



RESEARCH TRIANGLE INSTITUTE

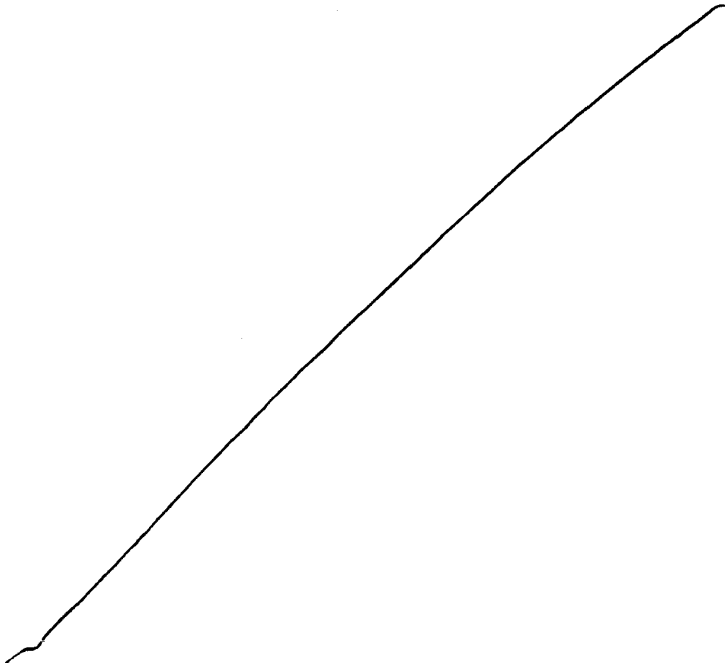
National Laboratory Certification Program

December 22, 1998

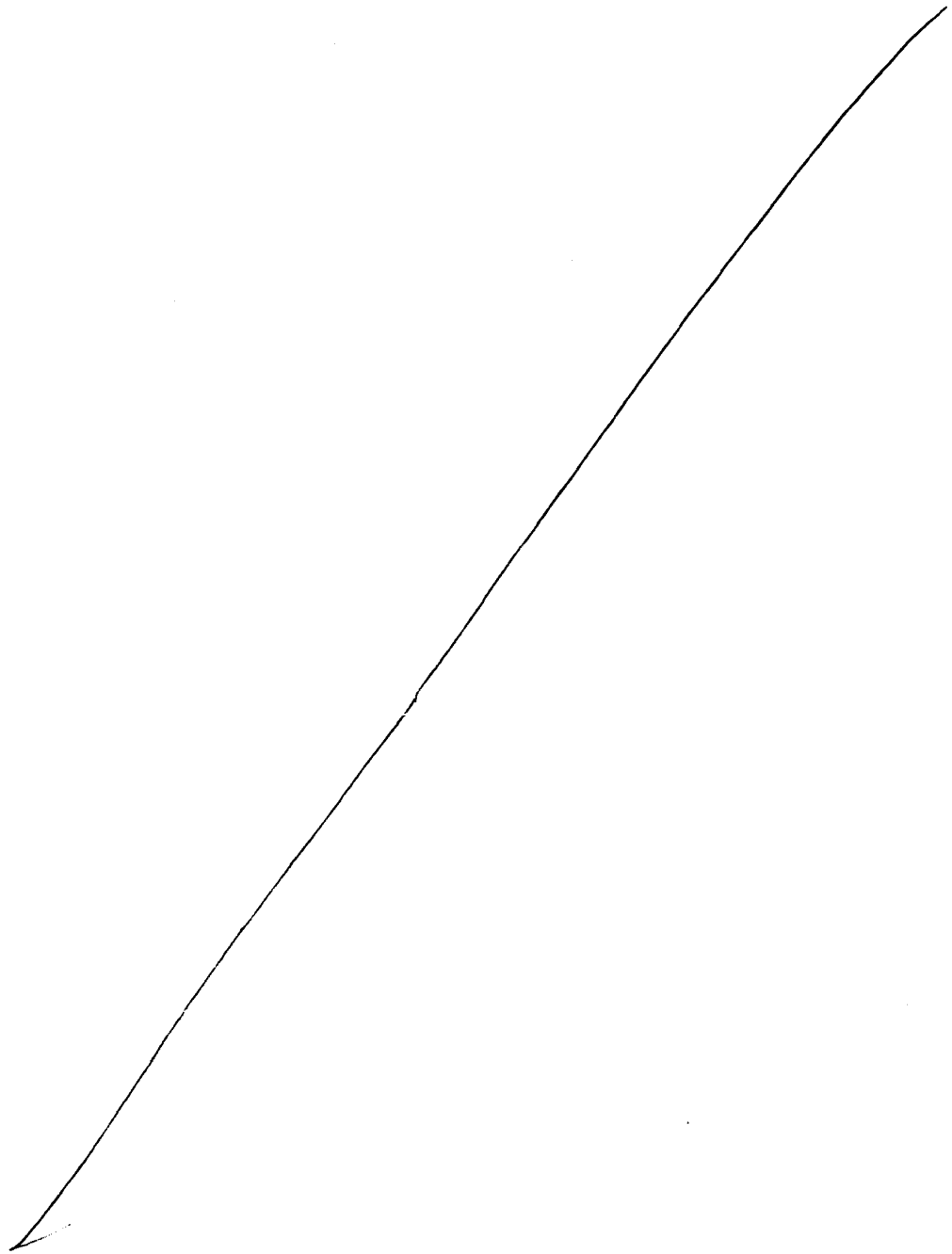
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

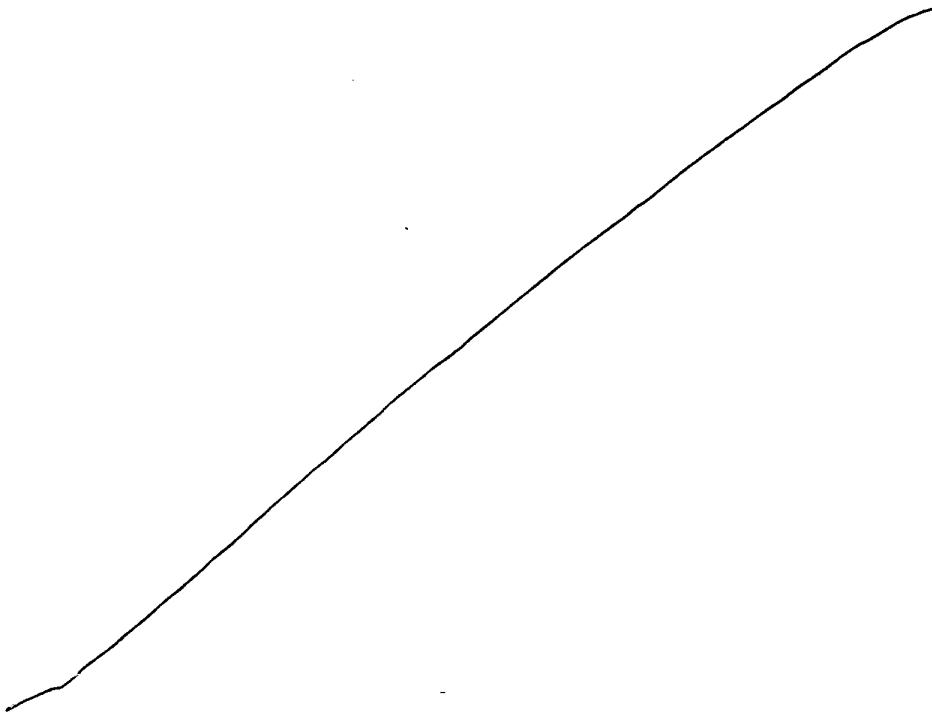
The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. However, the following issues were raised:



Dr. Wingert
Mr. Perini
Page 2 of 4
12/22/98



Dr. Wingert
Mr. Perini
Page 3 of 4
12/22/98



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 described 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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of the 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 Inspection Analyst

Dr. Wingert
Mr. Perini
Page 4 of 4
12/22/98

Enclosure

cc: Project Files/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: Laboratory Corporation of America Holdings

Location: Raritan, NJ

Document Reviewed: Application Form
 Inspection Report #M15 Date: 5 November 1998
 Other _____

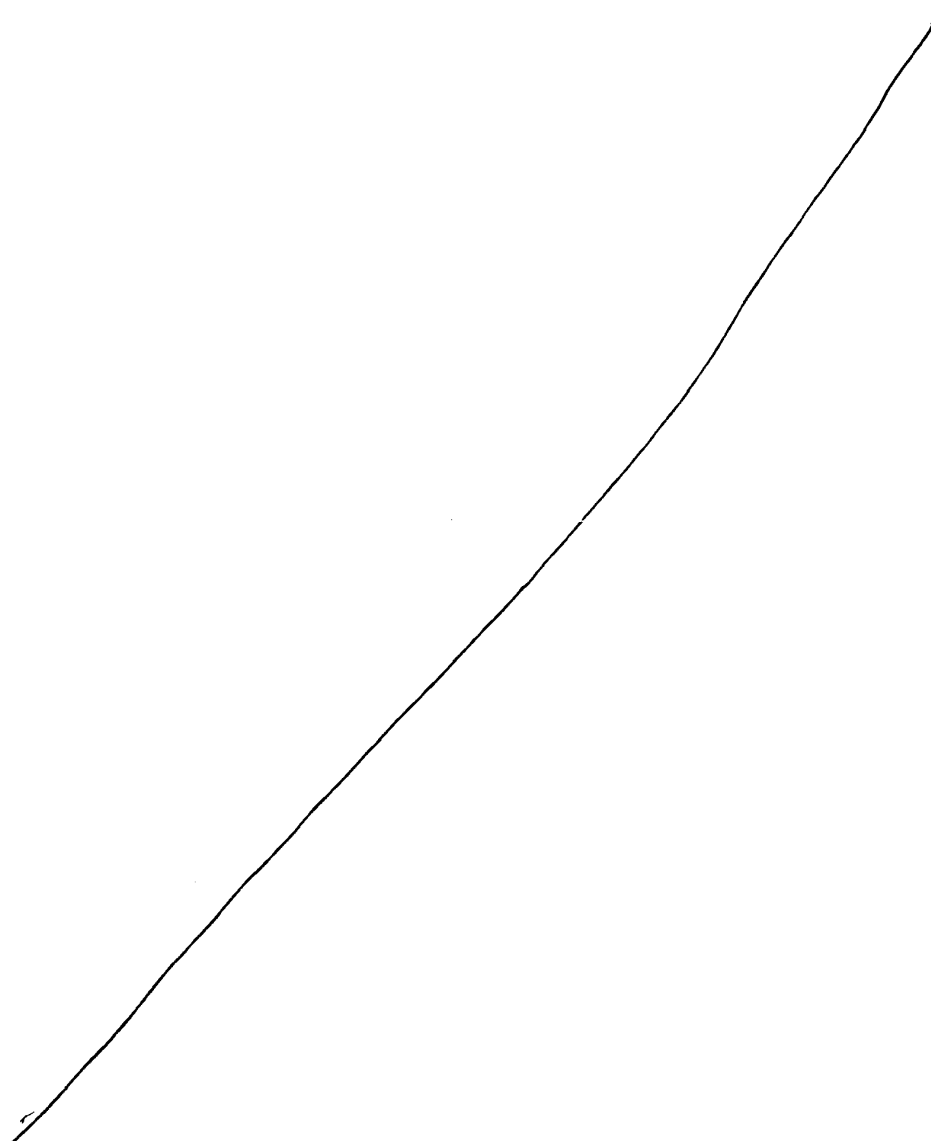
Status: Highly Acceptable Acceptable
 Unacceptable Failure

Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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. Records Audit

Section H. Personnel



Section I. Reagents



Section J. Quality Control and Standards



Section K. Reporting



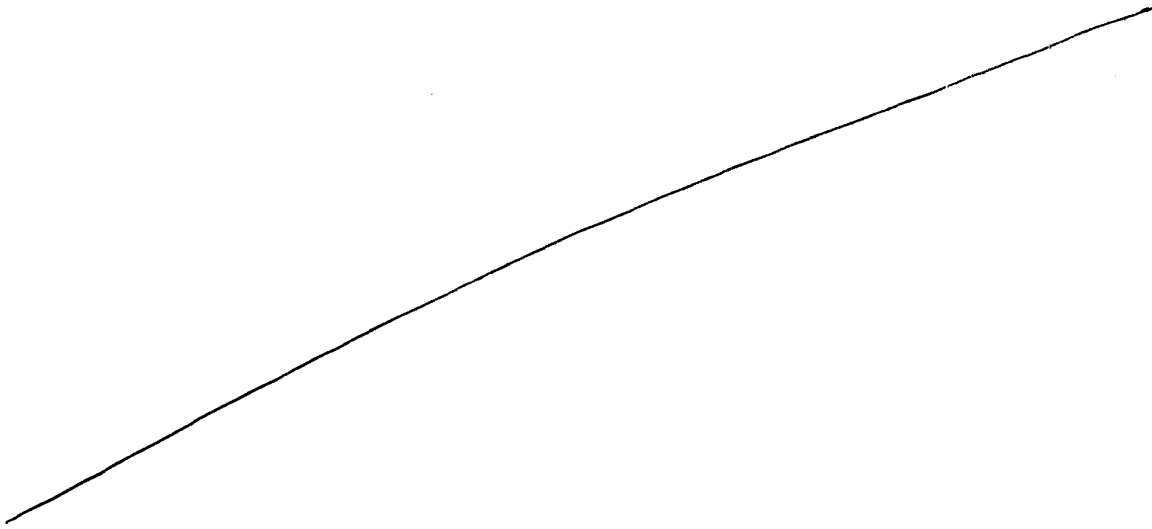
Section L. Equipment and Maintenance



Section M. Immunoassay



Section N. Gas Chromatography/Mass Spectrometry





received
1127/99 SDC

Laboratory Corporation of America Holdings
69 First Avenue
Raritan, NJ 08869-2240

January 25, 1999
Susan Crumpton
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 12194

Dear Ms. Crumpton:

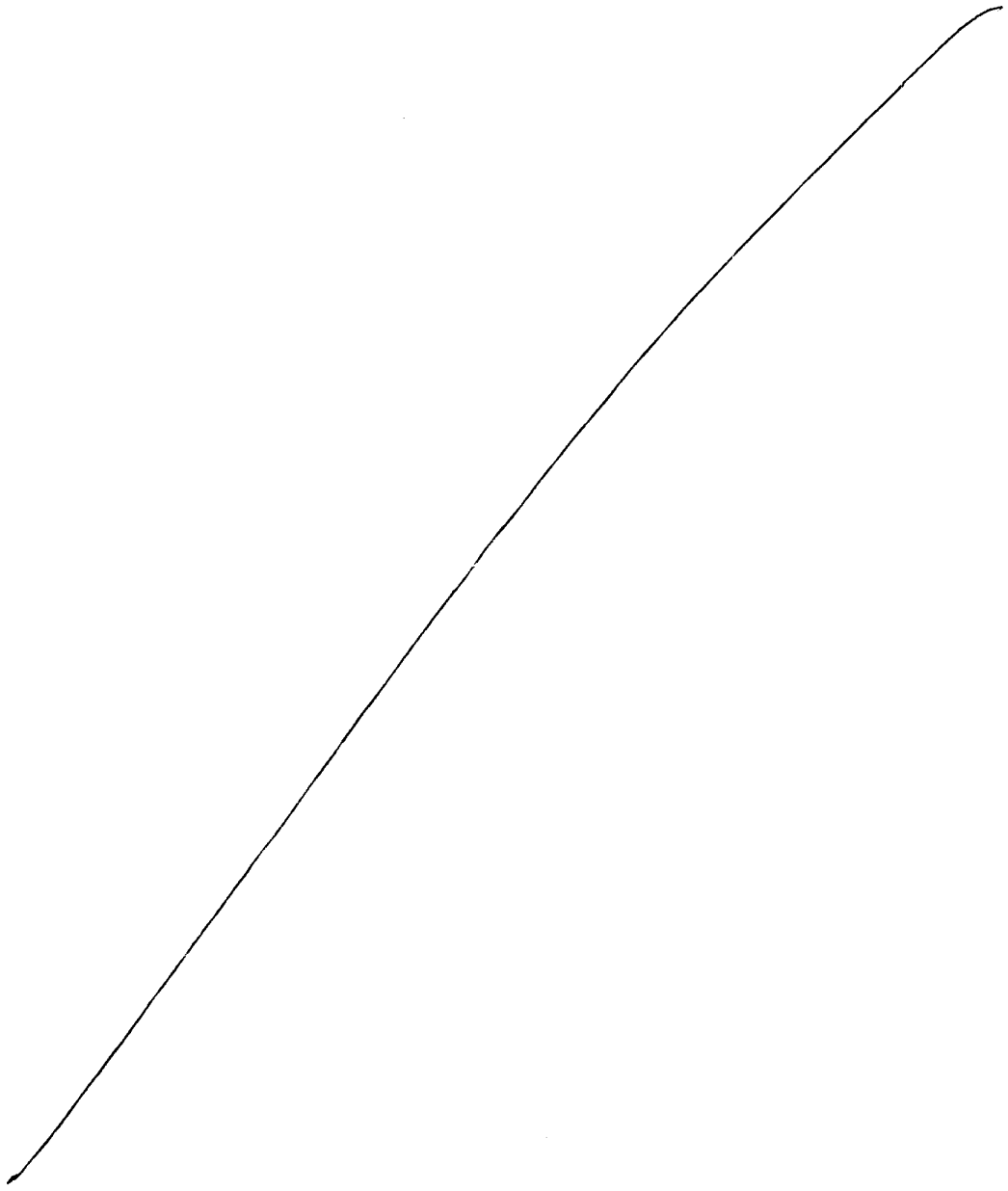
Enclosed are responses to deficiencies cited in the fifteenth maintenance inspection under the NLCP. These responses are organized to correspond to the sections and numbers in your letter of December 22, 1998. The requested documentation is provided with labelled attachments and minutes of meetings with the department staff.

As always, it is our intention to use the NLCP critique and required modifications to continue to improve our service to our clients and the Forensic Toxicology community.

Sincerely,


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

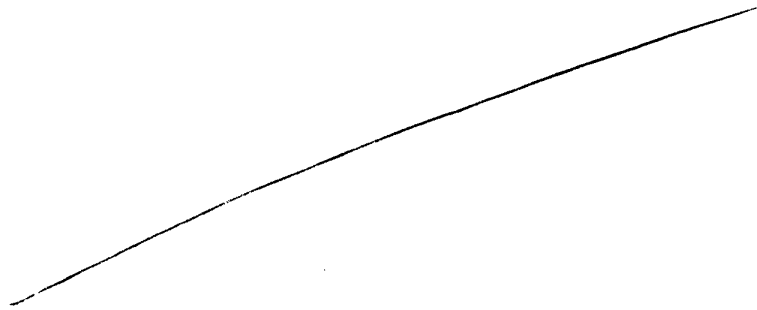
E.



F.



G.



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- See Reply in E.
- See Reply in E.



J.

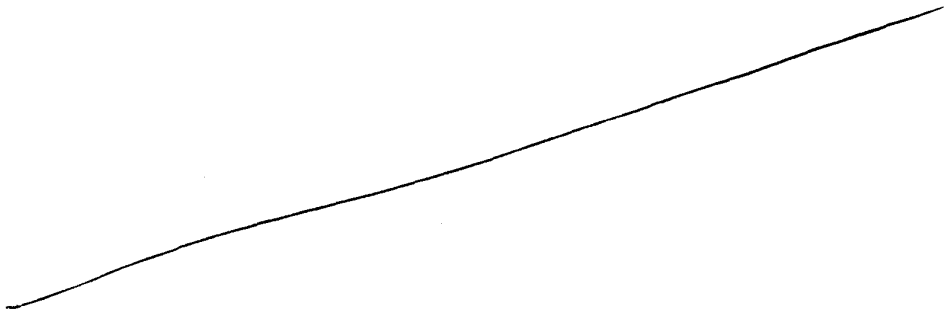


M.



N.





RESEARCH TRIANGLE INSTITUTE



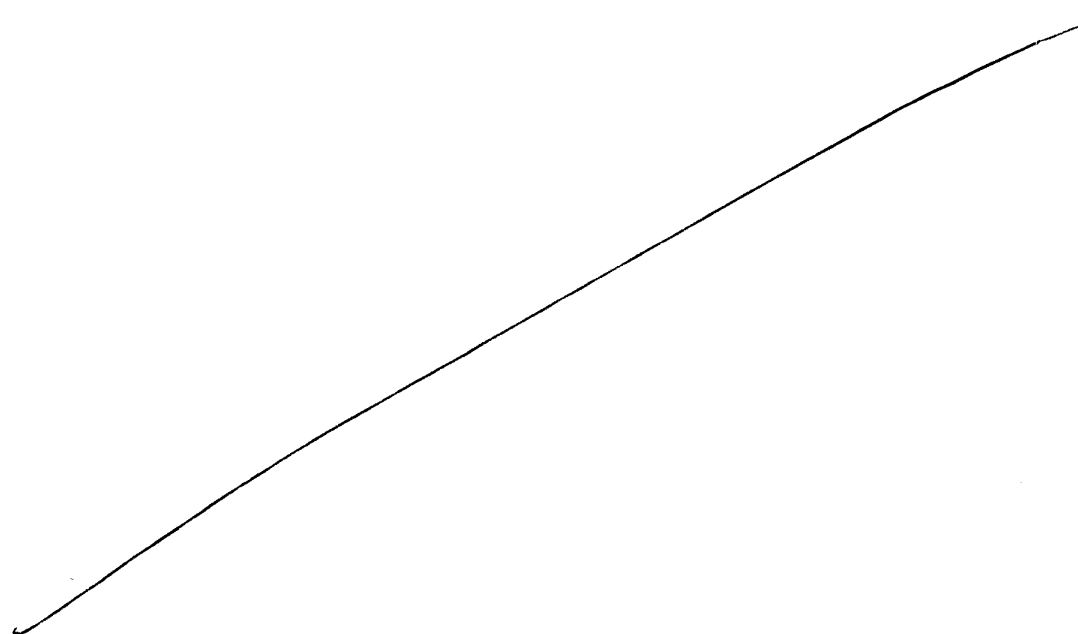
National Laboratory Certification Program

February 3, 1999

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 25, 1999, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of December 22, 1998. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following issues remain:



Dr. Wingert
Mr. Perini
Page 2 of 2
02/03/99

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program (NLCP). The laboratory must take steps to correct the issues cited above. All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during 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 Inspection Analyst

cc: Project Files/M15

RESEARCH TRIANGLE INSTITUTE



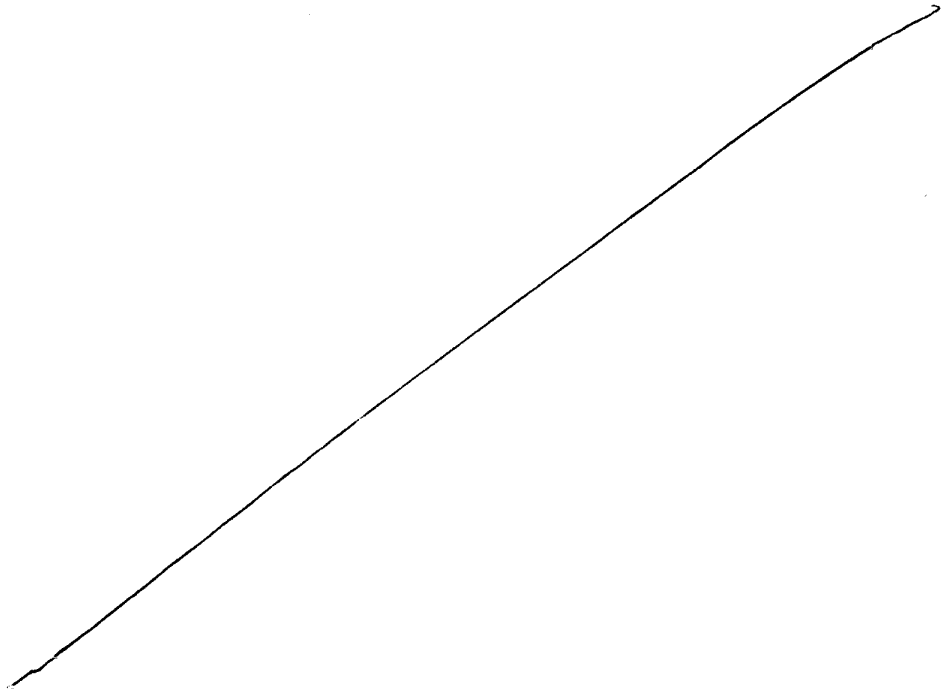
National Laboratory Certification Program

June 30, 1999

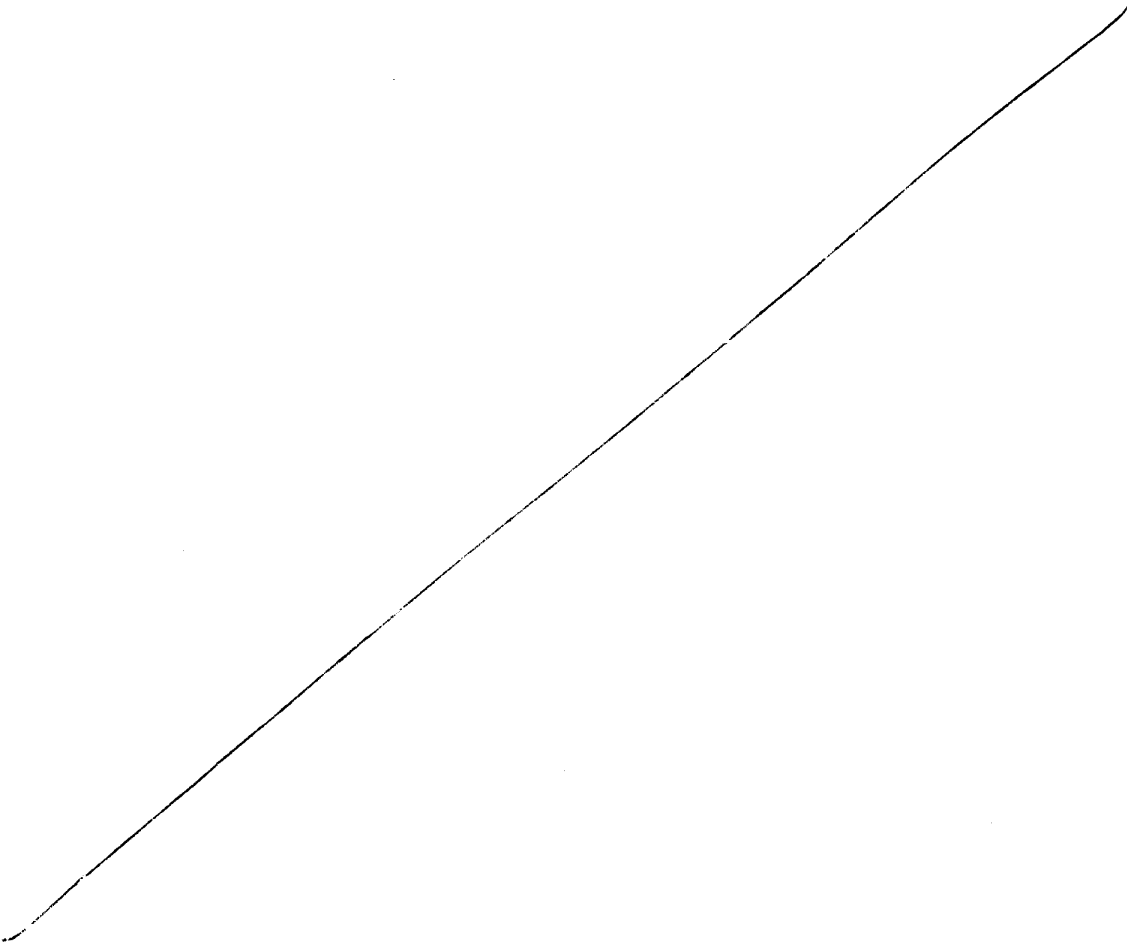
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:



Dr. Wingert
Mr. Perini
Page 2 of 3
06/30/99



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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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.

Dr. Wingert
Mr. Perini
Page 3 of 3
06/30/99

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
Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 015
Document No. Final

Laboratory: Laboratory Corporation of America Holdings

Location: Raritan, NJ

Document Reviewed: Application Form
 Inspection Report #M16 Date: 13 May 1999
 Other _____

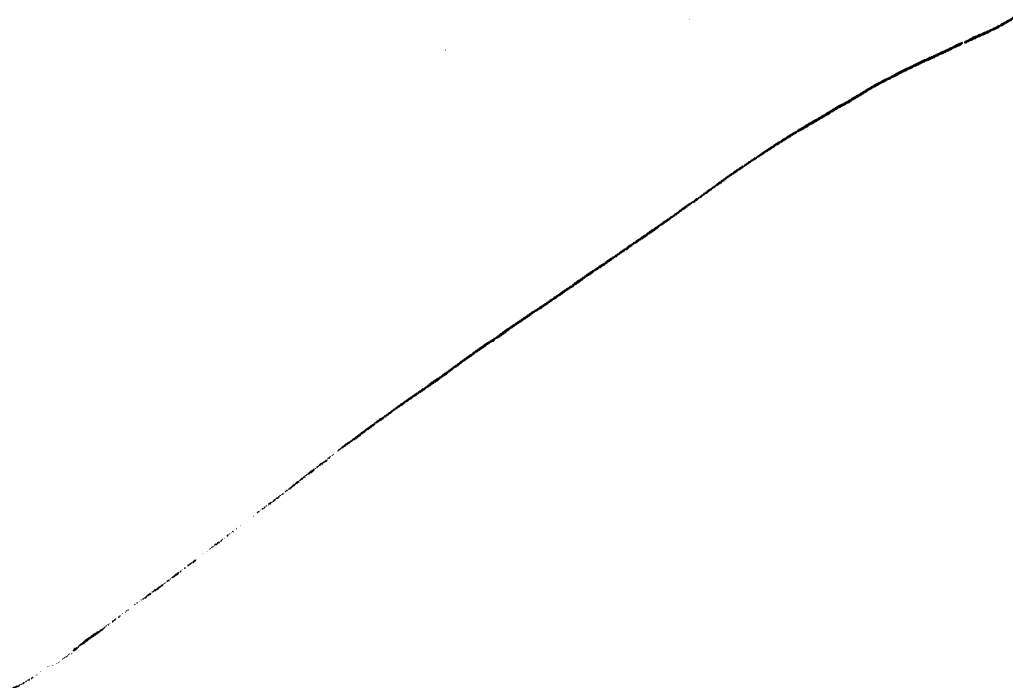
Status: Highly Acceptable Acceptable
 Unacceptable Failure

Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program pending the submission of evidence that appropriate corrective action has been taken.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

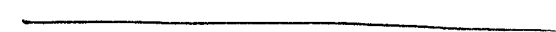
Section E. Standard Operating Procedures - Procedures Manual



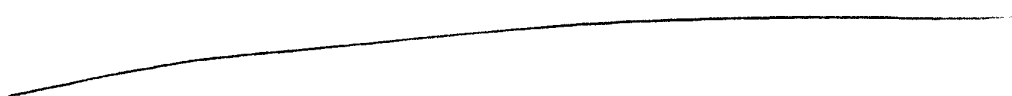
Section F. Chain-of-Custody, Accessioning, and Security



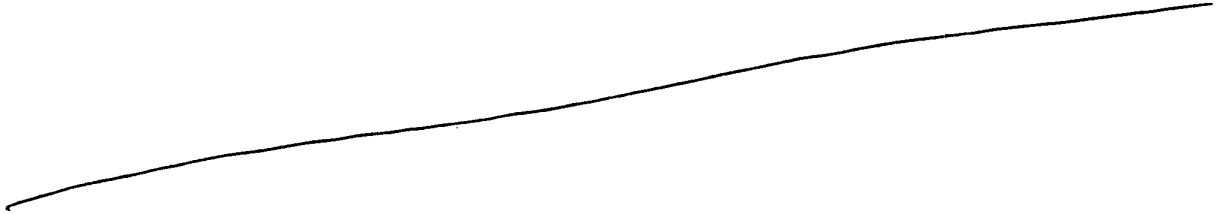
Section G. Quality Control



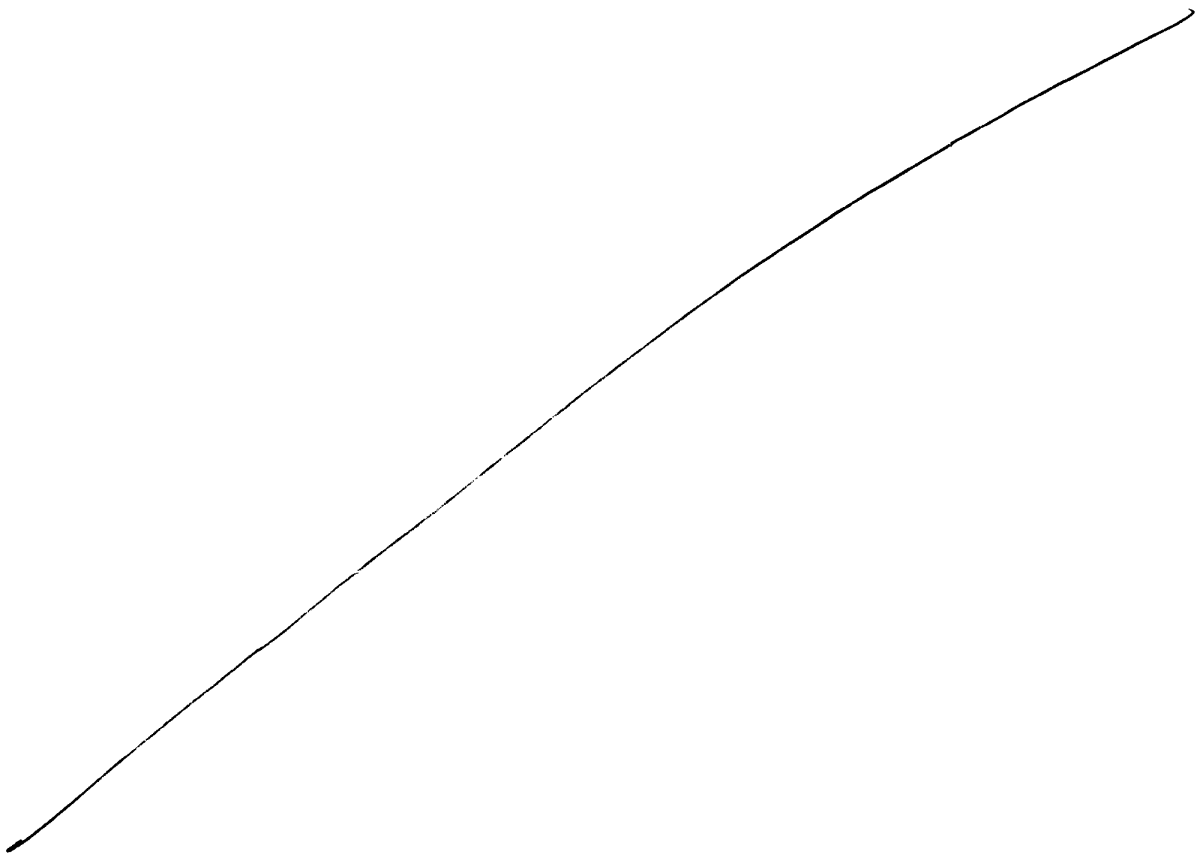
Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

received
8/4/99 SOC



August 3, 1999
Susan Crumpton
Research Triangle Institute, NLCP
3040 Cornwallis Rd.
Research Triangle Park, NC 27709

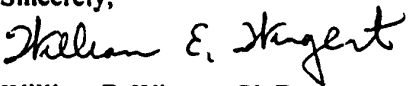
Dear Ms. Crumpton:

This is in reply to your critique from the sixteenth maintenance inspection of our laboratory.

[A large, diagonal handwritten line is drawn across the lower half of the page.]

It is our intent to use the critique from the NLCP inspection to continue to provide the best possible service to our clients and to the Forensic Toxicology community. If there is any additional information that I need to provide please contact me immediately.

Sincerely,



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



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 16, 1999

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 August 3, 1999, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of June 30, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Inspection Analyst

enclosure

cc: Dr. Michael Baylor
Project Files/M16





RESEARCH TRIANGLE INSTITUTE

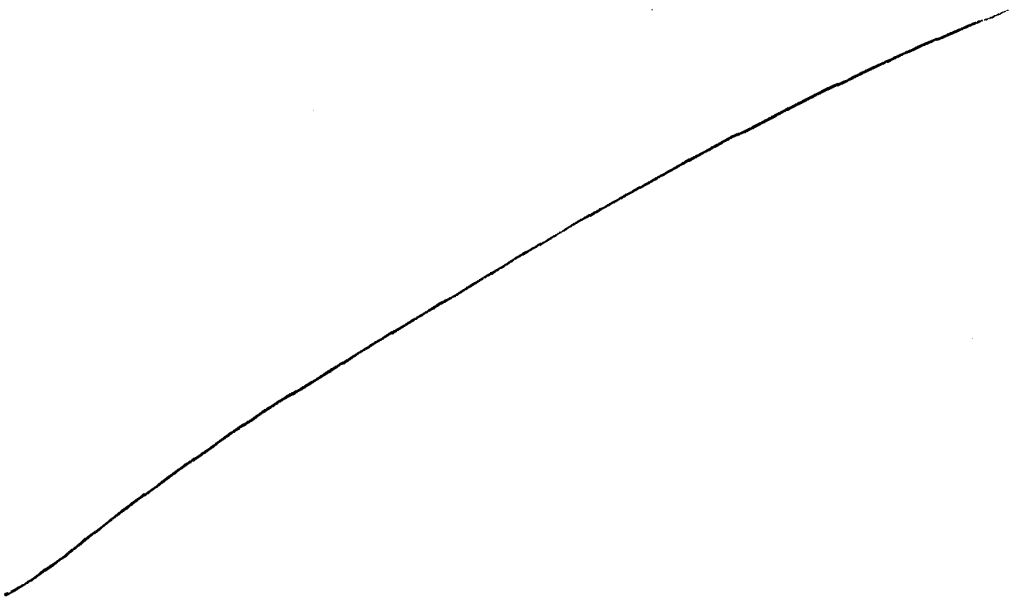
National Laboratory Certification Program

December 23, 1999

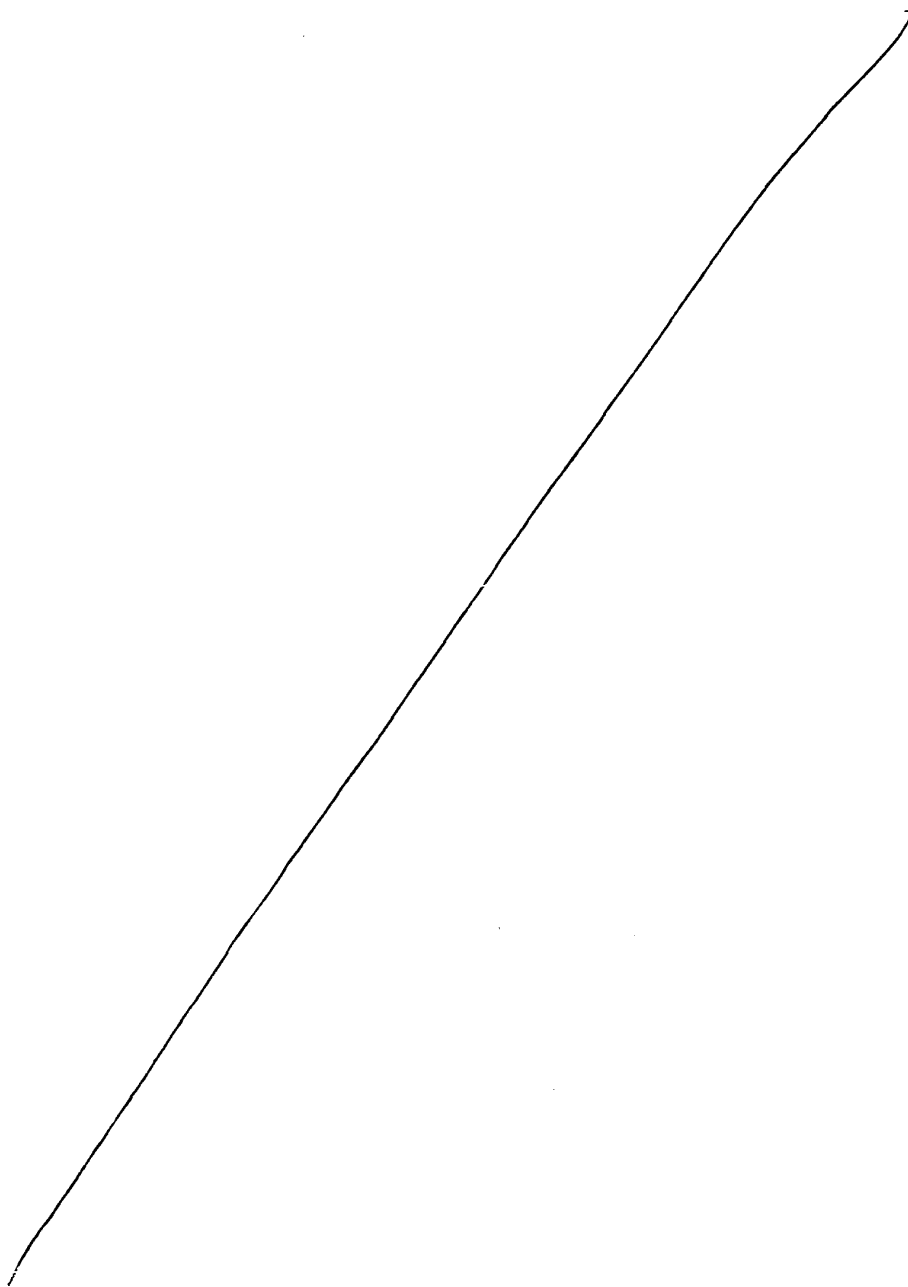
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Dr. Wingert
Mr. Perini
Page 2 of 3
12/23/99



Dr. Wingert
Mr. Perini
Page 3 of 3
12/23/99

RTI is recommending to HHS that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during 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 Inspection Analyst

Enclosure

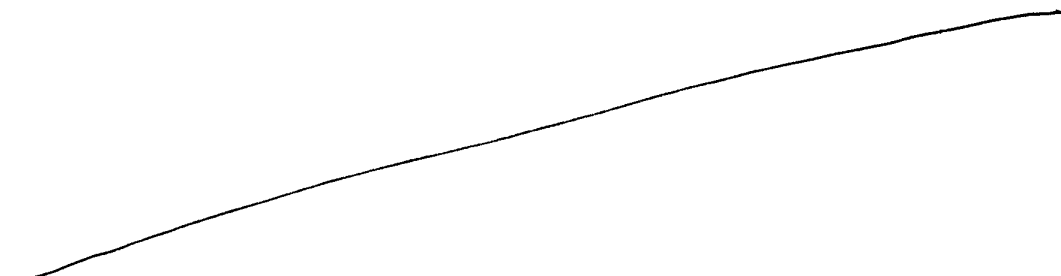
cc: Project Files/M17

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

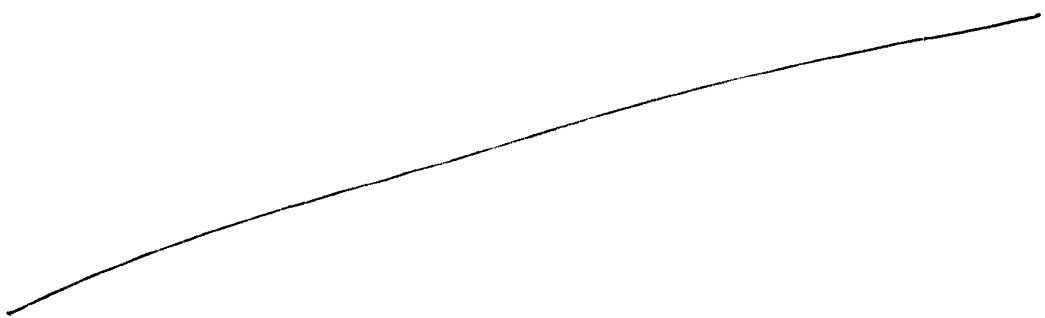
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Ver. Final

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 23, 2000

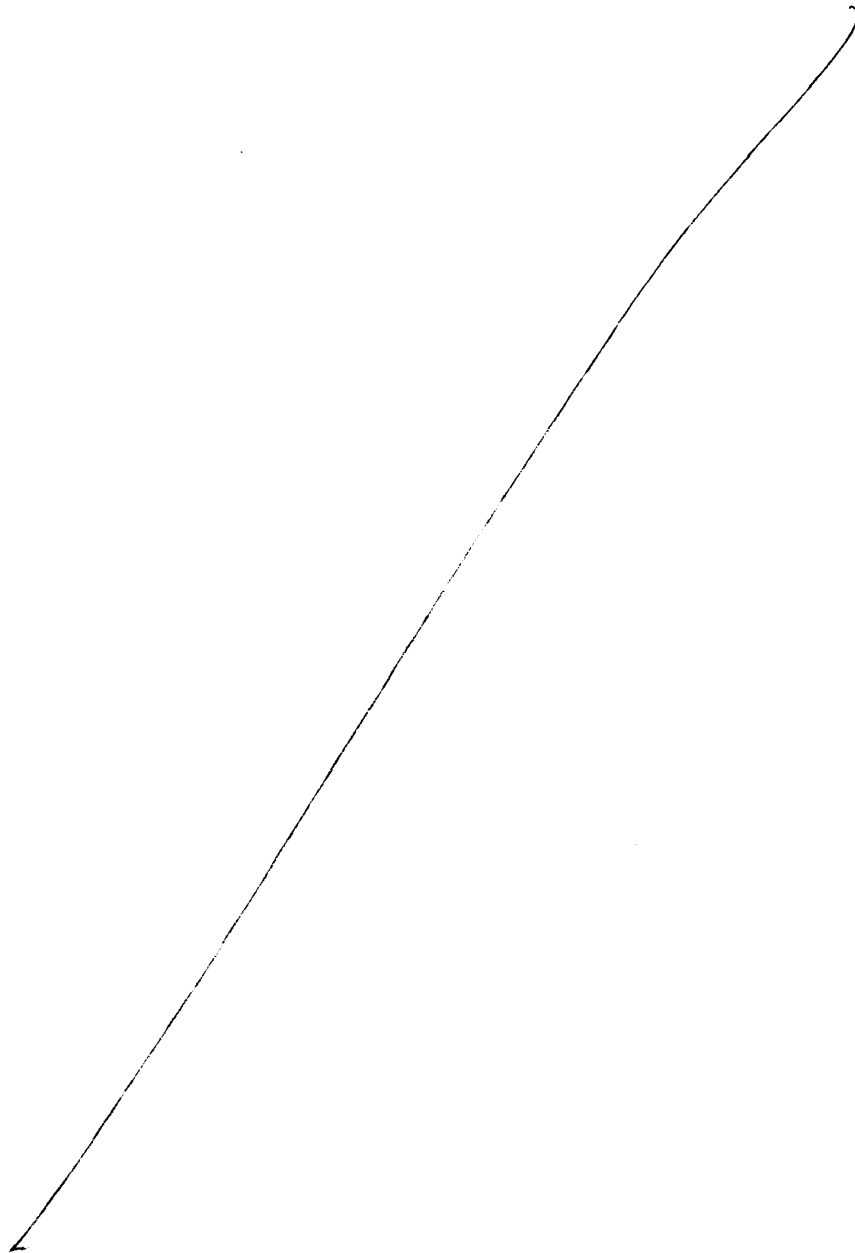
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

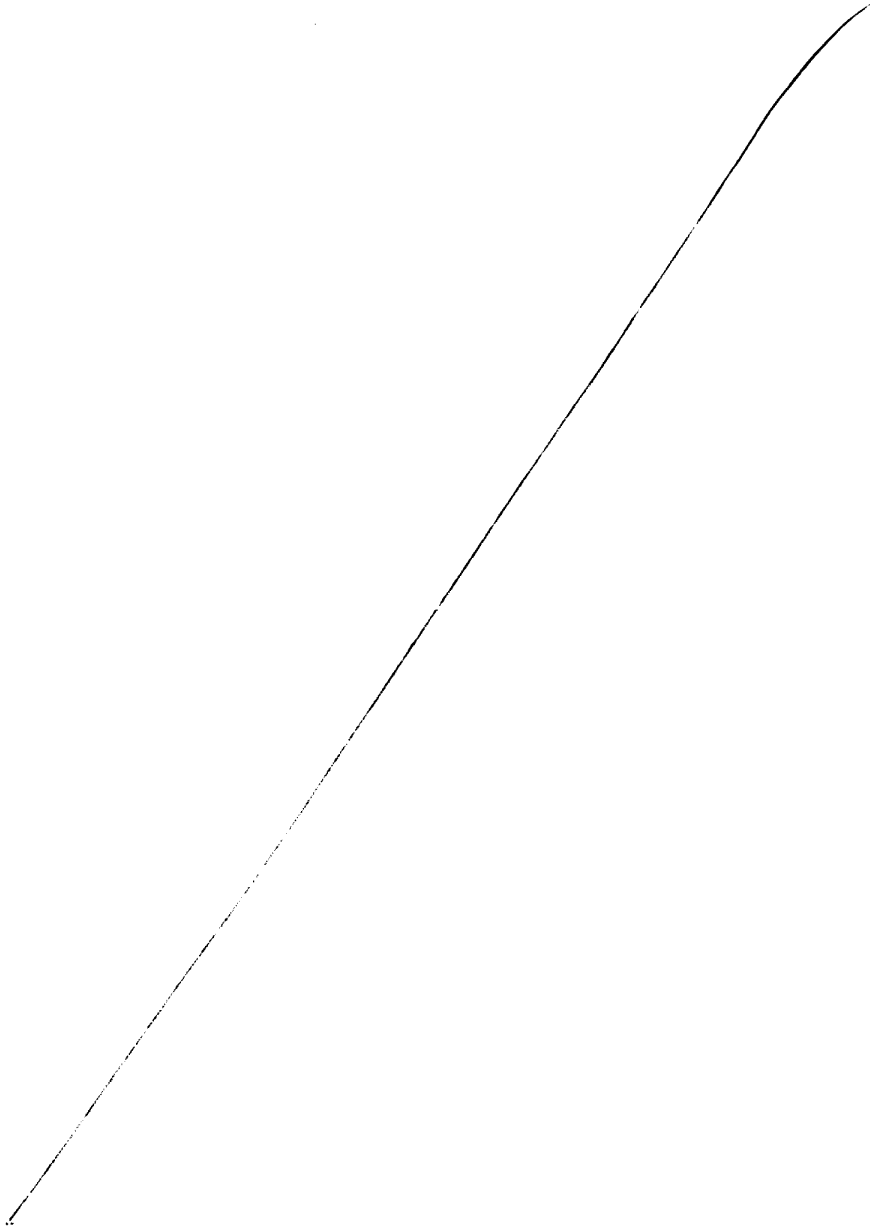
The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



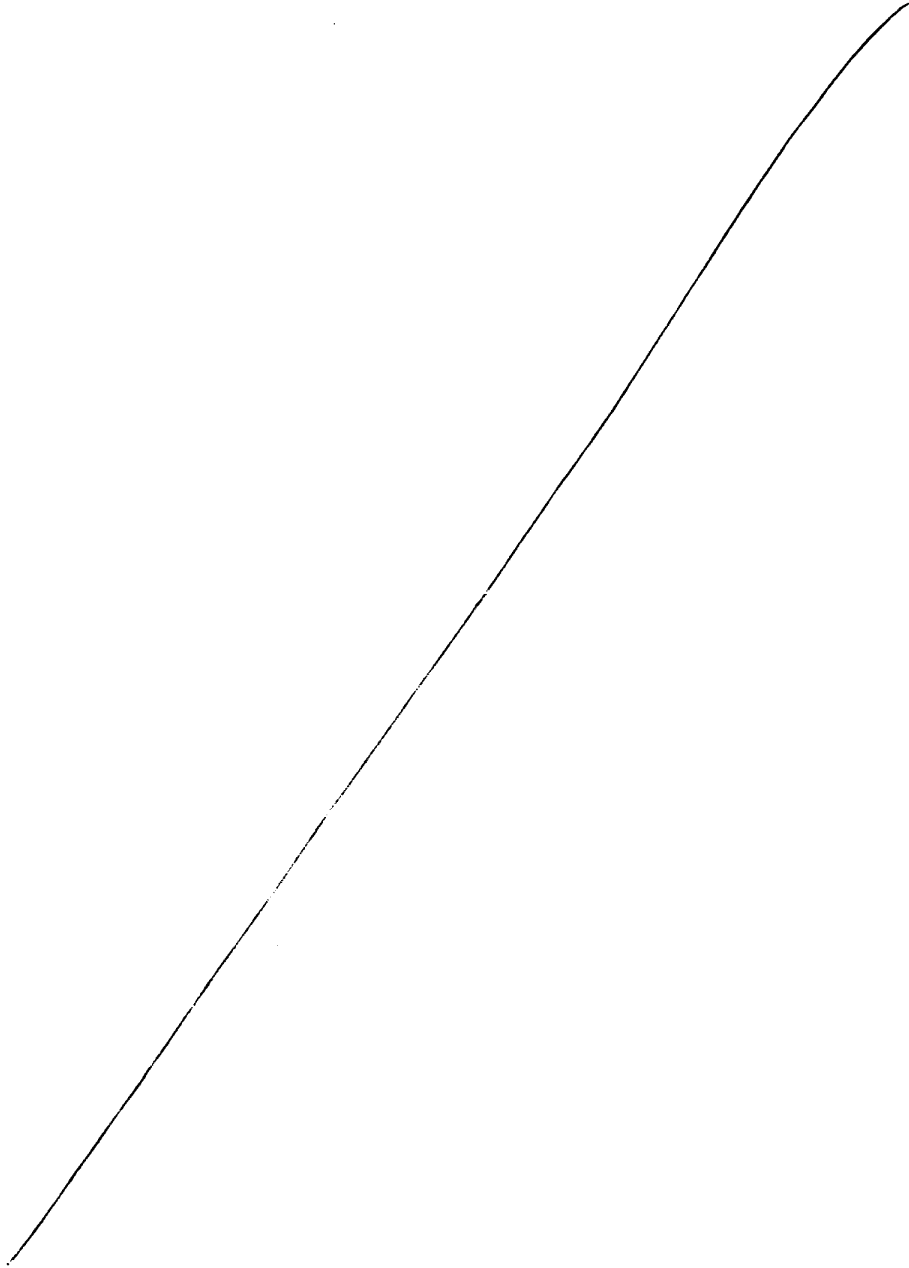
Dr. Wingert
Mr. Perini
June 23, 2000
Page 2 of 6



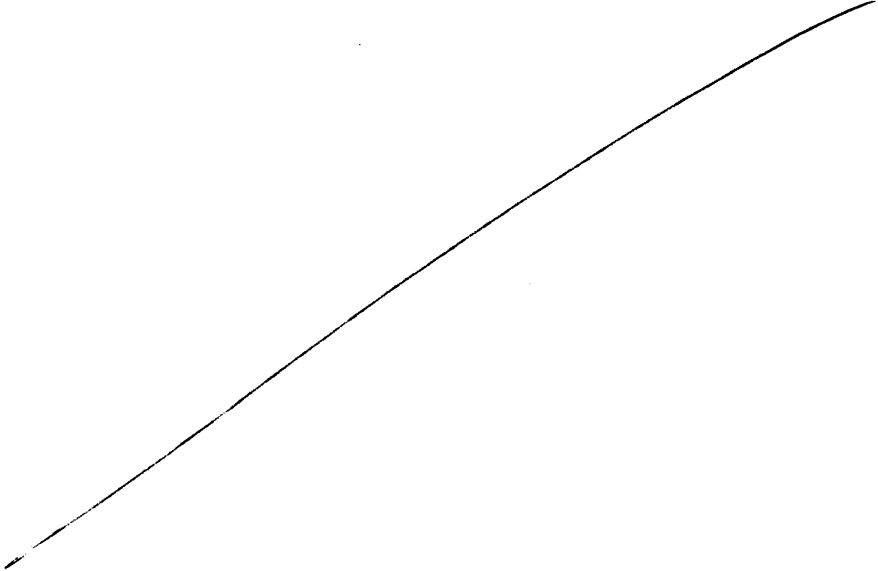
Dr. Wingert
Mr. Perini
June 23, 2000
Page 3 of 6



Dr. Wingert
Mr. Perini
June 23, 2000
Page 4 of 6



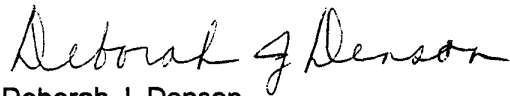
Dr. Wingert
Mr. Perini
June 23, 2000
Page 5 of 6



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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

Dr. Wingert
Mr. Perini
June 23, 2000
Page 6 of 6

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: Laboratory Corporation of America Holdings

Location: Raritan, NJ

Document Reviewed: Application Form
 Inspection Report #M18 Date: 4 May 2000
 Other _____

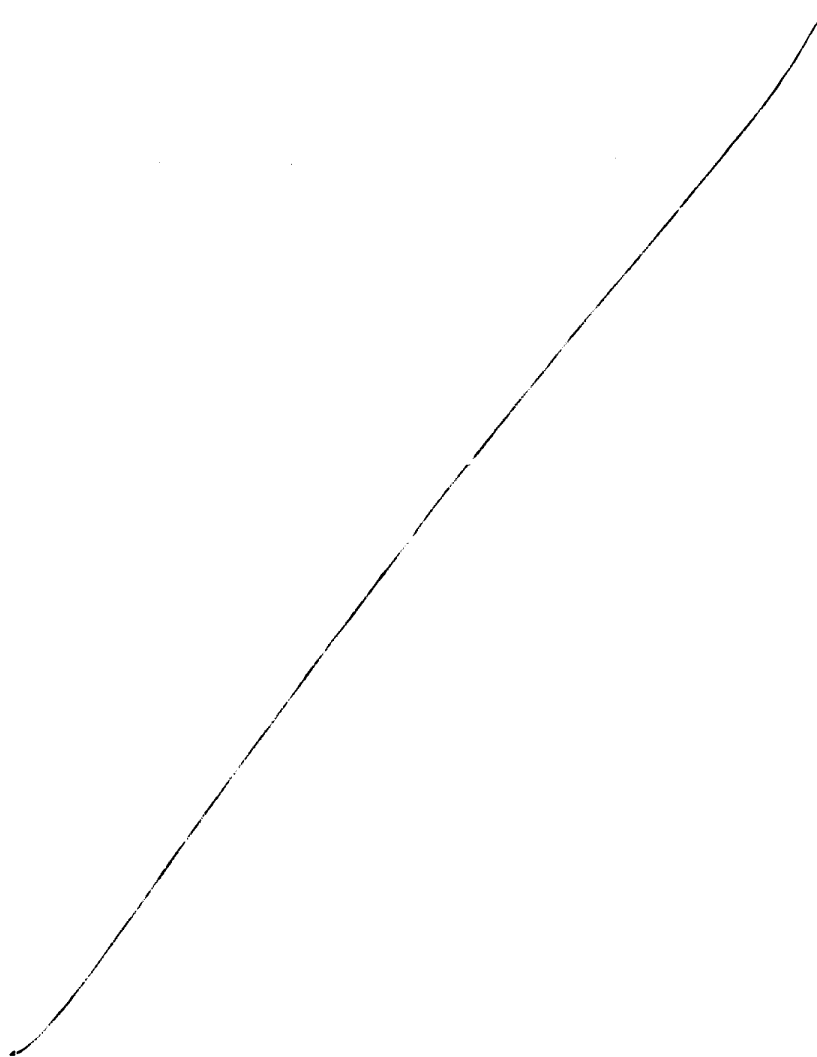
Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

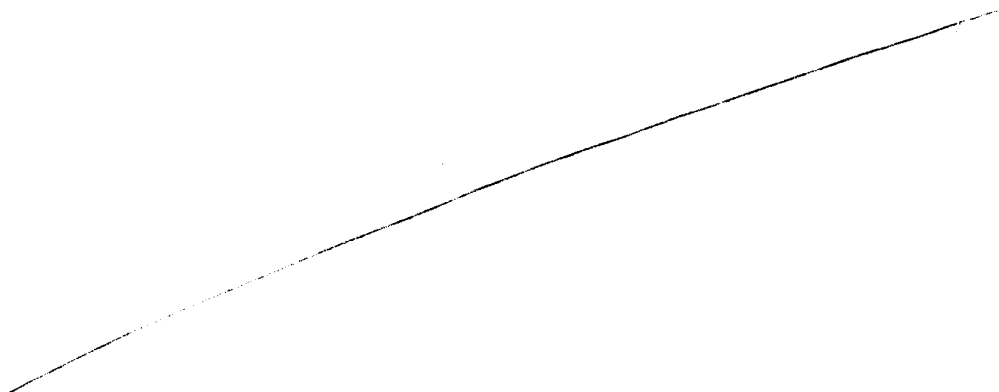
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

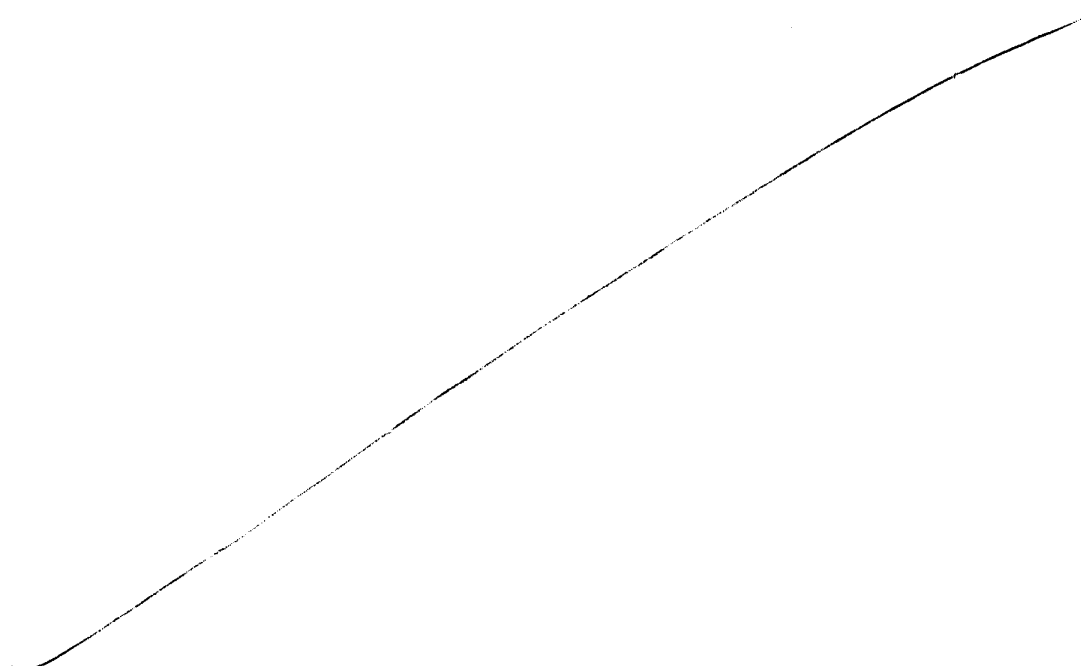
Section E. Standard Operating Procedures - Procedures Manual



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



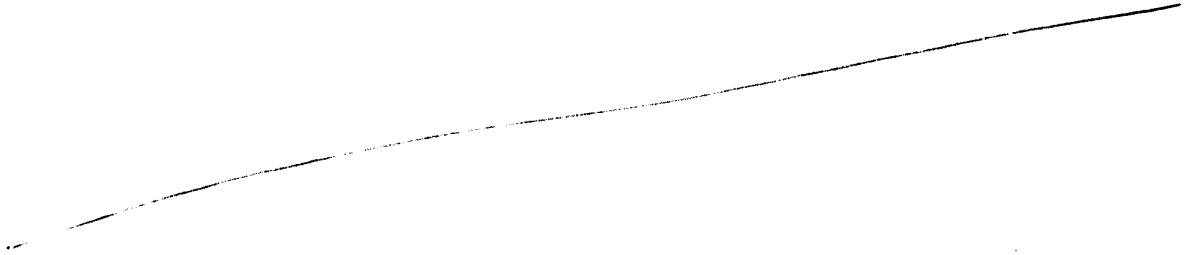
Section G. Quality Control



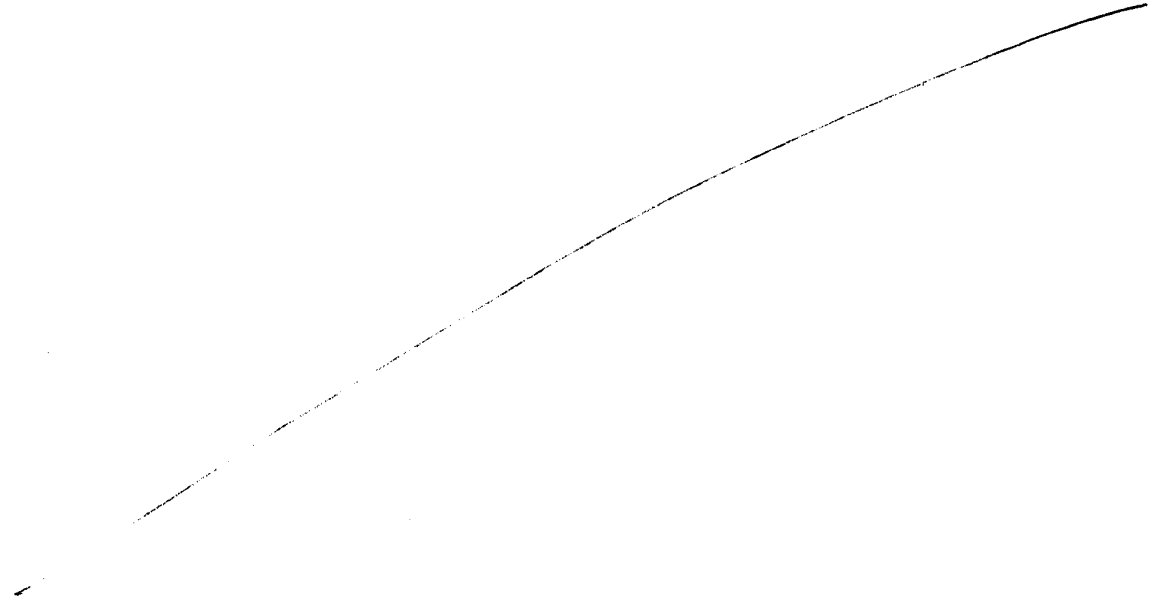
Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

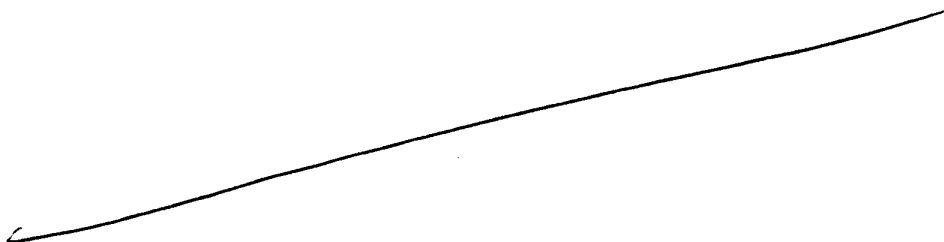


Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received
7/28/00 JD

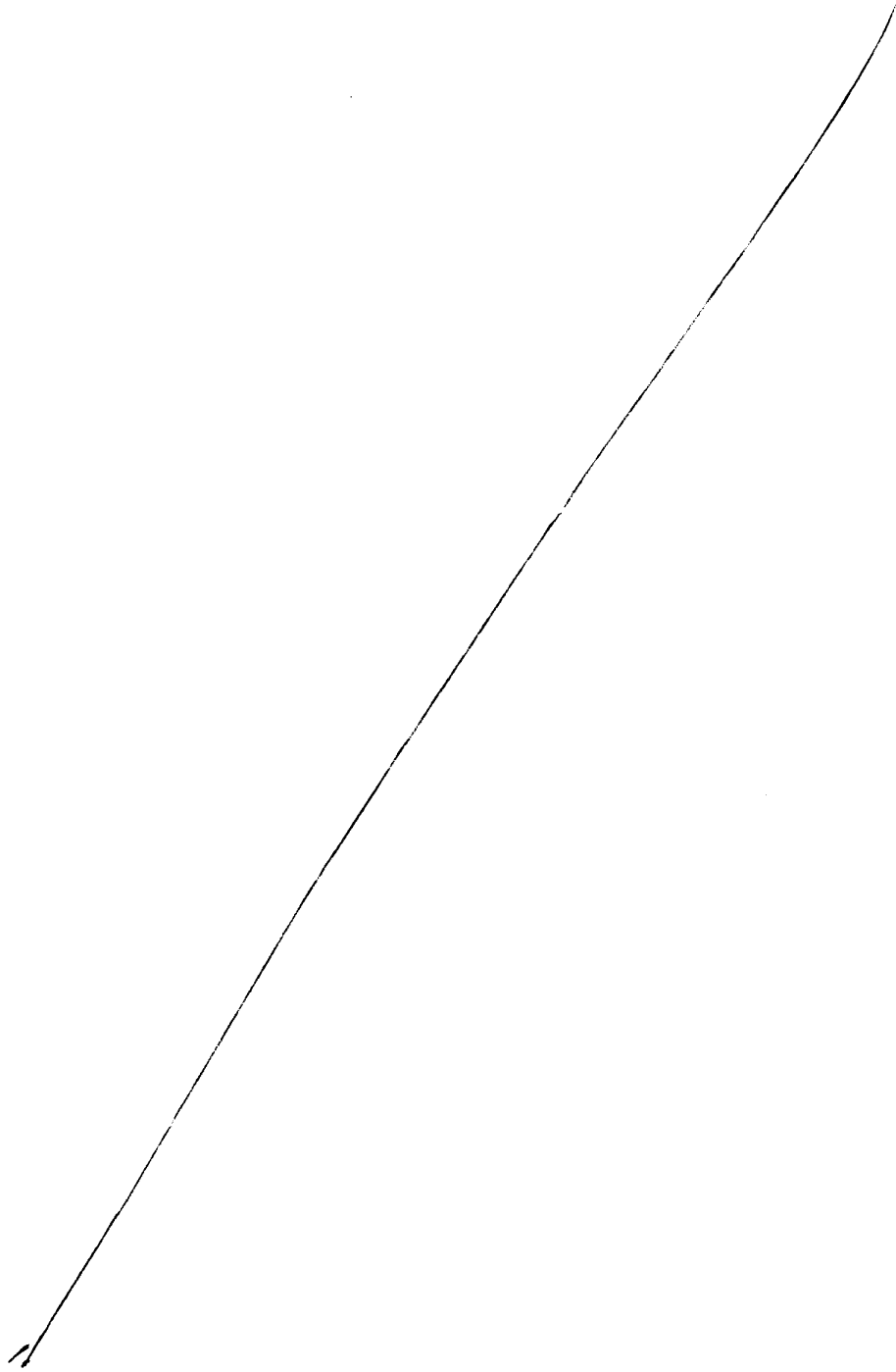


July 27, 2000
Deborah J. Denson, Technical Analyst
Research Triangle Institute, NLCP
3040 Cornwallis Road
Research Triangle Park NC 27709

Dear Ms. Denson:

The following responses are in reply to the critique from the eighteenth maintenance inspection of our laboratory by the NLCP.

[A large diagonal line is drawn across the page, likely indicating a redaction or a placeholder for content.]



If you have any questions, please do not hesitate to call me.

Sincerely,

William E. Wingert

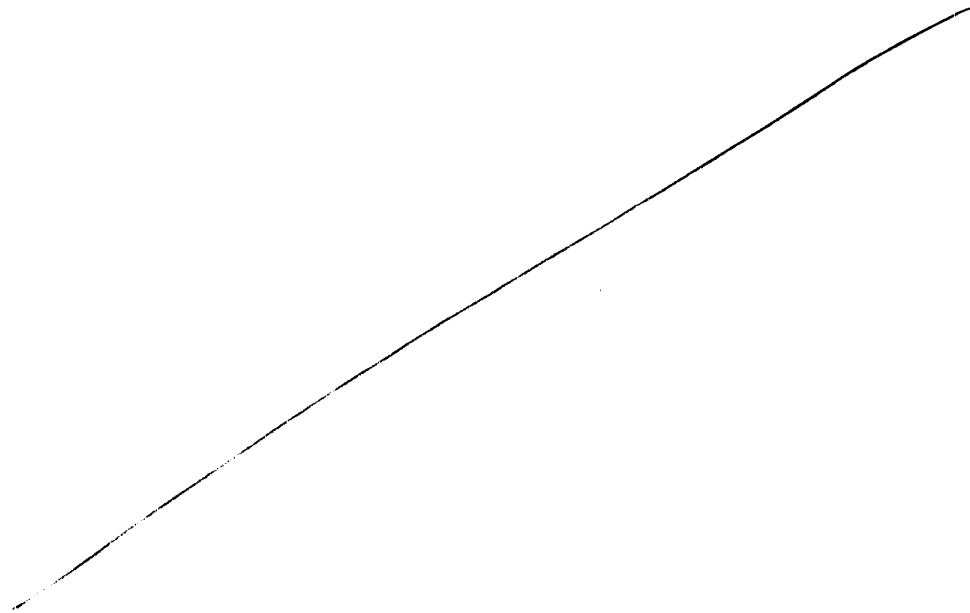
William E. Wingert, Ph.D.
Director, Forensic Toxicology

August 04, 2000

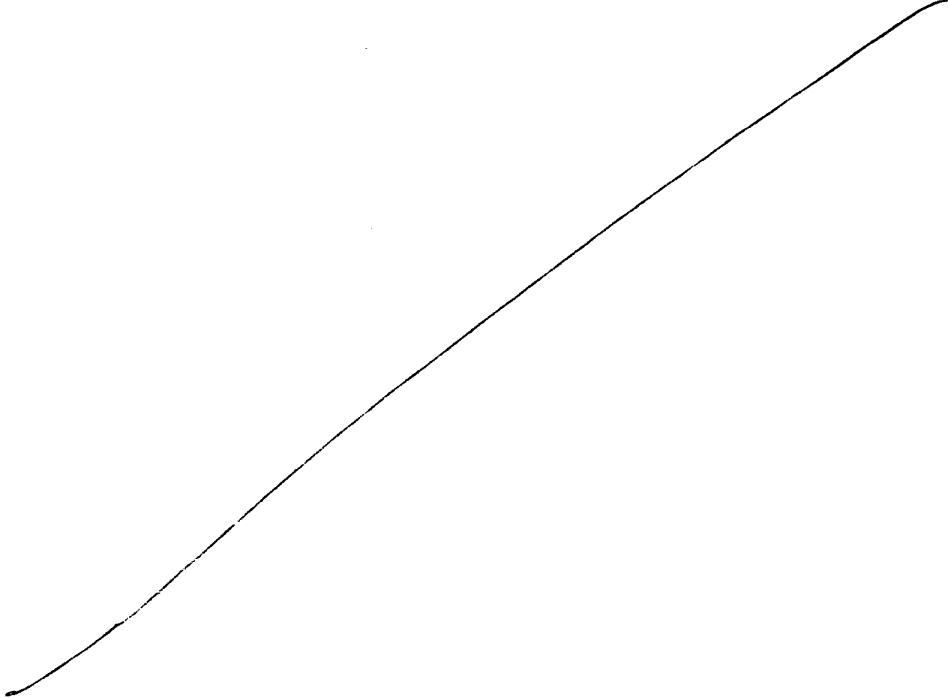
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

We have reviewed the material provided in your correspondence of July 27, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 23, 2000. 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:

A large, thin, black diagonal line that starts near the bottom left and extends towards the top right, crossing the page.

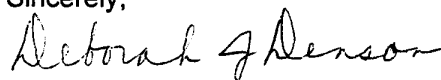
Dr. Wingert
Mr. Perini
August 4, 2000
Page 2 of 2



Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Michael Baylor, Ph.D. at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M18

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 10, 2001

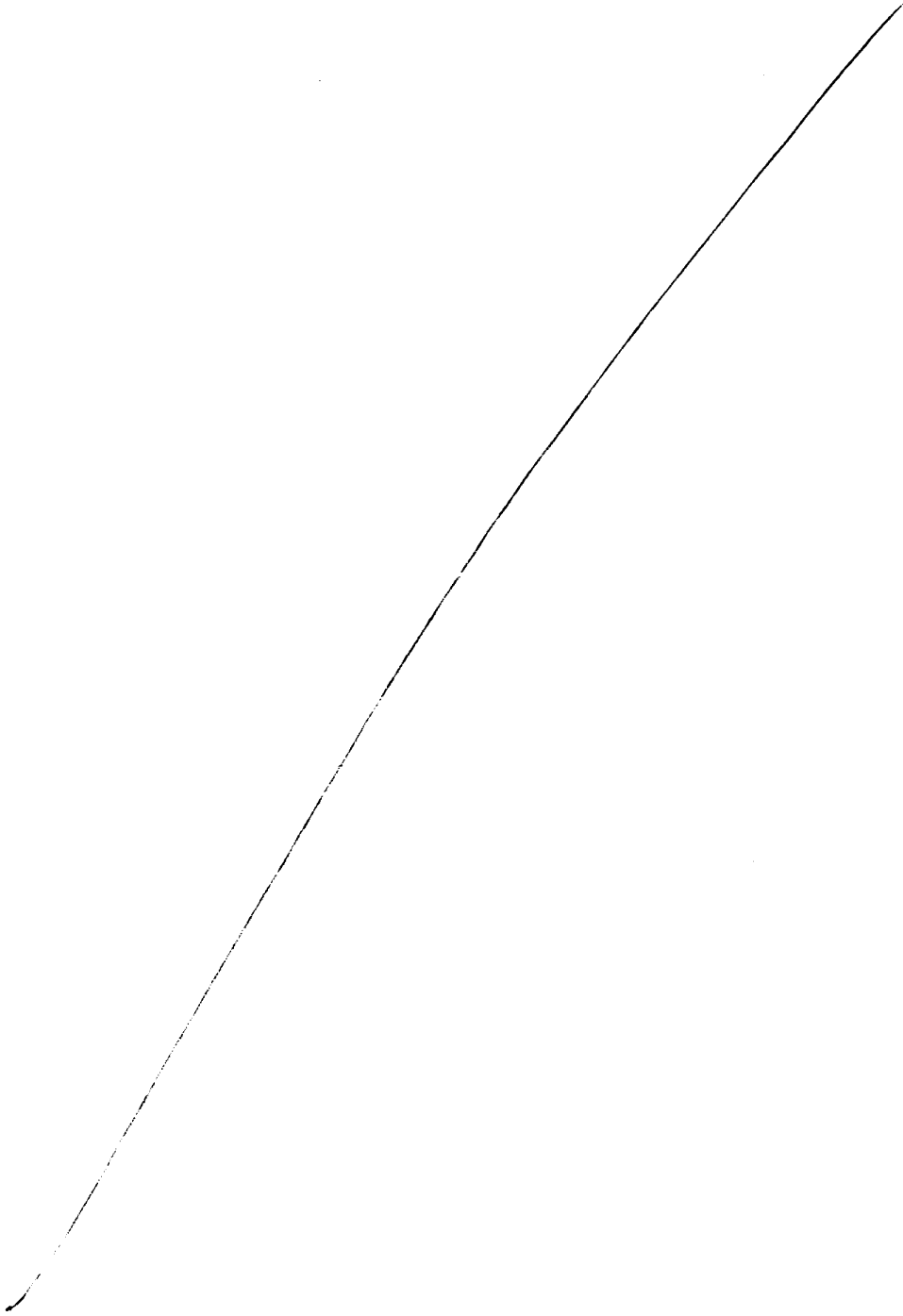
0153
Dr. William Wingert
Mr. David Perini
Laboratory Corporation of America Holdings
69 First Avenue
P.O. Box 500
Raritan, NJ 08869

Dear Dr. Wingert and Mr. Perini:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory appeared to meet most of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



Dr. Wingert and Mr. Perini
February 10, 2001
Page 2 of 3




Dr. Wingert and Mr. Perini
February 10, 2001
Page 3 of 3

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: Laboratory Corporation of America Holdings

Location: Raritan, NJ

Document Reviewed: Application Form
 Inspection Report #M19 Date: 9 November 2000
 Other _____

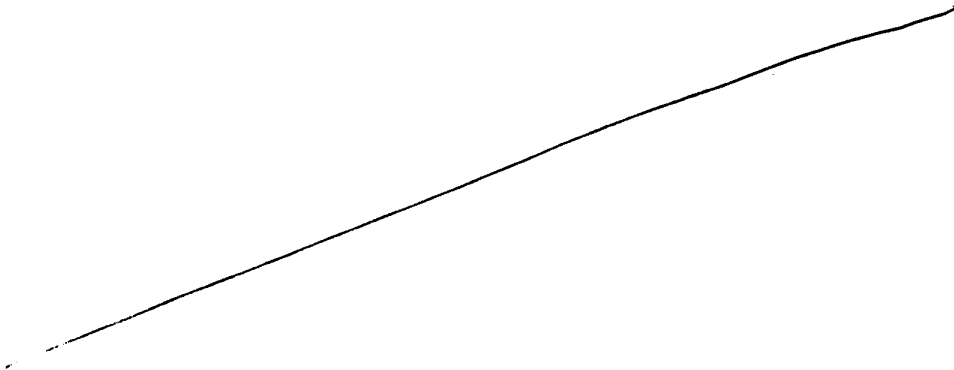
Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

The following deficiencies were identified, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

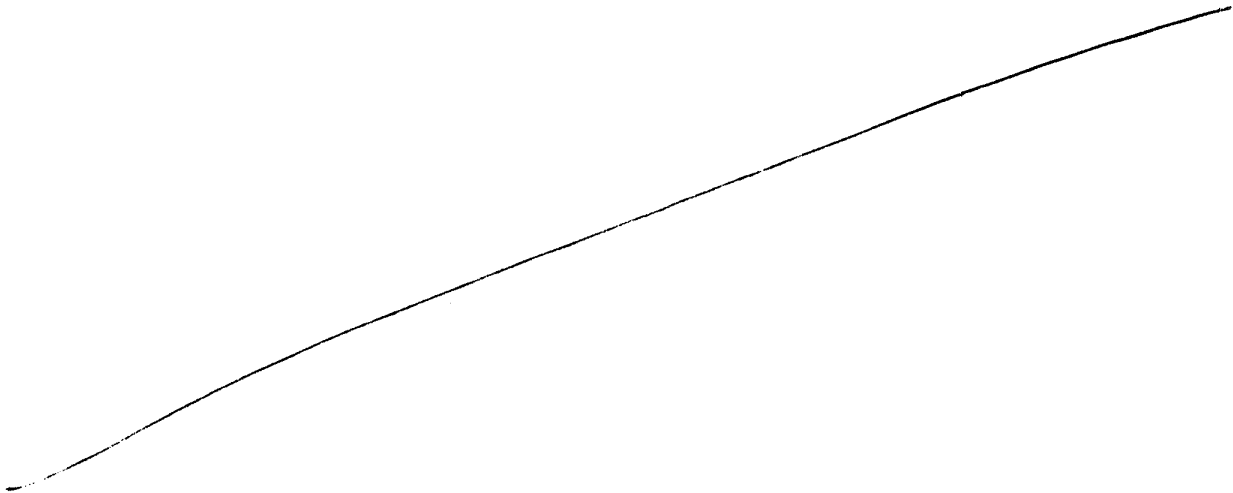
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control and Quality Assurance



Section H. Initial Tests

Section I. Specimen Validity Tests

Section J. Confirmatory Tests

Section K. Records Audit

Section L. Certification and Reporting

Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

