Volume _____

FINAL REPORT

AOAC GERMICIDAL SPRAY TEST
Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*

Test Agent
SNIPER®

Lot Numbers
108-167-3, 108-172-1

Test Organisms
Methicillin Resistant *Staphylococcus aureus,* ATCC 33591
Vancomycin Resistant *Enterococcus faecalis,* ATCC 51299

Test Guideline
EPA Guidelines 810.2200 (d)(9)(ii)

Author
Emily A. Winokurzew

Study Completion Date
11/30/12

Performing Laboratory
MICROBIOTEST
A Division of Microbac Laboratories, Inc.
105 Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
813-107

Protocol Identification Number
813.1.11.05.12

Sponsor
GER, Inc.
P.O. Box 667
Carencro, LA 70507

STATEMENT OF NO DATA CONFIDENTIALITY

Title: AOAC Germicidal Spray Test – Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*

Performed by: MICROBIOTEST
A Division of Microbac Laboratories, Inc
105 Carpenter Drive
Sterling, Virginia 20164

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B) or (C).

Submitter signature: _____ Date: _____

Typed Name of Signer: _____

Typed Name of Company: GER, Inc.

COMPLIANCE STATEMENT

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

Information on the identity, strength, purity, stability, uniformity, and dose solution analysis of the test agent resides with the sponsor of the study.

Study Director signature: Emily A. Winokurzew Date: 11/30/12

Typed Name: Emily A. Winokurzew

Typed Name of Laboratory: MicroBioTest, a division of Microbac Laboratories, Inc.

Sponsor signature: _____ Date: _____

Typed Name of Signer: _____

Typed Name of Company: GER, Inc.

Submitter signature: _____ Date: _____

Typed Name of Signer: _____

Typed Name of Company: GER, Inc.

QUALITY ASSURANCE UNIT STATEMENT

Title of Study: AOAC Germicidal Spray Test – Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*

The Quality Assurance Unit of MICROBIOTEST has inspected Project Number 813-107 in compliance with current Good Laboratory Practice regulations, (40 CFR § 160).

The dates that inspections were made and the dates that findings were reported to management and to the study director are listed below.

PHASE INSPECTED	DATE OF INSPECTION	DATE REPORTED TO STUDY DIRECTOR	DATE REPORTED TO MANAGEMENT
Protocol	11/20/12	11/20/12	11/20/12
In Process (Controls)	11/20/12	11/20/12	11/20/12
Final Report	11/29/12	11/29/12	11/29/12

Nathan S. Jones

Nathan S. Jones, RQAP-GLP
Quality Assurance Unit

11/30/12
Date

TABLE OF CONTENTS

TEST SUMMARY

TITLE: AOAC Germicidal Spray Test – Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*

STUDY DESIGN: This study was performed according to the signed protocol and project sheets issued by the Study Director (See Appendix).

TEST MATERIALS SUPPLIED BY THE SPONSOR OF THE STUDY:

1. SNIPER®, Lot No. 108-167-3, received at MICROBIOTEST on 11/02/12, and assigned DS No. C848

2. SNIPER®, Lot No. 108-172-1, received at MICROBIOTEST on 11/02/12, and assigned DS No. C850

SPONSOR: GER, Inc.
P.O. Box 667
Carencro, LA 70507

TEST CONDITIONS

Challenge microorganisms:

Methicillin Resistant *Staphylococcus aureus,* ATCC 33591
Vancomycin Resistant *Enterococcus faecalis,* ATCC 51299

Active ingredient in test product:

Chlorine Dioxide

Neutralizer:

Letheen Broth containing 0.5% Sodium Thiosulfate

Contact time:

5 minutes

Contact temperature and relative humidity:

Ambient Room Temperature (21C); 39% RH

Organic load:

Heat-inactivated horse serum added to the inoculum to yield a 5% organic load.

Carrier inoculation/dry time:

A one inch square area of each carrier (glass microscope slides) was inoculated with 0.01 mL of the challenge microorganism and dried for 40 minutes at 36C and 28% RH.

Test agent application(s):

Inoculated carriers were sprayed until thoroughly wet from a distance of 6" – 8"

Dilution:

Ready to Use

TEST CONDITIONS (continued)

Media and reagents:

Nutrient Broth
Letheen Broth containing 0.5% Sodium Thiosulfate
Letheen Broth
Phosphate Buffered Saline
Tryptic Soy Agar
Mueller Hinton Agar
Gram Stain Reagents
Heat-inactivated horse serum
Oxacillin antibiotic disc
Vancomycin antibiotic disc

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164, from 11/20/12 to 11/23/12. The study director signed the protocol 11/20/12. On the day of test conduct on 11/20/12, the testing started at 1:15 pm and ended at 1:55 pm. The study completion date is the date the study director signed the final report.

All changes or revisions of the protocol were documented, signed by the study director, dated and maintained with the protocol.

RECORDS TO BE MAINTAINED

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between MICROBIOTEST and the sponsor will be stored in the archives at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164, or at a controlled facility off site.

RESULTS

Results are presented in Tables 1 - 3. The challenge microorganisms were confirmed by colony morphology and Gram stain to be consistent with Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*. The sterility control exhibited no growth. The viability and neutralizer effectiveness controls exhibited growth. An evaluation for bacteriostasis exhibited no growth.

RESULTS (continued)

Table 1
Test Results
Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Microorganism	Contact Time	Lot No. 108-167-3	Lot No. 108-172-1
Methicillin Resistant *Staphylococcus aureus*	5 Minutes	0/10	0/10
Vancomycin Resistant *Enterococcus faecalis*	5 Minutes	0/10	0/10

Table 2
Neutralizer Effectiveness
Results Expressed as Growth (+) or No Growth (0) and
Average Colony Forming (CFU) per Tube

Microorganism	Lot No.	Tube Results		Confirmation Count CFU/tube
		Rep 1	Rep 2	
Methicillin Resistant *Staphylococcus aureus*	108-167-3	+	+	20
	108-172-1	+	+	
Vancomycin Resistant *Enterococcus faecalis*	108-167-3	+	+	16
	108-172-1	+	+	

RESULTS (continued)

Table 3
Carrier Counts
Results Expressed as Average Colony Forming Units (CFU) per Carrier

Methicillin Resistant *Staphylococcus aureus*		
Rep.	CFU/Carrier	Avg. CFU/carrier
1	8.0×10^5	1.0×10^6
2	1.1×10^6	
3	1.1×10^6	
Vancomycin Resistant *Enterococcus faecalis*		
Rep.	CFU/Carrier	Avg. CFU/carrier
1	7.8×10^5	7.4×10^5
2	7.5×10^5	
3	6.9×10^5	

Table 4
Antibiotic Resistance Confirmation
Results Expressed as Resistant, Intermediate, or Susceptible*

Microorganism	Antibiotic Disc	Measurement of Inhibition (mm)	Result*
Methicillin Resistant *Staphylococcus aureus*	Oxacillin	0 mm	Resistant
Vancomycin Resistant *Enterococcus faecalis*	Vancomycin	0 mm	Resistant

* Based on Zone Diameter Interpretive Standards provided by manufacturer of disc.

CONCLUSIONS

According to the regulatory agency, the test agent passes the AOAC Germicidal Spray Test if no visible growth is observed in any of the subculture broth tubes per lot per microorganism and the controls meet their stipulated criteria.

When tested as described, SNIPER® passed the AOAC Germicidal Spray Test when Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis,* each containing a 5% organic load, were exposed to the test agent for 5 minutes at 21C. All of the controls met the criteria established for a valid test. These conclusions are based on observed data.

APPENDIX

MICROBIOTEST
A Division of Microbac Laboratories, Inc.
105-B Carpenter Drive
Sterling, VA 20164

MICROBIOTEST PROTOCOL

AOAC GERMICIDAL SPRAY TEST USING Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*

Testing Facility
MICROBIOTEST
A Division of Microbac Laboratories, Inc.
105 Carpenter Drive
Sterling, VA 20164

Prepared for
GER, Inc.
P.O. Box 667
Carencro, LA 70507

November 5, 2012

MICROBIOTEST Protocol: 813.1.11.05.12

MICROBIOTEST Project No.: 813 - 107

OBJECTIVE:

This test is designed to prove germicidal effectiveness label claims for products registered with the Environmental Protection Agency and Canada (if applicable) as spray germicides. It evaluates the effectiveness of sprays and pressurized spray products as spot disinfectants for contaminated surfaces. The test is based on the Official Methods of Analysis, Sixteenth edition, 2009, AOAC; is required by EPA Product Performance Guidelines (OCSPP 810.2000 and 810.2200).

TESTING CONDITIONS:

Ten replicates will be evaluated using two lots of a single test agent. Glass carriers inoculated with Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis* will be sprayed for the specified times and distance directed by the sponsor or label instructions and transferred into individual tubes containing neutralizing recovery broth.

MATERIALS:

A. Test agents supplied by the sponsor: see last page.

The test agents are tested as supplied by the sponsor unless directed otherwise by written instructions. All operations performed on the test agents such as dilution or specialized storage conditions must be specified by the sponsor prior to initiation of testing.

The sponsor assures MICROBIOTEST, a Division of Microbac Laboratories, Inc. (MICROBIOTEST) testing facility management that the test agents have been appropriately tested for identity, strength, purity, stability, and uniformity as applicable

MICROBIOTEST will retain all unused test agents for a period of at least three months after completion of the test, then return them to the sponsor of the study or discard them in a manner that meets the approval of the safety officer of the laboratory.

B. Materials supplied by MICROBIOTEST, including, but not limited to:

1. Challenge microorganisms, required by the sponsor of the study:
   a. Methicillin Resistant *Staphylococcus aureus*, ATCC 33591
   b. Vancomycin Resistant *Enterococcus faecalis*, ATCC 51299

2. Media and reagents:
   a. Nutrient Broth (NB)
   b. Neutralizer: Recovery broth with required neutralizer(s)
   c. Letheen Broth (LB)
   d. Heat-inactivated horse serum (if required)
   e. Phosphate Buffered Saline (PBS)
   f. Tryptic Soy Agar (TSA)
   g. Mueller Hinton Agar (MHA)
   h. Oxacillin and Vancomycin Antibiotic Discs

3. Laboratory equipment and supplies, including glass microscope slides (1" x 3" with a 1" x 1" surface for contamination and treatment)

TEST SYSTEM IDENTIFICATION:

All test and control tube racks will be labeled with microorganism, test agent (if applicable) and project number prior to initiation of the study and during incubation. Petri dishes will be labeled with microorganism prior to initiation of the study and microorganism and project number during incubation.

EXPERIMENTAL DESIGN:

A. Inocula preparation:

Bacteria from stock cultures will be transferred into NB and incubated at 36±1C. Daily transfers will be made for at least three consecutive days (but no more than ten days). Tubes of ten mL NB will be inoculated with one loopful of inoculum per tube and incubated at 36±1C. After 48-54 hours, cultures will be used for contaminating the carriers. If requested by the sponsor, serum will be added to the cultures to achieve an organic load of 5%.

The inoculum will be agitated on a Vortex-type mixer for 3-4 seconds, then allowed to sit for ten minutes and decanted into a sterile flask.

A 0.01 mL (10 µL) aliquot of each culture will be transferred onto a one-square inch area on the sterile carriers (in Petri dishes) and immediately spread uniformly over the entire area with a sterile glass rod. Each dish will be covered promptly and the operation will be repeated for the rest of the carriers, for each microorganism. Carriers will be dried for 40±1 minutes at 36±1C. The humidity level of the incubator during the drying phase required for the inoculated carriers will be monitored and reported.

B. Carrier preparation:

The glass carriers will be sterilized by placing them in a Petri dish matted with filter paper, heating them in a hot air oven for two hours at 180C, cooling and storing them at room temperature until use.

C. Test agent preparation:

The test agent will be prepared and applied exactly as directed by the sponsor of the study.

D. Test:

Ten carriers per lot per microorganism will be sprayed for the time and distance directed by the sponsor or the label instructions. Each carrier will be held for the exposure time as specified by the sponsor; the excess liquid allowed to drain; then transferred to a tube of Neutralizer. The culture will be thoroughly shaken. The humidity level of the room during the test phase will be monitored and reported.

All subculture tubes containing the carriers will be incubated for 48±2 hours at 36±1C. All observations will be recorded as growth or no growth.

E. Controls:

1. Sterility controls:

One sterile carrier will be added to a tube of Neutralizer and incubated with the test in order to demonstrate the sterility of the media used in the study.

2. Viability controls:

Two inoculated carriers per microorganism will be independently transferred into tubes of Neutralizer and incubated with the test to serve as comparison for the test cultures.

3. Neutralizer effectiveness:

Two sterile carriers per lot per microorganism will be exposed to the disinfectant for the required contact time, and then transferred into individual tubes of Neutralizer. To each tube, 10-100 colony forming units (CFU) of the challenge microorganism will be added and the count of the bacteria inoculated into these tubes will be confirmed in duplicate TSA plates. The tubes and plates will be incubated with the test.

4. Carrier counts:

For each challenge microorganism, the average CFU per carrier will be determined using three inoculated carriers. Dried inoculated carriers will be placed individually into tubes containing 20 mL LB. The tubes will be subjected to ultrasound for 5 minutes in a cleaning sonicator. Serial ten-fold dilutions of each suspension will be performed in PBS blanks. Duplicate one mL aliquots from selected dilutions will be plated in TSA pour plates. All plates will be incubated with the test and the average CFU/carrier determined.

5. Antibiotic resistance:

An individual MHA plate will be streaked with the prepared challenge organism in a crosshatch pattern and the stipulated disc will be added on the agar plate. The plate will be incubated for 24±2 hours at 36±1C. Upon completion of incubation, the plate will be observed and the zone of inhibition (the area immediately surrounding the antibiotic disc) will be measured and documented. Using the Zone Diameter Interpretive Standards provided by the manufacturer of the antibiotic discs, the zone of inhibition will determine the organism to be Resistant, Intermediate, or Susceptible. The final determination will be reported in the final report.

6. Bacteriostasis control:

If, after two days incubation, no growth is observed in any of the test tubes, at least 20% of the test tubes will be streaked onto TSA and incubated for 24±2 hours at 36±1C. No growth on these plates will negate bacteriostasis as the cause for lack of growth in the test tubes.

7. Confirmation of challenge microorganisms:

All of the viability controls and at least 20% of the test tubes showing growth will be streaked onto TSA plates. All plates will be incubated for 24±2 hours at 36±1C. Gram stains will be performed from these streaks in order to confirm growth of the challenge microorganism.

TEST ACCEPTANCE CRITERIA:

The test will be acceptable for evaluation of the test results if the criteria listed below are satisfied. The study director may consider other causes that may affect test reliability and acceptance.

- The carrier counts must be ≥ 1×10^6 CFU/carrier
- The neutralizer must be effective and support growth of the challenge microorganism(s).
- The sterility control must be negative for growth
- The viability controls must exhibit growth

PRODUCT EVALUATION CRITERIA:

According to EPA, the compound passes the test if no visible growth is observed any of the subculture broth tubes per lot and the controls meet their stipulated criteria. There is no statistical method proposed for this protocol.

DATA PRESENTATION:

The final report will include the following information:

- The number of positive carriers.
- The average colony-forming units per carrier.
- The results of all controls.

PERSONNEL AND TESTING FACILITIES:

A study director will be assigned before initiation of the test. Resumes for technical personnel are maintained and are available on request. This study will be conducted at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164.

CONFIDENTIALITY:

All data generated at MICROBIOTEST are held in strictest confidence and are available only to the sponsor and the sponsor designated authorities (if applicable). In turn, no reference to MICROBIOTEST's promotion of the evaluated test articles may be made public by the sponsor.

REPORT FORMAT:

MICROBIOTEST employs a standard report format for each test design. Each final report provides the following information:

- Sponsor identification and test agent identification
- Type of test and project number
- Dates of study initiation and completion
- Interpretation of results and conclusions
- Test results
- Methods and evaluation criteria
- Signed Quality Assurance and Compliance Statements (if applicable)

RECORDS TO BE MAINTAINED:

All raw data, protocol, protocol modifications, test agent records, final report, and correspondence between MICROBIOTEST and the sponsor will be stored in the archives at MICROBIOTEST, 105 Carpenter Drive, Sterling, Virginia 20164 or in a controlled facility off site.

All changes or revisions to this approved protocol will be documented, signed by the study director, dated and maintained with this protocol. The sponsor will be notified of any change, resolution, and impact on the study as soon as practical.

The proposed experimental start and termination dates; additional information about the test agent; challenge microorganism used; media and reagent identification; and the type of neutralizers employed in the test will be addressed in a project sheet issued separately for each study. The date the study director signs project sheet number one will be the initiation date. All project sheets will be forwarded to the study sponsor.

MISCELLANEOUS INFORMATION:

The following information is to be completed by sponsor before initiation of study:

A. Name and address: GER, Inc.
P.O. Box 667
Carencro, LA 70507

B. Test agent: SNIPER®

Active ingredient(s): Chlorine dioxide, ClO2

Lot No 1: 108-172-1 (≥ 60 day sample: ☐ Yes ☒ No)

(Manufacture date: 10-30-12; Expiration date:_____)

Lot No 2: 108-167-3 (≥ 60 day sample: ☐ Yes ☒ No)

(Manufacture date: 10-30-12; Expiration date:_____)

Contact time: 5 minutes

Exposure temperature: Ambient room temperature 20±1C
☐ Other:_____

Dilution to be tested: ☒ Ready to Use
☐ Other:_____
(_____parts test agent +_____ parts diluent)

Diluent: ☒ Not applicable - Ready to Use
☐ Sterile Deionized Water
☐ _____ppm ± 2.9% AOAC hard water
☐ Other:_____

MISCELLANEOUS INFORMATION: (continued)

Spray application: ☒ Until thoroughly wet
☐ Other:_____

Spraying distance: ☒ 6-8"
☐ Other:_____

C. Organic load – serum added to achieve 5% in the inoculum: ☒ yes ☐ no

D. Precautions/storage conditions: MSDS and/or CofA provided: ☒ yes ☐ no

REPORT HANDLING:

The sponsor intends to submit this information to:
☒ US EPA ☐ US FDA ☐ Health Canada ☐ CAL DPR
☐ ARTG ☐ other: Internal Purposes

STUDY CONDUCT: ☐ GLP ☐ non-GLP

PROTOCOL APPROVAL:

Sponsor: Global Environmental Restoration, Inc Date: 11/5/12

Sponsor Name (print): Alan Bud Campbell, representing GER, Inc.

Study Director Signature: Emily A. Winokurzew Date: 11/19/12

Study Director Printed Name: Emily A. Winokurzew

Date Issued: 11/20/12 Project Sheet No. 1 Page No. 1 Laboratory Project Identification No. 813-107

STUDY TITLE: AOAC GERMICIDAL SPRAY TEST USING Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*	**STUDY DIRECTOR:** Emily A. Winokurzew Signature 11/20/12 Date		
TEST AGENT (S):	**LOT NO.:**	**DATE RECEIVED:**	**DS NO.:**
SNIPER®	108-167-3	11/02/12	C848
SNIPER®	108-172-1	11/02/12	C850
PERFORMING DEPARTMENT(S): Applied Microbiology Laboratory	**STORAGE CONDITION:** Location: C5 ■Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator		

PROTECTIVE PRECAUTION REQUIRED: MSDS ☐ Yes / ■ No

PHYSICAL DESCRIPTION: ☐ Solid ■Liquid ☐ Aerosol ☐ Other:

PURPOSE: See attached protocol. **AUTHORIZATION:** See client signature.

PROPOSED EXPERIMENTAL START DATE: 11/20/12 **TERMINATION DATE:** 11/23/12

CONDUCT OF STUDY: ☐ FDA ■EPA ☐R&D ■GLP ☐ GCP ☐ Other: internal purposes

SPONSOR: GER, Inc. P.O. Box 667 Carencro, LA 70507	**CONTACT PERSON:** Alan Bud Campbell Telephone No. 337-235-4710 Email: alanbud@environmentrestoration.com

TEST CONDITIONS:

Challenge organism(s):	Methicillin Resistant *Staphylococcus aureus*, ATCC 33591 Vancomycin Resistant *Enterococcus faecalis*, ATCC 51299
Active ingredient(s):	Chlorine Dioxide ClO_2
Neutralizer(s):	Letheen Broth containing 0.5% Sodium Thiosulfate
Contact Time(s):	5 minutes
Contact Temperature(s):	Room Temperature (20±1C)
Dilution(s):	Ready To Use
Diluent:	Not Applicable
Serum:	■Yes /☐ No (heat-inactivated **donor horse serum** added to the inoculum to achieve a 5% concentration)
Incubation Time(s):	48±2 hours (test and controls); 24±2 hours (bacteriostasis and or streaks)

Incubation Temperature(s): 36±1C

Comments: Each carrier will be treated until wet from a distance of 6-8 inches.

This project sheet has been reviewed by the sponsor:

Alan Bud Campbell 11/21/12

Signature Date

Date Issued: 11/20/12 Project Sheet No. 2 Page No. 1 Laboratory Project Identification No. 813-107

STUDY TITLE: AOAC GERMICIDAL SPRAY TEST USING Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*	**STUDY DIRECTOR:** Emily A. Winokurzew Signature 11/21/12 Date		
TEST AGENT (S):	**LOT NO.:**	**DATE RECEIVED:**	**DS NO.:**
SNIPER®	108-167-3	11/02/12	C848
SNIPER®	108-172-1	11/02/12	C850
PERFORMING DEPARTMENT(S): Applied Microbiology Laboratory	**STORAGE CONDITION:** Location: C5 ■Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator		
SPONSOR: GER, Inc. P.O. Box 667 Carencro, LA 70507	**CONTACT PERSON:** Alan Bud Campbell Telephone No. 337-235-4710 Email: alanbud@environmentrestoration.com		

EXPLANATION:
Protocol amendments(s):

1. On page 10 of the protocol, the study conduct box was inadvertently not checked off by the sponsor. This amendment serves to clarify that it is a GLP test.

The amendments or deviations have been reviewed and accepted by the sponsor:

Alan Bud Campbell 11-21-12
Signature Date

Date Issued: 11/30/12 Project Sheet No. 3 Page No. 1 Laboratory Project Identification No. 813-107

STUDY TITLE: AOAC GERMICIDAL SPRAY TEST USING Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*	**STUDY DIRECTOR:** Emily A. Winokurzew Emily A. Winokurzew 11/30/12 Signature Date		
TEST AGENT (S): SNIPER® SNIPER®	**LOT NO.:** 108-167-3 108-172-1	**DATE RECEIVED:** 11/02/12 11/02/12	**DS NO.:** C848 C850
PERFORMING DEPARTMENT(S): Applied Microbiology Laboratory	**STORAGE CONDITION:** Location: C5 ■Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator		
SPONSOR: GER, Inc. P.O. Box 667 Carencro, LA 70507	**CONTACT PERSON:** Alan Bud Campbell Telephone No. 337-235-4710 Email: alanbud@environmentrestoration.com		

EXPLANATION:
Protocol amendments(s):

2. Page 6 of the protocol indicates that the test acceptance criteria for carrier counts must be ≥ 1 x 10^6 CFU/carrier, however for supplemental microorganisms the criterion is ≥ 1 x 10^4 CFU/carrier. The design of this study is for supplemental registration purposes. This amendment serves to correct a typographical error.