FINAL REPORT

VIRUCIDAL SUSPENSION EFFICACY TEST
Influenza A Virus (H1N1)

TEST AGENT
Nanocomposite Material

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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 (LRF) was calculated in the following manner:

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

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

Table 1
Titer Results

Sample	Titer ($Log_{10}TCID_{50}$/mL)	Volume (mL)	Volume Correction[a]	Viral Load ($Log_{10}TCID_{50}$)
Cell viability/media sterility control	no virus detected, cells viable; media sterile			
Virus Stock Titer Control	6.50	-		-
Theoretical viral load per run**	-	-		5.98
Virus Recovery Control (with UV-A)[b]	5.00	3	2	5.78
Virus Recovery Control (without UV-A) [b]	5.75	3	2	6.53
Column Titer Control (with UV-A)	5.25	3	2	6.03
Column Titer Control (without UV-A)	5.75	3	2	6.53
Nanocomposite Materal (with UV-A) [b]	≤ 0.83 *	3	2	≤ 1.61

* No virus was detected. The titer was determined based on the Poisson distribution.
** The theoretical viral load was calculated based on the titer of the stock virus and the volume (0.3 mL) added into each reaction mixture.
[a] Volume correction accounts for the neutralization of the sample post contact time.
[b] Sample was processed by Sephacryl column.

RESULTS (continued)

Table 2
Neutralizer Effectiveness/Viral Interference and Cytotoxicity Controls

Dilution of the Neutralized Sample	Neutralizer Effectiveness/Viral Interference Control (with UV-A) [a]	Cytotoxicity with Control (with UV-A) [a]
10^-1	virus detected in 4 out of 4 wells	no cytotoxicity observed
10^-2	virus detected in 4 out of 4 wells	no cytotoxicity observed
10^-3	virus detected in 4 out of 4 wells	no cytotoxicity observed

[a] Sample was processed by Sephacryl column.

Table 3
Reduction Factor

Test Agent	Contact Time	Initial Viral Load ($Log_{10}TCID_{50}$)	Output Viral Load ($Log_{10}TCID_{50}$)	Log_{10} Reduction	Percent Reduction (%)
Nanocomposite Material	20 minutes	5.78	≤ 1.61	≥ 4.17	≥ 99.99

CONCLUSIONS

MicroBioTest personnel performed the inactivation procedure using Influenza A Virus (H1N1) (A/California/04/09) to spike the test agent solution. Samples were taken and titrated by 50% tissue culture infectious dose ($TCID_{50}$) endpoint assay using MDCK cells.

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