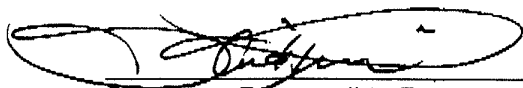


### Validity Testing Information Part I

Laboratory Name: LabCorp Raritan, NJ  
Address: 69 First Ave. Raritan, NJ 08865  
Responsible Person: David Perini (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

10/3/00

Date

DAVID Perini

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).

\_\_\_\_\_  
Signature, Responsible Person

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Responsible Person



**William E. Wingert, Ph.D.**

*Occupational Testing Services Division  
69 First Avenue South  
Raritan, New Jersey 08869  
Phone Number: 908-231-8279 Ext. 2225  
Fax Number: 908-526-1822  
E-Mail Address: wingerw@labcorp.com*

October 17, 2000  
Kenneth H. Davis, Jr.  
Research Triangle Institute, NLCP  
Research Triangle Park NC 27709

Dear Mr. Davis:

Enclosed are copies of the audits for validity testing on our 1100 and HP3000 computer systems. This includes all of the data that we have been able to pull at this time. I anticipate additional data to be available in the next few days and then will promptly forward it to RTI.

Sincerely,

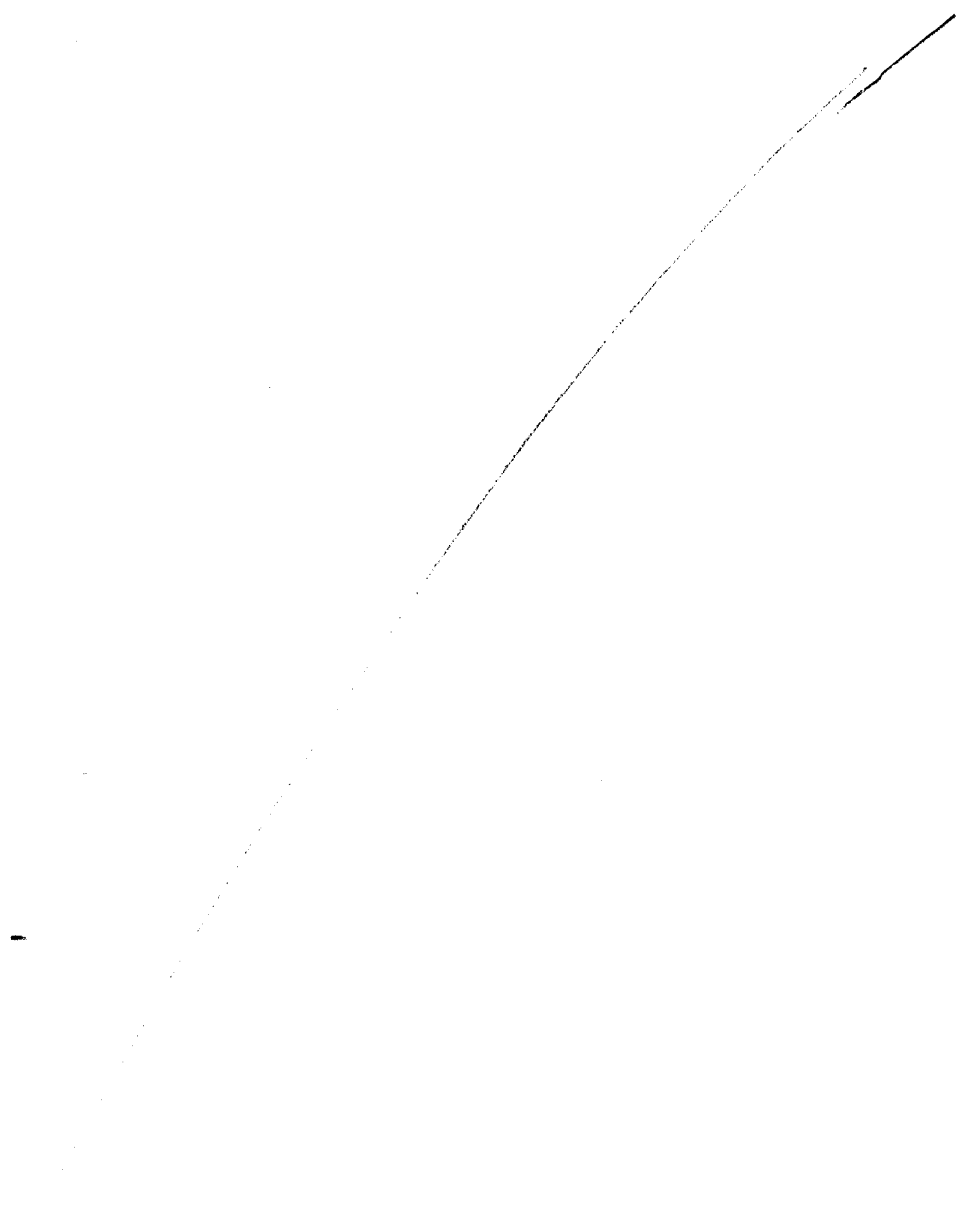
A handwritten signature in cursive script that reads "William E. Wingert".

William E. Wingert, Ph.D.  
Director, Forensic Toxicology

Adulterated or Substituted DOT Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - Raritan

<u>Specimen ID</u>	<u>Accession Nbr</u>	<u>Received Date</u>	<u>Reported Date</u>	<u>Reported Result</u>	<u>Quantitative Results</u>
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Adulterated or Substituted DOT Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - Raritan

<u>Specimen ID</u>	<u>Accession Nbr</u>	<u>Received Date</u>	<u>Reported Date</u>	<u>Reported Result</u>	<u>Quantitative Results</u>
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Laboratory Corporation of America® Holdings  
69 First Avenue  
Raritan, NJ 08869-2240

Telephone: 800-631-5250

**FACSIMILE TRANSMITTAL SHEET**

TO: Frank Wallace

FROM: William E. Wingert, Ph.D.

COMPANY: RTI

DATE: 11 / 1 / 00

FAX NUMBER: 919 541 7042

NUMBER OF PAGES INCLUDING COVER:

PHONE NUMBER:

SENDER'S PHONE NUMBER:  
800-437-4986 Northeast Division  
908-231-6279 Ext. 2225

RE: Subst / Adult. Audit

SENDER'S FAX NUMBER:  
908-526-1822

URGENT  FOR REVIEW  PLEASE COMMENT  PLEASE REPLY  PLEASE RECYCLE

NOTES/COMMENTS:

Frank,

Here is Raritan lab audit for Subst / Adult  
specimens from HP 3000 and 1100 Computer  
systems.

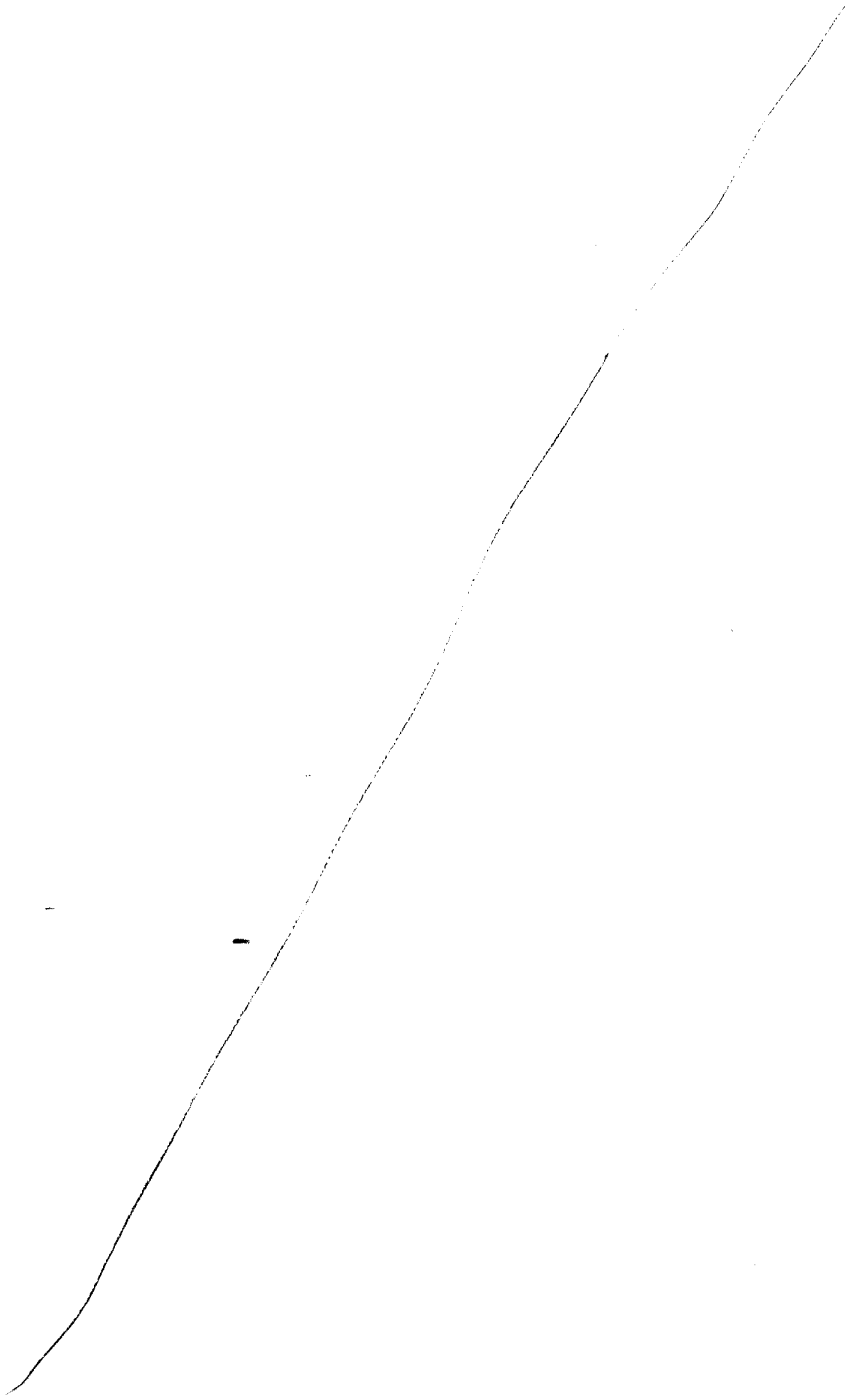


Adulterated or Substituted Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - Raritan

Specimen ID	Accession Num.	Received Date	Reported Date	Reported Result	Qualitative Results





1100 System Only

Specimen ID    Accession Number    Recv Date    Report Date    Result    Quantitative



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

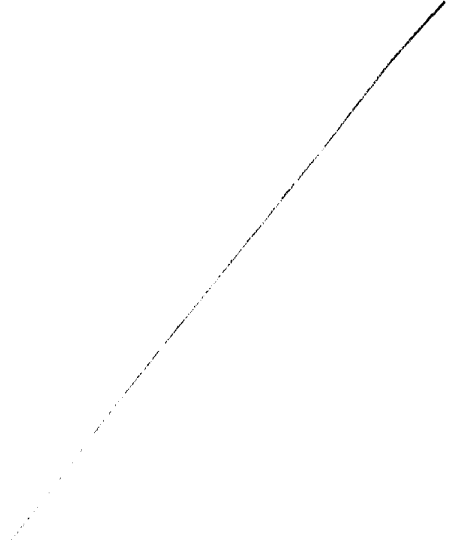
December 18, 2000

0153  
Dr. William Wingert  
Mr. David Perini  
Laboratory Corporation of America Holdings  
69 First Avenue  
P.O. Box 500  
Raritan, NJ 08869

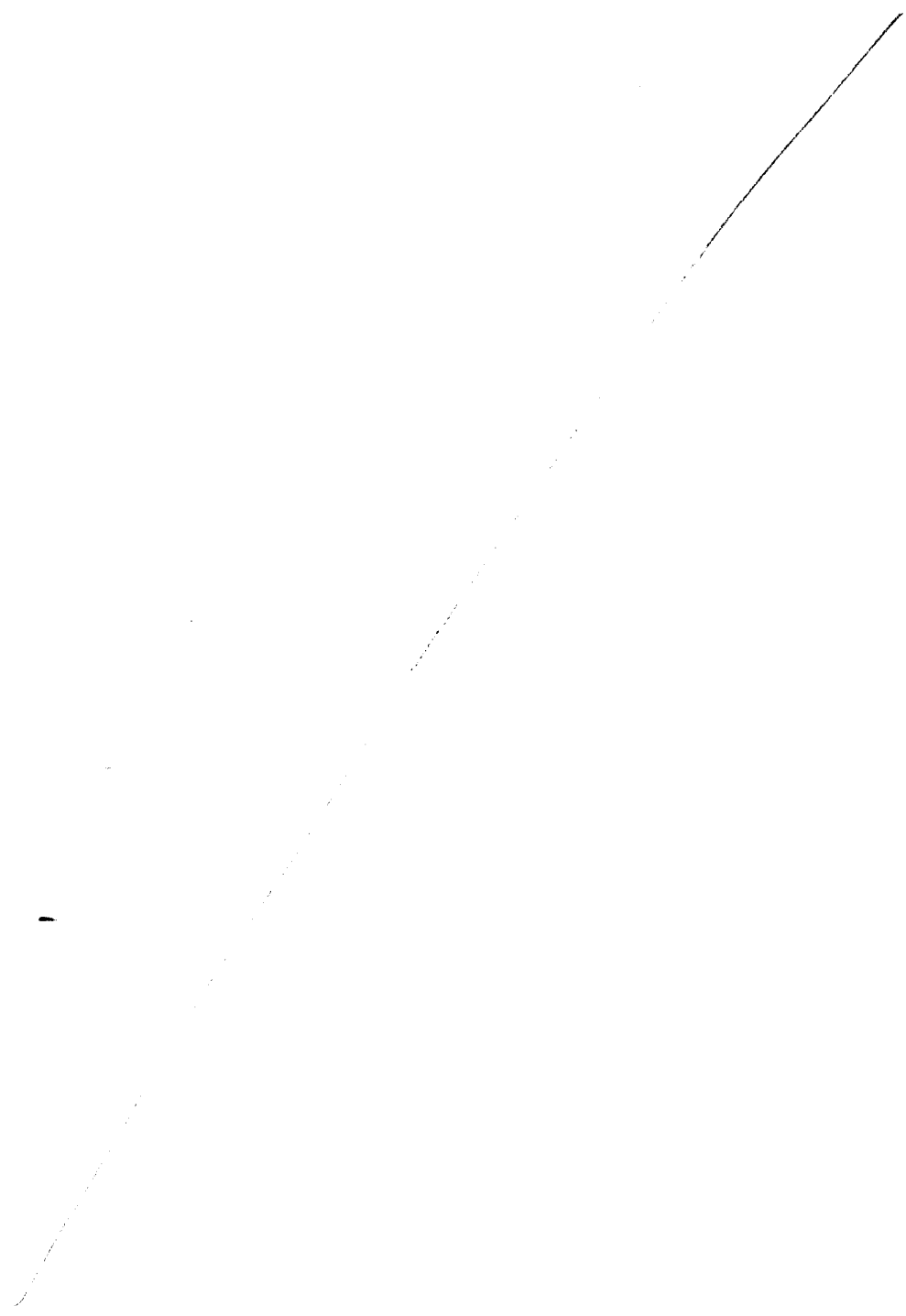
Dear Dr. Wingert and Mr. Perini:

The enclosed critique was developed from the inspection report associated with the November 15-17, 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:

Dr. Wingert  
Mr. Perini  
Page 2 of 4  
12/18/00



Dr. Wingert  
Mr. Perini  
Page 3 of 4  
12/18/00



Dr. Wingert  
Mr. Perini  
Page 4 of 4  
12/18/00

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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. The information from the MRO inquiry must be **submitted within 5 working days as noted above**. 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/svt153

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0153  
Document No: Final

Laboratory: Laboratory Corporation of America Holdings

Location: Raritan, NJ

Document Reviewed:  Specimen Validity Testing Inspection Report

Date: 15 November 2000

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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

Section O. Overall



**William E. Wingert, Ph.D.**

Occupational Testing Services Division  
69 First Avenue South  
Raritan, New Jersey 08869  
Phone Number: 908-231-8279 Ext. 2225  
Fax Number: 908-526-1822  
E-Mail Address: [wingerw@labcorp.com](mailto:wingerw@labcorp.com)

December 27, 2000  
Susan Crumpton, Technical Analyst  
Research Triangle Institute, NLCP  
3040 Cornwallis Road  
Research Triangle Park NC 27709

**received**  
12/29/00 SDC

Dear Ms. Crumpton:

This is in reply to your letter of December 18, 2000 concerning the specimen validity testing inspection of our laboratory.

Please contact me to advise how to proceed. I will be returning to the laboratory on January 2<sup>nd</sup>.

Sincerely,

William E. Wingert, Ph.D.  
Director, Forensic Toxicology



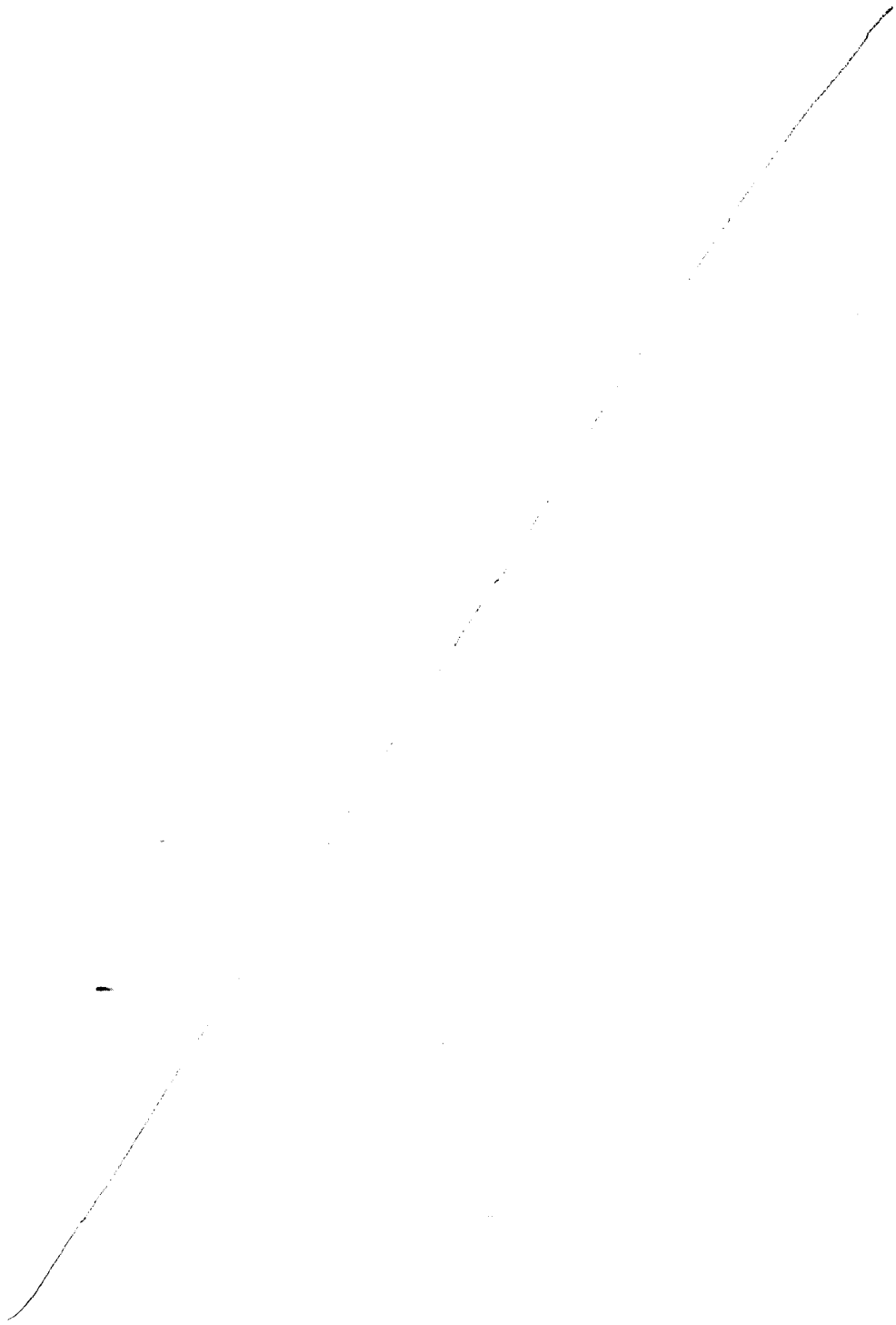
received  
1/19/01  
JDC

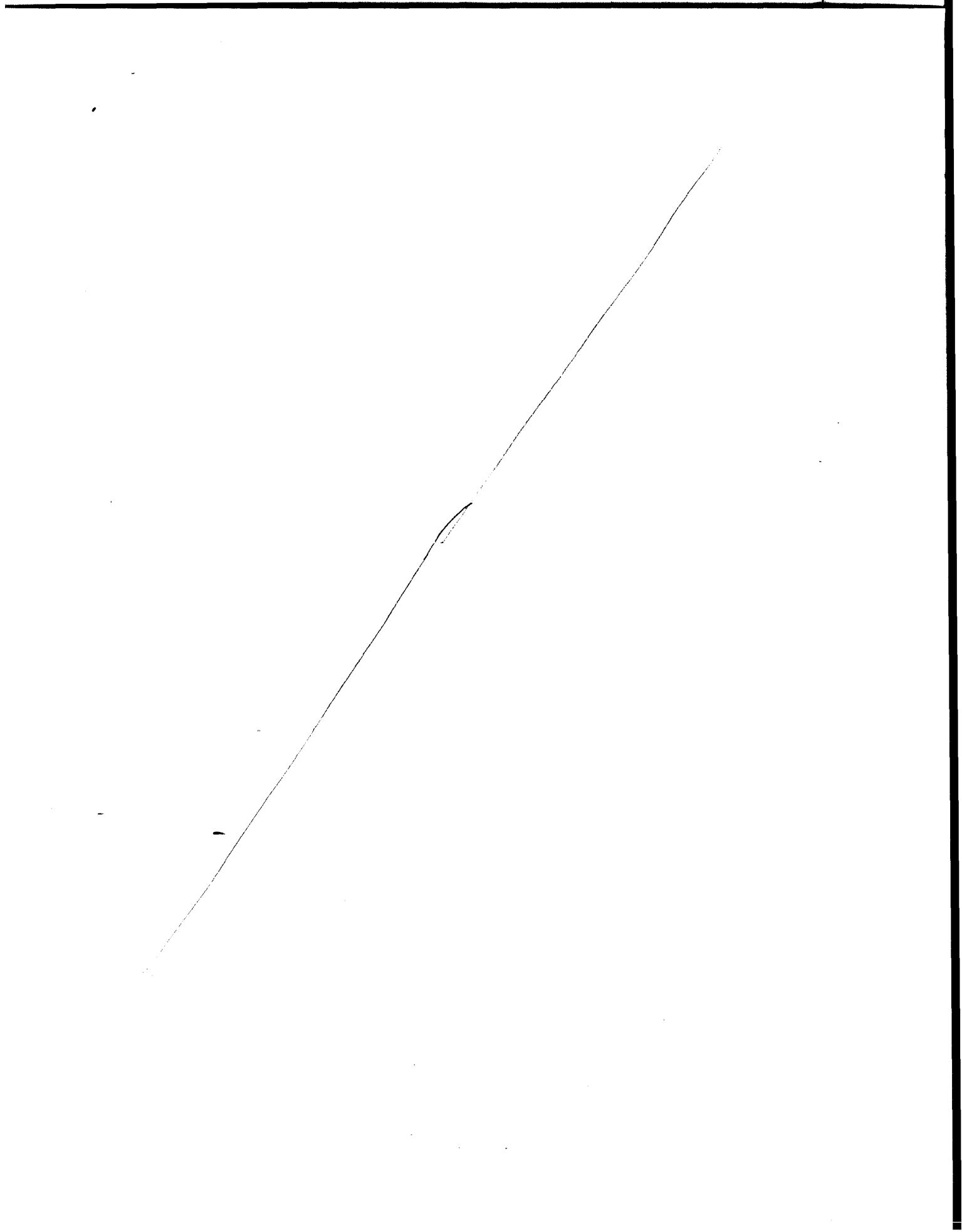
69 First Avenue  
Raritan NJ 08869

January 18, 2001  
Susan Crumpton, Technical Analyst  
Research Triangle Institute, NLCP  
3040 Cornwallis Road  
Research Triangle Park NC 27709

Dear Ms. Crumpton:

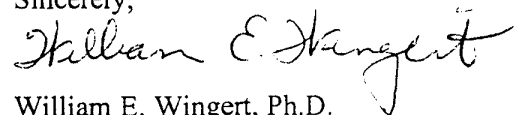
This is in reply to our specimen validity inspection critique from the NLCP dated December 18, 2000. Please note that some of the documentation that I am providing may pertain to more than item in the responses. This is denoted by references at the top of the attachments.





If there are any questions concerning the information provided, please do not hesitate to call me.

Sincerely,

A handwritten signature in cursive script that reads "William E. Wingert". The signature is written in black ink and is positioned above the typed name.

William E. Wingert, Ph.D.  
Director, Forensic Toxicology



# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 24, 2001

0153  
Dr. William Wingert  
Mr. David Perini  
Laboratory Corporation of America Holdings  
69 First Avenue  
P.O. Box 500  
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

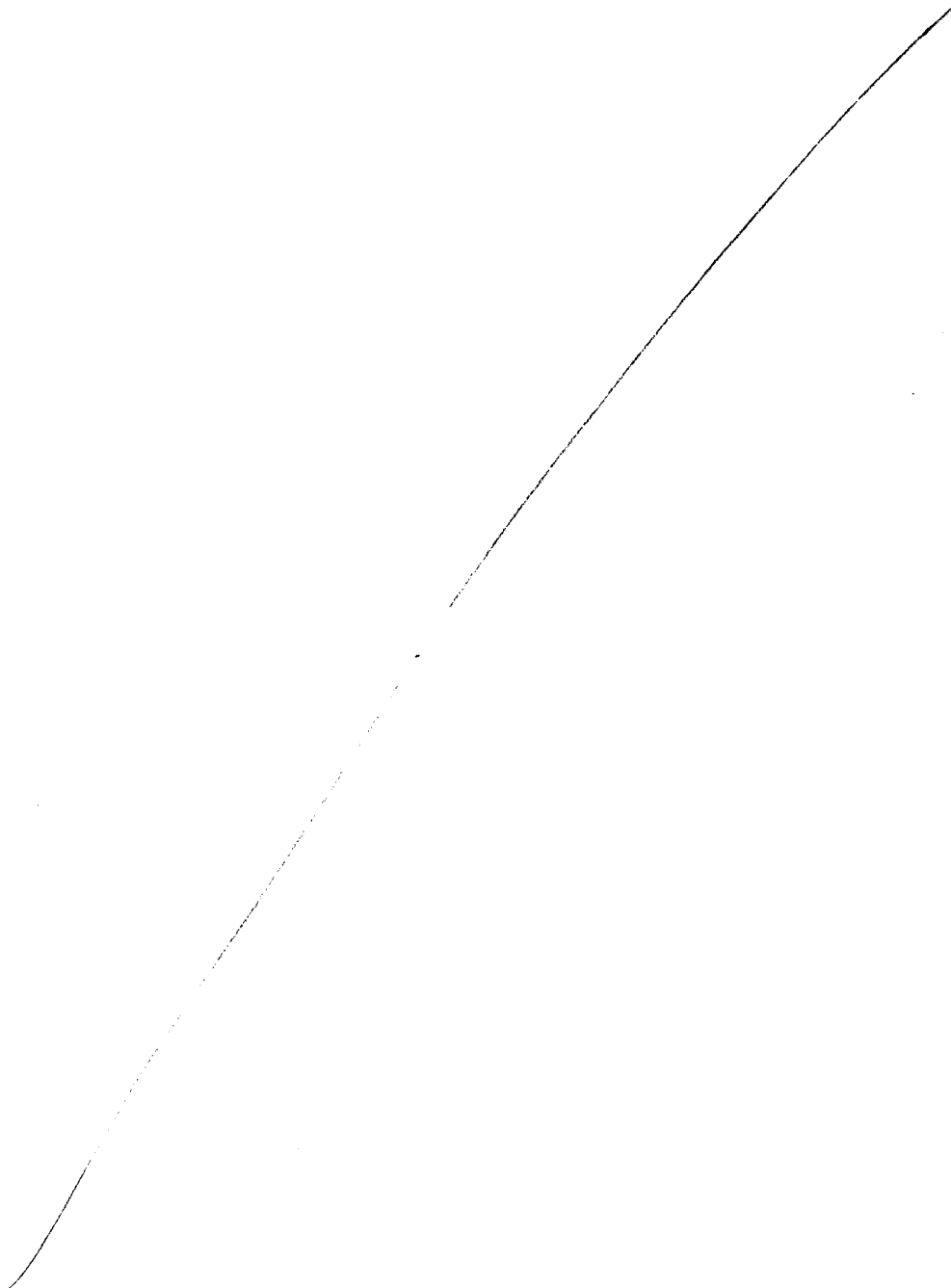
We have reviewed the material provided in your correspondence of January 18, 2001, submitted in response to issues raised during the November 15, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 18, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. However, the following issues require additional clarification and corrective action:

A large, thin, curved line that starts near the bottom left and extends diagonally upwards towards the right side of the page. It appears to be a signature or a placeholder for a signature.



Dr. Wingert  
Mr. Perini  
Page 2 of 5  
01/24/01

Dr. Wingert  
Mr. Perini  
Page 3 of 5  
01/24/01



Dr. Wingert  
Mr. Perini  
Page 4 of 5  
01/24/01

Dr. Wingert  
Mr. Perini  
Page 5 of 5  
01/24/01

The laboratory submitted some original documents to RTI. We have made copies for our records. **The originals are enclosed.**

The laboratory must submit, within 10 calendar days of receipt of this letter, documentation of corrective actions addressing the issues listed in this correspondence. All corrective actions must be implemented within 30 days of the receipt of this correspondence. ***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/SVT0153



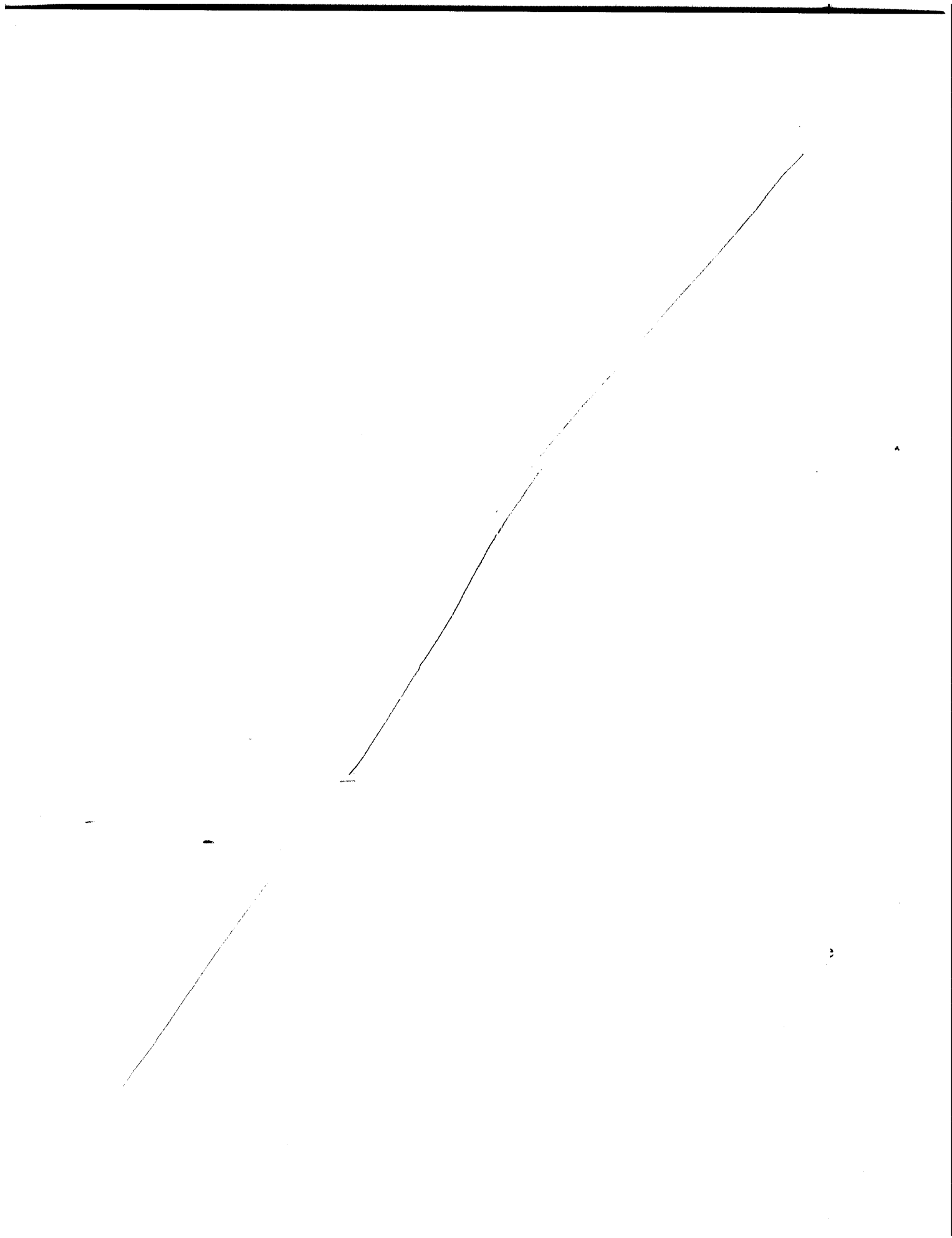
received  
SD/ 2/1/01

69 First Avenue  
Raritan NJ 08869

January 31, 2001  
Susan Crumpton, Technical Analyst  
Research Triangle Institute, NLCP  
3040 Cornwallis Road  
Research Triangle Park NC 27709

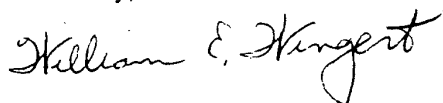
Dear Ms. Crumpton:

This is in reply to your correspondence of January 24, 2001 concerning our laboratory's specimen validity testing inspection of November 15, 2000.



If there are any questions concerning the information provided, please call me at 908-526-2400, ext 2225.

Sincerely,

A handwritten signature in cursive script that reads "William E. Wingert". The signature is written in black ink and is positioned above the typed name.

William E. Wingert, Ph.D.  
Director, Forensic Toxicology



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

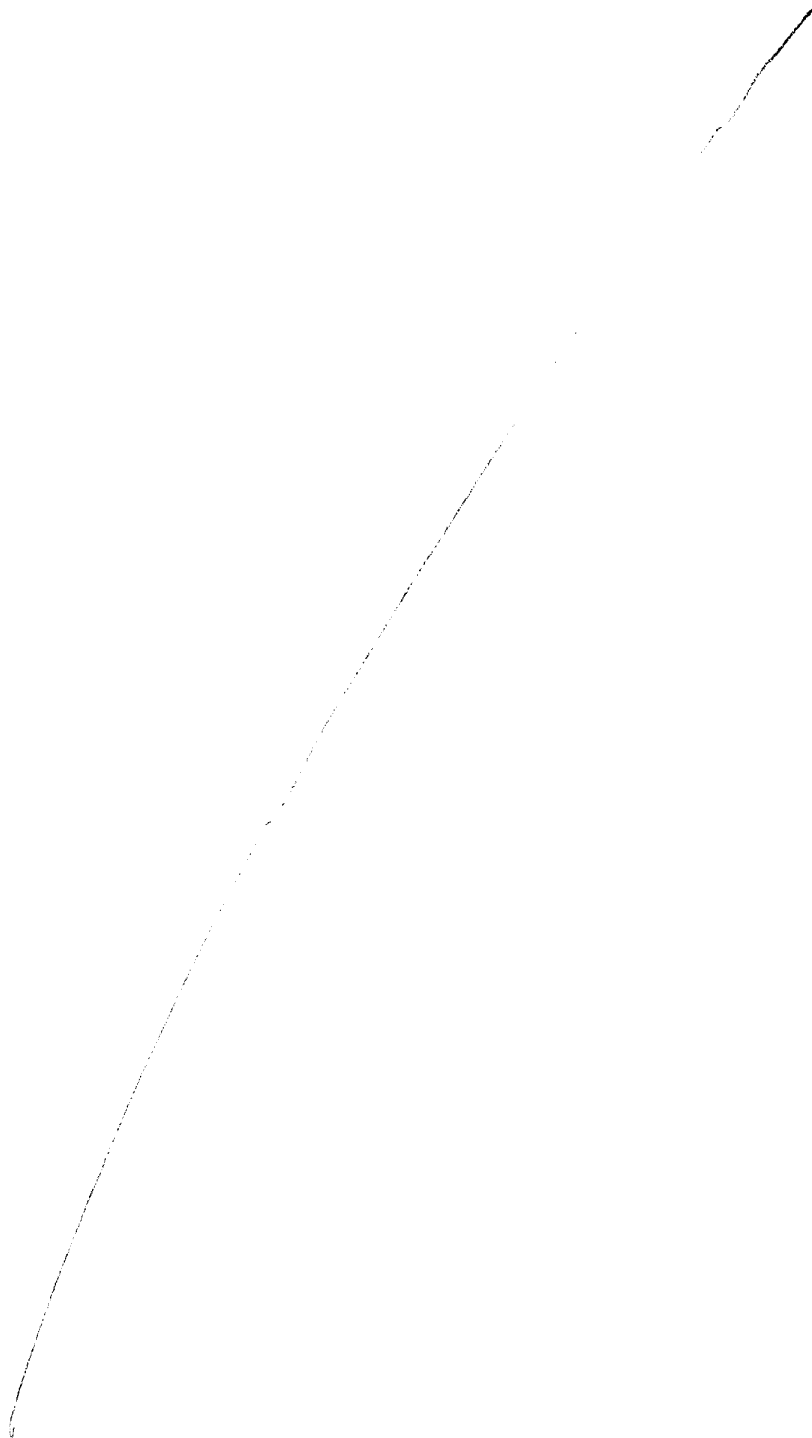
February 12, 2001

0153  
Dr. William Wingert  
Mr. David Perini  
Laboratory Corporation of America Holdings  
69 First Avenue  
P.O. Box 500  
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

We have reviewed the material provided in your correspondence of January 31, 2001, submitted in response to our correspondence of January 24, 2001. The laboratory has submitted information addressing issues raised during our review of the laboratory's January 18, 2001, correspondence documenting corrective action in response to the November 15, 2000, specimen validity testing inspection. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. The laboratory must address the following issues raised during review of the additional material submitted:

Wingert and Perini  
Page 2 of 3  
02/12/0



Wingert and Perini  
Page 3 of 3  
02/12/01

Based upon our review of the material submitted, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. The laboratory must take steps to address the issues 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

cc: Project Files/SVT0153