Microbac®

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

Volume _____

FINAL REPORT

VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)

Test Agent
SNIPER®

Lot Numbers
108-167-3
108-171-2

Test Organism
Human Immunodeficiency Virus Type 1, ZeptoMetrix

Test Guideline
EPA Guidelines 810.2200 (f)(2)

Author
S. Steve Zhou, Ph. D

Study Completion Date
11/27/12

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

Laboratory Project Identification Number
813-104

Protocol Identification Number
813.1.11.01.12

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

703.925.0100 (phone) • www.microbiotest.com • 703.925.9366 (fax)
www.microbac.com

STATEMENT OF NO DATA CONFIDENTIALITY

Title: VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)

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: _____ Date: 11/27/2012

Typed Name: S. Steve Zhou, Ph. D

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: VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)

The Quality Assurance Unit of MICROBIOTEST has inspected Project Number 813-104 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	11/07/12	11/07/12	11/07/12
In Process (Controls)	11/07/12	11/07/12	11/07/12
Final Report	11/21/12	11/21/12	11/21/12

Jeanne M. Anderegg
Manager, Quality Assurance Unit

11-27-12
Date

TABLE OF CONTENTS

TEST SUMMARY

TITLE: VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)

STUDY DESIGN: This study was performed according to the signed protocol and project sheet(s) 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. 108-171-2 (aged ≥60 days); received at MICROBIOTEST on 11/02/12; and assigned DS No. C849

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

TEST CONDITIONS

Challenge virus:

Human Immunodeficiency Virus Type 1, ZeptoMetrix

Host cell line:

C8166 cells

Active ingredient in test product:

Chlorine Dioxide

Neutralizer:

Fetal Bovine Serum (FBS) + 0.5% $Na_2S_2O_3$

Dilution medium/cell culture medium:

RPMI-1640 + 2% FBS

Contact time:

5 minutes and 10 minutes

Contact temperature and relative humidity:

Ambient Room Temperature (21C); at <20.0% RH

Carriers:

Glass petri dishes

Carrier inoculation/dry time:

2 x 2 inch area of glass carrier inoculated with 0.4 mL of virus and dried for 30 minutes at 21C and <20.0% RH

Organic load:

≥5% Serum

TEST CONDITIONS (continued)

Dilution:

Ready to use

Media and reagents:

RPMI-1640 + 2% FBS
Fetal Bovine Serum (FBS) + 0.5% $Na_2S_2O_3$

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164, from 11/07/12 to 11/19/12. The study director signed the protocol 11/07/12. On the day of test conduct on 11/07/12, the testing started at 2:24 pm and ended at 4:00 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.

CALCULATION OF TITER

The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the Spearman-Karber method using the following formula:

$$m = x_k + \left(\frac{d}{2}\right) - d\sum p_i$$

where:

m = the logarithm of the titer relative to the test volume
x_k = the logarithm of the smallest dosage which induces infection in all cultures
d = the logarithm of the dilution factor
p_i = the proportion of positive results at dilution i

The values were converted to $TCID_{50}$/mL using a sample inoculum of 0.05 mL.

RESULTS

Data are presented in Tables 1-4.

The Log_{10} Reduction Factor (LRF) was calculated in the following manner:

Log_{10} Reduction = Log_{10} $TCID_{50}$ (Plate Recovery Control) – Log_{10} $TCID_{50}$ (Test)

The Load (Log_{10} $TCID_{50}$) per carrier was calculated in the following manner:

Load (Log_{10} $TCID_{50}$) = Titer (Log_{10} $TCID_{50}$/mL) + Log_{10} [volume per carrier (mL)]

Key (for all tables):

C/y = Cytotoxicity observed in y wells inoculated; no viral cytopathic effect (CPE) could be determined.
X/y = X wells out of y wells inoculated exhibited viral CPE
0/y = 0 wells out of y wells inoculated exhibited viral CPE, no cytotoxicity or bacterial contamination was observed in any of the wells inoculated

RESULTS (continued)

Table 1
Test Agent Results

Dilution*	SNIPER®			
	Lot No. 108-167-3		Lot No. 108-171-2	
	5 Minutes	10 Minutes	5 Minutes	10 Minutes
10^{-2}	C/8	C/8	C/8	C/8
10^{-3}	0/8	0/8	0/8	0/8
10^{-4}	0/8	0/8	0/8	0/8
10^{-5}	0/8	0/8	0/8	0/8
10^{-6}	0/8	0/8	0/8	0/8
10^{-7}	0/8	0/8	0/8	0/8
Titer (Log_{10} $TCID_{50}$/mL)	≤3.80	≤3.80	≤3.80	≤3.80
Load (Log_{10} $TCID_{50}$) per carrier (0.4 mL challenge)	**≤3.40**	**≤3.40**	**≤3.40**	**≤3.40**
Log_{10} Reduction	**≥3.13**	**≥3.00**	**≥3.13**	**≥3.00**

*Dilution refers to the fold of dilution from virus inoculum.

Table 2
Neutralizer Effectiveness and Cytotoxicity Related Controls

Dilution*	SNIPER® (Lot No. 108-167-3)	
	Neutralizer Effectiveness Control	Cytotoxicity Control
10^{-2}	C/8	C/8
10^{-3}	8/8	0/8
10^{-4}	8/8	0/8

*Dilution refers to the fold of dilution from mock inoculum.

RESULTS (continued)

Table 3
Neutralizer Effectiveness and Cytotoxicity Related Controls

Dilution*	SNIPER® (Lot No. 108-171-2)	
	Neutralizer Effectiveness Control	Cytotoxicity Control
10^{-2}	C/8	C/8
10^{-3}	8/8	0/8
10^{-4}	8/8	0/8

*Dilution refers to the fold of dilution from mock inoculum.

Table 4
Viability Control Results

Cell Viability Control
0/8
Cells were viable; media was sterile

Table 5
Virus Recovery Controls

Dilution*	Plate Recovery Control	Plate Recovery Control
	5 minutes	10 minutes
10^{-3}	8/8	8/8
10^{-4}	8/8	8/8
10^{-5}	8/8	8/8
10^{-6}	1/8	0/8
10^{-7}	0/8	0/8
10^{-8}	0/8	0/8
Titer (Log_{10} $TCID_{50}$/mL)	6.93	6.80
Load (Log_{10} $TCID_{50}$) per carrier (0.4 mL challenge)	**6.53**	**6.40**

*Dilution refers to the fold of dilution from virus inoculum.
NA = Not Applicable

RESULTS (continued)

Table 6
Virus Stock Titer Control

Dilution*	Virus Stock Titer Control
10^{-4}	8/8
10^{-5}	8/8
10^{-6}	4/8
10^{-7}	0/8
10^{-8}	0/8
10^{-9}	0/8
Titer (Log_{10} $TCID_{50}$/mL)	**7.30**
Load (Log_{10} $TCID_{50}$) per carrier (0.4 mL challenge)	**NA**

CONCLUSIONS

According to the regulatory agencies, the test agent passes the Virucidal Efficacy Test if there is complete inactivation of the challenge virus at all dilutions. When cytotoxicity is evident, at least a three-log reduction in titer must be demonstrated beyond the cytotoxic level.

When tested as described, SNIPER® passed the Virucidal Efficacy Test when Human Immunodeficiency Virus Type 1 (HIV-1), containing ≥ 5% serum, was exposed to both lots of the test agent for 5 minutes and 10 minutes at 21C. All of the controls met the criteria for a valid test. These conclusions are based on observed data.

APPENDIX

Microbac®

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

MICROBIOTEST PROTOCOL

VIRUCIDAL EFFICACY TEST

Human Immunodeficiency Virus Type 1 (HIV-1)

Testing Facility
MICROBIOTEST
A Division of Microbac Laboratories, Inc.
105 Carpenter Drive
Sterling, VA20164

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

July 27, 2012

OBJECTIVE:

This test is designed to substantiate virucidal effectiveness claims for a product to be labeled as a virucide. It determines the potential of the test agent to disinfect hard surfaces contaminated with Human Immunodeficiency Virus Type 1. The test is designed to simulate consumer use and conforms to EPA OCSPP 810.2000 and 810.2200 Product Performance Test Guidelines, and follows the procedure outlined in the American Society for Test Materials (ASTM) test method designated E1053.

TESTING CONDITIONS:

Virus will be dried on a suitable sterile hard surface at ambient temperature. Two lots of one type of test agent will be used to treat the dried viruses. After a defined exposure period as specified by the sponsor, the test agent-virus mixture will be scraped from the surface, collected, neutralized and tested for the presence of infectious virions. One concentration of the test agent will be evaluated at one exposure (contact) time. One replicate run will be performed for each test condition.

MATERIALS:

A. Test, control and reference substances will be supplied by the sponsor of the study (see last page).

The test agent will be tested as supplied by the sponsor unless directed otherwise. All operations performed on the test agent such as dilution or specialized storage conditions must be specified by the sponsor before initiation of testing.

The sponsor assures MICROBIOTEST testing facility management that the test agent has 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, and then discard them in a manner that meets the approval of the safety officer.

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

1. Challenge virus requested by the sponsor of the study: Human Immunodeficiency Virus Type 1 (HIV-1)

2. Host cell lines: C8166 cells

3. Laboratory equipment and supplies.

4. Media and reagents:

   Media and reagents relevant to the virus-host system and test agent being tested will be documented in the first project sheet and data pack.

TEST SYSTEM IDENTIFICATION:

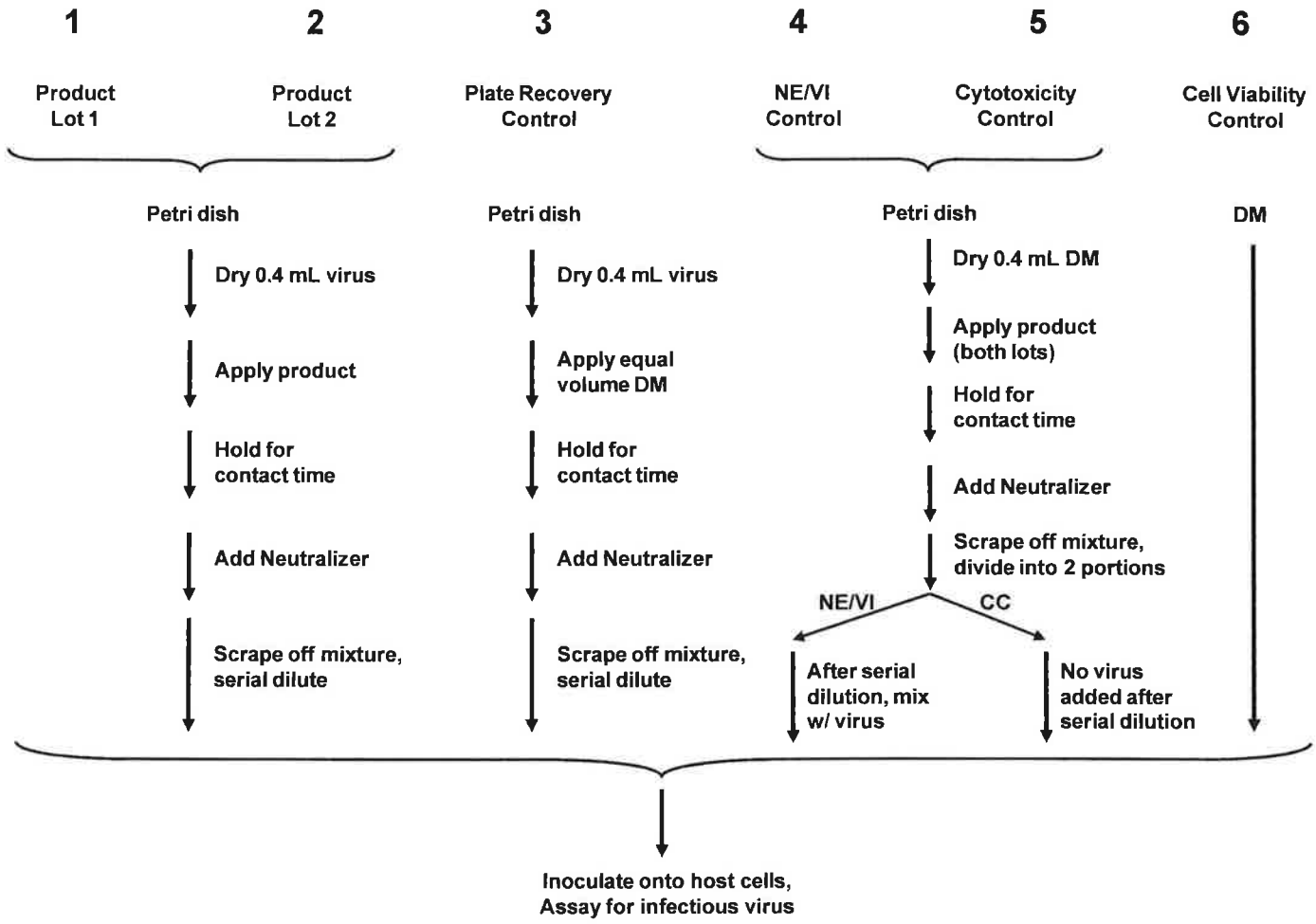
All Petri dishes, dilution tube racks, and host-containing apparatus will be appropriately labeled with the following information: virus, host, and test agent and/or project number.

EXPERIMENTAL DESIGN:

All of the procedures involved in performance of this study are described in a detailed series of SOPs that are maintained at MICROBIOTEST. SOPs and Logs are referred to in the raw data and are required as part of GLP regulations.

The study flow diagram is shown in Figure 1, with details described in the following sections.

FIGURE 1



DM: Dilution Medium
NE/VI: Neutralizer Effectiveness/Viral Interference control
CC: Cytotoxicity Control

Note: The volume of the virus to be applied onto each carrier may be changed depending on the titer of the virus. This volume will remain consistent among all test and control runs.

A. Inoculum preparation:

Viral stocks are purchased from reputable sources that identify them by scientifically accepted methods and may have been propagated at MICROBIOTEST. Records are maintained that demonstrate the origin of the virus. The virus stocks are stored at an ultra-low temperature.

Frozen viral stocks will be thawed on the day of the test (fresh stock cultures may be used at the discretion of the Study Director). Serum will be added to viral stock to achieve an organic load of 5% (if not already 5% or above) unless otherwise directed by the Sponsor.

B. Carrier preparation:

For each lot of the test agent, an aliquot of 0.4 mL of stock virus will be spread over an area of approximately 4 in^2 that has been marked on the underside of pre-sterilized glass Petri dishes. Note: The volume of the test virus to be applied onto each carrier may be changed at the discretion of the Study Director. This volume will remain consistent among all test and control runs. Then the virus will be allowed to dry at ambient temperature. The drying time and temperature will be recorded.

Two carriers (one carrier per lot) will be prepared for the test agent using virus. Another carrier will be prepared for the plate recovery control using virus. Additionally, two carriers (one carrier per lot) will be prepared for the neutralizer effectiveness/viral interference and cytotoxicity controls using dilution medium (DM) in lieu of virus.

C. Test agent preparation:

The test agent will be prepared exactly according to the sponsor's directions.

D. Test:

Two lots of the test agent will be tested at one contact time. One replicate will be tested for each lot of the test agent.

For direct liquid application products, for each replicate run, after the inoculum has dried, 2.0 mL of the test agent will be added. The dried virus film must be

completely covered by the test agent. The plates will remain at the temperature and for the time specified by the sponsor. After the contact period, the test agent will be neutralized with 2.0 mL of appropriate neutralizer and the mixture will be scraped from the surface of the dish with a cell scraper. This will be considered approximately a 10^{-1} dilution.

For spray type agents, the agent will be used as the sponsor directs, the volume dispensed will be measured and an equal volume of neutralizer will be used. Following the contact time, the procedure for processing the samples will be the same as described earlier.

If Sephacryl columns are used to aid-in the neutralization and to further reduce the cytotoxicity, each inoculum/test agent/neutralizer mixture sample will be loaded onto a pre-spun Sephacryl column. Following the passage through columns, the eluates will be aseptically collected and serially ten-fold diluted in DM. If columns are not used, serial ten-fold dilutions of the inoculum/test agent/neutralizer mixture will directly be prepared in DM.

E. Infectivity assay:

The residual infectious virus in both test and controls will be detected by viral-induced cytopathic effect (CPE).

Selected dilutions of the neutralized inoculum/disinfectant test agent mixture will be added to cultured host cells (at least four wells per dilution, per reaction mixture) and incubated at 36±2C with 5±1% CO_2 for a period of 9-12 days. The host cell cultures may be washed twice with phosphate buffered saline prior to inoculation. The inoculated culture will be observed and refed with fresh media as necessary, during the incubation period. These activities, if applicable, will be recorded. The host cells will then be examined microscopically for presence of infectious virions. The resulting virus-specific cytopathic effects and test agent-specific cytotoxic effects will be scored by examining both test and controls. These observations will be recorded.

F. Controls:

1. Plate recovery control:

This control will be performed in singlet run. The virus inoculum will be spread over the surface of a sterile glass Petri dish and left to dry at ambient temperature. A volume of DM equivalent to that of the test agent will be added to the dried virus. Post-contact time, virus will be subjected to the identical neutralization procedure as the test agent. This control will determine the relative loss in virus infectivity resulting from drying and neutralization alone.

The results from this control will be compared with the test results to confirm recovery of at least 4.0-log of infectious virus in this control following drying and neutralization. Its titer will be used to compare with the titers of the test results to reach the acceptable test criteria (see below).

2. Neutralizer effectiveness/Viral interference control:

This control will determine if residual active ingredient is present after neutralization and if the neutralized test agent interferes with the virus infection system. This control will be performed on both lots of the product at one replicate per lot.

The test agent will be processed exactly as the test procedure but in lieu of virus inoculum, dried DM will be exposed to the test agent and assayed as previously described. Post-treatment and neutralization, the neutralized DM/test agent mixture will be divided into two portions, one for cytotoxicity control and the other for neutralizer effectiveness/viral interference control, and processed as the test.

If columns are used, each portion will be passed through individual columns and the eluate will be serially diluted ten-fold in DM. If columns are not used, the neutralizer effectiveness sample (0.5 mL) will be directly diluted using serial ten-fold dilutions in DM.

Following serial dilution of the reaction mixture in DM, virus (100 µL of a low titer virus inoculum) will be added to each dilution and held for a period

equivalent or greater than the contact time. Then the selected dilutions will be used to inoculate host cells as described for the test procedure.

3. Cytotoxicity control:

This control will be performed on both lots of the product at one replicate per lot.

The cytotoxicity sample, acquired from the neutralizer effectiveness/viral interference control run, will be diluted and have no virus added. Selected dilutions will be inoculated and incubated in the same manner as the rest of the test and control samples. These effects are distinct from virus-induced cytopathic effects, which will be evident in the plate recovery control cultures.

4. Column titer control (to be performed only if a Sephacryl column is used):

This control will be performed to determine any affect the columns may have on infectious virus titer.

The sample for this control will be acquired from a portion of the PRC, prior to passing through the columns and will be serially diluted in DM, then processed in the same manner as the test.

5. Cell viability control:

This control will demonstrate that cells remain viable throughout the course of the assay period. In addition, it will confirm the sterility of the DM employed throughout the assay period. At least four wells of cells will receive only DM and will be incubated and processed with both test and other controls. This will serve as the negative control.

6. Virus Stock Titer control (VST)

An aliquot of the virus used in the study will be directly serially diluted and inoculated onto the host cells to confirm the titer of the stock virus. This control will demonstrate that the titer of the stock virus is appropriate for use and that the viral infectivity assay is performed appropriately.

G. Calculation:

The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) will be determined using the method of Spearman-Karber, or another appropriate method. The test results will be reported as the reduction of the virus titer due to treatment with test agent expressed as log_{10}.

PERSONNEL AND TESTING FACILITIES:

A study director will be assigned prior to initiation of the test. Resumes are maintained and are available on request. This study will be conducted at MICROBIOTEST, 105 Carpenter Drive, Sterling, Virginia 20164.

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 infectious virus recovered from the PRC control must be ≥ 4.0-log_{10}.
- Viral-induced cytopathic effect must be distinguishable from test agent induced cytotoxic effects (if any).
- Virus must be recovered from the neutralizer effectiveness/viral interference control (not exhibiting cytotoxicity).
- The Cell Viability Control (assay negative control) must not exhibit virus.

PRODUCT EVALUATION CRITERIA:

According to the regulatory agencies, the test agent passes the test if there is complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a three-log reduction in titer must be demonstrated beyond the cytotoxic level.

REPORT FORMAT:

MICROBIOTEST employs a standard report format for each test design. Each final report will provide at least the following information:

- Sponsor identification
- Test agent identification
- Type of assay and project number
- Dates of study initiation and completion
- Interpretation of results and conclusions
- Test results presented in tabular form
- Methods and evaluation criteria, if applicable
- Dates of study initiation and completion (GLP studies only)
- Signed Quality Assurance and Compliance Statements (GLP studies only)

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 virus and host cell line monolayers used 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 the protocol will be the initiation date. All project sheets issued will be forwarded to the study sponsor for appropriate action.

MISCELLANEOUS INFORMATION:

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

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

B. Test Agent Name: SNiPER®
Active Ingredient: Chlorine Dioxide
Lot 1 number: 108-167-3 ; ≥60 day aged: ☐ yes ☒ no
(Manufacture or expiration date: 10-30-12)
Lot 2 number: 108-171-2 ; ≥60 day aged: ☒ yes ☐ no
(Manufacture or expiration date: 8/02/11)

C. Testing conditions:

Dilution to be tested: ☒ Ready to use; or
☐ _____ (____ part test agent + _____ parts diluent)

Diluent: ☒ not applicable (ready to use)
☐ 400 ± 2.9% ppm AOAC hard water
☐ Other: _____

Exposure (Contact) time: ☒ 5 minutes
Exposure temperature: ☒ Room temperature (20±1C)

Spray application: ☐ not applicable
☐ _____number of sprays
☒ until thoroughly wet

Spraying distance: ☐ not applicable
☒ 6 – 8 inches
☐ Other:_____

D. Organic load in virus inoculum: ☒ ≥ 5% serum; or ☐ _____

E. Precautions/storage conditions: MSDS and/or C of A provided: ☒ yes ☐ no

F. Note: prior to dispensing, the bottles of test agent should be gently shaken 2-3 times.

Continued on next page.

MISCELLANEOUS INFORMATION: (continued)

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 BY SPONSOR:

Sponsor Signature: Alan Bud Campbell Date: 11/1/12

Sponsor Printed Name: Alan Bud Campbell

PROTOCOL APPROVAL BY STUDY DIRECTOR (MICROBIOTEST):

Study Director Signature: _____ Date: 11/07/2012

Study Director Printed Name: S. Steve ZHOU

Date Issued: 11/07/12 Project Sheet No. 1 Page No. 1 Laboratory Project Identification No. 813-104

STUDY TITLE: VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)	**STUDY DIRECTOR:** S. Steve Zhou, Ph.D. Signature 11/07/2012 Date		
TEST AGENT (S): SNIPER®	**LOT NO.:** 108-167-3 108-171-2	**DATE RECEIVED:** 11/02/12 11/02/12	**DS NO.:** C848 C849
PERFORMING DEPARTMENT(S): Virology	**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: 11/07/12 **TERMINATION DATE:** 11/20/12			
CONDUCT OF STUDY: ☐ FDA ■ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:			
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:	Human Immunodeficiency Virus Type 1, ZeptoMetrix
Host cell line:	C8166 cells, University of Pennsylvania
Active ingredient(s):	Chlorine Dioxide (ClO_2)
Dilution(s):	Ready to Use
Neutralizer:	Fetal Bovine Serum (FBS) + 0.5% $Na_2S_2O_3$
Dilution Medium:	RPMI-1640 + 2% FBS
Organic load:	≥5% Serum
Exposure time:	5 minutes and 10 minutes
Exposure temperature:	Room temperature (20±1C)
Incubation time:	9 - 12 days Incubation temperature: 36±2C and 5±1%CO_2
Comments:	Prior to dispensing, the bottles of test agent will be gently shaken 2-3 times. Carriers will be sprayed from a distance of 6-8 inches until thoroughly wet.

Date Issued: 11/07/12 Project Sheet No. 1 Page No. 2 Laboratory Project Identification No. 813-104

STUDY TITLE: VIRUCIDAL EFFICACY TEST – Human Immunodeficiency Virus Type 1 (HIV-1)	**STUDY DIRECTOR:** S. Steve Zhou, Ph.D. Signature 11/07/2012 Date		
TEST AGENT (S): SNIPER®	**LOT NO.:** 108-167-3 108-171-2	**DATE RECEIVED:** 11/02/12 11/02/12	**DS NO.:** C848 C849
PERFORMING DEPARTMENT(S): Virology	**STORAGE CONDITION:** Location: C5 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator		
CONDUCT OF STUDY: ☐ FDA ■ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:			
SPONSOR: GER, Inc. P.O. Box 667 Carencro, LA 70507	**CONTACT PERSON:** Alan Bud Campbell Telephone No. 337-235-4710 Email: alanbud@environmentrestoration.com		

Protocol Amendments:

1. Protocol indicates that one contact time (5 minutes) will be used. Per client request, two contact time points – 5 and 10 minutes – will be tested. The Neutralization Effectiveness/Viral Interference and Cytotoxicity control will be performed using the longer contact time only as a worst-case scenario. This amendment serves to document the change of the contact times to be tested.