

RESEARCH TRIANGLE INSTITUTE



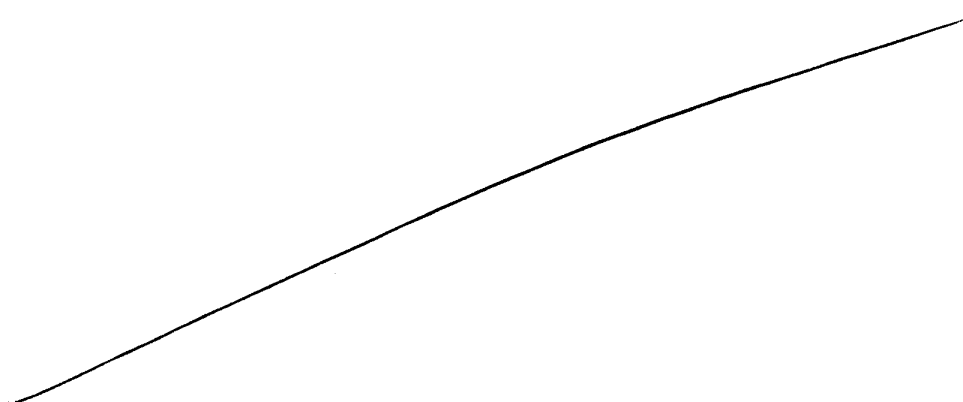
National Laboratory Certification Program

November 20, 1998

0249
Dr. Lance Presley
Dr. William R. Lynn
Ms. Barbara Rowland
LabCorp Occupational Testing Services, Inc.
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Dr. Presley, Dr. Lynn, and Ms. Rowland:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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. However, the following issue was raised:



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.

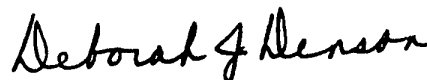
Dr. Presley, Dr. Lynn, Ms. Rowland

Page 2 of 2

11/20/98

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 Inspection Analyst

Enclosure

cc: Project Files/M13



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: LabCorp Occupational Testing Services, Inc.

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M13 Date: 22 October 1998
 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. 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

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 4, 1999

0249
Dr. Lance Presley
Dr. William R. Lynn
Ms. Barbara Rowland
LabCorp Occupational Testing Services, Inc.
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Dr. Presley, Dr. Lynn, and Ms. Rowland:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourteenth 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. However, the laboratory must correct/clarify the following:



Dr. Presley
Dr. Lynn
Ms. Rowland
Page 2 of 2
06/04/99

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

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M14

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: LabCorp Occupational Testing Services, Inc.

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M14 Date: 22 April 1999
 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.

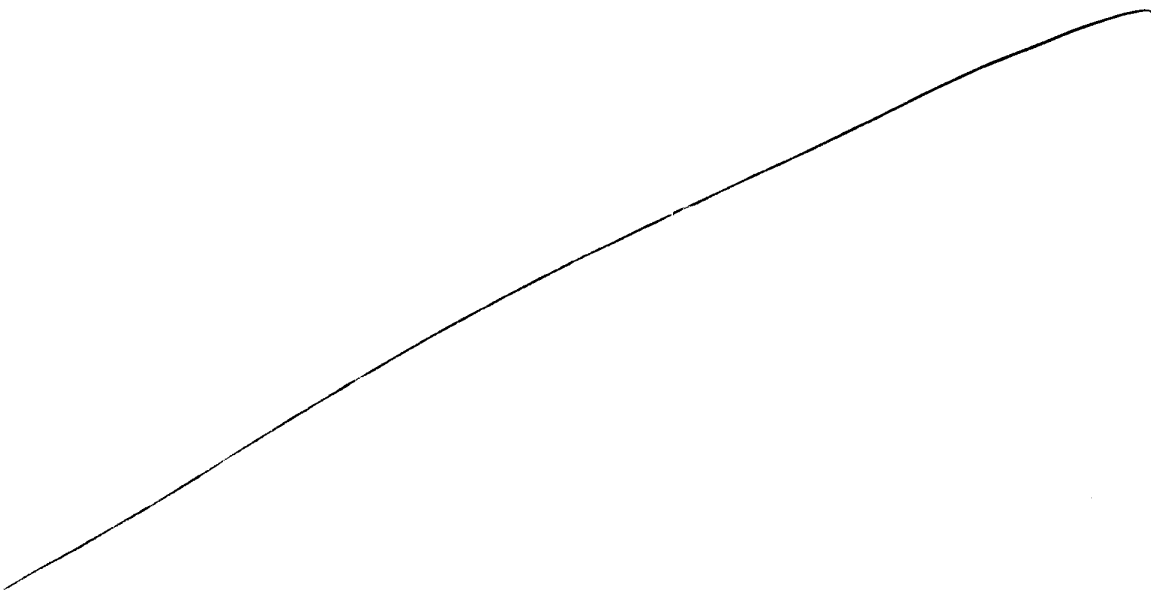
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

Ver. Final

Lab ID# 0249

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

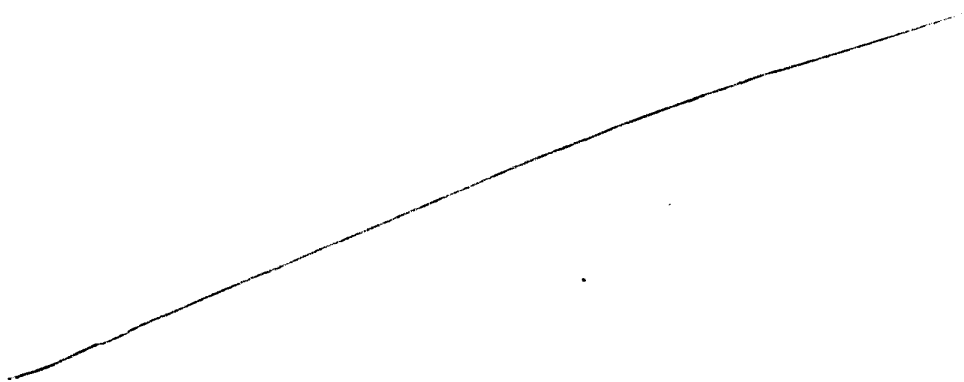
Section E. Standard Operating Procedures - Procedures Manual



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

All items in this section were judged to be acceptable.

Section G. Quality Control



Ver. Final

Lab ID# 0249

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Ver. Final

Lab ID# 0249

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 03, 1999

0249
Dr. Lance Presley
Ms. Barbara Rowland
LabCorp Occupational Testing Services, Inc.
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Dr. Presley and Ms. Rowland:

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 highly acceptable.

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 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: LabCorp Occupational Testing Services, Inc.

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M15 Date: 21 October 1999
 Other _____

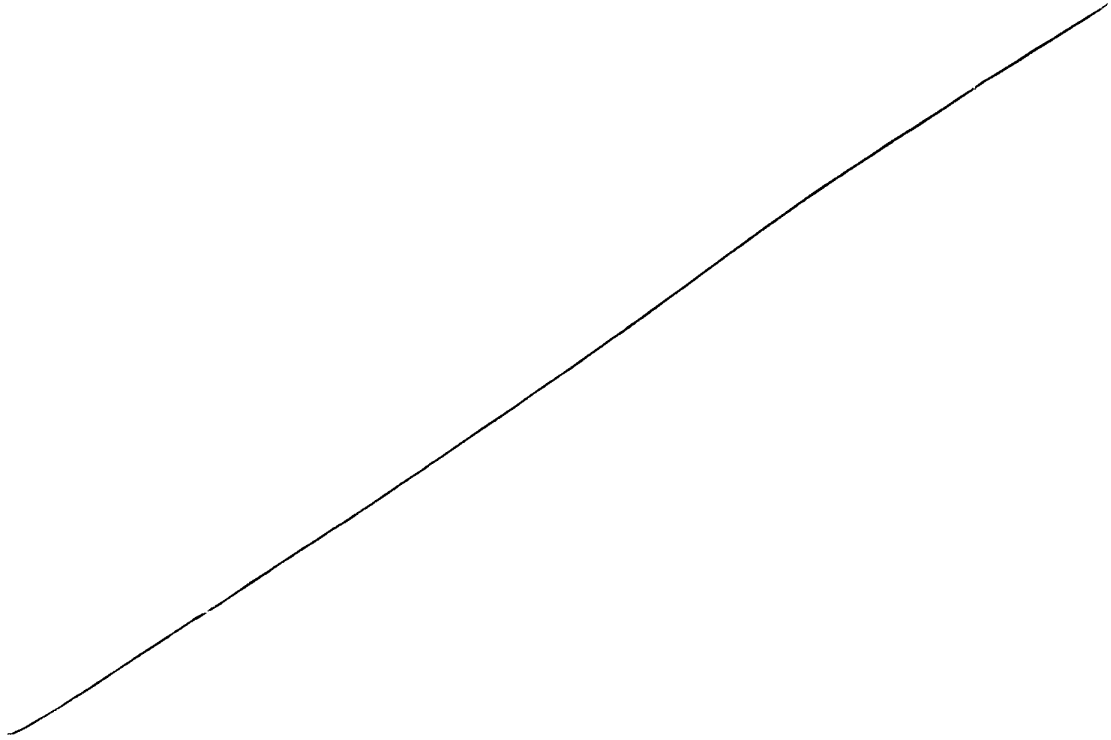
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

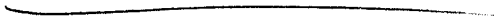
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



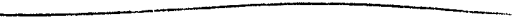
Section F. Chain-of-Custody, Accessioning, and Security



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



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

July 17, 2000

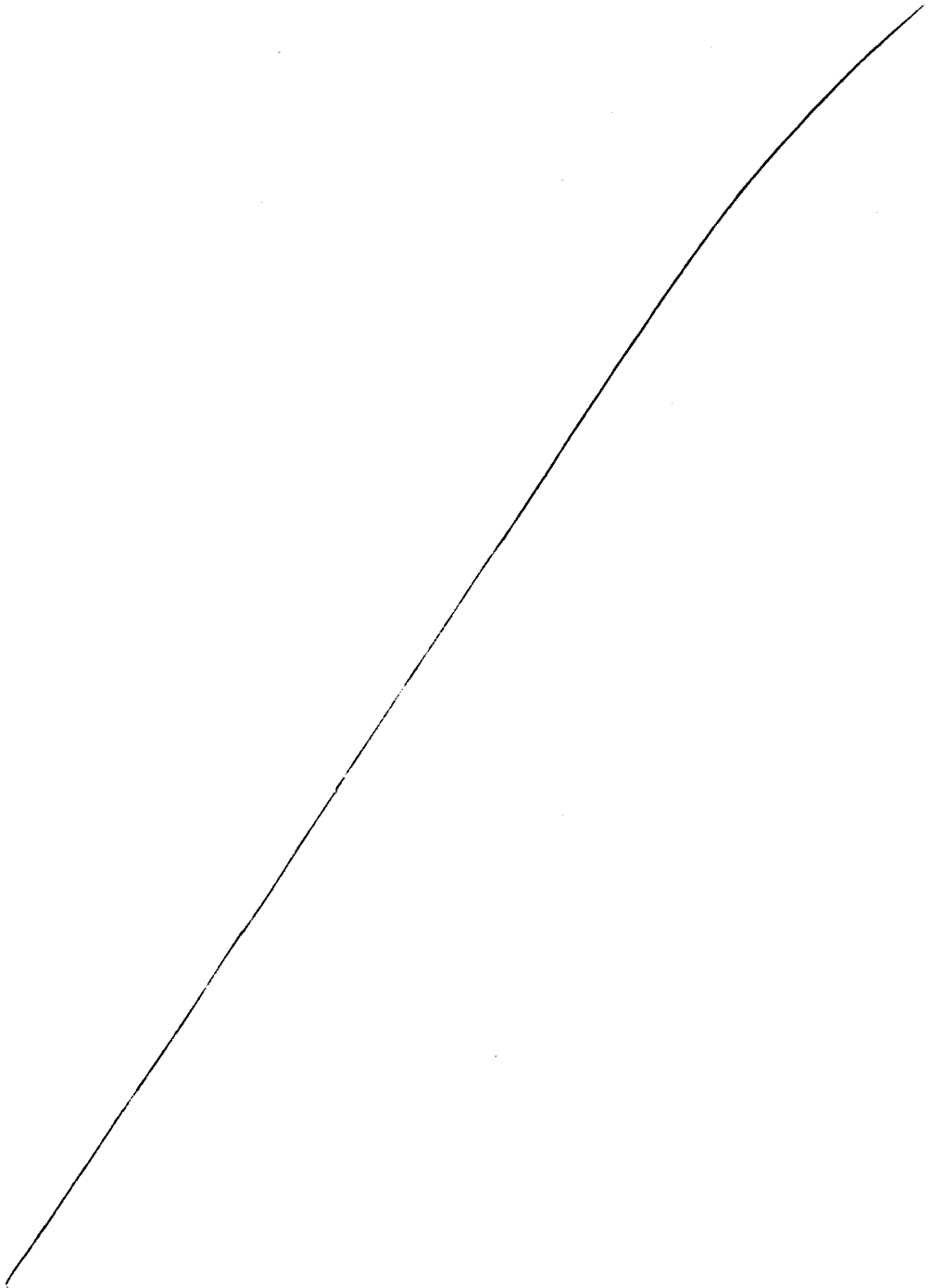
0249
Ms. Barbara Rowland
Laboratory Corporation of America Holdings
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Ms. Rowland:

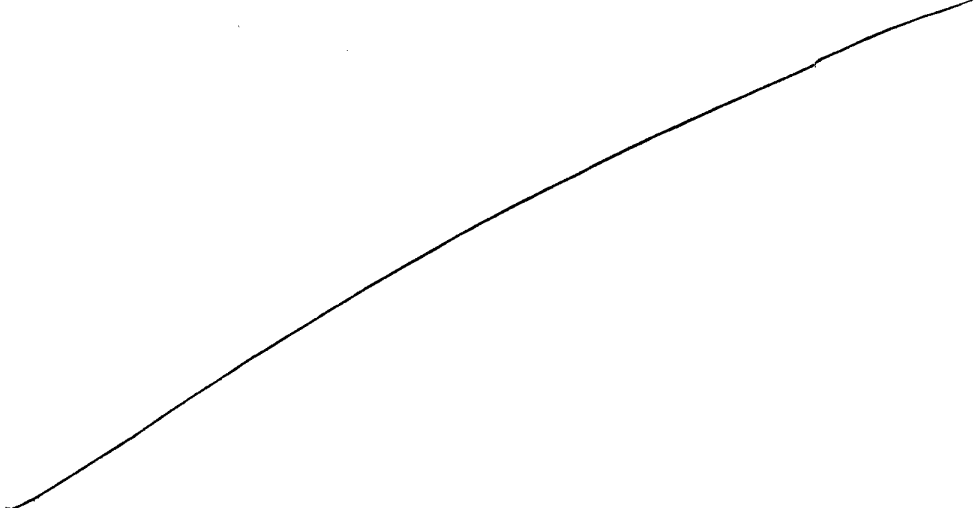
The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is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



Ms. Rowland
July 17, 2000
Page 2 of 3



Ms. Rowland
July 17, 2000
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/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: Laboratory Corporation of America Holdings

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M16 Date: 18 May 2000
 Other _____

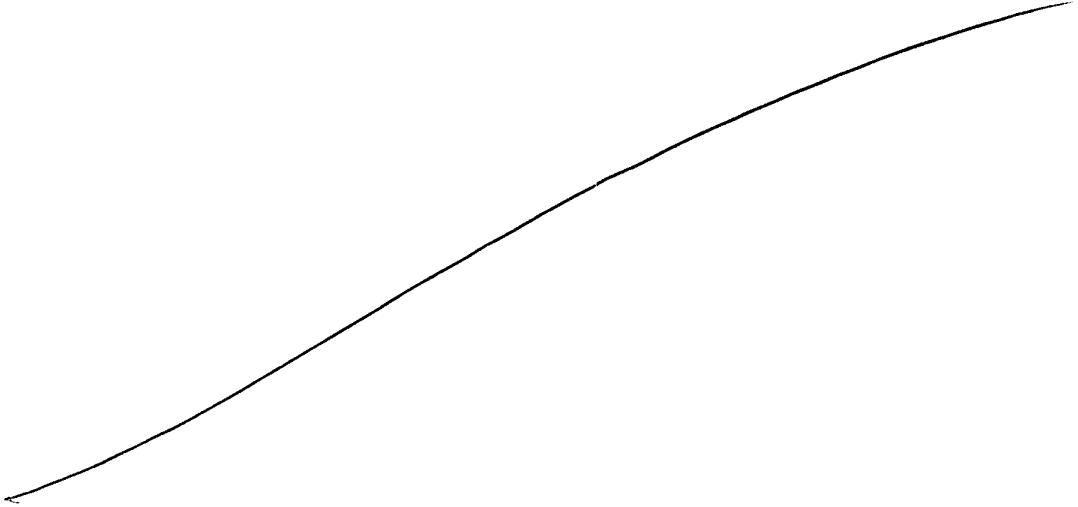
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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.

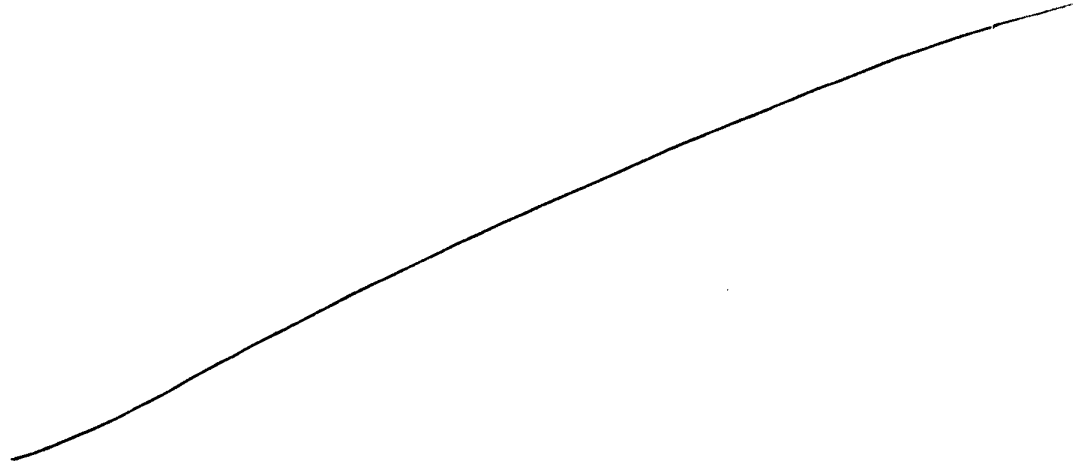
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

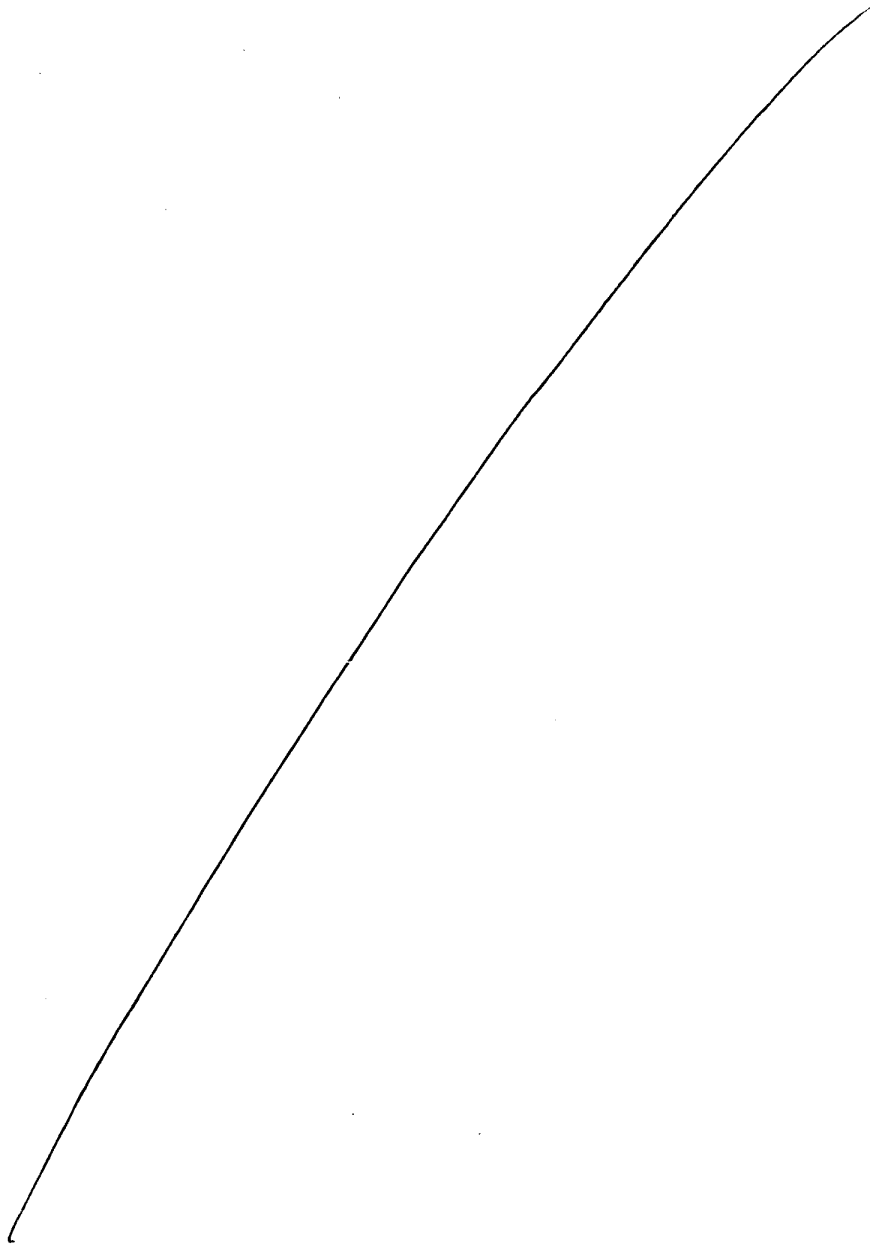
January 9, 2001

0249
Ms. Barbara Rowland
Laboratory Corporation of America Holdings
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Ms. Rowland:

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.





Ms. Rowland
Page 3 of 3
01/09/01

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 in Item H4 above. 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: Laboratory Corporation of America Holdings

Location: Memphis, TN

Document Reviewed: Application Form
 Inspection Report #M17
 Other _____

Date: 26 October 2000

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



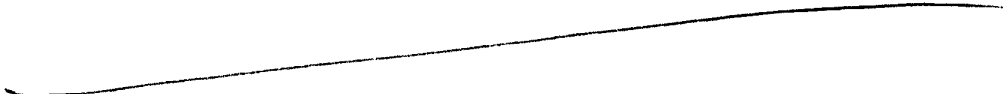
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel



received
1/22/01 SDC

Laboratory Corporation of America® Holdings
4022 Willow Lake Boulevard
Memphis, Tennessee 38118

Telephone: 901-375-0014
Fax: 901-795-1559

January 19, 2001

Lab 0249

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

Dear Ms. Crumpton,

The following response with enclosed documents represents corrective actions taken in order to address the issues cited in section H. 4 from the laboratory's seventeenth maintenance inspection of October 18-20,2000.

A large, curved signature line, likely representing the signature of the sender, which spans across the lower half of the page.

If you have any questions or I can be of any further assistance, please call me at 1-866-827-8042 Ext. 883.

Sincerely,

A handwritten signature in cursive script, appearing to read "Barbara Rowland".

Barbara Rowland, MPA
Responsible Person



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 2, 2001

0249
Ms. Barbara Rowland
Laboratory Corporation of America Holdings
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Ms. Rowland:

We have reviewed the material provided in your correspondence of January 19, 2001, submitted in response to issues raised during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of January 9, 2001. 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 Crompton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/0249

