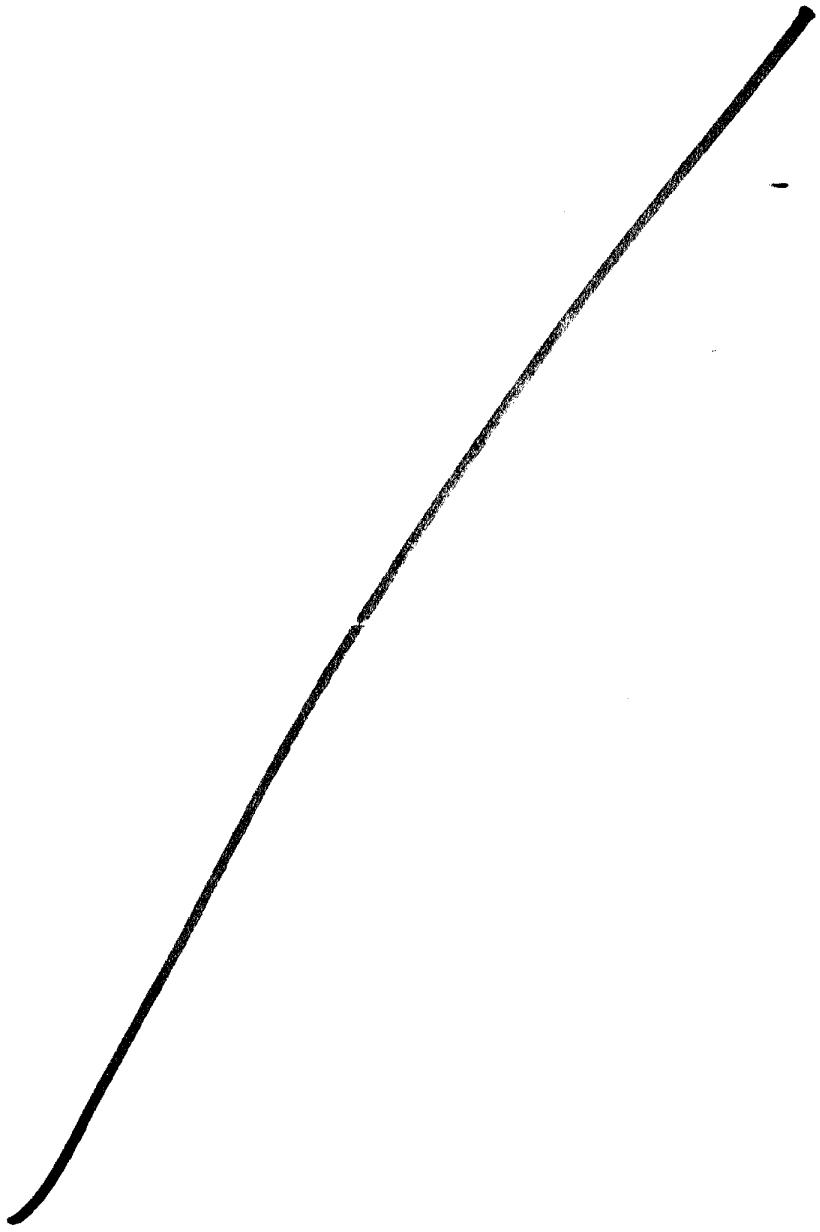
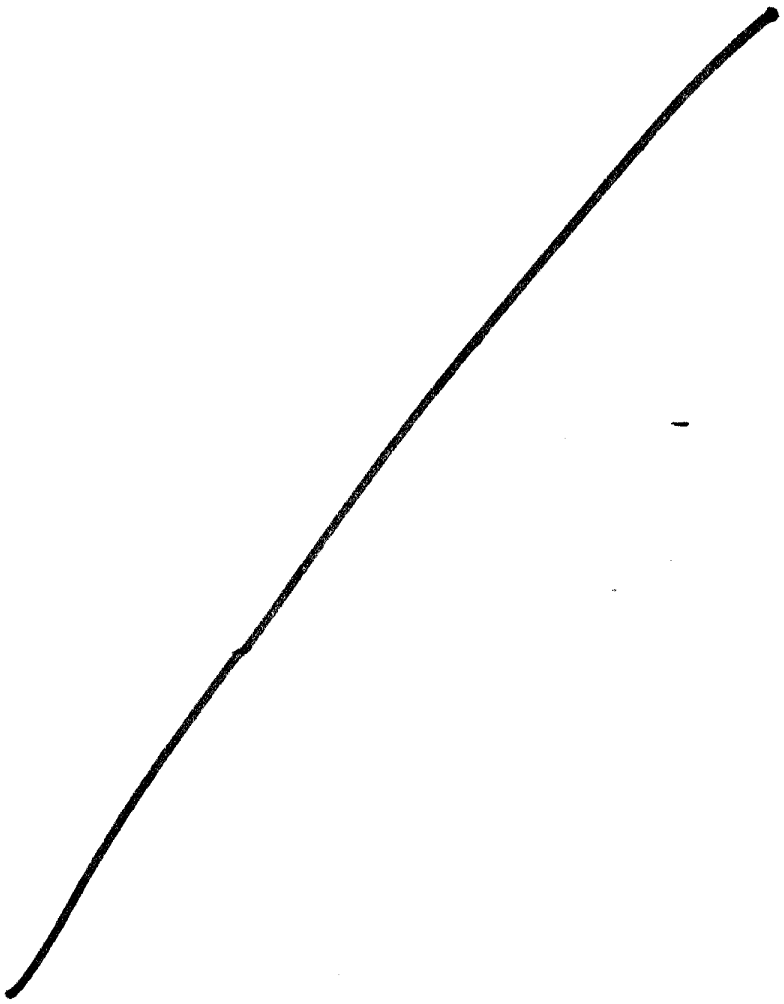
## Validity Testing Information Part I

Laboratory Name: Pacific Toxicology
Address: 6160 Variel Ave
Woodland Hills CA 91367
Responsible Person: Jeffrey K Maier (Printed Name)
Mike D Henson





I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

10-4-2000
Date

Jeffrey K. Maier
Printed Name, Responsible Person

# Validity Testing Information Part II

**Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for *each* DOT regulated specimen that was reported either adulterated or substituted:**

- **Specimen ID number**
- **Laboratory Accession Number**
- **Date of receipt**
- **Date reported**
- **Reported result (i.e., adulterated or substituted)**
- **Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)**

*Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.*

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

[redacted]

Signature, Responsible Person

10-16-08

Date

Jeffrey K. Maier

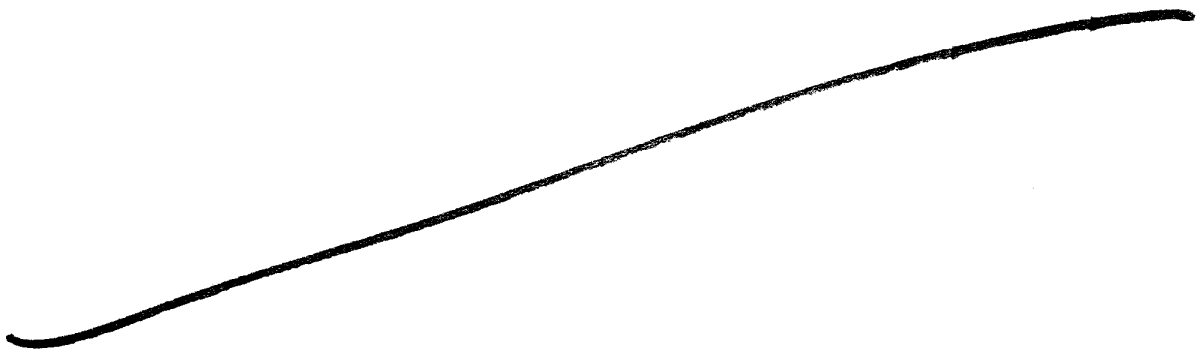
Printed Name, Responsible Person

Pacific Toxicology

447 SVT worklist.xls

# VALIDITY TESTING INFORMATION SHEET, PART II

| SPECIMEN ID NUMBER | LABORATORY ACCESION NUMBER | RECEIVED DATE | REPORTED DATE | REPORTED RESULT | CREATININE mg/dl | SPECIFIC GRAVITY | NITRITES ug/ml |
|---|---|---|---|---|---|---|---|





Pacific Toxicology Laboratories

RESEARCH TRIANGLE INSTITUTE

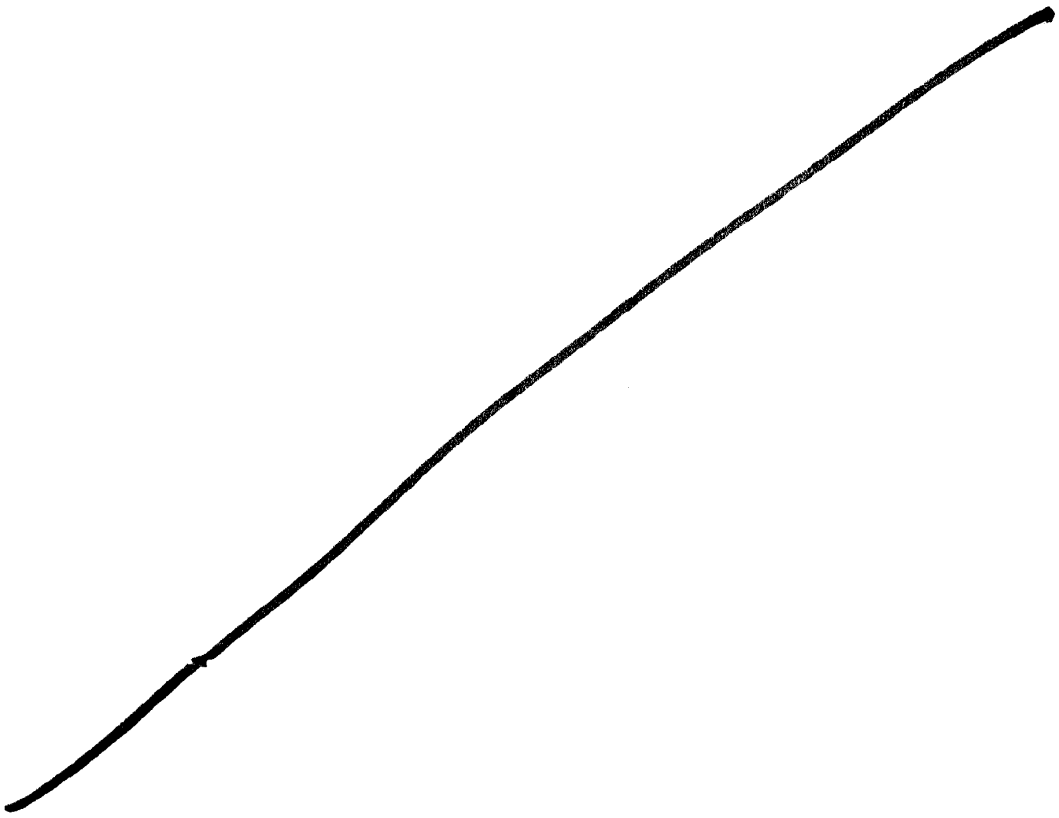
National Laboratory Certification Program

January 11, 2001

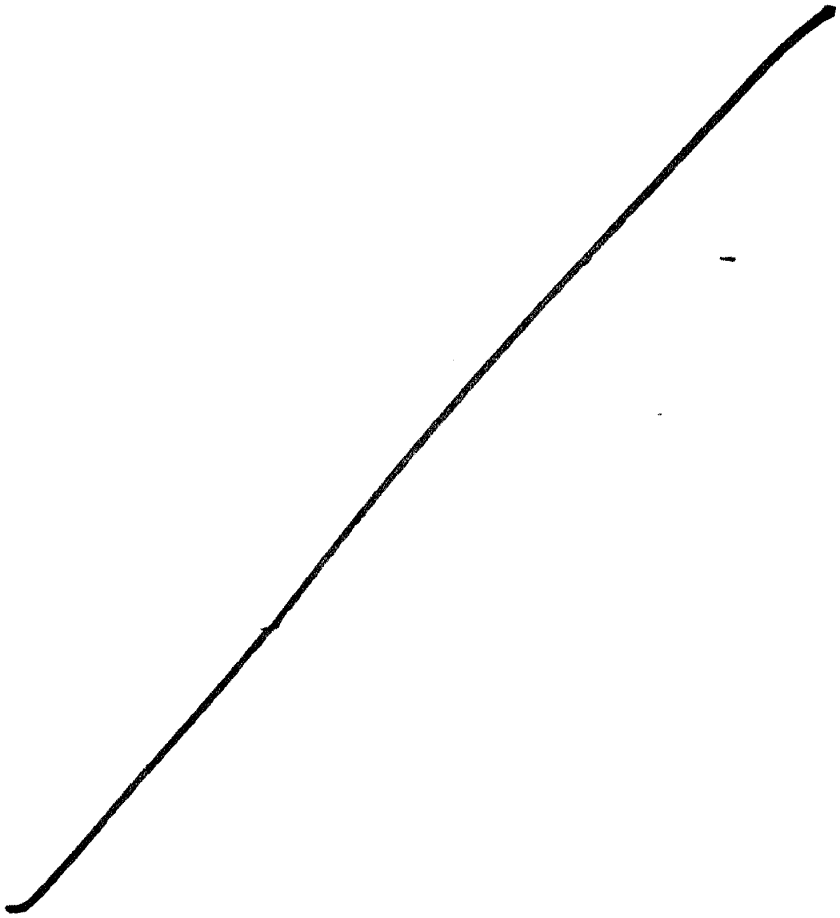
0447
Mr. Jeffrey Maier
Mr. Michael Henson
Pacific Toxicology Laboratories
6160 Variel Avenue
Woodland Hills, CA 91367

Dear Mr. Maier and Mr. Henson:

The enclosed critique was developed from the inspection report associated with the November 29, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042



The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.***

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/svt447

# NATIONAL LABORATORY CERTIFICATION PROGRAM

## Document Review and Critique

Laboratory I.D. Number: 0447
Document No. Final

Laboratory: Pacific Toxicology Laboratories

Location: Woodland Hills, CA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 29 November 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

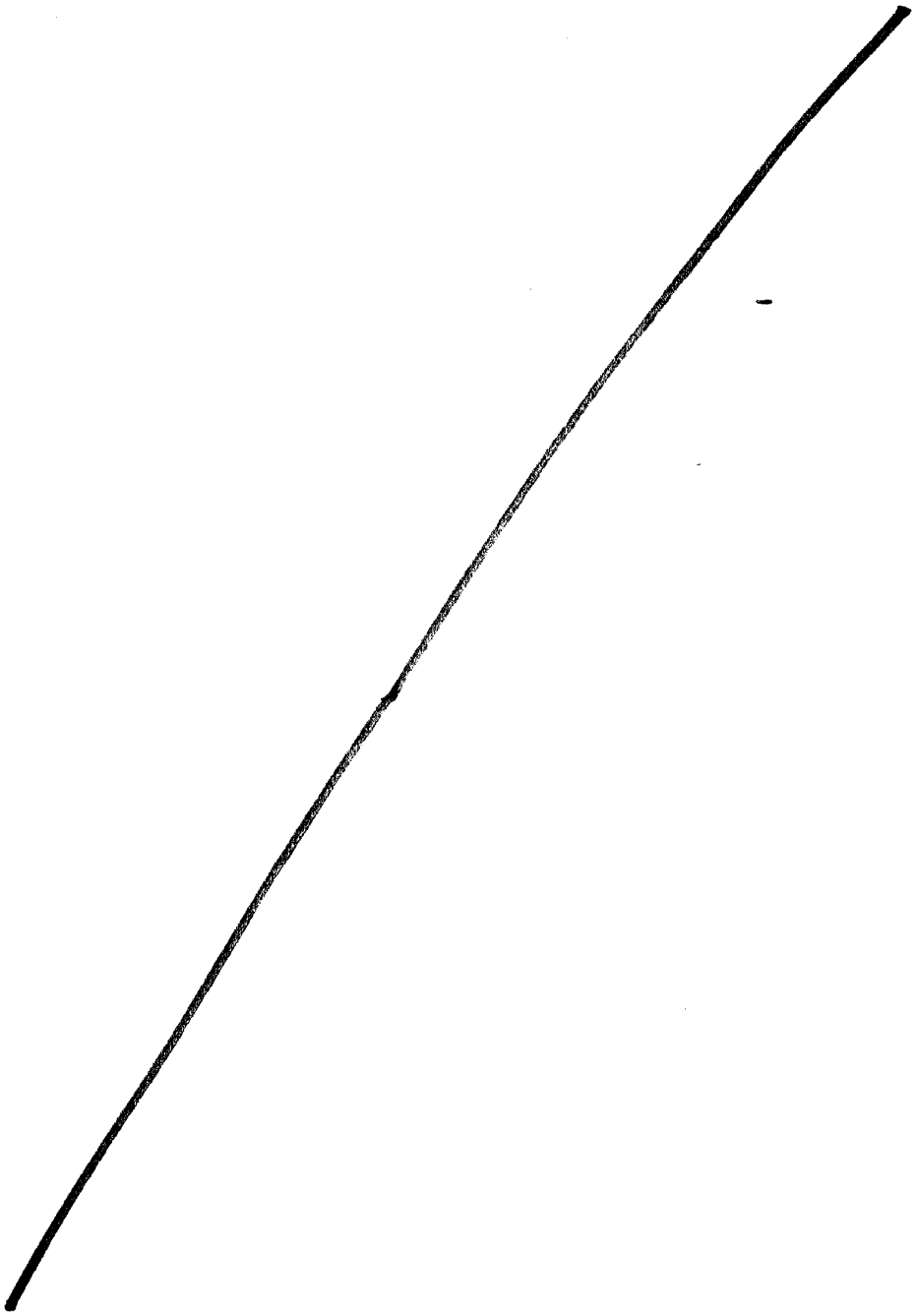
Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit



Section L. Certification and Reporting

PACIFIC TOXICOLOGY LABORATORIES PacTox 6160 Variel Ave. Woodland Hills, Ca 91367
(818) 598-3110 • FAX (818) 598-3116 • (800) 328-6942

February 16, 2001

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709-2194

RE: Pacific Toxicology Laboratories
Laboratory I.D. Number 0447
Response to Specimen Validity Testing Inspection
November 29, 2000

Dear Ms. Denson:

Enclosed please find our response to the critique and inspection report prepared from our specimen validity testing inspection under the National Laboratory Certification Program (NLCP) for review.

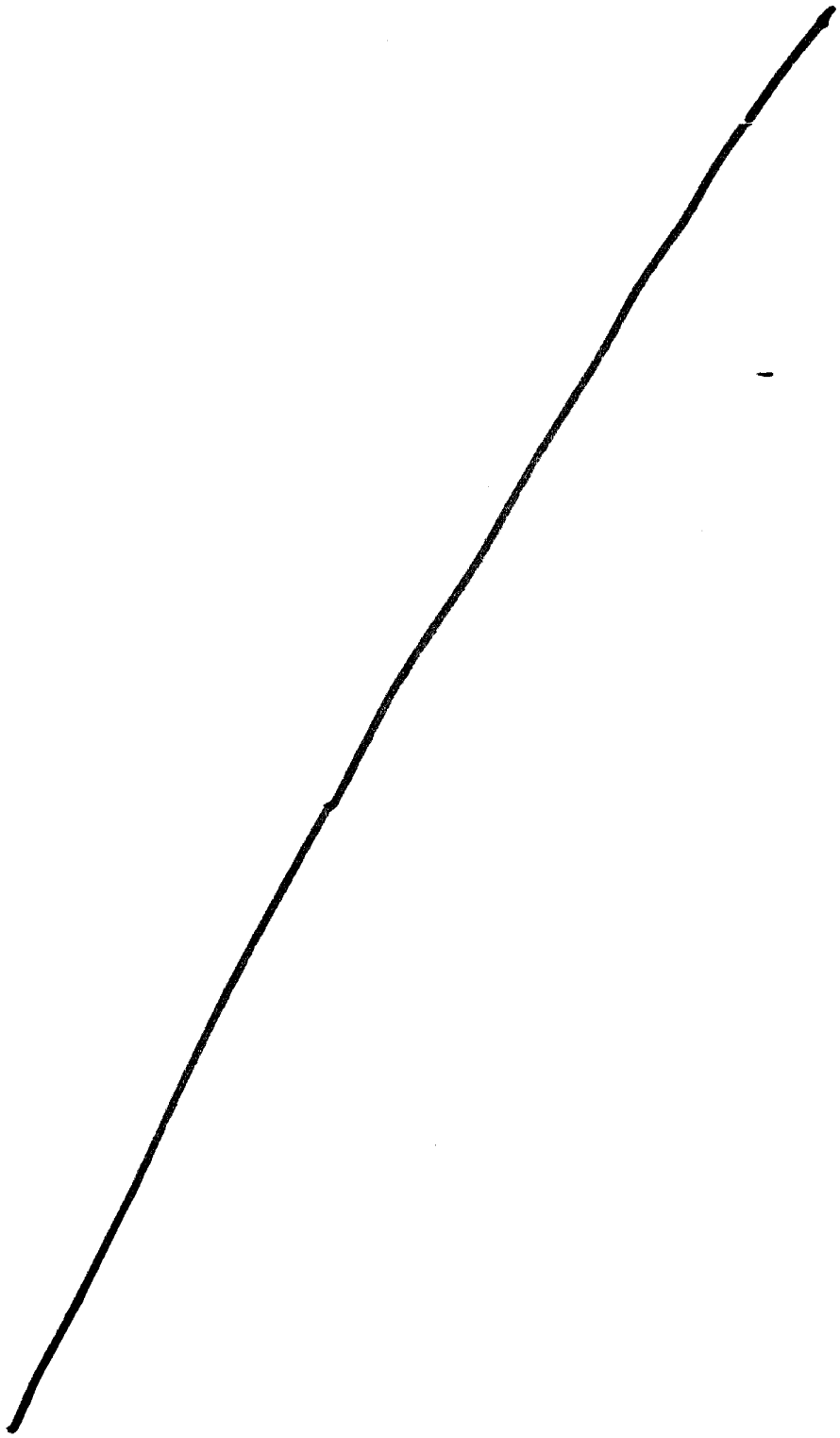
Please contact me directly at (818) 598-3110 with any questions.

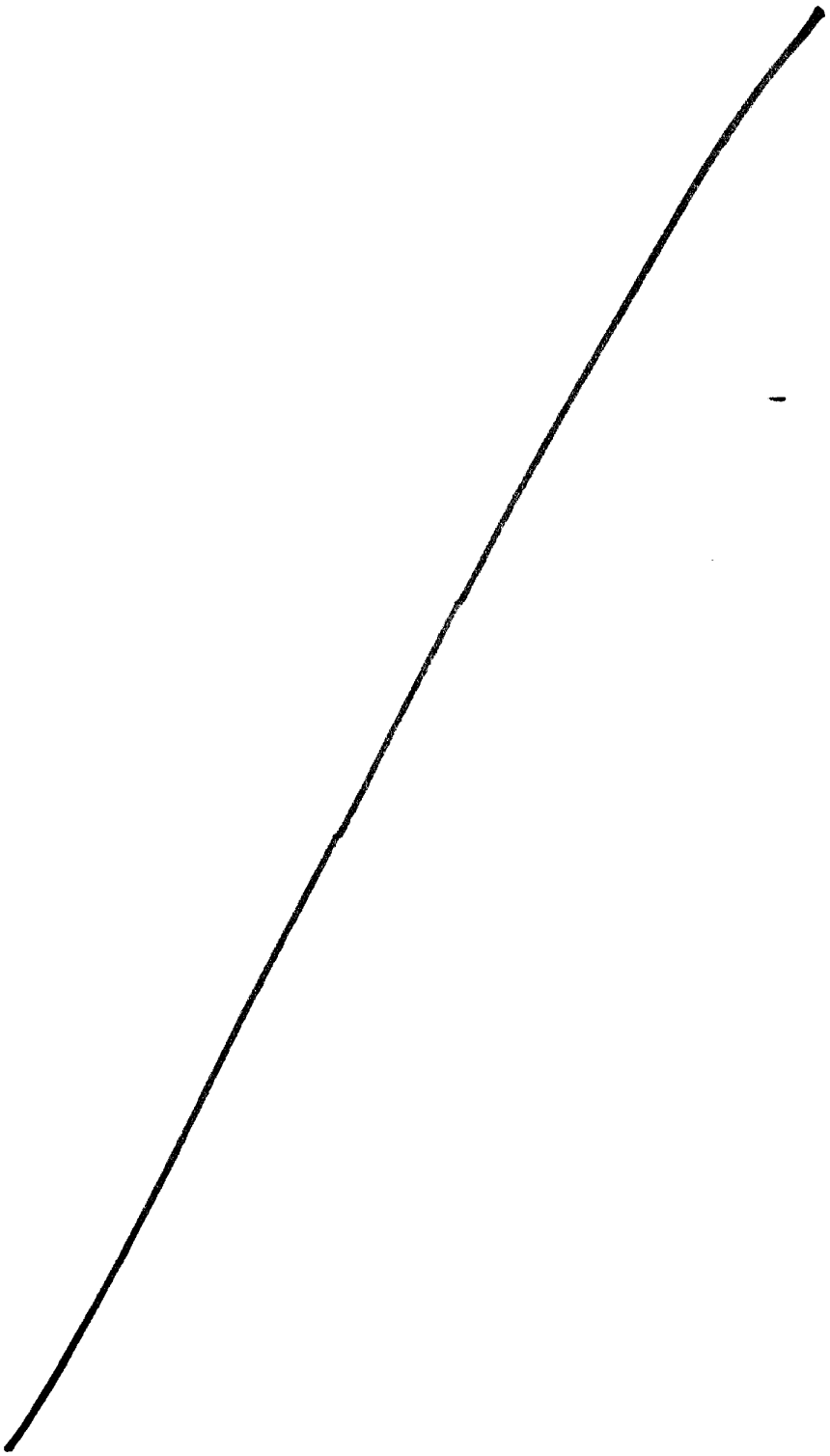
Sincerely,

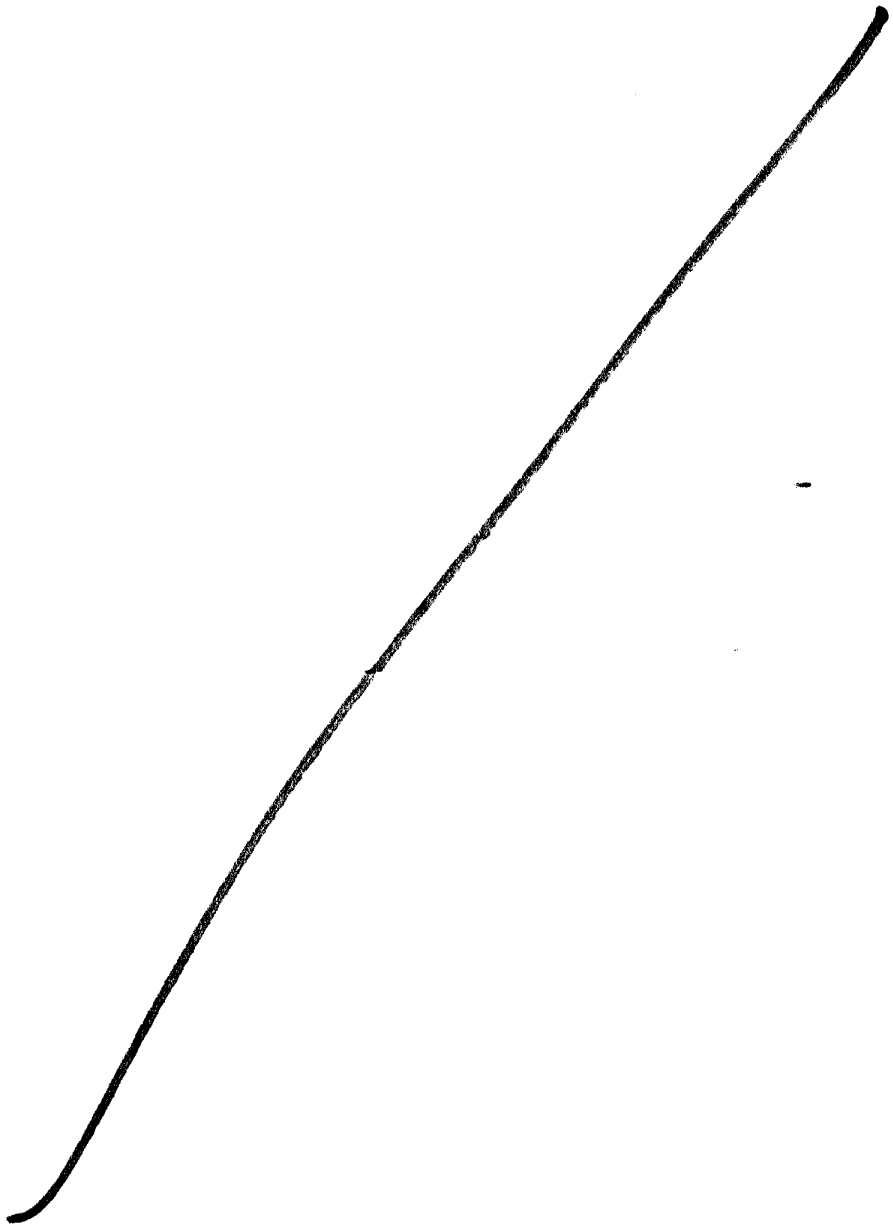
Jeffrey K. Maier
Responsible Person

Michael D. Henson
Responsible Person

Attachment







RESEARCH TRIANGLE INSTITUTE

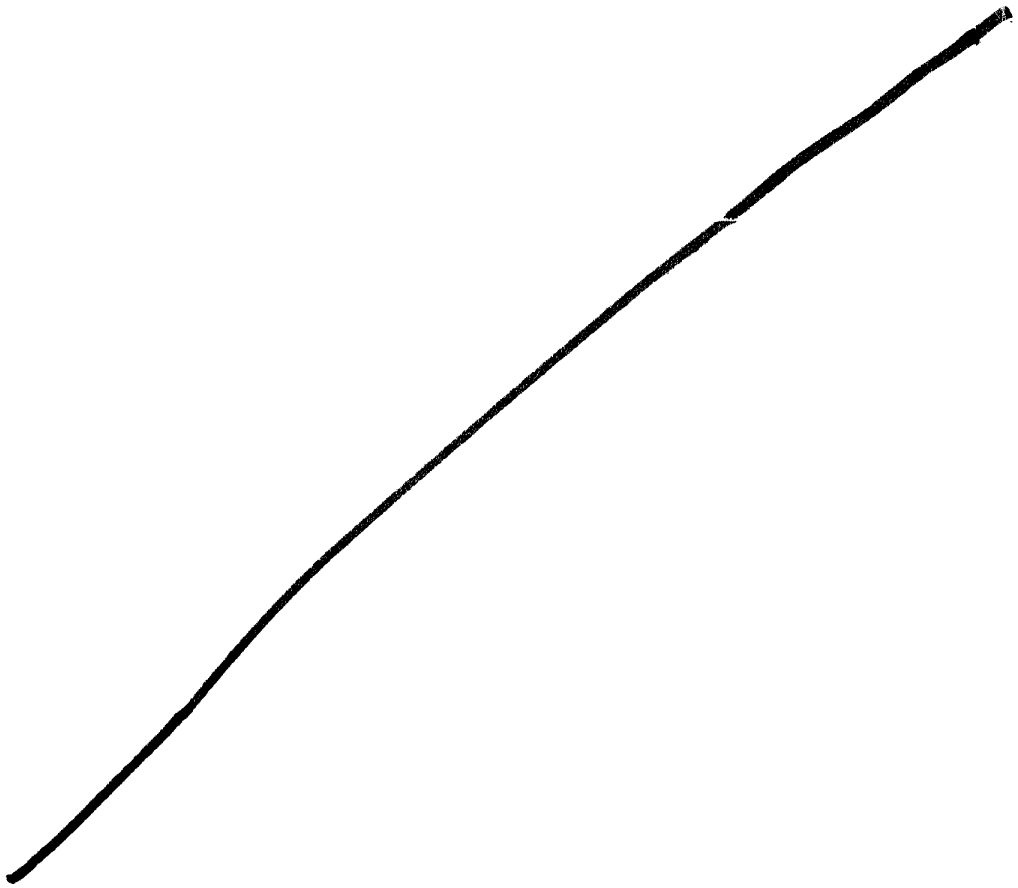
National Laboratory Certification Program

February 20, 2001

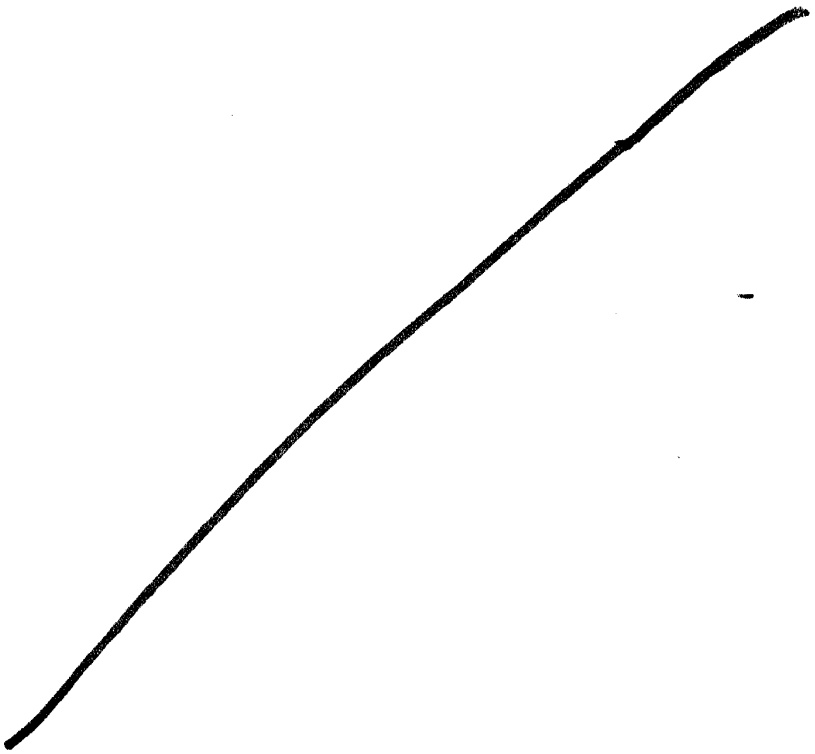
0447
Mr. Jeffrey Maier
Mr. Michael Henson
Pacific Toxicology Laboratories
6160 Variel Avenue
Woodland Hills, CA 91367

Dear Mr. Maier and Mr. Henson:

We have reviewed the material provided in your correspondence of February 16, 2001 submitted in response to issues raised during the November 29, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of January 11, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042



Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens or referral to the Department of Transportation for Public Interest Exclusion action.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT447