Sent By: LABONE;

9138881692;

Oct-5-00 5:03;

Page 2/4

Validity Testing Information Part I

Laboratory Name:

Address:

Responsible Person: Michael Peat (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, <u>fi</u>ctitious, 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 · 60
Date

e Person

HICHAGL A. PEAT

Printed Name, Responsible Person

Sent By: LABONE; 9138881692; Oct-5-00 5:04; Page 4/4

ATTACHMENT

NLCP PD 37

10.5.00

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

Date

MICHAEL A. PEAT

Printed Name, Responsible Person



MICHAEL A. PEAT, Ph.D.

President, Substance Abuse Testing Division and Executive Vice President, Toxicology

MEMO: FROM MICHAEL A. PEAT PH.D.

DATE:

OCTOBER 17, 2000

TO:

KEN DAVIS, RTI

CC:

LANCE PRESLEY, DAWN HAHN

FROM:

MIKE PEAT

RE:

AUDIT REQUEST FOR SUBSTITUTED AND ADULTERATED SPECIMENS

Please find attached three spreadsheets for the data requested.

The data included in the attached spreadsheets were retrieved in the following manner:

In conversations with Drs Mitchell and Baylor and you, we discussed the retrieval of these data for the upcoming inspection. We will immediately begin pulling data for the substituted specimens and await instructions regarding the adulterated ones.

Thank you for your patience and understanding in this matter.

MAP

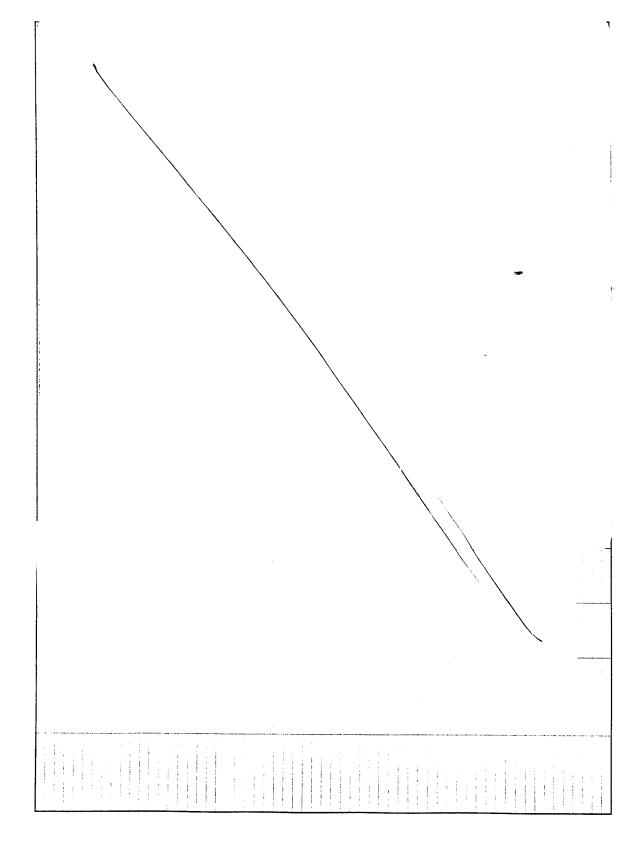
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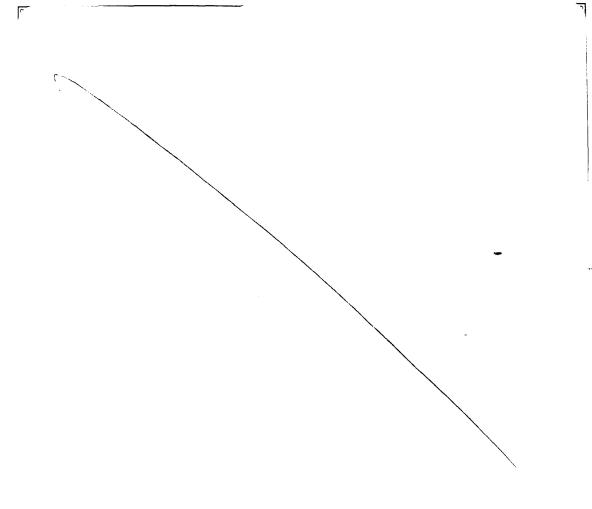
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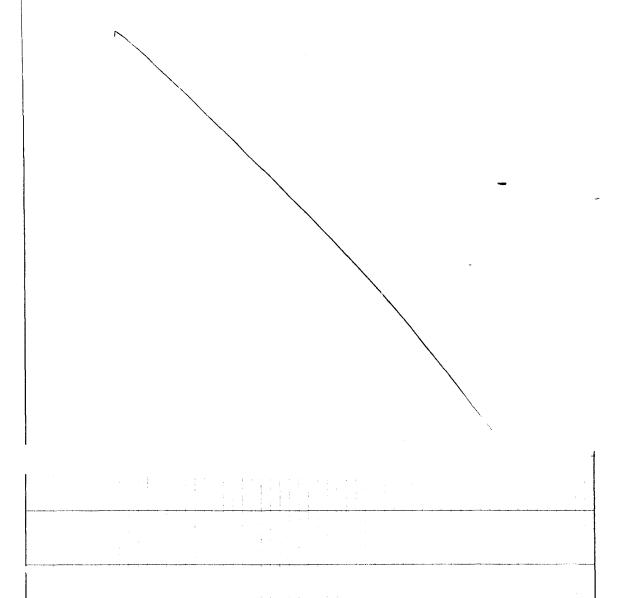
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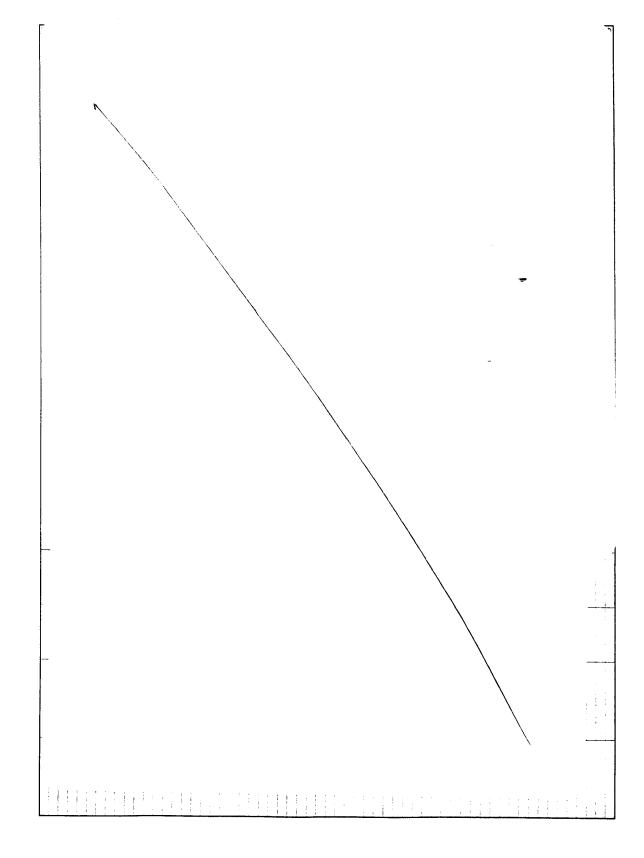
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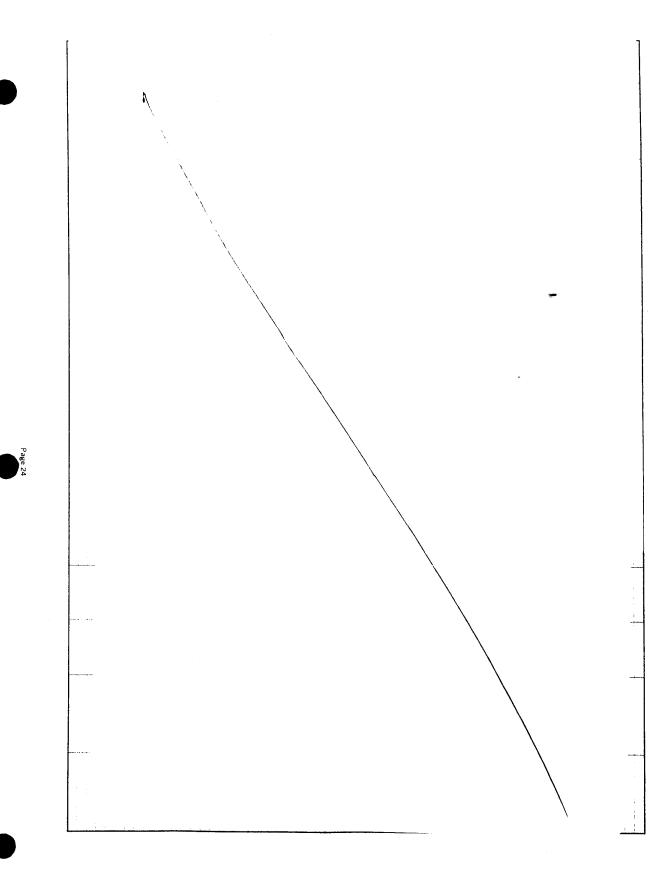
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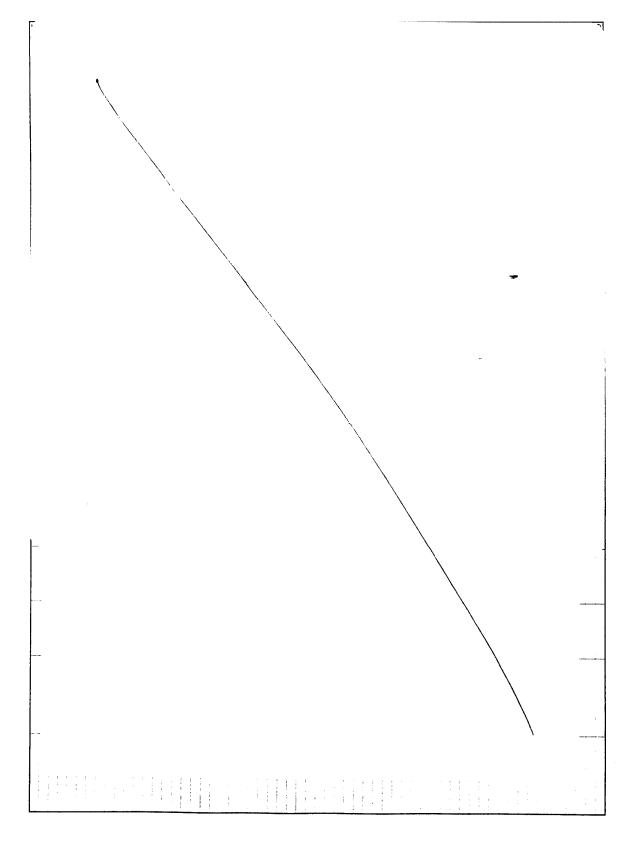
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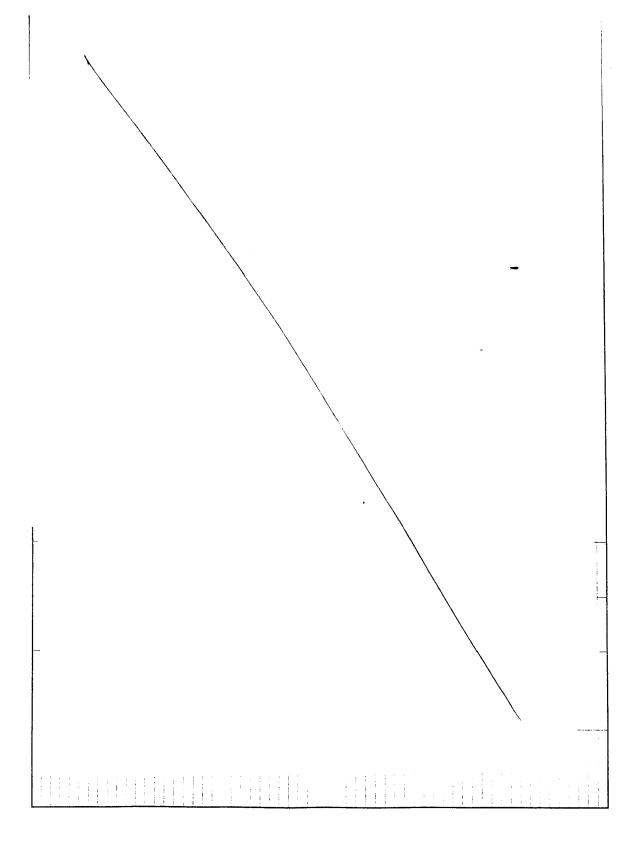
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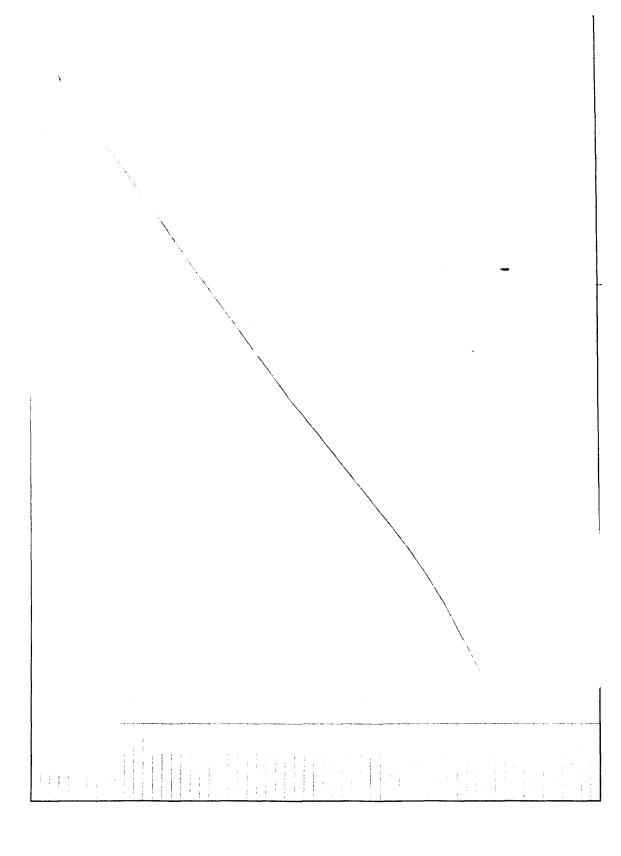
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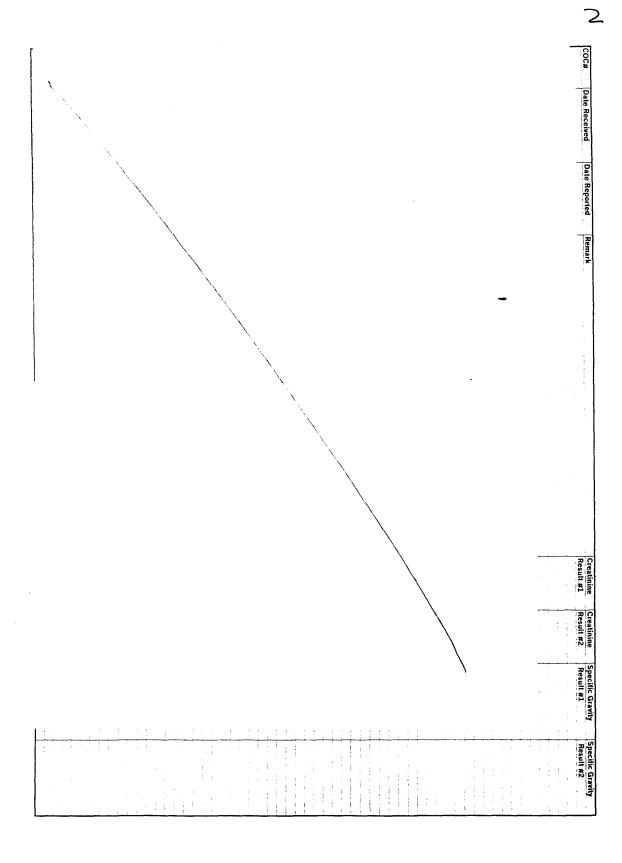










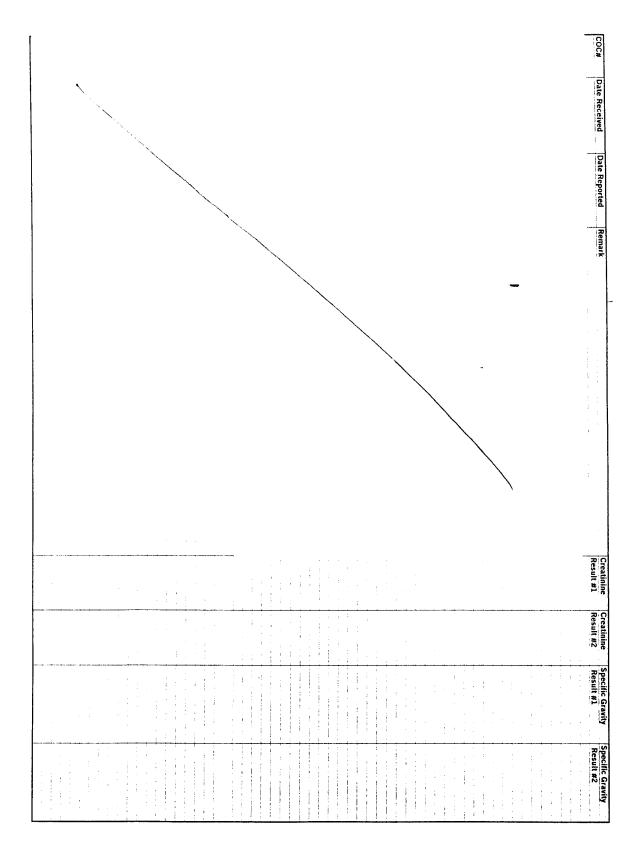


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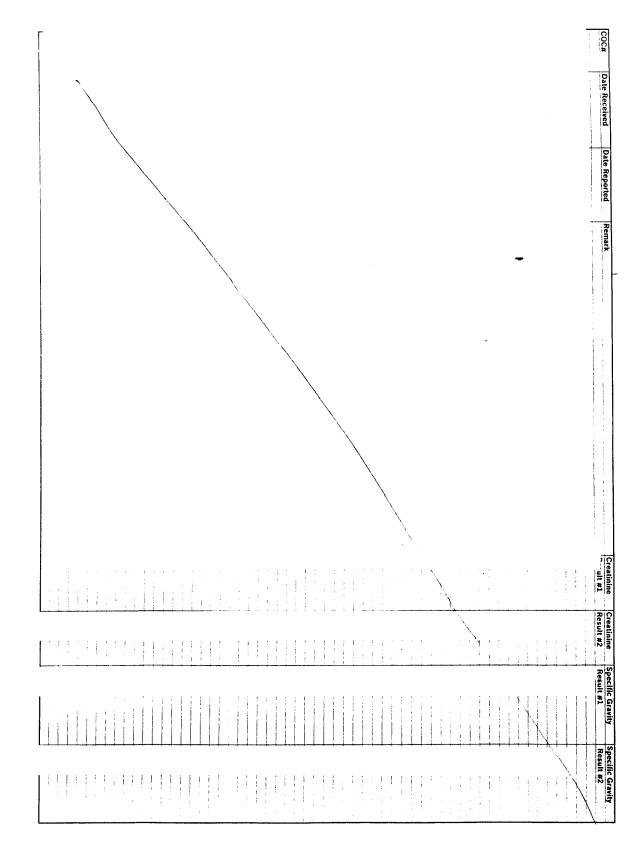
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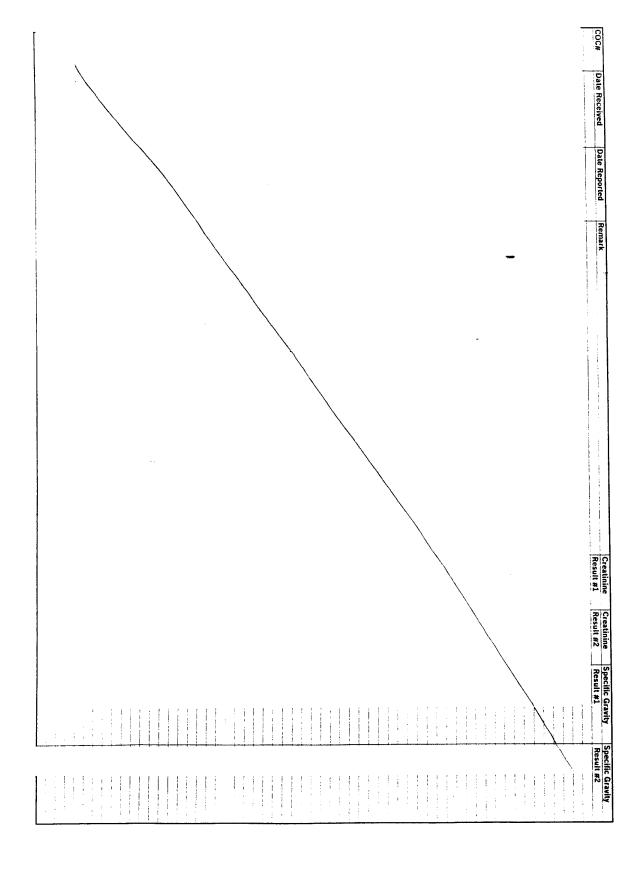




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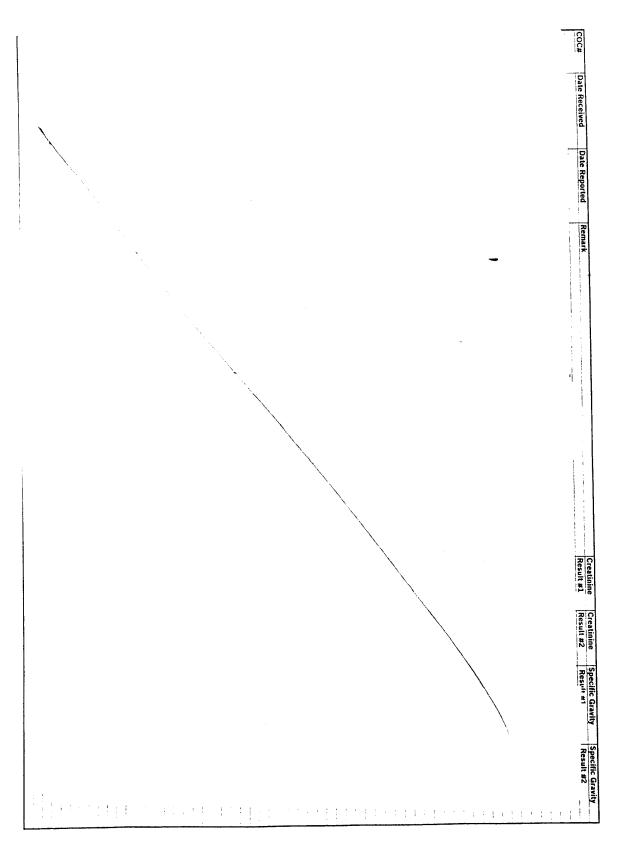


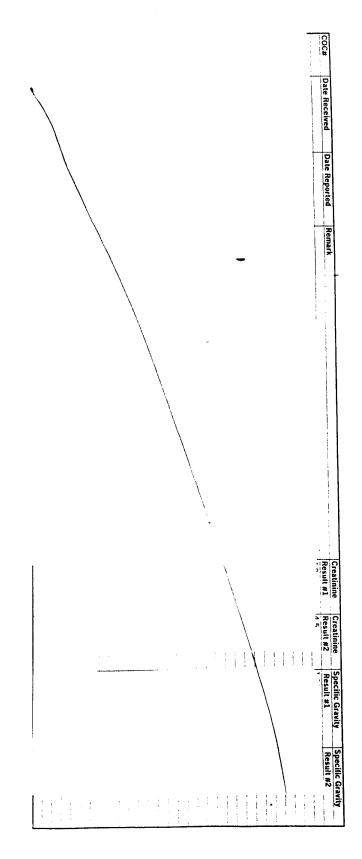


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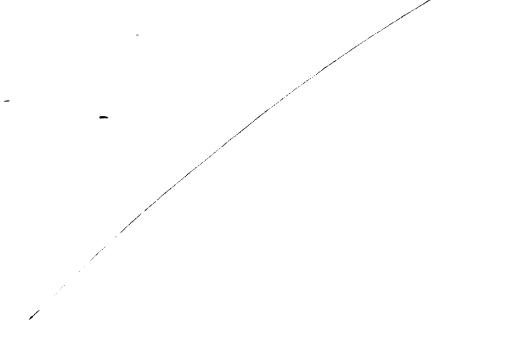
National Laboratory Certification Program

December 13, 2000

0325
Dr. Michael A. Peat
Dr. Lance Presley
LabOne Inc.
10101 Renner Boulevard
Lenexa, KS 66219

Dear Dr. Peat and Dr. Presley:

The enclosed critique was developed from the inspection report associated with the November 13-16, 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 address the following issues raised:



Drs. Peat and Presley Page 2 of 4 12/13/00 Drs. Peat and Presley Page 3 of 4 12/13/00 Drs. Peat and Presley Page 4 of 4 12/13/00

The laboratory must submit documentation that corrective actions have been implemented to address the other issues raised within 30 calendar days. 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. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens. All corrective actions 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/svt325

# **INQUIRY TO MRO**

Lab Num	ber
Name of	person contacted at MRO office:
Phone N	umber: ( <u>)</u>
Specii	men ID Number:
MRO Dis	position:
	Substituted, substitution admitted by donor during interview
	Substituted, substitution denied by donor during interview
	Substituted, substitution not admitted or denied during
	interview
	Substituted, donor not contacted
	Substituted, no comments regarding donor contact
	Refusal to test
	Interpreted as negative by MRO
	Records not available from MRO
	Cancelled, medical explanation
	Cancelled, other (briefly
	explain)
	Other (briefly
	ovnloin)

#### NATIONAL LABORATORY CERTIFICATION PROGRAM

## **Document Review and Critique**

Laboratory I.D. Number: <u>0325</u>

Document No. Final

Laboratory:

LabOne, Inc.

Location:

Lenexa, KS

Document Reviewed:

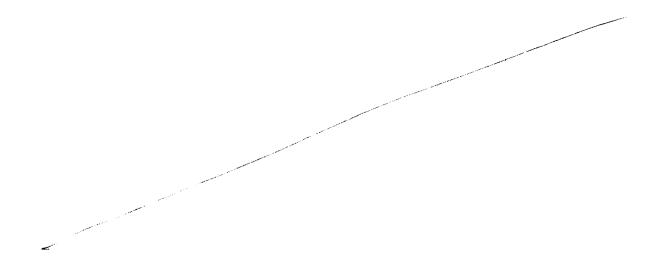
[XX] Specimen Validity Testing Inspection Report

Date: 13 November 2000

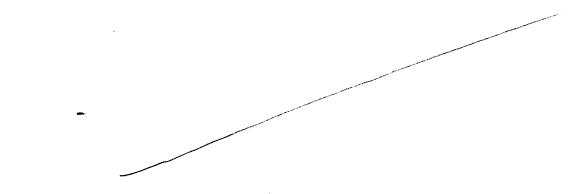
A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

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

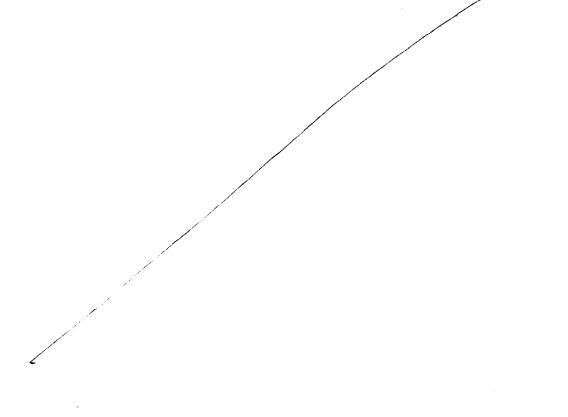


Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control and Quality Assurance

Ver. Final Lab ID# 0325



Section I. Specimen Validity Tests

Ver. Final Lab ID# 0325

Ver. Final	Lab ID# 0325
vei, riiiai	Lab ID# 05

Section K. Records Audit

Ver. Final	Lab ID# 0325

Section L. Certification and Reporting

Section O. Overall



December 18, 2000



Susan Crumpton Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709

This	letter	is in	reference	e to you	ur letter	dated	December	13, 2000	
	To the Address of the American and	h was a se service a service	manager and manager substance and the contract of the contract		and a trace of the second seco	to a state of the same production of	and the second s		
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Please call me at 1-800-873-8845, ext. 1626 if you have any questions.

Sincerely,

Dr. Lance Presley

Sr. Vice President of Toxicology





#### LANCE C. PRESLEY, Ph.D., DABFT Senior Vice President, Toxicology

January 11, 2001

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

Dear Ms Crumpton,

Enclosed you will find the requested documentation in response to your letter of December 13, 2000. Your letter gave the critique of our specimen validity testing inspection of November 13-16, 2000. As you requested, we are responding to the items as they were listed. Attachments are also labeled according to section.



If you need anything else, please let me know.

Sincerely,

Lance Presley, R.P.



## LANCE C. PRESLEY, Ph.D., DABFT

Senior Vice President, Toxicology

January 15, 2001

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

Dear Ms Crumpton,

Enclosed you will find additional requested documentation in response to your letter of December 13, 2000. Your letter gave the critique of our specimen validity testing inspection of November 13-16, 2000. As you requested, we are responding to the items as they were listed. Attachments are also labeled according to section.

These were inadvertently left out from the Friday letter. If you need anything else, please let me know.

Sincerely,

Lance Presley, R.P.





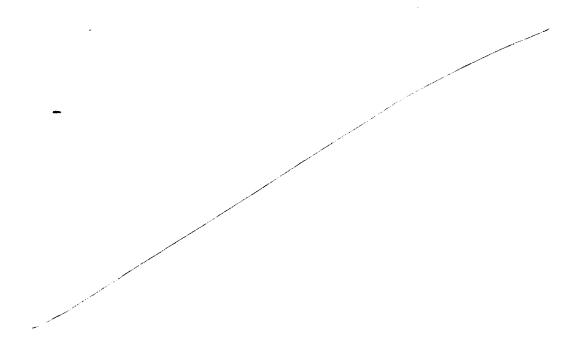
National Laboratory Certification Program

February 14, 2001

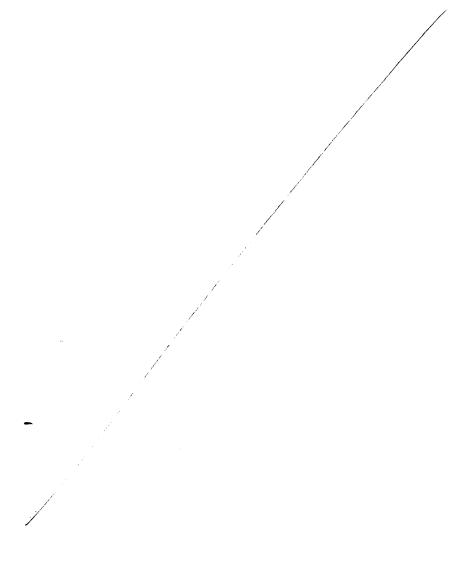
0325
Dr. Lance Presley
LabOne Inc.
10101 Renner Boulevard
Lenexa, KS 66219

Dear Dr. Presley:

We have reviewed the material provided in your correspondence of December 18, 2000, January 11, 2001, and January 15, 2001, submitted in response to issues raised during the November 13, 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 appropriate corrective actions have been completed to address the issues raised. The following issues remain or were raised during our review of the laboratory's submissions:



Dr. Presley Page 2 of 4 02/14/01 Dr. Presley Page 3 of 4 02/14/01



Based upon our review of the material submitted, it appears that the laboratory has taken steps to ensure that its specimen validity testing procedures are in compliance with program guidance. The laboratory must take corrective actions to address the issues

Dr. Presley Page 4 of 4 02/14/01

outlined above. 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 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) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

NLCP Technical Analyst

Enclosure

cc: Project Files/SVT0325