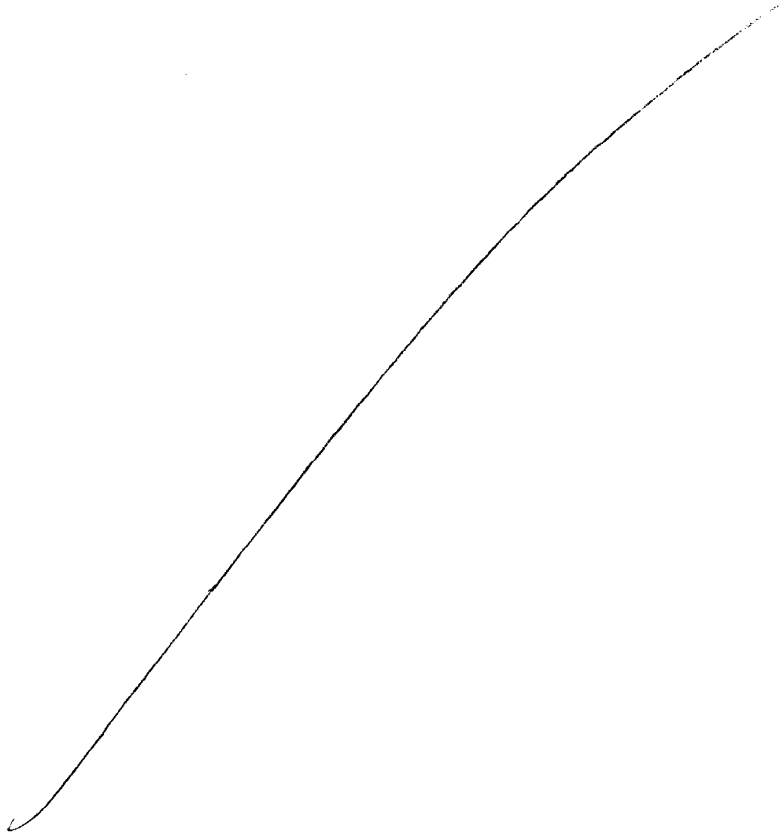
Validity Testing Information Part I

Laboratory Name: MEDTOX Laboratories Inc.
Address: 402 W. County Rd D, St Paul MN 55112

Responsible Person: Mitchell F. LcBard (Printed Name)



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).

Mitchell F LeBard — October 5, 2000

Signature, Responsible Person — Date

Mitchell F LeBard

Printed Name, Responsible Person

MEDTOX Laboratories, Inc.

Cover Plus 1 Page(s)

Date October 5, 2000

Time 13C

FAX TO: Kenneth H. Davis Jr

AT: RTI

FAX: 919-541-7042

FROM: MITCH LeBARD

1-800-832-3244 Toll-Free

COMMENTS: Per your request, if you should need any further information, please feel free to contact me at your earliest convenious

Thanks

Mitch

Z

402 West County Road D • Saint Paul, Minnesota • 55112

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).

Signature, Responsible Person

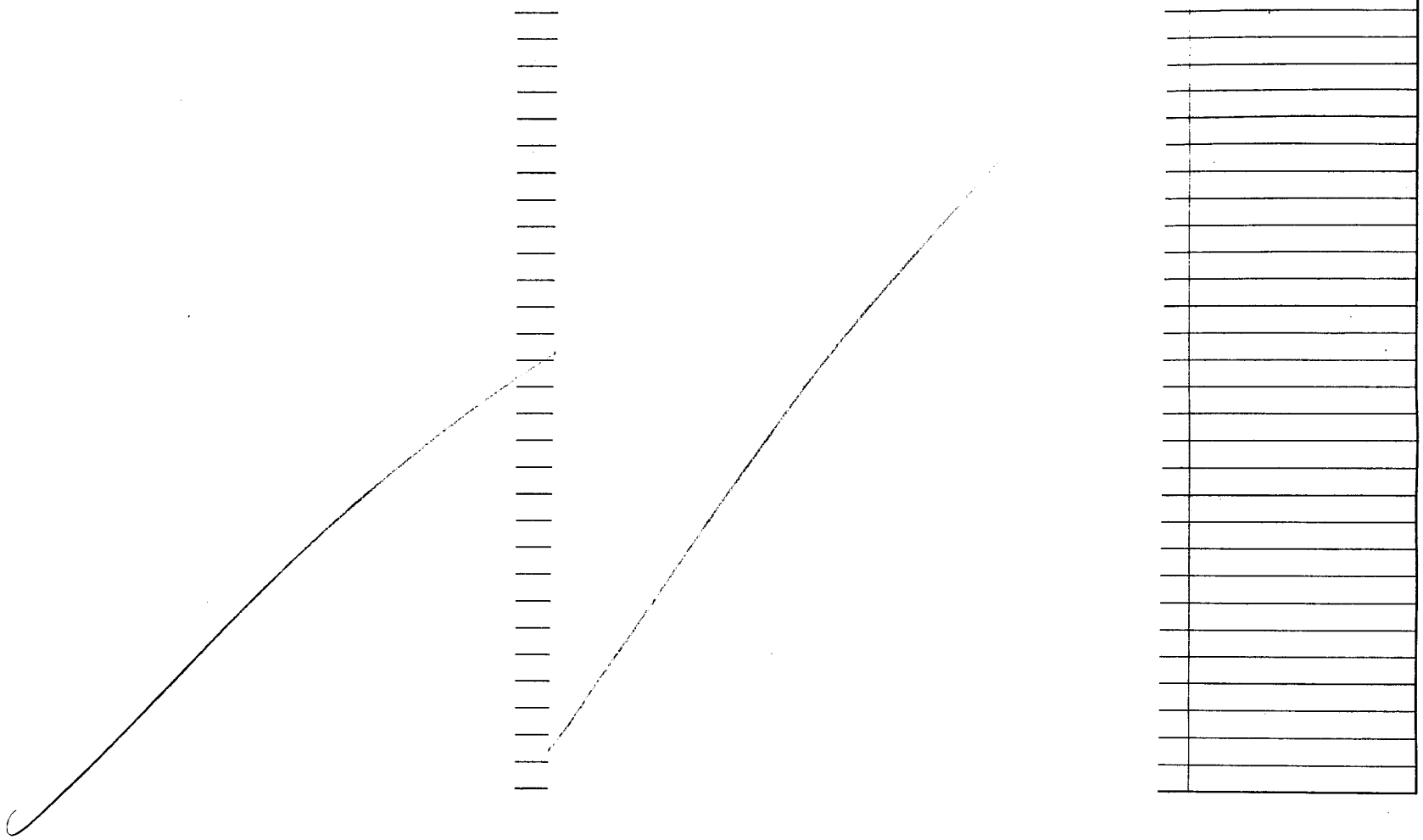
10/16/00
Date

Jennifer A Collins
Printed Name, Responsible Person

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

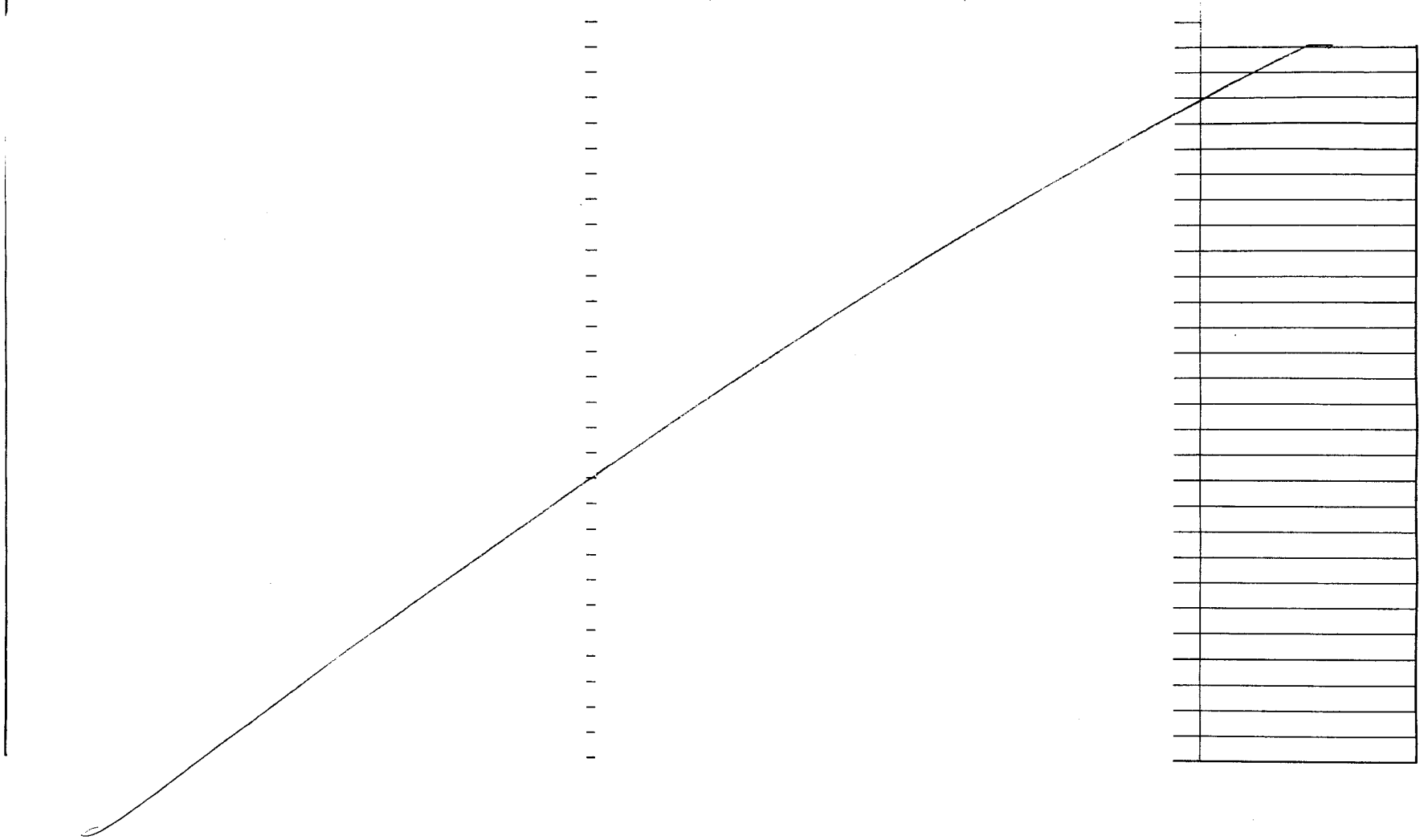
COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment
								5430				

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment



COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment



COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

COC	Accession	Date Received	Date Reported	Reported Results	Creatinine mg/dl	Sp.Gr.	pH	Nitrite µg/ml	Pyridine µg/ml	Chromium ng/ml	Glutaraldehyde	Comment

RESEARCH TRIANGLE INSTITUTE

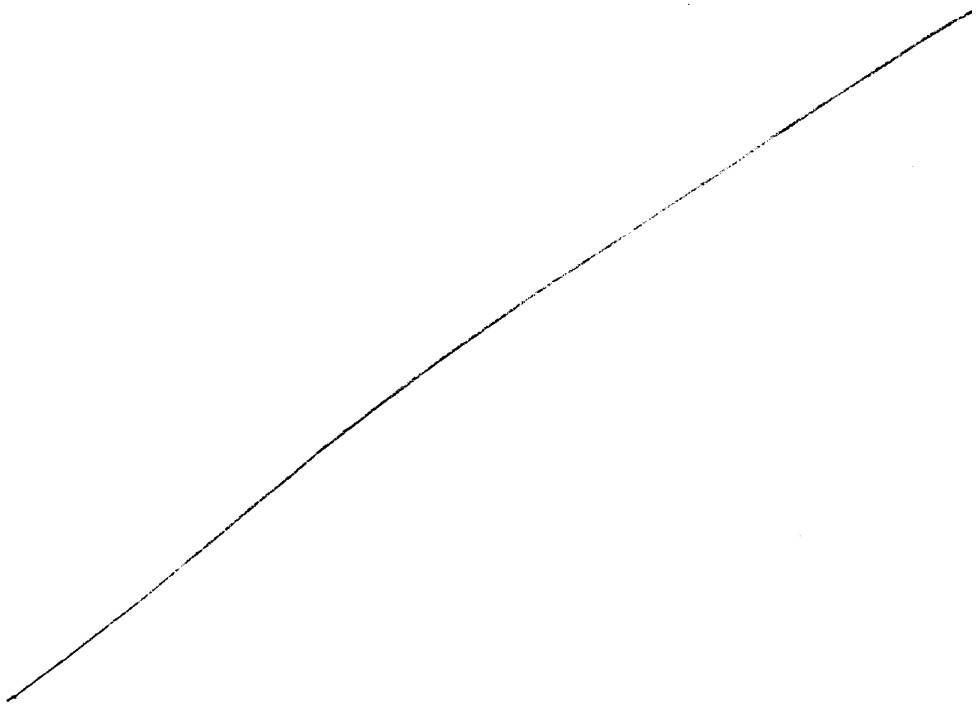
National Laboratory Certification Program

October 30, 2000

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

Dear Dr. Collins:

The enclosed critique was developed from the inspection report associated with the October 11, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full 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 raised. 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. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

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

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt094

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0094
Document No. Final

Laboratory: MedTox Laboratories, Inc.

Location: St. Paul, MN

Document Reviewed: [XX] Specimen Validity Testing Special Inspection Report

Date: 11 October 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

MEDTOX®
LABORATORIES, INC.

received

November 30, 2000

Ms. Deborah Denson
NLCP Technical Analyst
NLCP - Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

This is in response to the critique developed from the specimen validity testing inspection of MEDTOX Laboratories on October 11, 2000. The issues are addressed as numbered on your correspondence dated October 30, 2000.

This addresses all issues raised in your correspondence. Please notify me if any additional information is required.

Sincerely,

Jennifer A. Collins, Ph.D.
Director of Forensic Toxicology
MEDTOX Laboratories, Inc.

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

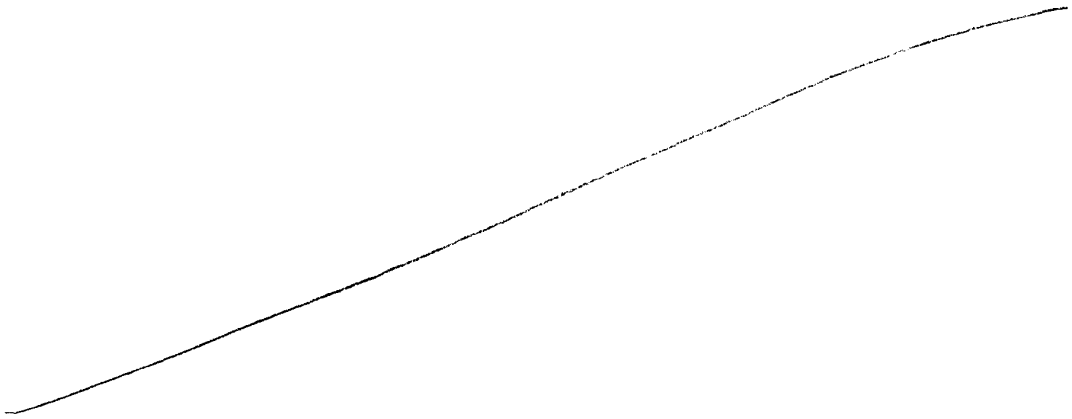
December 13, 2000

CORRECTED COPY

0094
Dr. Jennifer Collins
MedTox Laboratories, Inc.
402 West County Road D
St. Paul, MN 55112

Dear Dr. Collins:

We have reviewed the material provided in your correspondence of November 30, 2000 submitted in response to issues raised during the October 11, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of October 30, 2000. 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:



Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its 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.

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

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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT094