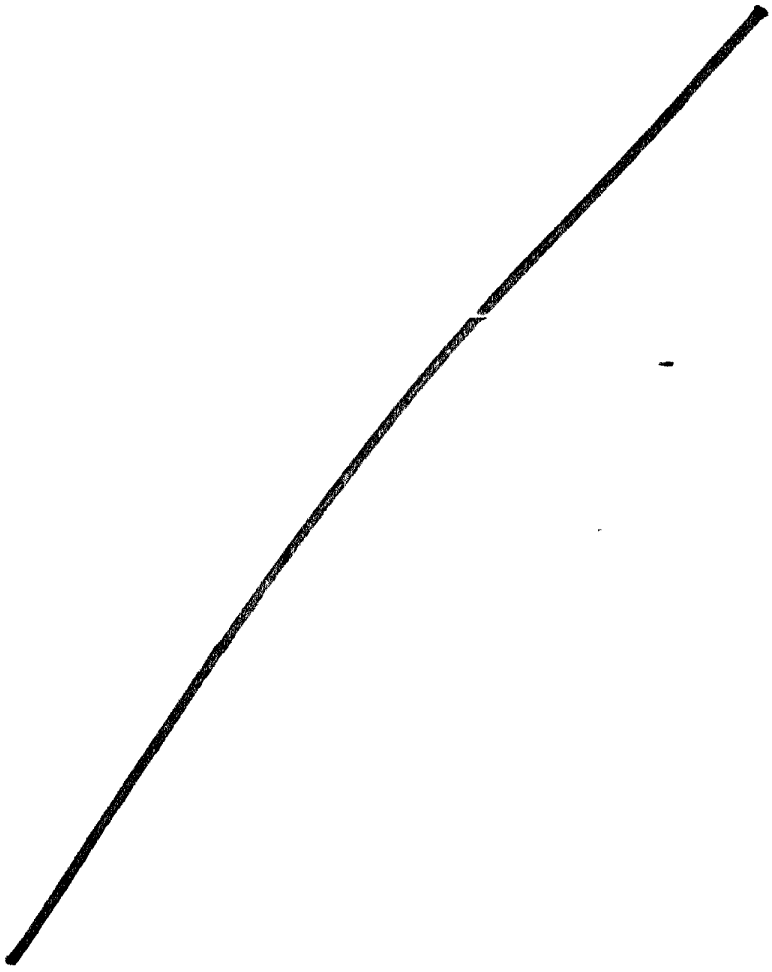
Validity Testing Information Part I

Laboratory Name: Baptist Med. Ctr. - Tox
Address: Little Rock, AR

Responsible Person: Samuel Mathews (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

10-5-00
Date

S.E. Mathews
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).

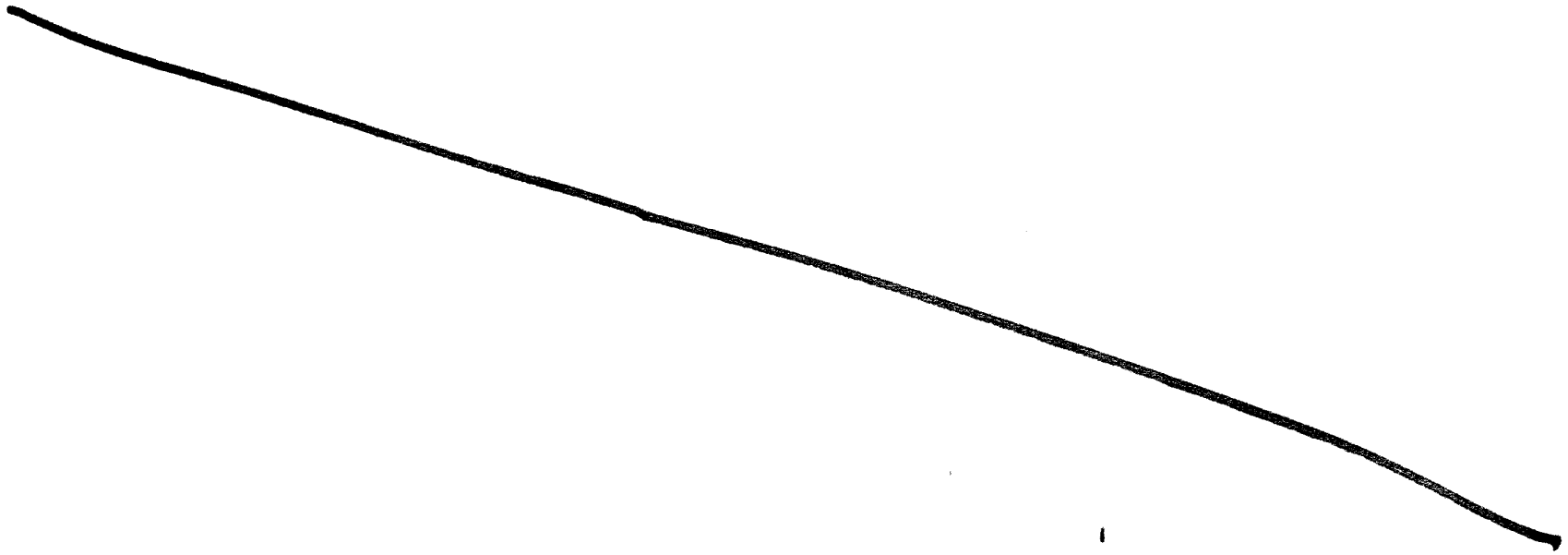
Signature, Responsible Person

10/17/00
Date

Samuel Mathews Ph.D.
Printed Name, Responsible Person

Adulterated/Substituted Sample Summary
October 1998 - October 2000
Baptist Medical Center, Toxicology Laboratory
Little Rock, AR

Specimen ID Number	Accession Number	Date Received	Date Reported	Reported Result	Measured Components



101700

RESEARCH TRIANGLE INSTITUTE

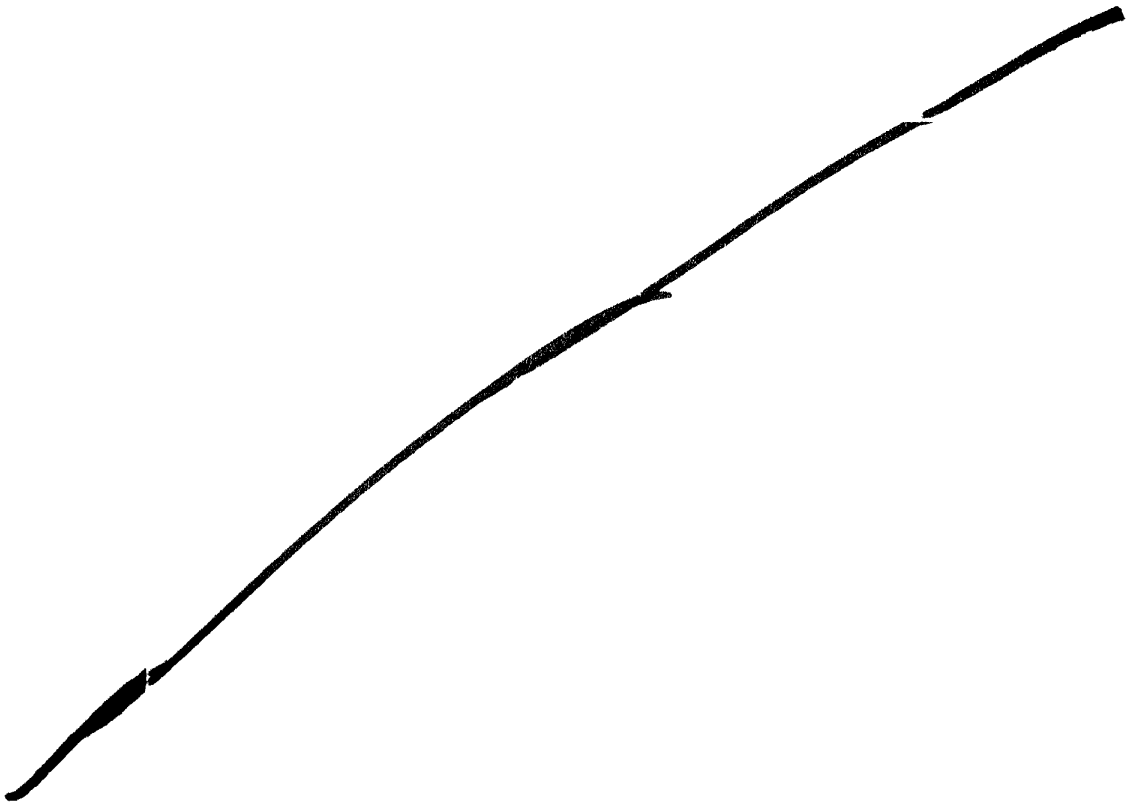
National Laboratory Certification Program

November 17, 2000

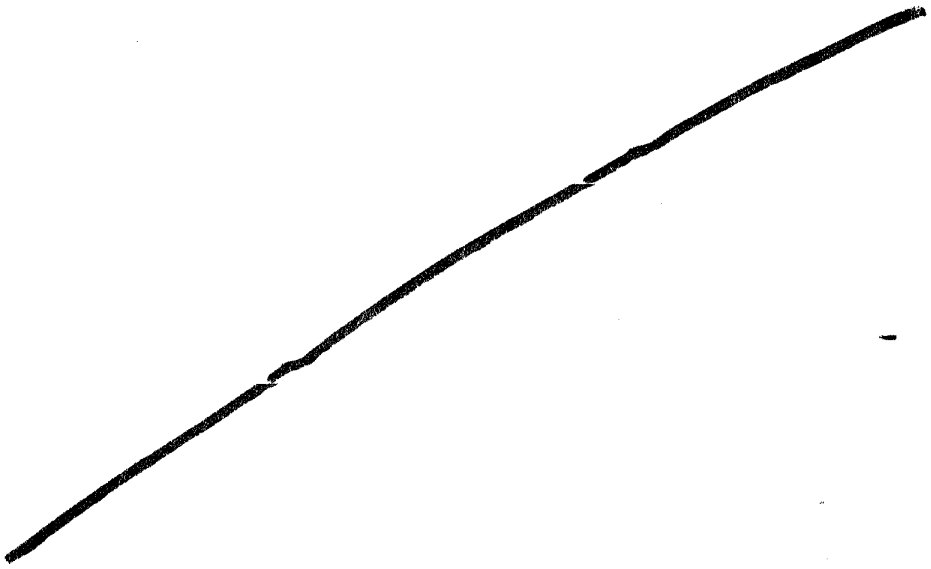
0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

The enclosed critique was developed from the inspection report associated with the October 25, 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 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/519

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0519
Document No. Final

Laboratory: Baptist Medical Center-Toxicology Laboratory

Location: Little Rock, AR

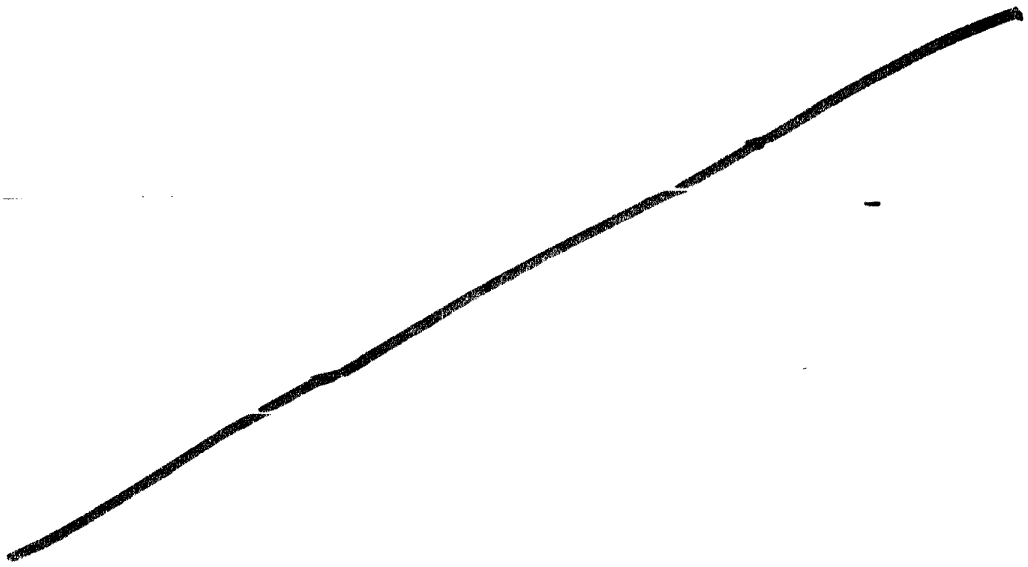
Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 25 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:

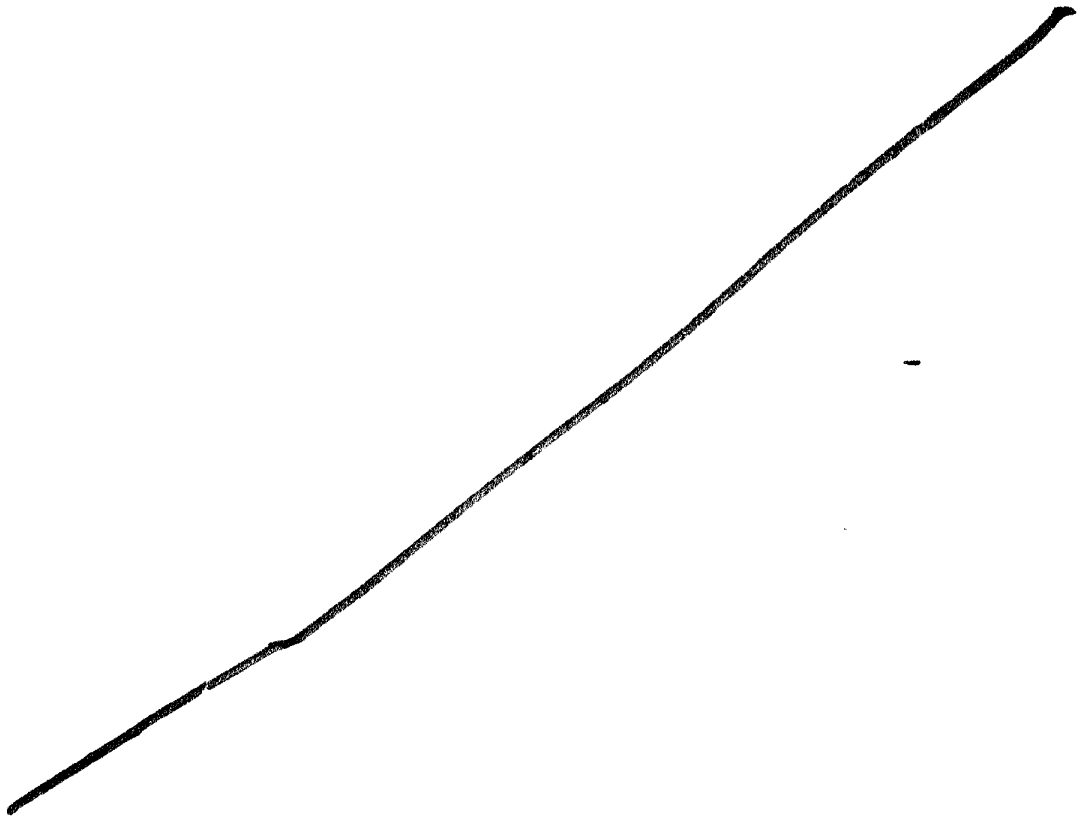
Section E. Standard Operating Procedures - Procedures Manual



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

Baptist
MEDICAL CENTER

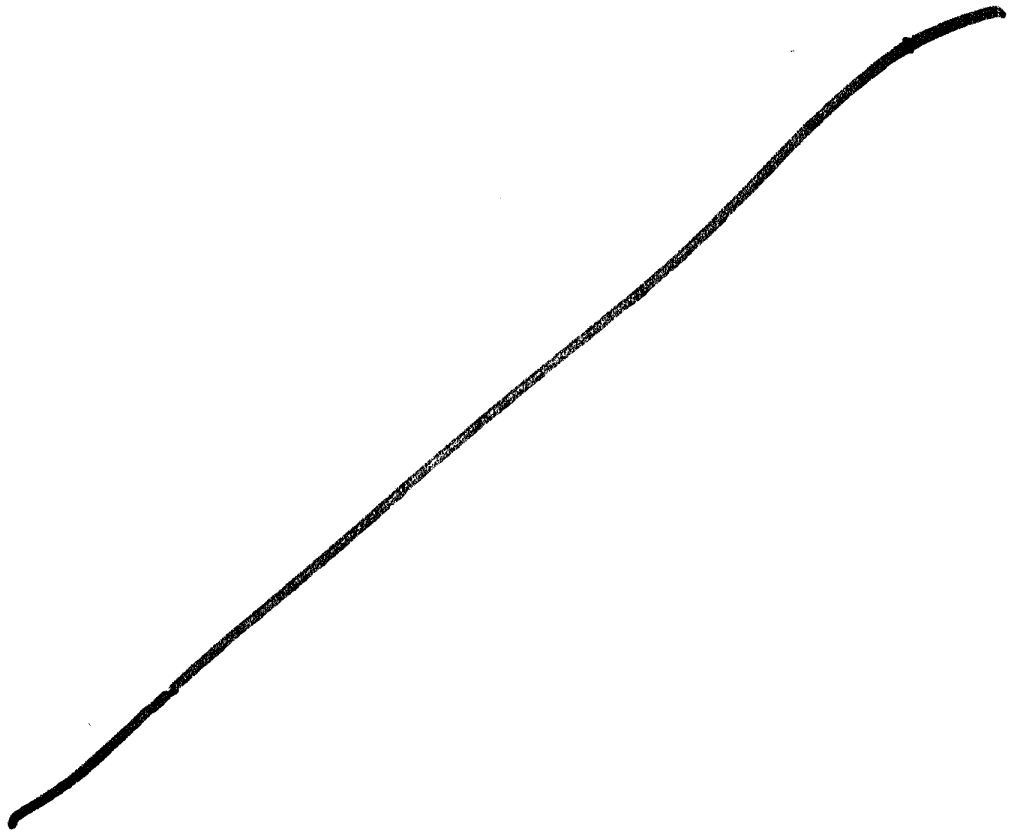
9601 Interstate 630, Exit 7
Little Rock, AR 72205-7299
501 202-2000

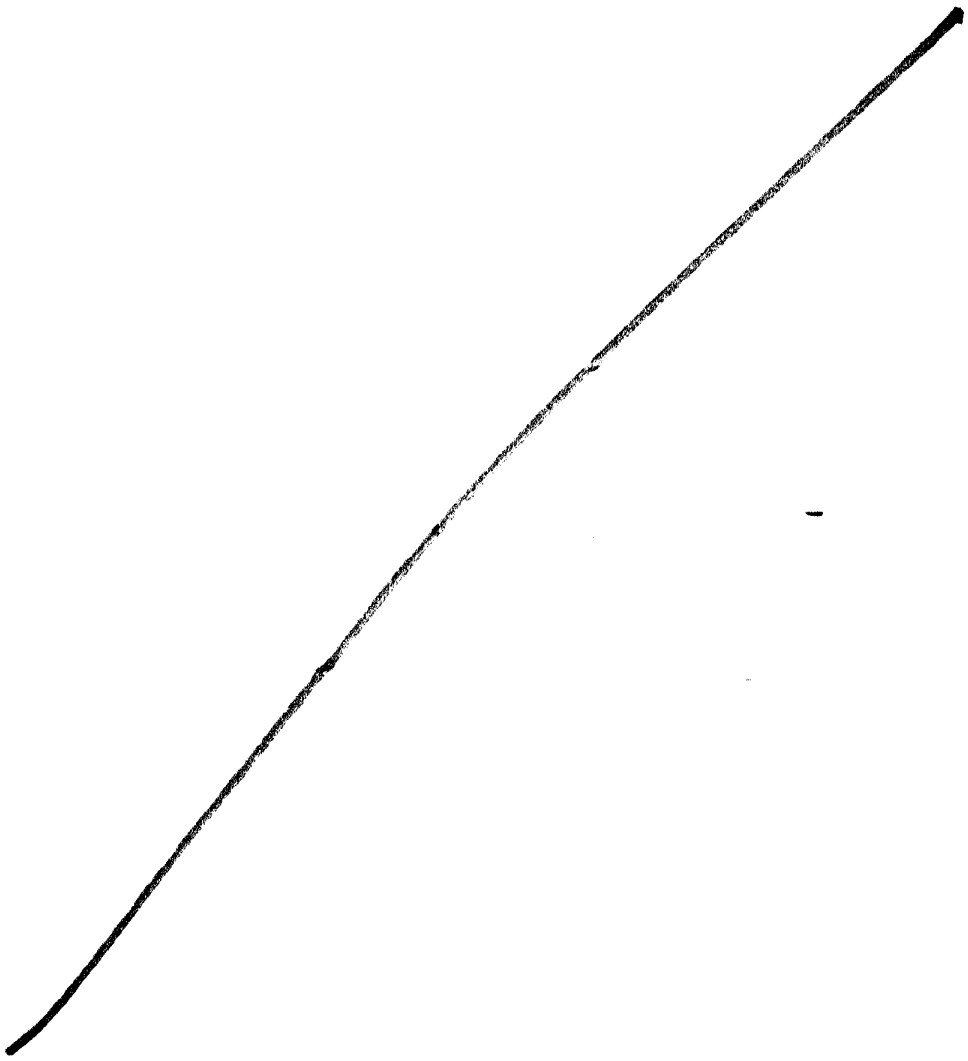
December 19, 2000

Ms. Deborah J. Denson
NLCP/RTI
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Denson:

This letter is our response to the items listed in your letter to us of November 17, 2000, reviewing issues brought up in our specimen validity inspection. As requested in your letter, the responses listed here will be presented in the same order and labeled as in your communication.





If there are any additional questions or issues to be addressed, please do not hesitate to notify me at 501-202-2783 or at tox@baptist-health.org.

Sincerely,

Samuel E. Mathews, Ph.D., DABCC
Responsible Person

RESEARCH TRIANGLE INSTITUTE

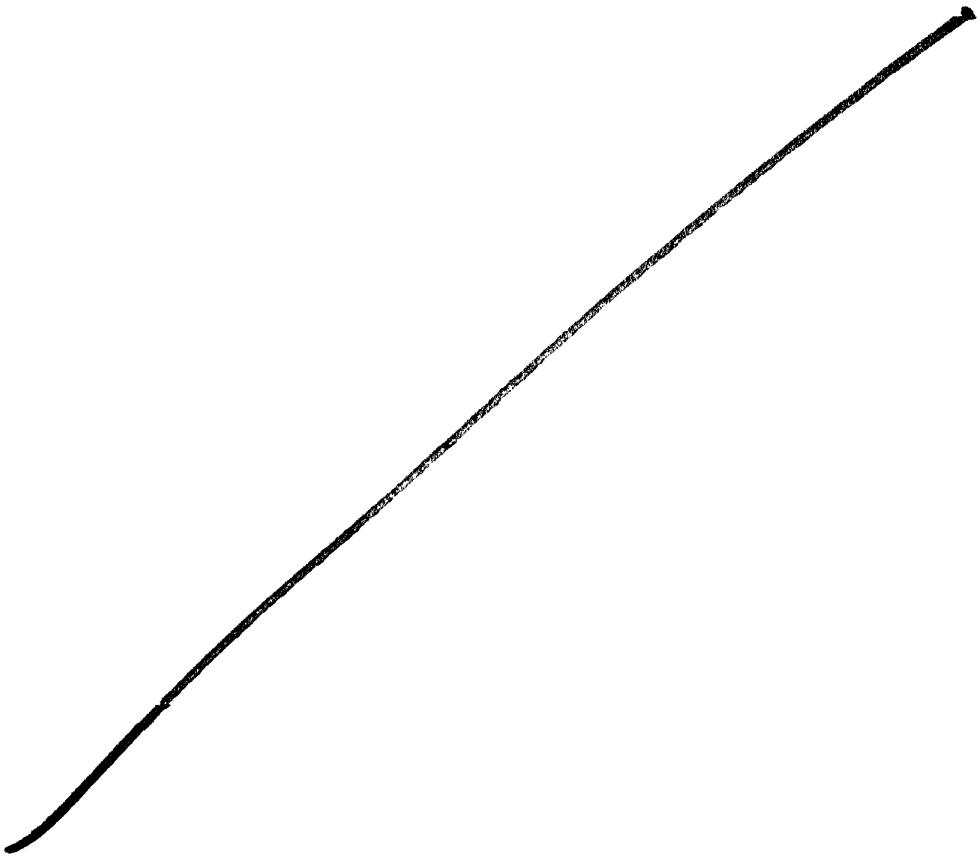
National Laboratory Certification Program

January 8, 2001

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

We have reviewed the material provided in your correspondence of December 19, 2000 submitted in response to issues raised during the October 25, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000. 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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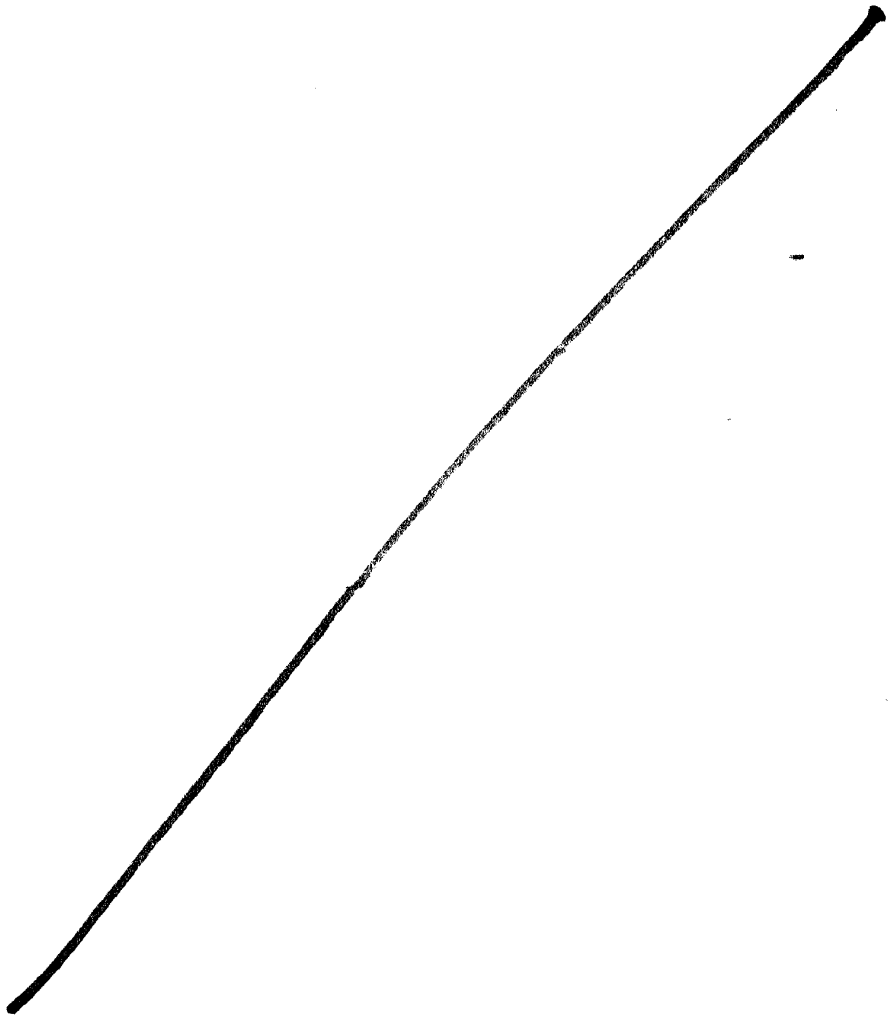
Telephone 919 541-6709 • Fax 919 541-7042



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/SVT519