NR	NR
Absolute Differential Values											
Neutrophils	4.0	2.6	2.0	1.5	2.4	0.8	1.7	2.3	3.6	1.8	2.6
Lymphocytes	7.9	3.3	5.3	3.3	3.1	2.8	3.9	3.3	3.8	3.6	5.5
Monocytes	0.2	0.2	0.1	0.3	0.3	0.3	0.2	0.2	0.3	0.2	0.3
Eosinophils	NR	1.0	0.7	0.2	0.1	0.1	0.2	0.4	0.7	0.1	0.8
Basophils	NR	0.07	NR	NR	0.06	NR	NR	0.06	NR	NR	NR
Chemistry											
Glucose	3.1	2.8	3.1	0.8	4.3	4	3.4	3.3	3.2	3	3.3
Blood Urea Nitrogen (BUN)	8.8	9.4	7.8	8.3	6.6	6.8	6.6	5.5	6.7	6.6	5.9
Creatinine	77.9	95.9	87	83.7	81.9	77.7	81.4	93.4	86.5	91.2	104.3
BUN/Cr Ratio	28	25	23	25	20	22	20	15	19	18	14
Sodium	141	148	145	142	145	146	145	142	142	144	141
Potassium	4.8	4.4	4.8	4.8	4.3	4.1	4.5	4.6	4.2	5.6	5
Na/K Ratio	29	34	30	30	34	36	32	31	34	26	28
Chloride	105	110	108	107	107	109	111	109	108	111	109
Carbon Dioxide	28	26.7	27.6	21.7	28.3	27.8	26.5	27.3	27.3	28.3	25.3

Appendix F7. Summary Clinical Laboratory Data for Sheep at 3 Months (OCL 503), cont.

Animal Number:	G57	G194	G261	R56	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M
Anion Gap	13	16	14	18	14	13	12	10	11	10	12
Calcium	2.7	2.7	2.7	2.7	2.7	2.6	2.5	2.6	2.7	2.6	2.5
Phosphorus	2.1	2.0	2.2	1.8	2.1	1.4	2.1	1.5	2.0	1.9	1.8
Total Protein	71	78	74	70	74	75	77	79	73	71	70
Albumin	31.1	34.0	34.3	34.5	34.5	34.0	31.2	28.6	37.1	29.7	30.1
Globulin	40	44	40	36	40	41	46	50	36	41	40
A/G Ratio	0.8	0.8	0.9	1.0	0.9	0.8	0.7	0.6	1.0	0.7	0.8
Total Bilirubin	5	4	5	4	5	2	3	5	3	5	3
Alkaline Phosphatase	222	213	239	94	138	170	233	144	117	121	291
ALT (Sgpt)	27	33	25	27	49	30	37	31	38	29	35
Gamma gt	54	58	35	60	24	32	25	19	22	32	39
Creatine Phosphokinase	447	117	81	157	308	55	260	119	72	167	188
Calculated Osmolality	283	296	290	282	289	290	288	281	282	288	281
AST (Sgot)	115	170	91	131	124	120	105	106	109	90	142
Sorbital Dehydrogenase-AO	24.0	38.6	20.1	18.9	39.5	56.3	21.2	17.8	22.5	36.6	72.2
Uric Acid	0	13	0	0	9	0	1	1	2	0	0
Morphology and Coagulation Parameters											
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	1	1	1	1	1	2	2	1	3	2
Part. Thromboplastin Time	69.5	60³	66	52.4	33.1	36	62.8	43.2	48.7	57.8	50.2
Prothrombin Time	38.3	60	37.1	43	26.7	30.3	34.8	40.2	35.7	34.3	32.7

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F8. Summary Clinical Laboratory Data for Sheep at 6 Months (OCL 503)

Animal Number:	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	6 M	6 M	6 M	6 M	6 M	6 M	6 M
Hematology							
White Cell Count	3.4	4.6	5.5	5.1	5.2	4.8	7.6
Red Cell Count	9.8	10.8	12.7	8.8	12.5	11.7	11.5
Hemoglobin	122	127	146	102	138	136	125
Hematocrit	0.3	0.4	0.4	0.3	0.4	0.4	0.4
Mean Corp Vol	34.2	33.2	32.8	33.6	29.5	31.6	32.6
Mean Corp Hemoglobin	12.4	11.7	11.5	11.6	11.0	11.7	10.9
Mean Corp Hemoglobin Conc	363	354	352	345	373	369	334
RDW	32.5	22.9	26.2	23.2	27.0	29.0	25.1
Platelet CNT	109	239	667	482	855	345	250
Mean Platelet Volume		NR	NR	inv	inv	inv	12.4
Differential Cell Count							
% Neutrophils	49	47	33	51	28	36	31
% Lymphocytes	30	46	59	41	64	57	65
% Monocytes	19	7	4	5	4	6	2
% Eosinophils	1	NR ¹	4	3	4	1	1
% Basophils	1	NR	NR	NR	NR	NR	1
Absolute Differential Values							
Neutrophils	1.6	2.2	1.8	2.6	1.5	1.7	2.4
Lymphocytes	1.0	2.1	3.3	2.1	3.4	2.7	4.9
Monocytes	0.6	0.3	0.2	0.3	0.2	0.3	0.2
Eosinophils	0.05	NR	0.22	0.15	0.21	0.05	0.08
Basophils	0.03	NR	NR	NR	NR	NR	0.08
Chemistry							
Glucose	4.2	4.8	4	3.7	3.2	3.1	3.8
Blood Urea Nitrogen (BUN)	4.8	7.3	5.8	9.5	5.4	5.6	9.7
Creatinine	83	87	95.8	82.6	92	85.6	100.3
BUN/Cr Ratio	15	21	15	29	15	16	24
Sodium	144	145	145	143	143	144	143
Potassium	4.7	5.3	5.2	4.9	4.8	5.3	4.8
Na/K Ratio	31	27	28	29	30	27	30
Chloride	110	111	110	108	108	110	109
Carbon Dioxide	29.5	27.6	26.6	26.5	29.1	27.3	23.2

Appendix F8. Summary Clinical Laboratory Data for Sheep at 6 Months (OCL 503), cont.

Animal Number:	R179	R193	R198	B53	B182	B183	B346
Time Post Embolization	6 M	6 M	6 M	6 M	6 M	6 M	6 M
Anion Gap	9	12	14	13	11	12	16
Calcium	2.7	2.6	2.7	2.6	2.8	2.6	2.5
Phosphorus	1.6	1.5	2.4	1.9	2.0	2.0	2.1
Total Protein	74	76	79	75	73	75	71
Albumin	34	35	35	34	35	33	34
Globulin	40	41	44	41	38	42	37
A/G Ratio	0.9	0.9	0.8	0.8	0.9	0.8	0.9
Total Bilirubin	3	3	4	5	4	3	4
Alkaline Phosphatase	157	99	224	195	109	113	225
ALT (Sgpt)	38	37	39	65	33	38	41
Gamma gt	26	46	46	21	65	55	38
Creatine Phosphokinase	691	156	103	523	136	3307	386
Calculated Osmolality	286	292	289	288	284	286	288
AST (Sgot)	117	132	91	162	102	133	125
Sorbital Dehydrogenase-AO	20.4	15.2	12.6	15.0	15.3	23.7	24.9
Uric Acid	0	5	0	12	3	1	3
Morphology and Coagulation Parameters							
Platelets	NA ²	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	1	1	1	1	1
Part. Thromboplastin Time	50.5	60³	55.8	37.4	54.5	60	60
Prothrombin Time	31.3	31.8	35.3	34.7	33.5	39.3	60

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix F9. Summary Clinical Laboratory Data for Sheep at 12 Months (OCL 503)

Animal Number:	B53	B182	B183	B346
Time Post Embolization	12 M	12 M	12 M	12 M
Hematology				
White Cell Count	5.08	6.37	5.37	6.85
Red Cell Count	10.6	12	13.6	10.5
Hemoglobin	116	132	134	122
Hematocrit	0.324	0.375	0.377	0.357
Mean Corp Vol	30.6	31.4	27.8	33.9
Mean Corp Hemoglobin	11	11.1	9.86	11.6
Mean Corp Hemoglobin Conc	358	352	355	342
RDW	22.7	22.5	24	23.5
Platelet CNT	498	534	943	123
Mean Platelet Volume	NR ¹	NR	NR	NR
Differential Cell Count				
% Neutrophils	40	33	30	28
% Lymphocytes	38	51	57	54
% Monocytes	19	3	7	15
% Eosinophils	1	13	5	1
% Basophils	1	NR	1	1
Absolute Differential Values				
Neutrophils	2.03	2.1	1.62	1.95
Lymphocytes	1.94	3.25	3.07	3.73
Monocytes	0.979	0.19	0.396	1.06
Eosinophils	0.055	0.83	0.243	0.041
Basophils	0.075	NR	0.035	0.066
Chemistry				
Glucose	3.2	3.2	3.7	3.5
Blood Urea Nitrogen (BUN)	7.7	7	7.5	7.6
Creatinine	84.7	79.5	90.5	94.7
BUN/Cr Ratio	23	22	21	20
Sodium	147	145	146	146
Potassium	4.2	4.8	5.3	5
Na/K Ratio	35	30	28	29
Chloride	112	110	110	114
Carbon Dioxide	24.6	24.1	25.6	17.8

Appendix F9. Summary Clinical Laboratory Data for Sheep at 12 Months (OCL 503), cont.

Animal Number:	B53	B182	B183	B346
Time Post Embolization	12 M	12 M	12 M	12 M
Anion Gap	15	16	16	19
Calcium	2.72	2.64	2.5	2.44
Phosphorus	1.33	1.93	1.79	1.86
Total Protein	76	74	71	70
Albumin	33.73	33.51	31.21	32.66
Globulin	42	40	40	37
A/G Ratio	0.8	0.8	0.8	0.9
Total Bilirubin	2	2	3	2
Alkaline Phosphatase	191	123	145	303
ALT (Sgpt)	30	33	33	35
Gamma gt	63	27	71	35
Creatine Phosphokinase	170	162	116	87
Calculated Osmolality	292	289	293	292
AST (Sgot)	190	133	136	298
Sorbital Dehydrogenase-AO	31.4	35	56.1	148.3
Uric Acid	10	6	13	5

Morphology and Coagulation Parameters

Platelets	NA ²	NA	NA	NA
RBC Morph	NA	NA	NA	NA
Aniso	NA	NA	NA	NA
Poik	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	1	1
Part. Thromboplastin Time	48.2	41	60³	60
Prothrombin Time	30.5	30.9	30	36.8

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix E, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as “60” for the purposes of calculating mean and standard deviation.

Appendix G. Means of Clinical Laboratory Data for Sheep Implanted with OCL 503

	Mean Values									One Standard Deviation								
Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12M	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
# of sheep	16	16	16	16	16	11	11	7	4	16	16	16	16	16	11	11	7	4
Hematology																		
White Cell Count	9.1	8.9	8.8	8.2	8.2	7.4	7.1	5.2	5.9	2.2	2.0	2.2	2.4	2.4	1.8	2.3	1.3	0.8
Red Cell Count	10.9	10.5	10.7	10.6	10.8	10.7	10.7	11.1	11.7	1.3	1.3	1.1	0.9	0.9	1.5	1.1	1.6	1.5
Hemoglobin	122	118	120	121	122	117	118	128	126	13.4	10.8	11.8	10.4	9.7	12.3	11.0	16.5	8.5
Hematocrit	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean Corp Vol	30.3	30.3	30.4	30.7	31.0	30.9	30.7	32.5	30.9	2.4	2.5	2.3	2.2	2.2	2.5	2.4	1.8	2.5
Mean Corp Hemoglobin	11.3	11.3	11.3	11.4	11.3	20.7	11.1	11.5	10.9	0.7	0.8	0.7	0.7	0.7	32.3	0.8	0.4	0.7
Mean Corp Hemoglobin Conc	373	374	371	373	366	358	362	356	352	10.6	8.9	7.7	10.4	11.5	8.7	11.7	18.8	6.9
RDW	22.4	22.6	22.3	22.3	22.6	22.3	21.8	26.6	23.2	2.5	0.9	1.6	1.5	1.2	1.2	1.1	2.5	0.7
Platelet CNT	461	467	562	462	444	340	455	421	525	312	279	255	274	339	204	279	266	335
Mean Platelet Volume	CNC ¹	7.8	8.2	CNC	9.9	8.4	10.5	12.4	CNC	CNC	CNC	1.6	CNC	CNC	0.3	1.6	CNC	CNC
Differential Cell Count																		
% Neutrophils	36.3	48.2	32.1	27.6	32.9	28.6	32.1	39.3	32.8	10.9	10.9	9.0	9.3	11.6	7.9	6.9	10.2	5.3
% Lymphocytes	53.5	45.1	59.9	64.8	58.9	61.6	58.7	51.7	50.0	11.1	11.5	9.4	9.5	13.2	10.4	8.2	11.1	8.4
% Monocytes	5.3	3.6	4.9	4.9	3.9	2.8	3.6	6.7	11.0	4.7	3.4	4.5	4.6	3.2	1.9	1.6	1.7	7.3
% Eosinophils	4.2	2.7	2.9	2.6	4.1	6.9	5.9	2.3	5.0	3.0	1.9	2.2	2.1	4.3	4.7	4.1	1.5	5.7
% Basophils	1.5	1.3	1.0	1.0	0.7	2.0	1.0	1.0	1.0	0.6	0.6	0.0	0.0	0.6		0.0		0.0
Absolute Differential Values																		
Neutrophils	3.3	4.3	2.8	2.3	2.8	2.2	2.3	2.0	1.9	1.5	1.5	1.2	1.0	1.6	0.8	0.9	0.5	0.2
Lymphocytes	4.8	3.9	5.3	5.3	4.8	4.5	4.2	2.8	3.0	1.4	1.1	1.4	1.7	1.8	1.2	1.5	1.2	0.8
Monocytes	0.5	0.4	0.4	0.4	0.3	0.2	0.2	0.3	0.7	0.5	0.4	0.4	0.3	0.3	0.2	0.1	0.1	0.4
Eosinophils	0.4	0.2	0.3	0.2	0.3	0.5	0.4	0.1	0.29	0.3	0.2	0.2	0.2	0.3	0.4	0.4	0.1	0.4
Basophils	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.06	0.1	0.1	0.0	0.0	0.0		0.0		0.0
Chemistry																		
Glucose	3.8	4.4	3.4	3.3	3.1	3.3	3.1	3.8	3.4	0.6	0.7	0.8	0.9	1.0	0.3	0.9	0.4	0.2
Blood Urea Nitrogen	5.3	3.9	6.1	6.5	8.1	7.8	7.2	6.9	7.5	1.4	1.3	1.1	1.2	1.2	0.9	1.2	2.4	0.3
Creatinine	84.9	85.3	78.3	83.0	83.2	78.3	87.4	89.5	87.4	8.7	12.3	9.8	8.3	9.7	6.7	8.2	7.8	6.6
BUN/Cr Ratio	15.9	11.5	19.8	19.6	24.7	25.4	20.8	19.3	22	5.0	3.7	3.8	3.9	5.1	3.8	4.3	6.7	1.3
Sodium	146	149	148	146	144	144	144	144	146	2.0	2.1	2.7	2.7	2.3	2.0	2.3	0.5	0.8
Potassium	4.8	4.5	4.9	5.0	4.8	4.7	4.7	5.0	4.8	0.5	0.3	0.5	0.4	0.6	0.3	0.4	0.2	0.5
Na/K Ratio	30.6	33.4	30.5	29.3	30.5	30.6	31.3	28.9	30.5	2.5	2.2	2.7	2.5	3.4	2.4	3.0	1.4	3.1
Chloride	111	115	112	111	110	110	109	109	111.5	2.5	2.3	1.9	2.3	1.9	1.8	1.8	1.0	1.9
Carbon Dioxide	26.0	24.9	27.8	27.3	24.9	25.6	26.8	27.1	23.0	1.9	2.3	2.7	2.8	2.3	1.8	1.9	2.5	3.5
Anion Gap	14.3	13.4	12.6	13.6	14.4	13.5	13.0	12.4	16.5	2.0	2.5	2.7	2.5	2.7	1.9	2.5	2.2	1.7
Calcium	2.6	2.5	2.6	2.6	2.6	2.6	2.6	2.6	2.6	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Phosphorus	2.3	1.9	2.2	2.1	2.1	2.0	1.9	1.9	1.7	0.4	0.4	0.4	0.3	0.4	0.3	0.3	0.1	0.3

Appendix G. Means of Clinical Laboratory Data for Sheep Implanted with OCL 503, Cont.

	Mean Values									One Standard Deviation								
Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12M	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12M
# of sheep	16	16	16	16	16	11	11	7	4	16	16	16	16	16	11	11	7	4
Total Protein	70.3	74.4	70.4	72.4	74.8	73.1	73.8	74.7	72.8	3.1	3.4	4.3	4.8	8.6	3.6	3.2	2.5	2.8
Albumin	30.5	32.1	29.2	30.4	31.3	32.1	32.6	34.3	32.8	1.8	2.2	1.9	2.6	2.3	1.3	2.6	0.9	1.1
Globulin	39.8	42.3	41.2	42.0	43.4	41.0	41.3	40.4	39.8	2.6	2.8	4.6	5.1	9.5	3.4	4.1	2.4	2.1
A/G Ratio	0.8	0.8	0.7	0.7	0.7	0.8	0.8	0.9	0.8	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0
Total Bilirubin	6.7	5.0	4.8	5.4	4.5	3.9	4.0	3.7	2.3	1.9	1.3	0.7	1.0	1.6	1.3	1.1	0.8	0.5
Alkaline Phosphatase	229	211	173	202	209	214	180	160	191	44.1	58.3	69.2	52.0	78.5	75.2	62.8	54.9	80.2
ALT (Sgpt)	30.7	37.1	27.4	30.6	29.2	32.6	32.8	41.6	32.8	4.0	10.8	5.2	5.6	3.5	4.0	6.8	10.6	2.1
Gamma gt	43.1	44.2	46.4	48.9	44.8	38.2	36.4	42.4	49.0	25.3	24.9	24.9	26.2	24.9	15.3	14.8	15.5	21.3
Creatine Phosphokinase	98	203	130	179	203	317	179	757	134	30.7	202	88.8	205	286	419	118	1146	39.2
Calculated Osmolality	290	294	294	291	288	287	286	288	292	3.5	4.2	6.2	5.1	4.8	4.5	4.9	2.6	1.7
AST (Sgot)	106	128	89	94	108	120	118	123	189	20.2	29.3	16.8	20.5	21.0	22.5	23.2	23.1	77.1
Sorbital Dehydrogenase-AO	24.7	115	20.0	27.3	26.1	33.1	33.4	18.2	67.7	9.4	116	9.8	23.0	11.7	14.5	17.6	4.8	54.8
Uric Acid	2.8	4.0	3.7	5.1	2.3	0.4	2.4	3.4	8.5	2.8	3.9	3.3	4.3	3.5	0.9	4.4	4.2	3.7
Morphology and Coagulation Parameters																		
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1.8	2.6	2.7	1.8	1.6	1.5	1.5	1.0	1.0	1.1	1.3	1.7	0.7	0.8	0.7	0.7	0.0	0.0
Part. Thromboplastin Time	50.8	54.4	44.0	47.3	53.2	55.4	52.7	54.0	52.3	21.9	9.4	9.9	23.8	17.0	16.1	11.9	8.2	9.4
Prothrombin Time	32.8	41.2	33.2	40.5	38.1	38.6	37.6	38.0	32.1	19.5	14.3	8.8	24.2	20.4	12.9	8.7	10.1	3.2

¹ Can not calculate² Not Applicable

Appendix H. Clinical Laboratory Data for Individual Sheep Implanted with Embosphere® Microspheres

- H1. Clinical Laboratory Data for Sheep Y28
- H2. Clinical Laboratory Data for Sheep Y33
- H3. Clinical Laboratory Data for Sheep Y110
- H4. Clinical Laboratory Data for Sheep Y184
- H5. Clinical Laboratory Data for Sheep G188
- H6. Clinical Laboratory Data for Sheep G196
- H7. Clinical Laboratory Data for Sheep G253
- H8. Clinical Laboratory Data for Sheep G410
- H9. Clinical Laboratory Data for Sheep R27
- H10. Clinical Laboratory Data for Sheep R32
- H11. Clinical Laboratory Data for Sheep R184
- H12. Clinical Laboratory Data for Sheep R199
- H13. Clinical Laboratory Data for Sheep B29
- H14. Clinical Laboratory Data for Sheep B34
- H15. Clinical Laboratory Data for Sheep B54
- H16. Clinical Laboratory Data for Sheep B197

Appendix H1. Clinical Laboratory Data for Sheep Y28 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	6.3	6.47	7.03	6.04	6.04
Red Cell Count	11.3	10.3	10.4	11.7	12.3¹
Hemoglobin	129	120	122	137	143
Hematocrit	0.352	0.325	0.331	0.378	0.396
Mean Corp Vol	31	31.5	31.8	32.4	32.1
Mean Corp Hemoglobin	11.4	11.6	11.7	11.8	11.6
Mean Corp Hemoglobin Conc	366	369	367	364	361
RDW	24.8	23.1	24.6	24	27.5
Platelet CNT	481	473	604	608	643
Mean Platelet Volume	NR ²	NR	NR	NR	NR
Differential Cell Count					
% Neutrophils	34	57	26	38	29
% Lymphocytes	61	33	68	55	57
% Monocytes	2	7	3	6	12
% Eosinophils	3	3	3	1	2
% Basophils	NR	NR	NR	NR	0
Absolute Differential Values					
Neutrophils	2.14	3.69	1.83	2.3	1.73
Lymphocytes	3.84	2.14	4.78	3.32	3.47
Monocytes	0.13	0.45	0.21	0.36	0.727
Eosinophils	0.19	0.19	0.21	0.06	0.099
Basophils	NR	NR	NR	NR	0.006
Chemistry					
Glucose	4.4	5.7	4.1	3.5	3.3
Blood Urea Nitrogen	3.4	1.4	7	6.8	6.1
Creatinine	87.9	79.4	66.1	71.9	88.4
BUN/Cr Ratio	10	4	27	24	17
Sodium	147	153	147	150	154
Potassium	4.5	4.3	5.2	5.2	6.1
Na/K Ratio	33	36	28	29	25
Chloride	110	119	114	118	116
Carbon Dioxide	25.9	31.6	26.2	25.3	31.4
Anion Gap	16	7	12	12	13
Calcium	2.55	2.53	2.53	2.66	2.76
Phosphorus	2.2	1.84	2.32	1.87	2.4
Total Protein	65	68	66	68	69
Albumin	31.65	33.68	31.5	34.34	34.92
Globulin	33	34	35	34	34
A/G Ratio	0.9	1	0.9	1	1
Total Bilirubin	7	6	5	5	5
Alkaline Phosphatase	334	312	418	340	299
ALT (Sgpt)	33	38	30	31	33
Gamma gt	66	71	77	66	73
Creatine Phosphokinase	69	97	82	213	396
Calculated Osmolality	290	300	294	299	307
AST (Sgot)	114	151	96	92	110
Sorbital Dehydrogenase-AO	47.3	118.8	19.7	28.2	25.7
Uric Acid	0	0	4	0	1
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

Appendix H1. Clinical Laboratory Data for Sheep Y28 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Adequate	Adequate	Increased	Increased
RBC Morph	See below	See below	See below	Normal	Normal
Aniso	1+	2+	1+	NR	NR
Poik	1+	1+	1+	NR	NR
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive
Fibrinogen Semi Quantitative	2	2	3	1	1
Part. Thromboplastin Time	33.8	56.8	30	49.7	49.3
Prothrombin Time	22	23.3	20.3	27	31.2
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H2. Clinical Laboratory Data for Sheep Y33 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	10.8¹	9.13	8.61	8.37	8.06
Red Cell Count	11.1	10.2	11.7	11	12.4
Hemoglobin	130	122	136	128	145
Hematocrit	0.354	0.327	0.373	0.355	0.397
Mean Corp Vol	32	32	32	32.2	31.9
Mean Corp Hemoglobin	11.8	12	11.7	11.6	11.6
Mean Corp Hemoglobin Conc	368	375	364	361	364
RDW	23	21.8	22.7	23.7	23.1
Platelet CNT	474	434	757	443	533
Mean Platelet Volume	NR ²	NR	NR	NR	NR
Differential Cell Count					
% Neutrophils	35	41	26	21	37
% Lymphocytes	59	56	55	71	39
% Monocytes	4	2	18	4	19
% Eosinophils	0	0	0	4	3
% Basophils	1	0	1	NR	2
Absolute Differential Values					
Neutrophils	3.81	3.78	2.26	1.77	3.02
Lymphocytes	6.41	5.11	4.7	5.94	3.14
Monocytes	0.478	0.183	1.54	0.33	1.57
Eosinophils	0.016	0.032	0.022	0.33	0.206
Basophils	0.068	0.024	0.08	NR	0.121
Chemistry					
Glucose	4	4.3	3.6	3.6	4.2
Blood Urea Nitrogen	3.9	3.3	7.6	8.5	7.9
Creatinine	84.6	87.7	101.7	86.8	101.8
BUN/Cr Ratio	12	9	19	25	19
Sodium	149	155	156	146	144
Potassium	4.9	4.6	6.9	5.1	4.7
Na/K Ratio	30	34	23	29	31
Chloride	112	120	117	110	111
Carbon Dioxide	27.5	26.1	32.8	29.6	18.7
Anion Gap	14	14	13	12	19
Calcium	2.54	2.6	2.79	2.56	2.48
Phosphorus	2.48	1.96	2.76	2.32	2.15
Total Protein	71	78	74	72	70
Albumin	28.95	32.17	30.45	31.15	32.45
Globulin	42	46	44	41	38
A/G Ratio	0.7	0.7	0.7	0.8	0.9
Total Bilirubin	5	5	5	5	5
Alkaline Phosphatase	226	253	185	217	176
ALT (Sgpt)	30	75	32	30	28
Gamma gt	23	24	30	29	26
Creatine Phosphokinase	101	1,542	187	210	111
Calculated Osmolality	294	304	314	293	289
AST (Sgot)	88	262	86	80	82
Sorbital Dehydrogenase-AO	15	36.1	12.7	15.2	15.2
Uric Acid	2	2	0	3	6
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07

Appendix H2. Clinical Laboratory Data for Sheep Y33 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Increased	Increased	Adequate	Increased
RBC Morph	Normal	See Below	See Below	See Below	See Below
Aniso	NR	NR	NR	NR	NR
Poik	NR	1+	1+	1+	1+
Fibrinogen Degradation Products	Negative	Positive	Negative	Negative	Positive
Fibrinogen Semi Quantitative	3	3	3	1	1
Part. Thromboplastin Time	37.7	37.9	43.2	36.9	27.8
Prothrombin Time	20.7	25.7	28.2	21.3	21.8
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H3. Clinical Laboratory Data for Sheep Y110 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	8.39	8.16	9.6¹	7.85	8.61
Red Cell Count	11	11.2	11.1	12.9	13
Hemoglobin	127	132	129	150	148
Hematocrit	0.337	0.342	0.341	0.396	0.391
Mean Corp Vol	30.8	30.6	30.7	30.8	30.1
Mean Corp Hemoglobin	11.6	11.8	11.6	11.7	11.4
Mean Corp Hemoglobin Conc	376	385	378	380	380
RDW	22.2	23.6	24.6	28	24.3
Platelet CNT	664	630	781	769	967
Mean Platelet Volume	NR ²	NR	NR	NR	NR
Differential Cell Count					
% Neutrophils	32	41	16	34	30
% Lymphocytes	60	47	78	44	57
% Monocytes	6	11	3	19	10
% Eosinophils	2	0	3	1	2
% Basophils	NR	1	NR	2	0
Absolute Differential Values					
Neutrophils	2.69	3.35	1.53	2.67	2.58
Lymphocytes	5.03	3.86	7.49	3.49	4.91
Monocytes	0.5	0.876	0.29	1.46	0.892
Eosinophils	0.17	0.12	0.29	0.71	0.181
Basophils	NR	0.059	NR	0.159	0.039
Chemistry					
Glucose	5	4.8	4.3	3.4	3.1
Blood Urea Nitrogen	4.3	3	7.1	8.2	6.1
Creatinine	96.5	97.5	83.1	83.4	101.3
BUN/Cr Ratio	11	8	21	25	15
Sodium	147	149	145	149	152
Potassium	4.7	4.9	5.4	5.2	5.3
Na/K Ratio	31	30	27	29	29
Chloride	108	114	113	114	113
Carbon Dioxide	29.3	31.7	26.9	22.7	27
Anion Gap	14	8	11	18	17
Calcium	2.69	2.7	2.68	2.97	2.8
Phosphorus	2.77	2.16	1.86	1.96	2.22
Total Protein	72	78	74	82	74
Albumin	31.6	35.14	33.12	37.92	34.72
Globulin	40	43	41	44	39
A/G Ratio	0.8	0.8	0.8	0.9	0.9
Total Bilirubin	6	6	5	4	5
Alkaline Phosphatase	200	247	214	195	166
ALT (Sgpt)	26	42	26	27	27
Gamma gt	23	24	25	28	33
Creatine Phosphokinase	75	307	71	282	831
Calculated Osmolality	291	294	291	298	302
AST (Sgot)	93	202	101	108	125
Sorbital Dehydrogenase-AO	54.9	901	95	51.5	50.6
Uric Acid	0	0	5	0	5
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

Appendix H3. Clinical Laboratory Data for Sheep Y110 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Adequate	Increased	Increased	Increased
RBC Morph	See below	See below	See below	See below	See Below
Aniso	1+	2+	1+	NR	NR
Poik	1+	3+	1+	2+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	2	4	2	2	1
Part. Thromboplastin Time	33.7	42.7	34.2	49.3	60.2
Prothrombin Time	29.5	26.7	26.8	40.3	36.7
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H4. Clinical Laboratory Data for Sheep Y184 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Hematology					
White Cell Count	7.99	8.2	9.38¹	10.61	7.772
Red Cell Count	11.1	11	10.6	11.5	10
Hemoglobin	125	130	122	136	117
Hematocrit	0.355	0.352	0.342	0.374	0.326
Mean Corp Vol	31.9	31.9	32.2	32.4	32.6
Mean Corp Hemoglobin	11.2	11.8	11.5	11.8	11.7
Mean Corp Hemoglobin Conc	351	370	357	364	360
RDW	24	24.2	23.1	24.5	22.5
Platelet CNT	333	493	596	784	320
Mean Platelet Volume	NR ²	12.3	NR	NR	NR
Differential Cell Count					
% Neutrophils	14	33	22	41	14
% Lymphocytes	78	57	71	50	64
% Monocytes	4	7	6	8	21
% Eosinophils	3	3	1	1	0
% Basophils	1	NR	NR	NR	1
Absolute Differential Values					
Neutrophils	1.12	2.71	2.07	4.34	1.12
Lymphocytes	6.23	4.67	6.66	5.31	4.95
Monocytes	0.32	0.57	0.56	0.85	1.6
Eosinophils	0.24	0.25	0.09	0.11	0.003
Basophils	0.08	NR	NR	NR	0.099
Chemistry					
Glucose	3.9	4.6	3.3	3.2	3.1
Blood Urea Nitrogen	5.5	4.1	5.9	7.8	7.4
Creatinine	90	97.1	72.6	81.7	93.5
BUN/Cr Ratio	15	11	20	24	20
Sodium	144	151	144	151	147
Potassium	4.5	4.6	4.8	4.9	5.1
Na/K Ratio	32	33	30	31	29
Chloride	110	118	112	120	117
Carbon Dioxide	25.5	29.9	27.2	24.8	25.5
Anion Gap	13	8	10	11	10
Calcium	2.33	2.31	2.32	2.57	2.38
Phosphorus	2.48	2.83	2.79	1.95	1.59
Total Protein	70	72	69	74	68
Albumin	24.8	25.68	22.53	24.98	22.63
Globulin	45	46	46	49	45
A/G Ratio	0.5	0.6	0.5	0.5	0.5
Total Bilirubin	8	7	7	8	7
Alkaline Phosphatase	225	200	117	234	211
ALT (Sgpt)	23	35	15	18	14
Gamma gt	31	36	35	26	24
Creatine Phosphokinase	115	118	108	139	189
Calculated Osmolality	286	298	286	301	293
AST (Sgot)	88	103	82	78	74
Sorbital Dehydrogenase-AO	56.7	161.7	88.8	32.9	15.3
Uric Acid	0	0	0	0	12
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

Appendix H4. Clinical Laboratory Data for Sheep Y184 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M
Morphology and Coagulation Parameters					
Platelets	Increased	Adequate	Increased	Increased	Adequate
RBC Morph	See below	See below	See below	See below	Normal
Aniso	1+	2+	1+	1+	NR
Poik	1+	3+	1+	2+	NR
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	2	2	3	3	2
Part. Thromboplastin Time	29.7	37.2	30.5	44.8	59.2
Prothrombin Time	22.5	24.3	26.2	29	42.3
Date of Bleed	3-Apr-07	5-Apr-07	11-Apr-07	18-Apr-07	2-May-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H5. Clinical Laboratory Data for Sheep G188 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	7.96	8.56	6.94	7.86	6.39	8.66	6.13
Red Cell Count	11.7	11.8	12.5¹	12.9	12.3	13.1	13.6
Hemoglobin	126	120	133	131	131	132	141
Hematocrit	0.319	0.324	0.341	0.347	0.339	0.352	0.362
Mean Corp Vol	27.1	27.3	27.3	26.9	27.5	26.9	26.5
Mean Corp Hemoglobin	10.7	10.2	10.7	10.1	10.6	10.1	10.3
Mean Corp Hemoglobin Conc	395	372	389	377	386	374	388
RDW	24.1	24.9	27	23.4	21.2	26.5	24.3
Platelet CNT	581	926	1,124	989	915	1,014	1,162
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR
Differential Cell Count							
% Neutrophils	58	58	32	16	28	50	37
% Lymphocytes	35	38	62	73	67	42	55
% Monocytes	6	3	3	6	4	1	1
% Eosinophils	1	1	3	5	0	7	7
% Basophils	NR	NR	NR	NR	1	NR	NR
Absolute Differential Values							
Neutrophils	4.61	4.96	2.22	1.26	1.76	4.32	2.27
Lymphocytes	2.79	3.25	4.3	5.74	4.27	3.64	3.37
Monocytes	0.48	0.26	0.21	0.47	0.279	0.09	0.06
Eosinophils	0.08	0.09	0.21	0.39	0.024	0.61	0.43
Basophils	NR	NR	NR	NR	0.049	NR	NR
Chemistry							
Glucose	3.5	4.2	3.3	3.5	3.9	3.2	3
Blood Urea Nitrogen	4.7	3	6.2	7.9	8.9	8.3	7.3
Creatinine	85.2	89.3	84.6	84.6	79.8	83.4	100.2
BUN/Cr Ratio	14	8	18	23	28	25	18
Sodium	148	152	153	143	146	143	148
Potassium	4.9	4.5	5.4	6.8	4.7	4.8	4.6
Na/K Ratio	30	34	28	21	31	30	32
Chloride	111	118	116	111	112	110	110
Carbon Dioxide	28.4	26.2	31.2	27.8	24.9	22.9	23.8
Anion Gap	14	12	11	11	14	15	19
Calcium	2.55	2.6	2.65	2.64	2.66	2.56	2.62
Phosphorus	2.65	2.2	2.23	2.31	2.01	2.22	2.1
Total Protein	71	77	76	72	70	74	78
Albumin	27.64	31.2	28.43	29.4	30.1	32.45	32.48
Globulin	43	46	48	43	40	42	46
A/G Ratio	0.6	0.7	0.6	0.7	0.8	0.8	0.7
Total Bilirubin	6	5	5	6	6	5	4
Alkaline Phosphatase	273	298	162	249	304	237	148
ALT (Sgpt)	21	19	18	20	34	42	41
Gamma gt	20	20	20	23	22	25	27
Creatine Phosphokinase	86	409	62	239	233	119	93
Calculated Osmolality	293	298	304	290	293	286	294
AST (Sgot)	95	106	73	89	114	131	129
Sorbital Dehydrogenase-AO	27.2	29.5	20.5	24.4	28.2	52	25.7
Uric Acid	5	2	2	4	7	3	0
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07	19-Jun-07	18-Jul-07

Appendix H5. Clinical Laboratory Data for Sheep G188 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Increased	Increased	Increased	Increased	Increased	Increased	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	NR	NR	NR	NR	1+	1+
Poik	NR	1+	1+	2+	2+	1+	NR
Fibrinogen Degradation Products	Positive @ 1:2 & 1:8	Negative	Negative	Negative	Negative	Positive	Negative
Fibrinogen Semi Quantitative	4	2	5	1	1	1	2
Part. Thromboplastin Time	28.2	>60	54.5	38.1	31.3	>60	28.3
Prothrombin Time	23.3	41.4	34.2	28	24.3	>60	32
Date of Bleed	24-Apr-07	26-Apr-07	2-May-07	9-May-07	23-May-07	19-Jun-07	18-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H6. Clinical Laboratory Data for Sheep G196 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	7.52	8.38	10.21¹	7.55	4.42	6.84	6.92
Red Cell Count	11	11.1	10.6	10.9	10.3	10.1	11.4
Hemoglobin	131	130	131	136	133	128	137
Hematocrit	0.362	0.363	0.352	0.367	0.36	0.37	0.396
Mean Corp Vol	33.1	32.6	33.2	33.7	35	36.5	34.9
Mean Corp Hemoglobin	11.9	11.7	12.3	12.5	12.9	12.7	12.1
Mean Corp Hemoglobin Conc	361	360	372	371	370	347	347
RDW	20.4	21.3	23.1	24	23.6	23.8	20.7
Platelet CNT	169	153	323	263	110	61.3	130
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR
Differential Cell Count							
% Neutrophils	46	38	53	30	32	16	22
% Lymphocytes	43	53	43	55	61	80	73
% Monocytes	8	8	4	13	7	3	2
% Eosinophils	2	0	NR	1		1	2
% Basophils	1	1	NR	0	NR	NR	1
Absolute Differential Values							
Neutrophils	3.46	3.16	5.41	2.3	1.41	1.09	1.52
Lymphocytes	3.23	4.45	4.39	4.12	2.7	5.47	5.05
Monocytes	0.6	0.692	0.41	1.01	0.31	0.21	0.14
Eosinophils	0.15	0.008	NR	0.79		0.07	0.14
Basophils	0.08	0.066	NR	0.036	NR	NR	0.07
Chemistry							
Glucose	4	5.5	3.4	3.6	0.9	3	3.1
Blood Urea Nitrogen	7.3	4.1	8	7.4	9.2	9.2	8.9
Creatinine	77.8	82.9	81	94.9	84	79.1	79.3
BUN/Cr Ratio	24	12	25	20	28	29	28
Sodium	145	149	149	145	147	144	140
Potassium	5.1	4.5	4.7	4.6	5.6	4.7	4.9
Na/K Ratio	28	33	32	32	26	31	29
Chloride	111	114	113	110	111	109	108
Carbon Dioxide	29.8	25.1	27.7	25.9	22.9	23.7	25.2
Anion Gap	9	14	13	14	19	16	12
Calcium	2.48	2.52	2.54	2.59	2.59	2.51	2.64
Phosphorus	2.21	2.12	2	1.99	1.94	1.64	1.75
Total Protein	69	75	67	70	73	72	71
Albumin	31.06	32.91	26.96	32.45	32.02	33	33.81
Globulin	38	42	37	38	41	39	37
A/G Ratio	0.8	0.8	0.8	0.9	0.8	0.8	0.9
Total Bilirubin	5	5	5	6	6	4	2
Alkaline Phosphatase	128	144	123	116	116	115	85
ALT (Sgpt)	34	32	27	32	31	47	30
Gamma gt	61	55	62	31	24	21	18
Creatine Phosphokinase	72	90	67	140	1,677	400	1,089
Calculated Osmolality	290	295	297	289	294	289	282
AST (Sgot)	126	130	94	110	155	157	166
Sorbital Dehydrogenase-AO	26.7	28.4	17.6	23.3	28.8	32.5	27.5
Uric Acid	3	5	10	15	1	2	0
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	4-Jul-07	1-Aug-07

Appendix H6. Clinical Laboratory Data for Sheep G196 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	NR	1+	NR	NR	1+	2+
Poik	NR	1+	NR	1+	1+	1+	2+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	2	2	1	2	1	1
Part. Thromboplastin Time	44.7	>60	39.1	41.3	56	53.5	>60
Prothrombin Time	24	30.03	27.5	24.7	31.5	50.1	35
Date of Bleed	8-May-07	10-May-07	16-May-07	23-May-07	6-Jun-07	4-Jul-07	1-Aug-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H7. Clinical Laboratory Data for Sheep G253 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	9.98¹	12.31	8.45	10.31	7.84	8.24	8.78
Red Cell Count	10.4	9.13	10.1	10.9	10.4	10.9	11.2
Hemoglobin	128	115	122	137	127	129	135
Hematocrit	0.34	0.303	0.34	0.36	0.345	0.354	0.369
Mean Corp Vol	32.8	33.2	33.7	32.9	33.1	32.5	32.8
Mean Corp Hemoglobin	12.3	12.5	12.1	12.5	12.2	11.8	12
Mean Corp Hemoglobin Conc	376	378	359	380	368	364	366
RDW	21.5	20.7	22.1	22.8	22.7	20.2	21.5
Platelet CNT	399	383	332	437	529	409	602
Mean Platelet Volume	NR ²	NR	NR	NR	9.1	NR	NR
Differential Cell Count							
% Neutrophils	24	41	17	26	15	23	27
% Lymphocytes	69	53	77	63	77	74	66
% Monocytes	5	3	4	4	1	3	4
% Eosinophils	0	3	2	6	7	NR	3
% Basophils	1	NR	NR	1	NR	NR	NR
Absolute Differential Values							
Neutrophils	2.43	5.05	1.43	2.68	1.17	1.89	2.38
Lymphocytes	6.91	6.52	6.51	6.5	6.04	6.1	5.79
Monocytes	0.519	0.37	0.34	0.41	0.08	0.25	0.35
Eosinophils	0.024	0.37	0.17	0.62	0.55	NR	0.26
Basophils	0.091	NR	NR	0.1	NR	NR	NR
Chemistry							
Glucose	4	4.3	3.6	3.1	3.6	3.4	3.2
Blood Urea Nitrogen	3.9	2.8	6.1	7.2	7.9	9.7	8.7
Creatinine	79.6	85.7	71.1	91.5	75.4	68.4	95.6
BUN/Cr Ratio	12	8	22	20	26	36	23
Sodium	147	150	146	149	143	143	142
Potassium	4.7	4.4	5.2	5.4	4.5	4.8	4.7
Na/K Ratio	31	34	28	28	32	30	30
Chloride	111	114	108	112	107	107	106
Carbon Dioxide	25.7	26.9	27.6	26.6	29.3	25.9	27
Anion Gap	15	14	16	16	11	15	14
Calcium	2.6	2.55	2.54	2.74	2.6	2.47	2.62
Phosphorus	2.58	2.41	2.53	2.95	2.37	2.4	2.06
Total Protein	76	76	71	83	68	67	74
Albumin	29.23	29.55	28.18	32.45	30.27	28.85	28.52
Globulin	47	46	43	51	38	38	45
A/G Ratio	0.6	0.6	0.7	0.6	0.8	0.8	0.6
Total Bilirubin	7	6	5	8	7	3	6
Alkaline Phosphatase	234	237	203	210	231	244	170
ALT (Sgpt)	27	34	27	29	31	39	36
Gamma gt	74	68	68	76	67	58	62
Creatine Phosphokinase	92	217	175	158	288	4,786	154
Calculated Osmolality	290	294	291	297	286	288	285
AST (Sgot)	67	93	76	75	107	174	142
Sorbital Dehydrogenase-AO	22.3	123	24.5	39.2	46.1	64.5	75.7
Uric Acid	1	7	4	4	0	0	0
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

Appendix H7. Clinical Laboratory Data for Sheep G253 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	Normal	See Below
Aniso	NR	NR	NR	1+	1+	NR	1+
Poik	NR	1+	2+	NR	1+	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	2	1	2	1	1	1
Part. Thromboplastin Time	39.5	>60	32.1	35	36.7	97.4	55.3
Prothrombin Time	24.3	36.3	25.5	29.1	31.2	>100	35.8
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H8. Clinical Laboratory Data for Sheep G410 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Hematology							
White Cell Count	12.81¹	12.1	13.31	12.8	11.9	12.3	8.7
Red Cell Count	10.8	9.6	9.51	10.5	10.2	10.9	10.4
Hemoglobin	122	108	103	116	114	116	111
Hematocrit	0.325	0.287	0.292	0.315	0.302	0.317	0.308
Mean Corp Vol	30.1	29.9	30.7	29.9	29.5	29	29.6
Mean Corp Hemoglobin	11.3	11.2	10.8	11	11.1	10.6	10.6
Mean Corp Hemoglobin Conc	375	375	351	367	377	367	359
RDW	22.2	20.7	20.7	20	21.9	20.7	21.3
Platelet CNT	346	395	259	659	508	576	332
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR
Differential Cell Count							
% Neutrophils	24	39	47	40	26	29	41
% Lymphocytes	54	55	48	53	66	63	57
% Monocytes	18	2	3	2	1	5	NR
% Eosinophils	4	3	1	5	6	3	2
% Basophils	NR	1	1	NR	1	NR	NR
Absolute Differential Values							
Neutrophils	3.07	4.72	6.26	5.12	3.1	3.56	3.57
Lymphocytes	6.92	6.7	6.39	6.78	7.85	7.75	4.96
Monocytes	2.31	0.201	0.4	0.26	0.12	0.62	NR
Eosinophils	0.51	0.346	0.13	0.64	0.71	0.37	0.17
Basophils	NR	0.089	0.13	NR	0.12	NR	NR
Chemistry							
Glucose	3.6	4.2	3.5	3.5	3.4	3.4	3.2
Blood Urea Nitrogen	5.7	3.1	8	8.1	7.1	8.8	7.8
Creatinine	82.9	79.8	67.1	78.6	70.2	65.2	72.4
BUN/Cr Ratio	17	10	30	26	25	34	27
Sodium	148	150	144	151	147	144	143
Potassium	4.9	4.9	5.2	5	5	5.1	4.7
Na/K Ratio	30	31	28	30	29	28	30
Chloride	113	115	112	115	111	110	108
Carbon Dioxide	22.5	27.7	26.5	26.5	28	26.9	24.5
Anion Gap	17	12	11	15	13	12	15
Calcium	2.59	2.58	2.49	2.61	2.51	2.58	2.57
Phosphorus	2.15	1.89	2.35	2.43	2.15	2.03	1.69
Total Protein	73	74	70	76	73	72	79
Albumin	31.43	30.71	29.13	30.18	31.17	32.04	32.28
Globulin	42	43	41	46	42	40	47
A/G Ratio	0.8	0.7	0.7	0.7	0.7	0.8	0.7
Total Bilirubin	6	5	5	6	5	5	3
Alkaline Phosphatase	268	291	236	208	274	282	135
ALT (Sgpt)	31	35	27	27	29	32	33
Gamma gt	87	83	84	78	76	76	72
Creatine Phosphokinase	60	106	57	51	82	170	359
Calculated Osmolality	294	295	289	302	293	290	286
AST (Sgot)	89	98	78	77	109	117	128
Sorbital Dehydrogenase-AO	18.2	92.9	13.2	1.7	31.9	49.5	29.2
Uric Acid	5	5	9	4	2	6	0
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

Appendix H8. Clinical Laboratory Data for Sheep G410 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M
Morphology and Coagulation Parameters							
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Increased	Adequate
RBC Morph	Normal	Normal	See Below	See Below	See Below	Normal	See Below
Aniso	NR	NR	NR	1+	1+	NR	1+
Poik	NR	NR	1+	NR	NR	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	3	2	4	2	1	1
Part. Thromboplastin Time	32.5	>60	54.5	50	46.9	63.1	62
Prothrombin Time	24.7	32.3	26.3	32.1	34.5	39.6	32
Date of Bleed	1-May-07	3-May-07	9-May-07	16-May-07	30-May-07	26-Jun-07	25-Jul-07

¹ Numbers in bold are outside of the reference range² Not Reported

Appendix H9. Clinical Laboratory Data for Sheep R27 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	5.02	5.93	7.61	6.01	5.95	6.51	5.81	5.14
Red Cell Count	12.1¹	11	9.77	10.7	11.6	12.8	12.9	13
Hemoglobin	129	116	110	113	122	132	133	140
Hematocrit	0.346	0.319	0.293	0.317	0.342	0.36	0.36	0.365
Mean Corp Vol	28.7	29	30	29.7	29.5	28.1	27.9	28.2
Mean Corp Hemoglobin	10.7	10.5	11.2	10.6	10.5	10.3	10.3	10.8
Mean Corp Hemoglobin Conc	373	363	375	358	357	366	370	384
RDW	21.6	21	21.7	21.2	21.2	21.6	24.7	27
Platelet CNT	280	149	109	296	441	594	373	857
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv
Differential Cell Count								
% Neutrophils	21	22	21	14	24	32	21	30
% Lymphocytes	73	74	75	83	72	61	70	65
% Monocytes	3	1	3	1	1	2	8	5
% Eosinophils	3	3	1	2	3	4	1	NR
% Basophils	NR	NR	NR	NR	NR	1	NR	NR
Absolute Differential Values								
Neutrophils	1.06	1.3	1.59	0.84	1.43	2.08	1.22	1.54
Lymphocytes	3.66	4.39	5.71	4.99	4.28	3.97	4.07	3.34
Monocytes	0.15	0.06	0.23	0.06	0.06	0.13	0.46	0.26
Eosinophils	0.15	0.18	0.08	0.12	0.18	0.26	0.06	NR
Basophils	NR	NR	NR	NR	NR	0.07	NR	NR
Chemistry								
Glucose	3.1	2.4	2.7	2.9	3.1	3.2	3.5	3.6
Blood Urea Nitrogen	6.1	7	7.8	8.2	8.3	7.7	7.5	6.7
Creatinine	96	85.9	93.9	94.5	87.9	87.9	94.4	91.2
BUN/Cr Ratio	16	20	21	22	24	22	20	18
Sodium	146	145	145	141	144	142	143	145
Potassium	4.4	4.3	4.5	4.5	4.2	5.1	5	5.1
Na/K Ratio	33	34	32	31	34	28	29	28
Chloride	111	112	110	109	112	108	108	109
Carbon Dioxide	21.1	22.5	26.2	23.4	24	25.2	25.8	29.3
Anion Gap	18	15	13	13	12	14	14	12
Calcium	2.45	2.32	2.31	2.46	2.57	2.4	2.47	2.5
Phosphorus	1.94	2.07	2.27	1.91	1.62	1.96	1.65	2.19
Total Protein	72	72	75	74	76	77	77	75
Albumin	27.72	28.08	26.44	27.22	29.69	29.31	30.55	32.36
Globulin	44	44	49	47	46	48	46	43
A/G Ratio	0.6	0.6	0.5	0.6	0.6	0.6	0.7	0.8
Total Bilirubin	4	4	3	4	3	3	2	3
Alkaline Phosphatase	283	252	200	212	243	211	218	163
ALT (Sgpt)	26	29	24	25	24	26	28	30
Gamma gt	18	14	19	32	32	39	35	63
Creatine Phosphokinase	49	181	136	104	87	507	151	221
Calculated Osmolality	289	287	289	282	287	285	286	289
AST (Sgot)	107	120	81	98	105	106	100	96
Sorbital Dehydrogenase-AO	59.8	59.7	20.4	24.7	22.5	25.1	32.3	13.6
Uric Acid	5	10	8	0	0	0	0	0
Date of Bleed ³	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

Appendix H9. Clinical Laboratory Data for Sheep R27 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Increased
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	1+	1+	1+	NR	1+	NR
Poik	1+	2+	NR	3+	1+	1+	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Positive	Positive @ 1:2, 1:8	Negative	Positive
Fibrinogen Semi Quantitative	2	1	2	1	2	2	1	2
Part. Thromboplastin Time	48	> 60	39.2	54	50.5	> 60	36.6	> 60
Prothrombin Time	34.5	38.7	35.7	32.8	40.1	> 60	32.2	> 60
Date of Bleed	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H10. Clinical Laboratory Data for Sheep R32 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	7.79	9.01	6.4	8.49	8.02	7.82	3.67	4.65
Red Cell Count	10.9	10.5	10.1	11	11.6	12.4¹	8.07	12
Hemoglobin	120	115	112	121	130	134	113	138
Hematocrit	0.332	0.314	0.303	0.328	0.347	0.359	0.263	0.369
Mean Corp Vol	30.4	29.9	30	29.8	29.8	28.8	32.6	30.6
Mean Corp Hemoglobin	10.9	10.9	11	11	11.2	10.8	14	11.4
Mean Corp Hemoglobin Conc	360	365	369	370	374	373	429	373
RDW	21.3	20.1	21.7	21.7	24.9	24.2	21.8	22.4
Platelet CNT	265	206	703	507	536	494	154	694
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count								
% Neutrophils	32	67	18	49	48	28	28	39
% Lymphocytes	50	25	77	50	48	53	67	52
% Monocytes	16	6	2	1	1	1	2	7
% Eosinophils	0	2	3	0	3	17	3	1
% Basophils	2	NR	NR	0	NR	1	NR	1
Absolute Differential Values								
Neutrophils	2.52	6.04	1.15	4.15	3.85	2.19	1.03	1.8
Lymphocytes	3.87	2.25	4.93	4.22	3.85	4.14	2.46	2.42
Monocytes	1.22	0.54	0.13	0.84	0.08	0.08	0.07	0.33
Eosinophils	0.038	0.18	0.19	0.017	0.24	1.33	0.11	0.05
Basophils	0.133	NR	NR	0.012	NR	0.08		0.05
Chemistry								
Glucose	3.7	5.2	4	4.2	3.3	3.1	3.1	3.4
Blood Urea Nitrogen	6.2	2.5	4.8	4.8	6.1	8.2	7	6.4
Creatinine	65.3	66.5	59.5	77.5	69.8	72.1	66.6	82.8
BUN/Cr Ratio	24	9	20	16	22	29	26	19
Sodium	143	146	149	145	145	147	143	146
Potassium	4.5	4.4	4.8	5	4.5	4.6	3.8	4.7
Na/K Ratio	32	33	31	29	32	32	38	31
Chloride	109	114	114	110	109	111	109	112
Carbon Dioxide	25.6	20.9	28.9	26.1	26.5	25.1	24.7	27.5
Anion Gap	13	16	11	14	14	16	13	11
Calcium	2.7	2.49	2.57	2.67	2.52	2.63	2.73	2.72
Phosphorus	2.16	2.06	2.06	2.7	2.78	1.86	1.8	2.02
Total Protein	70	70	65	64	71	72	78	74
Albumin	32.26	31.88	28.01	29.75	30.63	31.75	33.09	35.48
Globulin	38	38	37	34	40	40	45	39
A/G Ratio	0.9	0.8	0.8	0.9	0.8	0.8	0.7	0.9
Total Bilirubin	7	6	6	8	7	5	4	4
Alkaline Phosphatase	321	293	164	228	170	255	151	142
ALT (Sgpt)	33	33	25	29	28	31	39	39
Gamma gt	71	65	73	71	76	70	65	75
Creatine Phosphokinase	81	250	53	804	148	97	144	132
Calculated Osmolality	284	287	295	288	287	293	283	290
AST (Sgot)	113	117	77	95	106	131	142	114
Sorbital Dehydrogenase-AO	23.6	25.5	1	15.6	51.4	28.6	28.7	20
Uric Acid	9	4	5	5	0	0	0	4
Date of Bleed ³	8-May	10-May	16-May	23-May	6-Jun	4-Jul	1-Aug	24-Oct

Appendix H10. Clinical Laboratory Data for Sheep R32 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Increased	Increased	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	Normal	Normal	See Below	See Below	See Below
Aniso	NR	1+	1+	NR	NR	1+	1+	1+
Poik	NR	1+	NR	NR	NR	NR	1+	NR
Fibrinogen Degradation Products	Negative	Negative	Positive @ 1:2	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	3	3	2	2	1	2	2
Part. Thromboplastin Time	32.5	47.4	> 60	41	48.4	40	> 60	35.7
Prothrombin Time	24.7	29	> 60	26.7	35.6	35.6	35.1	31.7
Date of Bleed ³	8-May	10-May	16-May	23-May	6-Jun	4-Jul	1-Aug	24-Oct

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H11. Clinical Laboratory Data for Sheep R184 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	10.9¹	13	9.67	6	6.55	9.75	8.73	7.6
Red Cell Count	11.1	11.9	10.7	11.8	7.75	10.9	11.3	12.8
Hemoglobin	132	136	126	136	105	130	135	143
Hematocrit	0.347	0.372	0.345	0.382	0.303	0.38	0.384	0.393
Mean Corp Vol	31.3	31.4	32.1	32.4	39	34.9	34	30.7
Mean Corp Hemoglobin	11.9	11.5	11.8	11.6	13.6	11.9	11.9	11.2
Mean Corp Hemoglobin Conc	380	365	366	356	348	342	351	363
RDW	20.5	21.5	21.5	23.5	24.9	24.5	24	24.1
Platelet CNT	659	585	765	410	99.3	527	366	677
Mean Platelet Volume	10.8	7.16	7.68	NR ²	NR	7.45	NR	inv
Differential Cell Count								
% Neutrophils	24	41	18	29	24	27	33	29
% Lymphocytes	61	44	72	69	72	59	62	53
% Monocytes	3	1	3	NR	1	6	1	6
% Eosinophils	12	13	7	2	3	8	4	12
% Basophils	NR	1	NR	NR	NR	NR	NR	NR
Absolute Differential Values								
Neutrophils	2.61	5.33	1.74	1.74	1.56	2.63	2.88	2.2
Lymphocytes	6.65	5.72	6.96	4.14	4.72	5.75	5.41	4.03
Monocytes	0.33	0.13	0.29	NR	0.07	0.59	0.09	0.46
Eosinophils	1.31	1.69	0.68	0.12	0.2	0.78	0.35	0.91
Basophils	NR	0.13	NR	NR	NR	NR	NR	NR
Chemistry								
Glucose	4	4.5	3.6	0.6	3.3	3.3	3.5	4.1
Blood Urea Nitrogen	5.8	3.8	6.6	9.1	9.7	8.5	6.9	5.9
Creatinine	105.9	84.4	100.4	104.8	101.7	94.5	97.3	108.1
BUN/Cr Ratio	14	11	17	22	24	23	18	14
Sodium	145	148	147	143	144	142	140	140
Potassium	4.4	4.2	4.6	4.6	5	4.4	4.5	5.1
Na/K Ratio	33	35	32	31	29	32	31	27
Chloride	108	115	111	108	109	112	106	106
Carbon Dioxide	24	22.4	26.8	22.5	24.3	20.5	23.5	28.2
Anion Gap	17	15	14	17	16	14	15	11
Calcium	2.52	2.43	2.54	2.6	2.62	2.55	2.5	2.57
Phosphorus	1.74	1.81	1.69	1.61	1.99	1.39	1.11	1.84
Total Protein	71	76	73	78	85	77	75	73
Albumin	25.92	28.38	26.73	29.29	39.34	26.52	27.51	27.77
Globulin	45	48	46	49	45	50	47	45
A/G Ratio	0.6	0.6	0.6	0.6	0.9	0.5	0.6	0.6
Total Bilirubin	4	4	4	5	4	3	2	4
Alkaline Phosphatase	228	213	131	155	102	109	135	123
ALT (Sgpt)	26	32	27	28	24	22	26	25
Gamma gt	31	38	51	70	59	58	47	90
Creatine Phosphokinase	97	183	73	70	84	76	81	87
Calculated Osmolality	288	291	292	284	290	284	279	280
AST (Sgot)	118	136	104	115	99	110	132	112
Sorbital Dehydrogenase-AO	31.6	139	18.4	26.1	22.9	19.9	26.1	19.1
Uric Acid	2	0	0	0	0	1	5	0
Date of Bleed ³	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

Appendix H11. Clinical Laboratory Data for Sheep R184 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	Normal
Aniso	1+	1+	1+	1+	1+	NR	1+	NR
Poik	NR	NR	NR	1+	1+	1+	NR	NR
Fibrinogen Degradation Products	Negative	Positive @ 1:2	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	3	3	1	2	3	3	1
Part. Thromboplastin Time	42	36.3	35.2	68	>60	46.1	44.2	>60
Prothrombin Time	37.5	33.8	31.6	33.5	>60	35.3	38.3	33.3
Date of Bleed	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H12. Clinical Laboratory Data for Sheep R199 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Hematology								
White Cell Count	4.91	6.86	5.32	5.88	5.4	5.85	5.06	3.68
Red Cell Count	10.8	10.7	11.3	11.5	12.7¹	12.4	11.9	12.6
Hemoglobin	124	118	127	129	136	131	126	141
Hematocrit	0.32	0.316	0.336	0.34	0.375	0.356	0.344	0.387
Mean Corp Vol	29.5	29.5	29.7	29.5	29.6	28.6	28.8	30.8
Mean Corp Hemoglobin	11.4	11	11.2	11.2	10.8	10.5	10.5	11.2
Mean Corp Hemoglobin Conc	386	372	378	380	363	368	366	364
RDW	21.2	22.8	21.9	22.3	23.7	23.8	23.3	25.9
Platelet CNT	188	101	177	361	159	193	88.6	341
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv
Differential Cell Count								
% Neutrophils	32	58	30	43	39	31	28	47
% Lymphocytes	58	38	60	53	47	55	63	47
% Monocytes	1	3	4	1	4	3	4	5
% Eosinophils	9	1	6	3	10	11	4	1
% Basophils	NR	NR	NR	NR	NR	NR	1	NR
Absolute Differential Values								
Neutrophils	1.57	3.97	1.6	2.52	2.1	1.81	1.42	1.73
Lymphocytes	2.85	2.61	3.19	3.12	2.54	3.22	3.19	1.73
Monocytes	0.05	0.21	0.21	0.06	0.22	0.18	0.2	0.18
Eosinophils	0.44	0.07	0.32	0.18	0.54	0.64	0.2	0.04
Basophils	NR	NR	NR	NR	NR	NR	0.05	NR
Chemistry								
Glucose	4	4.8	3.3	3.4	4.1	4	3.5	4.4
Blood Urea Nitrogen	6.2	3.4	5.8	7.5	8.4	6.7	5.8	6
Creatinine	89.6	72.2	83.8	71.5	84.9	88.1	80.4	94.3
BUN/Cr Ratio	17	12	17	26	25	19	18	16
Sodium	143	149	149	142	145	143	143	143
Potassium	4.7	4.2	4.5	4.7	5.3	4.5	5.3	5.2
Na/K Ratio	30	35	33	30	27	32	27	28
Chloride	109	114	111	105	112	109	106	109
Carbon Dioxide	21.4	26.6	27.1	27.1	23.1	22	26.3	26.3
Anion Gap	17	13	15	15	15	17	16	13
Calcium	2.51	2.54	2.49	2.6	2.59	2.59	2.52	2.66
Phosphorus	2.36	2.02	2.29	2.49	1.85	1.91	2.35	2.28
Total Protein	72	72	69	71	73	74	74	75
Albumin	34.65	35.31	32.66	34.88	35.6	42.77	32.87	34.84
Globulin	37	37	36	36	37	31	41	40
A/G Ratio	0.9	1	0.9	1	1	1.4	0.8	0.9
Total Bilirubin	5	4	4	5	3	4	3	4
Alkaline Phosphatase	223	242	151	153	201	169	136	104
ALT (Sgpt)	41	35	31	37	33	34	37	37
Gamma gt	68	72	69	73	76	71	75	89
Creatine Phosphokinase	131	217	97	189	124	428	515	792
Calculated Osmolality	285	293	295	284	292	285	285	286
AST (Sgot)	163	158	140	184	194	168	153	164
Sorbital Dehydrogenase-AO	63.9	34.4	56.4	68.5	93.5	76	83.7	37.1
Uric Acid	3	0	6	4	0	2	0	0
Date of Bleed ³	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

Appendix H12. Clinical Laboratory Data for Sheep R199 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M
Morphology and Coagulation Parameters								
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See below	See below	See below	See below	See below	Normal	See below	Normal
Aniso	2+	1+	1+	1+	1+	1+	1+	NR
Poik	NR	NR	NR	1+	1+	NR	NR	NR
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Positive
Fibrinogen Semi Quantitative	1	3	1	1	2	1	1	1
Part. Thromboplastin Time	57.9	>60	42.5	71.2	>60	45.3	42.2	40.5
Prothrombin Time	39.1	38.8	35.8	34.5	35.8	53	37.7	30.3
Date of Bleed	10-Jul	12-Jul	18-Jul	25-Jul	8-Aug	5-Sep	3-Oct	19-Dec

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H13. Clinical Laboratory Data for Sheep B29 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	10.1¹	12.51	11.01	12	8.1	8.82	9.48	9.31	7.79
Red Cell Count	13.4	12.6	13.6	13.3	13.3	12.6	14.4	12.3	10.9
Hemoglobin	139	133	139	138	136	133	142	133	111
Hematocrit	0.358	0.34	0.361	0.365	0.359	0.355	0.395	0.346	0.314
Mean Corp Vol	26.7	27	26.6	27.5	27.1	28.2	27.4	28.2	28.9
Mean Corp Hemoglobin	10.4	10.6	10.2	10.4	10.2	10.6	9.84	10.8	10.3
Mean Corp Hemoglobin Conc	389	391	385	377	378	375	359	384	354
RDW	25.4	22.4	25.4	24.8	23.2	23.4	23.8	25.2	19.9
Platelet CNT	611	504	777	637	417	245	633	778	206
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv	NR
Differential Cell Count									
% Neutrophils	27	27	30	39	22	17	12	19	42
% Lymphocytes	63	59	68	59	72	73	78	75	54
% Monocytes	3	3	1	2	2	3	4	5	3
% Eosinophils	7	11	1	NR	4	7	5	1	1
% Basophils	NR	NR	NR	NR	NR	NR	1	NR	NR
Absolute Differential Values									
Neutrophils	2.73	3.37	3.30	4.68	1.79	1.50	1.15	1.77	3.27
Lymphocytes	6.36	7.38	7.49	7.08	5.83	6.44	7.39	6.98	4.21
Monocytes	0.30	0.38	0.11	0.24	0.16	0.26	0.38	0.47	0.23
Eosinophils	0.71	1.38	0.11	NR	0.32	0.62	0.47	0.09	0.08
Basophils	NR	NR	NR	NR	NR	NR	0.09	NR	NR
Chemistry									
Glucose	3.5	3.8	3	2.9	2.5	3.3	3.5	3.9	3.5
Blood Urea Nitrogen	4.7	4	4.9	6	7.1	6.5	5.7	5.2	6.2
Creatinine	80.6	82.3	72.1	82.8	73.3	70.5	84.2	84.4	80.5
BUN/Cr Ratio	15	12	17	18	24	23	17	15	19
Sodium	144	145	143	151	142	143	144	141	144
Potassium	4.7	4.3	4.6	4.7	4.4	4.6	4.8	4.5	4.4
Na/K Ratio	31	34	31	32	32	31	30	31	33
Chloride	106	111	109	112	107	106	107	106	109
Carbon Dioxide	24.9	23.7	28.2	27.1	25.1	28.1	21.7	26.6	25
Anion Gap	18	15	10	17	14	14	20	13	14
Calcium	2.55	2.56	2.63	2.63	2.7	2.66	2.65	2.5	2.37
Phosphorus	2.19	1.9	1.88	2.15	1.93	1.87	1.96	1.79	1.66
Total Protein	75	77	74	76	82	80	80	78	81
Albumin	32.67	33.49	32.85	31.9	33.55	34.22	31.63	32.53	27.01
Globulin	42	44	41	44	48	46	48	45	54
A/G Ratio	0.8	0.8	0.8	0.7	0.7	0.7	0.7	0.7	0.5
Total Bilirubin	9	4	4	4	3	4	3	3	3
Alkaline Phosphatase	227	244	193	191	157	161	139	93	109
ALT (Sgpt)	26	31	27	26	23	28	26	27	19
Gamma gt	79	89	104	105	96	93	70	72	110
Creatine Phosphokinase	114	502	110	168	78	105	463	200	154
Calculated Osmolality	285	285	282	299	282	284	286	280	286
AST (Sgot)	126	175	162	96	96	98	95	92	70
Sorbital Dehydrogenase-AO	71.3	178.5	189.6	58.2	65.8	75.1	69.1	24.3	69.8
Uric Acid	0	0	0	0	0	0	1	0	4
Date of Bleed ³	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

Appendix H13. Clinical Laboratory Data for Sheep B29 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Adequate	Increased	Adequate	Adequate	Adequate	Adequate	Adequate	Increased	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	2+	1+	1+	1+	1+	NR	---
Poik	1+	1+	2+	NR	1+	NR	1+	1+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative	Positive @ 1:2
Fibrinogen Semi Quantitative	1	2	2	2	1	1	1	1	1
Part. Thromboplastin Time	55	>60	60.3	37.3	>60	43.3	65.9	43.5	>60
Prothrombin Time	28.3	32.8	38.8	28.2	26.3	27.3	38.8	24	28.1
Date of Bleed	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H14. Clinical Laboratory Data for Sheep B34 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	7.68	8.89	9.34¹	8.13	8.1	5.54	5.84	6.51	5.5
Red Cell Count	9.92	11.7	11.9	12.4	12.7	12.5	9.87	12.6	13.7
Hemoglobin	126	135	136	140	139	133	117	149	154
Hematocrit	0.317	0.361	0.364	0.381	0.396	0.39	0.347	0.441	0.47
Mean Corp Vol	32	30.9	30.6	30.8	31	31.1	35.2	35	34.3
Mean Corp Hemoglobin	12.7	11.5	11.4	11.3	10.9	10.6	11.8	11.8	11.2
Mean Corp Hemoglobin Conc	396	373	372	368	351	340	337	338	327
RDW	24.8	22.2	22.9	25.2	25.5	25	27.4	26.2	25.7
Platelet CNT	1,478	621	670	831	388	149	413	437	349
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	inv	NR
Differential Cell Count									
% Neutrophils	22	57	27	25	20	25	22	41	28
% Lymphocytes	71	36	70	72	68	67	62	49	57
% Monocytes	1	1	2	1	4	2	2	2	3
% Eosinophils	6	6	1	2	8	6	14	8	12
% Basophils	NR	NR	0	NR	NR	NR	NR	NR	NR
Absolute Differential Values									
Neutrophils	1.69	5.07	2.52	2.04	1.62	1.39	1.28	2.67	1.53
Lymphocytes	5.45	3.2	6.5	5.85	5.51	3.71	3.62	3.19	3.14
Monocytes	0.08	0.09	0.224	0.08	0.32	0.11	0.12	0.13	0.17
Eosinophils	0.46	0.53	0.067	0.16	0.65	0.33	0.82	0.52	0.66
Basophils	NR	NR	0.029	NR	NR	NR	NR	NR	NR
Chemistry									
Glucose	3.5	4.8	3.9	3	3.7	1.7	3.8	4.5	4.5
Blood Urea Nitrogen	4.6	4	6.7	5.5	9.4	8	6.8	6.5	7.4
Creatinine	84.2	92.4	75.8	87.9	95.6	89.8	83.3	85.6	83.4
BUN/Cr Ratio	14	11	22	16	25	22	21	19	22
Sodium	147	148	145	147	145	143	141	141	145
Potassium	5	5	5	4.9	4.9	5.3	5.2	5.2	5.4
Na/K Ratio	29	30	29	30	30	27	27	27	27
Chloride	108	117	113	110	113	105	110	110	113
Carbon Dioxide	20.9	20.6	22	26.4	16.5	21.1	22.8	20.4	18.7
Anion Gap	23	15	15	16	20	22	13	16	19
Calcium	2.62	2.67	2.58	2.7	2.76	2.6	2.66	2.68	2.74
Phosphorus	2.16	1.51	1.69	1.9	1.74	1.93	2.07	1.68	1.53
Total Protein	78	82	75	79	83	85	82	84	81
Albumin	32.32	33.76	31.67	32.86	33.8	32.43	30.6	37.1	35.53
Globulin	46	48	43	46	49	53	51	47	45
A/G Ratio	0.7	0.7	0.7	0.7	0.7	0.6	0.6	0.8	0.8
Total Bilirubin	9	5	5	5	4	3	5	3	2
Alkaline Phosphatase	333	314	297	346	270	306	247	285	305
ALT (Sgpt)	33	37	28	59	29	33	41	38	33
Gamma gt	75	82	88	107	95	85	81	93	116
Creatine Phosphokinase	128	355	291	108	113	132	196	259	1135
Calculated Osmolality	291	293	290	291	292	286	283	283	292
AST (Sgot)	187	238	130	478	140	98	93	113	337
Sorbital Dehydrogenase-AO	155.1	213.7	57.8	13.4	75	34.9	26.5	31.2	155.6
Uric Acid	2	0	0	0	0	0	0	0	6
Date of Bleed ³	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

Appendix H14. Clinical Laboratory Data for Sheep B34 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Increased	Adequate	Adequate	Increased	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	1+	1+	1+	1+	1+	1+	1+	NR	NR
Poik	NR	1+	2+	1+	2+	1+	1+	2+	1+
Fibrinogen Degradation Products	Negative	Positive @ 1:2, 1:8	Negative	Negative	Negative	Positive @ 1:2	Negative	Negative	Negative
Fibrinogen Semi Quantitative	Hem	2	1	1	1	1	3	1	1
Part. Thromboplastin Time	64	>60	46.6	43.8	>60	>60	58.2	>60	>60
Prothrombin Time	30.8	>60	29.8	29.8	42.9	52.9	29.2	32.8	51.1
Date of Bleed	3-Jul	5-Jul	11-Jul	18-Jul	1-Aug	29-Aug	26-Sep	19-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H15. Clinical Laboratory Data for Sheep B54 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	10.5¹	12.61	9.01	9.01	7.39	6.4	7.07	4.79	4.33
Red Cell Count	12.2	10.9	11	10.7	10.8	12.1	12.1	11.1	10.7
Hemoglobin	126	117	115	111	115	121	119	124	122
Hematocrit	0.338	0.311	0.303	0.297	0.304	0.33	0.326	0.349	0.346
Mean Corp Vol	27.7	28.4	27.6	27.9	28.2	27.3	26.9	31.6	32.5
Mean Corp Hemoglobin	10.3	10.7	10.5	10.4	10.6	10	9.86	11.2	11.4
Mean Corp Hemoglobin Conc	373	377	379	372	378	368	366	354	352
RDW	23.1	23.4	22.5	23.6	22.3	21.6	23.5	26	23.1
Platelet CNT	432	389	449	699	685	619	706	411	355
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	NR	14.4
Differential Cell Count									
% Neutrophils	60	53	38	49	37	27	36	23	41
% Lymphocytes	39	39	61	49	61	67	51	71	44
% Monocytes	1	2	1	1	NR	5	4	5	13
% Eosinophils	NR	5	NR	1	2	1	9	1	0
% Basophils	NR	1	NR	NR	NR	NR	NR	NR	1
Absolute Differential Values									
Neutrophils	6.29	6.68	3.42	4.42	2.73	1.73	2.54	1.1	1.78
Lymphocytes	4.1	4.92	5.5	4.41	4.51	4.29	3.61	3.4	1.91
Monocytes	0.11	0.25	0.09	0.09	NR	0.32	0.28	0.24	0.562
Eosinophils	NR	0.63	NR	0.09	0.15	0.06	0.64	0.05	0.015
Basophils	NR	0.13	NR	NR	NR	NR	NR	NR	0.063
Chemistry									
Glucose	3.2	2.5	3.4	3.6	3.2	3.4	3.1	3.7	3.3
Blood Urea Nitrogen	7.1	5.1	5.2	6.8	6.7	8.3	6.1	8.7	7.5
Creatinine	86.7	97	89.1	82.9	77.2	85.6	87.2	84.4	86.3
BUN/Cr Ratio	21	13	15	21	22	24	18	26	22
Sodium	140	148	145	142	138	141	141	142	144
Potassium	4.8	4	5	4.7	4.6	4.4	4.3	4.9	4.3
Na/K Ratio	29	37	29	30	30	32	33	29	33
Chloride	108	112	108	109	106	107	106	108	110
Carbon Dioxide	20	21.2	29.2	24.5	22.6	24	26.5	26.9	21.8
Anion Gap	17	19	13	13	14	14	13	12	17
Calcium	2.59	2.6	2.58	3.56	2.58	2.52	2.54	2.6	2.65
Phosphorus	1.71	2.01	2.26	2.26	1.97	2.02	2.14	2.27	1.61
Total Protein	81	81	77	76	79	79	76	75	79
Albumin	31.15	31.26	30.02	30.09	30.99	31.83	29.56	34.05	33.81
Globulin	50	50	47	46	48	47	46	41	45
A/G Ratio	0.6	0.6	0.6	0.7	0.6	0.7	0.6	0.8	0.7
Total Bilirubin	7	6	7	7	6	5	5	6	4
Alkaline Phosphatase	231	190	168	165	150	237	273	250	286
ALT (Sgpt)	29	27	24	23	23	24	25	30	28
Gamma gt	37	34	23	24	53	30	24	30	76
Creatine Phosphokinase	104	135	93	87	126	125	157	112	94
Calculated Osmolality	280	290	288	283	275	282	279	286	287
AST (Sgot)	95	101	86	77	103	108	102	99	107
Sorbital Dehydrogenase-AO	18.7	20.2	13.1	12.5	20.3	21.1	22.5	17.1	18.8
Uric Acid	4	0	0	0	0	0	0	7	9
Date of Bleed ³	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

Appendix H15. Clinical Laboratory Data for Sheep B54 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below	See Below
Aniso	NR	1+	1+	2+	1+	NR	NR	NR	NR
Poik	1+	1+	1+	1+	3+	1+	1+	1+	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Fibrinogen Semi Quantitative	1	2	2	2	1	1	2	1	2
Part. Thromboplastin Time	69	>60	35.2	43.4	46.8	42.3	46.2	76.7	55.5
Prothrombin Time	36	>60	38.7	32.3	36.5	29.9	40.2	60.5	33.1
Date of Bleed	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix H16. Clinical Laboratory Data for Sheep B197 (Embosphere®)

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Hematology									
White Cell Count	9.03	9.88¹	7.67	8.93	10.1	6.1	5.53	5.71	5.96
Red Cell Count	8.14	9.68	10.2	11	11.7	11.6	10.9	11	11.4
Hemoglobin	94.7	117	120	129	139	130	120	131	133
Hematocrit	0.259	0.311	0.324	0.351	0.375	0.375	0.343	0.371	0.389
Mean Corp Vol	31.9	32.1	31.7	32	32	32.2	31.5	33.6	34.1
Mean Corp Hemoglobin	11.6	12.1	11.8	11.8	11.9	11.1	11	11.9	11.7
Mean Corp Hemoglobin Conc	365	376	371	368	371	346	350	354	343
RDW	17	20.8	22.2	20.3	22.7	23	20.2	22.4	23.5
Platelet CNT	251	353	539	428	470	371	138	422	373
Mean Platelet Volume	NR ²	NR	NR	NR	NR	NR	NR	NR	9.41
Differential Cell Count									
% Neutrophils	26	48	18	24	22	19	25	31	36
% Lymphocytes	63	41	72	72	59	67	54	62	47
% Monocytes	4	2	1	4	1	5	7	4	14
% Eosinophils	7	8	9	NR	17	9	14	2	1
% Basophils	NR	1	NR	NR	1	NR	NR	1	2
Absolute Differential Values									
Neutrophils	2.35	4.74	1.38	2.14	2.22	1.15	1.38	1.77	2.16
Lymphocytes	5.69	4.05	5.52	6.43	5.96	4.09	2.99	3.54	2.78
Monocytes	0.36	0.2	0.08	0.36	0.1	0.31	0.39	0.23	0.854
Eosinophils	0.63	0.79	0.69	NR	1.72	0.55	0.77	0.11	0.061
Basophils	NR	0.1	NR	NR	0.1	NR	NR	0.06	0.099
Chemistry									
Glucose	3.5	3.5	3.4	3.8	3	3.9	3.5	4.5	4.2
Blood Urea Nitrogen	5.4	4.5	4.6	5	7.1	6.8	5.2	7.8	6.4
Creatinine	61.3	86.1	65.7	60.3	82	74.4	78.3	71.1	72
BUN/Cr Ratio	22	13	18	21	22	23	17	28	22
Sodium	151	146	145	144	143	146	144	140	147
Potassium	3.7	4.7	4.4	4.4	4.8	4.3	4.4	5	4.8
Na/K Ratio	41	31	33	33	30	34	33	28	31
Chloride	119	110	108	109	107	109	108	107	111
Carbon Dioxide	21.7	25	28.3	26	27.8	25.6	26.4	27.2	23.1
Anion Gap	14	16	13	13	13	16	14	11	18
Calcium	2.17	2.69	2.69	2.63	2.75	2.74	2.74	2.57	2.68
Phosphorus	1.58	1.61	2.08	1.69	1.74	1.61	1.66	1.8	1.6
Total Protein	63	78	76	73	80	85	80	76	80
Albumin	27.38	34.01	33.9	33.73	35.19	34.79	33.99	35.34	36.16
Globulin	36	44	42	39	45	50	46	41	44
A/G Ratio	0.8	0.8	0.8	0.9	0.8	0.7	0.7	0.9	0.8
Total Bilirubin	3	5	5	4	5	3	3	4	3
Alkaline Phosphatase	187	177	170	186	175	218	185	165	183
ALT (Sgpt)	27	34	32	29	28	26	24	30	32
Gamma gt	24	35	61	29	26	28	28	61	36
Creatine Phosphokinase	66	648	86	108	333	70	70	290	67
Calculated Osmolality	297	288	286	285	285	290	285	282	293
AST (Sgot)	77	124	85	72	104	100	100	82	160
Sorbital Dehydrogenase-AO	21.6	95.4	20.1	22.1	30.7	34.3	52.1	14.2	40
Uric Acid	7	1	1	0	0	0	0	5	6
Date of Bleed ³	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

Appendix H16. Clinical Laboratory Data for Sheep B197 (Embosphere®), cont.

Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Morphology and Coagulation Parameters									
Platelets	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
RBC Morph	Normal	See Below	See Below	See Below	See Below	See Below	See Below	Normal	See Below
Aniso	NR	1+	1+	1+	2+	NR	NR	NR	NR
Poik	NR	1+	NR	1+	2+	1+	1+	NR	1+
Fibrinogen Degradation Products	Negative	Negative	Negative	Negative	Negative	Negative	Positive @ 1:2, 1:8	Negative	Negative
Fibrinogen Semi Quantitative	1	3	1	1	2	2	1	1	1
Part. Thromboplastin Time	>100	>60	39.8	49.3	68	61.1	55.5	57.8	>60
Prothrombin Time	45.8	36.5	23.3	29.3	33.3	27	31.2	28.1	28.3
Date of Bleed	26-Jun	28-Jun	4-Jul	11-Jul	25-Jul	22-Aug	19-Sep	12-Dec	26-Jun-08

¹ Numbers in bold are outside of the reference range² Not Reported³ Year of Bleed: 2007 until 6 months

Appendix I. Summary Clinical Laboratory Data for Sheep Implanted with Embosphere® Microspheres

- I1. Summary Clinical Laboratory Data for Sheep on Day -1
- I2. Summary Clinical Laboratory Data for Sheep on Day +1
- I3. Summary Clinical Laboratory Data for Sheep at 1 Week
- I4. Summary Clinical Laboratory Data for Sheep at 2 Weeks
- I5. Summary Clinical Laboratory Data for Sheep at 1 Month
- I6. Summary Clinical Laboratory Data for Sheep at 2 Months
- I7. Summary Clinical Laboratory Data for Sheep at 3 Months
- I8. Summary Clinical Laboratory Data for Sheep at 6 Months
- I9. Summary Clinical Laboratory Data for Sheep at 12 Months

Appendix I1. Summary Clinical Laboratory Data for Sheep on Day -1 (Embosphere®)

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1
Hematology																
White Cell Count	6.3	10.8	8.4	8.0	8.0	7.5	10.0	12.8	5.0	7.8	10.9	4.9	10.1	7.7	10.5	9.0
Red Cell Count	11.3	11.1	11	11.1	11.7	11	10.4	10.8	12.1	10.9	11.1	10.8	13.4	9.92	12.2	8.14
Hemoglobin	129	130	127	125	126	131	128	122	129	120	132	124	139	126	126	94.7
Hematocrit	0.4	0.4	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3
Mean Corp Vol	31	32	30.8	31.9	27.1	33.1	32.8	30.1	28.7	30.4	31.3	29.5	26.7	32	27.7	31.9
Mean Corp Hemoglobin	11.4	11.8	11.6	11.2	10.7	11.9	12.3	11.3	10.7	10.9	11.9	11.4	10.4	12.7	10.3	11.6
Mean Corp Hemoglobin Conc	366	368	376	351	395	361	376	375	373	360	380	386	389	396	373	365
RDW	24.8	23	22.2	24	24.1	20.4	21.5	22.2	21.6	21.3	20.5	21.2	25.4	24.8	23.1	17
Platelet CNT	481	474	664	333	581	169	399	346	280	265	659	188	611	1478	432	251
Mean Platelet Vol.	NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	10.8	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	34	35	32	14	58	46	24	24	21	32	24	32	27	22	60	26
% Lymphocytes	61	59	60	78	35	43	69	54	73	50	61	58	63	71	39	63
% Monocytes	2	4	6	4	6	8	5	18	3	16	3	1	3	1	1	4
% Eosinophils	3	0	2	3	1	2	0	4	3	0	12	9	7	6		7
% Basophils	NR	NR	NR	NR	NR	1	1	NR	NR	2	NR	NR	NR	NR	NR	NR
Absolute Differential Values																
Neutrophils	2.1	3.8	2.7	1.1	4.6	3.5	2.4	3.1	1.1	2.5	2.6	1.6	2.7	1.7	6.3	2.4
Lymphocytes	3.8	6.4	5.0	6.2	2.8	3.2	6.9	6.9	3.7	3.9	6.7	2.9	6.4	5.5	4.1	5.7
Monocytes	0.1	0.5	0.5	0.3	0.5	0.6	0.5	2.3	0.2	1.2	0.3	0.1	0.3	0.1	0.1	0.4
Eosinophils	0.19	0.02	0.17	0.24	0.08	0.15	0.02	0.51	0.15	0.04	1.31	0.44	0.71	0.46	NR	0.63
Basophils		0.07		0.08		0.08	0.09			0.13						
Chemistry																
Glucose	4.4	4	5	3.9	3.5	4	4	3.6	3.1	3.7	4	4	3.5	3.5	3.2	3.5
Blood Urea Nitrogen (BUN)	3.4	3.9	4.3	5.5	4.7	7.3	3.9	5.7	6.1	6.2	5.8	6.2	4.7	4.6	7.1	5.4
Creatinine	87.9	84.6	96.5	90	85.2	77.8	79.6	82.9	96	65.3	105.9	89.6	80.6	84.2	86.7	61.3
BUN/Cr Ratio	10	12	11	15	14	24	12	17	16	24	14	17	15	14	21	22
Sodium	147	149	147	144	148	145	147	148	146	143	145	143	144	147	140	151
Potassium	4.5	4.9	4.7	4.5	4.9	5.1	4.7	4.9	4.4	4.5	4.4	4.7	4.7	5	4.8	3.7
Na/K Ratio	33	30	31	32	30	28	31	30	33	32	33	30	31	29	29	41
Chloride	110	112	108	110	111	111	111	113	111	109	108	109	106	108	108	119
Carbon Dioxide	25.9	27.5	29.3	25.5	28.4	29.8	25.7	22.5	21.1	25.6	24	21.4	24.9	20.9	20	21.7

Appendix I1. Summary Clinical Laboratory Data for Sheep on Day -1 (Embosphere®), cont.

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1	Day -1
Anion Gap	16	14	14	13	14	9	15	17	18	13	17	17	18	23	17	14
Calcium	2.55	2.54	2.69	2.33	2.55	2.48	2.6	2.59	2.45	2.7	2.52	2.51	2.55	2.62	2.59	2.17
Phosphorus	2.2	2.48	2.77	2.48	2.65	2.21	2.58	2.15	1.94	2.16	1.74	2.36	2.19	2.16	1.71	1.58
Total Protein	65	71	72	70	71	69	76	73	72	70	71	72	75	78	81	63
Albumin	31.7	29.0	31.6	24.8	27.6	31.1	29.2	31.4	27.7	32.3	25.9	34.7	32.7	32.3	31.2	27.4
Globulin	33	42	40	45	43	38	47	42	44	38	45	37	42	46	50	36
A/G Ratio	0.9	0.7	0.8	0.5	0.6	0.8	0.6	0.8	0.6	0.9	0.6	0.9	0.8	0.7	0.6	0.8
Total Bilirubin	7	5	6	8	6	5	7	6	4	7	4	5	9	9	7	3
Alkaline Phosphatase	334	226	200	225	273	128	234	268	283	321	228	223	227	333	231	187
ALT (Sgpt)	33	30	26	23	21	34	27	31	26	33	26	41	26	33	29	27
Gamma gt	66	23	23	31	20	61	74	87	18	71	31	68	79	75	37	24
Creatine Phosphokinase	69	101	75	115	86	72	92	60	49	81	97	131	114	128	104	66
Calculated Osmolality	290	294	291	286	293	290	290	294	289	284	288	285	285	291	280	297
AST (Sgot)	114	88	93	88	95	126	67	89	107	113	118	163	126	187	95	77
Sorbital Dehydrogenase-AO	47.3	15	54.9	56.7	27.2	26.7	22.3	18.2	59.8	23.6	31.6	63.9	71.3	155.1	18.7	21.6
Uric Acid	0	2	0	0	5	3	1	5	5	9	2	3	0	2	4	7
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	3	2	2	4	1	1	1	2	1	1	1	1		1	1
Part. Thromboplastin Time	33.8	37.7	33.7	29.7	28.2	44.7	39.5	32.5	48	32.5	42	57.9	55	64	69	100
Prothrombin Time	22.0	20.7	29.5	22.5	23.3	24	24.3	24.7	34.5	24.7	37.5	39.1	28.3	30.8	36	45.8

¹ Not Reported.² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)

Appendix I2. Summary Clinical Laboratory Data for Sheep on Day +1 (Embosphere®)

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1
Hematology																
White Cell Count	6.5	9.1	8.2	8.2	8.6	8.4	12.3	12.1	5.9	9.0	13.0	6.9	12.5	8.9	12.6	9.9
Red Cell Count	10.3	10.2	11.2	11	11.8	11.1	9.13	9.6	11	10.5	11.9	10.7	12.6	11.7	10.9	9.7
Hemoglobin	120	122	132	130	120	130	115	108	116	115	136	118	133	135	117	117
Hematocrit	0.3	0.3	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.4	0.3	0.3
Mean Corp Vol	31.5	32	30.6	31.9	27.3	32.6	33.2	29.9	29	29.9	31.4	29.5	27	30.9	28.4	32.1
Mean Corp Hemoglobin	11.6	12	11.8	11.8	10.2	11.7	12.5	11.2	10.5	10.9	11.5	11	10.6	11.5	10.7	12.1
Mean Corp Hemoglobin Conc	369	375	385	370	372	360	378	375	363	365	365	372	391	373	377	376
RDW	23.1	21.8	23.6	24.2	24.9	21.3	20.7	20.7	21	20.1	21.5	22.8	22.4	22.2	23.4	20.8
Platelet CNT	473	434	630	493	926	153	383	395	149	206	585	101	504	621	389	353
Mean Platelet Volume		NR ¹	NR	12.3	NR	NR	NR	NR	NR	NR	7.16	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	57	41	41	33	58	38	41	39	22	67	41	58	27	57	53	48
% Lymphocytes	33	56	47	57	38	53	53	55	74	25	44	38	59	36	39	41
% Monocytes	7	2	11	7	3	8	3	2	1	6	1	3	3	1	2	2
% Eosinophils	3	0	0	3	1	0	3	3	3	2	13	1	11	6	5	8
% Basophils	NR	NR	NR	NR	NR	1	NR	1	NR	NR	1	NR	NR	NR	1	1
Absolute Differential Values																
Neutrophils	3.7	3.8	3.4	2.7	5.0	3.2	5.1	4.7	1.3	6.0	5.3	4.0	3.4	5.1	6.7	4.7
Lymphocytes	2.1	5.1	3.9	4.7	3.3	4.5	6.5	6.7	4.4	2.3	5.7	2.6	7.4	3.2	4.9	4.1
Monocytes	0.45	0.18	0.88	0.57	0.26	0.69	0.37	0.20	0.06	0.54	0.13	0.21	0.38	0.09	0.25	0.20
Eosinophils	0.19	0.03	0.12	0.25	0.09	0.01	0.37	0.35	0.18	0.18	1.69	0.07	1.38	0.53	0.63	0.79
Basophils	NR	0.02	0.06	NR	NR	0.07	NR	0.09	NR	NR	0.13	NR	NR	NR	0.13	0.10
Chemistry																
Glucose	5.7	4.3	4.8	4.6	4.2	5.5	4.3	4.2	2.4	5.2	4.5	4.8	3.8	4.8	2.5	3.5
Blood Urea Nitrogen (BUN)	1.4	3.3	3	4.1	3	4.1	2.8	3.1	7	2.5	3.8	3.4	4	4	5.1	4.5
Creatinine	79.4	87.7	97.5	97.1	89.3	82.9	85.7	79.8	85.9	66.5	84.4	72.2	82.3	92.4	97	86.1
BUN/Cr Ratio	4	9	8	11	8	12	8	10	20	9	11	12	12	11	13	13
Sodium	153	155	149	151	152	149	150	150	145	146	148	149	145	148	148	146
Potassium	4.3	4.6	4.9	4.6	4.5	4.5	4.4	4.9	4.3	4.4	4.2	4.2	4.3	5	4	4.7
Na/K Ratio	36	34	30	33	34	33	34	31	34	33	35	35	34	30	37	31
Chloride	119	120	114	118	118	114	114	115	112	114	115	114	111	117	112	110
Carbon Dioxide	31.6	26.1	31.7	29.9	26.2	25.1	26.9	27.7	22.5	20.9	22.4	26.6	23.7	20.6	21.2	25

Appendix I2. Summary Clinical Laboratory Data for Sheep on Day +1 (Embosphere®), cont.

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1	Day+1
Anion Gap	7	14	8	8	12	14	14	12	15	16	15	13	15	15	19	16
Calcium	2.53	2.6	2.7	2.31	2.6	2.52	2.55	2.58	2.32	2.49	2.43	2.54	2.56	2.67	2.6	2.69
Phosphorus	1.84	1.96	2.16	2.83	2.2	2.12	2.41	1.89	2.07	2.06	1.81	2.02	1.9	1.51	2.01	1.61
Total Protein	68	78	78	72	77	75	76	74	72	70	76	72	77	82	81	78
Albumin	33.7	32.2	35.1	25.7	31.2	32.9	29.6	30.7	28.1	31.9	28.4	35.3	33.5	33.8	31.3	34.0
Globulin	34	46	43	46	46	42	46	43	44	38	48	37	44	48	50	44
A/G Ratio	1	0.7	0.8	0.6	0.7	0.8	0.6	0.7	0.6	0.8	0.6	1	0.8	0.7	0.6	0.8
Total Bilirubin	6	5	6	7	5	5	6	5	4	6	4	4	4	5	6	5
Alkaline Phosphatase	312	253	247	200	298	144	237	291	252	293	213	242	244	314	190	177
ALT (Sgpt)	38	75	42	35	19	32	34	35	29	33	32	35	31	37	27	34
Gamma gt	71	24	24	36	20	55	68	83	14	65	38	72	89	82	34	35
Creatine Phosphokinase	97	1542	307	118	409	90	217	106	181	250	183	217	502	355	135	648
Calculated Osmolality	300	304	294	298	298	295	294	295	287	287	291	293	285	293	290	288
AST (Sgot)	151	262	202	103	106	130	93	98	120	117	136	158	175	238	101	124
Sorbital Dehydrogenase-AO	118.8	36.1	901	161.7	29.5	28.4	123	92.9	59.7	25.5	139	34.4	178.5	213.7	20.2	95.4
Uric Acid	0	2	0	0	2	5	7	5	10	4	0	0	0	0	0	1
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	3	4	2	2	2	2	3	1	3	3	3	2	2	2	3
Part. Thromboplastin Time	56.8	37.9	42.7	37.2	60³	60	60	60	60	47.4	36.3	60	60	60	60	60¹
Prothrombin Time	23.3	25.7	26.7	24.3	41.4	30.0	36.3	32.3	38.7	29	33.8	38.8	32.8	60	60	36.5

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix I3. Summary Clinical Laboratory Data for Sheep at 1 Week (Embosphere®)

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W
Hematology																
White Cell Count	7.0	8.6	9.6	9.4	6.9	10.2	8.5	13.3	7.6	6.4	9.7	5.3	11.0	9.3	9.0	7.7
Red Cell Count	10.4	11.7	11.1	10.6	12.5	10.6	10.1	9.51	9.77	10.1	10.7	11.3	13.6	11.9	11	10.2
Hemoglobin	122	136	129	122	133	131	122	103	110	112	126	127	139	136	115	120
Hematocrit	0.3	0.4	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.3	0.3
Mean Corp Vol	31.8	32	30.7	32.2	27.3	33.2	33.7	30.7	30	30	32.1	29.7	26.6	30.6	27.6	31.7
Mean Corp Hemoglobin	11.7	11.7	11.6	11.5	10.7	12.3	12.1	10.8	11.2	11	11.8	11.2	10.2	11.4	10.5	11.8
Mean Corp Hemoglobin Conc	367	364	378	357	389	372	359	351	375	369	366	378	385	372	379	371
RDW	24.6	22.7	24.6	23.1	27	23.1	22.1	20.7	21.7	21.7	21.5	21.9	25.4	22.9	22.5	22.2
Platelet CNT	604	757	781	596	1124	323	332	259	109	703	765	177	777	670	449	539
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	7.68	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	26	26	16	22	32	53	17	47	21	18	18	30	30	27	38	18
% Lymphocytes	68	55	78	71	62	43	77	48	75	77	72	60	68	70	61	72
% Monocytes	3	18	3	6	3	4	4	3	3	2	3	4	1	2	1	1
% Eosinophils	3	0	3	1	3		2	1	1	3	7	6	1	1		9
% Basophils	NR	NR	NR	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	NR
Absolute Differential Values																
Neutrophils	1.8	2.3	1.5	2.1	2.2	5.4	1.4	6.3	1.6	1.2	1.7	1.6	3.3	2.5	3.4	1.4
Lymphocytes	4.8	4.7	7.5	6.7	4.3	4.4	6.5	6.4	5.7	4.9	7.0	3.2	7.5	6.5	5.5	5.5
Monocytes	0.2	1.5	0.3	0.6	0.2	0.4	0.3	0.4	0.2	0.1	0.3	0.2	0.1	0.2	0.1	0.1
Eosinophils	0.21	0.02	0.29	0.09	0.21		0.17	0.13	0.08	0.19	0.68	0.32	0.11	0.07		0.69
Basophils	NR	0.08	NR	NR	NR	NR	NR	0.13	NR	NR	NR	NR	NR	0.03	NR	NR
Chemistry																
Glucose	4.1	3.6	4.3	3.3	3.3	3.4	3.6	3.5	2.7	4	3.6	3.3	3	3.9	3.4	3.4
Blood Urea Nitrogen (BUN)	7	7.6	7.1	5.9	6.2	8	6.1	8	7.8	4.8	6.6	5.8	4.9	6.7	5.2	4.6
Creatinine	66.1	101.7	83.1	72.6	84.6	81	71.1	67.1	93.9	59.5	100.4	83.8	72.1	75.8	89.1	65.7
BUN/Cr Ratio	27	19	21	20	18	25	22	30	21	20	17	17	17	22	15	18
Sodium	147	156	145	144	153	149	146	144	145	149	147	149	143	145	145	145
Potassium	5.2	6.9	5.4	4.8	5.4	4.7	5.2	5.2	4.5	4.8	4.6	4.5	4.6	5	5	4.4
Na/K Ratio	28	23	27	30	28	32	28	28	32	31	32	33	31	29	29	33
Chloride	114	117	113	112	116	113	108	112	110	114	111	111	109	113	108	108
Carbon Dioxide	26.2	32.8	26.9	27.2	31.2	27.7	27.6	26.5	26.2	28.9	26.8	27.1	28.2	22	29.2	28.3

Appendix I3. Summary Clinical Laboratory Data for Sheep at 1 Week (Embosphere®), cont.

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W	1 W
Anion Gap	12	13	11	10	11	13	16	11	13	11	14	15	10	15	13	13
Calcium	2.5	2.8	2.7	2.3	2.7	2.5	2.5	2.5	2.3	2.6	2.5	2.5	2.6	2.6	2.6	2.7
Phosphorus	2.3	2.8	1.9	2.8	2.2	2.0	2.5	2.4	2.3	2.1	1.7	2.3	1.9	1.7	2.3	2.1
Total Protein	66	74	74	69	76	67	71	70	75	65	73	69	74	75	77	76
Albumin	31.5	30.5	33.1	22.5	28.4	27.0	28.2	29.1	26.4	28.0	26.7	32.7	32.9	31.7	30.0	33.9
Globulin	35	44	41	46	48	37	43	41	49	37	46	36	41	43	47	42
A/G Ratio	0.9	0.7	0.8	0.5	0.6	0.8	0.7	0.7	0.5	0.8	0.6	0.9	0.8	0.7	0.6	0.8
Total Bilirubin	5	5	5	7	5	5	5	5	3	6	4	4	4	5	7	5
Alkaline Phosphatase	418	185	214	117	162	123	203	236	200	164	131	151	193	297	168	170
ALT (Sgpt)	30	32	26	15	18	27	27	27	24	25	27	31	27	28	24	32
Gamma gt	77	30	25	35	20	62	68	84	19	73	51	69	104	88	23	61
Creatine Phosphokinase	82	187	71	108	62	67	175	57	136	53	73	97	110	291	93	86
Calculated Osmolality	294	314	291	286	304	297	291	289	289	295	292	295	282	290	288	286
AST (Sgot)	96	86	101	82	73	94	76	78	81	77	104	140	162	130	86	85
Sorbital Dehydrogenase-AO	19.7	12.7	95	88.8	20.5	17.6	24.5	13.2	20.4	1	18.4	56.4	189.6	57.8	13.1	20.1
Uric Acid	4	0	5	0	2	10	4	9	8	5	0	6	0	0	0	1
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	3	3	2	3	5	2	1	2	2	3	3	1	2	1	2	1
Part. Thromboplastin Time	30	43.2	34.2	30.5	54.5	39.1	32.1	54.5	39.2	60³	35.2	42.5	60.3	46.6	35.2	39.8
Prothrombin Time	20.3	28.2	26.8	26.2	34.2	27.5	25.5	26.3	35.7	60	31.6	35.8	38.8	29.8	38.7	23.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as “60” for the purposes of calculating mean and standard deviation.

Appendix I4. Summary Clinical Laboratory Data for Sheep at 2 Weeks (Embosphere®)

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W
Hematology																
White Cell Count	6.0	8.4	7.9	10.6	7.9	7.6	10.3	12.8	6.0	8.5	6.0	5.9	12.0	8.1	9.0	8.9
Red Cell Count	11.7	11	12.9	11.5	12.9	10.9	10.9	10.5	10.7	11	11.8	11.5	13.3	12.4	10.7	11
Hemoglobin	137	128	150	136	131	136	137	116	113	121	136	129	138	140	111	129
Hematocrit	0.4	0.4	0.4	0.4	0.3	0.4	0.4	0.3	0.3	0.3	0.4	0.3	0.4	0.4	0.3	0.4
Mean Corp Vol	32.4	32.2	30.8	32.4	26.9	33.7	32.9	29.9	29.7	29.8	32.4	29.5	27.5	30.8	27.9	32
Mean Corp Hemoglobin	11.8	11.6	11.7	11.8	10.1	12.5	12.5	11	10.6	11	11.6	11.2	10.4	11.3	10.4	11.8
Mean Corp Hemoglobin Conc	364	361	380	364	377	371	380	367	358	370	356	380	377	368	372	368
RDW	24	23.7	28	24.5	23.4	24	22.8	20	21.2	21.7	23.5	22.3	24.8	25.2	23.6	20.3
Platelet CNT	608	443	769	784	989	263	437	659	296	507	410	361	637	831	699	428
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	38	21	34	41	16	30	26	40	14	49	29	43	39	25	49	24
% Lymphocytes	55	71	44	50	73	55	63	53	83	50	69	53	59	72	49	72
% Monocytes	6	4	19	8	6	13	4	2	1	1		1	2	1	1	4
% Eosinophils	1	4	1	1	5	1	6	5	2	0	2	3		2	1	
% Basophils	NR	NR	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR
Absolute Differential Values																
Neutrophils	2.3	1.8	2.7	4.3	1.3	2.3	2.7	5.1	0.8	4.2	1.7	2.5	4.7	2.0	4.4	2.1
Lymphocytes	3.3	5.9	3.5	5.3	5.7	4.1	6.5	6.8	5.0	4.2	4.1	3.1	7.1	5.9	4.4	6.4
Monocytes	0.4	0.3	1.5	0.9	0.5	1.0	0.4	0.3	0.1	0.8		0.1	0.2	0.1	0.1	0.4
Eosinophils	0.06	0.33	0.71	0.11	0.39	0.79	0.62	0.64	0.12	0.02	0.12	0.18		0.16	0.09	
Basophils	NR	NR	0.16	NR	NR	0.04	0.10	NR	NR	0.01	NR	NR	NR	NR	NR	NR
Chemistry																
Glucose	3.5	3.6	3.4	3.2	3.5	3.6	3.1	3.5	2.9	4.2	0.6	3.4	2.9	3	3.6	3.8
Blood Urea Nitrogen (BUN)	6.8	8.5	8.2	7.8	7.9	7.4	7.2	8.1	8.2	4.8	9.1	7.5	6	5.5	6.8	5
Creatinine	71.9	86.8	83.4	81.7	84.6	94.9	91.5	78.6	94.5	77.5	104.8	71.5	82.8	87.9	82.9	60.3
BUN/Cr Ratio	24	25	25	24	23	20	20	26	22	16	22	26	18	16	21	21
Sodium	150	146	149	151	143	145	149	151	141	145	143	142	151	147	142	144
Potassium	5.2	5.1	5.2	4.9	6.8	4.6	5.4	5	4.5	5	4.6	4.7	4.7	4.9	4.7	4.4
Na/K Ratio	29	29	29	31	21	32	28	30	31	29	31	30	32	30	30	33
Chloride	118	110	114	120	111	110	112	115	109	110	108	105	112	110	109	109
Carbon Dioxide	25.3	29.6	22.7	24.8	27.8	25.9	26.6	26.5	23.4	26.1	22.5	27.1	27.1	26.4	24.5	26

Appendix I4. Summary Clinical Laboratory Data for Sheep at 2 Weeks (Embosphere®), cont.

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W	2 W
Anion Gap	12	12	18	11	11	14	16	15	13	14	17	15	17	16	13	13
Calcium	2.7	2.6	3.0	2.6	2.6	2.6	2.7	2.6	2.5	2.7	2.6	2.6	2.6	2.7	3.6	2.6
Phosphorus	1.9	2.3	2.0	2.0	2.3	2.0	3.0	2.4	1.9	2.7	1.6	2.5	2.2	1.9	2.3	1.7
Total Protein	68	72	82	74	72	70	83	76	74	64	78	71	76	79	76	73
Albumin	34.3	31.2	37.9	25.0	29.4	32.5	32.5	30.2	27.2	29.8	29.3	34.9	31.9	32.9	30.1	33.7
Globulin	34	41	44	49	43	38	51	46	47	34	49	36	44	46	46	39
A/G Ratio	1	0.8	0.9	0.5	0.7	0.9	0.6	0.7	0.6	0.9	0.6	1	0.7	0.7	0.7	0.9
Total Bilirubin	5	5	4	8	6	6	8	6	4	8	5	5	4	5	7	4
Alkaline Phosphatase	340	217	195	234	249	116	210	208	212	228	155	153	191	346	165	186
ALT (Sgpt)	31	30	27	18	20	32	29	27	25	29	28	37	26	59	23	29
Gamma gt	66	29	28	26	23	31	76	78	32	71	70	73	105	107	24	29
Creatine Phosphokinase	213	210	282	139	239	140	158	51	104	804	70	189	168	108	87	108
Calculated Osmolality	299	293	298	301	290	289	297	302	282	288	284	284	299	291	283	285
AST (Sgot)	92	80	108	78	89	110	75	77	98	95	115	184	96	478	77	72
Sorbital Dehydrogenase-AO	28.2	15.2	51.5	32.9	24.4	23.3	39.2	1.7	24.7	15.6	26.1	68.5	58.2	13.4	12.5	22.1
Uric Acid	0	3	0	0	4	15	4	4	0	5	0	4	0	0	0	0
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	2	3	1	1	2	4	1	2	1	1	2	1	2	1
Part. Thromboplastin Time	49.7	36.9	49.3	44.8	38.1	41.3	35	50	54	41	68	71.2	37.3	43.8	43.4	49.3
Prothrombin Time	27	21.3	40.3	29	28	24.7	29.1	32.1	32.8	26.7	33.5	34.5	28.2	29.8	32.3	29.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)

Appendix I5. Summary Clinical Laboratory Data for Sheep at 1 Month (Embosphere®)

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M
Hematology																
White Cell Count	6.0	8.1	8.6	7.8	6.4	4.4	7.8	11.9	6.0	8.0	6.6	5.4	8.1	8.1	7.4	10.1
Red Cell Count	12.3	12.4	13	10	12.3	10.3	10.4	10.2	11.6	11.6	7.75	12.7	13.3	12.7	10.8	11.7
Hemoglobin	143	145	148	117	131	133	127	114	122	130	105	136	136	139	115	139
Hematocrit	0.4	0.4	0.4	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.3	0.4
Mean Corp Vol	32.1	31.9	30.1	32.6	27.5	35	33.1	29.5	29.5	29.8	39	29.6	27.1	31	28.2	32
Mean Corp Hemoglobin	11.6	11.6	11.4	11.7	10.6	12.9	12.2	11.1	10.5	11.2	13.6	10.8	10.2	10.9	10.6	11.9
Mean Corp Hemoglobin Conc	361	364	380	360	386	370	368	377	357	374	348	363	378	351	378	371
RDW	27.5	23.1	24.3	22.5	21.2	23.6	22.7	21.9	21.2	24.9	24.9	23.7	23.2	25.5	22.3	22.7
Platelet CNT	643	533	967	320	915	110	529	508	441	536	99.3	159	417	388	685	470
Mean Platelet Volume	NR ¹		NR	NR	NR	NR	NR	9.1	NR	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count																
% Neutrophils	29	37	30	14	28	32	15	26	24	48	24	39	22	20	37	22
% Lymphocytes	57	39	57	64	67	61	77	66	72	48	72	47	72	68	61	59
% Monocytes	12	19	10	21	4	7	1	1	1	1	1	4	2	4		1
% Eosinophils	2	3	2	0	0	0	7	6	3	3	3	10	4	8	2	17
% Basophils	NR	NR	NR	NR	1	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	1
Absolute Differential Values																
Neutrophils	1.7	3.0	2.6	1.1	1.8	1.4	1.2	3.1	1.4	3.9	1.6	2.1	1.8	1.6	2.7	2.2
Lymphocytes	3.5	3.1	4.9	5.0	4.3	2.7	6.0	7.9	4.3	3.9	4.7	2.5	5.8	5.5	4.5	6.0
Monocytes	0.7	1.6	0.9	1.6	0.3	0.3	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.3		0.1
Eosinophils	0.10	0.21	0.18	0.00	0.02	0.00	0.55	0.71	0.18	0.24	0.20	0.54	0.32	0.65	0.15	1.72
Basophils	0.01	0.12	0.04	0.10	0.05	NR	NR	0.12	NR	NR	NR	NR	NR	NR	NR	0.10
Chemistry																
Glucose	3.3	4.2	3.1	3.1	3.9	0.9	3.6	3.4	3.1	3.3	3.3	4.1	2.5	3.7	3.2	3
Blood Urea Nitrogen (BUN)	6.1	7.9	6.1	7.4	8.9	9.2	7.9	7.1	8.3	6.1	9.7	8.4	7.1	9.4	6.7	7.1
Creatinine	88.4	101.8	101.3	93.5	79.8	84	75.4	70.2	87.9	69.8	101.7	84.9	73.3	95.6	77.2	82
BUN/Cr Ratio	17	19	15	20	28	28	26	25	24	22	24	25	24	25	22	22
Sodium	154	144	152	147	146	147	143	147	144	145	144	145	142	145	138	143
Potassium	6.1	4.7	5.3	5.1	4.7	5.6	4.5	5	4.2	4.5	5	5.3	4.4	4.9	4.6	4.8
Na/K Ratio	25	31	29	29	31	26	32	29	34	32	29	27	32	30	30	30
Chloride	116	111	113	117	112	111	107	111	112	109	109	112	107	113	106	107
Carbon Dioxide	31.4	18.7	27	25.5	24.9	22.9	29.3	28	24	26.5	24.3	23.1	25.1	16.5	22.6	27.8

Appendix I5. Summary Clinical Laboratory Data for Sheep at 1 Month (Embosphere®), cont.

Animal Number:	Y28	Y33	Y110	Y184	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M	1 M
Anion Gap	13	19	17	10	14	19	11	13	12	14	16	15	14	20	14	13
Calcium	2.8	2.5	2.8	2.4	2.7	2.6	2.6	2.5	2.6	2.5	2.6	2.6	2.7	2.8	2.6	2.8
Phosphorus	2.4	2.2	2.2	1.6	2.0	1.9	2.4	2.2	1.6	2.8	2.0	1.9	1.9	1.7	2.0	1.7
Total Protein	69	70	74	68	70	73	68	73	76	71	85	73	82	83	79	80
Albumin	34.9	32.5	34.7	22.6	30.1	32.0	30.3	31.2	29.7	30.6	39.3	35.6	33.6	33.8	31.0	35.2
Globulin	34	38	39	45	40	41	38	42	46	40	45	37	48	49	48	45
A/G Ratio	1	0.9	0.9	0.5	0.8	0.8	0.8	0.7	0.6	0.8	0.9	1	0.7	0.7	0.6	0.8
Total Bilirubin	5	5	5	7	6	6	7	5	3	7	4	3	3	4	6	5
Alkaline Phosphatase	299	176	166	211	304	116	231	274	243	170	102	201	157	270	150	175
ALT (Sgpt)	33	28	27	14	34	31	31	29	24	28	24	33	23	29	23	28
Gamma gt	73	26	33	24	22	24	67	76	32	76	59	76	96	95	53	26
Creatine Phosphokinase	396	111	831	189	233	1677	288	82	87	148	84	124	78	113	126	333
Calculated Osmolality	307	289	302	293	293	294	286	293	287	287	290	292	282	292	275	285
AST (Sgot)	110	82	125	74	114	155	107	109	105	106	99	194	96	140	103	104
Sorbital Dehydrogenase-AO	25.7	15.2	50.6	15.3	28.2	28.8	46.1	31.9	22.5	51.4	22.9	93.5	65.8	75	20.3	30.7
Uric Acid	1	6	5	12	7	1	0	2	0	0	0	0	0	0	0	0
Morphology and Coagulation Parameters																
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	1	2	1	2	1	2	2	2	2	2	1	1	1	2
Part. Thromboplastin Time	49.3	27.8	60.2	59.2	31.3	56	36.7	46.9	50.5	48.4	60³	60	60	60	46.8	68
Prothrombin Time	31.2	21.8	36.7	42.3	24.3	31.5	31.2	34.5	40.1	35.6	60	35.8	26.3	42.9	36.5	33.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix I6. Summary Clinical Laboratory Data for Sheep at 2 Months (Embosphere®)

Animal Number:	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M
Hematology												
White Cell Count	8.7	6.8	8.2	12.3	6.5	7.8	9.8	5.9	8.8	5.5	6.4	6.1
Red Cell Count	13.1	10.1	10.9	10.9	12.8	12.4	10.9	12.4	12.6	12.5	12.1	11.6
Hemoglobin	132	128	129	116	132	134	130	131	133	133	121	130
Hematocrit	0.4	0.4	0.4	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.4
Mean Corp Vol	26.9	36.5	32.5	29	28.1	28.8	34.9	28.6	28.2	31.1	27.3	32.2
Mean Corp Hemoglobin	10.1	12.7	11.8	10.6	10.3	10.8	11.9	10.5	10.6	10.6	10	11.1
Mean Corp Hemoglobin Conc	374	347	364	367	366	373	342	368	375	340	368	346
RDW	26.5	23.8	20.2	20.7	21.6	24.2	24.5	23.8	23.4	25	21.6	23
Platelet CNT	1014	61.3	409	576	594	494	527	193	245	149	619	371
Mean Platelet Volume							7.45	NR	NR	NR	NR	NR
Differential Cell Count												
% Neutrophils	50	16	23	29	32	28	27	31	17	25	27	19
% Lymphocytes	42	80	74	63	61	53	59	55	73	67	67	67
% Monocytes	1	3	3	5	2	1	6	3	3	2	5	5
% Eosinophils	7	1		3	4	17	8	11	7	6	1	9
% Basophils	NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Absolute Differential Values												
Neutrophils	4.3	1.1	1.9	3.6	2.1	2.2	2.6	1.8	1.5	1.4	1.7	1.2
Lymphocytes	3.6	5.5	6.1	7.8	4.0	4.1	5.8	3.2	6.4	3.7	4.3	4.1
Monocytes	0.1	0.2	0.3	0.6	0.1	0.1	0.6	0.2	0.3	0.1	0.3	0.3
Eosinophils	0.6	0.1		0.4	0.3	1.3	0.8	0.6	0.6	0.3	0.1	0.6
Basophils	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Chemistry												
Glucose	3.2	3	3.4	3.4	3.2	3.1	3.3	4	3.3	1.7	3.4	3.9
Blood Urea Nitrogen (BUN)	8.3	9.2	9.7	8.8	7.7	8.2	8.5	6.7	6.5	8	8.3	6.8
Creatinine	83.4	79.1	68.4	65.2	87.9	72.1	94.5	88.1	70.5	89.8	85.6	74.4
BUN/Cr Ratio	25	29	36	34	22	29	23	19	23	22	24	23
Sodium	143	144	143	144	142	147	142	143	143	143	141	146
Potassium	4.8	4.7	4.8	5.1	5.1	4.6	4.4	4.5	4.6	5.3	4.4	4.3
Na/K Ratio	30	31	30	28	28	32	32	32	31	27	32	34
Chloride	110	109	107	110	108	111	112	109	106	105	107	109
Carbon Dioxide	22.9	23.7	25.9	26.9	25.2	25.1	20.5	22	28.1	21.1	24	25.6

Appendix I6. Summary Clinical Laboratory Data for Sheep at 2 Months (Embosphere®), cont.

Animal Number:	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M	2 M
Anion Gap	15	16	15	12	14	16	14	17	14	22	14	16
Calcium	2.56	2.51	2.47	2.58	2.4	2.63	2.55	2.59	2.66	2.6	2.52	2.74
Phosphorus	2.22	1.64	2.4	2.03	1.96	1.86	1.39	1.91	1.87	1.93	2.02	1.61
Total Protein	74	72	67	72	77	72	77	74	80	85	79	85
Albumin	32.5	33.0	28.9	32.0	29.3	31.8	26.5	42.8	34.2	32.4	31.8	34.8
Globulin	42	39	38	40	48	40	50	31	46	53	47	50
A/G Ratio	0.8	0.8	0.8	0.8	0.6	0.8	0.5	1.4	0.7	0.6	0.7	0.7
Total Bilirubin	5	4	3	5	3	5	3	4	4	3	5	3
Alkaline Phosphatase	237	115	244	282	211	255	109	169	161	306	237	218
ALT (Sgpt)	42	47	39	32	26	31	22	34	28	33	24	26
Gamma gt	25	21	58	76	39	70	58	71	93	85	30	28
Creatine Phosphokinase	119	400	4786	170	507	97	76	428	105	132	125	70
Calculated Osmolality	286	289	288	290	285	293	284	285	284	286	282	290
AST (Sgot)	131	157	174	117	106	131	110	168	98	98	108	100
Sorbital Dehydrogenase-AO	52	32.5	64.5	49.5	25.1	28.6	19.9	76	75.1	34.9	21.1	34.3
Uric Acid	3	2	0	6	0	0	1	2	0	0	0	0
Morphology and Coagulation Parameters												
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	1	1	2	1	3	1	1	1	1	2
Part. Thromboplastin Time	60 ³	53.5	97.4	63.1	60	40	46.1	45.3	43.3	60	42.3	61.1
Prothrombin Time	60	50.1	100	39.6	60	35.6	35.3	53	27.3	52.9	29.9	27

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix I7. Summary Clinical Laboratory Data for Sheep at 3 Months (Embosphere®)

Animal Number:	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M
Hematology												
White Cell Count	6.1	6.9	8.8	8.7	5.8	3.7	8.7	5.1	9.5	5.8	7.1	5.53
Red Cell Count	13.6	11.4	11.2	10.4	12.9	8.1	11.3	11.9	14.4	9.9	12.1	10.9
Hemoglobin	141	137	135	111	133	113	135	126	142	117	119	120
Hematocrit	0.4	0.4	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.3	0.3
Mean Corp Vol	26.5	34.9	32.8	29.6	27.9	32.6	34	28.8	27.4	35.2	26.9	31.5
Mean Corp Hemoglobin	10.3	12.1	12	10.6	10.3	14	11.9	10.5	9.84	11.8	9.86	11
Mean Corp Hemoglobin Conc	388	347	366	359	370	429	351	366	359	337	366	350
RDW	24.3	20.7	21.5	21.3	24.7	21.8	24	23.3	23.8	27.4	23.5	20.2
Platelet CNT	1162	130	602	332	373	154	366	88.6	633	413	706	138
Mean Platelet Volume		NR ¹	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Differential Cell Count												
% Neutrophils	37	22	27	41	21	28	33	28	12	22	36	25
% Lymphocytes	55	73	66	57	70	67	62	63	78	62	51	54
% Monocytes	1	2	4		8	2	1	4	4	2	4	7
% Eosinophils	7	2	3	2	1	3	4	4	5	14	9	14
% Basophils	NR	NR	NR	NR	NR	NR	NR	1	1	NR	NR	NR
Absolute Differential Values												
Neutrophils	2.3	1.5	2.4	3.6	1.2	1.0	2.9	1.4	1.2	1.3	2.5	1.4
Lymphocytes	3.4	5.1	5.8	5.0	4.1	2.5	5.4	3.2	7.4	3.6	3.6	3.0
Monocytes	0.1	0.1	0.4		0.5	0.1	0.1	0.2	0.4	0.1	0.3	0.4
Eosinophils	0.4	0.1	0.3	0.2	0.1	0.1	0.4	0.2	0.5	0.8	0.6	0.8
Basophils	NR	0.07	NR	NR	NR	NR	NR	0.05	0.09	NR	NR	NR
Chemistry												
Glucose	3	3.1	3.2	3.2	3.5	3.1	3.5	3.5	3.5	3.8	3.1	3.5
Blood Urea Nitrogen (BUN)	7.3	8.9	8.7	7.8	7.5	7	6.9	5.8	5.7	6.8	6.1	5.2
Creatinine	100.2	79.3	95.6	72.4	94.4	66.6	97.3	80.4	84.2	83.3	87.2	78.3
BUN/Cr Ratio	18	28	23	27	20	26	18	18	17	21	18	17
Sodium	148	140	142	143	143	143	140	143	144	141	141	144
Potassium	4.6	4.9	4.7	4.7	5	3.8	4.5	5.3	4.8	5.2	4.3	4.4
Na/K Ratio	32	29	30	30	29	38	31	27	30	27	33	33
Chloride	110	108	106	108	108	109	106	106	107	110	106	108
Carbon Dioxide	23.8	25.2	27	24.5	25.8	24.7	23.5	26.3	21.7	22.8	26.5	26.4

Appendix I7. Summary Clinical Laboratory Data for Sheep at 3 Months (Embosphere®), cont.

Animal Number:	G188	G196	G253	G410	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M
Anion Gap	19	12	14	15	14	13	15	16	20	13	13	14
Calcium	2.6	2.6	2.6	2.6	2.5	2.7	2.5	2.5	2.7	2.7	2.5	2.7
Phosphorus	2.1	1.8	2.1	1.7	1.7	1.8	1.1	2.4	2.0	2.1	2.1	1.7
Total Protein	78	71	74	79	77	78	75	74	80	82	76	80
Albumin	32.5	33.8	28.5	32.3	30.6	33.1	27.5	32.9	31.6	30.6	29.6	34.0
Globulin	46	37	45	47	46	45	47	41	48	51	46	46
A/G Ratio	0.7	0.9	0.6	0.7	0.7	0.7	0.6	0.8	0.7	0.6	0.6	0.7
Total Bilirubin	4	2	6	3	2	4	2	3	3	5	5	3
Alkaline Phosphatase	148	85	170	135	218	151	135	136	139	247	273	185
ALT (Sgpt)	41	30	36	33	28	39	26	37	26	41	25	24
Gamma gt	27	18	62	72	35	65	47	75	70	81	24	28
Creatine Phosphokinase	93	1089	154	359	151	144	81	515	463	196	157	70
Calculated Osmolality	294	282	285	286	286	283	279	285	286	283	279	285
AST (Sgot)	129	166	142	128	100	142	132	153	95	93	102	100
Sorbital Dehydrogenase-AO	25.7	27.5	75.7	29.2	32.3	28.7	26.1	83.7	69.1	26.5	22.5	52.1
Uric Acid	0	0	0	0	0	0	5	0	1	0	0	0
Morphology and Coagulation Parameters												
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	1	1	1	1	2	3	1	1	3	2	1
Part. Thromboplastin Time	28.3	60³	55.3	62	36.6	60	44.2	42.2	65.9	58.2	46.2	55.5
Prothrombin Time	32	35	35.8	32	32.2	35.1	38.3	37.7	38.8	29.2	40.2	31.2

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as “60” for the purposes of calculating mean and standard deviation.

Appendix I8. Summary Clinical Laboratory Data for Sheep at 6 Months (Embosphere®)

Animal Number:	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	6 M	6 M	6 M	6 M	6 M	6 M	6 M	6 M
Hematology								
White Cell Count	5.1	4.7	7.6	3.7	9.3	6.5	4.8	5.7
Red Cell Count	13	12	12.8	12.6	12.3	12.6	11.1	11
Hemoglobin	140	138	143	141	133	149	124	131
Hematocrit	0.4	0.4	0.4	0.4	0.3	0.4	0.3	0.4
Mean Corp Vol	28.2	30.6	30.7	30.8	28.2	35	31.6	33.6
Mean Corp Hemoglobin	10.8	11.4	11.2	11.2	10.8	11.8	11.2	11.9
Mean Corp Hemoglobin Conc	384	373	363	364	384	338	354	354
RDW	27	22.4	24.1	25.9	25.2	26.2	26	22.4
Platelet CNT	857	694	677	341	778	437	411	422
Mean Platelet Volume	NR ¹	NR	NR	inv	NR	inv	inv	inv
Differential Cell Count								
% Neutrophils	30	39	29	47	19	41	23	31
% Lymphocytes	65	52	53	47	75	49	71	62
% Monocytes	5	7	6	5	5	2	5	4
% Eosinophils	NR	1	12	1	1	8	1	2
% Basophils	NR	1	NR	NR	NR	NR	NR	1
Absolute Differential Values								
Neutrophils	1.5	1.8	2.2	1.7	1.8	2.7	1.1	1.8
Lymphocytes	3.3	2.4	4.0	1.7	7.0	3.2	3.4	3.5
Monocytes	0.3	0.3	0.5	0.2	0.5	0.1	0.2	0.2
Eosinophils	NR	0.05	0.91	0.04	0.09	0.52	0.05	0.11
Basophils	NR	0.05	NR	NR	NR	NR	NR	0.06
Chemistry								
Glucose	3.6	3.4	4.1	4.4	3.9	4.5	3.7	4.5
Blood Urea Nitrogen (BUN)	6.7	6.4	5.9	6	5.2	6.5	8.7	7.8
Creatinine	91.2	82.8	108.1	94.3	84.4	85.6	84.4	71.1
BUN/Cr Ratio	18	19	14	16	15	19	26	28
Sodium	145	146	140	143	141	141	142	140
Potassium	5.1	4.7	5.1	5.2	4.5	5.2	4.9	5
Na/K Ratio	28	31	27	28	31	27	29	28
Chloride	109	112	106	109	106	110	108	107
Carbon Dioxide	29.3	27.5	28.2	26.3	26.6	20.4	26.9	27.2

Appendix I8. Summary Clinical Laboratory Data for Sheep at 6 Months (Embosphere®), cont.

Animal Number:	R27	R32	R184	R199	B29	B34	B54	B197
Time Post Embolization	6 M	6 M	6 M	6 M	6 M	6 M	6 M	6 M
Anion Gap	12	11	11	13	13	16	12	11
Calcium	2.5	2.7	2.6	2.7	2.5	2.7	2.6	2.6
Phosphorus	2.2	2.0	1.8	2.3	1.8	1.7	2.3	1.8
Total Protein	75	74	73	75	78	84	75	76
Albumin	32.4	35.5	27.8	34.8	32.5	37.1	34.1	35.3
Globulin	43	39	45	40	45	47	41	41
A/G Ratio	0.8	0.9	0.6	0.9	0.7	0.8	0.8	0.9
Total Bilirubin	3	4	4	4	3	3	6	4
Alkaline Phosphatase	163	142	123	104	93	285	250	165
ALT (Sgpt)	30	39	25	37	27	38	30	30
Gamma gt	63	75	90	89	72	93	30	61
Creatine Phosphokinase	221	132	87	792	200	259	112	290
Calculated Osmolality	289	290	280	286	280	283	286	282
AST (Sgot)	96	114	112	164	92	113	99	82
Sorbital Dehydrogenase-AO	13.6	20	19.1	37.1	24.3	31.2	17.1	14.2
Uric Acid	0	4	0	0	0	0	7	5
Morphology and Coagulation Parameters								
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	2	2	1	1	1	1	1	1
Part. Thromboplastin Time	60³	35.7	60	40.5	43.5	60	76.7	57.8
Prothrombin Time	60	31.7	33.3	30.3	24	32.8	60.5	28.1

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³ The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as "60" for the purposes of calculating mean and standard deviation.

Appendix I9. Summary Clinical Laboratory Data for Sheep at 12 Months (Embosphere®)

Animal Number:	B29	B34	B54	B197
Time Post Embolization	12M	12M	12M	12M
White Cell Count	7.79	5.5	4.33	5.96
Red Cell Count	10.9	13.7	10.7	11.4
Hemoglobin	111	154	122	133
Hematocrit	0.314	0.47	0.346	0.389
Mean Corp Vol	28.9	34.3	32.5	34.1
Mean Corp Hemoglobin	10.3	11.2	11.4	11.7
Mean Corp Hemoglobin Conc	354	327	352	343
RDW	19.9	25.7	23.1	23.5
Platelet CNT	206	349	355	373
Mean Platelet Volume	NR ¹	NR	14.4	9.41
Differential Cell Count				
% Neutrophils	42	28	41	36
% Lymphocytes	54	57	44	47
% Monocytes	3	3	13	14
% Eosinophils	1	12	0	1
% Basophils	NR	NR	1	2
Absolute Differential Values				
Neutrophils	3.27	1.53	1.78	2.16
Lymphocytes	4.21	3.14	1.91	2.78
Monocytes	0.23	0.17	0.562	0.854
Eosinophils	0.08	0.66	0.015	0.061
Basophils	NR	NR	0.063	0.099
Chemistry				
Glucose	3.5	4.5	3.3	4.2
Blood Urea Nitrogen (BUN)	6.2	7.4	7.5	6.4
Creatinine	80.5	83.4	86.3	72
BUN/Cr Ratio	19	22	22	22
Sodium	144	145	144	147
Potassium	4.4	5.4	4.3	4.8
Na/K Ratio	33	27	33	31
Chloride	109	113	110	111
Carbon Dioxide	25	18.7	21.8	23.1
Anion Gap	14	19	17	18
Calcium	2.37	2.74	2.65	2.68
Phosphorus	1.66	1.53	1.61	1.6

Appendix I9. Summary Clinical Laboratory Data for Sheep at 12 Months (Embosphere®), cont.

Animal Number:	B29	B34	B54	B197
Time Post Embolization	12M	12M	12M	12M
Total Protein	81	81	79	80
Albumin	27.01	35.53	33.81	36.16
Globulin	54	45	45	44
A/G Ratio	0.5	0.8	0.7	0.8
Total Bilirubin	3	2	4	3
Alkaline Phosphatase	109	305	286	183
ALT (Sgpt)	19	33	28	32
Gamma gt	110	116	76	36
Creatine Phosphokinase	154	1135	94	67
Calculated Osmolality	286	292	287	293
AST (Sgot)	70	337	107	160
Sorbital Dehydrogenase-AO	69.8	155.6	18.8	40
Uric Acid	4	6	9	6
Morphology and Coagulation Parameters				
Platelets	NA ²	NA	NA	NA
RBC Morph	NA	NA	NA	NA
Aniso	NA	NA	NA	NA
Poik	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1	1	2	1
Part. Thromboplastin Time	60³	60	55.5	60
Prothrombin Time	28.1	51.1	33.1	28.3

¹ Not Reported² Not Applicable to calculate Mean and STDEV (These data are given in Tables with clinical data for individual animals)³The values in bold were reported as being >60 (Appendix H, Clinical Laboratory Data for Individual Animals).

Since the true value is unknown, they are given here as “60” for the purposes of calculating mean and standard deviation.

Appendix J. Means of Clinical Laboratory Data for Sheep Implanted with Embosphere® Microspheres

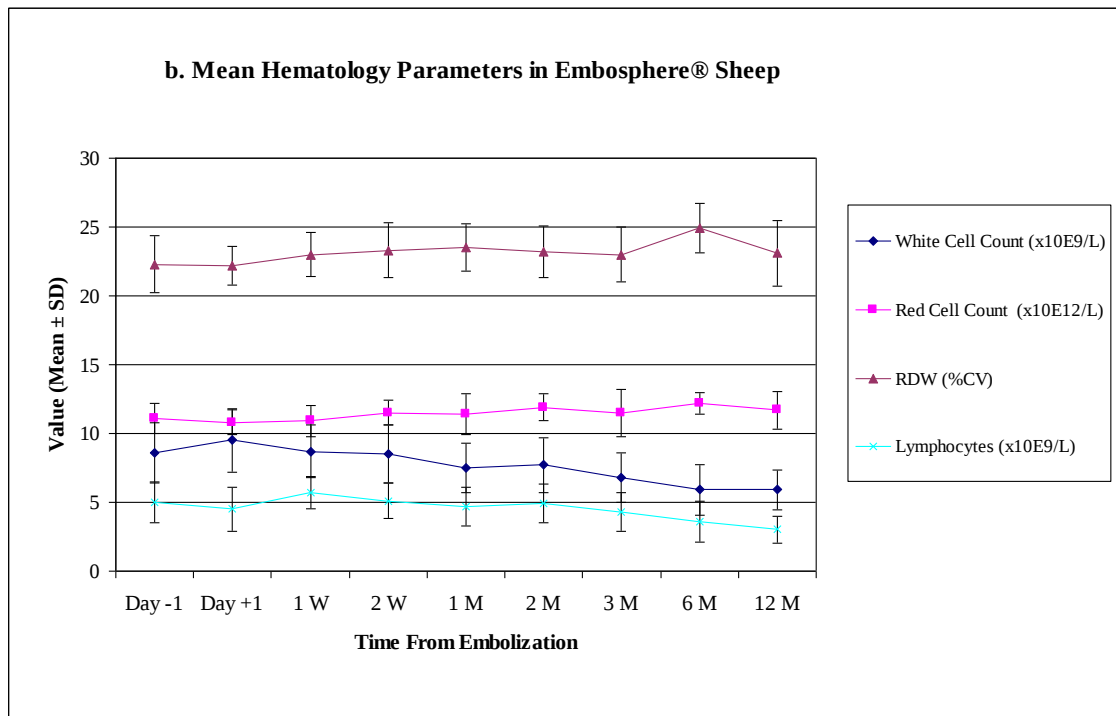
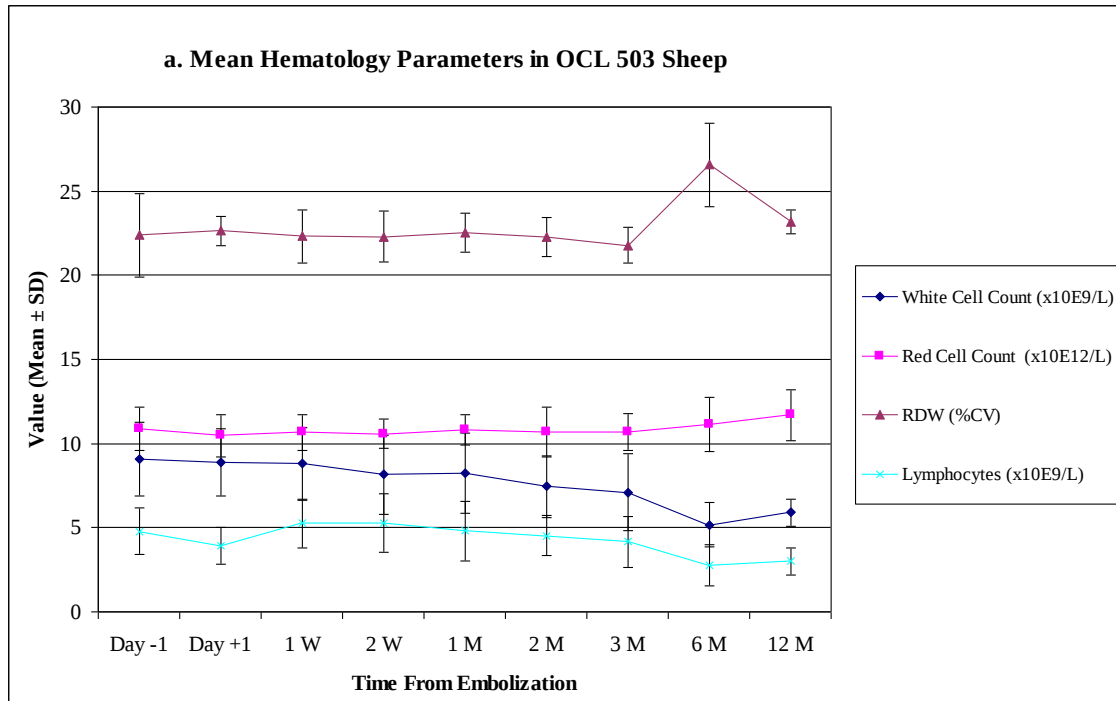
	Mean Values									One Standard Deviation								
Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Number of Sheep	16	16	16	16	16	12	12	8	4	16	16	16	16	16	12	12	8	4
Hematology																		
White Cell Count	8.6	9.5	8.7	8.5	7.5	7.7	6.8	5.9	5.9	2.2	2.3	1.9	2.1	1.8	2	1.8	1.8	1.4
Red Cell Count	11.1	10.8	10.9	11.5	11.4	11.9	11.5	12.2	11.7	1.1	0.9	1.1	0.9	1.5	1	1.7	0.8	1.4
Hemoglobin	126	123	124	131	130	129	127	137	130	9.3	8.6	10.2	10.6	12.4	5.4	11.1	7.8	18.3
Hematocrit	0.3	0.3	0.3	0.4	0.4	0.4	0.3	0.4	0.4	0	0	0	0	0	0	0	0	0.1
Mean Corp Vol	30.4	30.5	30.6	30.7	31.1	30.3	30.7	31.1	32.5	2	1.8	2.1	2	3	3.1	3.2	2.4	2.5
Mean Corp Hemoglobin	11.4	11.4	11.3	11.3	11.4	10.9	11.2	11.3	11.2	0.7	0.6	0.6	0.7	0.9	0.8	1.2	0.4	0.6
Mean Corp Hemoglobin Conc	374	373	371	370	368	361	366	364	344	12.7	8	10.1	7.8	10.8	13.1	23.8	15.8	12.3
RDW	22.3	22.2	23	23.3	23.5	23.2	23	24.9	23.1	2.1	1.4	1.6	2	1.7	1.9	2	1.8	2.4
Platelet CNT	476	425	560	570	483	438	425	577	321	312	213	270	209	249	261	312	196	77.2
Mean Platelet Volume	10.8	9.7	7.7	CNC ¹	9.1	7.5	CNC	CNC	11.9	CNC	3.6	CNC	CNC	CNC	CNC	CNC	CNC	3.5
Differential Cell Count																		
% Neutrophils	31.9	45.1	27.4	32.4	27.9	27	27.7	32.4	36.8	12.8	12.5	10.8	10.9	9.1	8.9	8.1	9.4	6.4
% Lymphocytes	58.6	46.8	66.1	60.7	61.7	63.4	63.2	59.3	50.5	12	12.3	10.5	11.3	10.4	10.4	8.1	10.5	6.0
% Monocytes	5.3	3.9	3.8	4.9	5.9	3.3	3.5	4.9	8.3	5	3	4	5.2	6.7	1.7	2.3	1.5	6.1
% Eosinophils	3.9	3.9	2.9	2.4	4.4	6.7	5.7	3.7	3.5	3.6	3.9	2.6	1.9	4.4	4.7	4.5	4.5	5.7
% Basophils	1.3	1	0.5	0.5	1	1	1	1	1.5	0.6	0	0.7	0.7	0	0	0	0	0.7
Absolute Differential Values																		
Neutrophils	2.8	4.2	2.5	2.8	2.1	2.1	1.9	1.8	2.2	1.3	1.3	1.5	1.3	0.8	1	0.8	0.5	0.8
Lymphocytes	5	4.5	5.7	5.1	4.7	4.9	4.3	3.6	3.0	1.5	1.6	1.2	1.3	1.4	1.4	1.4	1.5	1.0
Monocytes	0.5	0.3	0.3	0.5	0.4	0.3	0.2	0.3	0.5	0.6	0.2	0.3	0.4	0.5	0.2	0.1	0.1	0.3
Eosinophils	0.3	0.4	0.2	0.3	0.4	0.5	0.4	0.3	0.2	0.3	0.5	0.2	0.3	0.4	0.4	0.3	0.3	0.3
Basophils	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0	0	0.1	0.1	0	0	0	0	0.0
Chemistry																		
Glucose	3.8	4.3	3.5	3.2	3.2	3.2	3.3	4	3.9	0.5	0.9	0.4	0.8	0.8	0.6	0.2	0.4	0.6
Blood Urea Nitrogen	5.3	3.7	6.4	7.2	7.7	8.1	7	6.7	6.9	1.1	1.2	1.1	1.3	1.2	1	1.2	1.1	0.7
Creatinine	84.6	85.4	79.2	83.5	85.4	79.9	84.9	87.7	80.6	11	8.6	12.6	10.6	11	9.6	10.4	10.7	6.2
BUN/Cr Ratio	16.1	10.7	20.6	21.8	22.9	25.8	20.9	19.4	21.3	4.5	3.4	4	3.2	3.7	5.2	4.1	5.1	1.5
Sodium	146	149	147	146	145	143	143	142	145	2.7	2.8	3.5	3.6	3.7	1.7	2.2	2.3	1.4
Potassium	4.7	4.5	5	5	4.9	4.7	4.7	5	4.7	0.3	0.3	0.6	0.6	0.5	0.3	0.4	0.3	0.5
Na/K Ratio	31.4	33.4	29.6	29.7	29.8	30.6	30.8	28.6	31.0	3	2	2.7	2.7	2.4	2.1	3	1.6	2.8
Chloride	110	115	112	111	111	109	108	108	111	3	2.9	2.8	3.8	3.2	2.1	1.5	2.1	1.7
Carbon Dioxide	24.6	25.5	27.7	25.8	24.9	24.3	24.9	26.6	22.2	3.1	3.6	2.4	1.9	3.7	2.3	1.7	2.7	2.6
Anion Gap	15.6	13.3	12.6	14.2	14.6	15.4	14.8	12.4	17.0	3.1	3.3	1.8	2.2	2.9	2.5	2.4	1.7	2.2
Calcium	2.5	2.5	2.6	2.7	2.6	2.6	2.6	2.6	2.6	0.1	0.1	0.1	0.3	0.1	0.1	0.1	0.1	0.2
Phosphorus	2.2	2	2.2	2.2	2	1.9	1.9	2	1.6	0.3	0.3	0.3	0.4	0.3	0.3	0.3	0.2	0.1

Appendix J. Means of Clinical Laboratory Data for Sheep Implanted with Embosphere® Microspheres, cont.

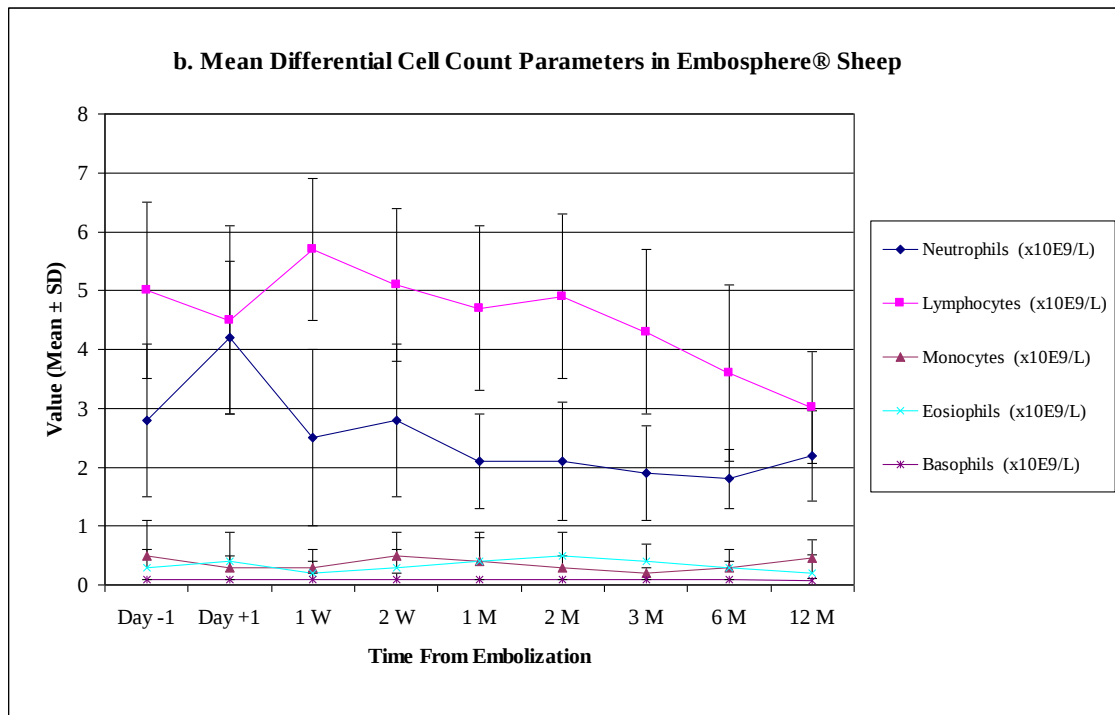
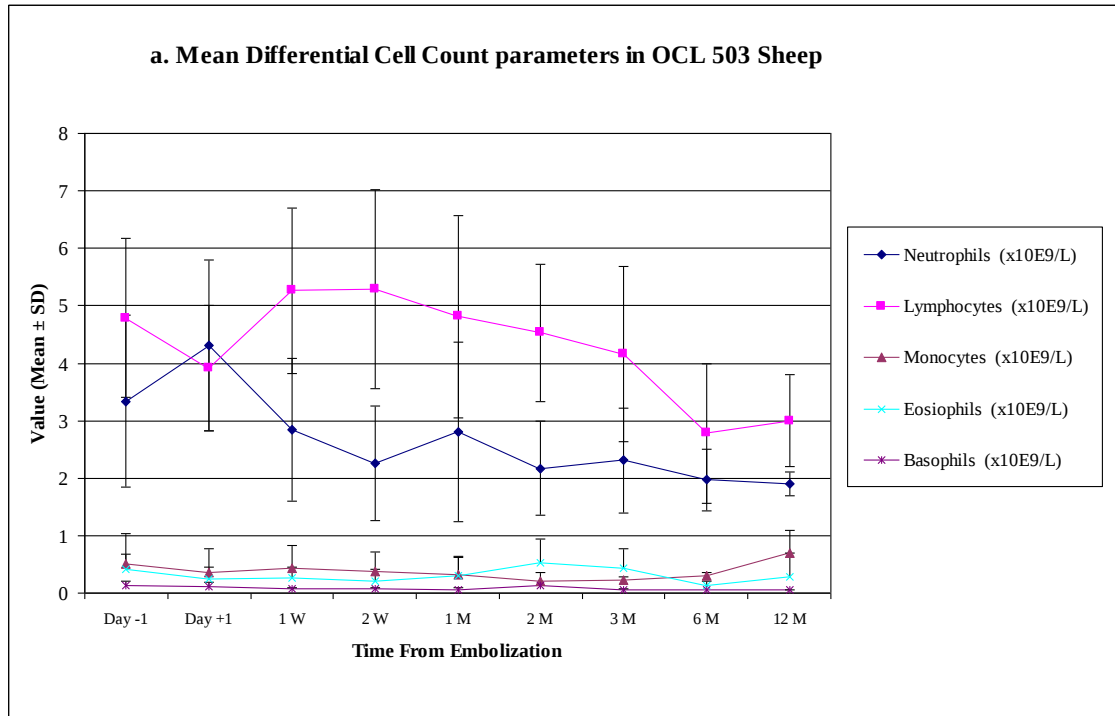
	Mean Values									One Standard Deviation								
Time Post Embolization	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12M	Day -1	Day +1	1 W	2 W	1 M	2 M	3 M	6 M	12 M
Number of Sheep	16	16	16	16	16	12	12	8	4	16	16	16	16	16	12	12	8	4
Total Protein	71.8	75.4	71.9	74.3	74.6	76.2	77	76.3	80.3	4.4	3.8	3.8	4.9	5.6	5.4	3.1	3.5	1.0
Albumin	30	31.7	29.5	31.4	32.3	32.5	31.4	33.7	33.1	2.7	2.7	3.1	3.1	3.7	4	2.1	2.9	4.2
Globulin	41.8	43.7	42.3	42.9	42.2	43.7	45.4	42.6	47.0	4.5	4.3	4.4	5.4	4.5	6.4	3.5	2.8	4.7
A/G Ratio	0.7	0.7	0.7	0.8	0.8	0.8	0.7	0.8	0.7	0.1	0.1	0.1	0.2	0.1	0.2	0.1	0.1	0.1
Total Bilirubin	6.1	5.2	5	5.6	5.1	3.9	3.5	3.9	3.0	1.7	0.9	1	1.5	1.4	0.9	1.3	1	0.8
Alkaline Phosphatase	245	244	196	213	203	212	169	166	221	55	50	74.4	61.1	62.2	62.1	53.7	68.5	91.8
ALT (Sgpt)	29.1	35.5	26.3	29.4	27.4	32	32.2	32	28.0	4.9	11.7	4.6	9.1	5	7.6	6.5	5.3	6.4
Gamma gt	49.3	50.6	55.6	54.3	53.6	54.5	50.3	71.6	84.5	25.2	25.2	27.2	29.6	26.8	25.1	22.9	20.8	36.8
Creatine Phosphokinase	90	335	109	192	306	585	289	262	363	24.4	359	62.5	175	412	1331	292	226	516
Calculated Osmolality	289	293	293	292	290	287	284	285	290	4.4	5.2	7.7	7	7.4	3.2	3.9	3.9	3.5
AST (Sgot)	109	145	97	120	114	125	124	109	169	31	51	25.7	99.1	28.9	27.6	24.9	25	118
Sorbital Dehydrogenase-AO	44.6	141	41.8	28.6	39	42.8	41.6	22.1	71.1	34.9	212	48.2	17.9	22.9	20.2	22.3	8.3	60.1
Uric Acid	3	2.3	3.4	2.4	2.1	1.2	0.5	2	6.3	2.7	3.1	3.5	3.9	3.5	1.9	1.4	2.9	2.1
Morphology and Coagulation Parameters																		
Platelets	NA ²	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RBC Morph	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aniso	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Poik	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Degradation Products	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fibrinogen Semi Quantitative	1.6	2.4	2.3	1.6	1.5	1.3	1.6	1.3	1.3	0.9	0.7	1.1	0.9	0.5	0.7	0.8	0.5	0.5
Part. Thromboplastin Time	46.8	53.6	42.3	47.1	51.3	56.0	51.2	54.3	58.9	18.9	9.6	10.1	10.4	11.4	15.6	11.5	13.4	2.3
Prothrombin Time	29.2	35.6	31.8	29.9	35.3	47.6	34.8	37.6	35.2	7.4	10.9	9.3	4.4	8.9	20.5	3.5	14.3	10.9

¹ Can not calculate² Not Applicable to calculate Mean and STDEV. These data are given in Tables with clinical data for individual animals

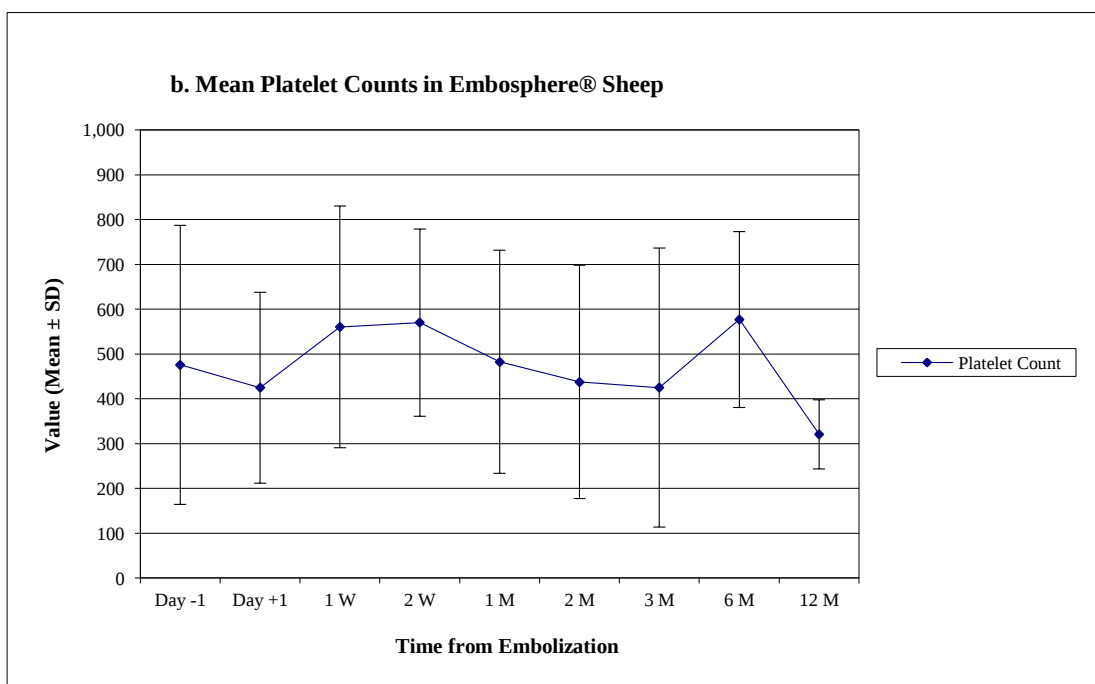
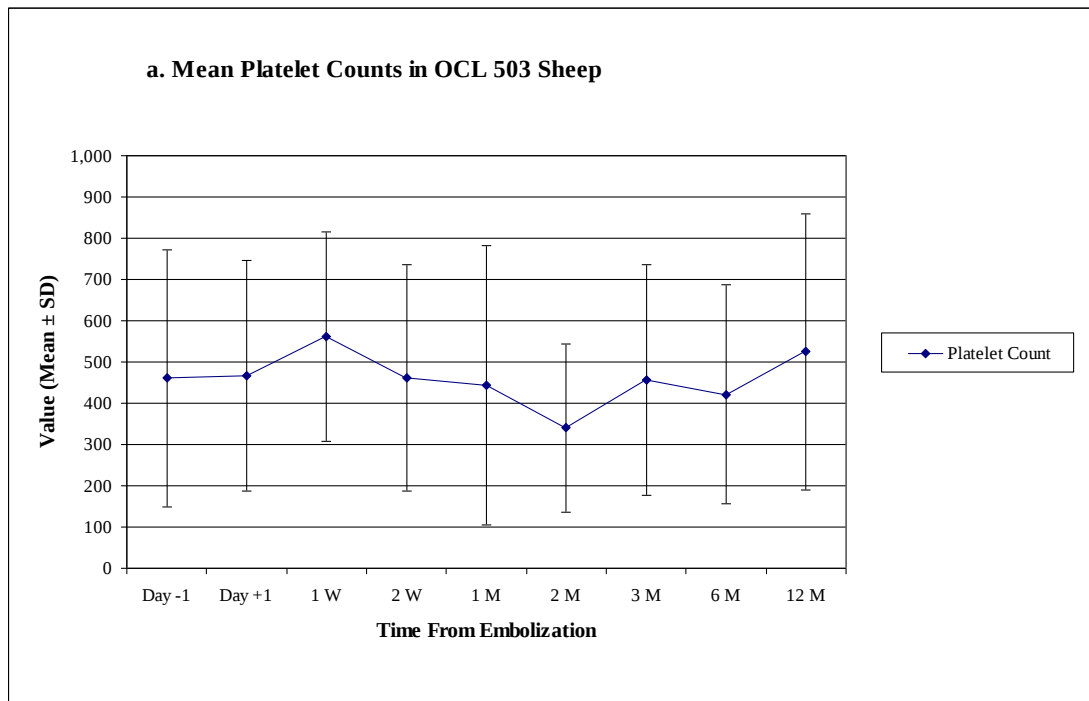
Appendix K. Graphs of Mean Hematology Parameters



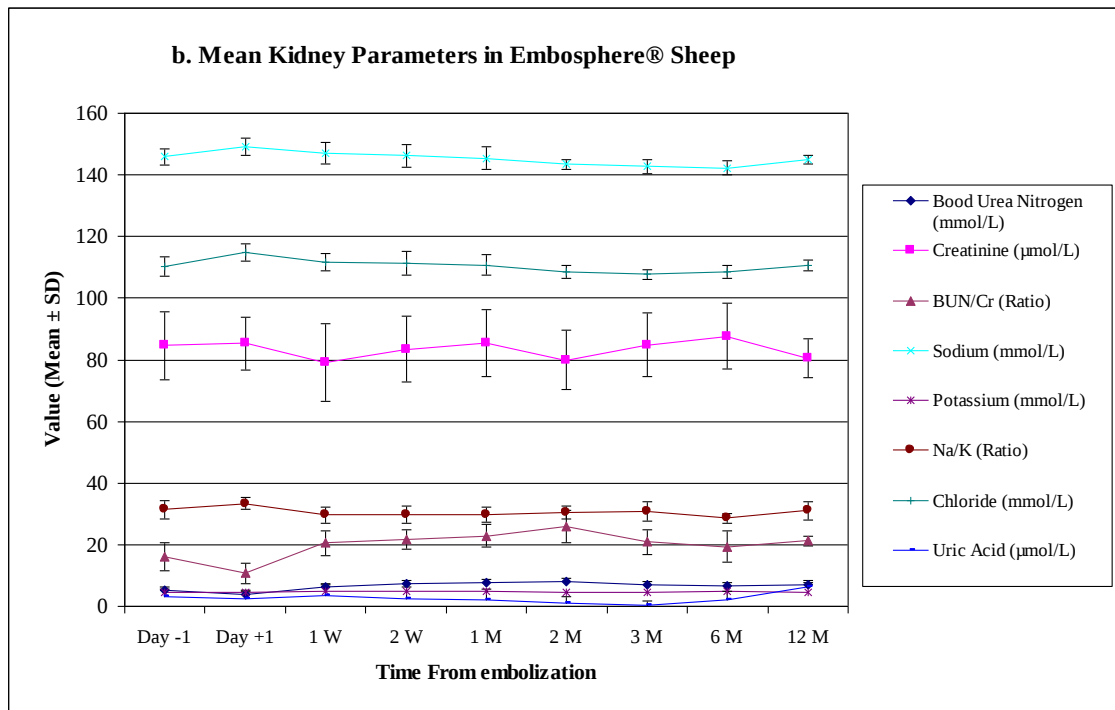
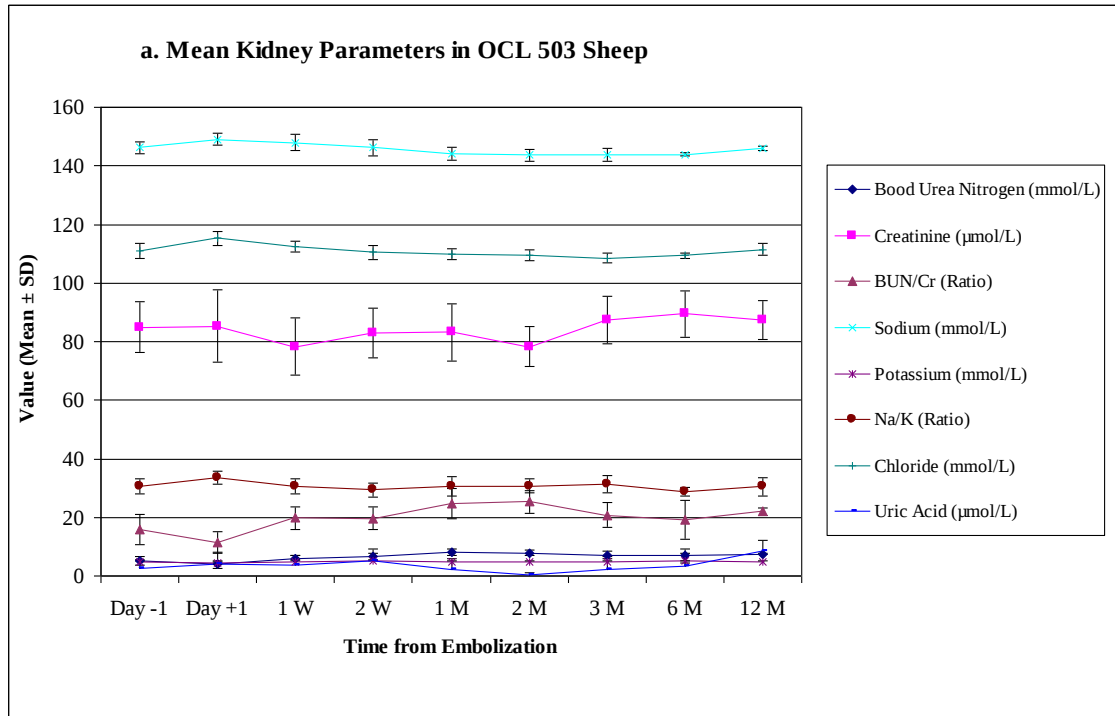
Appendix L. Graphs of Mean Differential Cell Counts



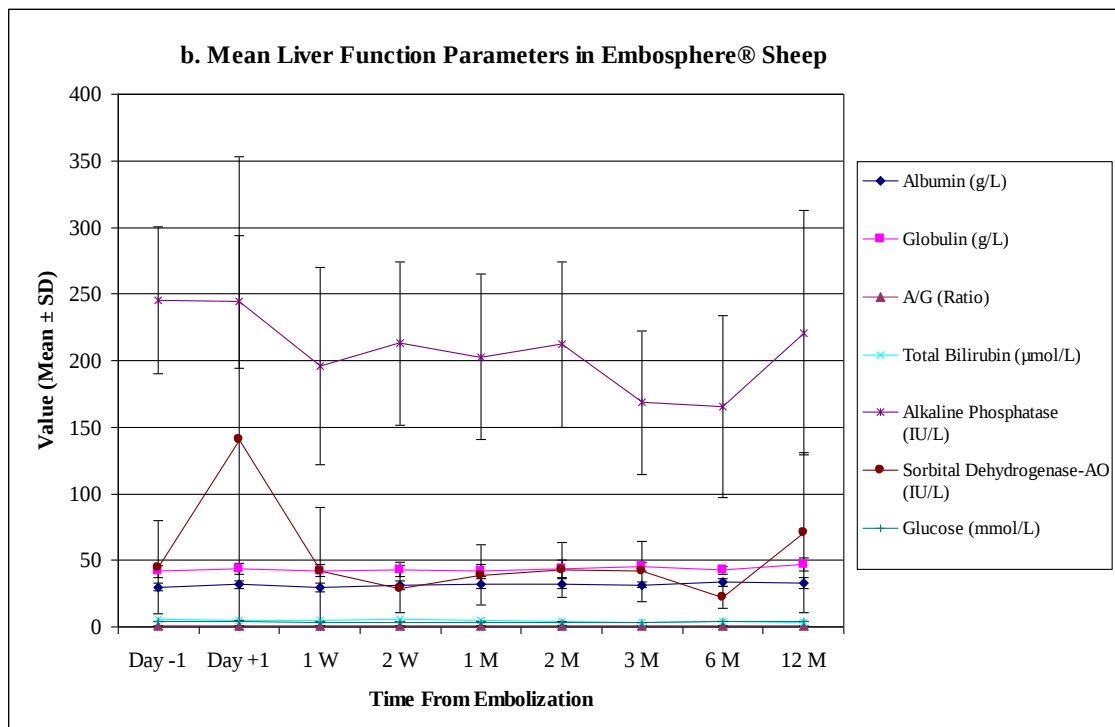
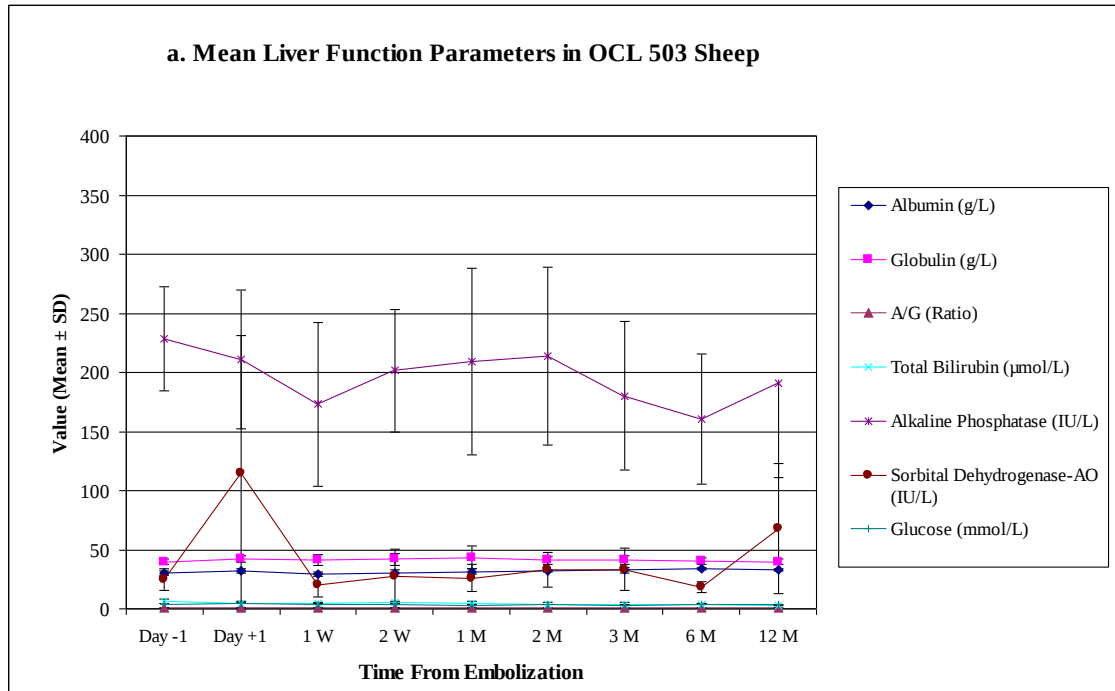
Appendix M. Graphs of Mean Platelet Counts

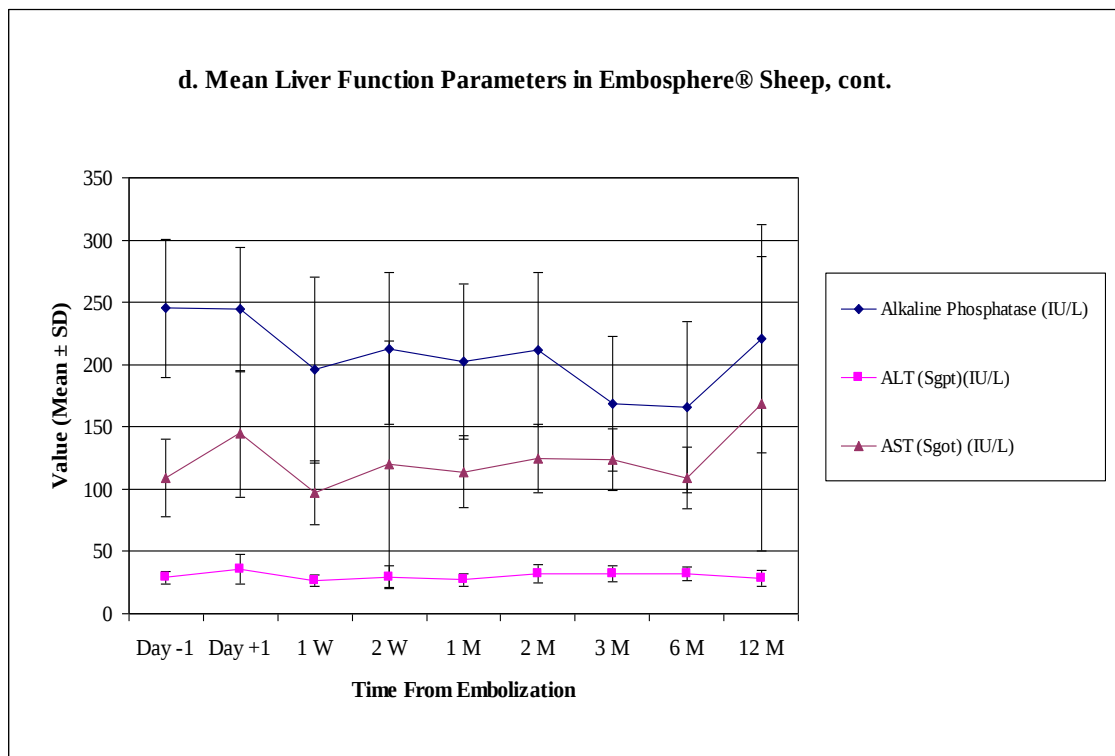
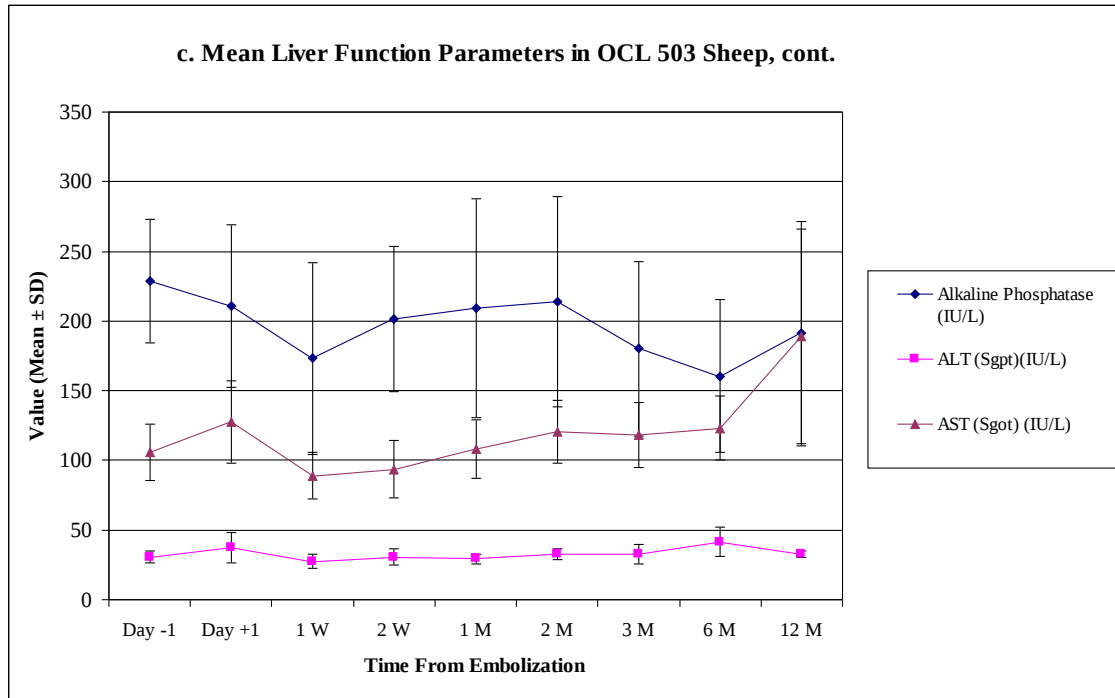


Appendix N. Graphs of Mean Kidney Function Parameters

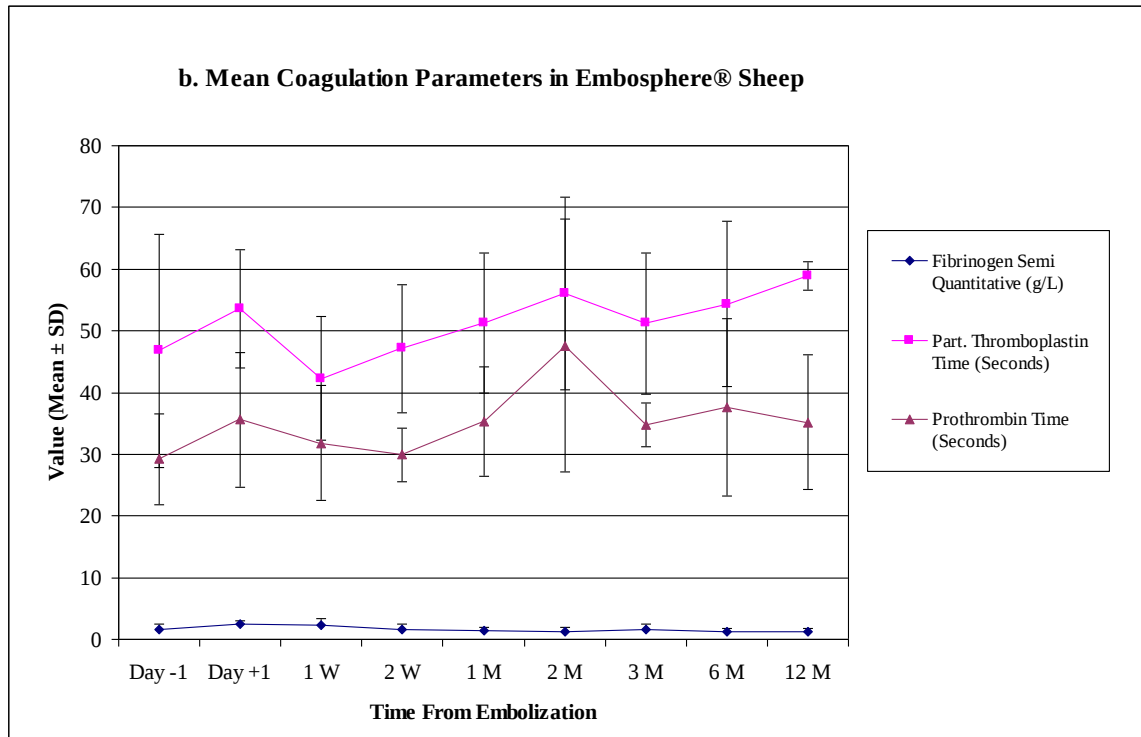
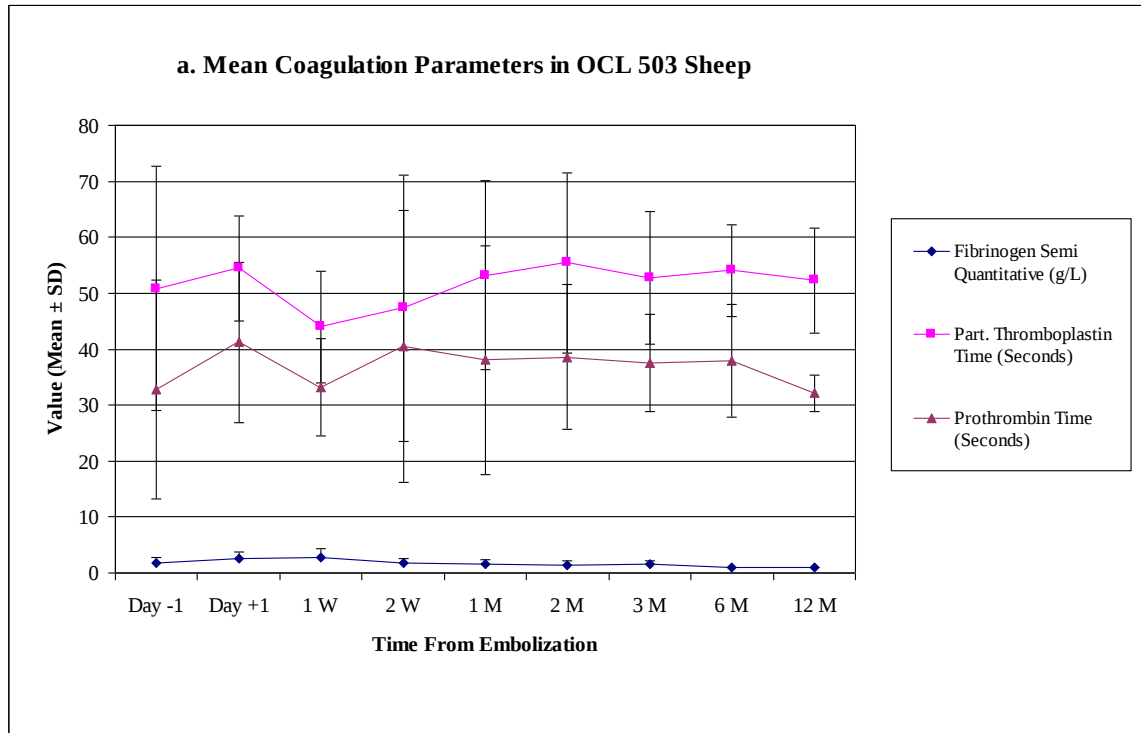


Appendix O. Graphs of Mean Liver Function Parameters

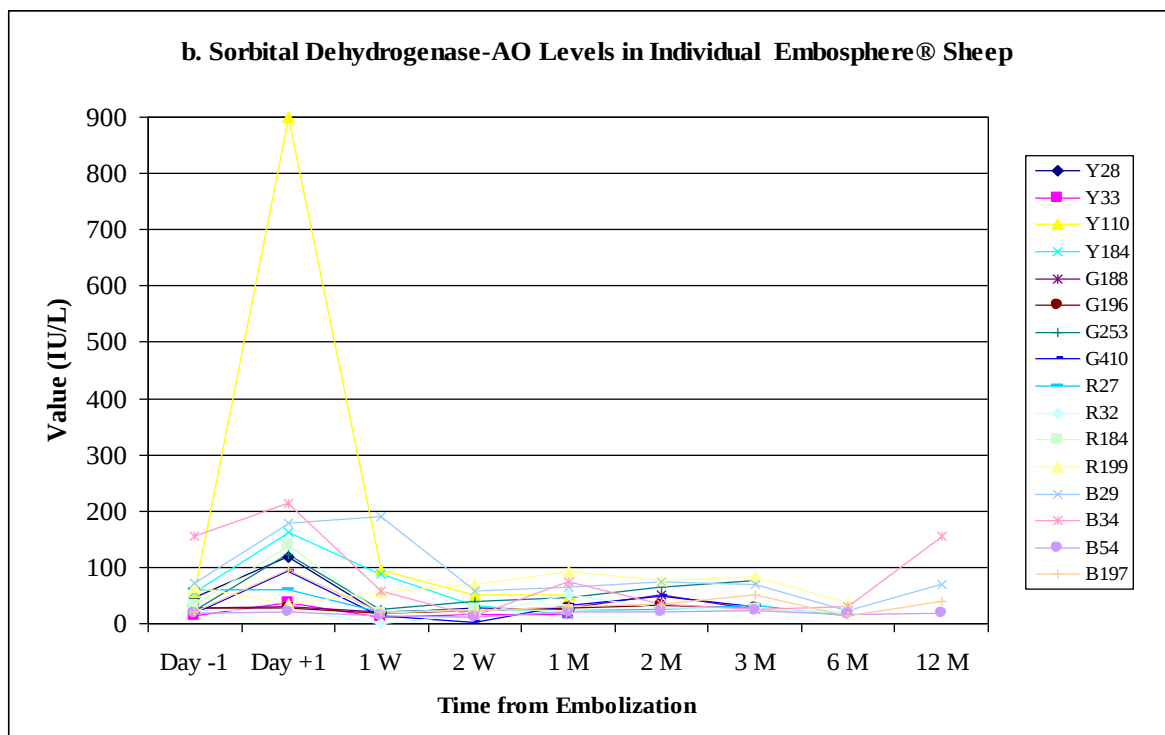
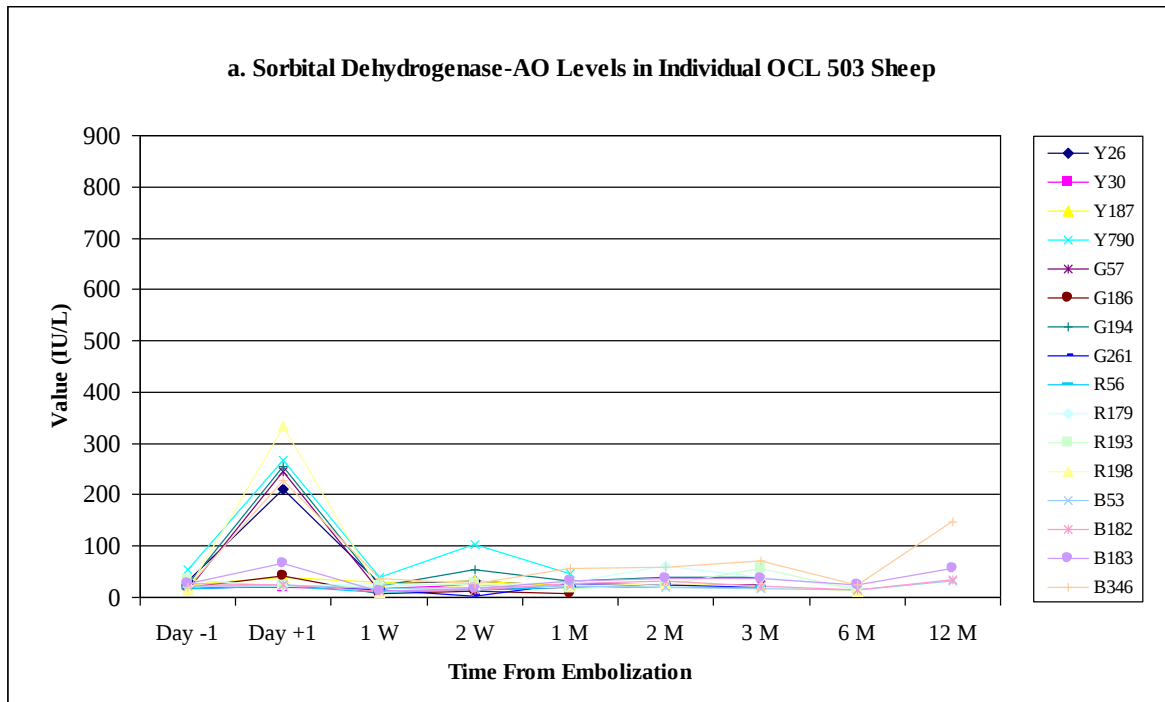


Appendix O. Graphs of Mean Liver Function Parameters, cont.

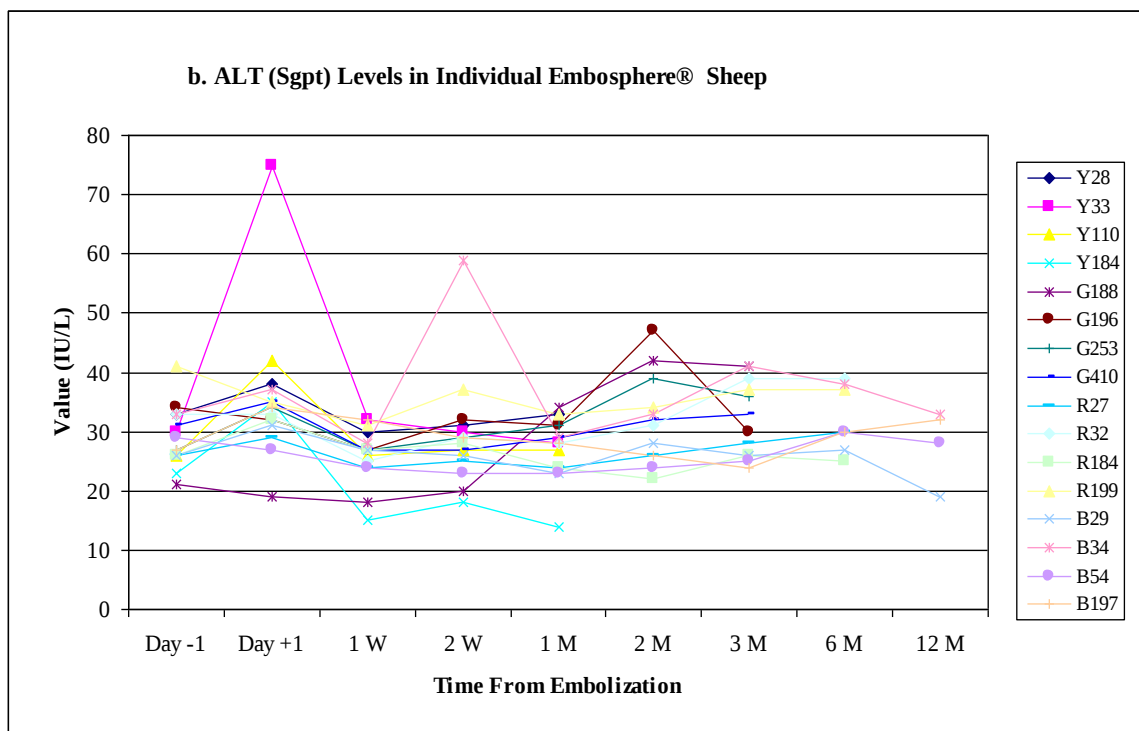
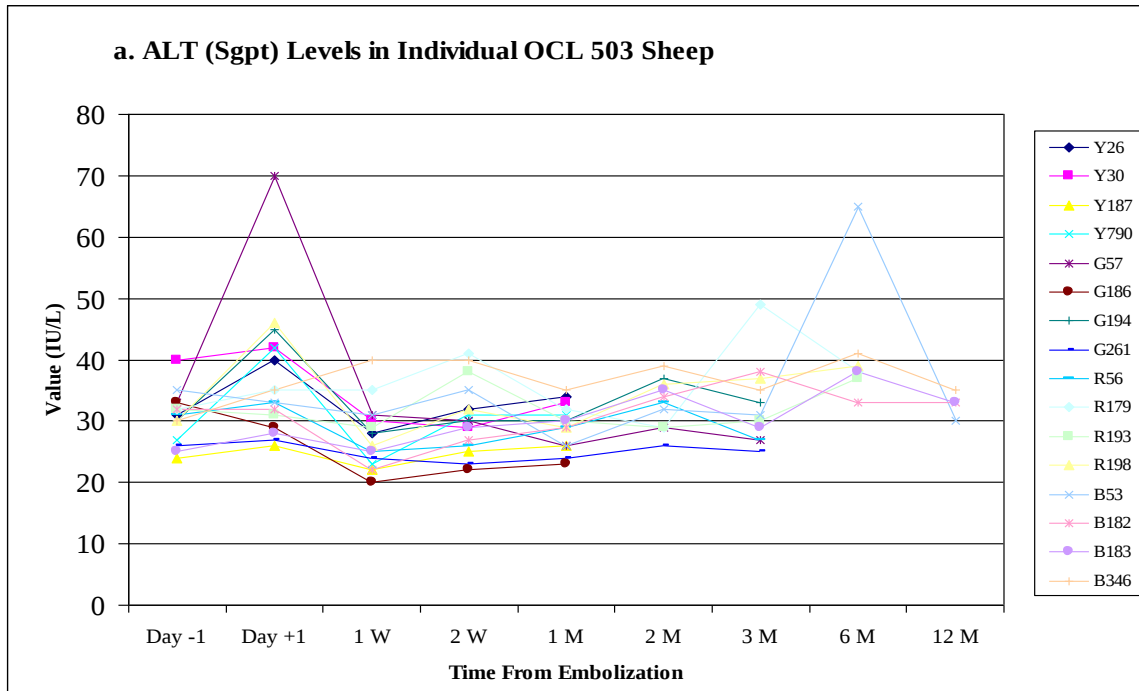
Appendix P. Graphs of Mean Coagulation Parameters



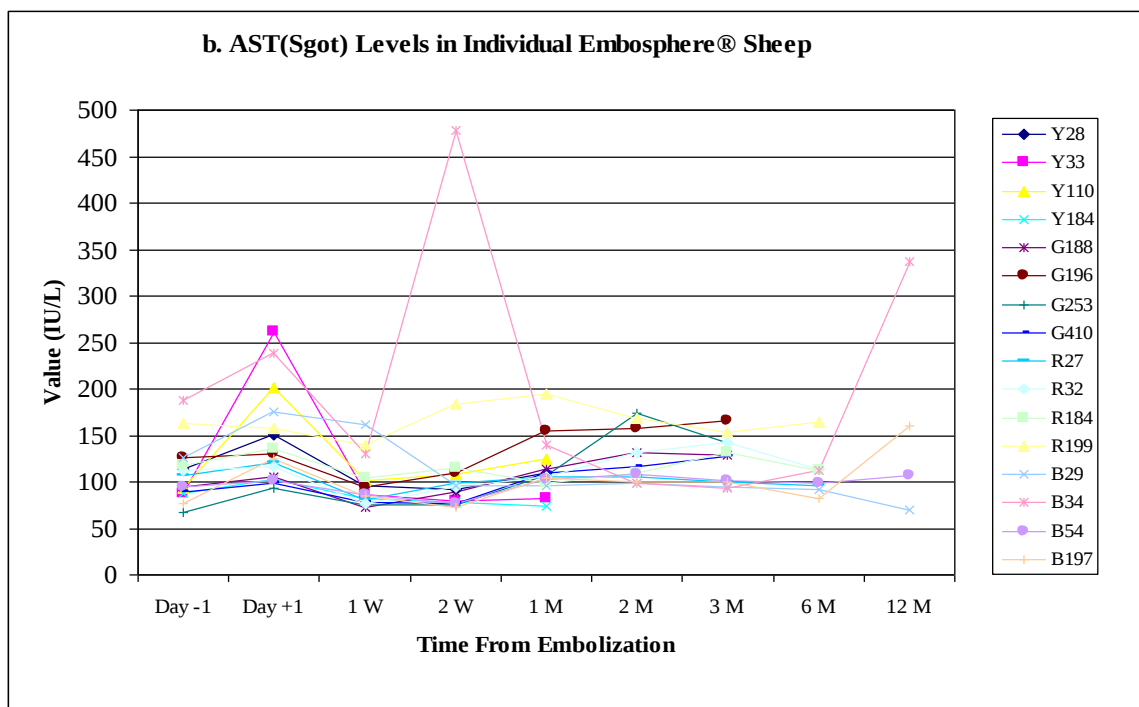
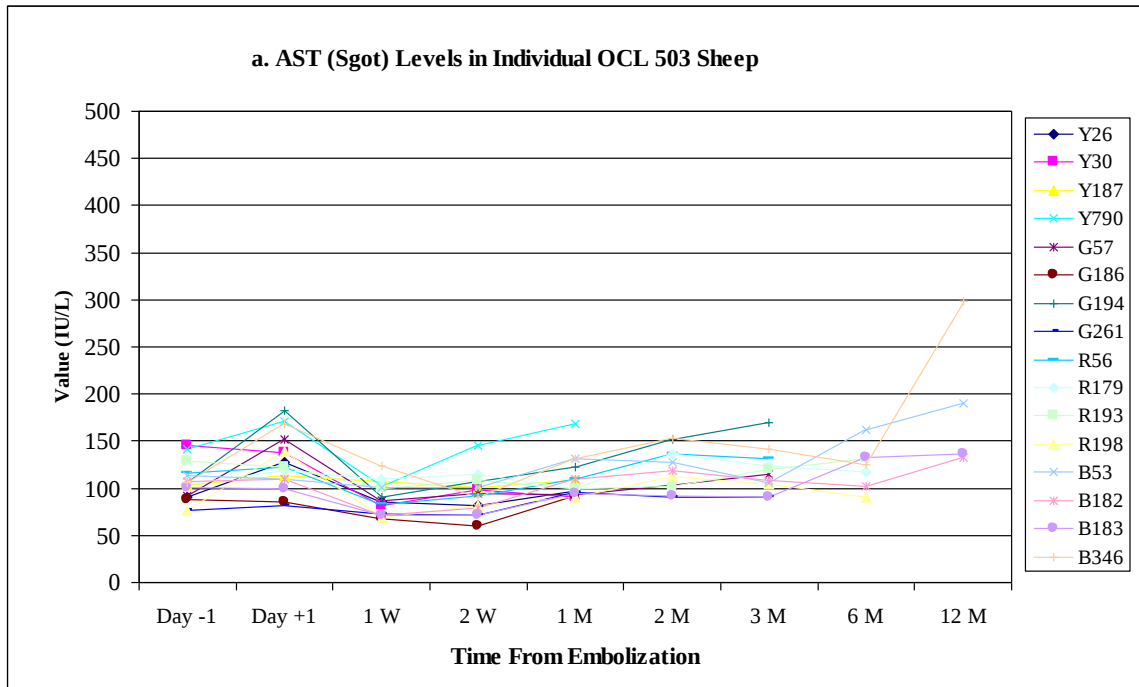
Appendix Q. Sorbital Dehydrogenase-AO Levels in Individual Sheep



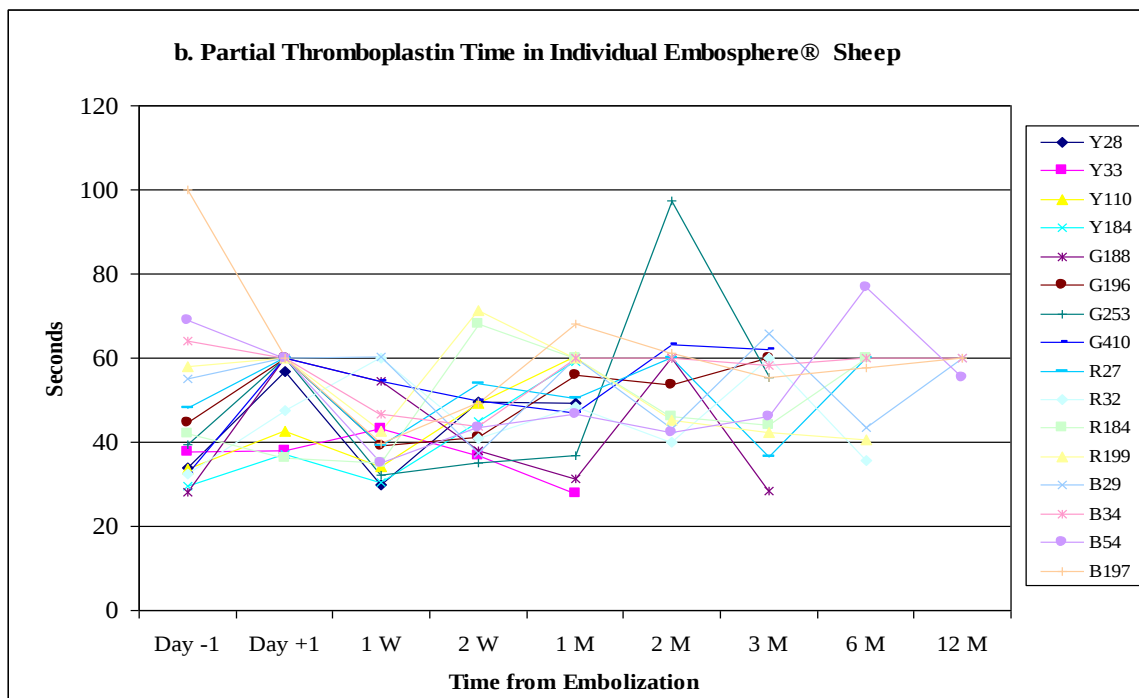
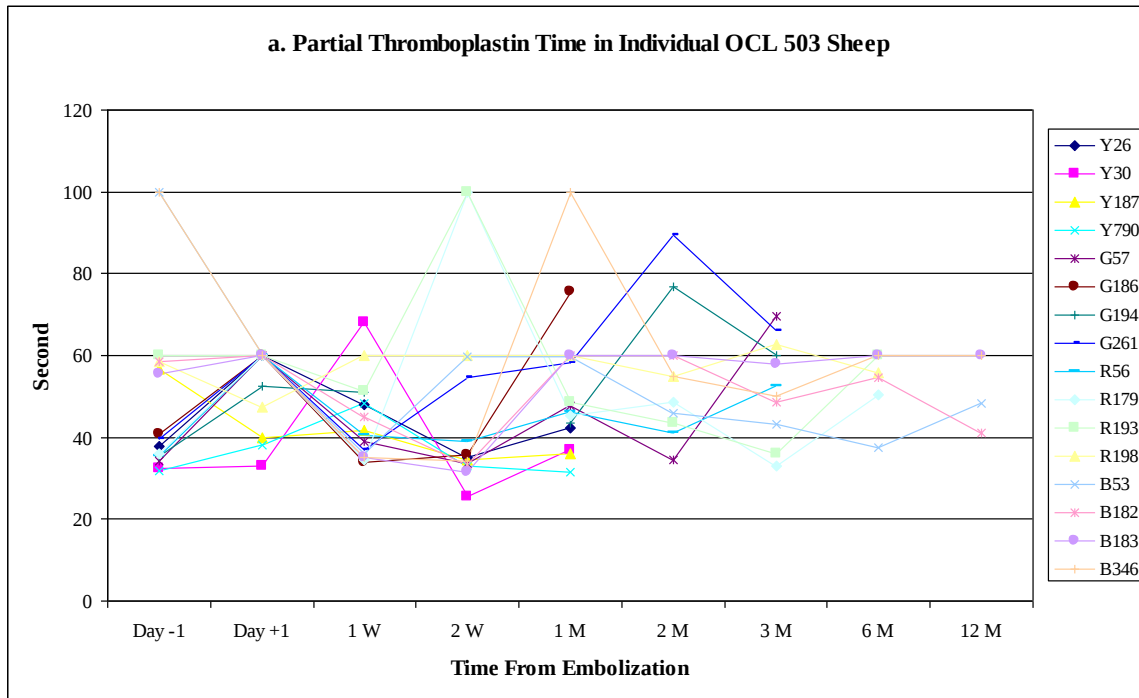
Appendix R. ALT (Sgpt) Levels in Individual Sheep



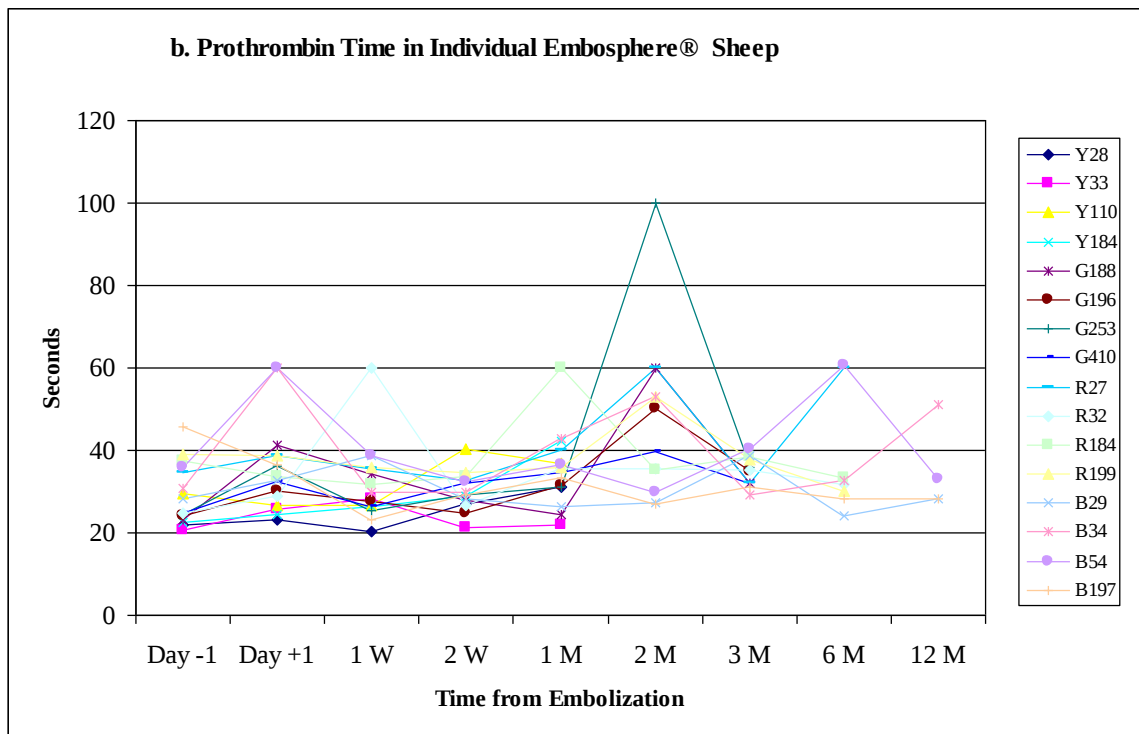
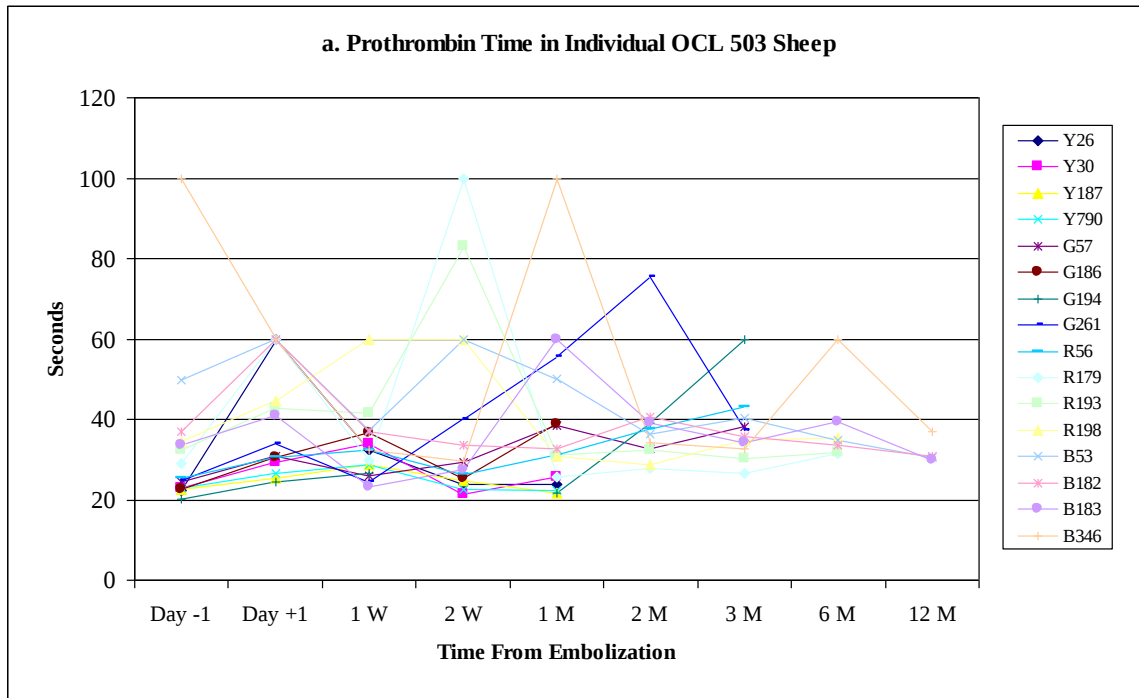
Appendix S. AST (Sgot) Levels in Individual Sheep



Appendix T. Partial Thromboplastin Time in Individual Sheep



Appendix U. Partial Prothrombin Time in Individual Sheep



Appendix V. Effectiveness of Implantation and Location of the Device

Animal Number	Implanted Device	Result of Implantation at Sacrifice	Histopathological Identification of Occluded Vasculature				
			Treated Uterine Artery Vasculature	Contralateral Uterine Vasculature	Vaginal Artery	Ovarian Artery	Bladder Artery
Y26	OCL 503	Occluded	Yes	No	No	No	No
Y30	OCL 503	Occluded	Yes	Yes	No	No	No
Y187	OCL 503	Occluded	Yes	No	No	No	No
Y790	OCL 503	Occluded	Yes	No	No	No	No
G57	OCL 503	Occluded	Yes	No	No	No	No
G186	OCL 503	Occluded	Yes	No	No	No	No
G194	OCL 503	Occluded	Yes	No	No	No	No
G261	OCL 503	Occluded	Yes	No	No	No	No
R56	OCL 503	Occluded	Yes	No	No	No	No
R179	OCL 503	Occluded	Yes	No	No	No	No
R193	OCL 503	Occluded	Yes	No	No	No	No
R198	OCL 503	Occluded	Yes	No	No	No	No
B53	OCL 503	Recanalized	--- ¹	---	---	---	---
B182	OCL 503	Recanalized	---	---	---	---	---
B183	OCL 503	Recanalizing	---	---	---	---	---
B346	OCL 503	Recanalized	---	---	---	---	---
Y28	Embospheres®	Occluded	Yes	DNE ²	No	No	No
Y33	Embospheres®	Occluded	Yes	No	No	No	No
Y110	Embospheres®	Occluded	Yes	No	Yes	No	No
Y184	Embospheres®	Occluded	Few	Few	Yes	No	No
G188	Embospheres®	Occluded	Yes	Few	No	No	No
G196	Embospheres®	Occluded	Yes	No	Yes	No	No
G253	Embospheres®	Occluded	Yes	Few	Yes	No	No
G410	Embospheres®	Occluded	Yes	No	Few	No	No
R27	Embospheres®	Occluded	Yes	No	Yes	No	No
R32	Embospheres®	Occluded	Yes	Yes	Yes	No	No
R184	Embospheres®	Occluded	Yes	Yes	No	Few	No
R199	Embospheres®	Occluded	Yes	Yes	No	No	No
B29	Embospheres®	Occluded	Yes	No	Yes	No	Few
B34	Embospheres®	Occluded	Yes	No	Yes	Few	No
B54	Embospheres®	Occluded	Yes	No	No	No	No
B197	Embospheres®	Occluded	Yes	No	Yes	No	No

¹ It was impossible to perform an analysis of microspheres and occlusive events as the arteries of OCL 503-treated sheep were recanalized or in the process of being recanalized twelve months post implantation.

² DNE = Did Not Examine

Appendix W. Summary Gross Postmortem and Histological Report for Sheep Implanted with OCL 503 or Embosphere® Microspheres

ONE YEAR GROSS POSTMORTEM AND HISTOPATHOLOGY

The gross and microscopic postmortem findings at one year were clearly different between OCL 500 and Embosphere® Microspheres experimental groups. Upon gross examination of all Embosphere® Microspheres treated sheep, the treated uterine artery stood out as a thick, rope-like cord in the mesometrium, unchanged from its appearance at all of the previous examination periods. In two sheep, the vaginal artery on the injected side had a similar appearance. In contrast, the uterine arteries of all of the OCL 500 treated sheep were grossly normal, and the treated artery of each animal could not be distinguished grossly from the untreated artery.

Microscopic examination yielded similar results. Sections of uterine arteries from all embosphere treated sheep had the lumen completely obstructed by Embosphere® Microspheres. There was a well developed interstitial collagenous matrix which held the Embosphere® Microspheres in place, and occasionally, smooth muscle from the arterial wall also invested the Embosphere® Microspheres. There was no evidence of degradation of Embosphere® Microspheres in the year since injection. Small numbers of lymphocytes were occasionally present in places in the connective tissue among the Embosphere® Microspheres, but it was fibrosis and not inflammation that was the characteristic of the material in the arterial lumen. In contrast, the injected uterine arteries of three of the four OCL 500 animals could not be differentiated microscopically from the untreated arteries at any point along the length of the artery and its branches in the mesometrium to its ramifications in the outer wall of the uterine horns. In the fourth OCL 500 animal, segments of uterine artery in the mesometrium had varying amounts of fibrous tissue in the arterial wall, or areas of the wall that were irregular in organization. However, in almost all of these segments, there was a clear arterial lumen lined by endothelial cells which contained fresh erythrocytes, confirming blood flow. The diameter of many of the branches of the uterine artery in the mesometrium of this latter animal was not as great as in the other three animals of this treatment group.

OVERALL HEMATOLOGY AND CLINICAL CHEMISTRY

Over the entire study there were no differences at any time point between the OCL 500 and Embosphere® Microspheres treated groups of sheep in any of the hematologic and clinical chemistry parameters that were studied. Many sheep had a post surgery alteration in total white cell count and fluctuations from normal in the differential counts of individual leucocyte types, as well as slight alterations in serum electrolytes and variable elevations in creatine phosphokinase and liver enzymes. Such changes were part of the normal effects of, and physiological response to, anesthesia and the physical manipulations of surgery, and parameters almost always returned to normal by seven days post surgery. One animal had elevated muscle enzymes and phosphorus accompanied by clinical signs of stiffness, and was removed from the study early. This animal was found to have an abscess in a cervical vertebral

body, and the changes in clinical chemistry parameters were secondary to the effects of this upon the musculoskeletal system. A second animal had elevated muscle enzymes and its condition was followed by the collection of blood and serum samples at time periods additional to those called for in the study protocol. These parameters eventually returned to normal ranges without any accompanying clinical signs, and their cause was not determined. This animal was normal at the termination of the study by gross and microscopic postmortem examination.

In neither of the latter animals was the alteration in hematologic and clinical chemistry parameters related to the test article, either temporally or, in the animal with the spinal abscess, by examination of the lesion.

In this study there were pseudo-deviations from normal values for certain parameters on both the hematologic and clinical chemistry panels. This was a factor related to the reference laboratory, which was using textbook values for sheep rather than values determined on their own equipment with blood from sheep in the region in which this study took place. When the pre-experimental hematologic and clinical chemistry values for all the sheep in this study are taken as a normal group, these apparent deviations disappear. The individual deviations and their significance are discussed for each animal on the individual interpretation sheets for each blood sample.

Appendix X. Resumes of Key Personnel

CURRICULUM VITAE – Dr. Richard J T Owen

HOME ADDRESS RR 260
Spruce Grove, Alberta
T7Y 1B1

Phone: (780) 407 6907 / (780) 407 1210
Fax: (780) 407 6176
e-mail drrichardowen@tbwifi.ca

BUSINESS ADDRESS: Radiology and Diagnostic Imaging
Walter C. Mackenzie Health Sciences Centre
University of Alberta Hospital
8440 – 112 Street
Edmonton, Alberta
Canada, T6G 2B7

CITIZENSHIP: Dual - British/Canadian
AGE: 45 Years

EDUCATION:

1987: University of Wales College of Medicine, Wales, MB b Ch
1991: Royal College of Physicians, England, MRCP (UK)
1996: Royal College of Radiologists, England, FRCR (UK)
1997: Royal College of Radiologists, England, CCST
2001: Medical Council of Canada, LMCC

LICENCES: College of Physicians & Surgeons of Alberta (2000) No: S09603
General Medical Council, London (1987) No: 3257166

RADIOLOGY RESIDENCY: Leicester teaching hospitals training scheme: 1991-96.

FELLOWSHIP TRAINING: Interventional Radiology, Calgary, Alberta; 1996-97

WORK EXPERIENCE:

June 2003-Present University Appointment: Assistant Professor, Department of Radiology and Diagnostic Imaging, Faculty of Medicine, University of Alberta, Edmonton, Canada. Staff Radiologist (Specialist Intervention), Medical Imaging Consultants, Edmonton.

Feb 2000 – Present Departments of Radiology; Grey Nuns Hospital, Royal Alexandra and University of Alberta Hospitals.

During my time in Edmonton I have continued my research interests and development of interventional radiology. I have introduced several new techniques (such as hepatic artery chemoembolization, radioembolization and pre-op portal vein embolization) and further developed established techniques (Browiac catheter placement, portacath placements, uterine artery embolization and gonadal vein embolization). I am actively involved in the clinical islet cell programme, was responsible for the Journal club for 2 years, act as the director for the fellowship programme and the mentor for the interventional fellow. I am the chairman of the regional Angio-interventional subgroup and represent radiology at the GI tumour group and the transplant group.

Jul 1997 –Jan 2000 Consultant in Radiology (Specialist intervention), Freeman Hospital, Newcastle, UK.
Academic appointment: Clinical Lecturer.

The Freeman Hospital has one of the largest vascular units in the UK and is a tertiary care center for several specialties. The hospital also houses the Northern region Liver and renal transplant services. The interventional service encompasses all specialties and modalities and during my appointment I consolidated my clinical experience in all areas.

During the post I set up a Central Venous line placement service, initiated the fellowship programme, become actively involved in the endovascular aortic stent trial and in the TIPSS trial.

Together with my colleague Dr Rose we established the Freeman as a training site for the Cook aortic endograft and ran several training courses.

I set up 2 randomised trials involving central venous catheter placement and subintimal angioplasty and was the college tutor for the 8 trainees attached to radiology.

In addition to the interventional commitment I had sessions in ultrasound, CT, General reporting and bariums as well as shared time in MRI.

Areas of Clinical experience:

- a) Diagnostic arteriography and venography in all areas (including neuro-radiology)
- b) Arterial and venous angioplasty, vascular stents, thrombolysis and embolisation techniques.
- c) Specialist procedures in renal and mesenteric domains.
- d) Placement of central venous catheters, dialysis access and A/V fistulae maintenance.
- e) Cholangiography, hepatic chemo and radio embolisation, stent placements and portosystemic shunts.
- f) Aortic stent grafts
- g) Biopsy and drainage procedures
- h) Specialist urological procedures
- I) Combined procedures in Interventional theatre
- J) Gynaecological interventions including uterine artery embolization.
- K) Islet transplantation

July 1996 - June 1997	Fellow (Interventional Radiology) Foothills Hospital, University of Calgary, Canada
Sep1991 - June 1996	Registrar (Radiology Resident) Leicester Royal Infirmary, Leicester Training Scheme, UK
July – Sep 1991	Registrar (Medicine). Glenfield General Hospital, Leicester, UK
Feb - July 1991	Senior House Officer (Accident & Emergency). Nuneaton General Hospital, Warwickshire, UK
Aug 1990 - Jan 1991	Senior House Officer (Obstetrics and Gynaecology). Nuneaton Maternity Hospital, Warwickshire, UK
Aug 1988 - Jan 1990	Senior House Officer (Internal Medicine). Nuneaton General Hospital, Warwickshire, UK
Aug 1987 - July 1988	House Physician/Surgeon. Cardiff Royal Infirmary (Surgery) Newport General Hospital (Medicine) University of Wales College of Medicine, Cardiff, UK

PUBLICATIONS:

- Owen R J T, Harper W M, Finlay D B, Belton I P. Isotope Bone Scans In Patients With Painful Knee Replacements: Do They Alter Management? *BJR*. 1995; 68:1204-1207.
- Owen R J T, Hickey F G, Finlay D B. A study of metatarsal fractures in children. *Injury* 1995 26(8): 537-538.
- Coakley F V, Owen R J T, Rees Y, Dennison A. Bladder opacification following enteral iopamidol as a sign of occult intestinal infarction. *BJR*; 1995 95 316-317.
- Owen R J T, Lamont A C. The impact of fetal screening on indications for cystourethrography in infants. *Pediatric Radiology* 1995; 25 (6): 492
- Coakley F V, Messios N, Morgan B, Owen R J T. Pitfalls in the diagnosis of subarachnoid haemorrhage. *BMJ* 1995; 311:871-872.
- Owen R J T, Baxter A, Lamont A C. Hypomelanosis of Ito; MR Findings. *Pediatric Radiology* 1995; 25(1):77
- Coakley F V, Messios N, Morgan B, Owen R J T. Head injury; The significance of a normal CT scan. *Journal of Neurology, Neurosurgery, and Psychiatry*. 1996; 60(3): 358.
- Owen R J T, Lamont A C, Brookes J . Postnatal investigation and early management of prenatally diagnosed hydronephrosis. *Clinical Radiology* 1996; 51:173-176.
- Owen R J T, Krarup K C. The Successful Use And Removal Of The Gunther Tulip Inferior Vena Caval Filter In Pregnancy. *Clinical Radiology* 1997.
- Sensier Y, Fishwick G, Owen R et al. A comparison between colour duplex ultrasonography and arteriography for imaging infrapopliteal arterial lesions. *Eur J Vasc End Surg* 1998 15(1) 44-50.

11. Gordon A C, Saliken J C, Johns D, Owen R et al. US guided puncture of the internal jugular vein: complications and anatomic considerations. *JVIR* 1998 9(2) 333-338
12. Dresner S M, Banergee B, Owen R, Lees T A. A popliteal aneurysm caused by an avulsion fracture of the femur: A case presenting with deep venous thrombosis. *Eur J Vasc End Surg*; 1999; 17: 180-182
13. Mahallati H, Owen RJT. Therapeutic embolization of a pseudoaneurysm of the Superior Gluteal artery occurring as a complication of bone marrow biopsy. *Can Assoc Radiol J.* 1999 50(4):265-267
14. Saliken JC, Gray RR, Donnelly BJ, Owen RJT et al. Extraprostatic biopsy improves the staging of localized prostate cancer. *Can Assoc Radiol J.* 2000;51(2):114-120
15. Owen RJT, Rose JDG. Endovascular Treatment of a portal vein tear during TIPSS. *CVIR.* 2000 Mar; 23(2) 230-232
16. Butler TJ, Jackson RW, Robson JY, Owen RJ, Delves HT, Sieniawska CE, Rose JD. In vivo degradation of tungsten embolisation coils. *Br J Radiol.* 2000 Jun;73(870):601-3
17. Owen RJ, Jackson R, Loose HW, Lees TA, Dunlop P, Rose JD. Percutaneous Ablation of an Internal Iliac Aneurysm Using Tissue Adhesive. *CVIR* 2000 Sep;23 (5): 389-391
18. Owen RJ, Haslam PJ, Elliot ST, Rose JD, Loose HW. Percutaneous Ablation of Peripheral Pseudoaneurysms using thrombin: A simple and effective solution. *CVIR* 2000 Nov-Dec;23 (6): 441-446
19. Casey JJ, Lakey JRT, Ryan EA, Paty BW, Owen R et al. Portal venous pressure changes following sequential clinical islet transplantation. *Transplantation* 2002 ;74(7):913-915
20. Owen RJ, Ryan EA, O'Kelly K, Lakey JR, McCarthy MC, Paty BW, Bigam DL, Kneteman NM, Korbitt GS, Rajotte RV, Shapiro AM. Percutaneous transhepatic pancreatic islet cell transplantation in type 1 diabetes: Radiologic aspects. *Radiology* 2003 Oct;229 (1):165-170
21. Penner RM, Owen RJ, Williams CN. Diagnosis of a bleeding Dieulafoy lesion on computed tomography and its subsequent embolization. *Can J Gastroenterol.* 2004 Aug;18(8):525-7
22. Villiger P, Ryan EA, Owen R, O'Kelly K, Oberholzer J, Al Saif F, Kin T, Wang H, Larsen I, Blitz SL, Menon V, Senior P, Bigam DL, Paty B, Kneteman NM, Lakey JR, Shapiro AM. Prevention of bleeding after islet transplantation: lessons learned from a multivariate analysis of 132 cases at a single institution. *Am J Transplant.* 2005 Dec;5(12):2992-8.
23. Baerlocher MO, McLaren K, Collingwood P, Giroux MF, Owen R, Poole A, Pugash R, Asch MR; Canadian Interventional Radiology Association. Conclusions and recommendations from the position paper on interventional radiology in Canada. *Can Assoc Radiol J.* 2007 Feb;58(1):11-4.
24. Suchak AA, O'Kelly K, Al Saif F, Shapiro AM, Owen RJ. Hepatic artery-portal venous fistula after percutaneous intraportal islet cell transplant. *Transplantation.* 2007 Mar 15;83(5):669-70.
25. Benko A, Fraser-Hill M, Magner P, Capusten B, Barrett B, Myers A, Owen RJ; Canadian Association of Radiologists. Canadian Association of Radiologists: consensus guidelines for the prevention of contrast-induced nephropathy. *Can Assoc Radiol J.* 2007 Apr;58(2):79-87.
26. Xiao Z, Dickey D, Owen RJ, Tulip J, Moore R. Interstitial photodynamic therapy of the canine prostate using intra-arterial administration of photosensitizer and computerized pulsed light delivery *J Urol.* 2007 Jul;178(1):308-13. Epub 2007 May 17.
27. Moore RB, Xiao Z, Owen RJ, Ashforth R, Dickey D, Helps C, Tulip J. Photodynamic Therapy of the Canine Prostate: Intra-arterial Drug Delivery. *Cardiovasc Intervent Radiol.* 2007 Oct 26;
28. Mahajan A, Rao G, Lees G, Owen R. A case of successful ablation of a gastrophrenic fistula with n-Butyl-2-Cyanocrylate. *Can J Gastroenterol.* 2008 Jan;22(1):69-70.
29. Chung J, Owen RJ. Using inferior vena cava filters to prevent pulmonary embolism. *Can Fam Physician.* 2008 Jan;54(1):49-55.
30. Baerlocher MO, Owen R, Poole A, Giroux MF. Interventional radiology deserves formal recognition as a distinct medical subspecialty: a statement from the Canadian Interventional Radiology Association. *J Vasc Interv Radiol.* 2008 Jan;19(1):9-12.
31. Moore RB, Xiao Z, Owen RJ, Ashforth R, Dickey D, Helps C, Tulip J. Photodynamic Therapy of the Canine Prostate: Intra-arterial Drug Delivery. *CVIR.* 2008 Jan (1)31 164-176

32. Chung J, Owen R, Turnbull R, Chyczij H, Winkelaar G, Gibney N. Endovascular repair in traumatic thoracic aortic injuries: comparison with open surgical repair. *J Vasc Interv Radiol*. 2008 Apr;19(4):479-86.

ABSTRACTS / PRESENTATIONS:

1. Lamont A L, Owen R J T, Brookes J. Postnatal Investigation And Early Management Of Prenatally Diagnosed Hydronephrosis. *European Society of Paediatric Radiology* - June 1994, Brussels.
2. Owen R J T, Lamont A L, Brookes J. Postnatal Investigation And Early Management Of Prenatally Diagnosed Hydronephrosis. *Scientific Meeting, Royal College of Radiologists* - 13th September 1994, Norwich.
3. Owen R J T, Hickey F, Finlay D B. A Survey Of Metatarsal Fractures In Children. Poster/Presentation, *Roentgen Centenary Congress*, 12th-16th June 1995. Birmingham.
4. Kunkler R B, Owen R J T, Kockelbergh R C. Bone Scintigraphy In The Management Of Bladder Cancer. *American Urological Association 4th May 1996, USA*.
5. Owen R J T, Esler C, Finlay D B. How significant is bone bruising on MRI of the knee. BIR/RCR meeting May 1996.
6. Owen R J T, Harper W M, Finlay D B, Belton I P. Isotope Bone Scans In Patients With Painful Knee Replacements: Do They Alter Management? Poster/Presentation, BIR/RCR May 1996.
7. Owen R J, Saliken J C, Johns D G, Donnely B, Wiseman D, Gray R R. Cryosurgery 18 Month follow up. *SCVIR. Washington USA*. 8th-13th March 1997
- 8 - 10. Owen R J, Saliken J C, Johns D G, Donnely B, Wiseman D, Gray R R. Sextant prostatic biopsy comparison with clinical staging. *SCVIR Washington DC*, March 12 1997, Society of Cryosurgery. Hawaii Feb 1997, CAR Meeting 1997
- 11 - 12. Owen R J, Saliken J C, Johns D G, Donnely B, Wiseman D, Gray R R. Evaluation of an extended prostate biopsy protocol. *Society of Cryosurgery*. Hawaii Feb 1996, CAR 1997
13. Owen R J, Gordon A C, Saliken J C, Johns D, et al. US guided puncture of the internal jugular vein: complications and anatomic considerations. *Northern Radiology meeting. Newcastle upon Tyne*, March 1998.
14. Owen R J, Gordon A C, Gray R, So B. A Comparative study of Temporary and Tunnelled Haemodialysis Catheter Survival. *Northern Radiology meeting. Newcastle upon Tyne*, March 1998.
15. Owen R J, Gordon A C, Gray R, Saliken J C. Central Venous Catheters for Haemodialysis. *Northern Radiology meeting. Newcastle upon Tyne*, March 1998.
16. Akomolafe B, Owen R J T et al. Angioplasty of the Profunda Femoris artery. South African Vascular Society, South Africa Aug 1999.
- 17 – 18. Owen R J, Elliott S, Rose J, Loose H. The Percutaneous Ablation of Pseudoaneurysms Using Thrombin: A Simple and Effective Solution. *Northern Vascular Society*, Windermere Oct 1999, BSIR, Manchester Nov 1999.
19. Owen R J, Chidambaram V, Manas D, Jackson R, Rose J. Endoluminal Revascularisation of Clotted native and Synthetic Arteriovenous Fistulae. *BSIR*, Manchester, Nov 1999
20. Jackson RW, Butler T, Robson JY, Owen R J T, Delves HT, Sieniawska, Rose JDG. In Vivo Degradation of Tungsten Embolisation Coils. *BSIR*, Manchester, Nov 1999
- 21-22. Owen R J T, Dunlop P, Lees TA, Wyatt MJ, Jones NA, Lambert D, Rose JDG. Combined Surgical and Radiological Procedures: The way Forward *BSIR*, Manchester, Nov 1999. VSS Nov 1999.
23. Owen R J, Jackson R, Chidambaram V, Haslam PJ, Manas D. Surgical versus radiological placement of ash dialysis catheters: A randomised study. *SCVIR San Diego* March 2000
24. Owen R J, Gray RR. Complex Case Presentation: Embolisation of Hepatic Artery Aneurysm with SMA Stent placement. *BSIR*, Newcastle, Nov 2000.
25. Owen R J, Ryan EA, O'Kelly K, Shapiro AMJ. Percutaneous Transhepatic Pancreatic Islet Cell Transplantation in Type 1 Diabetes. *BSIR*, Cardiff Nov 2001
26. Owen R J, Ashforth R, Logie L, Bailey B. Peripherally Inserted Catheters for Home Parenteral Therapy Program: A Survival Study. *BSIR*, Cardiff Nov 2001

27. Owen RJ, Shapiro AMJ Ryan EA, O'Kelly K, Lakey JR. Percutaneous Transhepatic Pancreatic Islet Cell Transplantation in Type 1 Diabetes. *CVIR*, Lucerne Oct 2002
28. McNally DM, Owen RJ, Sherlock R. Endovascular Management And Outcome Of Acquired Uterine Artery Arteriovenous Malformations. *SIR* Salt lake Mar 2003.
29. Owen RJ, McNally DM, Ryan EA, Ackerman T, Shapiro AM. Trans Hepatic Portal Vein Puncture In Islet Cell Transplantation: Should The Tract Be Embolized? *SIR* Salt lake Mar 2003 (Poster).
30. Owen RJ, Shapiro AMJ Ryan EA, O'Kelly K, Lakey JR. Percutaneous Transhepatic Pancreatic Islet Cell Transplantation in Type 1 Diabetes (Extended Results). *SIR* Salt Lake Mar 2003.
31. Barker SJ, Owen RJ, O'Kelly K, Lewanczuk RZ, Hamilton PG. Primary Hyperaldosteronism and the Preoperative Role of Selective Adrenal Vein Sampling. *International Congress of Radiology*. Montreal June 2004 (Poster)
32. Bhargava R, Ackermann T, Owen R, Shapiro A, Ryan E, Lakey J, Paty B, Senior P. Islet Transplantation: A pictorial Essay of Late Changes in the Abdomen. *Canadian Association of Radiologists*. 2005 Sep.
33. Mahajan A, Ashforth R, Olson J, Owen R. The Efficacy Of Ok-432 Sclerotherapy For The Treatment Of Pediatric Lymphatic Malformations. *SIR* Toronto Mar 2006
34. Owen RJ, Mercer J, Molinari M, Wada R, Rajotte RV, Shapiro A.M. Portal Vein Embolization of Radiolabelled Polyvinyl Alcohol Particles in a Porcine Model: Hepatic Distribution. *SIR* Toronto Mar 2006
35. Lambert RG, Siminoski KG, Dhillon SS, Ashforth RA, Schaffler GC, Owen RT et al. Efficacy of a Canadian Percutaneous vertebroplasty Programme. *SIR* Toronto Mar 2006
36. Chung J, Owen RJ, Winkelaar GB, Turnbull RG. Technical Considerations in the Endovascular Repair of Acute and Chronic Traumatic Aortic Injuries. Electronic Poster. *SIR* Seattle Mar 2007
37. Chung J, Owen RJ, Winkelaar GB, Turnbull RG. Endovascular repair of Acute and Chronic Traumatic Thoracic Aortic Injuries: A Comparative Study with Open Surgery. *SIR* Seattle Mar 2007
38. Chung J, Owen RJ, Winkelaar GB, Turnbull RG. Endovascular repair of Acute and Chronic Traumatic Thoracic Aortic Injuries: A Comparative Study with Open Surgery. *Western Vascular society* Victoria Nov 2007

INVITED PRESENTATIONS / VISITING LECTURER

Canadian Association of Medical Radiation Technologists. Lectures on Ultrasound guided injection of pseudoaneurysms & Vascular stents: Calgary, Alberta June 2001

Leicester Royal infirmary (UK); Lecture on Islet cell transplantation in diabetes and teaching sessions with residents. Visiting Lecturer July 2003

Radiological Society of North America. Invited speaker on Islet cell transplantation Chicago December 2003

Society of Interventional Radiology. Moderator scientific session (Hepatic Interventions) Phoenix March 2004

Alberta Society of Radiation Technologists. Speaker Edmonton (Islet cell transplantation in diabetes) May 2004

Cardiovascular and Interventional Society of Europe. Invited speaker Barcelona (Hepatic intervention session) Sept 2004

Calgary. Resident research day Invited speaker (thrombosed dialysis access management) and judge May 2005

Canadian Interventional Radiology Association. AGM Company sponsored forum (Cutting balloon) June 2005

Society of Interventional Radiology. Invited speaker Toronto (Contrast nephropathy a radiologists perspective) March 2006

Winnipeg Endovascular Forum. Invited speaker (Cutting balloon) June 2006

Society of interventional radiology. Invited speaker on islet cell transplantation. Seattle March 2007

Winnipeg Endovascular forum. Invited Speaker on Endovascular treatment of trauma and upper limb interventions. Apr 2007

Canadian Interventional Radiology Association. AM Organizer and Invited speaker on thrombolysis in renal access grafts and on the use of glue in IR. May 2007

Canadian Interventional Radiology Association. AM Organizer and Invited speaker on Use of contrast agents in renal failure and complicated case presentations. May 2008

Cross Cancer Institute. Invited speaker on vertebral body augmentation. June 2008

GRANT APPLICATIONS / FUNDING / AWARDS:

Principle Investigator - Pump priming grant from the Royal College of Radiologists 1999 (£6000) Subintimal Angioplasty Versus Conventional Intra-Luminal Angioplasty In Superficial Femoral Artery Occlusions. Owen RJT, Lees T, Rose JDG.

Principle Investigator - Char Amersham award 2003 (\$12000). Portal Vein Embolization Of Radiolabelled Polyvinyl Alcohol Particles In A Porcine Model.

Co-investigator – National Cancer Institute of Canada; Operating grant. 2004 Novel Intravesical Molecular Therapy for superficial Bladder Cancer.

Co-Investigator – Alta Chem Pharma; Operating grant. 2004 Development of Hypocrellin B SO17 for Photodynamic Therapy (PDT) of Prostate Cancer.

Co – Investigator - ViRexx Medical Corp. Operating grant. Development of new embolotherapeutic agent – A Preclinical Study of the safety and Efficacy of OCL-501 in a porcine splenic infarct model.

Site principle investigator in multinational multicentre trial – Phase III study of Yttrium labeled particles in embolization in advanced HCC – Nordion MDS sponsor.

Principle investigator - local trial – Animal safety study of a new embolic agent, ViRexx Corp/ sponsor (\$50,000)

Site PI CORAL (NIH Study) Cardiovascular outcomes in renal artery lesions. NIH sponsored

Co-Investigator (P Tandon) Pro biotics and their effects on portal pressures. Local funding

I have also been able to gain funding from several commercial companies to assist ancillary staff in attending educational meetings as well as assisting in the procurement of funding for the radiology research nurse programme.

RESEARCH IN PROGRESS:

Embolization of traumatic uterine AV malformations

Portal vein embolization of radiolabelled polyvinyl alcohol particles in a porcine model

The use of von Willebrand factor as an embolization agent in an animal model

The use of a novel embolic agent in an animal model

The use of tissue adhesive in percutaneous islet cell transplantation procedures

Long term results of angioplasty in hemodialysis fistula using the ‘cutting balloon’

Radioembolization, trans arterial Chemoembolization in liver tumors

Photodynamic therapy

SOCIETY MEMBERSHIPS:

Royal College of Radiologists (UK), since 1991

Royal college of Physicians (UK), since 1991

British Society of Interventional Radiology, since 1995

Society of Interventional Radiology, since 1996

Cardiovascular and Interventional Radiological Society of Europe, since 1998

Alberta Medical Association, since 2000

Canadian Medical Association, since 2000

Canadian Interventional Radiology Association, since 2001

NATIONAL BODIES:

Treasurer for Canadian Interventional Radiology Association, since June 2004

Programme Chair 2007 AGM Canadian interventional Radiology Association – Banff Alberta, Canada

Programme Chair 2008 AGM Canadian interventional Radiology Association – Montreal, Quebec, Canada

Recreational activities:

Soccer player and coach, Golf, Squash, Swimming, Snow boarding, Gardening and fishing

CURRICULUM VITAE – DR. P.N. NATION

HOME ADDRESS: 18208 Ellerslie Road
Edmonton, Alberta
T6W 1A5
(780) 430-8128

BUSINESS ADDRESS: Animal Pathology Services (APS) Ltd.,
18208 Ellerslie Road,
Edmonton,
Alberta T6W 1A5
(780) 720-5378

CITIZENSHIP: Canadian

AGE: 58 Years

EDUCATION:

1967	St. Andrew's College, Aurora, ON	Senior Matriculation (Honors)
1972	Simon Fraser University, Burnaby, BC	BSc. (Biology)
1974	University of Saskatchewan, Saskatoon, SK	DVM
1976	University of Saskatchewan, Saskatoon, SK	MVSc (Veterinary Pathology)
1980	Diplomate of American College of Veterinary	Dipl. ACVP Pathologists
1987	Faculty of Medicine, University of Calgary, Calgary, AB	Ph.D. (Neurotoxicology)

UNDERGRADUATE AWARDS:

1972 Louis Hewitt Award in Public Health and Epidemiology
1973 Co-recipient of Pfizer Co. Award for Academics and Leadership
1974 Class of '74 Public Relations Award
Pitman Moore Award for Scholastic, Social and Athletic Achievement
Canadian Veterinary Medical Association Award for Contribution to the Profession

GRADUATE AWARDS:

1975 Co-recipient of Rogar STB graduate Student Award
1986 Canadian Pharmacology Society Graduate Student Award

OTHER:

2004 Alberta Veterinarian of the Year

WORK EXPERIENCE:

June 1 1974 - May 31, 1976 Professional Associate I
Dept of Veterinary Pathology
Western College of Veterinary Medicine
University of Saskatchewan
Saskatoon, Sask. S7N 0W0

A service/training position performing duties in general veterinary diagnostic pathology, all species, high component of comparative pathology/physiology

July 1 1976 - Sept 1 1976 Visiting Veterinary Pathologist
Department of Pathobiology
University of Connecticut, Storrs,
Connecticut USA

Term academic veterinary diagnostic position

Oct 1976 - Sept 1980 Veterinarian II
Animal Health Division
Alberta Agriculture:
Fairview (1976 - 1978)
Airdrie (1978 - 1980)

Veterinary diagnostic pathology position having service, educational and research components. All species were examined with emphasis on food producing animals, horses, pets and zoo species.

Sept 1980 - Feb 1985

Head, Regional Animal Health Laboratory
Animal Health Division
Alberta Agriculture
P.O. Bag 1
Airdrie, Alberta T4B 2C1

Veterinary diagnostic pathology position supervising a staff of ten permanent and up to five part-time employees in addition to performing service, educational and research activities as previously.

Feb 1985 - July 1987

Fellow of the Alberta Heritage Fund for
Medical Research
Dept of Pharmacology and Therapeutics
Faculty of Medicine, University of Calgary
3330 Hospital Drive N.W.
Calgary, AB T2N 4N1

Research position held while conducting neurotoxicology study for PhD thesis. Thesis title "Drug Interactions on Neuronal Membranes."

July 1987 - Dec 1991

Head, Pathology Branch
Alberta Agriculture O.S. Longman Bldg
6909 - 116 Street
Edmonton, AB T6H 4P2

Middle management position supervising six laboratory managers and a laboratory scientist at four separate locations in the province. Total staff size of 41 permanent positions. Budget \$2.1 million.

Dec 1991 – Dec 1999

Comparative Pathologist
Health Science Lab Animal Services
Room 140 Heritage Medical Research Centre
University of Alberta, Edmonton, AB T6G 2S2

President Veterinary Pathology Laboratory
9520 – 27 Avenue, Edmonton, AB T6N 1B2

Full time service position in lab animal services in the University of Alberta providing diagnostic assistance and advice to medical researchers concerning laboratory animals. Professional services were sub-contracted by the University of Alberta to Veterinary Pathology Laboratory, a private veterinary diagnostic laboratory servicing North-central Alberta. This particular contract involved providing clinical pathology and anatomic services to veterinary practitioners concentrating on the traditional companion animal and food producing species but also including exotics, lab animals and avians.

Dec 1999 – April 2005

Director,
Health Science Lab Animal Services
Room 140 Heritage Medical Research Centre
University of Alberta
Edmonton, AB T6G 2S2

April 2005 – present

President
Animal Pathology Services APS Ltd.
18208 Ellerslie Road,
Edmonton, AB T6W 1A5

1979 - 1985

Adjunct Assistant Professor
Dept of Pathology, Faculty of Medicine
University of Calgary

1999 – Present

3330 Hospital Drive N.W.
Calgary, AB T2N 1N4
Adjunct Associate Professor,
Dept of Pathology and Laboratory Medicine,
University of Alberta
Edmonton, AB T6G 2S2

ACADEMIC COMMITTEE ACTIVITIES:

- 1989 - 1992 Member of two graduate student committees at University of Calgary.
- 1990 - 1991 Executive secretary of Alberta Agriculture Research Institute "Poultry, Pork and other livestock" research grant scientific review committee.
- 1990 - 1991 Northern Bison Management Board.
- 1992 – Present Animal Health Technician Program Advisory Committee, Lakeland College, Vermilion, Alberta.
- 1993 – 2005 Member of the Faculty (of Agriculture) Animal Policy and Welfare Committee, University of Alberta
- 1998 - 2005 Member of the University (of Alberta) Animal Policy and Welfare Committee
- 1999 - 2005 Member of the Health Sciences Animal Policy and Welfare Committee

PROFESSIONAL ASSOCIATION ACTIVITIES:

A. PAST

- 1973 President of Western Veterinary Medical Students' Association.
- 1974 - 1976 Member of Saskatchewan Veterinary Medical Association.
- 1974 - 1976 Member of Public Relation Committee, Saskatchewan VMA
- 1978 - 1982 Chairman of Continuing Education Committee Alberta VMA
- 1983 Academic Program Chairman for the Canadian Veterinary Medical Association annual convention.
- 1974 - 1981 Member of Wildlife Disease Association
- 1974 - 1982 Member of American Veterinary Medical Association
- 1984 President, Canadian Association of Veterinary Pathologists
- 1988 President, Western Conference of Veterinary Diagnostic Pathologists
- 1994 President of Western Conference of Veterinary Diagnostic Pathologists
- 1999 Chairman of Practice Inspection Committee, Alberta, VMA

B. PRESENT

- Licensed to practice veterinary medicine in Alberta.
- Member of Canadian Veterinary Medical Association 1974 to present.
- Member of Alberta Veterinary Medical Association 1977 to present.
- Member of Canadian Association of Veterinary Pathologists 1976 to present.
- Member of American College of Veterinary Pathologists 1980 to present.
- Certified specialist in veterinary pathology, CVMA, 1981 to present.
- Member of Canadian Association of Laboratory Animal Science 1995 to present
- Member of Canadian Association of Laboratory Animal Medicine 1995 to present
- Member, Registration Committee, Alberta VMA
- Member, Council of the Alberta VMA

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1. Nation P.N. and Allen J.R. Antibodies to *Toxoplasma gondii* in Saskatchewan cats, sheep and cattle. Can Vet J. 17:308-310. 1976
2. Nation P.N. and Wobeser G. Renal coccidiosis in wild ducks in Saskatchewan. J Wildlife Diseases. 13:370-375. 1977.
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15. Nation P.N. and Williams E.S. Maggots, mutilations and myth: patterns of post-mortem scavenging of the bovine carcass. *Can Vet J.* 30:742-747. 1989.
- Chalmers G.A., Nation P.N. and Pritchard J. Terminal ileitis in lambs. *Can Vet J.* 31:292-295. 1990.
17. Buret A., Gall D.G., Nation P.N., and Olson M.E. Intestinal protozoa and epithelial cell kinetics, structure and function. *Parasitology Today.* 6:375-380. 1990.
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20. Nation P.N. Veterinarians in Alberta universities. Chapter 14, p. 167-176 in D.W. MacDonald, Ed. A short history of the veterinary profession in Alberta. 1955-90. *Alberta Vet. Med. Assn.* 1993.
21. Nation P.N. and Roth S.H. Synergistic effects of monensin in combination with permethrin or neomycin on neuronal activity. *Vet and Human Toxicology.* 35:414-418. 1993.
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10. Coppock. R. W., Khan, A. A., Geleta, L., Dziwenka, M. M., Nation, and Hiltz, M. N. Translocation of Biomarker Chemicals into Sheep Tissues after Oral Exposure to Crude Oils. Poster presentation, Society of Toxicology annual meeting, 2002-03-27

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2. Nation P.N. and Williams E.S. Maggots, mutilations and myth: patterns of post-mortem scavenging of the bovine carcass. SAVT Newsletter Aug 1999.
3. Nation, P. N. Necropsy: Introduction. CALAS newsletter 36:7 – 8, 2002.

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3. Chalmers, G.A., Nation, P.N., and Pritchard, J. Border disease - a cause of terminal ileitis in lambs? Can Vet J. 31:611, 1990.
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1. Bayens-Simmonds J, Purcell TP, and Nation PN. Use of magnetic resonance imaging in the diagnosis of central vestibular disease. Can Vet J. 38:38. 1997.

Appendix Y. Revisions

Original Report Date:

2 September 2008

Date	Comments	Initials
12 Nov 09	Changes to the report: 1. specified the catheters used for embolization, 2. added a description of the process for selecting R/L uterine artery for treatment 3. clarified that jugular cannulation is for the purpose of administering a saline drip during surgery and is not part of the embolization procedure (and that the cervical abscess associated with the jugular cannulation of sheep G186 is unrelated to treatment with OCL 503) 4. specified that sheep G186 was sacrificed at week 7 post treatment, 5 weeks prior to its scheduled sacrifice at 3 months post treatment, in accordance with guidelines for the humane care and use of research animals 5. changed the report date, version number and sponsor company, and 6. Corrected typographical and minor formatting errors. Changes were made in response to an external review by a regulatory consultant.	
1 Dec 11	Changes to the report: 1. corrected the dose of Excenel per 20 May 10 email from B. Tchir 2. corrected typographical and minor formatting errors, and 3. changed the report date and version number	