Validity Testing Information Part I

Laboratory Name: Poisonlab
Address: 7272 Clairemont Mesa Blvd. San Diego CA
Responsible Person: Robert West (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).

Robert West — Signature, Responsible Person

10/4/00 — Date

Robert West — 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:

- **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).

Robert West
Signature, Responsible Person

10/25/00
Date

Robert West
Printed Name, Responsible Person

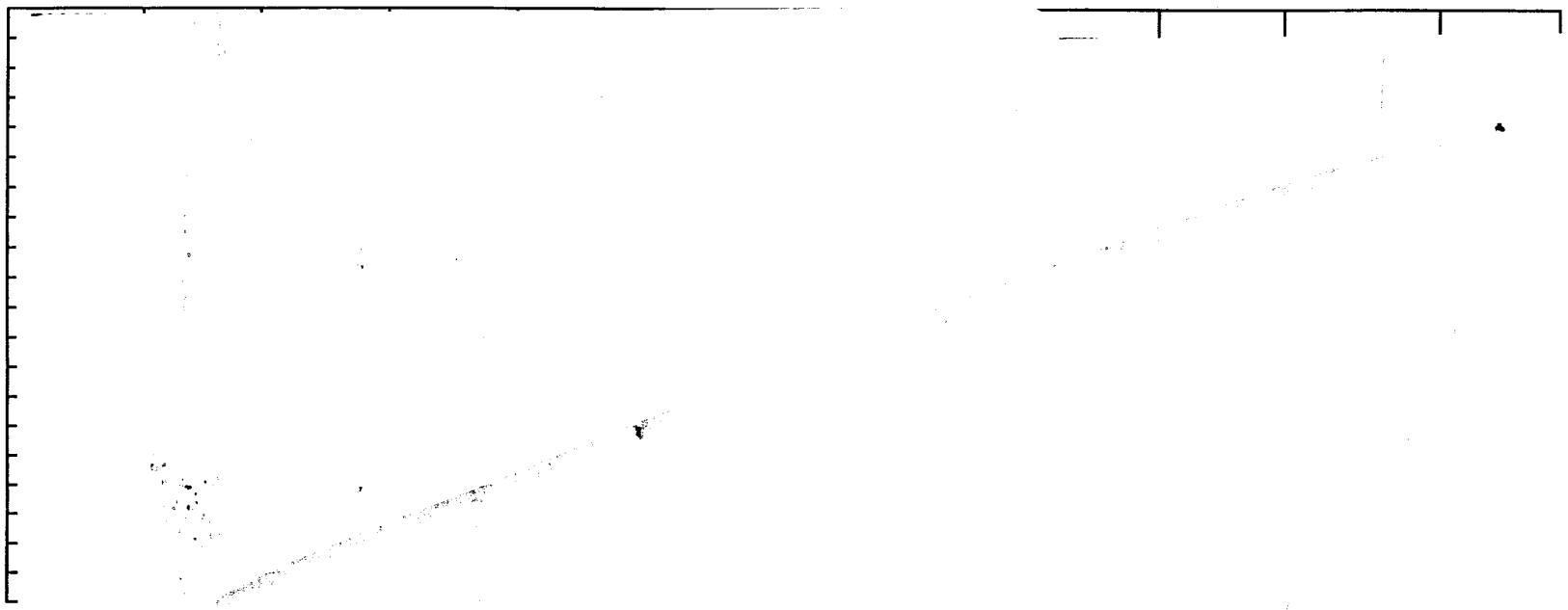
VALIDITY TESTING INFORMATION PART II
OCTOBER 2000, POISONLAB

SID	PID	RCV DATE	RPT DATE	RESULT	CREAT 1	CREAT 2	SPEC GR	NITRITE 1	NITRITE 2	CHROM	PH

NITRITE 2	CHROM	PH

VALIDITY TESTING INFORMATION PART II
OCTOBER 2000, POISONLAB

VALIDITY TESTING INFORMATION PART II
OCTOBER 2000, POISONLAB



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 22, 2000

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

Dear Mr. West:

The enclosed critique was developed from the inspection report associated with the November 1, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full 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 correct/clarify 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 raised. 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. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

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/svt124

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0124
Document No. Final

Laboratory: Poisonlab, Inc.

Location: San Diego, CA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 1 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

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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

PoisonLab℠
ReferenceToxicology

12/20/00

received
SDC 12/22/00

Susan Crumpton
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton;

I am responding your request for documentation relating to our recent special inspection of Nov.1, 2000.

7272 Clairemont Mesa Boulevard • San Diego • California • 92111 Phone 619.279.2600 Facsimile 619.279.2259

Sincerely;

Robert West
Laboratory Director
LabCorp-OTS
San Diego, CA

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 8, 2001

0124
Mr. Robert West
Poisonlab, Inc.
7272 Clairemont Mesa Blvd.
San Diego, CA 92111

Dear Mr. West:

We have reviewed the material provided in your correspondence of December 20, 2000, submitted in response to issues raised during the November 1, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 22, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken. However, the following issues require additional clarification and corrective action:

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

Based upon our review of the material submitted, it appears that the laboratory has taken steps to ensure 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) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0124