Validity Testing Information Part I

Laboratory Name: UNILAB CORPORATION
Address: 18408 OXNARD ST, TARZANA CA 91356

Responsible Person: ANDREW J. FISCHINGER (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).

Andrew J Fischinger Ph.D
Signature, Responsible Person

10-3-00
Date

Andrew J. Fischinger, Ph.D.
ANDREW J. FISCHINGER 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:

(LAB0135_101599) SEE FILE ON ENCLOSED FLOPPY
Andrew J Fischinger
Andrew J. Fischinger, Ph.D.

- **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).

Andrew J Fischinger Ph.D
Signature, Responsible Person

10-15-00
Date

Andrew J. Fischinger, Ph.D.
Printed Name, Responsible Person

UNILAB # 0135
EXCEL FILE 0135_101100

TESTS NOT PERFORMED 12/1/98 THRU 10/15/00 (COMPUTER) & 12-1-98 → 10-15-00 (MANUAL)
(SEE TNP Results) 12-22 10-15-00
(2nd pg.)

10/16/00

Accession	Specimen ID	Date Received	Date Reported	Result	Creatinine	S.G.	pH	NO2	Message

Andrew J Fischinger PhD
Andrew J. Fischinger, Ph.D. 10-15-0

Accession	Specimen ID	Date Received	Date Reported	Result	Creatinine	S.G.	pH	NO2	Message

OUR VALID pH RANGE
IS 4.5 – 8.5

AJF
10-15-00

Andrew J Fischinger (PhD)
Andrew J. Fischinger, Ph.D. 10-15-00

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 15, 2000

0135
Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fishinger:

The enclosed critique was developed from the inspection report associated with the November 15, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in 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:

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 listed in this correspondence. The laboratory must also review the enclosed critique and

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

take all necessary corrective actions. 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. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection. ***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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt0135

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0135
Document No. Final

Laboratory: UNILAB

Location: Tarzana, CA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 15 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

UNILAB

Ms. Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Park
North Carolina 27709-2194 USA

January, 16, 2001

Dear Ms. Denson,

Enclosed please find Validation Testing final corrective actions addressed for all items from your December 15, 2000 critique.

The attached two explanatory and detailed pages, with all the attached documentation, were finalized on 1-9-01, for the incipient review asked for by the team leader for the January 11th. through the 12th. inspection of our laboratory. The complete folder was with the inspectors for their review and critique during the inspection.

As requested in your letter of December 15, 2000, we are sending you all our above mentioned responses, to show that all corrective actions were indeed implemented within 30 days receipt of the December 15, 2000 NLCP correspondence.

Sincerely,

Andrew J. Fischinger PhD

Andrew J. Fischinger Ph.D.
Responsible Person Lab.# 0135

Validation Testing corrective actions from Dec. 15, 2000 critique letter. Ajf 1-9-01

Andrew J. Fischinger, Ph.D. 1-9-01

Andrew J. Fischinger, Ph.D.

Andrew J. Fischinger, Ph.D. 1-09-08

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 29, 2001

0135

Dr. Andrew J. Fischinger
UniLab Toxicology
18408 Oxnard Street
Tarzana, CA 91356

Dear Dr. Fischinger:

We have reviewed the material provided in your correspondence of January 16, 2001 submitted in response to issues raised during the November 15, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 15, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

The laboratory's submission included original copies of some documents. A copy of this information has been made for our records. The original documents are being returned to the laboratory for placement into the laboratory's records. The following is a review of the material submitted:

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Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that 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 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.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J Denson

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT135