GLP REPORT

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta, T6E 6S4
Canada

CONFIDENTIAL

STUDY TITLE:

Cytotoxicity Study Using the ISO Agarose Overlay Method (Solid)

TEST ARTICLE:

Occlusin 500 Artificial Embolization Device

IDENTIFICATION NO.:

Batch: FL288

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Summary

An *in vitro* biocompatibility study, based on the requirements of the International Organization for Standardization (ISO 10993-5), was conducted on the test article, Occlusin 500 Artificial Embolization Device, Batch: FL288, to determine the potential for cytotoxicity. Triplicate wells were dosed with enough test article to cover a 1 cm x 1 cm area. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex, as a positive control. Each was placed on an agarose surface directly overlaying a confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in 5% CO_2 for 24 hours, the cell culture was examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). The culture was then examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles.

Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the ISO since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

Study and Supervisory Personnel: Scott A. Summers
Susan M. Pellitieri, B.A.

Approved by: Michelle E. Longstreet

Michelle E. Longstreet, B.S.
Study Director

6-21-07
Date Completed

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data has been accurately recorded and verified, as indicated by the signature below.

Study Director: Michelle E. Longstreet 6-21-07

Michelle E. Longstreet, B.S. Date

1. Introduction

Purpose
The test article identified below was subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 5: Test for Cytotoxicity *in vitro* Method. The test was performed to determine the potential of the test article to cause cytotoxicity.

Dates
The test article was received on May 17, 2007. The cells were dosed on June 5, 2007, and the observations were concluded on June 6, 2007.

GLP Compliance
The study initiated by protocol signature on May 30, 2007, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article:	Occlusin 500 Artificial Embolization Device
Identification No.:	Batch: FL288
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	The sponsor elects not to provide this information to NAMSA and takes full responsibility for this data and can supply this information if requested to do so.
Physical Description of the Test Article:	Dry, white polymer beads approximately 400 µm
Storage Conditions:	Refrigerated
Test Article Preparation:	Triplicate wells were dosed with enough test article to cover a 1 cm x 1 cm area.
Negative Control Preparation:	Triplicate wells were dosed with a 1 cm length of high density polyethylene.
Positive Control Preparation:	Triplicate wells were dosed with a 1 cm x 1 cm portion of latex.

3. Test System

Test System Management
L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source) were propagated and maintained in open flasks containing single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells were seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain confluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

Preparation of Agarose Overlay
The culture wells were selected which contained a confluent cell monolayer. The growth medium in each well was replaced with 2 ml of equal amounts of double strength Minimum Essential Medium supplemented with 10% serum and 4% antibiotics (2X MEM), supplemented with neutral red, and 2% agarose (final concentration 1% agarose, 1X MEM). The MEM-agarose mixture (2 ml) was then placed in the cell culture wells and allowed to solidify over the cells to form the agarose overlay.

4. Methods

The test article was placed on the solidified agarose surface in three separate cell culture wells. Similarly, the negative control and the positive control were each placed on the solidified agarose surface in three cell culture wells. The wells were labeled with the corresponding lab number and dosing date, and incubated at 37°C in 5% CO_2 for 24 hours.

Following incubation, the cultures were examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). After macroscopic examination, the cell monolayers were examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the article.

Scoring for cytotoxicity was based on the following criteria:

Grade	Reactivity	Condition of Cultures
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen and up to 4 mm
3	Moderate	Zone extends 5 -10 mm beyond specimen
4	Severe	Zone extends greater than 10 mm beyond specimen

NOTE: This chart (direct excerpt from USP) fails to accommodate 1 mm - 4 mm zones. The USP was notified of this. They responded that 1 mm - 4 mm zones should be categorized as mild (2).

For the suitability of the system to be confirmed, the negative control must have been a grade of 0 (reactivity none) and the positive control must have produced a zone of lysis (reactivity moderate to severe). The test article passed the test if all three monolayers exposed to the test article showed no greater than a grade of 2 (reactivity mild). The test would have been repeated if the controls did not perform as anticipated and/or if the test wells did not yield the same conclusion (e.g., one well passed and the other two wells failed).

5. Results

The scores obtained were as follows:

ARTICLES		ZONE OF LYSIS (mm)	GRADE	REACTIVITY
Test Article:	(1)	0	0	None
	(2)	0	0	None
	(3)	0	0	None
Negative Control:	(1)	0	0	None
	(2)	0	0	None
	(3)	0	0	None
Positive Control:	(1)	8	3	Moderate
	(2)	7	3	Moderate
	(3)	8	3	Moderate

6. Conclusion

Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the ISO since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and ISO 13485:2003.

7. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities is provided with this final report.

8. Proposed Dates

The study dates were finalized by the study director following receipt of the sponsor approved protocol and appropriate material for the study. Initiation of the study was the date on which the study director signed the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) were provided to the sponsor (or representative of the sponsor).

9. Records

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

10. References

21 CFR 58 (GLP Regulations).

ISO 10993-5 (1999) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

United States Pharmacopeia (USP).

Wilsnack, R. E., F. J. Meyer and J. G. Smith, "Human Cell Culture Toxicity Testing of Medical Devices and Correlation to Animal Tests," *Biomaterials, Medical Devices and Artificial Organs* 1 (1973): 543-562.

11. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation were documented and approved by the study director as protocol amendments. Copies were distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

Statement of Quality Assurance Activities

Phase Inspected	Auditor	Date
Scoring	L. M. Byrd	June 6, 2007
Final Report Review	K. J. Evener	June 21, 2007

Reports to Management and Study Director(s)	Date
Periodic Status Report	June 8, 2007

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Karen J. Evener — June 21, 2007

Karen J. Evener, B.E.
Auditor, Quality Assurance

Date

STORE IN REFRIGERATOR
(+4°C)
CALIBRATION #: 7420
TECH/DATE: JS 5-17-07

LP SAMPLE SU

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thwood, Ohio 43619
66.666.9455 (toll free)
F 419.662.4386

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Irvine,
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F 949.951.3280

T 770.563.1660
F 770.563.1661

Ohio
6750 Wales Rd
Northwood, Ohio 43619
T 866.666.9455
F 419.666.2954

07T_36169
25447_001 25447

SPONSOR FINAL REPORT WILL BE ADDRESSED AND MAILED TO

VIREXX MEDICAL CORP. — **COMPANY NAME*** — PAUL TIEGE — **ATTN***
8223 Roper Rd — **ADDRESS***
Edmonton — **CITY*** — Alberta — **STATE*** — T6E 6S4 — **ZIP***
CANADA — **COUNTRY***
780 989 6715 — **PHONE***
780 436 0068 — **FAX***
ptiege@virexx.com — **E-MAIL***

INVOICE INFORMATION
VIREXX MEDICAL CORP. — **BILLING ADDRESS (include Company Name if different from mailed to)***
V0725-185PT — **PURCHASE ORDER NUMBER***
T07-2410 and T07_2708 — **COST ESTIMATE AND PROPOSAL NUMBER**
☐ VISA ☐ MasterCard ☐ American Exp.
CARD HOLDER NAME
CREDIT CARD NUMBER — **EXPIRATION DATE**
780 989 6721 — 780 436 0068
ACCOUNTS PAYABLE PHONE* — **ACCOUNTS PAYABLE FAX***

TEST ARTICLE NAME *USE EXACT WORDING DESIRED ON FINAL REPORT* * +
Occlusion 500 Artificial Embolization Device
embolotherapy
INTENDED CLINICAL USE OF TEST ARTICLE:*

☑ BATCH ☐ CODE ☐ LOT — FL288
CHECK ONE — **IDENTIFICATION NUMBER***

N/A
CONTROL ARTICLE NAME*

☐ BATCH ☐ CODE ☐ LOT
CHECK ONE — **IDENTIFICATION NUMBER***
NAMSA recommends only one lot, batch, or code per test article submission.

QUANTITY SUBMITTED:* 8 vials Occlusion 500
(please specify quantities for each lot/batch/code provided)
dry white polymer beads ~ 400 µm
PHYSICAL DESCRIPTION OF TEST ARTICLE (Chemical/Material type/Color)*

TEST ARTICLE IS CATEGORIZED AS BEING A (check all that apply):* +
☑ MEDICAL DEVICE ☐ BIOLOGIC ☐ TISSUE
☐ PHARMACEUTICAL ☐ CHEMICAL ☐ OTHER

+ A detailed composition list and current MSDS sheet must accompany any chemical or biologic test article. A certificate of testing or reprocessing must be submitted for any human tissue derived sample or clinically used medical device

TEST ARTICLE BEING SUBMITTED IS:*
☑ STERILIZED ☐ NOT STERILIZED
☐ **NAMSA TO STERILIZE BY:** ☐ EO (additional charge) ☐ STEAM

Mixtures of test or control articles with carriers require analysis to demonstrate proper concentration, homogeneity, and stability.*
☐ Sponsor will provide analytical methods; or
☐ Sponsor will perform analysis on representative aliquots provided by NAMSA.

STORAGE CONDITIONS*
☐ ROOM TEMPERATURE ☑ REFRIGERATION ☐ FREEZER
☐ OTHER:

TEST AND CONTROL ARTICLE CHARACTERIZATION: The sponsor assures the above test article has been characterized for identity, strength, purity, and composition as required by FDA Good Laboratory Practice Regulations of 21 CFR Part 58.105. Stability testing is the responsibility of the sponsor and is subject to FDA audit. Characterization and stability information are also required for control articles. Please check the statement(s) applicable to the test and control articles for both Stability and Strength, Purity and Composition sections below.

Test Article	Control Article	Stability (Choose One)
☑	☐	Stability testing is in progress; article is stable for duration of intended testing.
☐	☐	Stability testing is complete and on file with sponsor. Expiration date (test): Expiration date (control):
☐	☐	Marketed product stability characterized by its labeling.

Test Article	Control Article	Strength, Purity, and Composition (Choose One)
☐	☐	Sponsor provided data in a Certificate of Analysis or other appropriate documentation and results will be reflected in the final report.
☑	☐	Sponsor elects not to provide this information to NAMSA and takes full responsibility for this data and can supply this information if requested to do so.

If requesting to return sample, please check the courier and include your:
☐ UPS ☐ Federal Express ☐ Other: _____ Account Number: _____

(AUTHORIZED BY SPONSOR) Michelle C. Longstaff — DATE 15 MAY 07
NAMSA STUDY DIRECTOR — DATE 5-29 incorrect date 5-30-07 MEL 5-30-07

T051707_021
FEDEX VIREXX
Received 5-17-07

GLP PROTOCOL

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619-1011

SPONSOR:

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta,
Canada

STUDY TITLE:

Cytotoxicity Study Using the ISO Agarose Overlay Method

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Approvals

Sponsor Representative (Sponsor): PAUL TIEGE

Date Approved: 14 MAY 07

Study Director (NAMSA): Michelle E. Longstaff

Date Initiated: 5-30-07

1. Introduction

Purpose
The purpose of this study is to evaluate the biocompatibility of a test material using an *in vitro* mammalian cell culture test based on the requirements of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity *in vitro* Methods. The test material shall be representative of either the final product or a component of the final product that is to be tested.

GLP Compliance
Good Laboratory Practice – This nonclinical laboratory study will be conducted in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58.

2. Materials

Test Article
The sponsor will submit the test article to be evaluated. Detailed information about the test article will be provided by the sponsor on the NAMSA Sample Submission Form or on a similar attachment to the protocol.

Preparation
The following is to be completed by the sponsor or study director. Further instructions may be attached to the protocol. The sample will be prepared as follows:

Preparation of Test Article:

___ Solid (flat) - cut into a section having an approximate 1 cm x 1 cm surface area
___ Solid (tubing or similar shapes) - cut into cross sections covering an approximate 1 cm x 1 cm area - or use 1 cm length
(1) ___ Solid (pellets) - use whole pellets, enough to cover an approximate 1 cm x 1 cm area
✓ Granules or powder, enough to cover an approximate 1 cm x 1 cm area
___ Liquid - paper filter disc (12.7 mm) containing 0.1 ml of test article. Requires the use of a filter disc control dosed with 0.9% Sodium Chloride Solution , USP (SC).
___ Solid to be extracted - paper filter disc (12.7 mm) containing 0.1 ml of extract (see next section for extraction conditions)
___ Other (specify) _____

NOTE: The test article will be prepared in triplicate. Therefore, the amount of test article required is three times that indicated above.

NOTE: If appropriate, materials with superabsorbent properties shall be moistened with culture medium or 0.9% Sodium Chloride Solution , USP prior to testing to prevent dehydration of the agarose.

Ratio of test article to extraction vehicle (select one):

✓ Material thickness less than 0.5 mm - ratio of 120 cm^2:20 ml
___ Material thickness greater than or equal to 0.5 mm - ratio of 60 cm^2:20 ml
___ Irregularly shaped objects and/or sponsor option - ratio of 4 g:20 ml
___ Other (explain): _____

NOTE: Only a single test article preparation will be prepared.

Test Article Preparation Instructions:

each vial of occlusin 505 has an approximate total SA of 44 cm2
please extract 3 vials, 132 cm^2, in an appropriate volume.
NA MEL 5-30-07

(1) completed by sponsor MEL 5-30-07

Extraction Vehicle (select all that apply):

___ Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)
___ 0.9% Sodium Chloride Solution , USP (SC)

The extraction conditions should not in any instance cause physical changes such as fusion or melting, which results in a decrease in the available surface area. A slight adherence of the pieces can be tolerated.

Extraction Conditions (select one):

___ 37°C, 24 hours (required for all MEM extracts0
___ 50°C, 72 hours
___ 70°C, 24 hours
___ 121°C, 1 hour
___ Other (specify):_____

NA MEL 5-30-07

NOTE: The preferable extraction condition is 37°C for 24 hours using 1X MEM to simulate physiological conditions. At temperatures greater than 37°C, 1X MEM cannot be used.

(1) **Disposition of Test/Control Article (select one):**

___ Discard ___ Return unused article ___ Return unused and used article

Special Laboratory Instructions:

Control Article

Negative Control: High density polyethylene, (approximate 1.0 cm length)

Filter Disc Control: Filter disc (12.7 mm) containing 0.1 ml of SC or extracted vehicle (if applicable)

Positive Control: Current NAMSA positive control material (approximate 1.0 cm x 1.0 cm)

*NOTE: The current NAMSA positive control material has been qualified as an acceptable replacement for the USP control material.

3. Test System

Test System and Justification

Mammalian cell culture monolayer, L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source), has been used historically to evaluate cytotoxicity of biomaterials and medical devices (Wilsnack, *et al.*, 1973). All stock cultures of cells will be tested to confirm the absence of mycoplasma contamination.

Test System Management

L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source) will be propagated and maintained in open flasks containing single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells will be seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain confluent monolayers of cells prior to use. Aseptic procedures will be used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

Preparation of Agarose Overlay

The culture wells will be selected which contains a confluent cell monolayer. The growth medium in each well will be replaced with 2 ml of equal amounts of double strength Minimum Essential Medium supplemented with 10% serum and 4% antibiotics (2X MEM), supplemented with neutral red, and 2% agarose (final concentration 1% agarose, 1X MEM). The MEM-agarose mixture (2 ml) will be placed in the cell culture wells and allowed to solidify over the cells to form the agarose overlay.

(1) completed by sponsor MEL 5-30-07

4. Method

An appropriately prepared test article section (see Preparation of Test Article) will be placed on the solidified overlay surface in three separate cell culture wells. Similarly, the negative control, filter disc control (if applicable) and the positive control sections will each be placed on the solidified overlay surface in three separate cell culture wells. The wells will be labeled with the corresponding lab number and dosing date and incubated at 37°C in 5% CO_2 for 24-26 hours.

Following incubation the cultures will be examined macroscopically for cell decolorization around the test article and controls and to determine the zone of cell lysis (if any). After macroscopic examination, the cell monolayers will be examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles.

5. Evaluation and Statistical Analysis

Scoring for cytotoxicity will be based on the following criteria:

Grade	Reactivity	Condition of Cultures
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen and up to 4 mm
3	Moderate	Zone extends 5 -10 mm beyond specimen
4	Severe	Zone extends greater than 10 mm beyond specimen

NOTE: This chart (direct excerpt from USP) fails to accommodate 1 mm - 4 mm zones. The USP was notified of this. They responded that 1 mm - 4 mm zones should be categorized as mild (2).

For the suitability of the system to be confirmed, the negative control and filter disc control (if applicable) must have a grade of 0 (reactivity none) and the positive control must have produced a zone of lysis (reactivity moderate to severe). The test article passes the test if all three monolayers exposed to the test article show no greater than a grade of 2 (reactivity mild). Repeat the test if the controls do not perform as anticipated and/or if all three wells do not yield the same conclusion (e.g., one well passes and the other two wells fail).

6. Report

The final report will include the test and control preparation, information on the cell line, the methods, the score for the test article and controls at 24 hours and any additional pertinent information.

7. Quality Assurance

Inspections will be conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report will also be reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities will be provided with the final report.

8. Proposed Dates

The study dates will be finalized by the study director following receipt of the sponsor-approved protocol and appropriate material for the study. Initiation of the study will be the date on which the study director signs the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) will be provided to the sponsor (or representative of the sponsor).

9. Records

Test and control article preparation, cell line and passage number, observations, and dates of relevant activities (such as the study initiation and termination) will be recorded.

All raw data pertaining to this study and a copy of the final report will be retained in designated NAMSA archive files.

10. References

21 CFR 58 (GLP Regulations).

ISO 10993-5 (1999) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

United States Pharmacopeia (USP).

Wilsnack, R. E., F. J. Meyer and J. G. Smith, "Human Cell Culture Toxicity Testing of Medical Devices and Correlation to Animal Tests," *Biomaterials, Medical Devices and Artificial Organs* 1 (1973): 543-562.

11. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation will be documented and approved by the study director as protocol amendments. Copies will be distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

NAMSA

PEOPLE › SCIENCE › SOLUTIONS

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May 31, 2007

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta, T6E 6S4 Canada

PROTOCOL AMENDMENT I

Test Article: Occlusin 500 Artificial Embolization Device

Identification: Batch: FL288

NAMSA Submission ID.: 07T_36169

We have received appropriate test article and approved protocol(s) for the program to be conducted in accordance with the Good Laboratory Practice (GLP) Regulations on the material described above. Below is a projected schedule for the work to be performed.

NAMSA Code	NAMSA Lab Number	Study	Estimated Start Date:	Estimated Report Release Date:
V0015_110	07T_36169_02	Cytotoxicity Study Using the ISO Agarose Overlay Method	June 4, 2007	June 21, 2007
V0014_130	07T_36169_03	Cytotoxicity Study Using the ISO Elution Method - 1X MEM Extract	June 4, 2007	June 22, 2007
T0625_500	07T_36169_04	ISO Systemic Toxicity Study - Extract - 0.9% SC Extract	June 4, 2007	June 28, 2007
T0625_500	07T_36169_05	ISO Systemic Toxicity Study - Extract - SO Extract	June 4, 2007	June 28, 2007

Michelle E. Longstreet

Michelle E. Longstreet, B.S.
Study Director

6-4-07
Date

cc: QA (NAMSA)
GLP study file