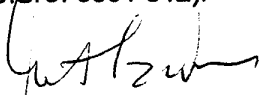


## Validity Testing Information Part I

Laboratory Name: ACL  
Address: 8901 W. Lincoln Ave., West Allis, WI 53227  
Responsible Person: ANTHONY WUI (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

10/3/00

\_\_\_\_\_  
Date

ANTHONY WU  
\_\_\_\_\_  
Printed Name, Responsible Person



Dr. John Mitchell  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
P.O. Box 12194  
Research Triangle Park, NC 27709-2194

October 3, 2000

Dear Dr. Mitchell:

Per Mr. Kenneth Davis's letter of September 29, 2000, I am sending to you the completed "Validity Testing Information Part I", first by Fax followed by a hard copy via US mail. We are also actively gathering the information needed for Part II, which will be forwarded to you on or before October 17, 2000.

If you have any questions, please call me at 414-328-7843.

Respectfully,

A handwritten signature in black ink, appearing to read "Anthony Wu", is written over a faint, illegible typed name.

Anthony Wu, Ph.D.  
Responsible Person and  
Toxicologist

encls.

c:

A single, thin, diagonal line is drawn across the page, starting from the left margin and extending towards the right, positioned below the "c:" label.



Dr. John Mitchell  
NLCP  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

October 13, 2000

Dear Dr. Mitchell:

Enclosed please find a complete copy of the Validity Testing Information Part II, spreadsheet/audit for each DOT regulated specimen that was reported either as adulterated or substituted since ACL Labs started providing such services on December 1, 1998, and a diskette (electronic format) of the same.

If you have any further questions, please call me at 414-328-7843.

Respectfully,

A handwritten signature in black ink, appearing to read "Anthony Wu", is written over the typed name.

Anthony Wu, Ph.D.  
Responsible Person and  
Toxicologist

encls.

c:

A single, long, diagonal handwritten checkmark is drawn below the "c:" label.

## 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

10/13/2000  
Date

ANTHONY WU, D.D.  
Printed Name, Responsible Person

VALIDITY TESTING INFORMATION, PART II

ID #	Access #	Receipt Date	Reported Date	Result (A/S)	GH1 (mg/dl)	Sp. Gr.	pH	Adulterant	Adulterant Conc.
[A large diagonal line is drawn across the table area, indicating that no data has been recorded.]									

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 28, 2000

0039  
Dr. Anthony Wu  
ACL Laboratories  
8901 W. Lincoln Avenue  
West Allis, WI 53227

Dear Dr. Wu:

The enclosed critique was developed from the inspection report associated with the November 8-10, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures appear to be in compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999).

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to clarify 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/svt039  
Dr. Joseph Manno



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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: 0039  
Document No. Final

Laboratory: ACL Laboratories

Location: West Allis, WI

Document Reviewed:  Specimen Validity Testing Inspection Report

Date: 8 November 2000

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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

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Section F. Chain-of-Custody, Accessioning, and Security

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Section G. Quality Control and Quality Assurance

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Section I. Specimen Validity Tests

---

Section K. Records Audit

---

Section L. Certification and Reporting

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received  
12/19/00

Ms. Susan Crumpton  
NLCP Technical Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

December 14, 2000

Re:

\_\_\_\_\_

Dear Ms. Crumpton:

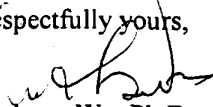
Per your letter of November 28, 2000, regarding the above-captioned case, \_\_\_\_\_  
\_\_\_\_\_ has now informed me that the final disposition of this specimen is as follows:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If you have any further questions, please call me at 414-328-7843.

Encls.

Respectfully yours,

  
Anthony Wu, Ph.D.  
Responsible Person and  
Toxicologist

C:

\_\_\_\_\_

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 21, 2000

0039  
Dr. Anthony Wu  
ACL Laboratories  
8901 W. Lincoln Avenue  
West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of December 14, 2000,

The NLCP staff at RTI will review this issue with the technical staff at the Department of Health and Human Services (HHS). We will notify the laboratory of any required corrective action in separate correspondence. 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*  
Susan Crumpton  
NLCP Technical Analyst

cc: Project Files/SVT039

