Volume _____

FINAL REPORT

VIRUCIDAL EFFECTIVENESS TEST
Human Coronavirus

TEST AGENT: Trionic

Data Requirements
EPA Guidelines 810.2100 (g)

Author
M. Khalid Ijaz, DVM, Ph.D.

Study Completion Date
01/28/2005

Performing Laboratory
MICROBIOTEST, INC.
105 Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
531-105

Submitted to: EBIOX / SAFA / IPS
Healthcare Enterprise House
17 Chesford Grange
Warrington, England WA1 4RQ

Page 1 of 26
STATEMENT OF NO DATA CONFIDENTIALITY

Title: Virucidal Effectiveness Test – Human Coronavirus

Performed by: MICROBIOTEST, INC.
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:

Zheng Chen, Nausheen Javed, Samina S. Raja

Study Director: MICROBIOTEST, INC.

[Signature]

M. Khalid Ijaz, DVM, Ph.D. 01/28/05 Date

Submitted by:

Name

Title

Signature

Date

Sponsor: EBIOX / SAFA / IPS

Name

Title

Signature

Date
## QUALITY ASSURANCE UNIT STATEMENT

**Title of Study:** Virucidal Effectiveness Test – Human Coronavirus

The Quality Assurance Unit of MICROBIOTEST has inspected the Project Number 531-105 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.

<table>
<thead>
<tr>
<th>PHASE INSPECTED</th>
<th>DATE OF INSPECTION</th>
<th>DATE REPORTED TO STUDY DIRECTOR</th>
<th>DATE REPORTED TO MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>01/07/05</td>
<td>01/13/05</td>
<td>01/18/05</td>
</tr>
<tr>
<td>In Process</td>
<td>01/07/05</td>
<td>01/13/05</td>
<td>01/18/05</td>
</tr>
<tr>
<td>Final Report</td>
<td>01/18/05</td>
<td>01/18/05</td>
<td>01/24/05</td>
</tr>
</tbody>
</table>

Nathan S. Jones, ROQP-GLP
Quality Assurance Unit

Date: 01/24/05
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TEST SUMMARY

TITLE: Virucidal Effectiveness Test – Human Coronavirus

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:

1. Trionic, Lot No. TP396, received at MICROBIOTEST, INC. 12/09/04, and assigned DS No. 7087

2. Trionic, Lot No. TP399, received at MICROBIOTEST, INC. 12/09/04, and assigned DS No. 7088

SPONSOR: EBIOX / SAFA /IPS
Healthcare Enterprise House
17 Chesford Grange
Warrington, England WA1 4RQ
TEST CONDITIONS

Challenge virus:

Human Coronavirus, ATCC VR-740

Host:

MRC-5 cells, Diagnostic Hybrids, Inc.

Active ingredient in test product:

Twin chain quaternary ammonium compound and biguanide

Neutralizer used:

Fetal bovine serum

Dilution:

Pre-diluted by the sponsor

Contact time:

5 minutes

Contact temperature:

Room temperature (23C)

Organic load:

Viral stock contained at least 5% organic load

Carrier Inoculation:

Carriers were inoculated with 0.2mL of viral stock and dried for 30 minutes

Media and reagents:

Minimum Essential Medium Eagle's containing 10% fetal bovine serum
Fetal bovine serum
Earle's Balanced Salt Solution
Phosphate Buffered Saline containing 0.5% fetal bovine serum
Sephacryl S-1000
STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MICROBIOTEST, INC., 105 Carpenter Drive, Sterling, VA 20164, from 01/05/05 to 01/17/05. The study director signed the protocol 01/04/05. 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, INC., 105 Carpenter Drive, Sterling, VA 20164, or at a controlled facility off site.

RESULTS

Results are presented in Tables 1 – 4. A titration was performed to determine the titer of the viral stock. The 50% cell culture infectious dose (CCID$_{50}$) per mL was determined using the method of Reed and Muench, 1938. The cell viability control demonstrated MRC-5 cell viability and media sterility. Virus was not recovered in the cell viability control.
RESULTS (continued)

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Human Coronavirus titer (CCID$_{50}$/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trionic Lot No. TP396</td>
</tr>
<tr>
<td></td>
<td>5 minute contact time</td>
</tr>
<tr>
<td>$10^{-2}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>$10^{-3}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>$10^{-4}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>$10^{-5}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>$10^{-6}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>$10^{-7}$</td>
<td>- - - -</td>
</tr>
<tr>
<td>CCID$_{50}$/mL</td>
<td>$\leq 10^{1.50}$</td>
</tr>
</tbody>
</table>

Table 2
Neutralizer Effectiveness and Cytotoxicity Related Controls
Lot No. TP396

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Cytotoxicity Control</th>
<th>Cytotoxicity-related Viral Interference Control</th>
<th>Neutralizer Effectiveness Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10^{-2}$</td>
<td>0 0 0 0</td>
<td>+ + + +</td>
<td>+ + + +</td>
</tr>
<tr>
<td>$10^{-3}$</td>
<td>0 0 0 0</td>
<td>+ + + +</td>
<td>+ + + +</td>
</tr>
<tr>
<td>$10^{-4}$</td>
<td>0 0 0 0</td>
<td>+ + + +</td>
<td>+ + + +</td>
</tr>
</tbody>
</table>

Key: + = Human Coronavirus infected cells detected, cytopathic effects observed  
= Human Coronavirus infected cells not detected, no cytopathic effects observed  
0 = No cytotoxicity observed
RESULTS (continued)

Table 3
Control Results

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Human Coronavirus titer (CCID$_{50}$/mL)</th>
<th>Plate Recovery</th>
<th>Column Titer</th>
<th>Virus Stock Titer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>$10^{-1}$</td>
<td></td>
<td>PNS</td>
<td>PNS</td>
<td>+ + + +</td>
</tr>
<tr>
<td>$10^{-2}$</td>
<td></td>
<td>+ + + +</td>
<td>+ + + +</td>
<td>+ + + +</td>
</tr>
<tr>
<td>$10^{-3}$</td>
<td></td>
<td>+ + + +</td>
<td>+ + + +</td>
<td>+ + + +</td>
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<tr>
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<tr>
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<tr>
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</tr>
<tr>
<td>$10^{-8}$</td>
<td></td>
<td>ND</td>
<td>ND</td>
<td>- - - -</td>
</tr>
<tr>
<td>CCID$_{50}$/mL</td>
<td>$10^{5.50}$</td>
<td>$10^{5.50}$</td>
<td>$10^{6.50}$</td>
<td></td>
</tr>
</tbody>
</table>

Table 4
Control Results

<table>
<thead>
<tr>
<th>Cell Viability Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>- - - -</td>
</tr>
</tbody>
</table>

Key: PNS = Post-neutralized sample
+ = Human Coronavirus infected cells detected, cytopathic effects observed
- = Human Coronavirus infected cells not detected, no cytopathic effects observed
ND = Not determined

CONCLUSIONS

When tested as described, Trionic passed the Virucidal Effectiveness Test when Human Coronavirus was exposed to the test agent for 5 minutes at 23°C. All of the controls met the criteria for a valid test. These conclusions are based on observed data.
APPENDIX I
PROJECT SHEET(S)
**STUDY TITLE:** Virucidal Effectiveness Test – Human Coronavirus  
**TEST MATERIAL(S):** Trionic Concentrate  
**PERFORMING DEPARTMENT(S):** BSL-3 Laboratory  
**PROTECTIVE PRECAUTION REQUIRED:** MSDS □ Yes / □ No  
**PHYSICAL DESCRIPTION:** □ Solid ■ Liquid □ Aerosol □ Other  
**PURPOSE:** See attached protocol  
**PROPOSED EXPERIMENTAL START DATE:** 01/05/05  
**TERMINATION DATE:** 01/19/05  
**CONDUCT OF STUDY:** □ FDA ■ EPA □ R&D ■ GLP □ GCP □ Other:  
**SPONSOR:** EBI0X Limited  
59 Hill Street  
Liverpool, England L85SB  
**CONTACT PERSON:** Keith MacGregor  
Telephone No. 011-44-797-117-1208  
FAX No. 011-44-194-381-6818  

**TEST CONDITIONS:**

- **Challenge Organism:** Human Coronavirus, ATCC VR-740  
- **Host Cell Line:** MRC-5, Diagnostic Hybrids, Inc.  
- **Active ingredients:** Twin chain quaternary ammonium compound and biguanide  
- **Neutralizer:** Fetal bovine serum  
- **Contact Time:** 5 minutes  
- **Contact Temperature:** Room temperature  
- **Serum:** □ Yes / □ No (Virus already contains at least 5% organic load)  
- **Incubation Time:** 10-14 days  
  **Incubation Temperature:** $33\pm1^\circ C$ in $5\%\pm1\%$ CO$_2$  
- **Cell Culture Medium (CCM):** Minimum Essential Medium Eagle's containing 10% fetal bovine serum  
- **Comments:** The test agent was pre-diluted by the sponsor.
1. Although the last page of the protocol stipulates Trionic Plus as the test agent, the sponsor has requested via email that Trionic Concentrate, lot nos. TP396 and TP399, (not Trionic Plus) be tested against Human coronavirus. This product is pre-diluted and ready to use. This amendment serves to clarify the test agent that will be tested as directed by the sponsor.

2. A cytotoxicity-related viral interference control will be performed. This control is performed because the test agent may not be effective against the challenge virus yet be toxic to the cells employed to detect its infectivity and may inhibit accurate interpretation of the test. To determine the possibility of such interference by residual cytotoxic molecules, host cells treated with serially diluted neutralized test agent will be infected with a known number of infectious virus. Post-incubation they will be scored and compared with non-treated infected host cells control. This will rule out any possibility of cytotoxicity-related viral interference remaining in the neutralized test agent post-contact time. This amendment serves to indicate that a cytotoxicity-related viral interference control will be performed.
<table>
<thead>
<tr>
<th>STUDY TITLE: Virucidal Effectiveness Test – Human Coronavirus</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST MATERIAL(S): Trionic</td>
</tr>
<tr>
<td>LOT NO.</td>
</tr>
<tr>
<td>TP396</td>
</tr>
<tr>
<td>12/09/04</td>
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<tr>
<td>TP399</td>
</tr>
<tr>
<td>12/09/04</td>
</tr>
<tr>
<td>DS NO.</td>
</tr>
<tr>
<td>7087</td>
</tr>
<tr>
<td>7088</td>
</tr>
<tr>
<td>PERFORMING DEPARTMENT(S): Aerobiology Laboratory</td>
</tr>
<tr>
<td>STORAGE CONDITIONS: Location: E1:D3</td>
</tr>
<tr>
<td>Dark ■Ambient Room Temperature  ■</td>
</tr>
<tr>
<td>CONDUCT OF STUDY: □FDA ■EPA □R&amp;D ■GLP □GCP □Other:</td>
</tr>
<tr>
<td>SPONSOR: Ebiox / Safa / IPS Healthcare Enterprise House</td>
</tr>
<tr>
<td>17 Chesford Grange</td>
</tr>
<tr>
<td>Warrington, England WA1 4RQ</td>
</tr>
<tr>
<td>CONTACT PERSON: Lyn Barnes</td>
</tr>
<tr>
<td>Telephone: 011-44-192-589-8200</td>
</tr>
<tr>
<td>Fax: 011-44-192-589-8285</td>
</tr>
</tbody>
</table>

EXPLANATION:

3. The correct name of the test agent is Trionic, not Trionic Concentrate. This amendment serves to indicate the correct name of the test agent.
EXPLANATION:

4. Per sponsor notification, the sponsor address and contact person has changed as indicated above. This amendment serves to indicate that the sponsor address and contact has changed.
MICROBIOTEST PROTOCOL

VIRUCIDAL EFFECTIVENESS TEST

Human Coronavirus

Prepared for
EBIOX LIMITED
59 Hill Street
Liverpool, L85SB
England

APRIL 1, 2004

Page 17 of 26
OBJECTIVE:

This test is designed to substantiate virucidal effectiveness claims for a product to be labeled as a virucide. It determines the potential of the test agent to disinfect hard surfaces contaminated with viruses. The test is designed to simulate consumer use and conforms to EPA Guidelines DIS/TSS-7, November 1981, and follows the procedure outlined in the American Society for Test Materials (ASTM) test method designated E 1053-97.

TESTING CONDITIONS:

Virus will be dried on a sterile glass Petri dish at ambient temperature. Two lots of disinfectant will be used to treat the dried virus according to the label claims. After a defined exposure period, the test agent-virus mixture will be scraped from the surface, collected, neutralized and assayed for the presence of infectious virions.

MATERIALS:

A. Test, control and reference substances will be supplied by the sponsor of the study (see last page).

The test agent will be tested as supplied by the sponsor unless directed otherwise. All operations performed on the test agent such as dilution or specialized storage conditions must be specified by the sponsor before initiation of testing.

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

MICROBIOTEST will retain all unused test agents for a period of at least three months after completion of the test, then discard them in a manner that meets the approval of the safety officer.
MICROBIOTEST Protocol: Virucidal Effectiveness Test - Coronavirus

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

1. Challenge virus (requested by the sponsor of the study): Human Coronavirus (ATCC VR-740)

2. Host: See Project Sheet One.

3. Laboratory equipment and supplies.

4. Media and reagents:
   a. Eagle’s minimum essential medium containing 10% fetal bovine serum (CCM)
   b. Phosphate buffered saline (PBS)
   c. Earle’s balanced salt solution (EBSS)
   d. Neutralizer(s)
   e. Sephacryl columns (if necessary)
   f. PBS containing 0.5% fetal bovine serum

TEST SYSTEM IDENTIFICATION:

All Petri dishes, dilution tube racks, and host-containing apparatus will be labeled with the following information: virus, host, test agent and project number.

EXPERIMENTAL DESIGN:

All of the procedures involved in performance of this study are described in a detailed series of SOPs that are maintained at MICROBIOTEST. SOPs and Logs are referred to in the raw data and are required as part of GLP regulations.

A. Inoculum preparation:

Viral stocks are purchased from American Type Culture Collection (ATCC) or other reputable sources that identify them by scientifically accepted methods and are propagated at MICROBIOTEST. Records are maintained that demonstrate the origin of the virus. The virus stocks will be 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).

B. Carrier preparation:

An aliquot of 0.2 mL of stock virus will be spread, with the cell scraper, over an area of approximately 4 in\(^2\) that has been marked on the underside of pre-sterilized Petri dishes. Then the virus will be allowed to dry for 30 to 60 minutes at room temperature. The drying time and temperature will be recorded. One carrier will be prepared for each lot and the Plate recovery control, additionally; one plate will be prepared for the Neutralizer effectiveness control using EBSS.

C. Test agent preparation:

The agent will be prepared according to the sponsor's directions or proposed label claims.

E. Test:

At least 10\(^4\) infectious units of the virus inoculum will be spread over the surface of one sterile glass Petri dishes with a cell scraper and allowed to dry for 30 to 60 min at room temperature. After the inoculum has dried, 2.0 mL of the test agent will be added. The plates will remain at the temperature and for the time specified by the sponsor.

After the contact period, the test agent will be neutralized with 2.0 mL of appropriate neutralizer and the mixture will be scraped from the surface of the dish with a cell scraper. This will be considered approximately one log\(_{10}\) dilution.

If columns are required for proper neutralization, 0.5 mL of each sample will be loaded into separate pre-spun Sephacryl columns. The columns will be spun for 4 minutes at 1000 rpm. The samples will be aseptically removed from the columns and dispensed into dilution tubes containing EBSS. The final dilution will be 1:10. Ten-fold serial dilutions will be performed. If columns are not used, serial tenfold dilutions of neutralized virus will be prepared in EBSS.
For spray type agents, the agent will be used as per sponsor's instructions, the volume dispensed will be measured and an equal volume of neutralizer will be used. Following spraying and contact time, the procedure for processing the samples will be the same as described earlier (see above).

F. Cell culture:

The residual infectious virus in both test and controls will be detected by cytopathic effect. Selected dilutions of the neutralized inoculum/test agent mixture will be added to cultured host cells, and incubated at 35±2°C for 90-120 minutes for viral adsorption. Post-adsorption, the sample containing EBSS will be aspirated, plates washed once with EBSS and refed with CCM. The cultures will be incubated at 35±2°C for 10-14 days. Post-incubation the cytopathic effects (CPE) will be scored by examining both test and controls. The observations will be recorded.

G. Controls:

1. Neutralizer effectiveness: (NE)

This control will determine if any residual active ingredient is present after neutralization.

One lot of the test agent will be used for the neutralizer effectiveness control. This control will be processed exactly as the test procedure but instead of viral inoculum, EBSS will be added. Post-test, and neutralization, a 1.0-mL sample will be divided into two portions, [one for cytotoxicity control (see below) and one for neutralizer effectiveness] and loaded onto pre-spun columns if required.

If columns are used, each sample will be passed through an individual column. If columns are not used, the neutralizer effectiveness sample will be ten-fold serially diluted in EBSS and virus (100 μL of stock) will be added to each dilution and incubated for a period equivalent to the contact time. Then these samples will be used to inoculate host cells as described for the test procedure.
2. Cytotoxicity: (CT)

The cytotoxicity sample, acquired from the neutralizer effectiveness control, will be ten-fold serially diluted in EBSS, having no virus added. Select dilutions will be inoculated and incubated in the same manner as the rest of the test and controls. These effects are distinct from cytopathic effects due to virus infection, which will be evident in the stock titer and plate recovery cultures.

3. Plate recovery: (PRC)

The virus inoculum will be spread over the surface of a sterile glass Petri dish and left to dry at ambient temperature for 30 to 60 minutes. A volume of EBSS equivalent to that of the test agent will be added to the dried virus. Post-contact time, virus will be subjected to the identical neutralization procedure as the test agent. This control will determine the relative loss in virus infectivity resulting from drying and neutralization alone.

When samples are required to pass through the Sephacryl columns, a column titer control (CTC) will also be performed (by assaying a portion of PRC before passing through the columns) to determine any affect on infectious virus titer while passing the columns (see below).

The results from this control are compared with the test results to confirm recovery of at least four log of infectious virus in this control following drying and neutralization. Its titer is used to compare with the titers of the test results to reach the acceptable test criteria (see below).

4. Column titer control:

This control will be performed only if Sephacryl columns are used. It is performed to determine any affect on infectious virus titer while passing the columns.

The sample for this control will be acquired from a portion of the Plate recovery control, prior to passing through the columns.
This sample is directly ten-fold serially diluted in EBSS, then processed in the same manner as the rest of the test and controls.

5. Virus stock titer: (VST)

In order to determine the original virus titer, an aliquot of the virus inoculum will be tenfold serially diluted in EBSS, and assayed (see above) as described for the test and other controls.

6. Cell viability control: (CVC)

Four wells will be inoculated with EBSS during viral adsorption and CCM 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 also confirm the sterility of the media employed throughout the assay period.

H. Calculation:

The CCID₅₀/mL will be determined from the virus stock, test and plate recovery data using the method of Reed and Muench, Am. J. of Hyg. 1938, 27:493. The test results shall be reported as the reduction of the virus titer due to treatment with test material expressed as log₁₀.

PRODUCT EVALUATION CRITERIA:

According to the regulatory agencies, the test agent passes the test if there is complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a three-log reduction in titer must be demonstrated beyond the cytotoxic level.
MICROBIOTEST Protocol: Virucidal Effectiveness Test - Coronavirus

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.

- The infectious virus recovered from the PRC control must be \( \geq 4 \log_{10} \).
- Viral-induced toxicity must be distinguishable from test agent induced cytotoxic effects.

DATA PRESENTATION:

The final report will include the following information in tabular form (if appropriate) for both the test and control cultures:

- Virus stock titer
- Test results
- Plate recovery
- Neutralizer system employed and effectiveness data
- Cytotoxicity results
- The volume of virus used, drying time and ambient temperature of the test
- Host recovery system

REPORT FORMAT:

MICROBIOTEST employs a standard report format for each test design. Each final report provides the following information:

- Sponsor identification
- Test agent identification
- Type of assay and project number
- Dates of study initiation and completion
- Interpretation of results and conclusions
- Test results presented in tabular form
- Methods and evaluation criteria
- Signed Quality Assurance and Compliance Statements
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 MICROBIOTEST, INC., 105B Carpenter Drive, Sterling, Virginia 20164. Chemical analyses, if required, will be performed at an analytical laboratory to be identified in the final report.

RECORDS TO BE MAINTAINED:

All raw data, protocol, protocol modifications, test agent records, final report, and correspondence between MICROBIOTEST and the sponsor will be stored in the archives at MICROBIOTEST, INC., 105B 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 agent; challenge virus and specific host used; media and reagent identification; and the type of neutralizers employed in the test will be addressed in a project sheet issued separately. The date the study director signs project sheet number one will be the initiation date. All project sheets will be forwarded to the study sponsor.
MISCELLANEOUS INFORMATION:

The following information is to be completed by the sponsor prior to initiation of the study:

A. Name and address: EBIOX LIMITED
   59 Hill Street
   Liverpool, L85SB
   England

B. Test Agent: TRIONIC PLUS

   Lot 1: TP 264
   Lot 2: TP 265
   Lot 3: (for Health Canada submission only): 

   Dilution to be tested: AS INSTRUCTED
   Diluent: WATER

   Exposure time: AS FOR PARVO TEST 532.104.05.04
   Exposure temperature: ±2°C
   Room temperature

C. All virucidal studies are conducted in the presence of at least 5% organic load.

D. Precautions/storage conditions: refer to MSDS or certificate of analysis
   [ ] provided  [ ] not provided

   Additional information: 

REPORT HANDLING:

The sponsor intends to submit this information to: [ ] the EPA  [ ] the FDA
[ ] Health Canada  [ ] CAL DPR  [ ] ARTG  [ ] non GLP  [ ] other

PROTOCOL APPROVAL:

Sponsor: Wani Merely

Date: 26/4/2004

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MICROBIOTEST, INC.