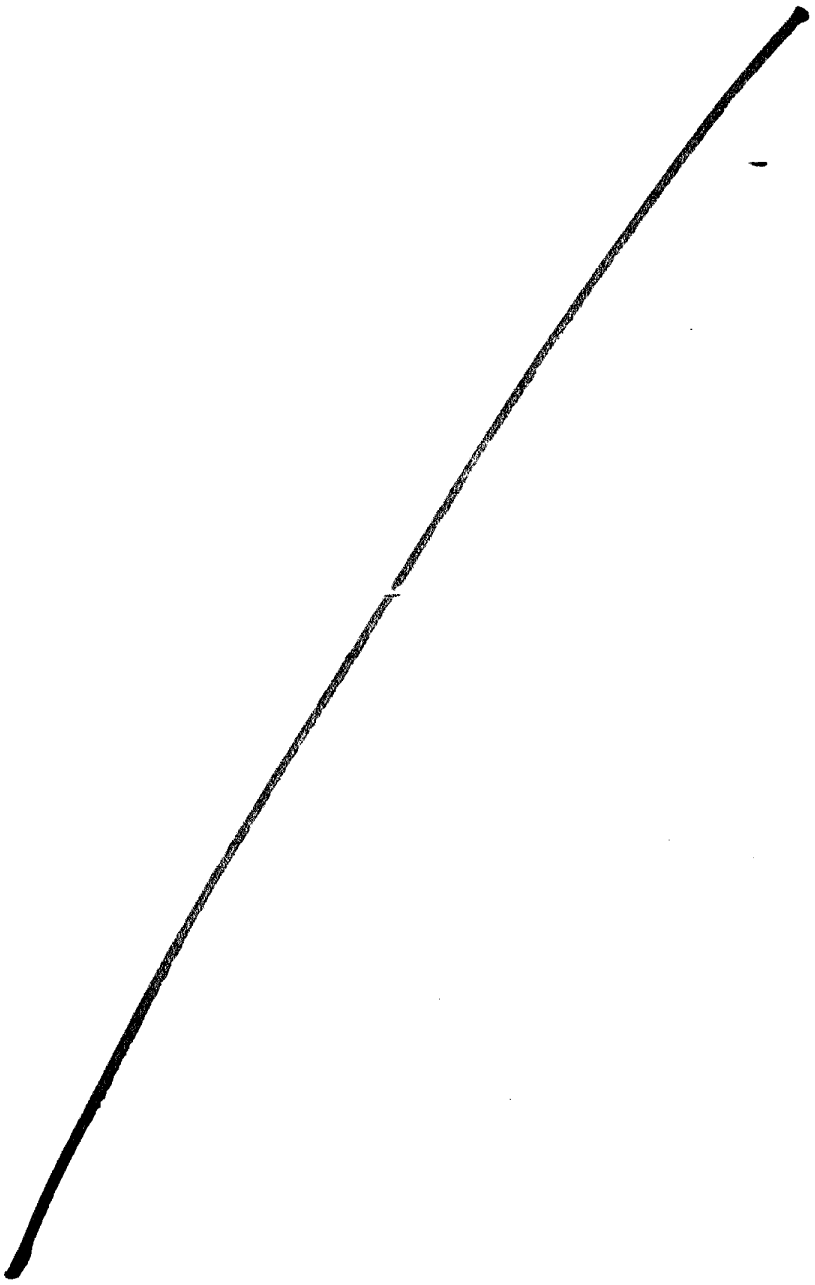
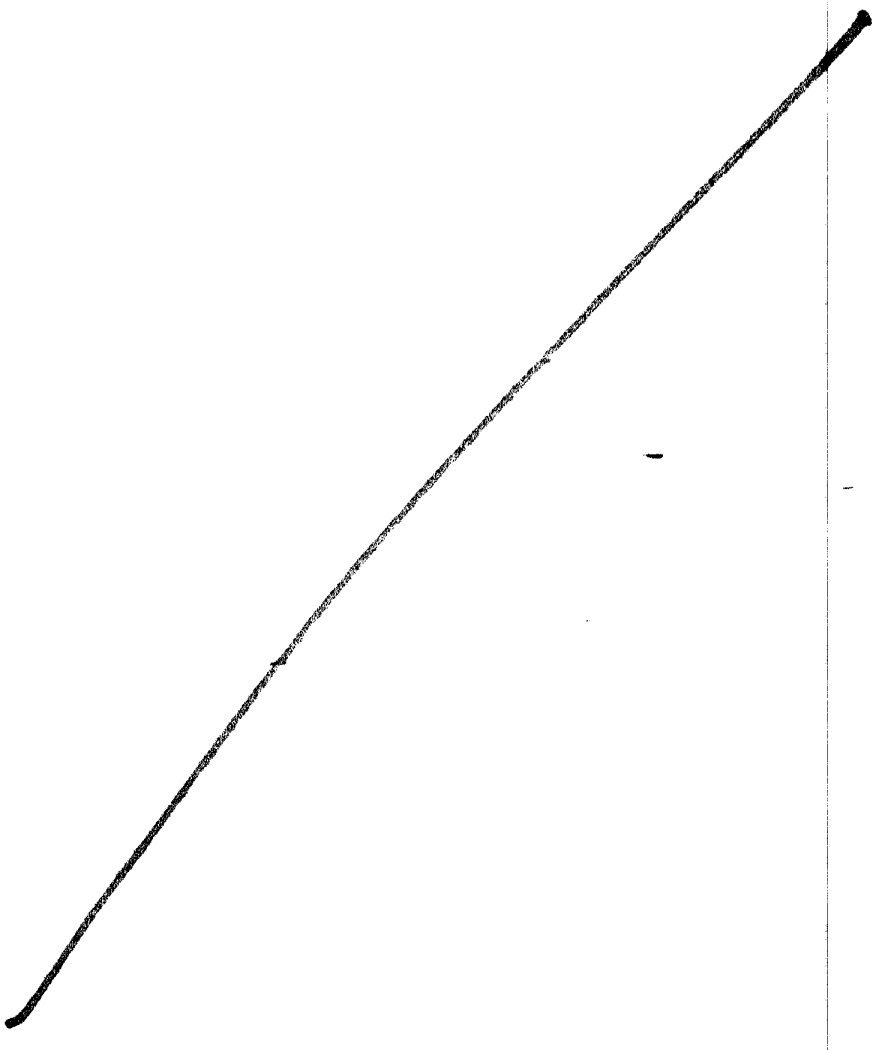
# Validity Testing Information Part I

Laboratory Name: Physicians Reference Laboratory
Toxicology Section
Address: 7800 W. 110th Street
Overland Park, KS 66211

Responsible Person: David K. Roberts Ph.D (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

10/04/00
Date

David K Roberts Ph.D.
Printed Name, Responsible Person

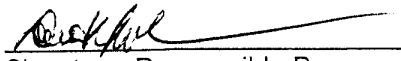
# Validity Testing Information Part II

**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).



Signature, Responsible Person

10/04/00

Date

David K. Roberts Ph.D.

Printed Name, Responsible Person

RTI adulterated substituted specimen audit Oct2000

**Physicians Reference Laboratory**
7800 W. 110th Street
Overland Park, KS 66210
(913) 339-0372
FAX (913) 339-0449

| # | Specimen ID # | LAN | Receipt Date | Report Date | Adulterated | Substituted | Creatinine | SG |
|---|---|---|---|---|---|---|---|---|
| [redacted] | | | | | | | | |

Creat units = mg/dL

Prepared by Dr. Roberts 10/4/00

**Physicians Reference Laboratory**
7800 W. 110th Street
Overland Park, KS 66210
(913) 339-0372
FAX (913) 339-0449

| # | Specimen ID # | LAN | Receipt Date | Report Date | Iulterat | Substituted | Creatinine | SG | Run # |
|---|---|---|---|---|---|---|---|---|---|
| [redacted] | | | | | | | | | |

Creat units = mg/dL

**Physicians Reference Laboratory**
7800 W. 110th Street
Overland Park, KS 66210
(913) 339-0372
FAX (913) 339-0449

| # | Specimen ID # | LAN | Receipt Date | Report Date | Adulterated | Substituted | Creatinine | SG |
|---|---|---|---|---|---|---|---|---|
| [redacted] | | | | | | | | |

Creat units = mg/dL

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 12, 2001

0412
Dr. David K. Roberts
Physicians Reference Laboratory
7800 West 110th Street
Overland Park, KS 66210

Dear Dr. Roberts:

The enclosed critique was developed from the inspection report associated with the December 7, 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/svt412

# NATIONAL LABORATORY CERTIFICATION PROGRAM

## Document Review and Critique

Laboratory I.D. Number: 0412
Document No. Final

Laboratory: Physicians Reference Laboratory

Location: Overland Park, KS

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 7 December 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.

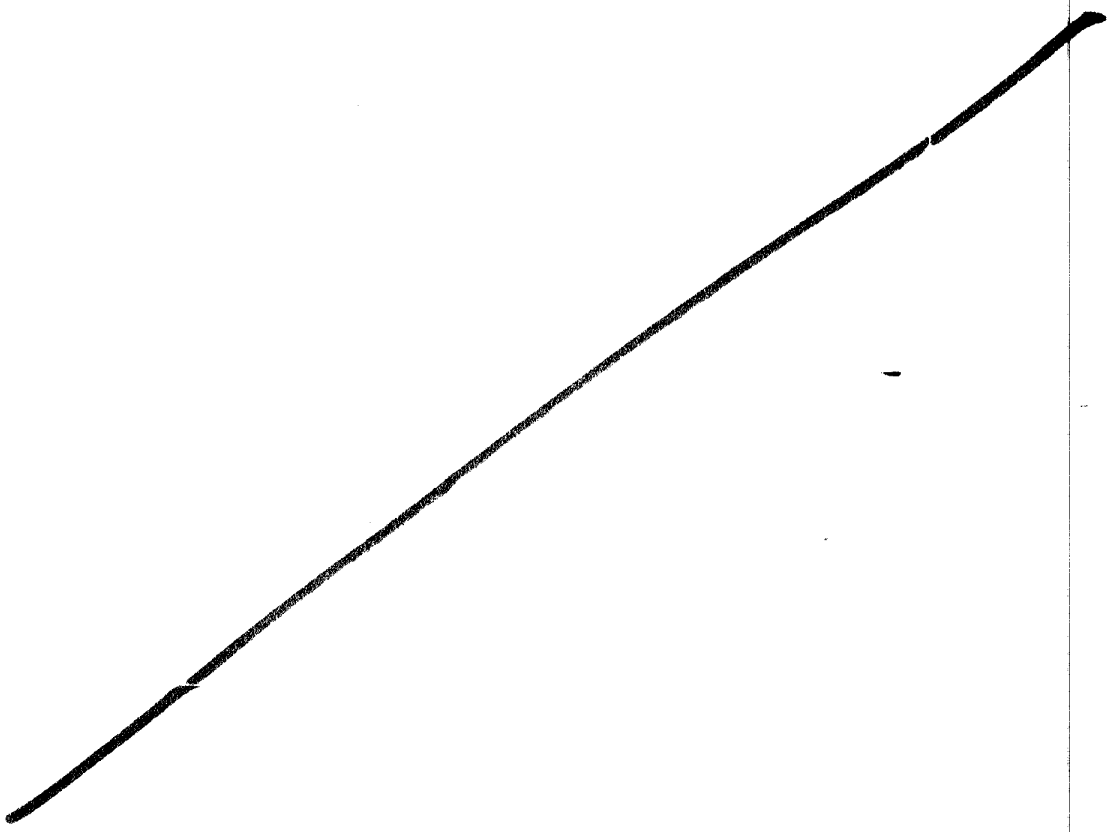
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

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

PHYSICIANS REFERENCE LABORATORY
Toxicology Section
7800 W. 110th Street
Overland Park, KS 66210

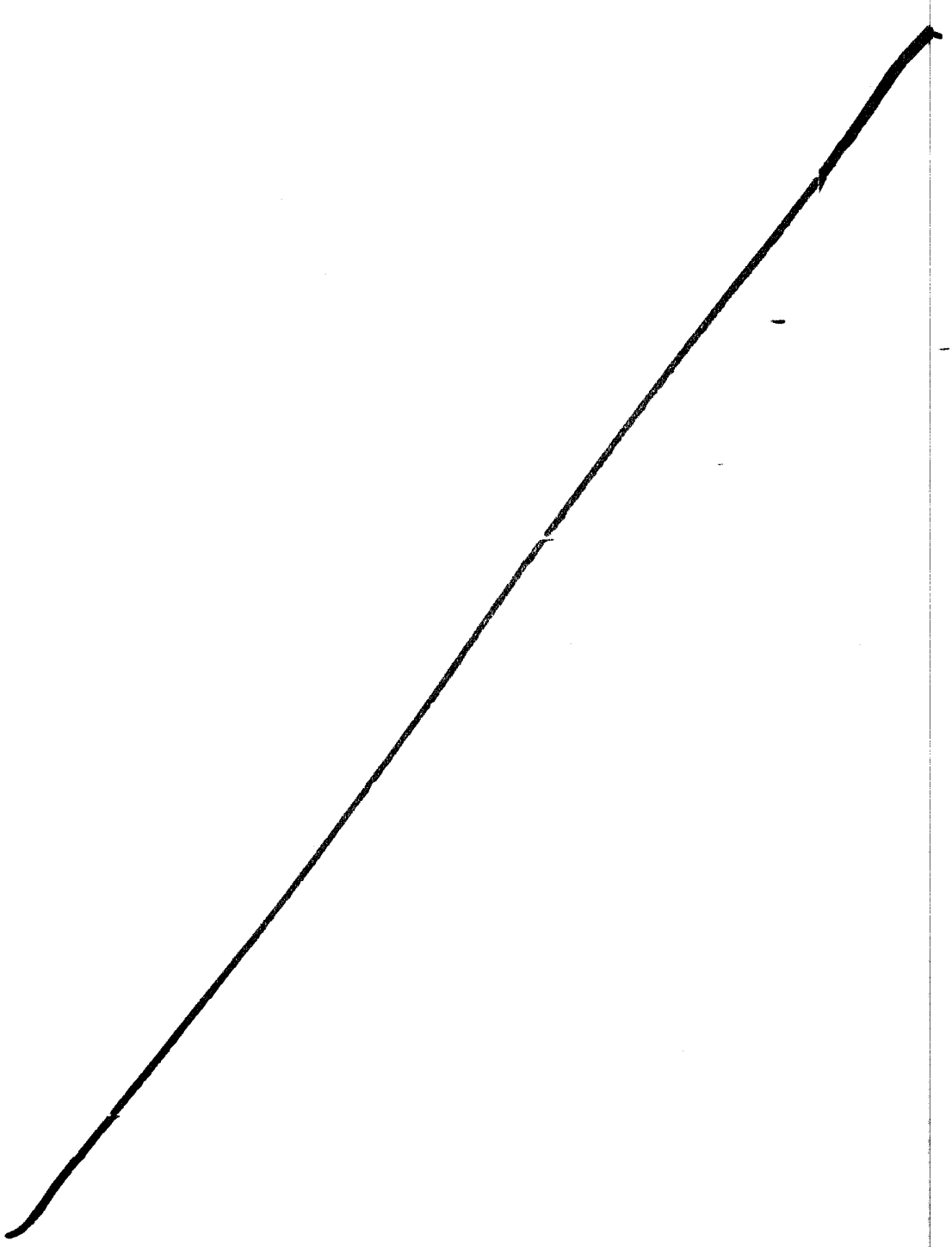
February 7, 2001

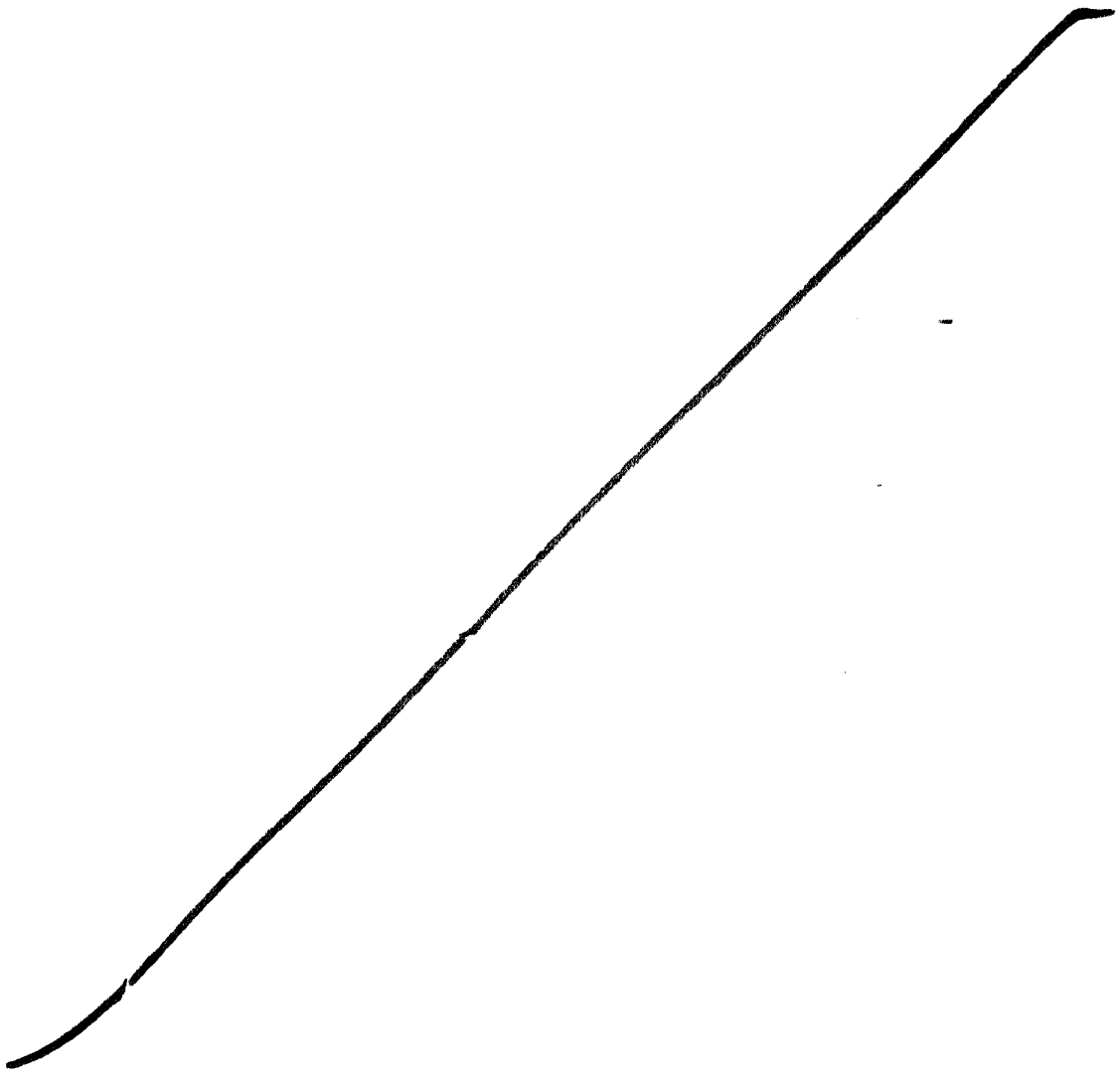
Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC

Re: 12/07/00 SVT Inspection Report Response

Dear Ms. Denson:

Our laboratory has taken the following actions in regards to your letter dated 01/12/01.





Thank you, in advance, for your review of our response. Please do not hesitate to contact us if you have any questions or require additional information. We look forward to hearing from you in this regard.

Respectfully,

David K. Roberts, Ph.D.
Toxicology Director

Enclosures: Exhibits

RESEARCH TRIANGLE INSTITUTE

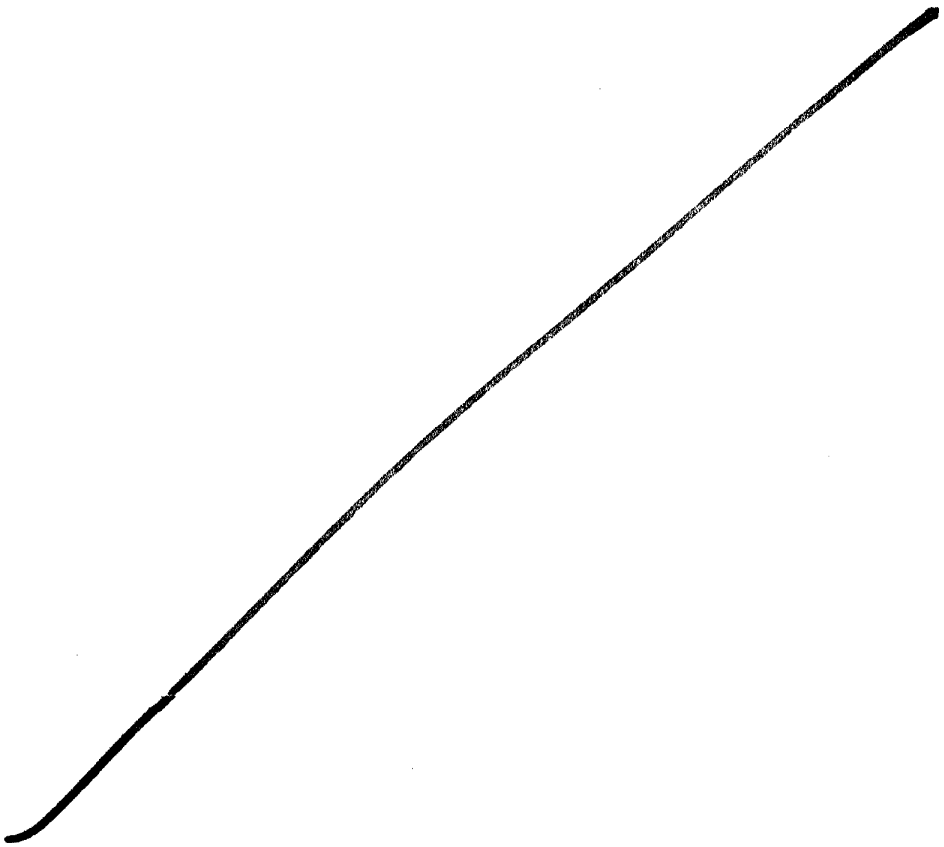
National Laboratory Certification Program

February 9, 2001

0412
Dr. David K. Roberts
Physicians Reference Laboratory
7800 West 110th Street
Overland Park, KS 66210

Dear Dr. Roberts:

We have reviewed the material provided in your correspondence of February 07, 2001 submitted in response to issues raised during the December 07, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of January 12, 2001. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:



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Telephone 919 541-6709 • Fax 919 541-7042

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.

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/SVT412