Validity Testing Information Part I

Laboratory Name: One Source Toxicology
Address: 1705 Center Deer Park TX 7753[illegible]

Responsible Person: Jack Zaun (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

10/3/01
Date

Steve Harris (ACT)
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

Printed Name, Responsible Person

RTI 10/2000

Specimen ID	Accession #	Date Received	Date Reported	Creatinine	Specific Gravity	Reported Result

Lab 608

RESEARCH TRIANGLE INSTITUTE

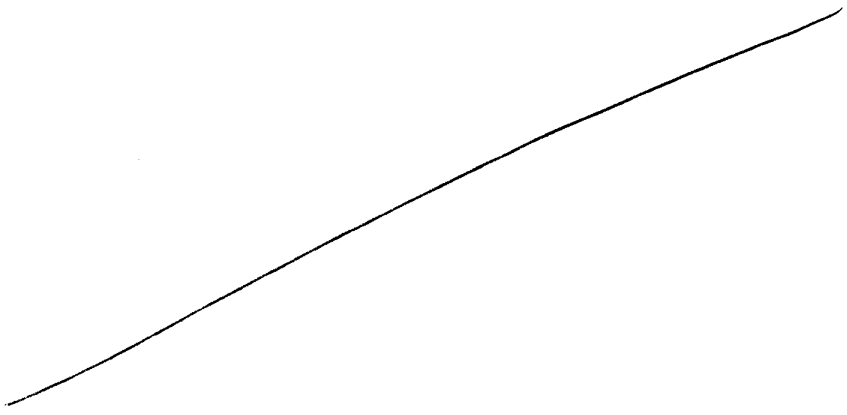
National Laboratory Certification Program

December 13, 2000

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
1705 Center Street
P. O. Box 260
Deer Park, TX 77536

Dear Dr. Zaun:

The enclosed critique was developed from the inspection report associated with the November 29, 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:



Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens. If you have any

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

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/svt608

INQUIRY TO MRO

Lab Number _____

Name of person contacted at MRO office: _____

Phone Number: (____)_____

Specimen ID Number: _____

MRO Disposition:

- ❑ Substituted, **substitution admitted by donor during interview**
- ❑ Substituted, **substitution denied by donor during interview**
- ❑ Substituted, **substitution not admitted or denied during interview**
- ❑ Substituted, **donor not contacted**
- ❑ Substituted, **no comments regarding donor contact**
- ❑ **Refusal to test**
- ❑ **Interpreted as negative by MRO**
- ❑ **Records not available from MRO**
- ❑ Cancelled, **medical explanation**
- ❑ Cancelled, **other (briefly explain)**_____
- ❑ **Other (briefly explain)**_____

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0608
Document No. Final

Laboratory: One Source Toxicology Laboratory, Inc.

Location: Deer Park, TX

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 29 November 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

One Source Toxicology Laboratory, Inc.
Wholly owned subsidiary of Employer Support Services, Inc. (ESSI)

1705 Center Street
P.O. Box 260
Deer Park, Texas 77536-0260
Phone: 713.920.2659
Toll Free: 888.747.3774
Fax: 281.479.0489
www.onesourcetox.com

February 9, 2001

Susan Crumpton
NLCP Technical Analyst
NLCP/Research Triangle Institute
Bldg. 3
3040 Cornwallis Rd.
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

I hope this meets the requirements.

Thank you,

Jack W. Zaun, Ph.D., R.P.

One Source Toxicology, Inc.
P.O. Box 260
Deer Park, Tx. 77536-0260

Facsimile Transmittal Form

Date: 2-9-2001

No. of Pages: 2
(Including Cover)

Company: NLCP / RTI

To Whom: Susan Crumpton

Fax No.: 1-919-541-7042

From: JW Zaun at One Source Toxicology (281) 479-0489

Comments:

CONFIDENTIALITY NOTICE

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 12, 2001

0608
Dr. Jack Zaun
One Source Toxicology Laboratory, Inc.
1705 Center Street
P. O. Box 260
Deer Park, TX 77536

Dear Dr. Zaun:

We have reviewed the material provided in your correspondence of February 9, 2001, submitted in response to issues raised during the November 29, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 13, 2000.

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 taken in response to the specimen validity testing inspection 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/SVT608

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