MICROBAC®

FINAL REPORT

VIRUCIDAL EFFICACY SUSPENSION TEST – SARS-associated Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus), UK Variant (B.1.1.7)

Test Substance
Nanocomposite Material (JM-TTA01)

Lot Number
N/A

Test Organism
SARS-associated Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus), UK Variant (B.1.1.7)

Author
Cameron Wilde

Study Completion Date
09/07/21

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

Laboratory Project Identification Number
852-104

Protocol Identification Number
852.V.21.001

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.)

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	6.80	-	-	-
Cell Viability Control			no virus was detected, cells remained viable; media was sterile			
Virus Recovery Control	20 minutes	Rep 1	5.93	3	2	6.71
Nanocomposite Material (JM-TTA01)	20 minutes	Rep 1	≤ 2.80 *	3	2	≤ 3.58

[a] Volume correction accounts for the neutralization of the sample post contact time.
* No virus was detected; the theoretical titer was determined based on the Spearman-Karber formula

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

Dilution*	Nanocomposite Material (JM-TTA01)	
	NE/VI	CT
10^{-1}	Cytotoxicity observed in all inoculated wells	Cytotoxicity observed in all inoculated wells
10^{-2}	virus detected in all inoculated wells	no virus detected 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.

RESULTS

Table 3
Reduction Factors

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	6.71	≤ 3.58	≥ 3.13

Note: "≥" refers to a complete inactivation of virus

CONCLUSIONS

When tested as described, Nanocomposite Material (JM-TTA01) was evaluated for its ability to inactivate SARS-associated Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus), UK Variant (B.1.1.7). 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.

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-CoV-2 UK Variant, hCoV-19/England/204820464/2020 (UK/VUI/3/2020), Lineage B.1.1.7, source: BEI Resources NR-54000

2. Host cell lines: Vero E6 cells, 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.