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HYATT REGENCY MILWAUKEE

OCT-05-2000 10:26

Validity Testing Information Part I

Laboratory Name: Address:

1225 NE 2nd Are

nd Are Purtlend, OR 97232

Responsible Person: _

____ (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.G. 3801/812).

Signature, Responsible Person

Printed Name, Responsible Person



LEGACY LABORATORY SERVICES

FAZ TRANSMITTAL COVER SHEET

CONFIDENTIAL

MetroLab

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PLEASE NOTE

If you do not have a plain paper FAX, any laboratory report included in this transmittal must be copied onto plain paper to be maintained as a permanent medical record

	onto piatri paper to be	maintained as a permanent medical record
DATE:	10/17/00	SUMMER OF PAGES: - (Including Cover Sheer)
TO:	NAME:	Suz Clark
ORG	ANIZATION/DEPT:	PTI
	FAX NUMBER:	(919) 54/-7042
FROM;	NAME:	MetroLab
	Telephone: Organization/Dept: Address:	(503) 413-5295 (800) 950-5295 MetroLab/Legacy Lab Service-TOXICOLOGY 1225 NE 2ND Avenue PORTLAND, OR 97232
	FAX NUMBER:	(503) 413-4621
)/ESSAGE	the type already	ax the first torm or first purt lowe tommon.
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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.

1 certity 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 may to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31), S.C. 3891-812).

Signature, Responsible Person

KENT JOHNSON

Printed Name, Responsible Person

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National Laboratory Certification Program

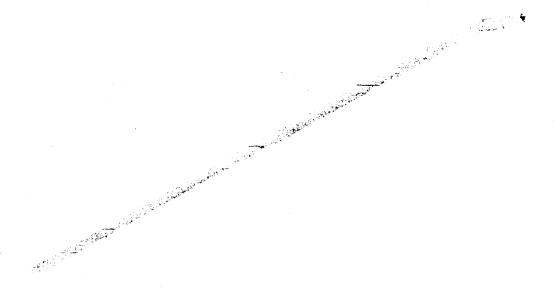
March 1, 2001

0149 Mr. Kent G. Johnson
MetroLab-Legacy Laboratory Services
1225 NE 2nd Avenue
Portland, OR 97232

Dear Mr. Johnson:

The enclosed critique was developed from the inspection report associated with the February 08, 2001 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:

Mr. Johnson March 1, 2001 Page 2 of 2



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 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Deborat & De Deborah J. Denson

NLCP Technical Analyst

Enclosure

Project Files/svt149

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: <u>0149</u>

Document No. Final

Laboratory:

MetroLab-Legacy Laboratory Services

Location:

Portland, OR

Document Reviewed:

[XX] Specimen Validity Testing Inspection Report

Date: 8 February 2001

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

Ver. Final

Lab ID# 0149

Section K. Records Audit

Section L. Certification and Reporting