AQUAOX Disinfectant

Virucidal Efficacy - Test Summary

Human Coronavirus, strain 229E, ATCC VR-740

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid
Batch:	AX-13196-0210

SUMMERY OF RESULTS

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Human Coronavirus, strain 229E, ATCC VR-740
Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 log10

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.994% reduction in viral titer following a 30 second exposure time to Human Coronavirus as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25LOG10.

Respiratory syncytial virus, Strain Long, ATCC VR-26

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU) A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Respiratory syncytial virus, Strain Long, ATCC VR-26

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 log10

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.994% reduction in viral titer following a 30 second exposure time to Respiratory syncytial virus as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25LOG10.

Adenovirus type 2, Strain Adenoid 6, ATCC VR-846

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU) A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Adenovirus type 2, Strain Adenoid 6, ATCC VR-846

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.9997% reduction in the stock virus titer as compared to the titer of the virus control. The log reduction in viral titer was 6.50 log10

STUDY CONCLUSION

Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.9997% reduction in viral titer following a 30 second exposure time to Adenovirus type 2 at room temperature (20.0°C), as compared to the titer of the virus control. The log reduction in viral titer was 6.50LOG10

Human Immunodeficiency Virus type 1, Strain HTLV-IIIe

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU)
	A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	A Human Immunodeficiency Virus type 1, Strain HTLV-IIIe

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.999% reduction in the stock virus titer as compared to the titer of the virus control. The log reduction in viral titer was ≥5 log10

STUDY CONCLUSION

Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.999% reduction in viral titer following a 30 second exposure time to Human Immunodeficiency Virus type 1, at room temperature (20.0°C), as compared to the titer of the virus control. The log reduction in viral titer was ≥5LOG10

Duck Hepatitis B virus as a surrogate virus for human Hepatitis B virus

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU) A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Duck Hepatitis B virus as a surrogate virus for human Hepatitis B virus

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.9994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 5.25 log10.

STUDY CONCLUSION

Under the conditions of this investigation, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.9994% reduction in viral titer following a 30 second exposure time to duck Hepatitis B virus as compared to the titer of the corresponding virus control. The log reduction in viral titer was 5.25 log10.

Poliovirus type 1, strain Chat, ATCC VR-1562

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU) A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Poliovirus type 1, strain Chat, ATCC VR-1562

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.999% reduction in the stock virus titer as compared to the titer of the virus control. The log reduction in viral titer was ≥5 log10

STUDY CONCLUSION

Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.9998% reduction in viral titer following a 30 second exposure time to Poliovirus type 1, at room temperature (20.0°C), as compared to the titer of the virus control and a 99.9994% . reduction in viral titer following a 60 second exposure time to Poliovirus type 1, at room temperature (20.0°C), as compared to the titer of the virus control. The log reduction in viral titer was ≥5.75LOG10 and 5.25LOG10 respectively.

Herpes simplex virus type 2, strain G, ATCC VR-734

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU)
	A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Herpes simplex virus type 2, strain G, ATCC VR-734

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 log10.

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.994% reduction in viral titer following a 30 second exposure time to Herpes simplex virus type 2 as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25LOG10

Herpes simplex virus type 2, strain G, ATCC VR-734

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU)
	A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Herpes simplex virus type 2, strain G, ATCC VR-734

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 log10.

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.994% reduction in viral titer following a 30 second exposure time to Herpes simplex virus type 2 as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25LOG10

Bovine viral diarrhea virus as a surrogate virus for Hepatitis C virus, strain Oregon C24v, genotype 1, cytopathic

GENERAL STUDY INFORMATION

Study Title:	Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay
Project Number:	A15626
Protocol Number:	INI01091313.COR
Testing Facility:	ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use (RTU)
	A near neutral Hypochlorous Acid solution with 225ppm Free Available Chlorine produced by Aquaox.
Virus:	Bovine viral diarrhea virus as a surrogate virus for Hepatitis C virus, strain Oregon C24v, genotype 1, cytopathic

SUMMERY OF RESULTS

Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.97% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 3.50log10.

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquax (Batch # AX-13196-0210), ready to use, demonstrated a 99.97% reduction in viral titer following a 30 second exposure time to Bovine viral diarrhea virus as compared to the titer of the corresponding virus control. The log reduction in viral titer was 3.50LOG10.

FINAL STUDY REPORT

STUDY TITLE

Evaluation of Antiviral Properties of a Product
Using a Virucidal Suspension Assay

Virus: Human Coronavirus

PRODUCT IDENTITY

AQUAOX
Batch #AX-13196-0210

AUTHOR

Shanen Conway, B.S.
Study Director

STUDY COMPLETION DATE

December 11, 2013

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

PROJECT NUMBER

A15626

GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58.

The studies not performed by or under the direction of ATS Labs are exempt from this Good Laboratory Practice statement and include: characterization and stability of the compound(s).

QUALITY ASSURANCE UNIT SUMMARY

Study: Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. These studies have been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance to standard operating procedures and standard protocols. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the integrity of the study.

Phase Inspected	Date of Phase Inspection	Date Reported to Study Director	Date Reported to Management
Critical Phase Audit	October 1, 2013	October 1, 2013	October 1, 2013
Draft Report	October 28, 2013	October 28, 2013	October 28, 2013
Final Report	December 11, 2013	December 11, 2013	December 11, 2013

The findings of these inspections have been reported to Management and the Study Director.

STUDY PERSONNEL

STUDY DIRECTOR:	Shanen Conway, B.S.

Personnel Involved:

Kelleen Gutzmann, M.S.	- Director, Virology & Microbial ID Operations
Katherine A. Paulson, M.L.T.	- Senior Virologist
Matthew Cantin, B.S.	- Lead Virologist
Erica Flinn, B.A.	- Associate Virologist

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay

Project Number: A15626

Protocol Number: INI01091313.COR

Testing Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance: Aquaox Hypochlorous Acid Batch # AX-13196-0210

Batch: AX-13196-0210

Test Substance Characterization
Test substance characterization as to content, stability, solubility, storage, etc., (21 CFR, Part 58, Subpart F [58.105)) is the responsibility of the Sponsor.

STUDY DATES

Date Sample Received: September 11, 2013
Study Initiation Date: September 23, 2013
Experimental Start Date: October 1, 2013
Experimental End Date: October 11, 2013
Study Completion Date: December 11, 2013

OBJECTIVE

The objective of this study was to evaluate the antiviral propertles of a product against Human Coronavirus when exposed (in suspension) for the specified exposure period. This protocol is a modification of the Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension (ASTM E 1052).

SUMMARY OF RESULTS

Test Substance:	Aquaox Hypochlorous Acid Batch # AX-13196-0210
Dilution Tested:	Ready to use
Virus:	Human Coronavirus, strain 229E, ATCC VR-740
Exposure Time:	30 seconds
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	1% fetal bovine serum
Efficacy Result:	Under these test conditions, Aquaox (Batch # AX-13196-0210) demonstrated a 99.994% reduction in the stock virus titer as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 log10-

TEST SYSTEM

1. Virus

The 229E strain of Human Coronavirus used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-740). Stock virus was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells. The cells were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for five minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at 50-70°C until the day of use. On the day of use an aliquot of stock virus (ATS Labs Lot HCV-69) was removed, thawed and maintained at a refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Human Coronavirus on WI-38 cells.

2. Indicator Cell Cultures

Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75). The cells were propagated by ATS Labs personnel. The cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2 On the day of testing, the cells were observed as having proper cell integrity and confluency, and therefore, were acceptable for use in this study.

All cell culture documentation was retained for the cell cultures used in the assay with respect to source, passage number, growth characteristics, seeding densities and the general condition of the cells.

3. Test Medium

The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B.

The following table lists the test and control groups, the dilutions assayed, and the number of cultures per dilution. See the report text for a more detailed explanation.

PARAMETERS TESTED FOR VIRUCIDAL EFFICACY **ASSAY**		
Test or Control Group	Dilutions Assayed (10010)	Cultures per Dilution
Cell Control	N/A	4
Virus Control	-2,-3,-4,-5,-6,-7,-8	4
Test Batch+ virus	-2,-3,-4,-5,-6,-7,-8	4
Cytotoxicity Control	-2,-3,-4	4
Neutralization Control	-2,-3,-4	4

TEST METHOD

1. Preparation of Jest Substance

Aquaox (Batch# AX-13196-0210) was used as it was received from the Sponsor. The test substance removed from the original container was in solution as determined by visual observation. The test substance was at the exposure temperature prior to use in testing.

2. Treatment of Virus Suspension

For the exposure time assayed, a 1.80 ml aliquot of the test substance was dispensed into a sterile tube and mixed with a 200 µl aliquot of the stock virus suspension. The mixture was vortex mixed for 10 seconds and held for the remainder of the specified exposure time at room temperature (20.0°C). The exposure time assayed was 30 seconds. Following the exposure time, a 100 µl aliquot was removed from the tube and the mixture was immediately titered by 10-fold serial dilutions (100 µl + 0.9 ml test medium) and assayed for the presence of virus. Note: To decrease the test substance cytotoxicity, the first dilution was made in FBS with the remaining dilutions in test medium.

3. Treatment of Virus Control

For the exposure time assayed, a 200 µl aliquot of stock virus suspension was exposed to a 1.80 ml aliquot of test medium in lieu of test substance and treated as previously described. Following the exposure time, a 100 µl aliquot was removed from the tube and the mixture was immediately titered by 10-fold serial dilutions (100 µl + 0.9 ml test medium) and assayed for the presence of virus. All controls employed the FBS neutralizer as described in the Treatment of Virus Suspension section. A virus control was performed for the exposure time tested. The virus control titer was used as a baseline to compare the percent and log reductions of the test parameter following exposure to the test substance.

4. Cytotoxicity Control

A 1.80 ml aliquot of the test substance was mixed with a 200 µl aliquot of test medium containing the Sponsor requested organic soil load in lieu of virus and treated as previously described. The cytotoxicity control was held for the longest exposure time. The cytotoxicity of the cell cultures was scored at the same time as virus-test substance and virus control cultures. Cytotoxicity was graded on the basis of cell viability as determined microscopically. Cellular alterations due to toxicity were graded and reported as toxic (T) if greater than or equal to 50% of the monolayer was affected.

5. Neutralization Control

Each cytotoxicity control mixture (above) was challenged with low titer stock virus to determine the dilution(s) of test substance at which virucidal activity, if any, was retained. Dilutions that showed virucidal activity were not considered in determining reduction of the virus by the test substance.

Using the cytotoxicity control dilutions prepared above, an additional set of indicator cell cultures was inoculated with a 100 µl aliquot of each dilution in quadruplicate. A 100 µl aliquot of low titer stock virus was inoculated into each cell culture well and the indicator cell cultures were incubated along with the test and virus control plates.

6. Infectivity Assay

The WI-38 cell line, which exhibits cytopathic effect (CPE) in the presence of Human Coronavirus, was used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes were inoculated in quadruplicate with 100 µl of the dilutions prepared from test and control groups. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were microscopically scored periodically for ten days for the absence or presence of CPE, cytotoxicity, and for viability.

7. Statistical Methods: Not applicable

PROTOCOL CHANGES

Protocol Amendments:
No protocol amendments were required for this study.

Protocol Deviations:
No protocol deviations occurred during this study.

TEST CRITERIA

A valid test requires 1) that stock virus be recovered from the virus control and 2) that the cell controls be negative for virus.

RECORD RETENTION

Study Specific Documents
All of the original raw data developed exclusively for this study shall be archived at ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of the final study report.
7. Study-specific SOP deviations made during the study.

Test Substance Retention
The test substance will be discarded following study completion per Sponsor approved protocol. It is the responsibility of the Sponsor to retain a sample of the test substance.

REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides; Environmental Assessment; Hazardous Substances and Oil Spill Response, E 1052 (current version).
2. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides; Environmental Assessment; Hazardous Substances and Oil Spill Response, E 1482 (current version).
3. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A., and Lennette, E.T. editors. Seventh edition, 1995.

STUDY RESULTS

Cytotoxicity and Neutralization Controls

Test substance cytotoxicity was not observed in any dilution assayed (S1.50 10910). The neutralization control demonstrated that the test substance was neutralized at s:1.50 IOQ10-

30 Second Exposure Time

The titer of the virus control was 5.75 log10. Following exposure, test virus infectivity was not detected in the virus-test substance mixture at any dilution tested (s;1.50 10910).

STUDY CONCLUSION

Under the conditions of this investigation, in the presence of a 1% fetal bovine serum organic soil load, Aquaox (Batch # AX-13196-0210), ready to use, demonstrated a 99.994% reduction in viral titer following a 30 second exposure time to Human Coronavirus as compared to the titer of the corresponding virus control. The log reduction in viral titer was 4.25 LOG10.

In the opinion of the Study Director, there were no circumstances that may have adversely affected the quality or integrity of the data.

ATTACHMENT I – Certificate of Analysis

Issued: July 16, 2013
Last Revised: July 29, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16165, Sierra Lakes Parkway,
Suite 160-714,
Fontana, CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	07 / 15 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13196-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	226	ppm
pH	6.03	n/a
Conductivity	1225	µS/cm
ORP	943	mV
Osmolality	22	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lel
QA Regulatory Specialist

Date: 7/29/13

EXACT COPY
INITIALS MM DATE 12-10-13