MICROBAC

FINAL REPORT

VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-associated Coronavirus (SARS-CoV)

Test Substance
Nanocomposite Material (JM-TTA01)

Lot Number
N/A

Test Organism
SARS-associated Coronavirus, Strain: CDC 200300592, source: ZeptoMetrix/CDC

Author
Cameron Wilde

Study Completion Date
05/06/2020

Performing Laboratory
Microbac Laboratories, Inc.
105 Carpenter Drive
Sterling, VA 20164, USA

Laboratory Project Identification Number
852-103

Protocol Identification Number
852.1a.03.16.20

Sponsor
JM Material Technology Inc.
O. 5F.-3, No. 40-2, Sec. 1, Minsheng N. Rd.
Guishan Township, Taoyuan County 333
Taiwan (R.O.C.)

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GOOD LABORATORY PRACTICE 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 article resides with the sponsor of the study.

The following technical personnel participated in this study:

Cameron Wilde, David Rieth

Study Director:

Cameron Wilde — Date: 05/06/2020

QUALITY ASSURANCE UNIT STATEMENT

The Quality Assurance Unit of Microbac has inspected Project Number 852-103 to be 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	04/07/20 04/08/20	04/09/20	04/09/20
In Process (Test)	04/07/20	04/09/20	04/09/20
Final Report	04/29/20	05/01/20	05/01/20

Jeanne M. Anderegg, RQAP-GLP
Quality Assurance Manager

05-06-2020
Date

TEST SUMMARY

TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST - SARS-associated Coronavirus (SARS-CoV)

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

TEST METHOD: ASTM E1052-11: Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension

TEST MATERIAL: Nanocomposite Material (JM-TTA01), Lot No. Not applicable, received at Microbac on 03/30/20 and assigned DS No. K327.

SPONSOR: JM Material Technology Inc.
O. 5F.-3, No. 40-2, Sec. 1, Minsheng N. Rd.
Guishan Township, Taoyuan County 333
Taiwan (R.O.C.)

TEST CONDITIONS

Challenge virus:

SARS-associated Coronavirus (SARS-CoV), Strain: CDC 200300592, source: ZeptoMetrix/CDC

Host:

Vero E6 cells, ATCC CRL-1586

Organic Load:

5.0% serum in virus inoculum

Active ingredient(s):

TiO_2, Silver

Preparation of test substance:

The test substance was ready to use.

Neutralizer(s):

Minimum Essential Medium (MEM) + 10% Fetal Bovine Serum (FBS) + 0.5% Lecithin + 1 mM EDTA + 0.01 N NaOH

Contact time:

20 minutes

Contact temperature and relative humidity (RH):

20±2°C (actual: 20°C)

Dilution medium:

MEM + 2% FBS

Test substance dilution tested:

Ready to use

Test substance diluent:

Not applicable

TEST CONDITIONS

Incubation time:

4 – 9 days (actual: 7 days)

Incubation temperature:

36 ± 2°C with 5 ± 3% CO_2

Preparation of virus inoculum:

Frozen viral stock was thawed on the day of the test. Stock virus contained an organic load of 5.0%

Test substance application:

0.3 mL of virus stock was added to 2.7 mL of test substance. A UV-A lamp (365 nm, 115 volts, 15 Watt) was held at a distance of 35 cm for the duration of the contact time.

Media and reagents:

MEM + 2% FBS
MEM + 10% FBS + 0.5% Lecithin + 1 mM EDTA + 0.01 N NaOH

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, VA 20164, from 04/07/20 – 04/24/20. The study director signed the protocol on 04/06/20. The study completion date is the date the study director signed the final report. The individual test dates are as follows:

- Testing on 04/07/20 was invalidated due to contamination
- Testing started at 3:40 pm on 04/17/20 and ended at 10:10 am on 04/24/20

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 substance records, the final report, and correspondence between Microbac and the sponsor will be stored in the archives at Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, VA 20164, or at a controlled facility off site.

TEST PROCEDURES

Indicator Cells:

Vero E6 cells were obtained from ATCC and maintained in cell culture at 36 ± 2°C with 5 ± 3% CO_2 prior to seeding. The indicator cell plates were prepared 12 – 30 hours prior to inoculation with test sample. The cells were seeded in 24-well plates at a density of 1.5 x 10^5 cells/mL at 1.0 mL per well.

Inoculum preparation:

The stock virus was prepared by infection of Vero E6 cells. The cultures were frozen at 60 to -90°C several days after infection. After freezing and thawing, cell-free stocks were prepared by centrifugation. The stock virus was then aliquoted and stored at -60°C or below until used in testing.

Challenge Virus:

Virus was not diluted prior to use in testing. The stock virus contained 5.0% serum.

Virus Suspension Test

A 0.3 mL aliquot of virus was transferred to a vial containing 2.7 mL of test substance. A UV-A lamp (365 nm, 115 volts, 15 Watt) was turned on a held at a distance of 35 cm for the duration of the contact time. Immediately after the contact exposure, the test virus/product suspension was neutralized with 3 mL of neutralizer, mixed thoroughly, and serially diluted in Dilution Medium (DM). Each dilution was plated in four replicates.

Virus Recovery Control

One replicate of the Virus Control were performed. A 0.3 mL aliquot of the test virus was added to 2.7 mL of DM. No UV-A lamp was used. The mixture was held for the contact time at test temperature. Immediately after the contact exposure, the test virus/product suspension was neutralized with 3 mL of neutralizer, mixed thoroughly, and serially diluted in Dilution Medium (DM). Each dilution was plated in four replicates.

TEST PROCEDURES

Neutralization Effectiveness/Viral Interference Control

A 0.3 mL aliquot of DM was added to a vial containing 2.7 mL of test substance. A UV-A lamp (365 nm, 115 volts, 15 Watt) was turned on a held at a distance of 35 cm for the duration of the contact time. Immediately after the contact exposure, the test virus/product suspension was neutralized with 3 mL of neutralizer, mixed thoroughly, and serially diluted in Dilution Medium (DM). Subsequent dilutions of this mixture were made in DM. An aliquot of the virus was added to each dilution and thoroughly mixed. Each dilution was plated in four replicates.

Cytotoxicity Control

A 0.3 mL aliquot of DM was added to a vial containing 2.7 mL of test substance. A UV-A lamp (365 nm, 115 volts, 15 Watt) was turned on a held at a distance of 35 cm for the duration of the contact time. Immediately after the contact exposure, the test virus/product suspension was neutralized with 3 mL of neutralizer, mixed thoroughly, and serially diluted in Dilution Medium (DM). Each dilution was plated in four replicates.

Cell Viability/Media Sterility Control

This control demonstrated that the cells remained viable throughout the course of the assay period. In addition, it confirmed the sterility of the DM employed throughout the assay period. Four wells of cells received only DM and were incubated and processed with the other test and controls.

Virus Stock Titer Control:

An aliquot of the virus stock used in the study was directly serially ten-fold diluted and inoculated onto host cells at four replicate wells per dilution to confirm the titer of the stock virus. This control demonstrated that the titer of the stock virus was appropriate for use and that the viral infectivity assay was performed appropriately.

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 cytopathic effects (CPE) must be distinguishable from test substance induced toxicity.
- The cell viability control must remain viable throughout the course of the assay period and exhibit absence of virus.

CALCULATIONS

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 of 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)

The values were converted to $TCID_{50}$/mL using a sample inoculum of 1.0 mL.

CALCULATIONS

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. 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 n 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] (e.g., neutralization)

Note: The volume (mL) of the Undiluted (10^0) sample was used in the above equation.

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

LRF = Initial Viral Load (Log_{10} $TCID_{50}$) – Output Viral Load (Log_{10} $TCID_{50}$)

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	7.50	-	-	-
Cell Viability Control			no virus was detected, cells remained viable; media was sterile			
Virus Recovery Control	20 minutes	Rep 1	6.50	3	2	7.28
Nanocomposite Material (JM-TTA01)	20 minutes	Rep 1	≤ 2.83 *	3	2	≤ 3.61

[a] Volume correction accounts for the neutralization of the sample post contact time.
[b] Cytotoxicity observed at 10^{-1} and 10^{-2} dilution
* No virus was detected; the theoretical titer was determined based on the Poisson method.

RESULTS (continued)

Table 2
Neutralizer Effectiveness/Viral Interference (NE/VI) and Cytotoxicity (CT) Controls

Dilution*	NE/VI	CT
10^{-1}	Cytotoxicity observed in all inoculated wells	Cytotoxicity observed in all inoculated wells
10^{-2}	Cytotoxicity observed in all inoculated wells	Cytotoxicity observed in all inoculated wells
10^{-3}	virus detected in all inoculated wells	no virus detected in all inoculated wells

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

Table 3
Viral Reduction

Test Substance	Contact Time	Replicate	Initial Load ($Log_{10}TCID_{50}$)*	Output Load ($Log_{10}TCID_{50}$)	Log_{10} Reduction
Nanocomposite Material (JM-TTA01)	20 minutes	Rep 1	7.28	≤ 3.61	≥ 3.67

CONCLUSIONS

When tested as described, Nanocomposite Material (JM-TTA01) was evaluated for its ability to inactivate SARS-associated Coronavirus. The results are presented in Tables 1 – 3.

All of the controls met the criteria for a valid test. These conclusions are based on observed data.

APPENDIX I

MICROBAC®

Microbac Protocol

VIRUCIDAL EFFICACY SUSPENSION TEST -

SARS-associated Coronavirus (SARS-CoV)

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

Prepared for
JM Material Technology Inc.
O. 5F.-3, No.40-2, Sec. 1, Minsheng N. Rd.
Guishan Township, Taoyuan County 333
Taiwan (R.O.C.)

March 18, 2020

Microbac Protocol: 852.1a.03.16.20

Microbac Project: 852-103

Microbac Laboratories, Inc.
105 Carpenter Drive | Sterling, VA 20164 | 703.925.0100 p | 703.925.9366 f | www.microbac.com

OBJECTIVE:

This study is designed to measure the virucidal effectiveness of a liquid test substance. It determines the potential of the test substance to inactivate the target virus – SARS-associated Coronavirus (SARS-CoV) - in suspension. The test follows the ASTM International test method designated E1052 "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension".

TESTING CONDITIONS:

One test substance, one batch (lot), will be tested. The test substance will be challenged with SARS-CoV in suspension at ambient temperature and held for the stipulated contact time. One contact time will be tested at one replicate (N=1). Note: During the contact time, a UV-A lamp will be turned on to irradiate the appropriate test and control samples.

For each run, the volume of virus inoculum added to test substance will be kept at 10% of the total volume of the test in order to minimize buffer interference and to minimize reduction of virucidal activity. Upon completion of the contact time, an aliquot or the entirety of the test substance-virus reaction mixture will be neutralized with an equal volume of neutralizer, passed through a Sephacryl column if required, and then serially diluted in a dilution medium and inoculated onto an appropriate host cell system. The inoculated host system will be incubated and scored 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 substance will be tested as supplied by the sponsor unless directed otherwise. All operations performed on the test substance such as dilution or specialized storage conditions must be specified by the sponsor before initiation of testing.

The sponsor assures Microbac testing facility management that the test substance has been appropriately tested for identity, strength, purity, stability, and uniformity as applicable.

Upon the completion of the test, Microbac will return all unused test substances per the Sponsor's instructions unless otherwise directed by the Sponsor.

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

1. Challenge virus (requested by the sponsor of the study): SARS-associated Coronavirus, Strain: CDC 200300592, Source: ZeptoMetrix / United States Center for Disease Control and Prevention (CDC)

2. Host cell line: Vero E6 cells, source: ATCC CRL-1586

3. Laboratory equipment and supplies, including but not limited to:

   a. UV-A Lamp – 365 nm wavelength, 115 volts, 15 Watt

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.

C. Materials supplied by the Sponsor (see "Miscellaneous Information" section):

1. Test substance – 1 liquid solution, 1 lot

TEST SYSTEM IDENTIFICATION:

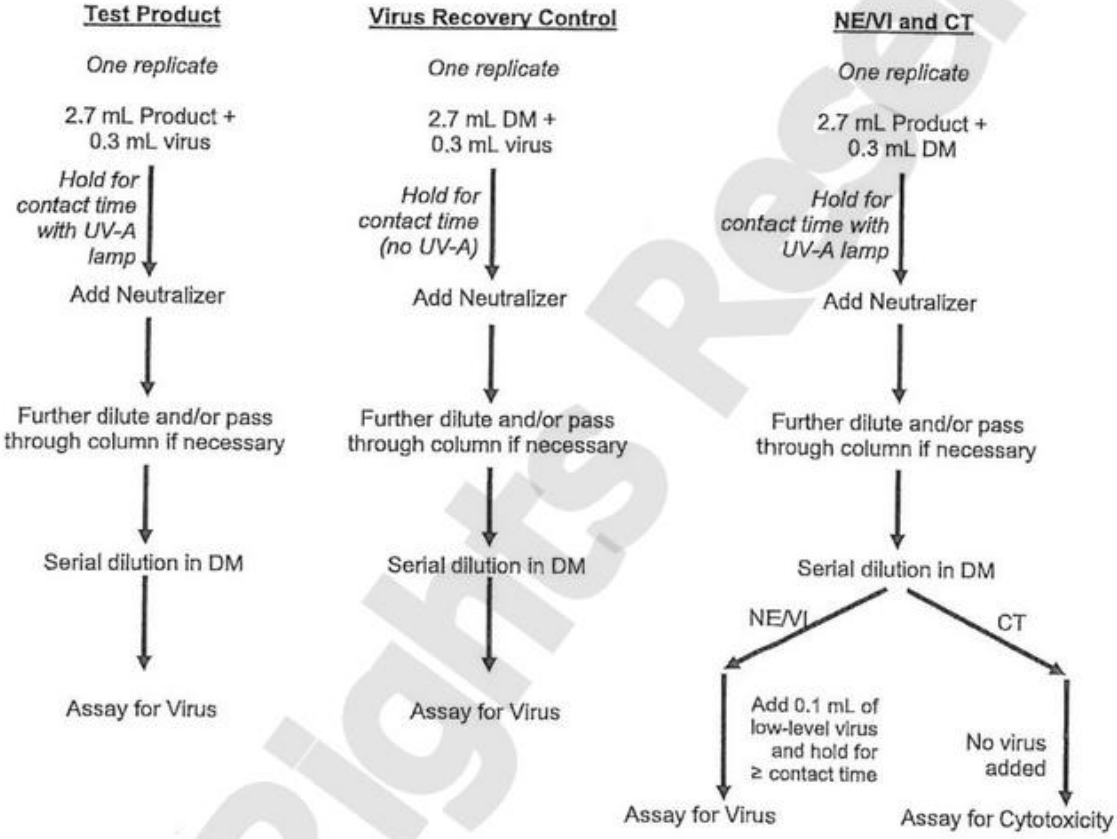
All dilution tube racks, and host cell-containing apparatus will be labeled with virus identification and project number.

EXPERIMENTAL DESIGN:

All the procedures involved in performance of this study are described in a detailed series of SOPs that are maintained at Microbac. 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.

FIGURE 1

Title: VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-CoV



DM: *Dilution Medium*
NE/VI: *Neutralizer Effectiveness/Viral Interference*
CT: *Cytotoxicity Control*

Note: One test product will be tested, at one contact time and one replicate (N=1). The NE/VI and CT controls will be performed for the test product at one contact time and one replicate.

A. Inoculum preparation:

Viral stocks are purchased from reputable sources that identify them by scientifically accepted methods and are propagated at Microbac. 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). The challenge virus stock will contain 5.0% serum.

B. Test substance preparation:

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

The test substance(s) will be prepared exactly according to the sponsor's directions (if provided). If the sponsor requests dilution of the test substance, the diluted test substance will be used for testing within three hours of preparation. The test substance will be pre-equilibrated to the test temperature prior to use in the study as applicable.

C. Test

One test substance will be evaluated at one contact time at one replicate (N=1).

For each run, an aliquot of 0.3 mL virus stock will be added to 2.7 mL of the product test solution (post dilution, if applicable) and mixed by vortexing. A stopwatch will be started immediately to monitor the contact time. A UV-A lamp will be turned on and held at a distance of 35 cm to irradiate the samples during the contact time. No stirring is required.

Upon completion of the contact time, an aliquot or the entirety of the reaction mixture will be pulled and immediately mixed with an equal volume of a neutralizer medium and then vortexed. The "post-neutralized sample" (PNS) is considered undiluted (10^0).

Selected dilutions will be inoculated onto the host cells to assay for the quantity of infectious virus units, as described in the "Infectivity Assay" section. If Sephacryl

columns are used to aid in the neutralization and to further reduce the cytotoxicity, each inoculum/test substance/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 substance/neutralizer mixture will directly be prepared in DM.

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.

1. Virus recovery control (VRC):

   This control will be performed at one replicate (N=1) at one contact time, concurrently with the test substance runs. No UV-A lamp will be used for this control.

   A 2.7-mL aliquot of DM will be spiked with 0.3 mL of virus and mixed by vortexing. A stopwatch will be started immediately after virus addition to monitor the contact time.

   Upon completion of the contact time, an aliquot or the entirety of the reaction mixture will be immediately mixed with an equal volume of a neutralizer medium via vortexing. This "post-neutralized sample" (PNS) is considered undiluted (10^0).

   Selected dilutions will be inoculated onto the host cells to assay for the quantity of infectious virus, as described in the "Infectivity Assay" section.

   The results from this control will be used as the input viral load and compared with the test substance results to evaluate the viral reduction by the test substance.

2. Neutralizer effectiveness/viral interference (NE/VI) control:

   This control will determine if residual active ingredient is present after neutralization and if the neutralized test substance interferes with virus infectivity. This control will be performed at one replicate.

A 2.7-mL aliquot of the test substance will be spiked with 0.3 mL of DM (in lieu of virus), mixed by vortexing and held for the contact time (the longer of the two). A UV-A lamp will be turned on and held at a distance of 35 cm to irradiate the samples during the contact time. No stirring is required.

Upon completion of the contact time, an aliquot or the entirety of the reaction mixture will be immediately mixed with an equal volume of a neutralizer medium via vortexing. This "post-neutralized sample" (PNS) is considered undiluted (10^0). The PNS 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, each portion will be directly diluted using serial ten-fold dilutions in DM.

Following the serial dilutions of the sample, for the NE/VI control, 100 µL of a low titered virus (containing no more than approximately 5,000 units of virus) will be added to 4.5 mL of each dilution and held for a period of no shorter than the contact time. Then these selected dilutions will be inoculated onto the host cells as described for the test procedure.

3. Cytotoxicity control (CT):

   This control will be performed at one replicate.

   Selected dilutions of the sample obtained from the NE/VI control test setup 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. It will be performed in singlet runs.

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:

   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 stock as 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 substance (or DM) 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±2°C in 5±3% CO_2 for 4 – 9 days. The host cells may be washed twice with phosphate buffered saline prior to inoculation. The host cell cultures will be observed and refed, as necessary, during the incubation period. The host cells will be examined for presence of infectious virus following the completion of the incubation period. The resulting virus-specific CPE and test-article specific cytotoxic effects, if present, will be scored by examining both test and controls. If necessary, virus will be detected via staining with virus-specific antibody. 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 titer due to treatment with test substance expressed as log_{10}.

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) x Volume correction (e.g., neutralization)]

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} $TCID_{50}$)

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 substance 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 Microbac Laboratories, Inc., 105 Carpenter Drive, Sterling, Virginia 20164.

REPORT FORMAT:

A standard report format will be used for this test design. Each final report will provide at least the following information:

- Sponsor identification
- Test substance identification
- Type of assay and project number
- Study start and end time (clock time)
- 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)
- Certificate of Analysis (for GLP studies only; if provided by the Sponsor)

RECORDS TO BE MAINTAINED:

For all GLP studies, the original signed final report will be sent to the Sponsor.

All raw data, protocol, protocol modifications, test substance records, final report, and correspondence between Microbac and the sponsor will be stored in the archives at Microbac Laboratories, Inc., 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 substance, 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 the sponsor prior to initiation of the study (please check all applicable open boxes):

A. Name & address: JM Material Technology Inc.
O. 5F.-3, No.40-2, Sec. 1, Minsheng N. Rd.
Guishan Township, Taoyuan County 333
Taiwan (R.O.C.)

B. Test substance information:

Test substance name	Nanocomposite Material (JM-TTA01)
Batch (Lot) No.	
Manufacture Date	2020/03/13
Expiration Date	2021/03/12
Active ingredient(s)	TiO_2, Silver
Dilution	☑ Ready to use □ _____ (_____ parts test substance + _____ parts diluent)
Diluent	☑ Not applicable □ _____ ppm ±2.9% AOAC hard water □ Other: _____
Contact Temperature	■ Ambient Room Temperature (20±2°C)
Contact Time	20 min
Organic Load	■ 5.0% serum in virus inoculum

C. □ UV-A Lamp instructions: The UV-A lamp (365 nm, 115 volts, 15 Watt) will be held at a distance of 35 cm for the duration of the contact time for the appropriate samples.

D. **REPORT HANDLING:**

The Sponsor intends to submit this information to: _____

E. **TEST CONDUCT:** GLP

PROTOCOL APPROVAL BY SPONSOR:

Sponsor Signature: Mandy Lu Date: Mar 20, 2020

Printed Name: MANDY LU

STIDY DIRECTOR (Microbac) APPROVAL:

Study Director Signature: Cameron Wilde Date: 04/06/2020

Printed Name: Cameron Wilde

Microbac Laboratories, Inc. 105 Carpenter Dr., Sterling, Virginia 20164

Date Issued: 04/07/20 Project Sheet No. 1 Page No. 1 Laboratory Project Identification No. 852-103			
STUDY TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-associated Coronavirus (SARS-CoV)	**STUDY DIRECTOR:** Cameron J. Wilde Signature 04/07/2020 Date		
TEST MATERIAL(S): Nanocomposite Material (JM-TTA01)	**BATCH (LOT)** N/A	**DATE RECEIVED:** 03/30/20	**DS NO.** K327
PERFORMING DEPARTMENT(S): Virology and Toxicology	**STORAGE CONDITIONS:** Location: F5 ■ 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: 04/07/20 **TERMINATION DATE:** 04/16/20			
CONDUCT OF STUDY: ☐ FDA ☐ EPA ☐R&D ■ GLP ☐ GCP ☐ Other:			
SPONSOR: JM Material Technology Inc. O. 5F.-3, No.40-2, Sec. 1, Minsheng N. Rd. Guishan Township. Taoyuan County 333 Taiwan (R.O.C)	**CONTACT PERSON:** Alex Tsu alex@jm-tech.com.tw		

TEST CONDITIONS:

Challenge organism	SARS-CoV, strain: CDC 200300592, Souce: ZeptoMetrix / United States Center for Disease Control and Prevention (CDC)
Host cell line:	Vero E6 cells, ATCC CRL-1586
Organic load:	5.0% serum in viral inoculum
Dilution medium:	Minimum Essential Medium (MEM) + 2% Fetal Bovine Serum (FBS)
Active ingredient(s):	TiO_2, Silver
Neutralizer:	MEM + 10% FBS + 0.5% Lecithin + 1 mM EDTA + 0.01 N NaOH
Dilution:	Ready to use
Contact time(s):	20 minutes
Contact temperature:	Ambient Room Temperature (20±2°C)
Incubation time:	4 – 9 days
Incubation temperature:	36±2°C with 5±3% CO_2
Note:	A UV-A lamp (365 nm, 115 volts, 15 Watt) will be held at a distance of 35 cm for the duration of the contact time for the appropriate test and control samples).

Date Issued: 04/07/20 Project Sheet No. 1 Page No. 2 Laboratory Project Identification No. 852-103

STUDY TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-associated Coronavirus (SARS-CoV)	**STUDY DIRECTOR:** Cameron J. Wilde Signature 04/07/2020 Date		
TEST MATERIAL(S): Nanocomposite Material (JM-TTA01)	**BATCH (LOT)** N/A	**DATE RECEIVED:** 03/30/20	**DS NO.** K327
PERFORMING DEPARTMENT(S): Virology and Toxicology	**STORAGE CONDITIONS:** Location: F5 ■ Dark ■Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐Refrigerator ☐ Other:		
CONDUCT OF STUDY: ☐ FDA ☐ EPA ☐R&D ■ GLP ☐ GCP ☐ Other:			
SPONSOR: JM Material Technology Inc. O. 5F.-3, No.40-2, Sec. 1, Minsheng N. Rd. Guishan Township. Taoyuan County 333 Taiwan (R.O.C)	**CONTACT PERSON:** Alex Tsu alex@jm-tech.com.tw		

PROTOCOL AMENDMENT(S):

1. Protocol Page 11, Section B: The "Batch (Lot) No." is not filled in. It should state "Not applicable". This amendment serves to clarify the Protocol.

2. Protocol page 11, Section C: The "☐" box is not checked. It should be checked "☑". This amendment serves to clarify the Protocol.

3. Protocol page 12, Section D: The area for submission is left blank. It should state "None". This amendment serves to clarify the Protocol.

Microbac Laboratories, Inc. 105 Carpenter Dr., Sterling, Virginia 20164

Date Issued: 05/01/20 Project Sheet No. 2 Page No. 1 Laboratory Project Identification No. 852-103			
STUDY TITLE: VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-associated Coronavirus (SARS-CoV)	**STUDY DIRECTOR:** Cameron J. Wilde Signature 05/04/2020 Date		
TEST MATERIAL(S): Nanocomposite Material (JM-TTA01)	**BATCH (LOT)** N/A	**DATE RECEIVED:** 03/30/20	**DS NO.** K327
PERFORMING DEPARTMENT(S): Virology and Toxicology	**STORAGE CONDITIONS:** Location: F5 ■ Dark ■Ambient Room Temperature ☐ Desiccator ☐ Freezer ☐Refrigerator ☐ Other:		
CONDUCT OF STUDY: ☐ FDA ☐ EPA ☐R&D ■ GLP ☐ GCP ☐ Other:			
SPONSOR: JM Material Technology Inc. O. 5F.-3, No.40-2, Sec. 1, Minsheng N. Rd. Guishan Township. Taoyuan County 333 Taiwan (R.O.C)	**CONTACT PERSON:** Alex Tsu alex@jm-tech.com.tw		

PROTOCOL AMENDMENT(S):

4. Protocol Page 8, Section D4: The control states "The sample for this control will be acquired from a portion of the PRC…". It should state "The sample for this control will be acquired from a portion of the VRC…". This amendment serves to correct the typographical error in the Protocol.