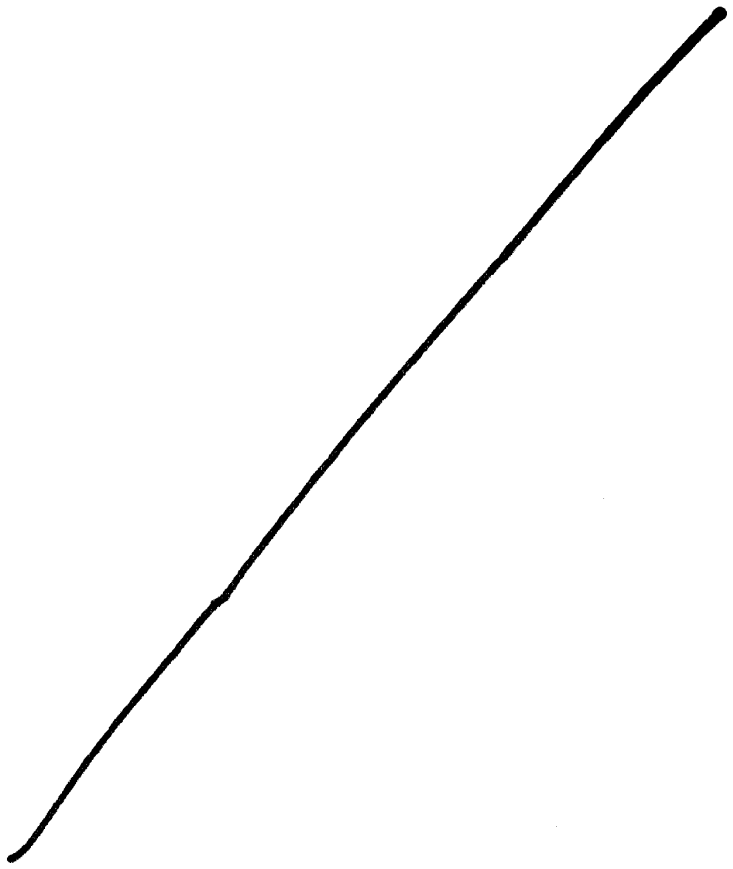
Validity Testing Information Part I

Laboratory Name: TOXICOLOGY + DRUG MONITORING LAB
Address: 2703 CLARK - COLUMBIA, MO 65202

Responsible Person: PAUL CARY (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).

Paul L. Cary
Signature, Responsible Person

10.5.00
Date

PAUL CARY
Printed Name, Responsible Person

LAB 345

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).

PK Cary
Signature, Responsible Person

10.16.00
Date

PAUL CARY
Printed Name, Responsible Person

University Hospital and Clinics
University of Missouri Health Sciences Center

Toxicology and Drug
Monitoring Laboratory

2703 Clark Lane
Suite B, Lower Level
Columbia, MO 65202

PHONE (573) 882-1273
FAX (573) 886-9792

Lab 345

October 16, 2000

Mr. Kenneth H. Davis, Jr.
Program Director
National Laboratory Certification Program
Research Triangle Institute
P. O. Box 12194
3040 Cornwallis Road,
Research Triangle Park, North Carolina 27709-2194

RE: Validation Testing Information - Part II

Dear Ken:

In response to your correspondence dated September 29, 2000, please be advised that the laboratory has completed an audit of all testing performed on DOT regulated samples from December 1, 1998 (implementation date of PD 35) to October 13, 2000.

I trust the information provided is sufficient to comply with NLCP requirements. If you have any questions or if I can provide you with additional information, please do not hesitate to contact me.

Respectfully yours,

Paul L. Cary
Scientific Director
Toxicology and Drug
Monitoring Laboratory

PLC:mac

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

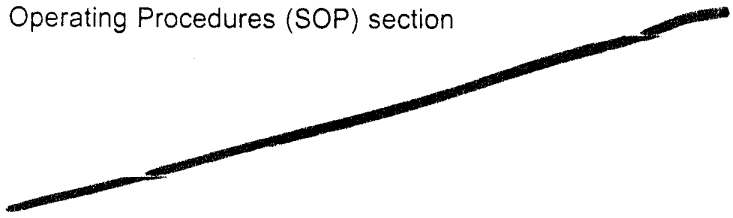
February 5, 2001

0345
Mr. Paul L. Cary
Toxicology & Drug Monitoring Lab
University of Missouri Hospital & Clinics
2703 Clark Lane - Suite B, Lower Level
Columbia, MO 65202

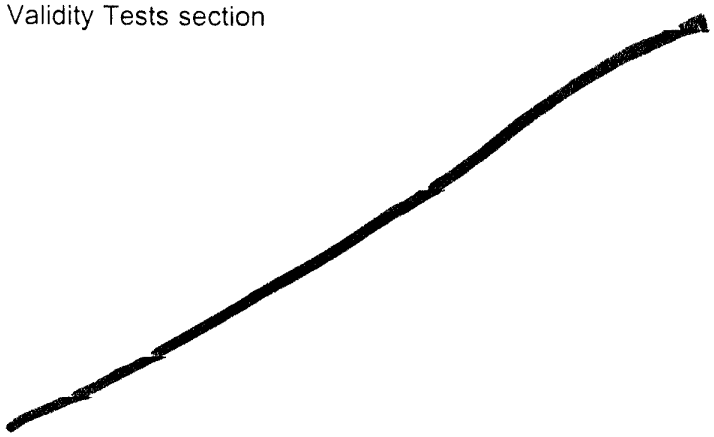
Dear Mr. Cary:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection appeared to meet most of the minimum technical criteria. However, the laboratory must take steps to correct the following issues raised:

E. The Standard Operating Procedures (SOP) section



I. The Specimen Validity Tests section



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
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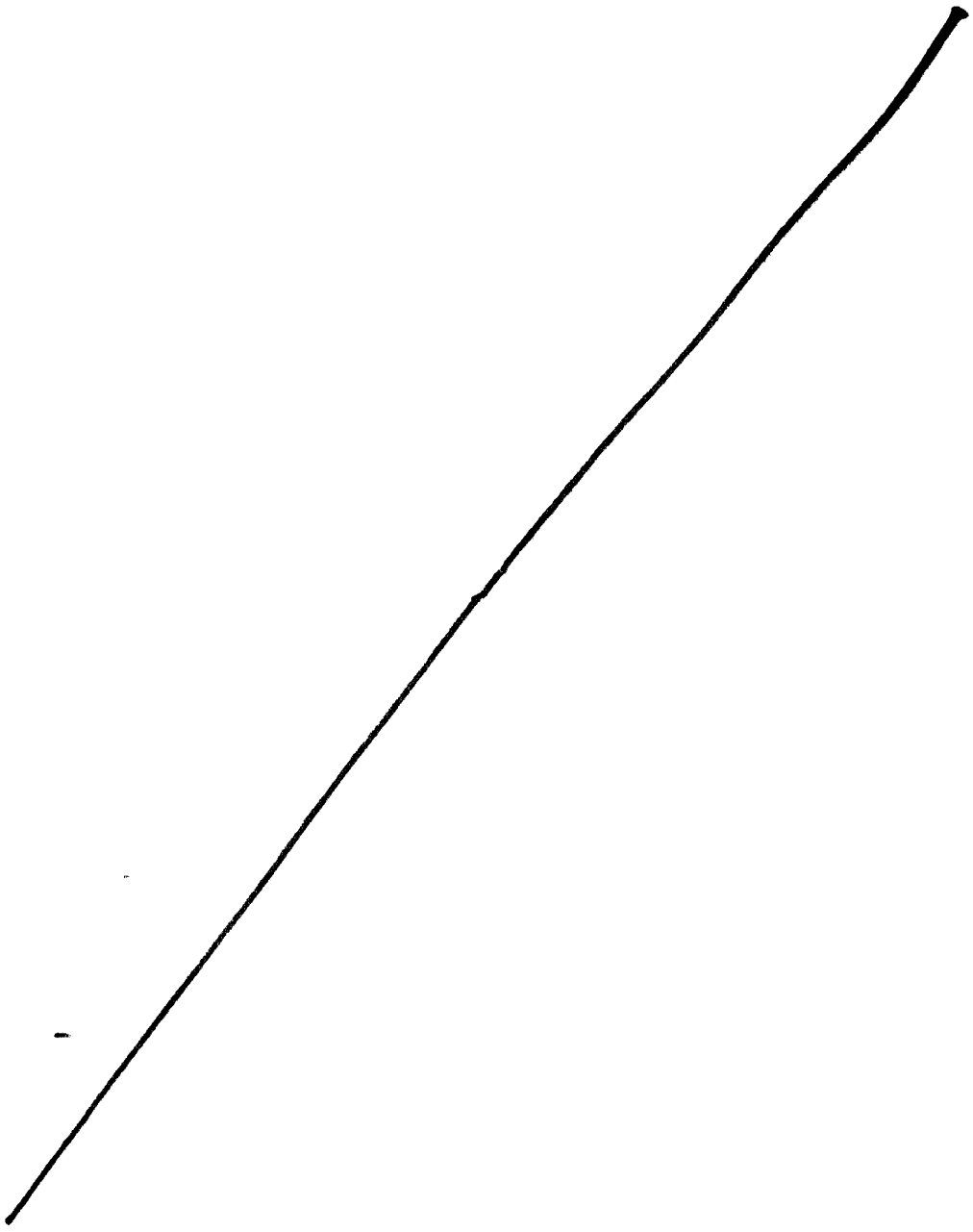


The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these issues have been successfully addressed, RTI will

recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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. ***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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure
cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0345
Document No. Final

Laboratory: Toxicology & Drug Monitoring Laboratory

Location: Columbia, MO

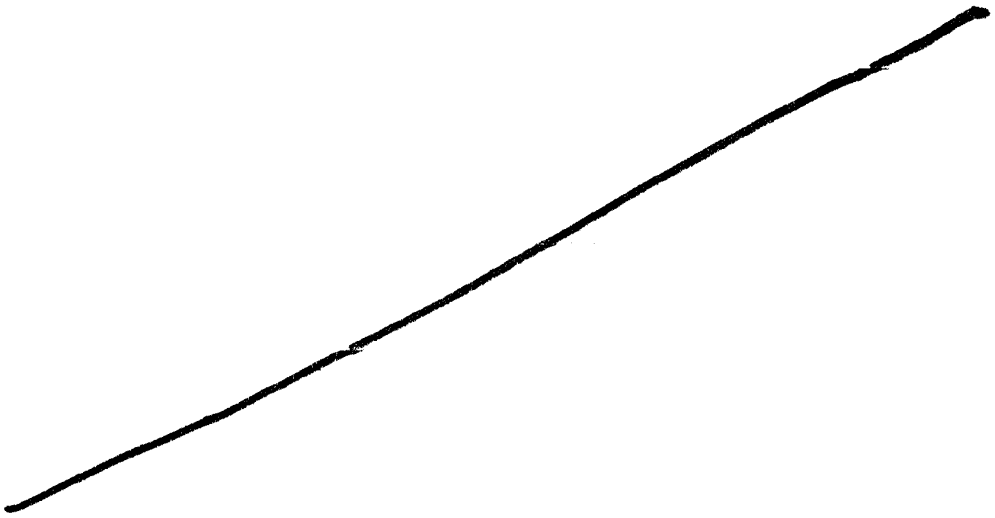
Status:
[XX] Appeared to meet most of the minimum technical criteria
[ ] Appeared to meet a number of the minimum technical criteria
[ ] Failed to meet a number of the minimum technical criteria
[ ] Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

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

Section E. Standard Operating Procedures - Procedures Manual

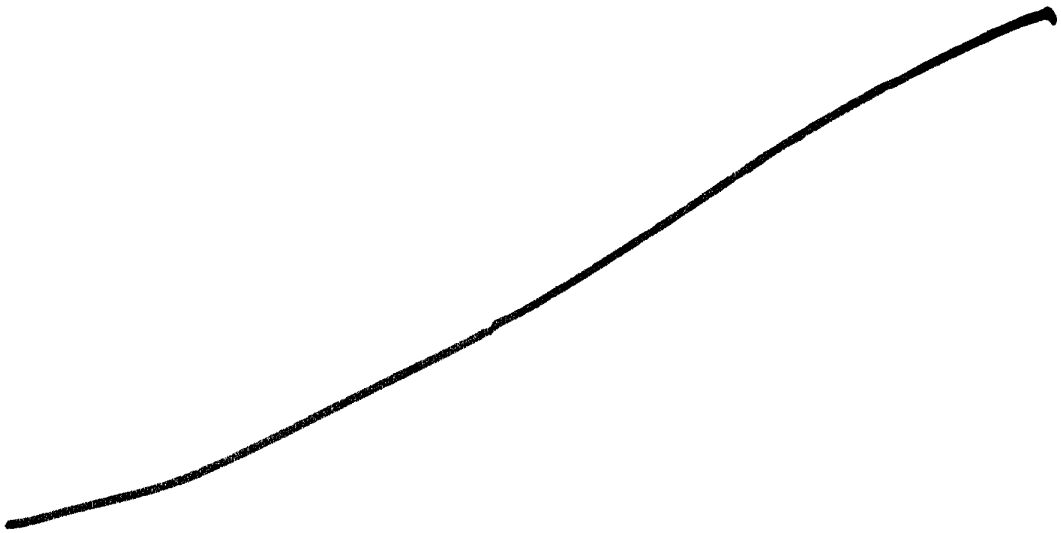


Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section H. Initial Tests

Section I. Specimen Validity Tests



Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel