



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 22, 1998

Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

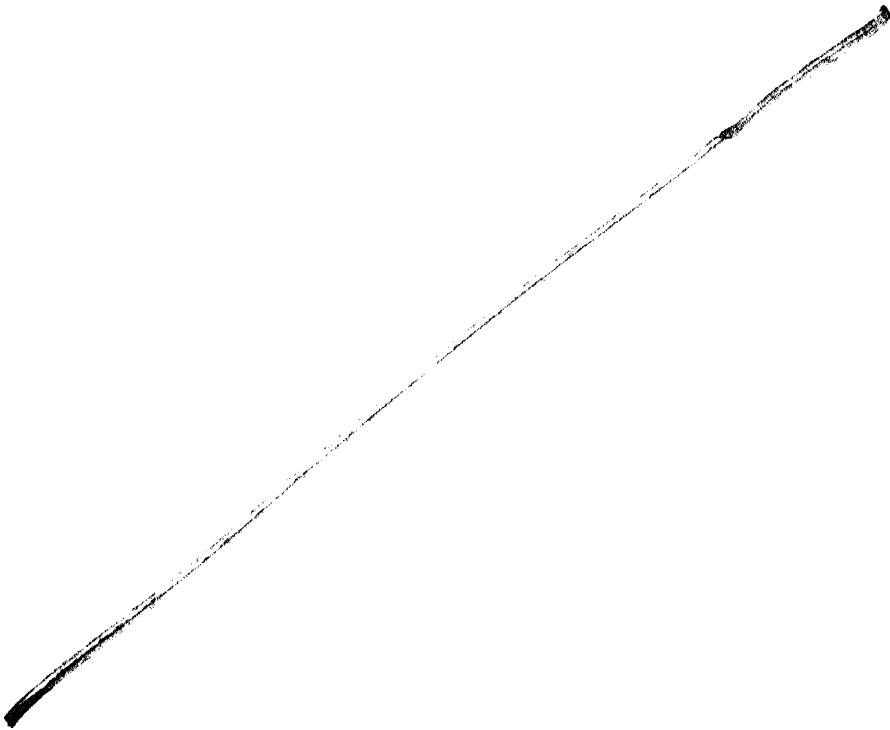
Dear Dr. Costantino:

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. However, the following issues were raised:

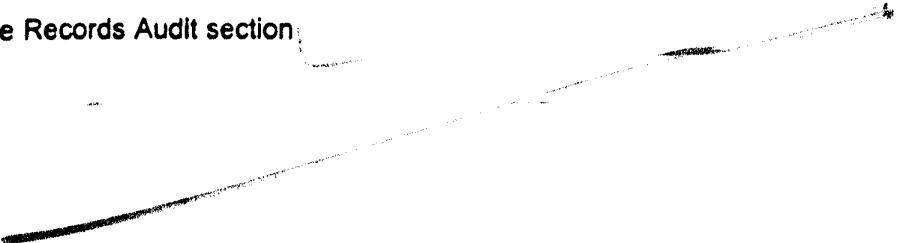
E. The Standard Operating Procedures section

F. The Chain of Custody, Accessioning, and Security section

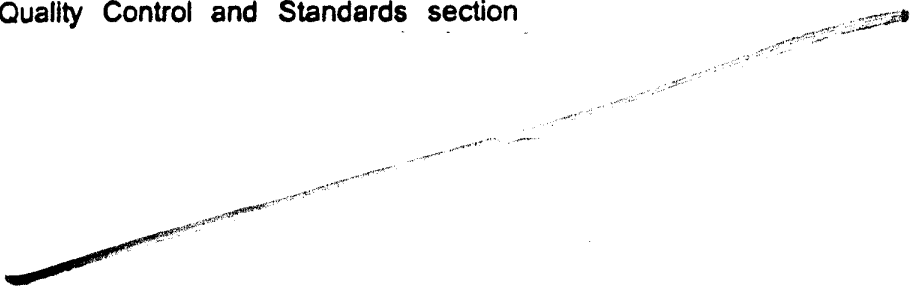




G. The Records Audit section



J. The Quality Control and Standards section

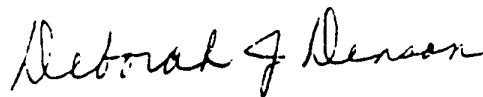


N. The Gas Chromatography/Mass Spectrometry section

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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Dr. Costantino
Page 4 of 4
12/23/98

Enclosure

cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0037
Document No. Final

Laboratory: American Medical Laboratories, Inc.

Location: Chantilly, VA

Document Reviewed: Application Form
 Inspection Report #M17 Date: 5 November 1998
 Other _____

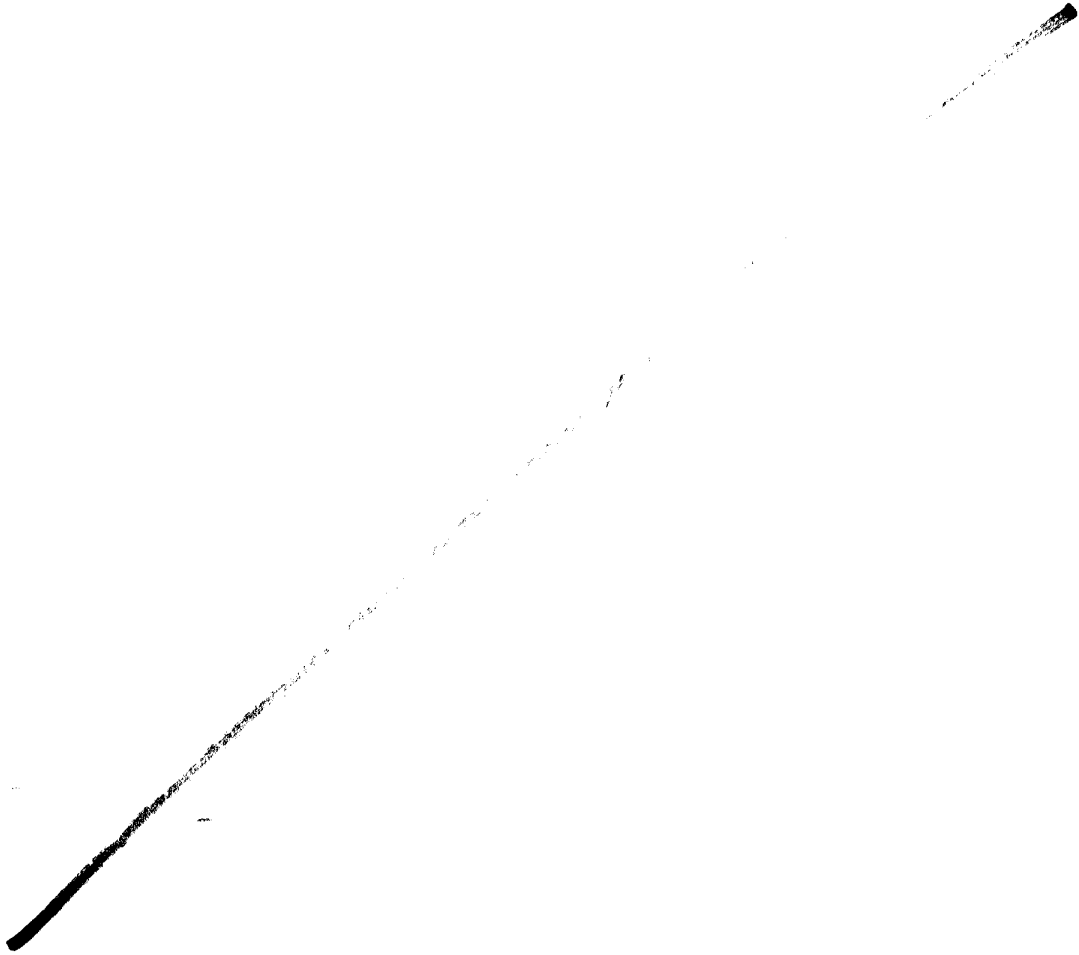
Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the independent 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.

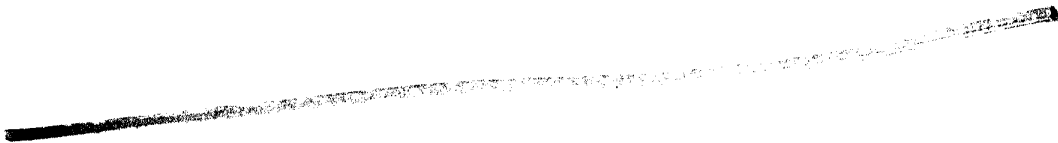
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



AMERICAN MEDICAL LABORATORIES, INC. *

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

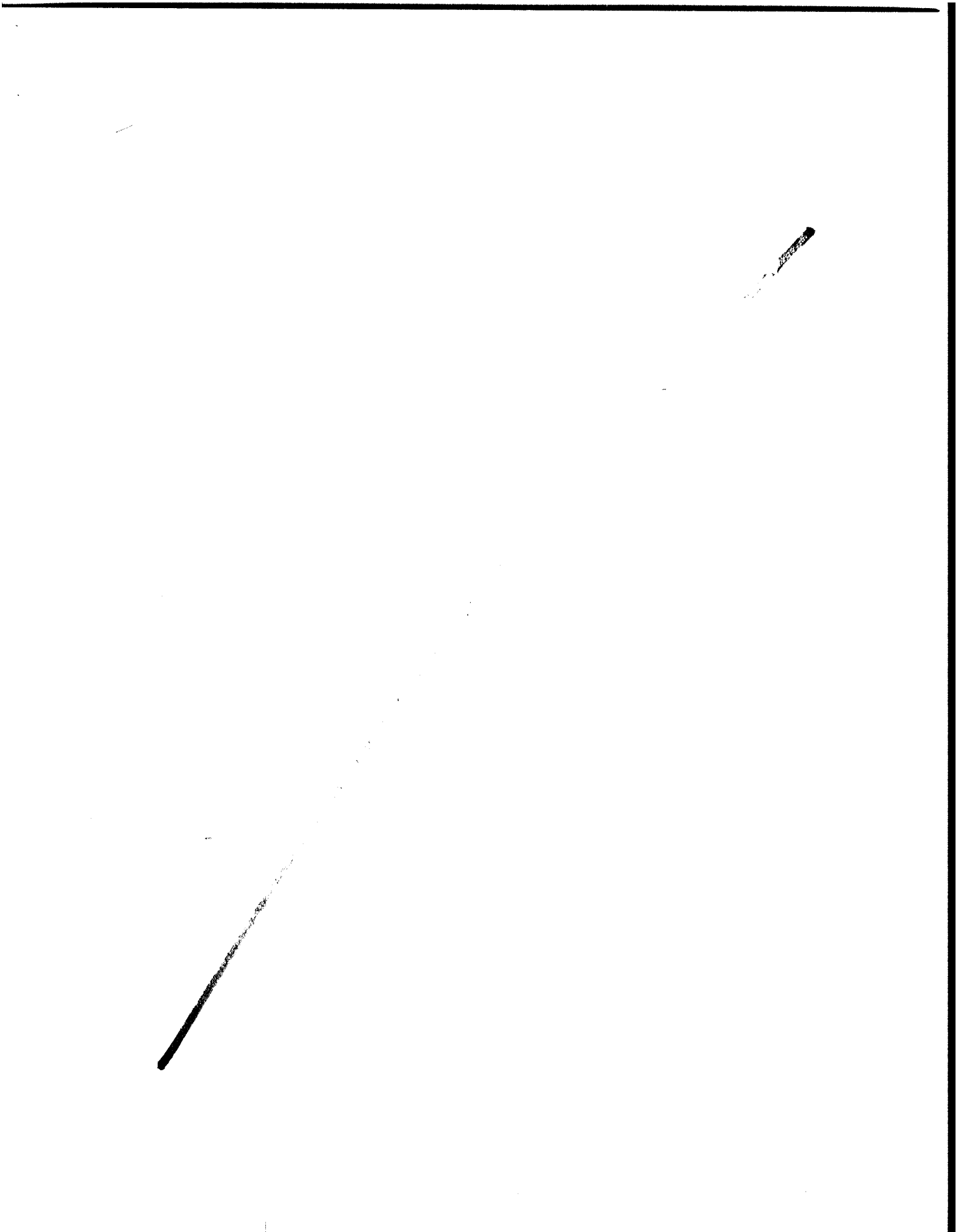
received
2/1/99 DN

Deborah Denson
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

January 20, 1999

Dear Ms. Denson:

The following changes are in response to your letter of December 22, 1998 :



Please notify me immediately if you have questions or concerns regarding this response to the critique developed from the inspection reports as described in your letter.

Sincerely,



Dr. Anthony G. Costantino, DABFT
Vice-President, Toxicology
American Medical Laboratories, Inc.
NLCP Laboratory 0037



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 4, 1999

0037

Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

We have reviewed the material provided in your correspondence of January 20, 1999, submitted in response to issues raised during the seventeenth 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 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) 541-7265 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M17



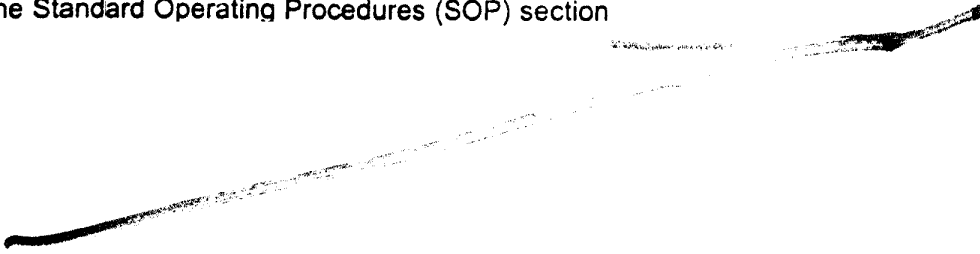
June 14, 1999

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

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. However, the laboratory must correct the following issue raised:

E. The Standard Operating Procedures (SOP) section



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 issue 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

Dr. Costantino
Page 2 of 2
06/14/99

Enclosure

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0037
Document No. Final

Laboratory: American Medical Laboratories, Inc.

Location: Chantilly, VA

Document Reviewed: Application Form
 Inspection Report #M18 Date: 6 May 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

December 22, 1999

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

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'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.

E. The Standard Operating Procedures (SOP) section

F. The Chain of Custody, Accessioning, and Security section

G. The Quality Control section



I. The Confirmatory Tests section :

- ~~_____~~
- L. The Computers, Software, and Laboratory Information Management System (LIMS) section
- ~~_____~~

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 section G above. In responding to these issues, please organize the material in your document in accordance with the 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M19

~~_____~~

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0037
Document No. Final

Laboratory: American Medical Laboratories, Inc.

Location: Chantilly, VA

Document Reviewed: Application Form
 Inspection Report #M19 Date: 4 November 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



AMERICAN MEDICAL LABORATORIES, INC.®

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

received
2/2/00 SDC



January 31, 2000

Susan Crumpton
NLCP @RTI
3040 Cornwallis Road
RTP, NC 27709

Dear Ms. Crumpton:

This letter is to address issues raised in the critique developed as a result of the nineteenth maintenance inspection of this laboratory. The responses are in the order that they appear in the critique and referred to by those same numbers.

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

Sincerely,

Anthony G. Costantino, Ph.D. D-ABFT
Sr. Vice President and Director of Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 7, 2000

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

We have reviewed the material provided in your correspondence of January 31, 2000, submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of December 22, 1999. The following is a summary of our review:



Dr. Costantino
Page 2 of 2
02/07/00

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. at (919) 541-7043.

Sincerely,

A handwritten signature in cursive script that reads "Susan Crumpton". The signature is written in black ink and is positioned above the printed name and title.

Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M14



AMERICAN MEDICAL LABORATORIES, INC.®

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

received
SDC 2/25/00



February 24, 2000

Susan Crumpton
NLCP @RTI
3040 Cornwallis Road
RTP, NC 27709

Dear Ms. Crumpton:

This laboratory

If there any further questions please call me at (800) 336-3718 EXT. 6028

Sincerely,

Anthony G. Costantino, Ph.D. D-ABFT
Sr. Vice President and Director of Toxicology

RESEARCH TRIANGLE INSTITUTE



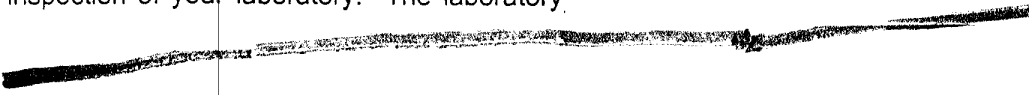
National Laboratory Certification Program

February 29, 2000

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

We have reviewed the material provided in your correspondence of February 24, 2000, submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory. The laboratory



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 taken to address issues raised in the nineteenth maintenance inspection 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

cc: Dr. Michael Baylor
Project Files/m19





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 13, 2000

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:


The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth 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.

E. The Standard Operating Procedures (SOP) section


G. The Quality Control section

H. The Initial Tests section






I. The Confirmatory Tests section



J. The Records Audit section



K. The Reporting section



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.

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 30, 2001

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-first 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.

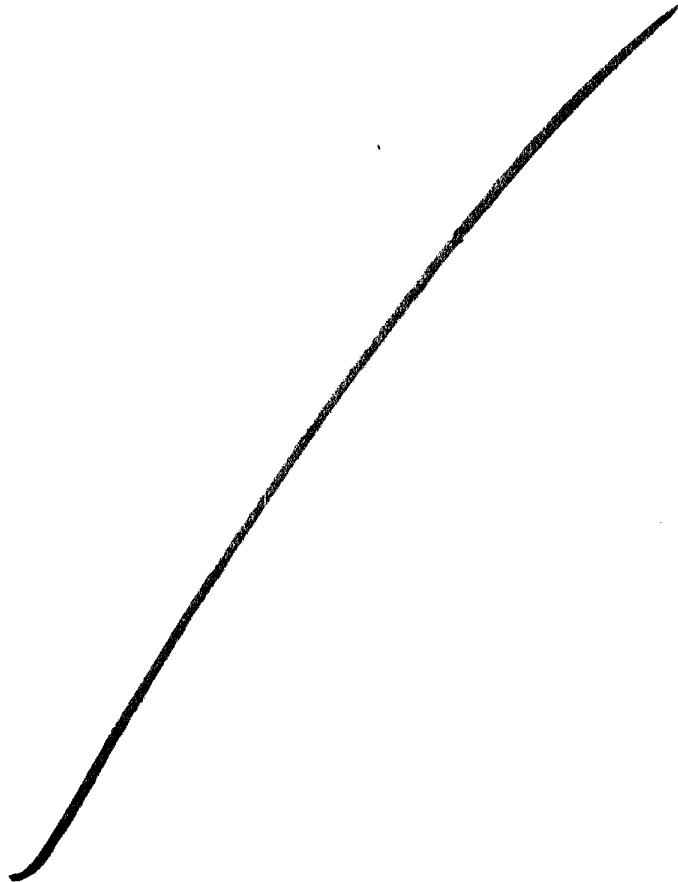
E. The Standard Operating Procedures (SOP) section

F. The Chain-of-Custody, Accessioning, and Security section



Dr. Costantino
January 30, 2001
Page 2 of 4



G. The Quality control and Quality Assurance Section



Dr. Costantino
January 30, 2001
Page 3 of 4

- 
- I. The Specimen Validity Test section
- 

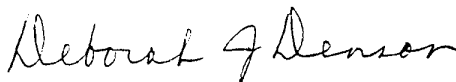
Dr. Costantino
January 30, 2001
Page 4 of 4

L. The Certification and Reporting section

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 Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M21

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0037
Document No. Final

Laboratory: American Medical Laboratories, Inc.

Location: Chantilly, VA

Document Reviewed: Application Form
 Inspection Report #M21 Date: 2 November 2000
 Other _____

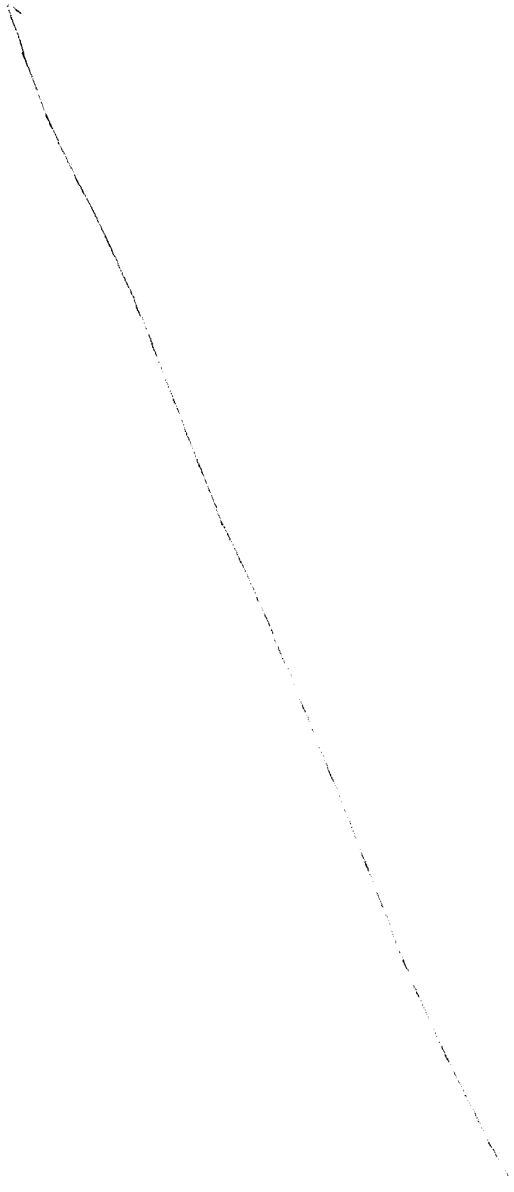
Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

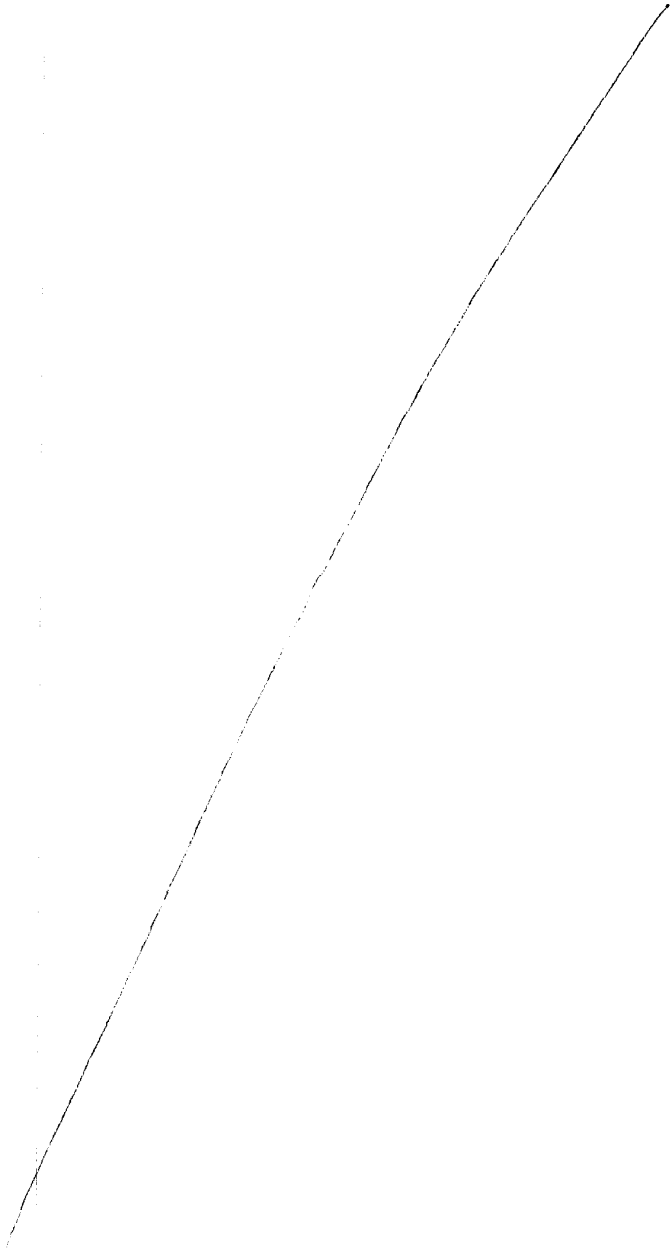
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

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





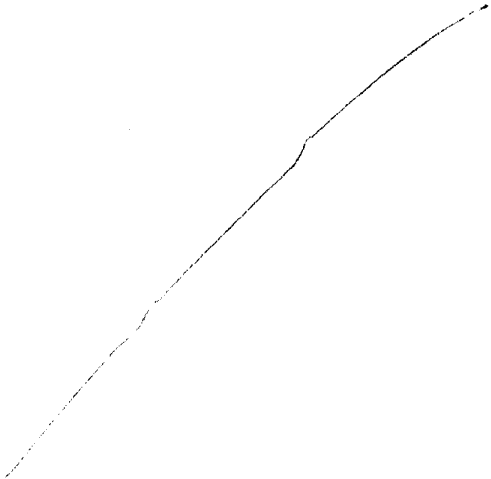
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

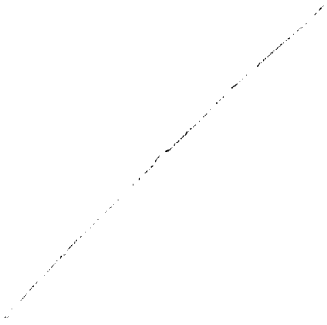
Section H. Initial Tests

Section I. Specimen Validity Tests

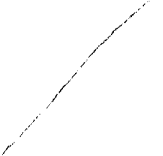
Section J. Confirmatory Tests



Section K. Records Audit



Section L. Certification and Reporting



Section M. Laboratory Information Management System (LIMS)

Section N. Personnel

AML[®]

AMERICAN MEDICAL LABORATORIES, INC. ³

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

received

3/06/01 DD

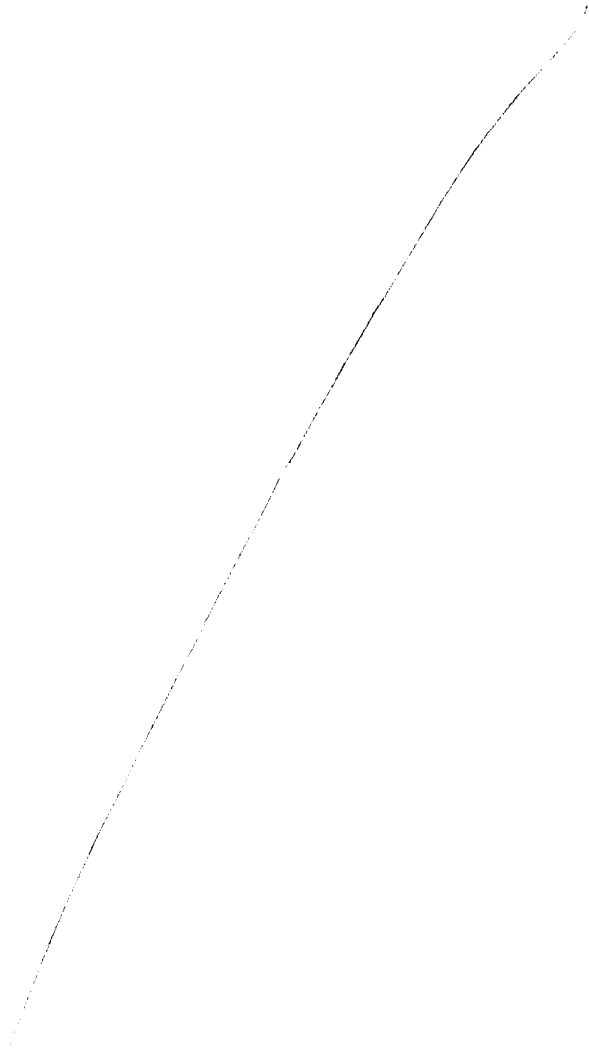


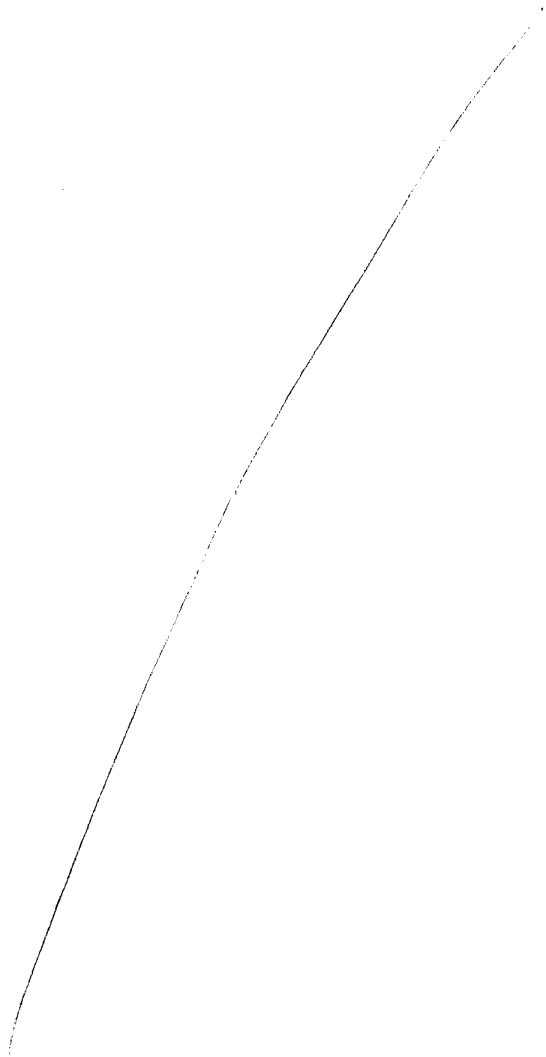
March 3, 2001

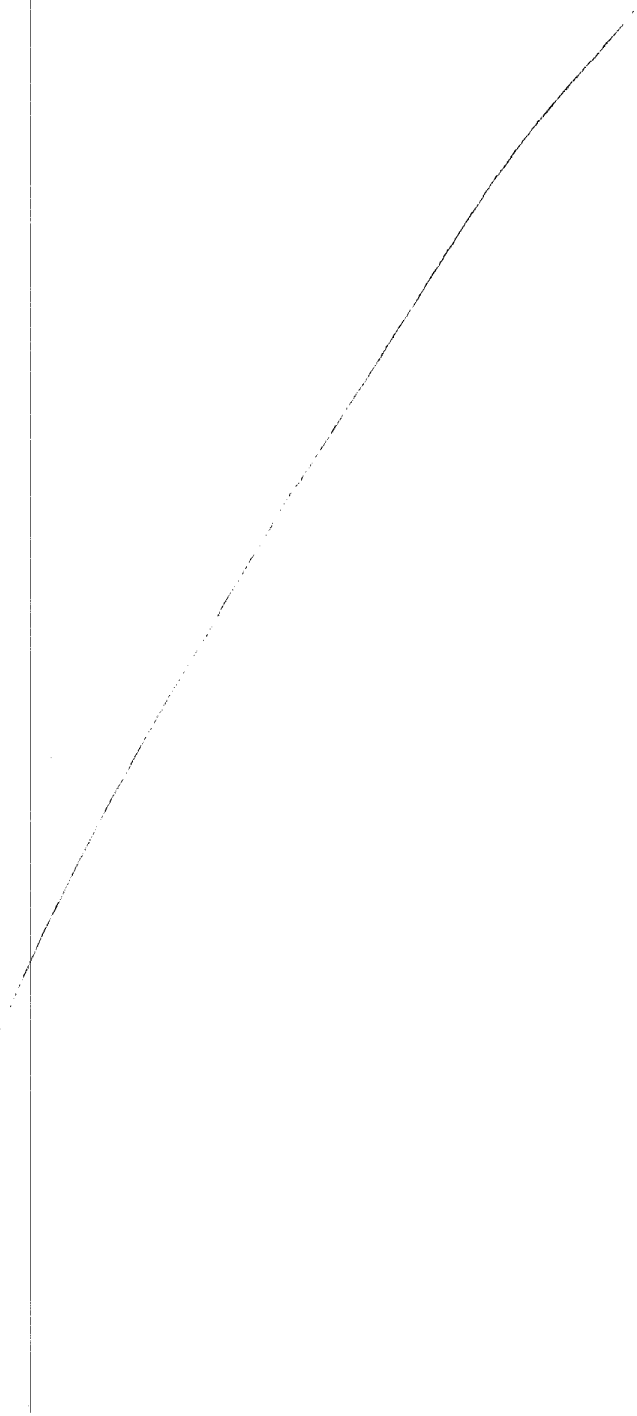
Ms. Deborah J. Denson
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 20151

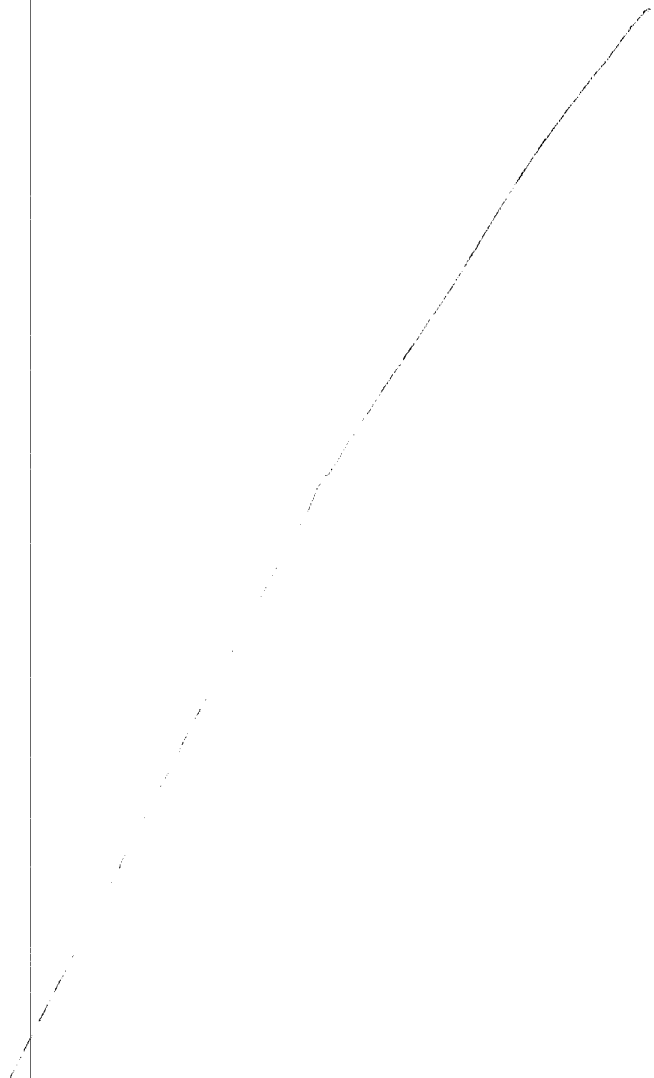
Dear Ms. Denson,

This letter is in response to the critique developed from the twenty-first maintenance inspection of this laboratory. The response is organized to follow the Document Review and Critique.



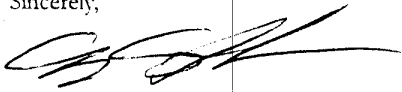






March 5, 2001

Sincerely,

A handwritten signature in black ink, appearing to read 'AG Costantino', written over a horizontal line.

Anthony G. Costantino, Ph.D. D-ABFT

Director of Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 13, 2001

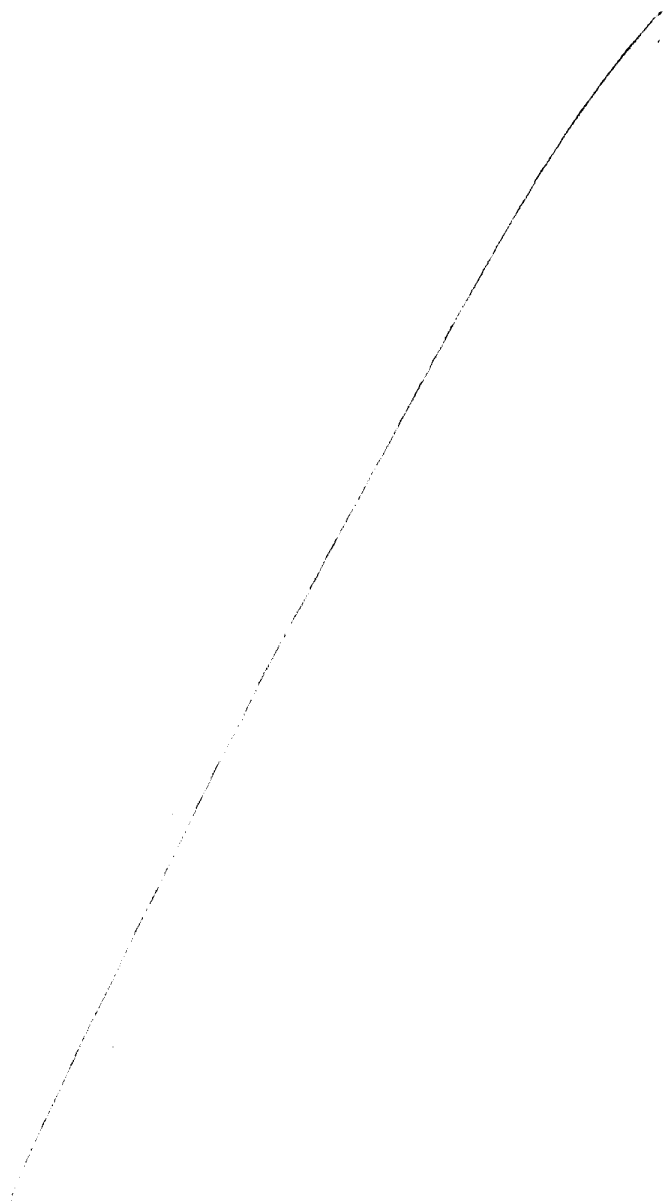
0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

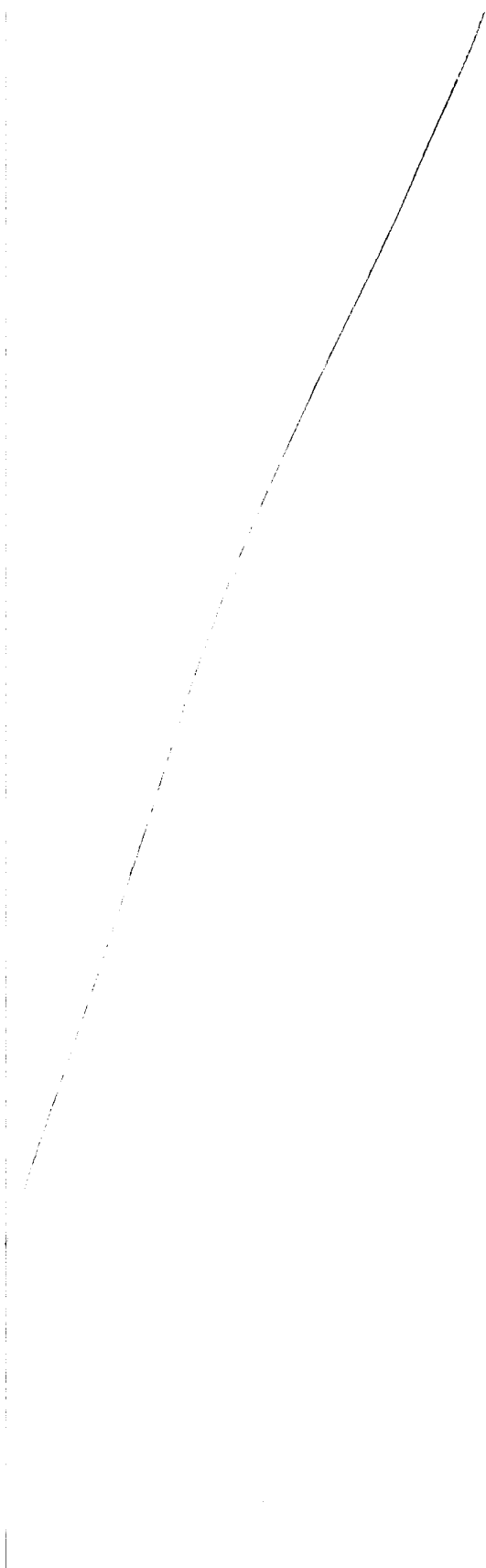
We have reviewed the material provided in your correspondence of March 03, 2001 submitted in response to issues raised during the twenty-first maintenance inspection of your laboratory as outlined in our correspondence of January 03, 2001. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

0037

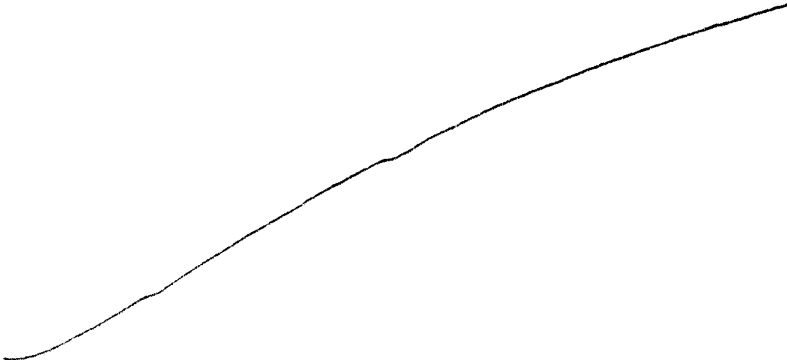
Dr. Costantino
March 13, 2001
Page 2 of 4



Dr. Costantino
March 13, 2001
Page 3 of 4



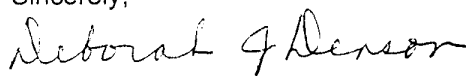
Dr. Costantino
March 13, 2001
Page 4 of 4



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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M21