Validity Testing Information Part I

Laboratory Name: Oregon Medical Labs
Address: [illegible]

Responsible Person: Stephen C. Erfurth, PhD (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).

Stephen Erfurth PhD
Signature, Responsible Person

10-03-00
Date

Stephen C. Erfurth, Ph.D
Printed Name, Responsible Person

OREGON MEDICAL LABORATORIES - TOXICOLOGY

Facsimile Cover Letter

Please deliver the following pages to:

Name: Research Triangle Institute NLM FAX No: (919) 541-7042

Dept.: _____ Phone: _____

From: Dr. Forsyth Fax: 1-541-341-8095

We are transmitting 3 pages including this cover letter.

Date: 10/3/00 Time: 1024

FOR ASSISTANCE - Call 1-800-626-3616, ext. 8112

OREGON MEDICAL LABORATORIES - TOXICOLOGY

Facsimile Cover Letter

Please deliver the following pages to:

Name: FRANK WALLIS FAX No: (919) 541-7042

Dept.: RT 1 Phone:

From: GRANT BEARDSLEY Fax: 1-541-341-8095

We are transmitting 3 pages including this cover letter.

Date: 10/18/00 Time: 0740

FOR ASSISTANCE - Call 1-800-826-3616, ext. ~~8112~~ 8137

6946 1/94

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

10-11-00
Date

Stephen C. Erfurth, Ph.D

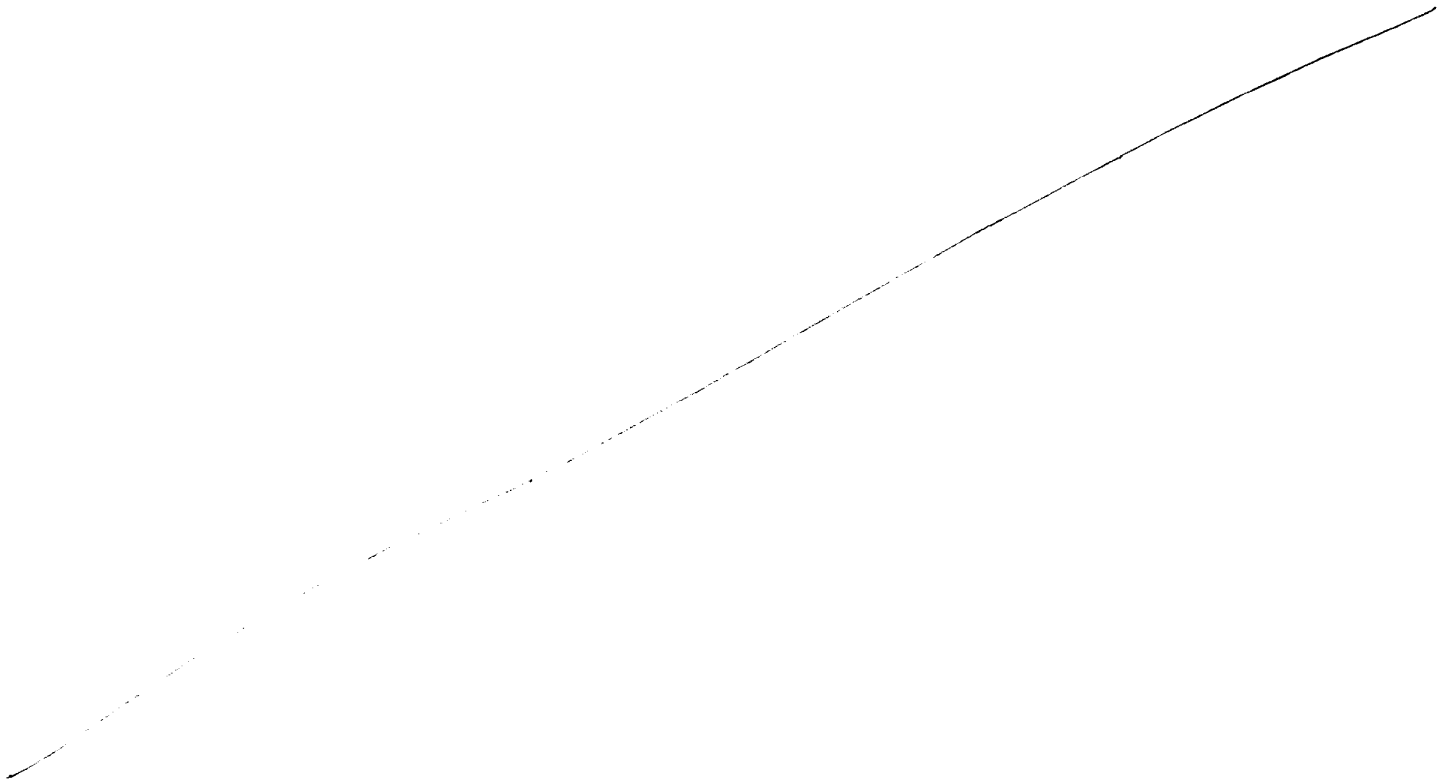
Printed Name, Responsible Person

10/10/00

Received 10-23-00

Oregon Medical Laboratories, Eugene, OR #0306

Spec ID#	Accession	Receipt	Reported	Reported Result	Creatinine	Nitrite	Sp Grav	pH



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 13, 2000

0306
Dr. Stephen C. Erfurth
Oregon Medical Laboratories
722 East 11th Avenue
Eugene, OR 97401

Dear Dr. Eurfurth:

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:

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 listed in this correspondence. The laboratory must also review the enclosed critique and 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt306

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0306
Document No. Final

Laboratory: Oregon Medical Laboratories

Location: Eugene, OR

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

11. The following issues were identified:

Section L. Certification and Reporting

Oregon Medical Laboratories

722 E. 11th Avenue
Post Office Box 972
Eugene, Oregon 97440-0972

541•687•2134 1•800•826•3616

Pathologists
Mathews B. Fish, M.D.
David A. Rutz, M.D.
David S. Meyers, M.D.
Brent D. Kahn, M.D.
Michael J. Hahn, M.D.
L. Samuel Vickers, M.D.
Curtis R. Liu, M.D.
Jeffrey A. Houck, M.D.
Sandra L. Moran, M.D.
Kathleen C. Masterson, M.D.
Clinical Chemist
Stephen C. Erfurth, Ph.D.
Clinical Microbiologist
Anthony H. Gonzalez, Ph.D.

January 12, 2001

Deborah J. Denson
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

RE: **Corrective actions, SVT Inspection of laboratory #0306**

Dear Ms. Denson:

We received you letter dated December 13, 2000 on December 14, 2000 regarding our specimen validity testing (SVT) inspection last November 15th. The laboratory procedures listed in your correspondence have been address and are summarized here:

Please telephone 1-541-687-2134 to contact either Grant Beardsley (x.8137) or myself (x.8092) if we can provide any additional information or clarification relative to this document.

Sincerely,

Stephen C. Erfurth, Ph.D.
Responsible Person

Enclosures:
Attachments as Exhibits 1 - 4

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 6, 2001

0306
Dr. Stephen C. Erfurth
Oregon Medical Laboratories
722 East 11th Avenue
Eugene, OR 97401

Dear Dr. Eurfurth:

We have reviewed the material provided in your correspondence of January 12, 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 13, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:

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

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

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/SVT306