Validity Testing Information Part I

Laboratory Name: Advanced Toxicology Network
Address: 3560 Air Center Cove Ste 101 Memphis TN 38118

Responsible Person: Roger Rutter (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).

Janet L Putnam (ALT)
Signature, Responsible Person

10/2/2000
Date

Janet L. Putnam (ALT)
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).

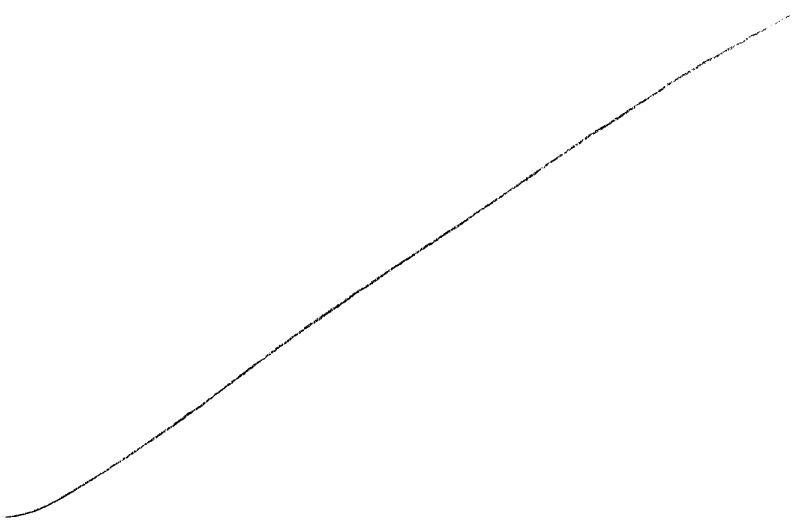
Signature, Responsible Person

Date

Printed Name, Responsible Person

Validity Testing Information
Part II

Specimen ID	Accession #	Rec'vd Date	Rep'td Date	Creatinine	SG



End of Listing as of 10.10.2000

Validity Testing Information Part I

Laboratory Name: Advanced Toxicology Network
Address: 3568 Air Center Cove
Memphis, TN 38118
Responsible Person: Roger L. Ritter (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).

RLR

Signature, Responsible Person

RLR 10/11/02

Date

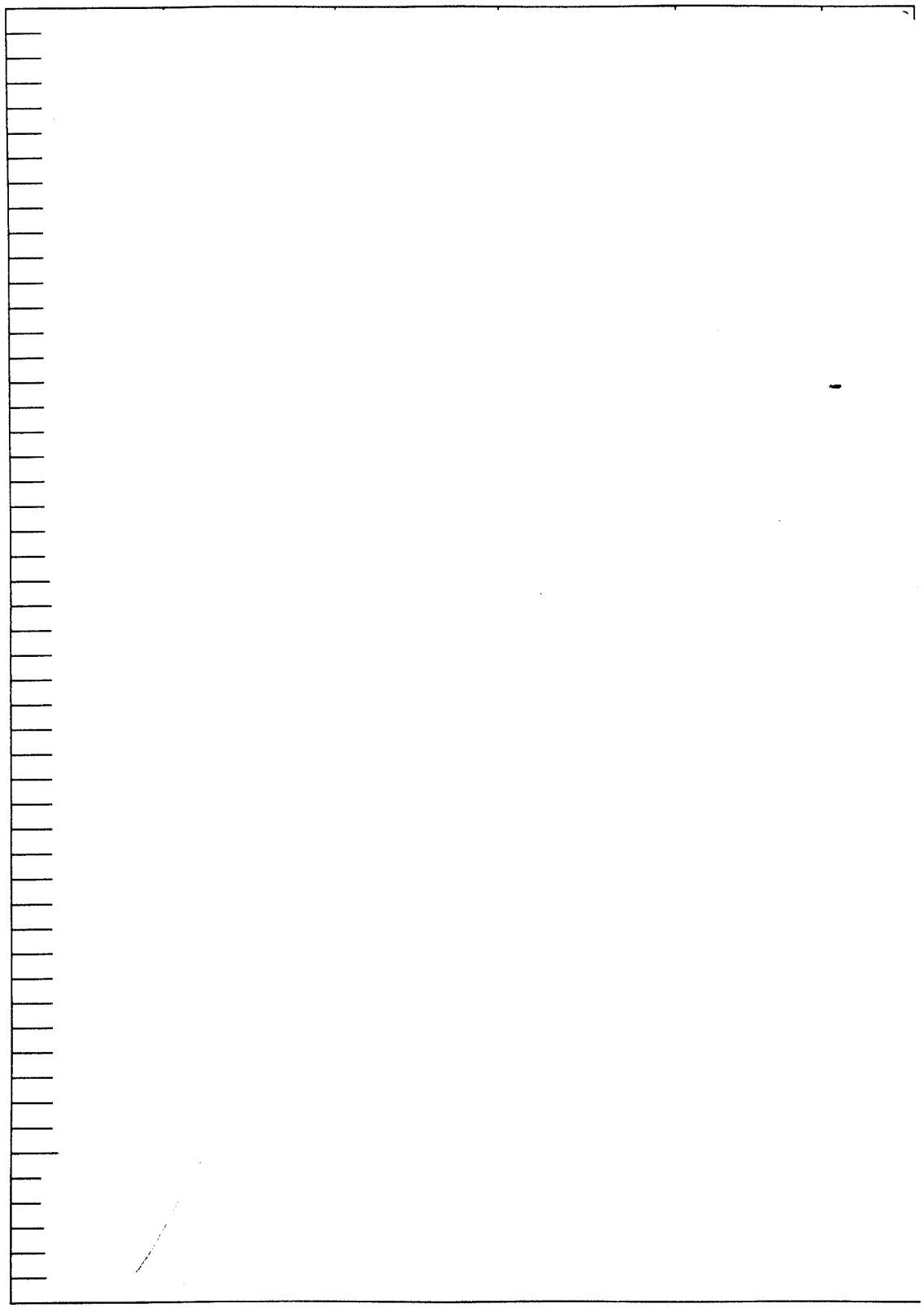
ROGER L. RUTTER

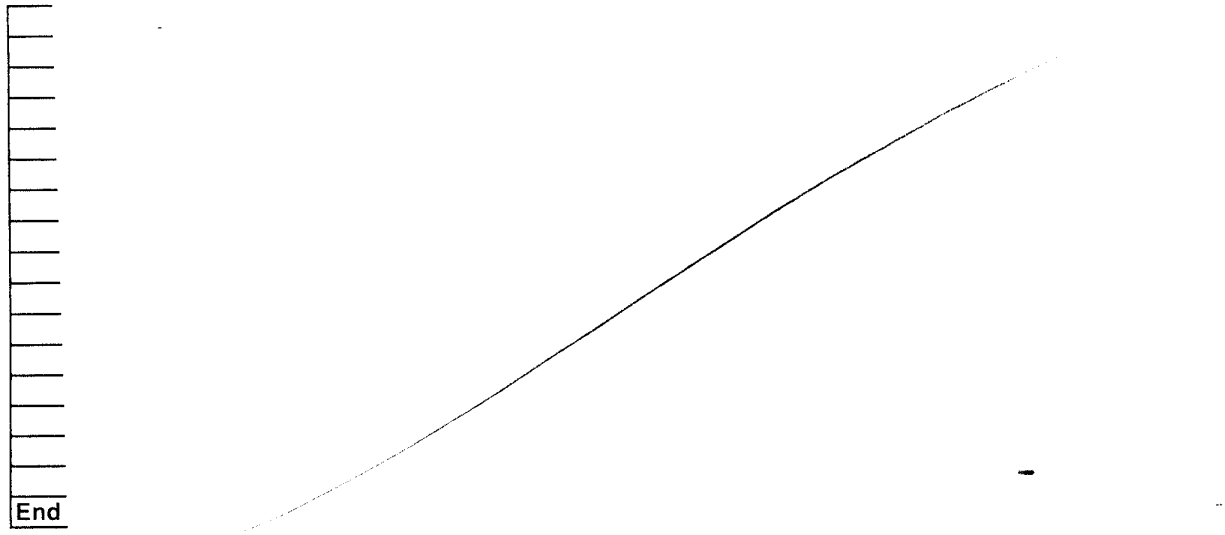
Printed Name, Responsible Person

* DATES for QUESTIONS 3 + 5a have been corrected.

RLR
10/11/02

	Validity Testing Information				
		Part II			
Specimen ID	Accession #	Rec'vd Date	Rep'td Date	Creatinine	SG




End

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 7, 2000

0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

The enclosed critique was developed from the inspection report associated with the October 18-20, 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt215

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0215
Document No. Final

Laboratory: Advanced Toxicology Network

Location: Memphis, TN

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 18 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

ATN

received
12/8/00 SDC

December 7, 2000

Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road, Box 12194
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton,

Thank you for your correspondence of 7 November 2000 and the critique contained therein. The following is ATN's response to the Document Review and Critique associated with the October 18-20, 2000, specimen validity testing inspection.

ADVANCED TOXICOLOGY NETWORK
3560 AIR CENTER COVE, SUITE 101, MEMPHIS, TN 38118 (888) 290-1150

Section G

Section I

We look forward to your review of this response.

Sincerely,

Roger L. Rutter
Responsible Person
e-mail: Roger Rutter@atnlabs.com

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 12, 2000

0215
Mr. Roger Rutter
Advanced Toxicology Network - Memphis
3560 Air Center Cove
Suite 101
Memphis, TN 38118

Dear Mr. Rutter:

We have reviewed the material provided in your correspondence of December 7, 2000, submitted in response to issues raised during the October 18-20, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 7, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following were noted during our review of submitted material:

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
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 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. ***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 during 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT215