Validity Testing Information Part I

Laboratory Name: St. Anthony Toxicology Laboratory (0168)
Address: 1000 N Lee St. Okla. City, OK 73101

Responsible Person: Michael W. Fowler, 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).

Michael W. Fowler

Signature, Responsible Person

10/4/00

Date

Michael W. Fowler, 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).

Michael W. Fowler
Signature, Responsible Person

10/12/00
Date

Michael W. Fowler
Printed Name, Responsible Person

St. Anthony Hospital Toxicology Laboratory

#0168
1000 North Lee
Oklahoma City, Oklahoma 73102

Specimen ID#	Accession #	Received Date	Reported Date	Reported Result	Creatinine	Specific Gravity	pH	Adulterant ID	Concentration

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 5, 2001

0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

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 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 correct/clarify the following issue 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. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.*** All corrective actions 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt168

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0168
Document No. Final

Laboratory: St. Anthony Hospital Toxicology Laboratory

Location: Oklahoma City, OK

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

St. Anthony Hospital

1000 North Lee Street
Post Office Box 205
Oklahoma City, Oklahoma 73101

(405) 272-7000

February 5, 2001

Ms. Susan Crumpton
NLCP Research Triangle Institute
3040 Cornwallis Road
PO Box 123194
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

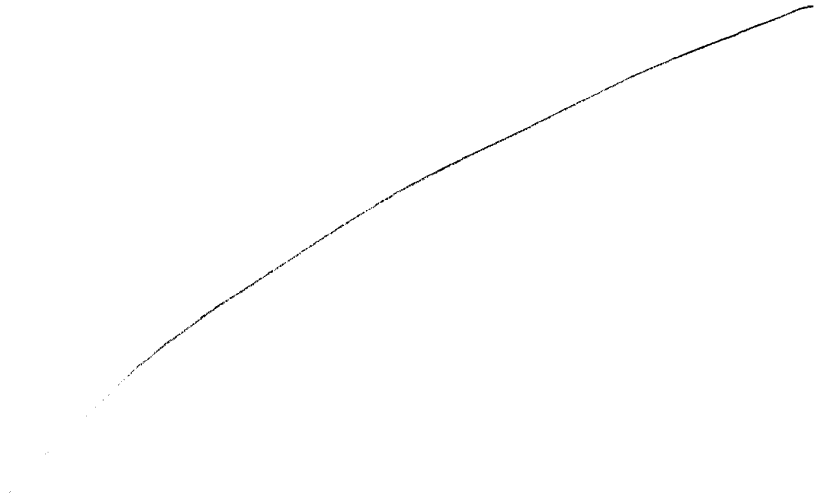
Enclosed you will find our response to the Special Validity Testing Inspection Report. If you have any question ontact ...uc.edu or call me at (405)272-6037.

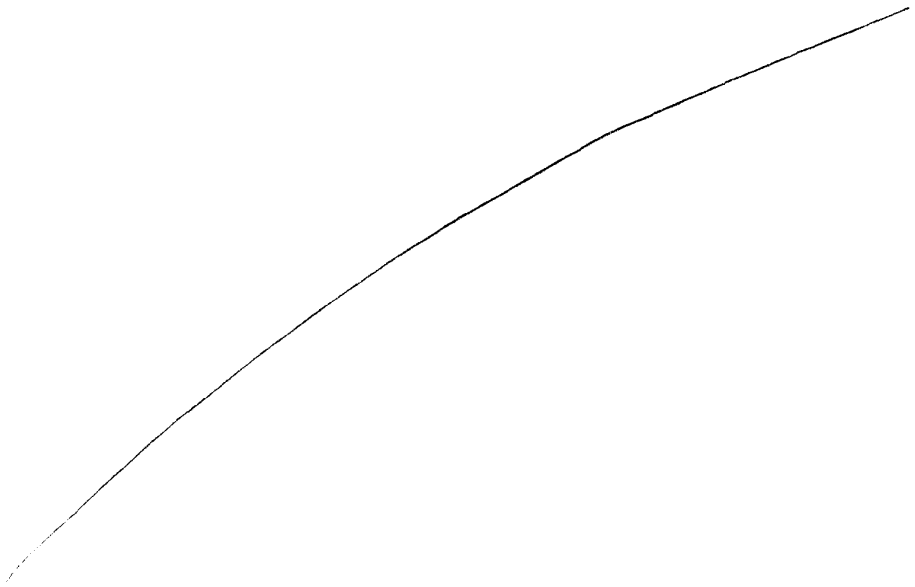
Sincer

...ael W. Fowler, Ph.D. (lab No. 0168)
Director of Toxicology

Special Validity Testing Inspection Response

February 6, 2001





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

March 1, 2001

0168
Dr. Michael Fowler
St. Anthony Hospital Toxicology Laboratory
1000 North Lee Street
P.O. Box 205
Oklahoma City, OK 73101

Dear Dr. Fowler:

We have reviewed the material provided in your correspondence of February 5, 2001, submitted in response to issues raised during the December 7, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of January 5, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

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 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0168

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