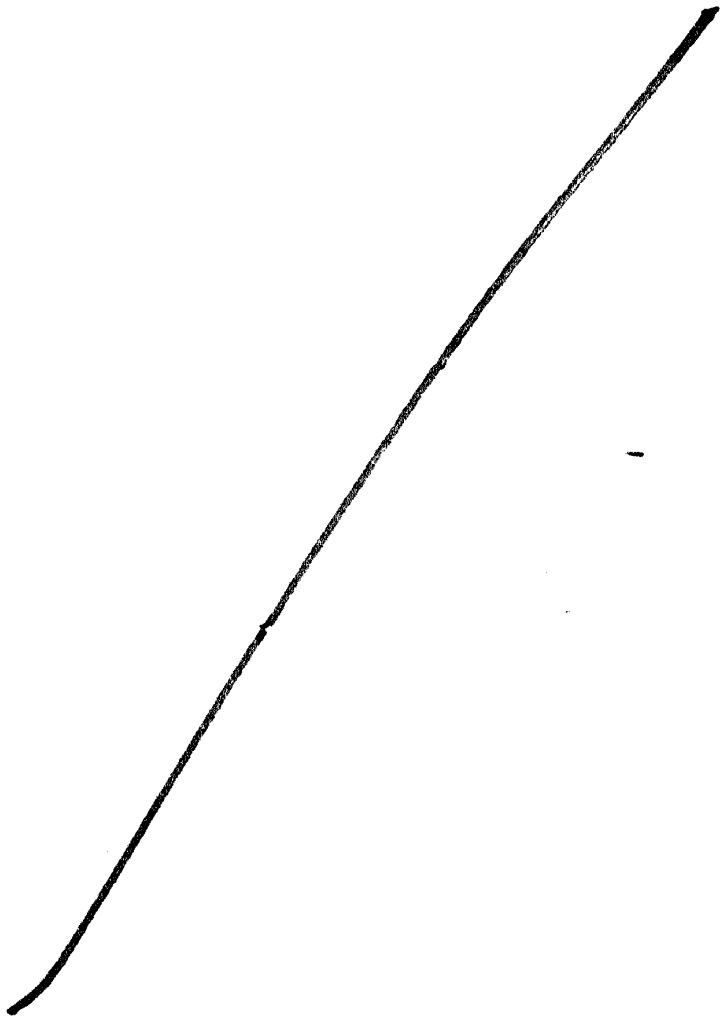
Validity Testing Information Part I

Laboratory Name: Cox Toxicology
Address: 1423 N. Jefferson Ave
Springfield, MO 65802
Responsible Person: William D. Hemphill (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

Oct 5, 2000
Date

W.D. HEMPHILL, Ph.D.
Printed Name, Responsible Person

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417-269-3093 October 5, 2000

Validity Testing Information Part 1
Addendum

Respectively,

Ike Hemphill, Ph.D, DABFT

	A	B	C	D	E	F	G	H	I
1	COX TOXICOLOGY (LAB 0443) SPRINGFIELD, MO								
2	NLCP Specimen Validity Testing Summary (October, 2000)								
3									
4	**Date Range:**	**9/28/98 -**	**10/4/2000**	**DOT Samples**					
5	**Spec. ID**	**LAN**	**Receive Date**	**Report Date**	**Adulterant**	**Quant.**	**Creat. Result**	**Sp. Gr.**	**Reported Result**
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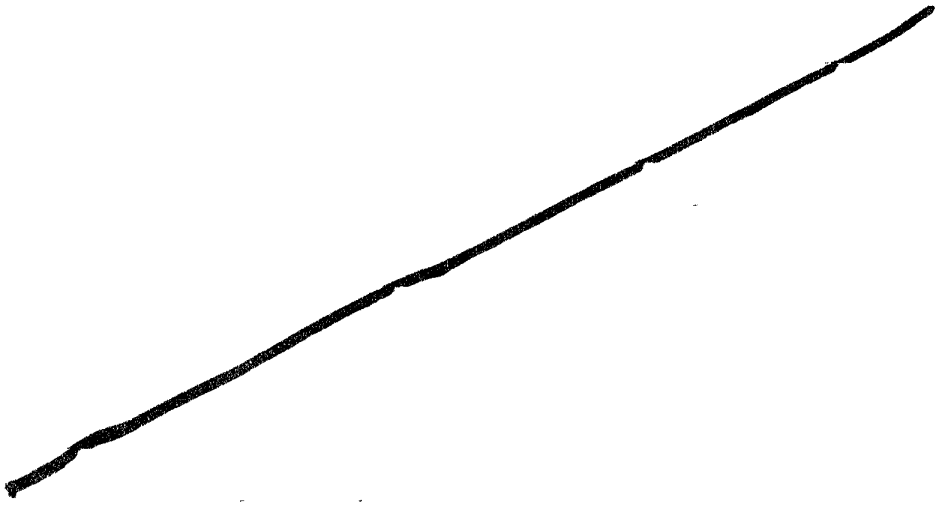
Cox Toxicology 417-269-3093 phone
417-269-8856 fax

October 29, 2000

Dr. John Mitchell
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, N.C. 27709-2194

Subject: Specimen Validity Testing Audit

Dr. Mitchell, this letter is in reference to a facsimile communication from RTI on 29 October, 2000



Respectively,

W.D. Hemphill

W.D. Hemphill, Ph.D., DABFT
ikeh@hotmail.com

	A	B	C	D	E	F	G	H	I
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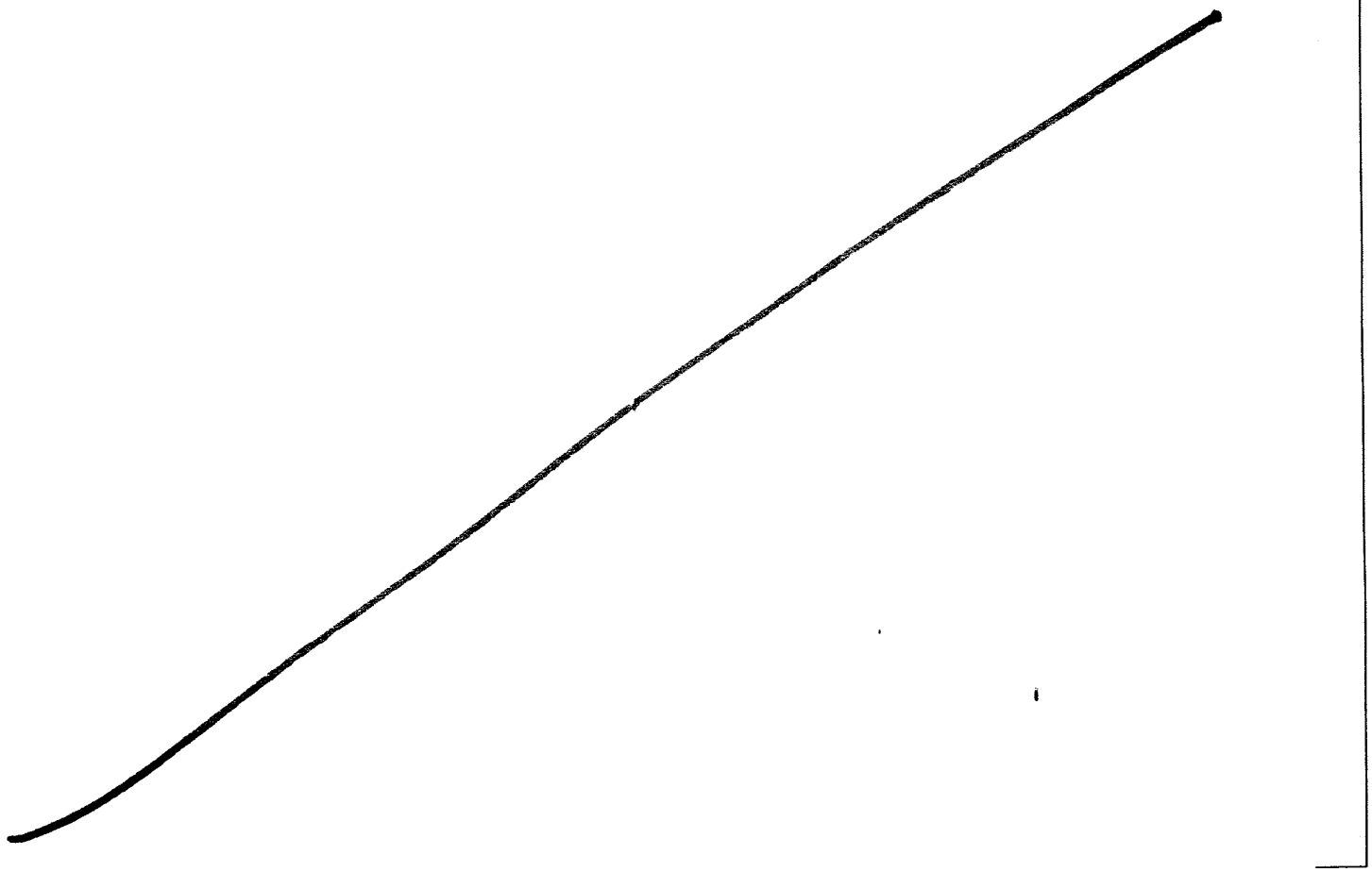

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RESEARCH TRIANGLE INSTITUTE

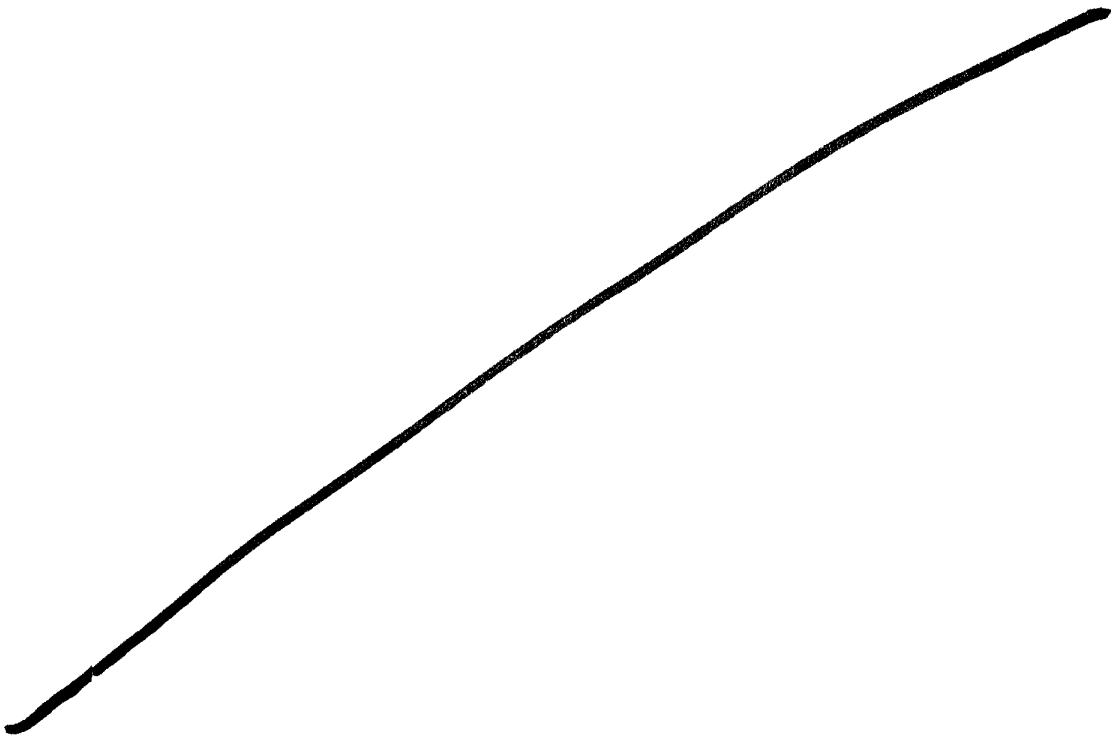
National Laboratory Certification Program

January 02, 2001

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

The enclosed critique was developed from the inspection report associated with the November 29, 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
NLCP Technical Analyst

Enclosure
cc: Project Files/svt443

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0443
Document No. Final

Laboratory: Cox Health Systems, Department of Toxicology

Location: Springfield, MO

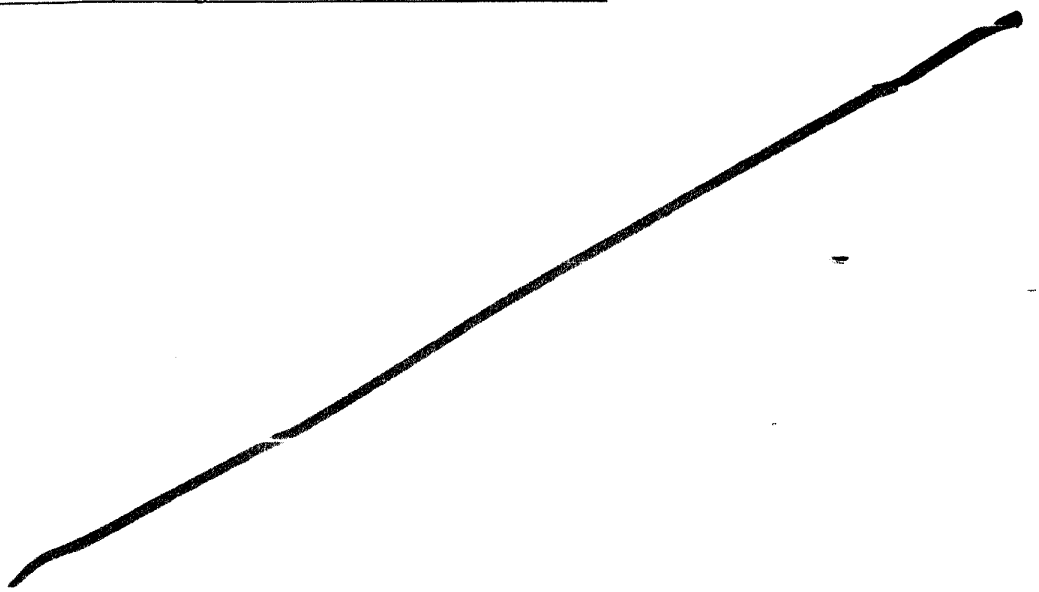
Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 29 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:

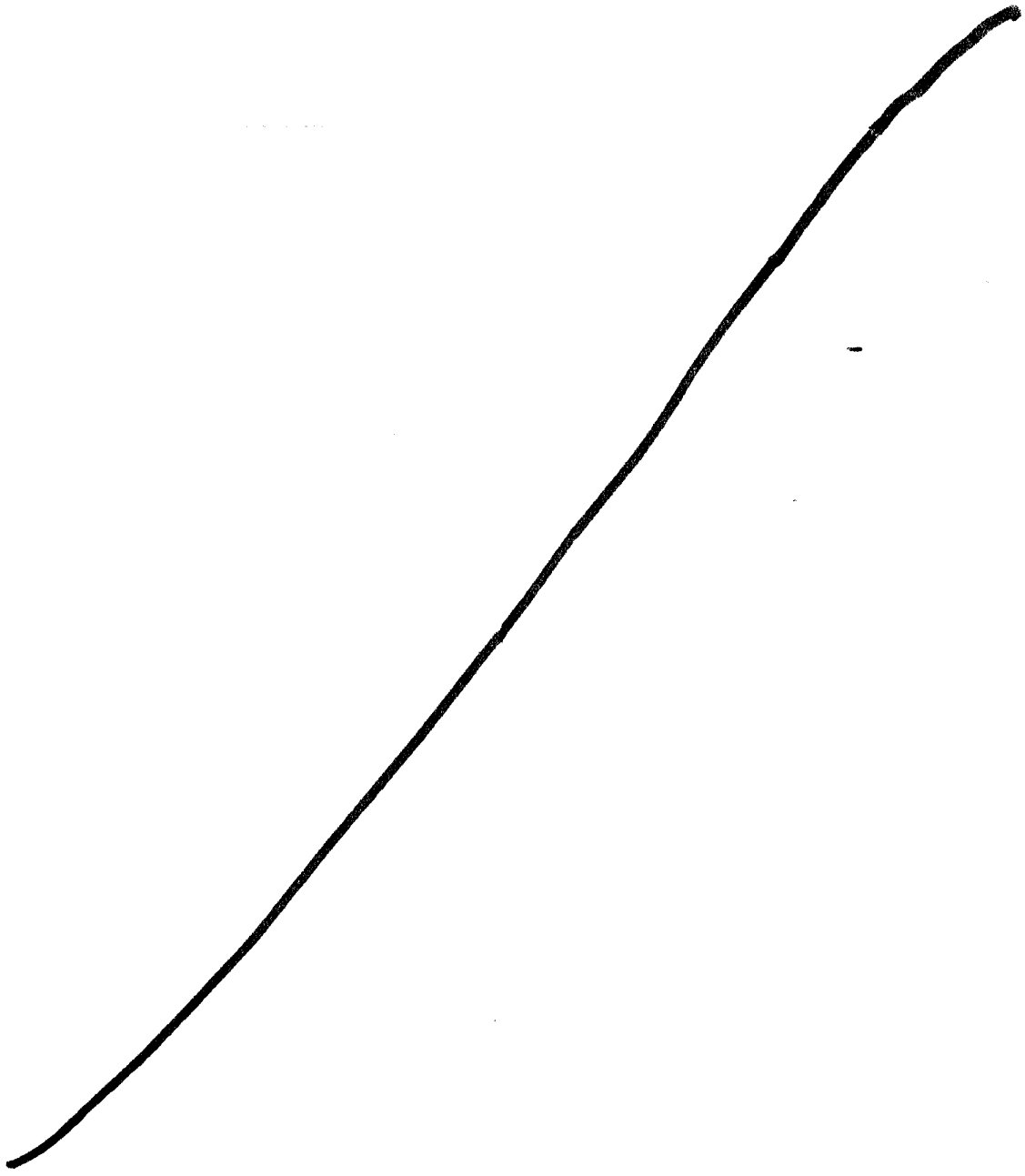
Section E. Standard Operating Procedures - Procedures Manual



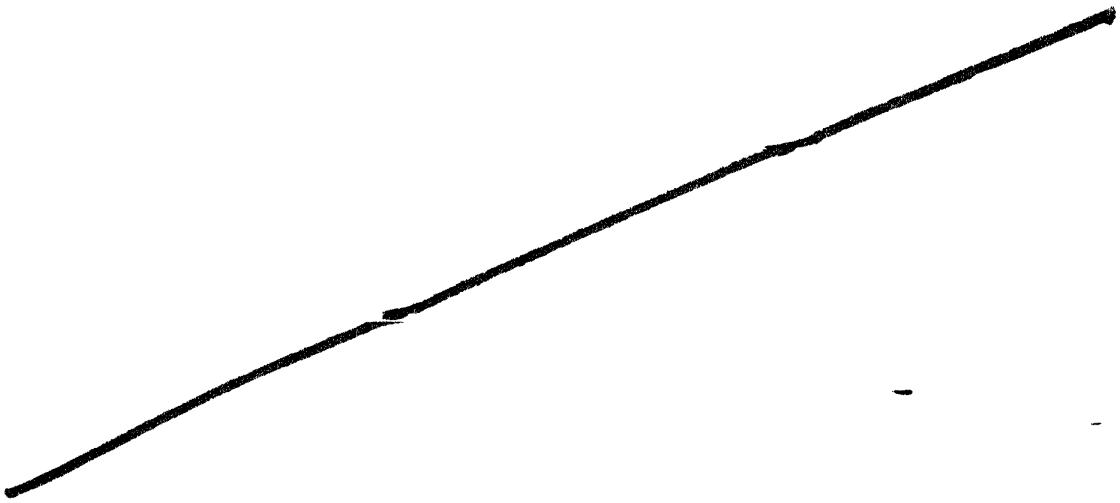
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Testing



Section K. Records Audit



Section L. Certification and Reporting

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Toxicology phone: 417/269-3093 LAB 0443
fax: 417/269-8856

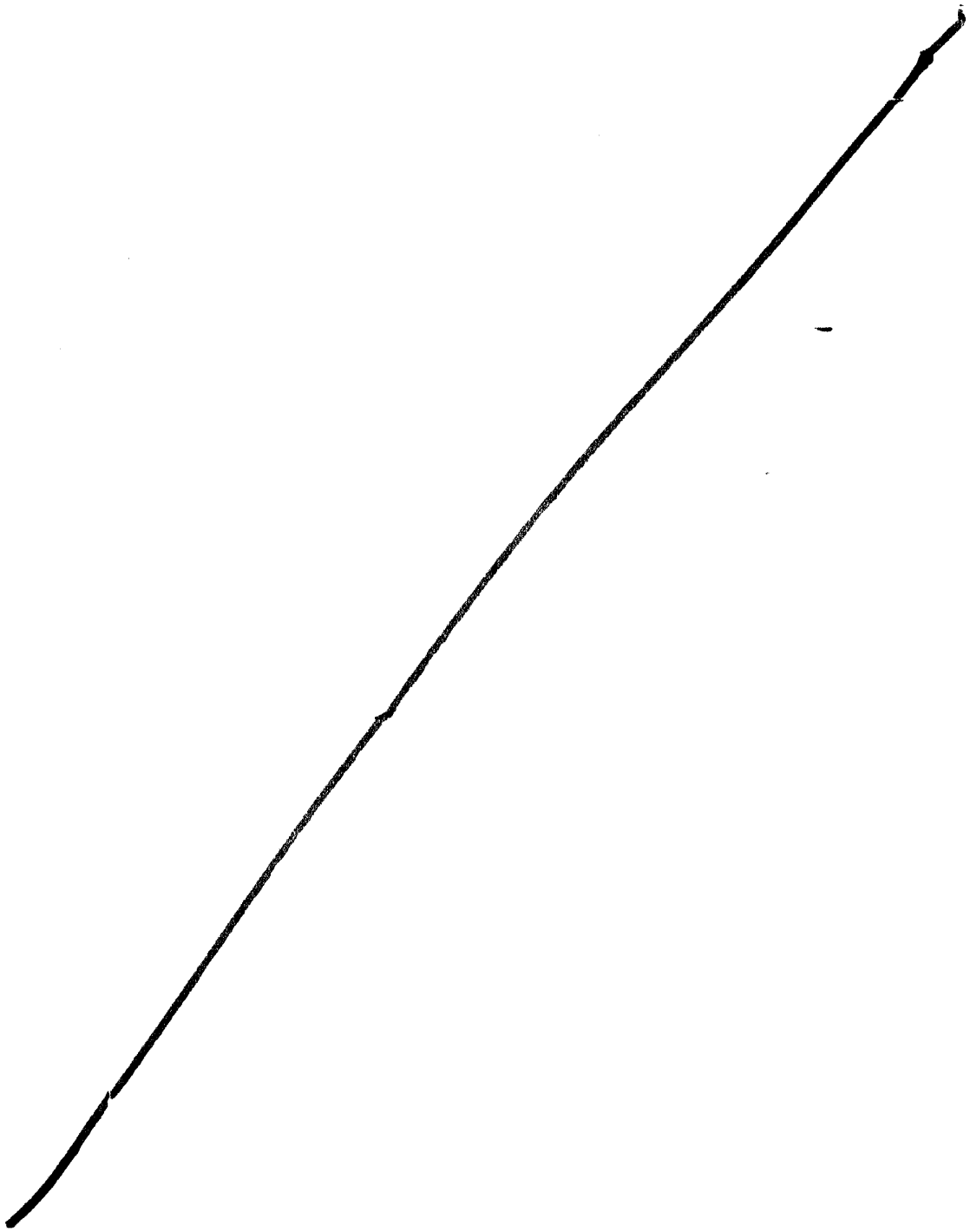
Feb 18, 2001

Deborah J. Denson
NLCP-RTI
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

Subject: Specimen Validity Inspection, 11/29/00, Corrective Actions

Ms. Denson:

Please find enclosed documentation supporting the corrective actions that have been put in place in regard to the above indicated Specimen Validity (SV) Inspection.



Respectively,

W.D. Hemphill, Ph.D., DABFT
ikeh@hotmail.com

RESEARCH TRIANGLE INSTITUTE

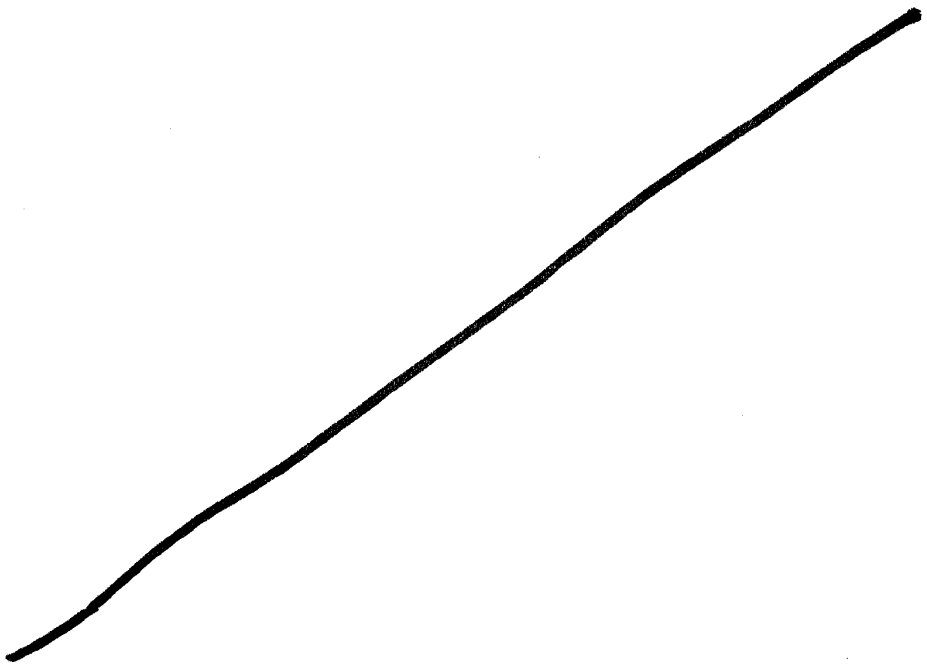
National Laboratory Certification Program

March 1, 2001

0443
Dr. William D. Hemphill
Cox Health Systems
Department of Toxicology
1423 N. Jefferson Ave.
Springfield, MO 65802

Dear Dr. Hemphill:

We have reviewed the material provided in your correspondence of February 18, 2001 submitted in response to issues raised during the November 29, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of January 02, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:



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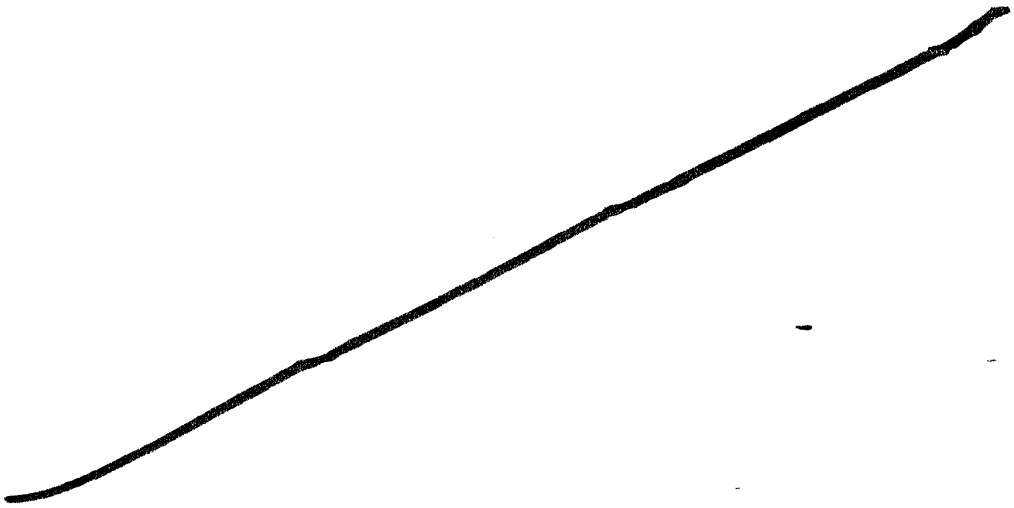
Telephone 919 541-6709 • Fax 919 541-7042



Based upon our review of the material submitted, it appears that the laboratory's 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 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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT443