FINAL REPORT

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

TEST AGENT
3M Avagard™ 9250 Antiseptic Handrub

Author
Salimatu Lukula, M.S.

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

Laboratory Project Identification Number
109-237

Sponsor
3M Health Care
3M Infection Prevention Division
222 Tian Lin Road,
Shanghai 200233 | China

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COMPLIANCE STATEMENT

This study meets the requirements for 21 CFR § 58 with the following exceptions:

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

The following technical personnel participated in this study:

Cory Chiossone

Study Director: MicroBioTest

Salimatu Lukula 2/29/16

Salimatu Lukula, M.S. Date

QUALITY ASSURANCE UNIT STATEMENT

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

The Quality Assurance Unit of MicroBioTest has inspected the Project Number 109-237 in compliance with current Good Laboratory Practice regulations (21 CFR § 58).

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	01/27/16 01/29/16	01/29/16	01/29/16
In-Process	01/29/16	01/29/16	01/29/16
Final Report	02/12/16	02/12/16	02/12/16

Savanna Green 2-26-16

Savanna Green Date
Quality Assurance Associate II

TEST SUMMARY

TITLE: VIRUCIDAL EFFICACY SUSPENSION 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 AGENT:

3M Avagard™ 9250 Antiseptic Handrub, received at MicroBioTest on 12/08/2015, and assigned DS No. F1071

SPONSOR:

3M Health Care
3M Infection Prevention Division
222 Tian Lin Road,
Shanghai 200233 | China

TEST CONDITIONS

Challenge virus:

Human Immunodeficiency Virus Type 1 (HIV-1) Strain IIIB, Zeptometrix

Host:

C8166 cells, University of Pennsylvania

Active ingredients:

Chlorhexidine Gluconate 0.45-0.55% (w/v) Ethanol 63.1-77% (v/v)

Dilution Medium:

Minimum Essential Medium (MEM) + 2% Fetal Bovine Serum (FBS)

Neutralizer used:

MEM + 10% FBS + 1% Polysorbate 80 + 1% Tamol + 0.5% Lecithin

Contact times:

30 seconds, 2 minutes

Contact temperature:

Ambient Room temperature 20±1C (20C actual)

Test agent application:

Suspension test – direct mixing (2.7 mL aliquot of the test agent was spiked with 0.3 mL of the virus suspension and thoroughly mixed by vortex mixing)

Media and reagents:

Minimum Essential Medium (MEM) + 2% Fetal bovine Serum (FBS)
MEM + 10% FBS + 1% Polysorbate 80 + 1% Tamol + 0.5% Lecithin

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MicroBioTest, Division of Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, VA 20164. Testing was laboratory initiated on 01/29/16 and was completed on 02/09/16. The study director signed the protocol on 01/29/16. The study completion date is the date the study director signed the final report.

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

RECORDS TO BE MAINTAINED

All testing data, protocol, protocol modifications, test agent records, the final report, and correspondence between MicroBioTest and the sponsor will be stored in the archives at MicroBioTest, Division of Microbac Laboratories, Inc., 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 dilution at which half the wells are infected 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
- $\sum p_i$ = the sum of p_i (starting with the highest dilution producing 100% infection)

When a sample contains a low concentration of virus there is a discrete probability that if only a fraction of the sample is tested for virus, that fraction will test negative due to random distribution of virus throughout the total sample. The probability, p, that the sample analyzed does not contain infectious virus is expressed by: $p = [(V-v)/V]^y$, where V is the total volume of the container, v is the volume of the fraction being tested, and y is the absolute number of infectious viruses randomly distributed in the sample. If V is sufficiently large relative to v, the Poisson distribution can approximate p:

$P = e^{-cv}$ or $c = -[Ln(P)] / v$

Where c is the concentration of infectious virus and v is the total sample volume.

CALCULATION OF TITER (continued):

The amount of virus which would have to be present in the total sample in order to achieve a positive result with 95% confidence (p = 0.05) is calculated as

$c = -[Ln(0.05)] / v = 3 / v$

If all wells are negative, the virus titer after the process is considered to be less than or equal to this value. The total volume of sample assayed is v = v'nd, where v' is the test volume in a well, n is the number of wells per sample, and d is the sample dilution.

RESULTS

Results are presented in Tables 1-3.

The Viral load was determined in the following manner:

Viral Load (log_{10} $TCID_{50}$) = Titer (log_{10} $TCID_{50}$/mL) + Log_{10} [Volume (mL) x Volume Correction]

The log_{10} Reduction Factor was calculated in the following manner:

Log_{10} Reduction Factor = Initial viral load (Log_{10}) – Output viral load (Log_{10})

Conversion of Log_{10} reduction to percent reduction

Log_{10} reduction = A
% reduction = B

$$B = \left[1 - \frac{1}{10^{A}} \right] \times 100$$

Example:

3.5 Log_{10} reduction = {1 – 1/ [power (10, 3.5)]} x 100 = 99.97%

RESULTS (continued)

Table 1
Titer Results

Sample	Contact time	Replicate	Titer ($Log_{10}TCID_{50}$/mL)	Volume (mL)	Volume Correction [a]	Viral Load ($Log_{10}TCID_{50}$)
Virus Stock Titer Control	N/A	N/A	6.93	-	-	-
Cell Viability Control			no virus was detected, cells remained viable; media was sterile			
Virus Recovery Control	2 minutes	Replicate 1	6.18	3	2	6.96
		Replicate 2	6.30	3	2	7.08
						7.02
3M Avagard™ 9250 Antiseptic Handrub[b]	30 seconds	Replicate 1	≤ 2.83 *	3	2	≤ 3.61
		Replicate 2	≤ 2.83 *	3	2	≤ 3.61
						≤ 3.61
	2 minutes	Replicate 1	≤ 2.83 *	3	2	≤ 3.61
		Replicate 2	≤ 2.83 *	3	2	≤ 3.61
						≤ 3.61

[a] Volume correction accounts for the neutralization of the sample post contact time.
[b] Cytotoxicity observed at the 10^{-1} dilution
* No virus was detected, the theoretical titer was determined based on the Poisson distribution

Table 2
Neutralizer Effectiveness/Viral Interference and Cytotoxicity Controls

Dilutions*	Neutralizer Effectiveness/Viral Interference Control	Cytotoxicity Control
10^{-1}	cytotoxicity observed	cytotoxicity observed
10^{-2}	virus detected in all inoculated wells	no cytotoxicity observed
10^{-3}	virus detected in all inoculated wells	no cytotoxicity observed

* Dilution refers to the fold of the diliuton from the neutralized sample

Table 3
Viral Reduction

Test Agent	Contact Time	Initial Load* ($Log_{10}TCID_{50}$)	Output Load* ($Log_{10}TCID_{50}$)	Log_{10} Reduction*	Percent Reduction*
3M Avagard™ 9250 Antiseptic Handrub	30 seconds	7.02	≤ 3.61	≥ 3.41	≥ 99.96
	2 minutes		≤ 3.61	≥ 3.41	≥ 99.96

* Results represent the average of two replicates.

CONCLUSIONS

3M Avagard™ 9250 Antiseptic Handrub was evaluated for the ability to inactivate Human Immunodeficiency Virus Type 1 (HIV-1). MicroBioTest personnel performed the inactivation procedure using HIV-1 virus to spike the test agent solution. Samples were titrated by 50% tissue culture infectious dose ($TCID_{50}$) endpoint assay using C8166 cells.

When tested as described, 3M Avagard™ 9250 Antiseptic Handrub (Lot No. 510110D1) inactivated HIV-1 by ≥3.41 log_{10} when the target virus was exposed to the test agent for 30 seconds and 2 minutes at 20C.

Table 3 reports the individual Log_{10} virus reduction factors for the test agent treatment procedure. All of the controls met the criteria for a valid test. These conclusions are based on observed data.

APPENDIX

MicroBioTest Protocol

VIRUCIDAL EFFICACY SUSPENSION TEST -

Human Immunodeficiency Virus Type 1 (HIV-1)

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

Prepared for
3M Health Care
3M Infection Prevention Division
3M Center, 270-4N-03
St. Paul, MN 55144

October 27, 2015

MicroBioTest Protocol: 109.12.10.27.15

MicroBioTest Project: 109-237

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OBJECTIVE:

This study is designed to measure virucidal effectiveness of a test product. If determines the potential of the test product to inactivate virus in suspension. The test follows the ASTM International test method designated E1052-11 "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension".

TESTING CONDITIONS:

The test products will be evaluated against the challenge virus in suspension. One test product, one lot, will be evaluated for inactivation of Human Immunodeficiency Virus Type 1 (HIV-1) at two exposure (contact) time points. Two replicates (N=2) will be performed for each condition. To minimize buffer interference and to minimize reduction of virucidal activity, the volume of virus inoculum added to test material will be kept to equal or less than 10% of the total volume of the test. Aliquots will be removed at the completion of the contact time from the test product/virus reaction mixture; neutralized (quenched); and inoculated onto appropriate host cell system. The inoculated host system will be incubated and read for presence of infectious virus.

MATERIALS:

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

The test product will be tested as supplied by the sponsor unless directed otherwise. All operations performed on the test product 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 product has been appropriately tested for identity, strength, purity, stability, and uniformity as applicable.

MicroBioTest will retain all unused test products for a period of one year upon 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):
   - **Human Immunodeficiency Virus Type 1 (HIV-1)**, strain: IIIB (B); ZeptoMetrix

2. Host: C8166 cells

3. Laboratory equipment and supplies.

4. Media and reagents:

   Media and reagents appropriate to the virus-host system will be used and documented in the data pack and project sheets.

TEST SYSTEM IDENTIFICATION:

All dilution tube racks, and host cell-containing apparatus will be labeled with virus identification and 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 procedures used in different phases of the study will be documented in the data pack.

The study flow diagram is summarized in Figure 1, with details described below.

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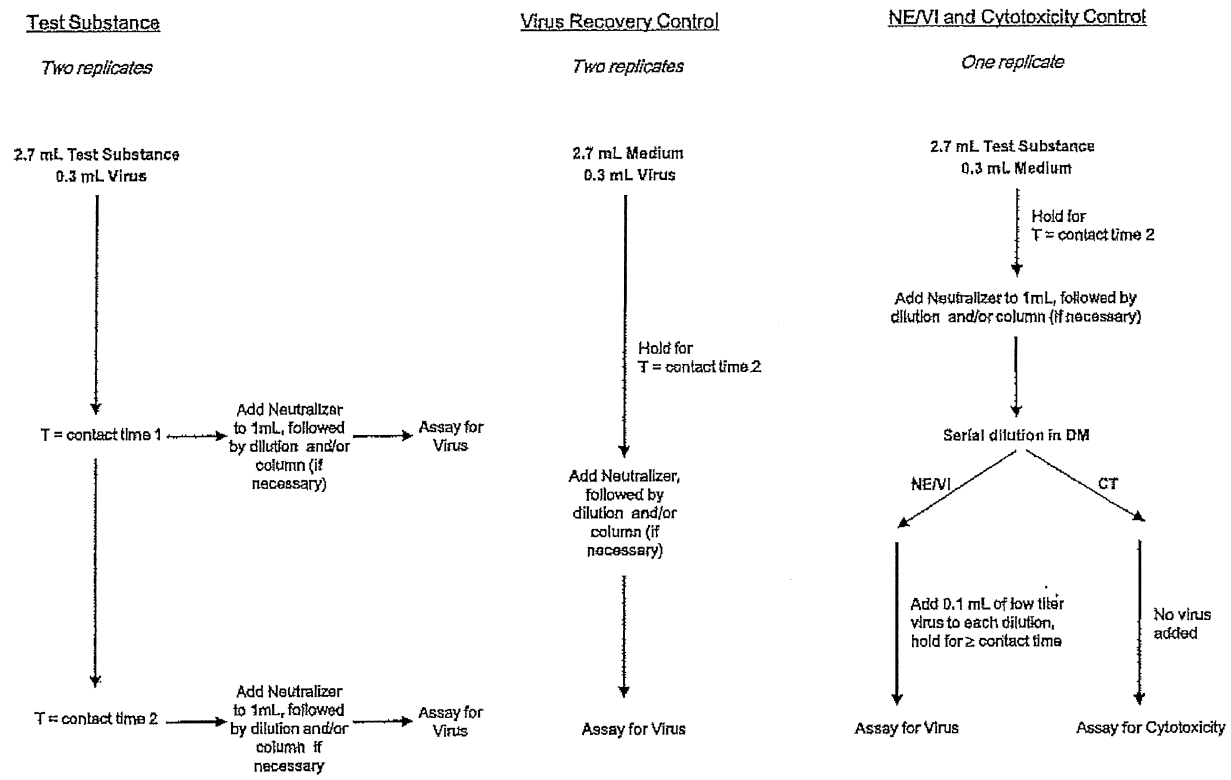
FIGURE 1

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



DM: Dilution Medium

NE/VI: Neutralizer Effectiveness/Viral Interference

CT: Cytotoxicity Control

Note: One test product, one lot, will be evaluated at one concentration and two contact times, in duplicate runs (N=2). The NE/VI and CT controls will be performed at N=1.

A. Inoculum preparation:

Viral stocks are purchased from reputable sources that identify them by scientifically accepted methods. 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.

B. Test product preparation:

The test product is a liquid. It will be tested at one concentration (See Miscellaneous Information page for details).

The prepared liquid test product should be pre-equilibrated to the test temperature as applicable.

C. Test

One test product, one lot, will be evaluated at one concentration and two contact times, in duplicate runs (N=2).

For each run, a 2.7-mL aliquot of the test product will be spiked with 0.3 mL of the virus suspension and mixed thoroughly by vortexing. Upon completion of each contact time, a 1.0-mL aliquot of the reaction mixture will be pulled and immediately mixed with an equal volume of neutralizer. The neutralized sample may be further quenched by dilution with dilution medium to remove cytotoxicity. The quenched sample will be serially tenfold diluted with dilution medium (DM) and selected dilutions will be inoculated onto host cells to assay for infectious virus.

If Sephacryl columns are used to further remove cytotoxicity, each sample will be loaded onto separate pre-spun columns. The eluates will be collected and serially ten-fold diluted. If columns are not used, serial tenfold dilutions of the neutralized virus-test product mixture will be directly conducted using an appropriate diluent medium.

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D. Controls:

All controls will be performed at the same time as the test, incubated under the same conditions and assayed in the same manner as the test (see above).

1. Virus recovery control:

This control will be performed in duplicate runs (N=2). A 2.7-mL aliquot of the medium will be spiked with 0.3 mL of virus suspension and thoroughly mixed by vortexing. After the contact time (the longest contact time point will be used for this control as a worst case), an aliquot of the reaction mixture will be mixed with an equal volume of neutralizer. The neutralized sample will be serially tenfold diluted with dilution medium and selected dilutions will be inoculated onto host cells to assay for infectious virus. The virus control results from this control will be used as the input viral load and compared with the test product treatment results to evaluate viral reduction by the test product.

2. Neutralizer effectiveness/viral interference control:

This control will determine if residual active ingredient is present after neutralization and if the neutralized test product interferes with virus infectivity. This control will be performed in a singlet run using the longer contact time as the worst case scenario.

A 2.7-mL aliquot of the test product will be mixed thoroughly with 0.3 mL of medium by vortexing, held for contact time (the longer contact time), and then neutralized by adding equal volume of neutralizer. The neutralized mixture will then be serially tenfold diluted using dilution medium. Each dilution will be divided into two portions, one for Neutralizer effectiveness/viral interference control, and the other for cytotoxicity control

For the Neutralizer effectiveness/viral interference control, 100 µL of a low titered (10^{-2} to 10^{-3}) virus stock will be added to 4.5 mL of selected dilutions of the solution and held for a period equivalent or greater than the longer contact time. The virus-spiked solution will be used to inoculate host cells as described for the test procedure.

3. Cytotoxicity control:

   This control will be performed in a singlet run using the longer contact time as the worst case scenario.

   Selected dilutions of the sample obtained from the Neutralizer effectiveness/viral interference control run will be inoculated onto host cells and incubated together with other test and control samples as described for the test procedure. The condition of the host cells will be recorded at the end of the incubation period. The cytotoxic effects should be distinct from virus-specific cytopathic effects, which will be evident in the stock titer and virus 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 CCM, then processed in the same manner as the test.

5. Cell viability control:

   At least four wells will be inoculated with an appropriate media during the incubation phase of the study. This control will demonstrate that cells remain viable throughout the course of the assay period. In addition, it will confirm the sterility of the media employed throughout the assay period.

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.

E. Infectivity assay:

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

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

F. Calculation:

The 50% tissue culture infective dose per mL ($TCID_{50}$/mL) will be determined using the method of Spearman-Karber (Kärber G. Arch. Exp. Pathol. Pharmakol, 1931,162:480-483) or other appropriate methods such as Reed and Muench (Am. J. of Hyg. 1938, 27:493). In the case where a sample contains no detectable virus, a statistical analysis may be performed based on Poisson distribution (International Conference On Harmonization, 1999, Topic Q5A:24-25) to determine the theoretical maximum possible titer for that sample. These analyses will be described in detail in the final report.

The test results will be reported as the reduction of the virus load by the test product expressed as **log_{10} and percent** reduction.

The Virus Load will be calculated in the following manner:
Virus Load (Log_{10} $TCID_{50}$) = Virus Titer (Log_{10} $TCID_{50}$/mL) + Log_{10} [Volume (mL)]

The Log_{10} Reduction Factor (LRF) will be calculated in the following manner:
Log_{10} Reduction Factor = Virus Recovery Control (Log_{10} $TCID_{50}$) – Test (Log_{10} $TCID_{50}$)

The percentage of virus inactivation was calculated in the following manner:
[1 - Output Viral Load/Initial Viral Load] x 100 = [1 - $10^{(-Log_{10}\ Reduction\ Factor)}$] x 100

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.

- Virus must be recovered from the neutralizer effectiveness/viral interference control (not exhibiting cytotoxicity).
- Viral-induced CPE must be distinguishable from test product induced toxicity.
- The cell viability control must remain viable throughout the course of the assay period and exhibit absence of virus.

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.

REPORT FORMAT:

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

- Sponsor identification
- Test product identification
- Type of assay and project number
- 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 product 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 product, 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 study 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 Sponsor prior to initiation of the study (please check off all applicable boxes):

A. Name and address: 3M Health Care
3M Infection Prevention Division
3M Center, 270-4N-03
St. Paul, MN 55144

B. Test product name: 3M Avagard 425 Antiseptic Hand Rub 62%
Active ingredient: chlorhexidine gluconate 0.45 ± 5% (w/v) Ethanol 68-72% (v/v)
Lot No.: 5/c//cD1

Exposure time #1: ☒ 30 seconds or ☐ _____
Exposure time #2: ☒ 2 minutes or ☐ _____

Exposure temperature: ☒ Room temperature (20±2C)

Dilution to be tested: ☒ Ready to use or ☐ _____

Diluent: ☒ Not applicable (Product is ready-to-use)
☐ Sterile deionized water
☐ Other _____

C. Precautions/storage conditions: refer to MSDS or certificate of analysis
☒ provided ☐ not provided

D. Organic Load in inoculum: ☒ Not applicable or ☐ _____

Continued on next page

F. H.

MISCELLANEOUS INFORMATION (Continued):

REPORT HANDLING:

The sponsor intends to submit the final report to: Customers

STUDY CONDUCT: ☒ GLP

PROTOCOL APPROVAL BY SPONSOR

Sponsor Signature: Fiona Hao Date: 2015.11.16

Printed Name: Fiona Hao

STIDY DIRECTOR APPROVAL (MicroBioTest):

Study Director Signature: Salimatu Lukula Date: 1/29/16

Printed Name: Salimatu Lukula

MicroBioTest, A Division of Microbac Laboratories, Inc. 105 Carpenter Dr., Sterling, Virginia 20164

Date Issued: 01/29/16 Project Sheet No. 1 Page No. 1 Laboratory Project Identification No. 109-237

STUDY TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST Human Immunodeficiency Virus Type 1 (HIV-1)	**STUDY DIRECTOR:** Salimatu Lukula M.S. Salimatu Lukula 1/29/16 Signature Date		
TEST MATERIAL(S): **3M Avagard™ 9250 Antiseptic Handrub**	**LOT NO.** 510110D1	**DATE RECEIVED:** 12/8/15	**DS NO.** F1071
PERFORMING DEPARTMENT(S): Virology and Molecular Biology	**STORAGE CONDITIONS:** Location: H4 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator ☐ Other:		

PROTECTIVE PRECAUTION REQUIRED: MSDS ■Yes / ☐ No

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

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

PROPOSED EXPERIMENTAL START DATE: 01/29/16 **TERMINATION DATE:** 02/12/16

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

SPONSOR: 3M Health Care 3M Infection Prevention Division 3M Center, 270-4N-03 St. Paul, MN 55144	**CONTACT PERSON: Fiona Hao** E-mail: fhao@mmm.com

TEST CONDITIONS:

Challenge organism:	Human Immunodeficiency Virus Type 1 (HIV-1) Strain: IIIB (B), Zeptometrix
Host cell line:	C8166 cells, University of Pennsylvania
Active ingredient(s):	Chlorhexidine Gluconate 0.45-0.55% (w/v) Ethanol 63.1-77% (v/v)
Organic load:	Not Applicable
Dilution medium:	Minimum Essential Medium (MEM) + 2% Fetal Bovine Serum (FBS)
Neutralizer:	MEM + 10% FBS + 1% Polysorbate 80 + 1% Tamol + 0.5% Lecithin
Dilution:	Ready to use
Contact time(s):	30 seconds and 2 minutes
Contact temperature:	Room Temperature (20±2°C)
Incubation time:	9 – 12 days
Incubation temperature:	36±2°C with 5±1% CO_2

Date Issued: 02/23/16 Project Sheet No. 2 Page No. 1 Laboratory Project Identification No. 109-237

STUDY TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST Human Immunodeficiency Virus Type 1 (HIV-1)	**STUDY DIRECTOR:** Salimatu Lukula M.S. Salimatu Lukula 2/25/16 Signature Date		
TEST MATERIAL(S): **3M Avagard™ 9250 Antiseptic Handrub**	**LOT NO.** 510110D1	**DATE RECEIVED:** 12/8/15	**DS NO.** F1071
PERFORMING DEPARTMENT(S): Virology and Molecular Biology	**STORAGE CONDITIONS:** Location: H4 ■ Dark ■ Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐ Refrigerator ☐ Other:		
CONDUCT OF STUDY: ☐ FDA ☐ EPA ☐ R&D ■ GLP ☐ GCP ☐ Other:			
SPONSOR: 3M Health Care 3M Infection Prevention Division 222 Tian Lin Road, Shanghai 200233 | China	**CONTACT PERSON: Fiona Hao** E-mail: fhao@mmm.com		

PROTOCOL AMENDMENTS:

1. Protocol page 7 states that the Column Titer Control will be sampled from the PRC and diluted in CCM. The correct statement is that the Column Titer Control came from the VRC and was diluted in DM. This amendment serves to correct the typographical errors on page 7 of the protocol.

2. Project Sheet No.1 and Protocol states the Sponsor address as 3M Center, 270-4N-03, St. Paul, MN 55144. The correct Sponsor address is 222 Tian Lin Road, Shanghai 200233, China. This amendment serves to correct the sponsor address in Project sheet No.1 and Protocol.