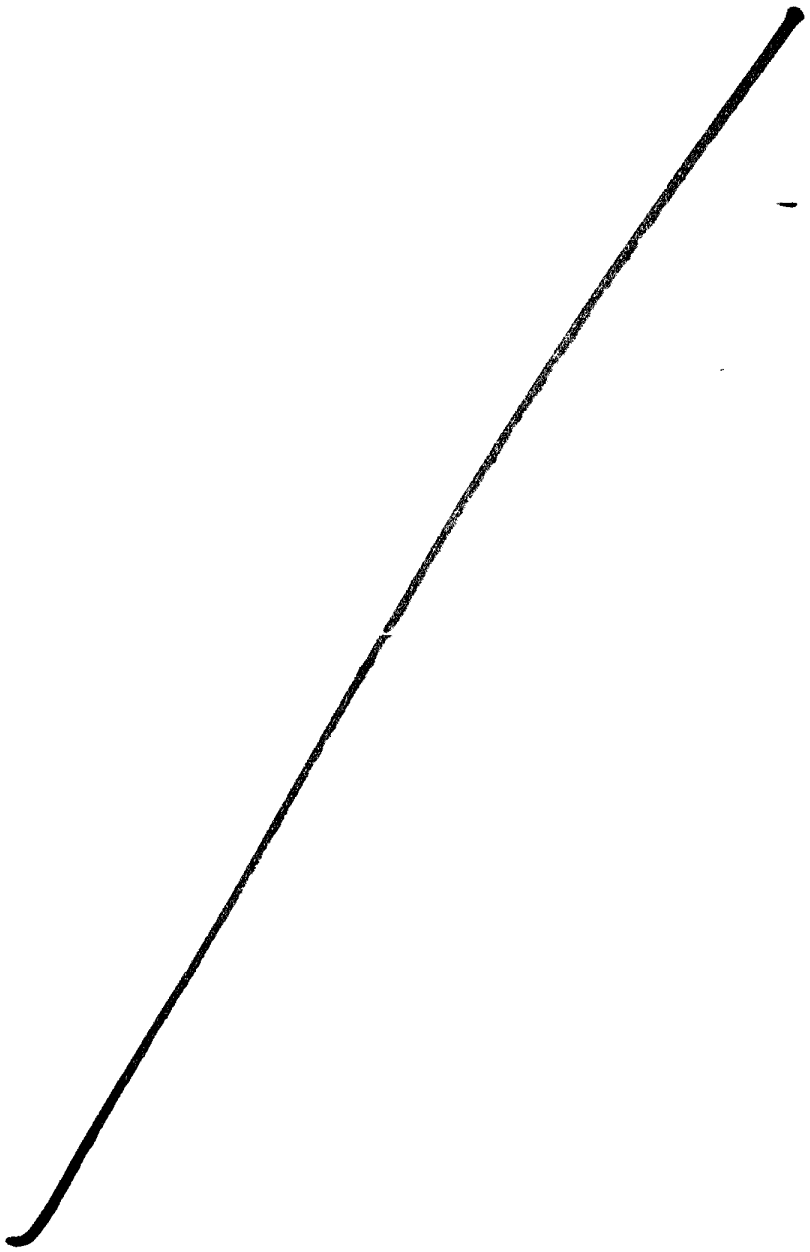
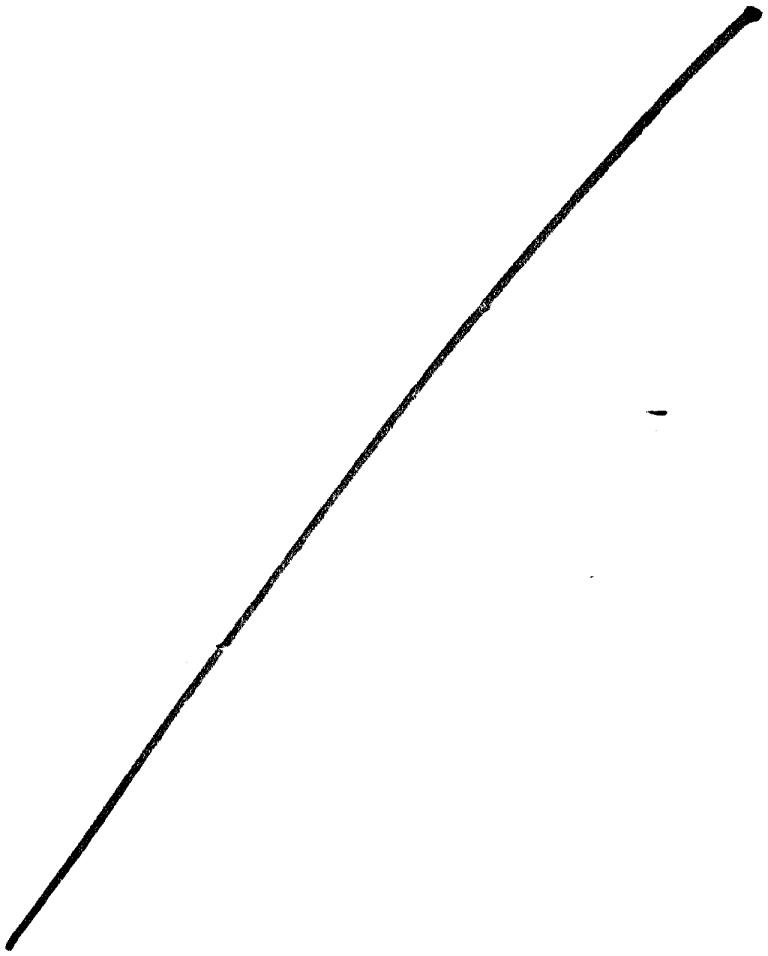
# Validity Testing Information Part I

Laboratory Name: Medical College of Ohio Hospital Toxicology Laboratory
Address: 3000 Arlington Avenue Toledo, Ohio 43614

Responsible Person: Dr. Robert B. Forney, Jr. (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).

Signature, Responsible Person

10/3/00
Date

ROBERT B. FORNEY, PHD
Printed Name, Responsible Person

DENNIS DARLING

10.3.00

**Department of Pathology**
Medical College of Ohio
Hospital, Room 0102
3000 Arlington Avenue
Toledo, Ohio 43614-2598

**Medical College of Ohio**
**Hospitals**
Healing Begins with Knowledge

**Toxicology**
(419) 383-5213

October 3, 2000

Dr. John M. Mitchell, Ph.D.
National Laboratory Certification Program
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Dr. Mitchell:

Please find enclosed the information you requested:

**The completed Validity Testing Information Part I**
**The completed Validity Testing Information Part II (hard copy and floppy)**

If you require further documentation concerning this matter, please contact me a 419-383-5213.

Sincerely,

Robert B. Forney, Ph.D.
Director of Toxicology

## 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).

Robert B Forney — 10/3/02

Signature, Responsible Person — Date

ROBERT B. FORNEY, PhD

Printed Name, Responsible Person

Dennis C. Darling — 10-3-02

DENNIS DARLING

VALIDITY TESTING INFORMATION PART II

| # | ID | ACCESSION NUMBER | DATE REC'D | DATE REPRT'D | REPORT | QUANTIFICATION |
|---|---|---|---|---|---|---|

10/3/00

10/3/00

VALIDITY TESTING INFORMATION PART II

| # | ID | ACCESSION NUMBER | DATE REC'D | DATE REPRT'D | REPORT | QUANTIFICATION |
|---|---|---|---|---|---|---|

RESEARCH TRIANGLE INSTITUTE

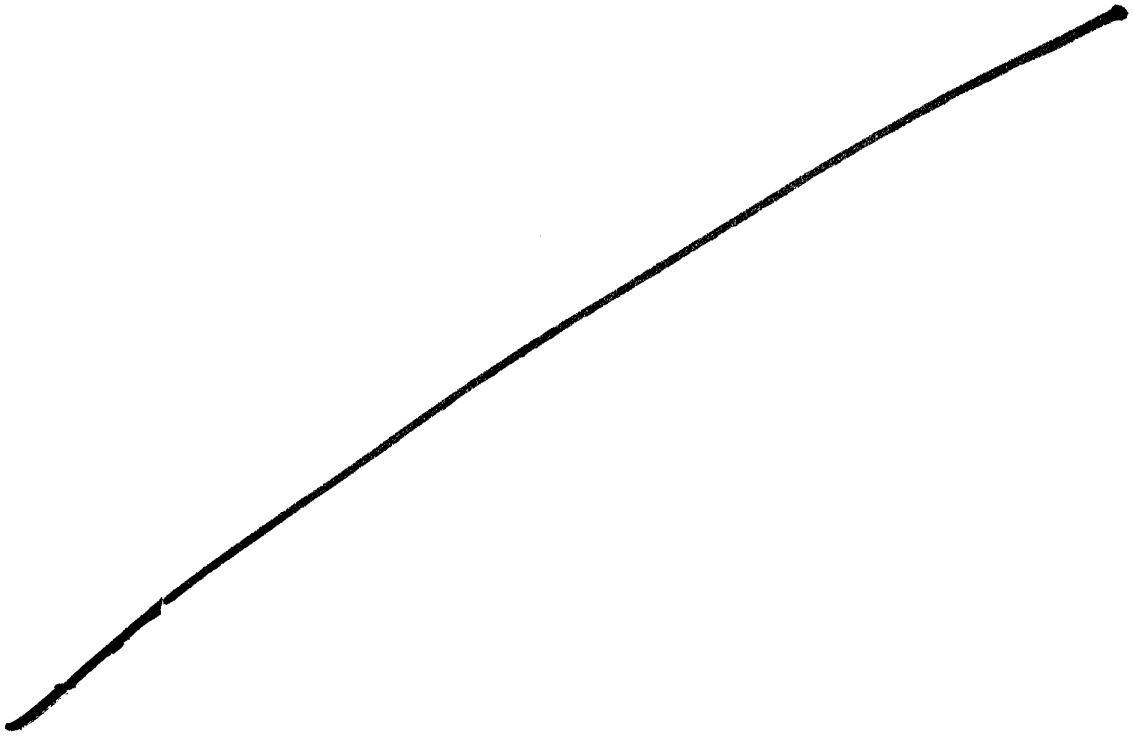
National Laboratory Certification Program

October 27, 2000

0396
Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Forney:

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/svt396

# NATIONAL LABORATORY CERTIFICATION PROGRAM

## Document Review and Critique

Laboratory I.D. Number: 0396
Document No. Final

Laboratory: Medical Colleg[illegible] spitals Toxicology Laboratory

Location: To[illegible]

Document Reviewed: [XX] Specimen Validity Testing 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.

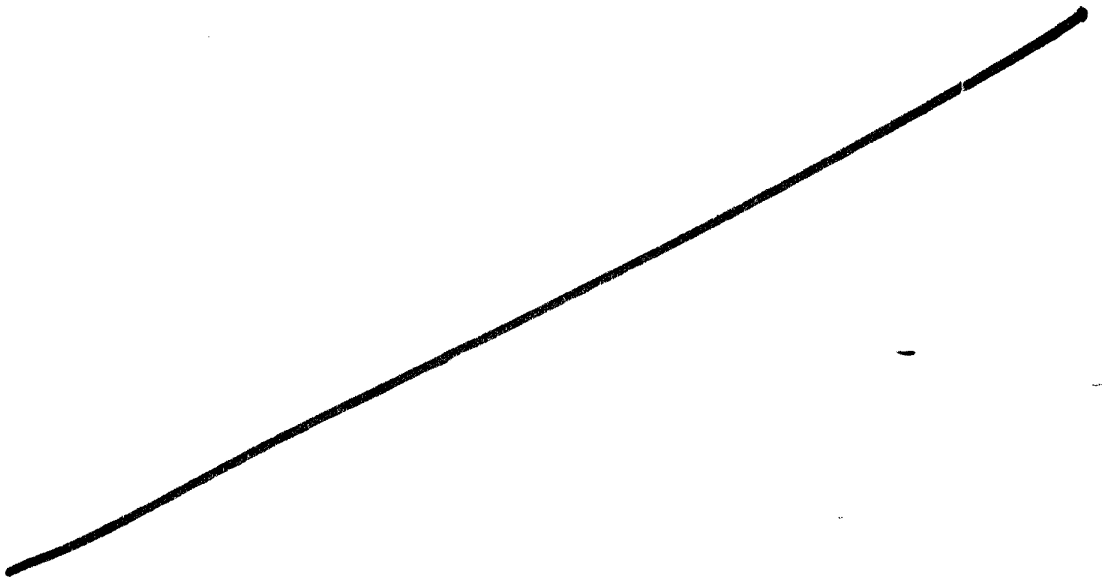
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

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

**Department of Pathology**
Medical College of Ohio
Hospital, Room 0102
3000 Arlington Avenue
Toledo, Ohio 43614-2598

**Medical College of Ohio**

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(419) 383-5213

November 30, 2000

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Re: Responses to Specimen Validity Testing Inspection Critique
Laboratory Identification No. 0396

Dear Ms. Denson:

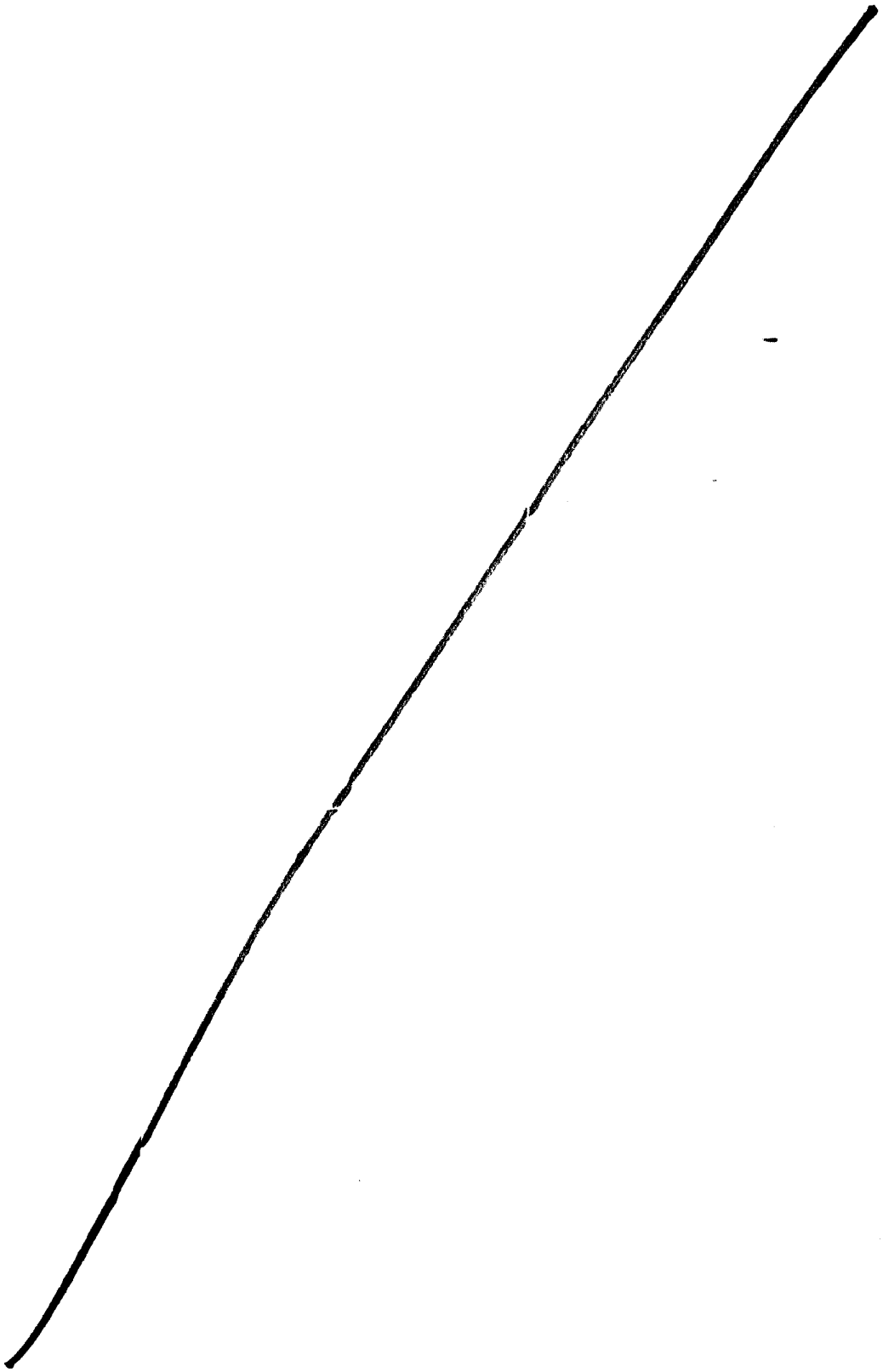
Attached are our responses to the Specimen Validity Testing Inspection Critique dated October 27, 2000.

Thank you for your attention.

Very truly yours,

Robert B. Forney, Jr., Ph.D.

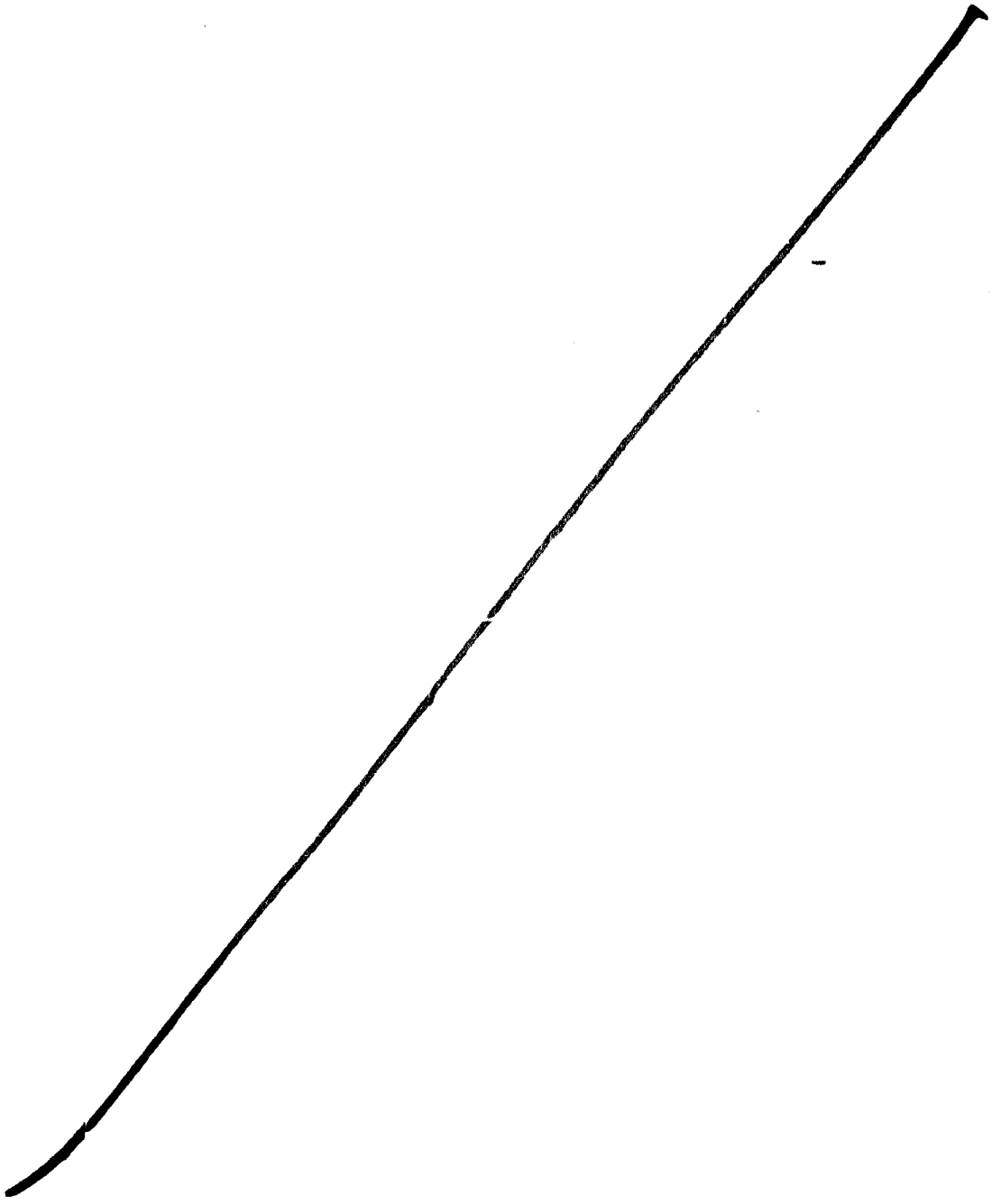
Encl.
RBF:jhs



D. Denson, NLCP Inspection Analyst

NIDA RESPONSES
NOVEMBER 30, 2000

**SECTION I SPECIMEN VALIDITY TESTS**



RESEARCH TRIANGLE INSTITUTE

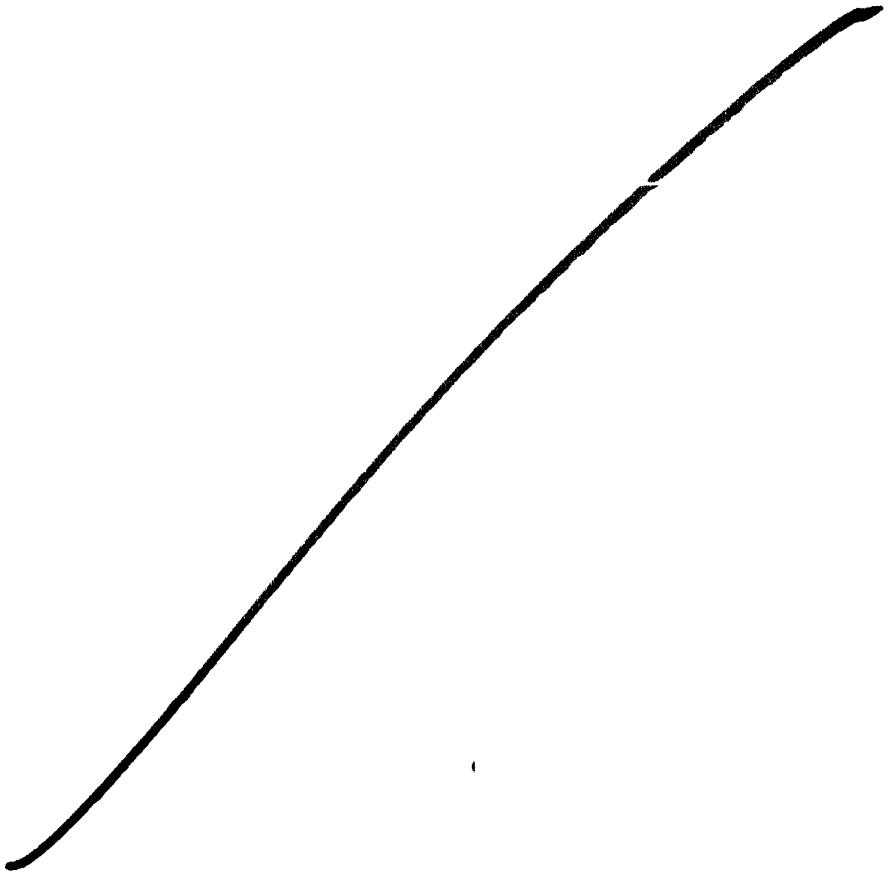
National Laboratory Certification Program

December 11, 2000

0396
Dr. Robert Forney
Mr. Dennis Darling
Medical College Hospitals Toxicology Lab
3000 Arlington Ave.
Toledo, OH 43699

Dear Dr. Forney and Mr. Darling:

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 27, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. However, the following issues require additional clarification or corrective action:



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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.***

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/SVT396