EPA INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)
U.S. EPA (2225A)
1200 Pa. Ave., NW
Washington, DC 20460

DATE 12/7/06

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ms Donna Suchmann

INVESTIGATION ID NUMBER
200719553401

FIRM NAME AND ADDRESS:
MICROBIOTEST, INC
105B CARPENTER DRIVE
STERLING, VA 20164

FACILITY INSPECTED ADDRESS
SAME

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

BASED UPON WHAT I REVIEWED, OBSERVED AND THROUGH INTERVIEWS WITH FACILITY/STUDY PERSONNEL NO MAJOR GLP VIOLATIONS WERE NOTED DURING THE COMPLIANCE INSPECTION (W/ ONGOING STUDY) OR THE DATA AUDIT OF THE FINAL REPORTS FOR THE FOLLOWING STUDIES:

A. MRID NO. 46779501 (LAB NO. 123-231)
B. MRID NO. 46826106 (LAB NO. 531-108) *
C. MRID NO. 46829607 (LAB NO. 320-370)
D. MRID NO. 46829902 (LAB NO. 320-372)
E. MRID NO. 46832701 (LAB NO. 123-232)
F. MRID NO. 46836017 (LAB NO. 320-375)

IT WAS NOTED THAT: 1) ALL OF THE DATA HAVE BEEN RETAINED FOR THE STUDIES AUDITED
2) STUDIES CAN BE RECONSTRUCTED FROM THE DATA.
3) THE STUDIES - FINDINGS + CONCLUSIONS ARE SUPPORTED BY THE STUDY DATA.

* THE SPONSOR DID NOT PROVIDE THE TEST SUBSTANCE CHARACTERIZATION DATA TO THE LABORATORY FOR THE EPA INSPECTOR TO REVIEW

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT
THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE
X [signature] 12/7/06

TITLE
PRESIDENT

PREPARED BY:
Robert L. CYPHER

TITLE
Compliance Officer|Toxicologist

EPA

INSPECTION OBSERVATIONS

ADDRESS (EPA OFFICE): HQ USEPA
1200 Pennsylvania Ave. NW
Washington, DC 20460

DATE: 29 April 2011

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Donna B Suchmann

TITLE: President (Managing Direc

FIRM NAME AND ADDRESS:
Microbiotest,
105 B Carpenter Drive
Sterling, Virginia

FACILITY INSPECTED ADDRESS:
Same as Firm address

DURING AN INSPECTION/AUDIT OF YOUR FACILITY, THE FOLLOWING WERE OBSERVED:

QAU need to indicate the specific phase inspection (none the in life phase) on the QA statement. 160.35(b)(3) and issue phase report as soon as possible.

QAU need to submit to management a written status reports on each study a QA quarterly Assurance report (Monthly) was ~~avaible~~ available for review but was a requirement from the parent company. This report needs to be expanded or a new report must be generated 160.35(b)(4)

Need to maintain receipt documents of the test substance/product being tested. 160.107(d). (Copy of courier, correspondence from sponsor, etc)

The Protocol amendments for unused test substance not returned to sponsor after 3 months study completion. 160.120(b)

The study audits final reports need to state the objective of the study 160.~~190~~ 185 (A)(2)

No chemical characterization data from sponsors. Sponsors provides a certificate of Analysis or a report of indicating the concentration values

~~Final report~~ Final reports should list all facilities performing the study 160.185(a)(1) and a copy of raw data or where the data is located

Equipment such as pH meter ~~should include~~ slog should be more detailed to include the studies and buffers used for calibration

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SIGNATURE

TITLE Director 4/29/2011

PREPARED BY: Elmer Griffin

TITLE Compliance Statement

Form 3540-38 (12-95)

INSPECTION OBSERVATIONS

ADDRESS (EPA OFFICE): 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

DATE: April 29, 2011

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Donna B Buchmann

INSPECTION IDENTIFICATION NUMBER: 20113 9553401

FIRM NAME AND ADDRESS: MICRO Biotest
105 B Carpenter Drive
Sterling Virginia

FACILITY INSPECTED ADDRESS: Firm Address

DURING AN INSPECTION/AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

(1) Materials (study files) retained in the archives ~~use~~ were not indexed to permit expedient retrieval. 160.190(a)

(2) Master Schedule Sheet some entries were not completed, no listing of the test material DS # (which is the test substance) or the date the protocol was signed or the test system. 160.35(b)(1)

(3) SOP M1000.QP.006.R00 indicates that QA will review the master schedule at least once ~~for~~ to ensure all GLP requirements are met for the GLP studies. At least once should be explain more through

(4) Chemical archives need ~~to~~ to have the retained GLP ~~test~~ substances separated from the current substances. An inventory log / index log should be in place to list the chemical expiration date and storage location and returned to sponsor or discarded information 160.107 SOP for storage retention of test substances need to be update to reflect the protocols statements and how long the samples will be retained.

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SIGNATURE: [signature] TITLE: Director 4/29/2011

PREPARED BY: Elmer Griffin TITLE: Compliance Statement

EPA 3540-38 (12/95)

EPA INSPECTION OBSERVATIONS	ADDRESS (EPA OFFICE): 1200 Pennsylvania Avenue, NW Washington, D.C 20460
	DATE: April 29, 2011
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Donna B. Suchmann	TITLE: President (Managing Director)
FIRM NAME AND ADDRESS: MicroBiotest	FACILITY INSPECTED ADDRESS / INVESTIGATION ID: 105 B Carpenter Drive Sterling, VA

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Study MRID No: 83439.12. Project No: 198-529
AOAC Tuberculocidal Activity of a Germicidal spray with Caviciide 1.

1. Protocol deviation: Unused test substance have not been discarded. Protocol requires discarding unused test substance after 3 months of completion of study. 40 CFR 160.120 (b)
2. Records to be maintained in protocol should be expanded to a list of raw data to be maintained. 40 CFR 160.120 (a)(13)
3. Test substance characterization data were not available 40 CFR 160.105 (a) and (b)
4. Receipt of test system is missing (Mycobacterium bovis)
5. QA statement stated an "in process" activity. This should be listed as what phase was inspected.
6. QA statement: QA inspection reports were submitted to S.D + management 3 months after QA inspection was performed.
7. Final report did not describe the objective of the study and the criteria for "passing" (40 CFR 160.185 (a)(11)

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SIGNATURE	TITLE: Director 4/29/2011
PREPARED BY: Elmer Griffin	TITLE: Compliance Officer

EPA 3540-38 (12-95)

EPA INSPECTION OBSERVATIONS	ADDRESS (EPA OFFICE) 1200 Pennsylvania Avenue NW Washington, D.C. 20460
	DATE April 29, 2011
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Donna B Suchmann	TITLE President (Managing Director)
FIRM NAME AND ADDRESS: MicroBiotest	FACILITY INSPECTED ADDRESS / INVESTIGATION ID 105 B Carpenter Drive Sterling, VA

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Study MRID. 483439-11, Lab. Project No: 198-524
AOAC Germicidal Spray Test Health Care with Cavicide 1

1 Protocol Deviation: Unused test substance have not been discarded. Protocol requires discarding unused test substance after 3 months of completion of study 40 CFR 160.120 (b)

2. Records to be maintained in protocol should be expanded to a list of raw data to be maintained. 40 CFR 160.120.a(

3. Test substance characterization data were not available (sponsor did not provide the data) 40 CFR 160.105 (a) and (b)

4. Final report did not describe the objective of the study and the criteria for conclusion (40 CFR 160.185.(a)(11)

5. QA statement stated an "in-process" activity this should be listed as the phase inspected.

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SIGNATURE	TITLE Director 4/29/2011
PREPARED BY Compliance Elmer Griffin	TITLE Compliance Officer

EPA 3540-38 (12-95)