Validity Testing Information Part I

Laboratory Name: Metro Lab
Address: 1225 NE 2nd Ave Portland, OR 97232

Responsible Person: Kent Johnson (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

10/5/00
Date

Kent G. Johnson
Printed Name, Responsible Person

LEGACY Health System
MetroLab

LEGACY LABORATORY SERVICES

FAX TRANSMITTAL COVER SHEET

CONFIDENTIAL

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

DATE: 10/17/00 **NUMBER OF PAGES:** 26 (Including Cover Sheet)

TO:
NAME: Suz Clark
ORGANIZATION/DEPT: PTI
FAX NUMBER: (919) 541-7042

FROM:
NAME: MetroLab
TELEPHONE: (503) 413-5295 (800) 950-5295
ORGANIZATION/DEPT: MetroLab/Legacy Lab Service-TOXICOLOGY
ADDRESS: 1225 NE 2ND Avenue
PORTLAND, OR 97232
FAX NUMBER: (503) 413-4621

MESSAGE: I will refax the first form or first part that you already have. Tomorrow.

[signature]

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

10/16/00
Date

KENT JOHNSON
Printed Name, Responsible Person

VALIDITY AUDIT	NOVEMBER 1998				VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT	NOVEMBER 1998			
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

NOVEMBER1998DONE

VALIDITY AUDIT			DECEMBER 1998		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

DECEMBER 1998

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT	JANUARY 1999				* VALIDITY QUANTITATIVE TEST RESULT							
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT	JANUARY 1999			
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

JANUARY1999DONE

VALIDITY AUDIT			FEBRUARY 1999		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

*

VALIDITY AUDIT	FEBRUARY 1999			
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

FEB1999DONE

VALIDITY AUDIT			MARCH 1999		* VALIDITY QUANTITATIVE TEST RESULT							
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT		MARCH 1999		
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

MARCH1999DONE

VALIDITY AUDIT	APRIL 1999				* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

*

VALIDITY AUDIT	APRIL 1999			
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT			MAY1999		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT		MAY 1999		
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

MAY1999DONE

VALIDITY AUDIT JUNE 1999					* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT		JUNE 1999		
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT JULY 1999					* VALIDITY QUANTITATIVE TEST RESULT							
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT		JULY 1999		
DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT			AUGUST 1999		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

AUGUST 1999

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT					* VALIDITY QUANTITATIVE TEST RESULT								
	SEPTEMBER 1999												
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

SEPTEMBER 1999

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT			OCTOBER 1999		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800 ORIGINAL	NEW ALIQ	NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.

VALIDITY AUDIT

OCTOBER 1999

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT	NOVEMBER 1999	* VALIDITY QUANTITATIVE TEST RESULT									
DATE RECEIVED	LAB ACCESSION #	RESULT	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
					ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

NOVEMBER 1999

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT

DECEMBER 1999

* VALIDITY QUANTITATIVE TEST RESULT

DATE RECEIVED	LAB ACCESSION #	RESULT	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
					ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

DECEMBER 1999

DATE RECEIVED	LAB ACCESSION	CLIENT #	RESULT	PURPOSE OF TEST

DECEMBER 1999DONE

VALIDITY AUDIT	JANUARY 2000				* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			JANUARY 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

JAN2000DONE

VALIDITY AUDIT

FEBRUARY 2000

* VALIDITY QUANTITATIVE TEST RESULT

DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			FEBRUARY 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

FEB2000DONE

VALIDITY AUDIT			MARCH 2000		* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			MARCH 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

/ALIDITY AUDIT

APRIL 2000

* VALIDITY QUANTITATIVE TEST RESULT

DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			APRIL 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

APR2000DONE

VALIDITY AUDIT MAY 2000					* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			MAY 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

MAY2000DONE

VALIDITY AUDIT JUNE 2000					* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			JUNE 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

JUNE 2000DONE

VALIDITY AUDIT JULY 2000					* VALIDITY QUANTITATIVE TEST RESULT								
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
							ORIGINAL	NEW ALIQ					

VALIDITY AUDIT JULY 2000

DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

JULY2000 DONE

VALIDITY AUDIT			AUGUST 2000	* VALIDITY QUANTITATIVE TEST RESULT							
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
						ORIGINAL	NEW ALIQ					

VALIDITY AUDIT

AUGUST 2000

DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

VALIDITY AUDIT		SEPTEMBER 2000			* VALIDITY QUANTITATIVE TEST RESULT					
DATE RECEIVED	LAB ACCESSION #	RESULT	SPECIMEN ID #	DATE REPORTED	CREATININE AU800		NITRITE	pH AU800	pH METER	SPECIFIC GRAVITY AU800	REFRAC.
					ORIGINAL	NEW ALIQ					

VALIDITY AUDIT			SEPTEMBER 2000	
DATE RECEIVED	LAB ACCESSION #	CLIENT #	RESULT	PURPOSE OF TEST

SEPT 2000 DONE

RESEARCH TRIANGLE INSTITUTE

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:

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 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.

Sincerely,

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/svt149

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0149
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

Section K. Records Audit

Section L. Certification and Reporting