

Vol. _____

FINAL REPORT

**Virucidal Effectiveness Test
Avian Influenza virus
Using unglazed, clay tiles**

**Test Agent System:
Dry Steam Vapor System, 2400 Series,
TANCS® Equipped**

Data Requirements

EPA Guidelines 810.2100 (g)

Author

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Study Completion Date

pending

Performing Laboratory

MICROBIOTEST

105 Carpenter Drive

Sterling, Virginia 20164

Laboratory Project Identification Number

567-106

**Submitted to: Advanced Vapor Technologies, LLC
7719 230th Street, SW
Edmonds , WA 98026**

STATEMENT OF NO DATA CONFIDENTIALITY

TITLE: Virucidal Effectiveness Test – Avian Influenza virus - Using unglazed, clay tiles

PERFORMED BY: MICROBIOTEST
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 § 10(d)(1)(A), (B) or (C).

Company Agent _____

_____ Date

COMPLIANCE STATEMENT

This study meets the requirements for 40 CFR § 160 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:

Lauren A. Blaszak, Tracey J. Kelly

Study Director: MICROBIOTEST

Lauren A. Blaszak Date

Submitted by: _____
Name Title

Signature Date

Sponsor: ADVANCED VAPOR TECHNOLOGIES, LLC

Name Title

Signature Date

QUALITY ASSURANCE UNIT STATEMENT

Title of Study: Virucidal Effectiveness Test - Avian Influenza Virus - Using unglazed, clay tiles

The Quality Assurance Unit of MICROBIOTEST has inspected the Project Number 567-106 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.

<u>PHASE INSPECTED</u>	<u>DATE OF INSPECTION</u>	<u>DATE REPORTED TO STUDY DIRECTOR</u>	<u>DATE REPORTED TO MANAGEMENT</u>
Protocol	11/29/06	12/15/06	12/29/06
In Process	11/29/06 12/04/06	11/29/06 12/04/06	12/29/06
Final Report	12/15/06	12/15/06	12/29/06

Nathan S. Jones, RQAP–GLP
Manager, Quality Assurance Unit

Date

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TEST SUMMARY

TITLE: Virucidal Effectiveness Test - Avian Influenza Virus - Using unglazed, clay tiles

STUDY DESIGN: This study was performed according to the signed protocol and project sheets issued by the Study Director.

See Project Sheets (Appendix I)
See signed protocol (Appendix II)

TEST MATERIALS SUPPLIED BY THE SPONSOR OF THE STUDY:

Dry Steam Vapor System, 2400 Series, TANCS® equipped, Serial No. 5505053936, received at MICROBIOTEST 09/28/06, and assigned DS No. 8432.

Note: The Dry Steam Vapor System equipment was operated by a representative of the sponsor.

Note: the 6cm x 6cm x 1.2cm tiles were received by the sponsor on 11/16/06.

SPONSOR: Advanced Vapor Technologies, LLC
7719 230th Street, SW
Edmonds, WA 98026

TEST CONDITIONS

Challenge virus:

Avian Influenza virus, (H9N2), Turkey/Wis/66; SPAFAS

Host:

Embryonated chicken eggs; BE eggs

Organic load:

Viral stock contained $\geq 5\%$ organic load

Active ingredient in test product:

Dry steam vapor generated from tap water

Contact time:

The Dry Steam Vapor System was operated by a representative of the sponsor to treat the test tiles for a contact time of 7 seconds. The nozzle brush was held over the tile and gently moved in a back and forth motion.

Contact temperature:

Ambient temperature (22C)

Dilution:

Ready to use

Tile Inoculation:

A marked 4 × 4 centimeter area of the smooth surface of unglazed clay test tiles (approximately 6 × 6 × 1.2 centimeters) was inoculated with 0.2mL viral stock and dried for 20 minutes at 22C.

Media and reagents:

Earle's balanced salt solution

Phosphate buffered saline

Chicken red blood cells

Tap water

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164, from 11/29/06 to 12/05/06. The study director signed the protocol 11/29/06. 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.

RESULTS

Results are presented in Tables 1 – 4. The 50% embryo infectious/lethal dose per mL (EID/ELD₅₀/mL) was determined from the test and relevant control data using the method of Reed and Muench, Am. J. of Hyg. 1938, 27:493. The host viability control demonstrated host viability and media sterility. Virus was not detected in the host viability control. All controls including toxicity, and recovery titer met the criteria required for a valid test. Infectious virus was not detected in the host system after exposure to the test agent as described.

The log₁₀ reduction (LR) was calculated in the following manner:

Log₁₀ reduction = Infectious virus titer recovered from tile recovery control - Infectious virus titer recovered from test.

RESULTS (continued)

Table 1
 Test Results

Dilution	Dry Steam Vapor System, 2400 Series, TANCS® equipped	
	TILE 1	TILE 2
10 ⁻²	0 0 0 0	0 0 0 0
10 ⁻³	0 0 0 0	0 0 0 0
10 ⁻⁴	0 0 0 0	0 0 0 0
10 ⁻⁵	0 0 0 0	ND 0 0 0
10 ⁻⁶	0 0 0 0	0 0 0 0
10 ⁻⁷	0 0 0 0	0 0 0 0*
EID/ELD ₅₀ /mL	≤10 ^{1.50}	≤10 ^{1.50}

Table 2
 Toxicity Control

Dilution	Dry Steam Vapor System, 2400 Series, TANCS® equipped
10 ⁻²	0 0 0 0
10 ⁻³	0 0 0 0

Table 3
 Control results

Dilution	Avian Influenza Virus Tile Recovery Control
10 ⁻²	+ + + +
10 ⁻³	+ + + +
10 ⁻⁴	+ + + +
10 ⁻⁵	+ 0 + 0*
10 ⁻⁶	+ 0* 0 0
10 ⁻⁷	0 0 ND 0*
EID/ELD ₅₀ /mL	10 ^{5.50}

Host Viability Control
0 0 0 0*

Key: + = Avian Influenza virus infected embryos were detected, hemagglutination observed
 0 = Avian Influenza virus infected embryos not detected, no hemagglutination observed;
 no toxicity
 ND = Not Done; no hemagglutination performed
 0* = Non-vialbe embryo at candling, Avian Influenza virus infected embryos not detected,
 no hemagglutination observed

RESULTS (continued)

Table 4
Log₁₀ Reduction

Dry Steam Vapor System, 2400 series, TANCS® equipped	
TILE 1	TILE 2
≥4.00	≥4.00

CONCLUSIONS

When tested as described, Dry Steam Vapor system, 2400 series, TANCS® equipped, passed the Virucidal Effectiveness Test when Avian Influenza virus, containing at least 5% organic load, was exposed to the test agent for 7 seconds at 22C. All of the controls met the criteria for a valid test. These conclusions are based on observed data.