Validity Testing Information Part I

Laboratory Name: _____
Address: _____

Responsible Person: _____ (Printed Name)

Does your laboratory conduct validity testing on DOT regulated specimens?

Yes No

If **No**, stop, sign page 2 of part I, and return to RTI

If **Yes**, answer the following questions and provide the required specimen results.

1. When did the laboratory begin doing validity testing on DOT regulated specimens?

   Date: _____

2. When did the laboratory implement NLCP PD 35 (dated September 28, 1998)?

For:		
	Nitrite	Date: _____
	Creatinine	Date: _____
	Specific Gravity	Date: _____

3. When did the laboratory implement NLCP PD 37 (dated July 28, 1999)?

For:		
	Nitrite	Date: _____
	Creatinine	Date: _____
	Specific Gravity	Date: _____

4. If implementation for questions 2 and 3 above were done in stages, please explain:_____

5. Does your laboratory test for:

   Creatinine Yes No

   If Yes,

   a. Do you determine its concentration to at least one significant decimal place(e.g. no truncation or rounding to whole numbers)?
      Yes No

   b. When did you start using at least one decimal place?

      Date: _____

Specific Gravity Yes No

If Yes,

a. Do you determine its value to at least three decimal places?
Yes No

b. When did your laboratory start determining specific gravity to three decimal places?

Date: _____

c. If a refractometer is used, are the readings digital?

Yes No

If yes, has a reading of LLL on the digital refractometer, ever been interpreted as equivalent to 1.000?

Yes No

pH Yes No

If Yes,

a. What quantitative method is used? _____

Nitrite Yes No

If Yes,

a. What quantitative method is used? _____

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

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 I

Laboratory Name: TOXICOLOGY TESTING SERVICE, INC
Address: 5426 N.W. 79th AVE MIAMI, FL 33166

Responsible Person: TERRY P. HALL, 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

10-5-00
Date

TERRY D. HALL, 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).

Terry D. Hacc PhD — Signature, Responsible Person

10-17-00 — Date

TERRY D. HACC, Ph.D. — Printed Name, Responsible Person

Toxicology Testing Service, Inc.
RAPID DRUG IDENTIFICATION USING MASS SPECTROMETRY
5426 N.W. 79th AVENUE
MIAMI, FLORIDA 33166

TELEPHONE
305-593-1595

NLCP # 0001
October 17, 2000

VALIDITY TESTING INFORMATION
PART II

SPECIMEN ID No.	LAB ACCESSION #	DATE REC'D	DATE REPORTED	REPORTED RESULT	CREATININE	SPECIFIC GRAVITY

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 17, 2000

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

The enclosed critique was developed from the inspection report associated with the October 30, 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 issues raised:

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address this issue.

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/svt001

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

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0001
Document No. Final

Laboratory: Toxicology Testing Service, Inc.

Location: Miami, FL

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 30 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

Toxicology Testing Service, Inc.
RAPID DRUG IDENTIFICATION USING MASS SPECTROMETRY
5426 N.W. 79th AVENUE
MIAMI, FLORIDA 33166

TELEPHONE
305-593-1595

December 23, 2000

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Dear Ms. Crumpton:

I have received your letter of November 17, 2000.

Please contact me at (305) 593-2260 if you have any further questions.

Sincerely,

Terry D. Hall, Ph.D.
Laboratory Director

Toxicology Testing Service, Inc.
RAPID DRUG IDENTIFICATION USING MASS SPECTROMETRY
5426 N.W. 79th AVENUE
MIAMI, FLORIDA 33166

TELEPHONE
305-593-1595

February 2, 2001

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Dear Ms. Crumpton:

I have received your letter of January 16, 2001.

Please contact me at (305) 593-2260 if you have any further questions.

Sincerely,

Terry D. Hall, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 16, 2001

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

We have reviewed the material provided in your faxed correspondence of December 23, 2000, received at RTI on January 5, 2001. The laboratory submitted information in response to issues raised during the October 30, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000. The following is a review of the material submitted:

The laboratory must submit information to address this issue within 10 calendar days of receipt of this letter. 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.***

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/SVT0124

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

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 12, 2001

0001
Dr. Terry D. Hall
Toxicology Testing Service, Inc.
5426 N.W. 79th Avenue
Miami, FL 33166

Dear Dr. Hall:

We have reviewed the material provided in your faxed correspondence of February 7, 2001, submitted in response to issues raised during the October 30, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000, and January 16, 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 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/SVT0001

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