

0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

The enclosed critique was developed from the inspection reports of the two 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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

E. The Standard Operating Procedures section



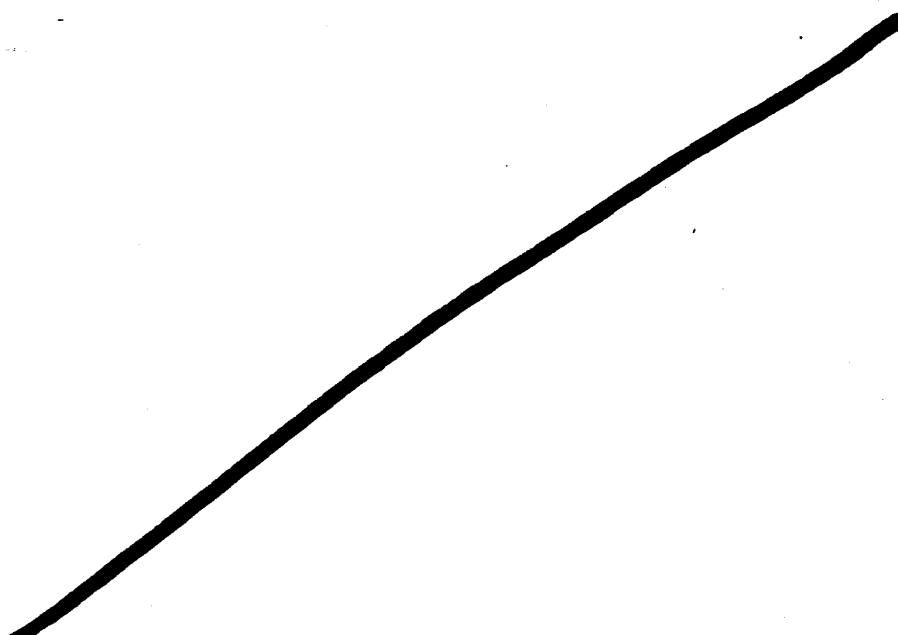
F. The Chain of Custody, Accessioning, and Security section



H. The Personnel section



Dr. Kelly
Page 2 of 2
10/28/98



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 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) 541-8176 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: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories

Location: Las Vegas, NV

Document Reviewed: Application Form
 Inspection Report #M14
 Other _____

Date: 24 September 1998

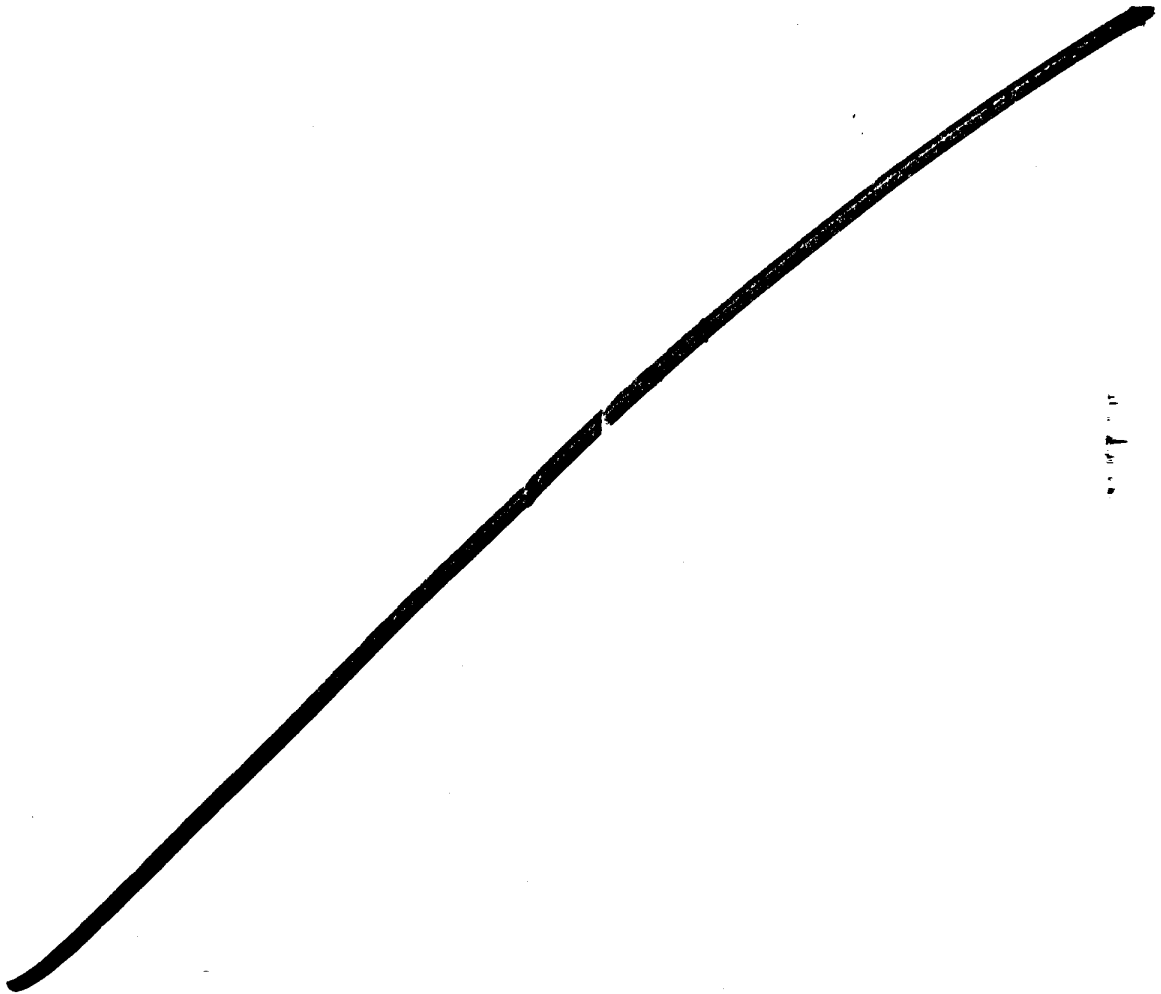
Status: Highly Acceptable Acceptable
 Unacceptable Failure

Inspection reports, from the two 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



[Redacted]

Section G. Records Audit

[Redacted]

Section H. Personnel

[Redacted]

11-1-88

Section I. Reagents

[Redacted]

Section J. Quality Control and Standards

[Redacted]

Section K. Reporting

[Redacted]

Section L. Equipment and Maintenance

[Redacted]

Section M. Immunoassay

[Redacted]

Section N. Gas Chromatography/Mass Spectrometry





**ASSOCIATED
PATHOLOGISTS
LABORATORIES**

4230 Burnham Ave.
Suite 250
Las Vegas, Nevada 89119-5480
(702) 733-7866

REC 01 11/25/98
Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Nevada State Lab License No. 4
CAP. No. 89109-004-011

November 25, 1998

Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
P. O. Box 12194
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

Thank you for your communication of October 28, 1998 (received on October 29, 1998), relating to the recent fourteenth maintenance inspection of our laboratory. Here are our responses to the various issues mentioned in your letter.

E. Standard Operating Procedures:



~~_____~~
F. Chain-of Custody, Accessioning and Security:
~~_____~~

H. Personnel

~~_____~~

Please contact us if you require further information.

Sincerely,

ASSOCIATED PATHOLOGISTS LABORATORIES (#0148)

Raymond C. Kelly, Ph.D.

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology
Responsible Person

RCK:me



RESEARCH TRIANGLE INSTITUTE

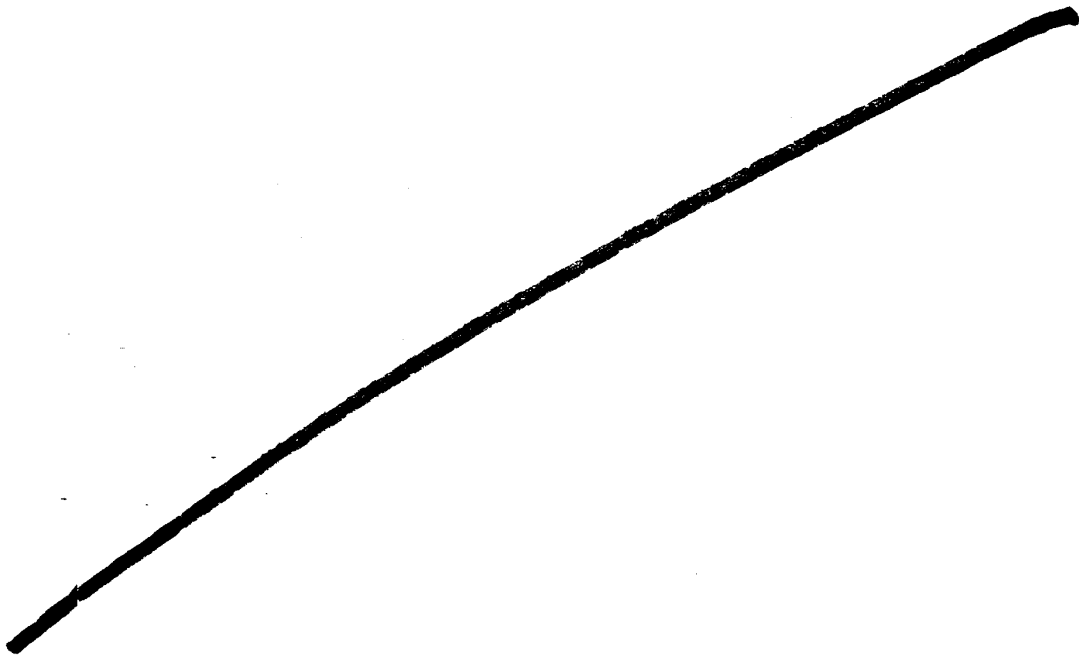
National Laboratory Certification Program

December 9, 1998

0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

We have reviewed the material submitted in your correspondence of November 25, 1998, provided in final response to issues raised during the fourteenth maintenance inspection of your laboratory as originally outlined in our correspondence of October 28, 1998. It appears that the laboratory has taken appropriate actions to address most issues raised. However, the following issue remains:



11/12

Dr. Kelly
Page 2 of 2
12/09/98

Based upon our review of the material submitted, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP). 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 assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan D. Crumpton
NLCP Inspection Analyst

cc: Project Files/M14

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

May 7, 1999

0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

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 HHS that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must 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/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories, Inc.

Location: Las Vegas, NV

Document Reviewed: Application Form
 Inspection Report #M15 Date: 25 March 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.

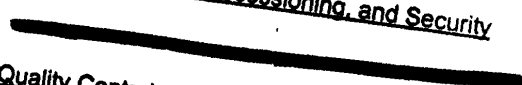
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

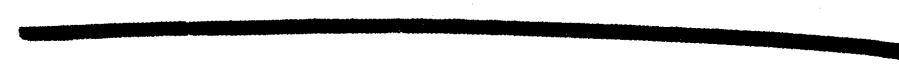
Section E. Standard Operating Procedures - Procedures Manual




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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit



[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

000000

0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

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. However, the laboratory must correct/clarify the following issues raised:

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



G. The Quality Control section



H. The Initial Tests section



N. The Personnel 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.

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/M16



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories

Location: Las Vegas, NV

Document Reviewed: Application Form
 Inspection Report #M16
 Other _____

Date: 30 September 1999

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

[Redacted content]

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

[Redacted content]

Section G. Quality Control

[Redacted content]

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

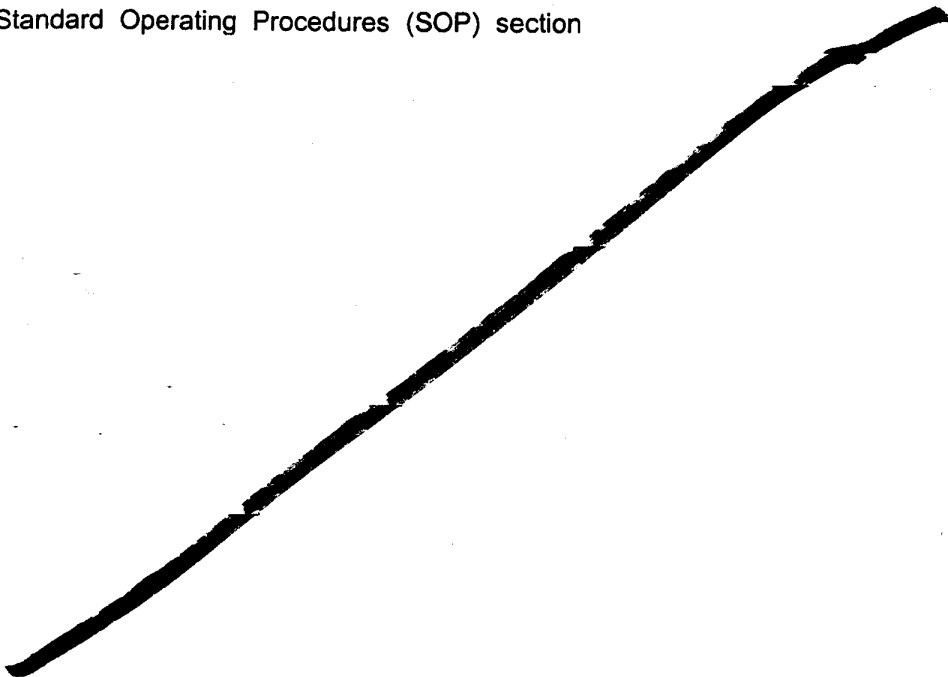
0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

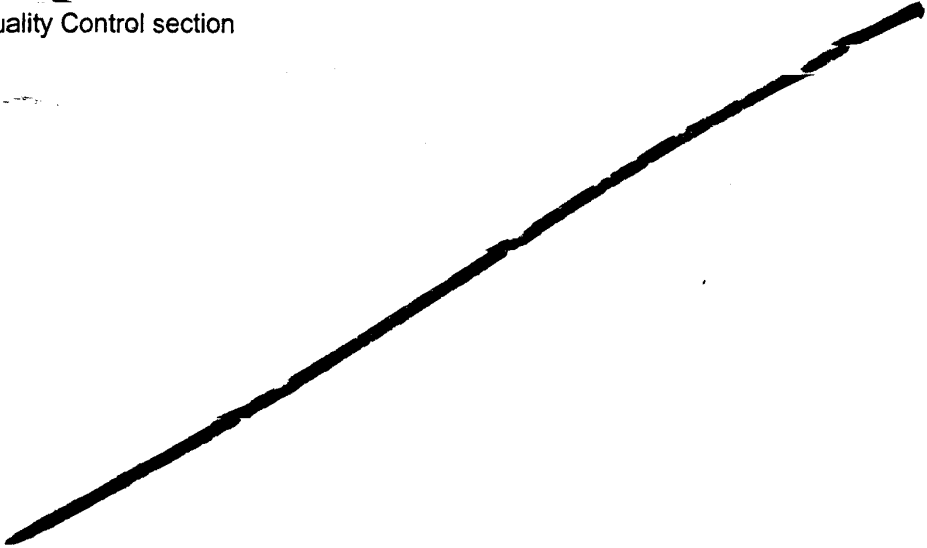
The National Laboratory Certification Program (NLCP) staff at RTI have reviewed the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory and the report of the inspector who conducted the April 12-14, 2000 performance testing (PT) inspection of your laboratory under the NLCP.

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the 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:

E. The Standard Operating Procedures (SOP) section



G. The Quality Control section



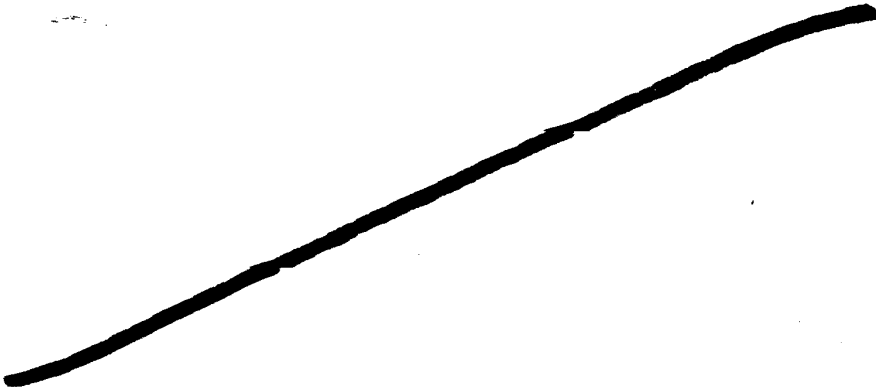
I. The Confirmatory Tests section



J. The Records section



The following comments are based on the inspector's report from the April 12-14, 2000, NLCP PT inspection:



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 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: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories, Inc.

Location: Las Vegas, NV

Document Reviewed: Application Form
 Inspection Report #M17 Date: 13 April 2000
 Other _____

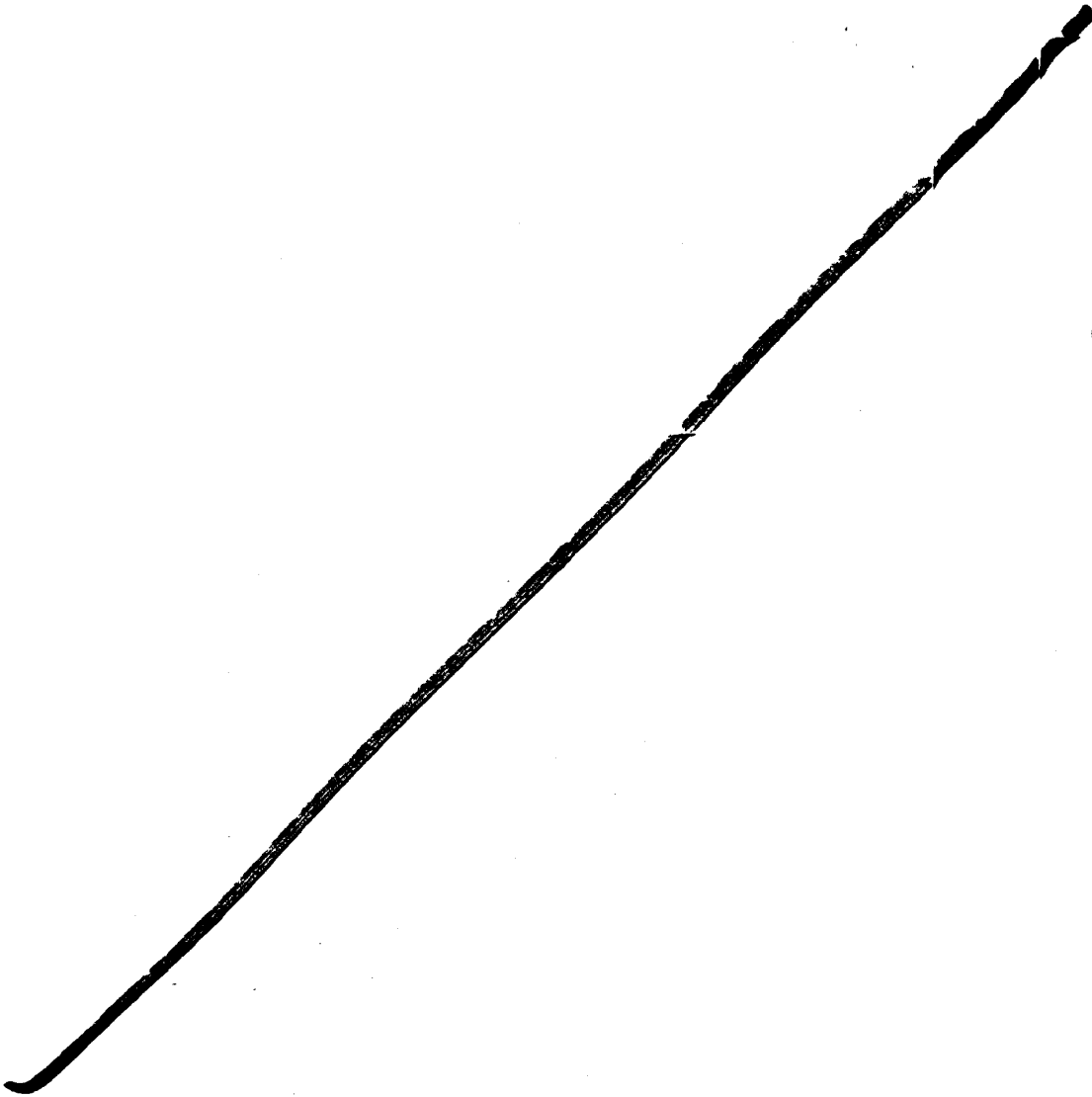
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



[Redacted]

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

[Redacted]

Section G. Quality Control

[Redacted]

Section H. Initial Tests

[Redacted]

Section I. Confirmatory Tests

[Redacted]

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

July 6, 2000

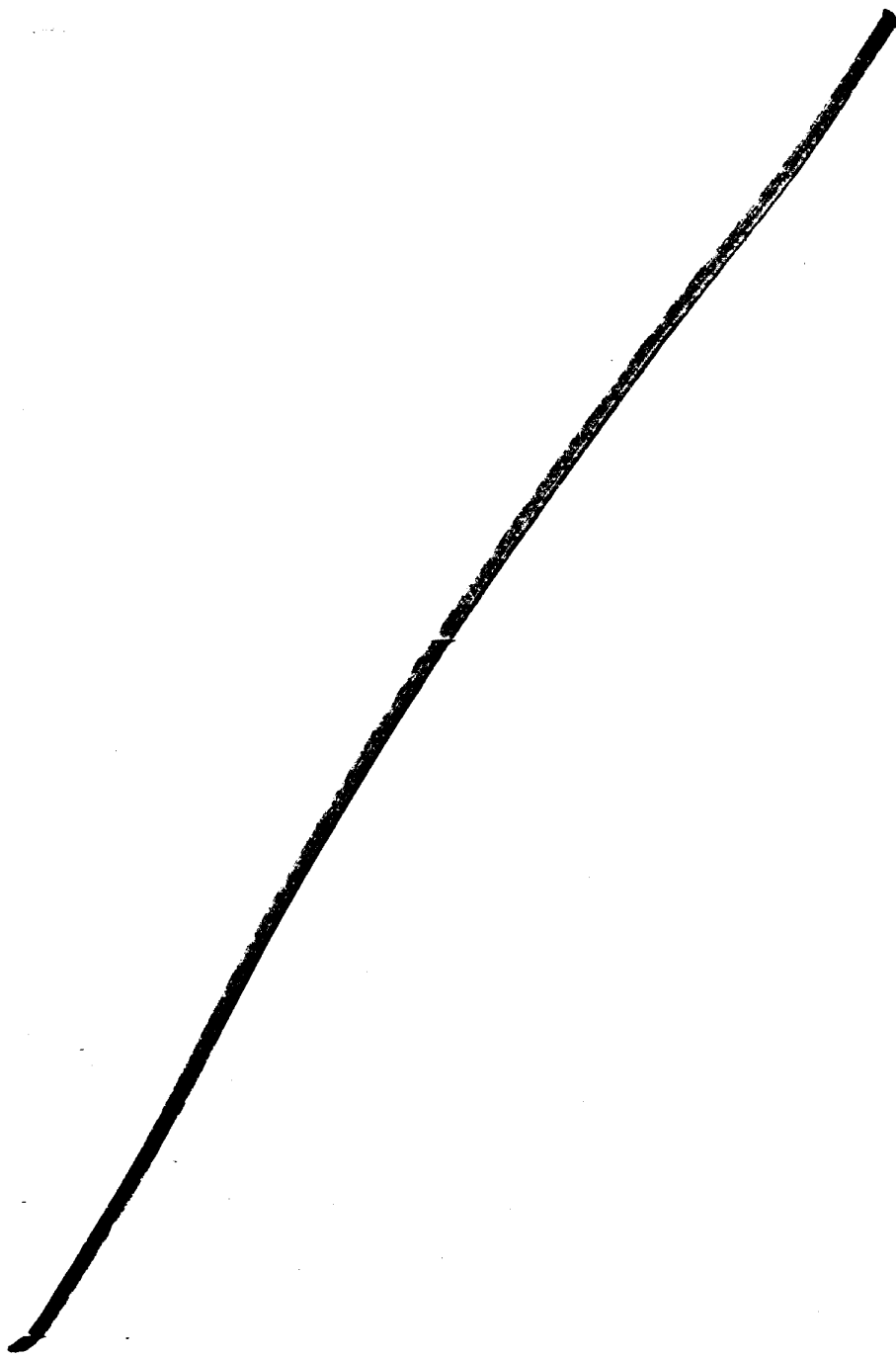
received
SDC 7/16/00

Susan Crumpton
NLCP Technical Analyst
National Laboratory Certification Program
Research Triangle Institute
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

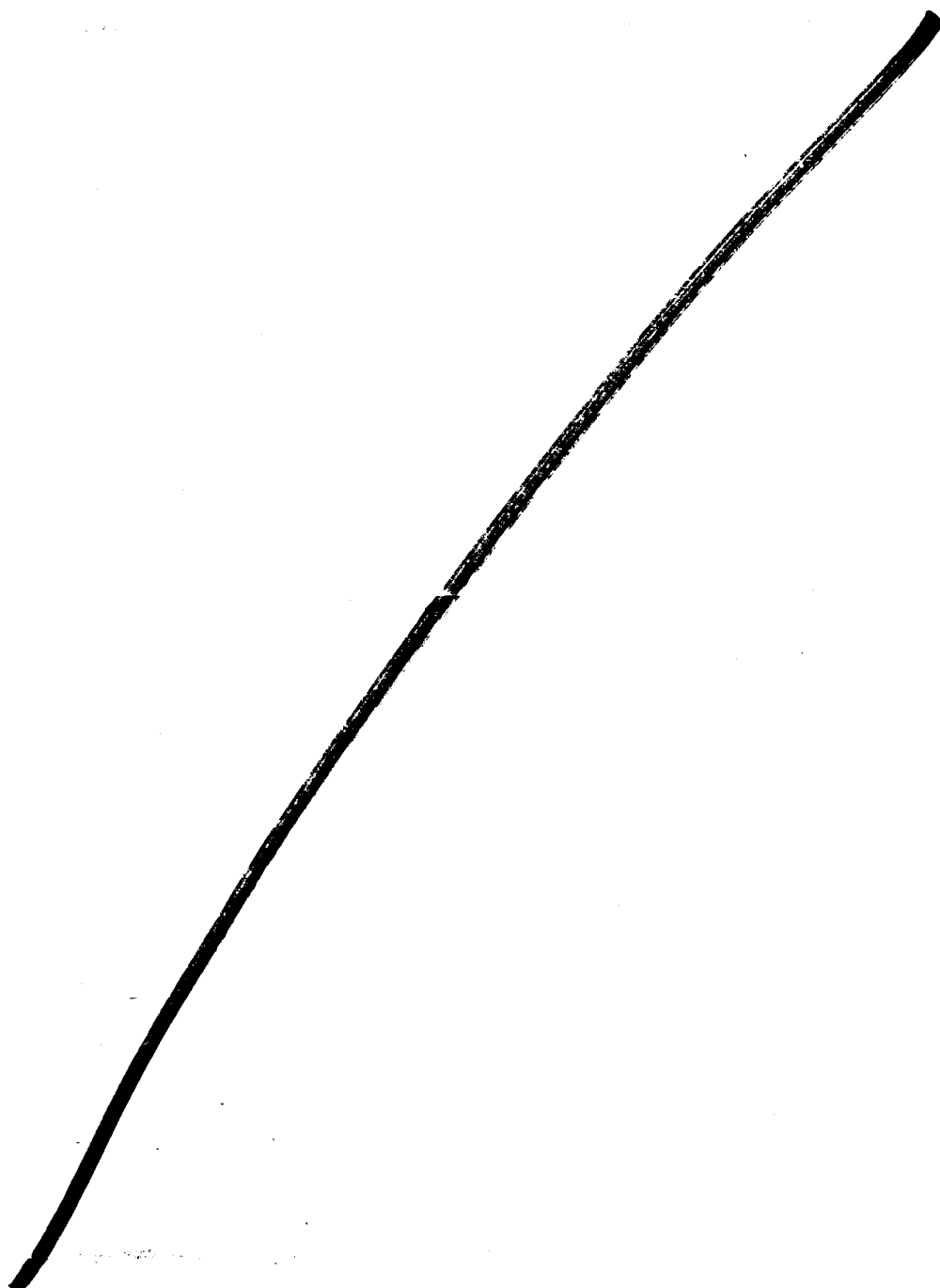
We are responding to your communication of June 5, 2000, in which you provided a critique for our seventeenth maintenance inspection, April 12-14, 2000. I will take each item in the order given in your letter.

Ms. Crumpton, Page Two



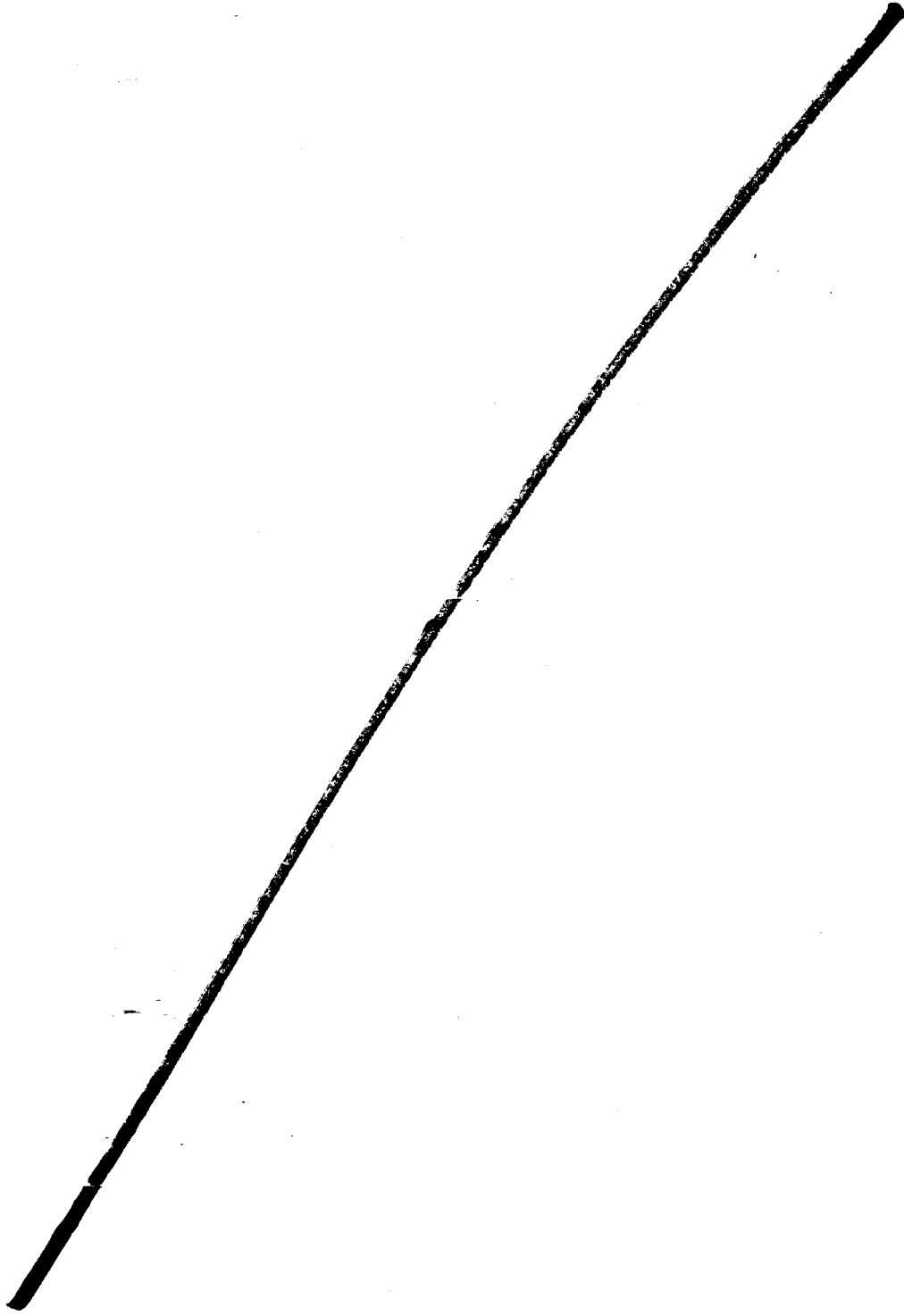
11

Ms. Crumpton, Page Three



11/1/88

Ms. Crumpton, Page Four



10/1/55

Ms. Crumpton, Page Five



Please contact me if you require further information.

Sincerely,

ASSOCIATED PATHOLOGISTS LABORATORIES

Raymond C. Kelly, Ph.D.

Raymond C. Kelly, Ph.D., DABFT
Director of Toxicology and Responsible Person, NLCP Testing

RCK:me

RESEARCH TRIANGLE INSTITUTE



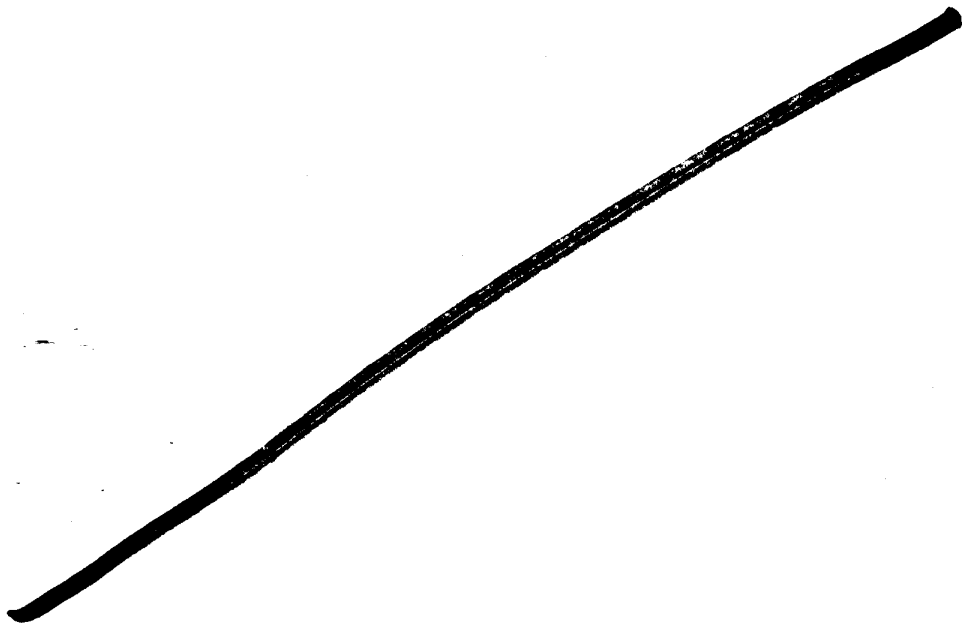
National Laboratory Certification Program

July 14, 2000

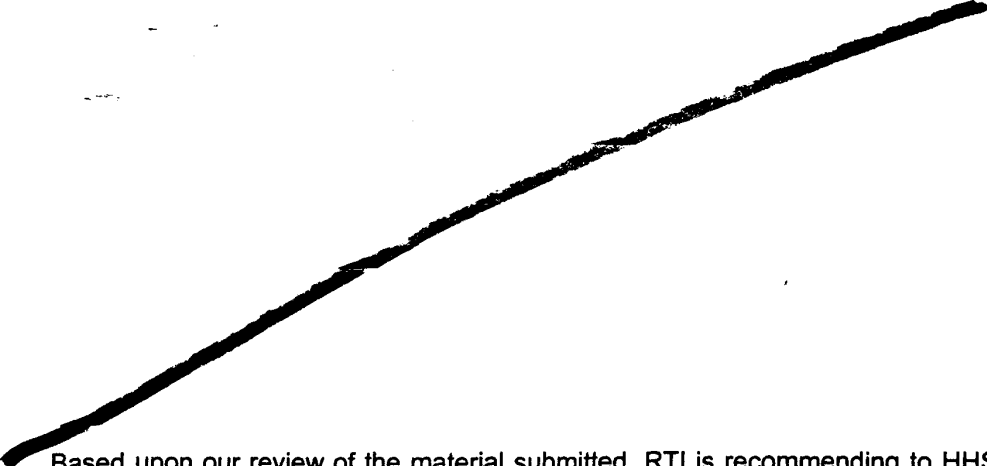
0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

We have reviewed the material provided in your correspondence of July 6, 2000, submitted in response to issues raised during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of June 5, 2000. 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 remaining issues:



Dr. Kelly
Page 2 of 2
07/14/00



Based upon our review of the material submitted, RTI is recommending to 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. at (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/m17

0148
Dr. Raymond C. Kelly
Associated Pathologists Laboratories
4230 South Burnham Avenue
Suite 250
Las Vegas, NV 89119

Dear Dr. Kelly:

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.

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

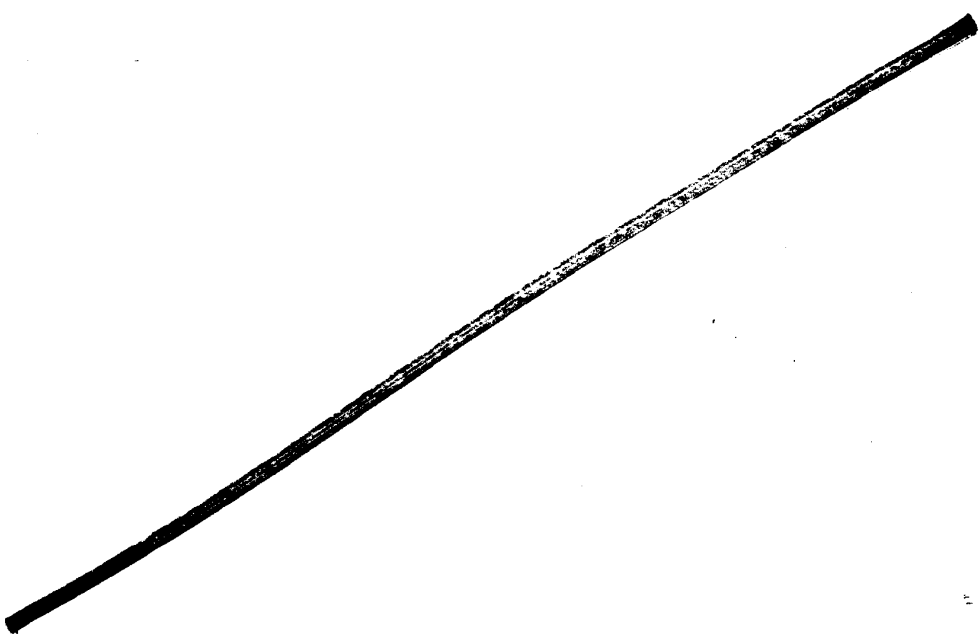


G. The Quality Control section



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.

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/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0148
Document No. Final

Laboratory: Associated Pathologists Laboratories, Inc.

Location: Las Vegas, NV

Document Reviewed: Application Form
 Inspection Report #M18 Date: 19 October 2000
 Other _____

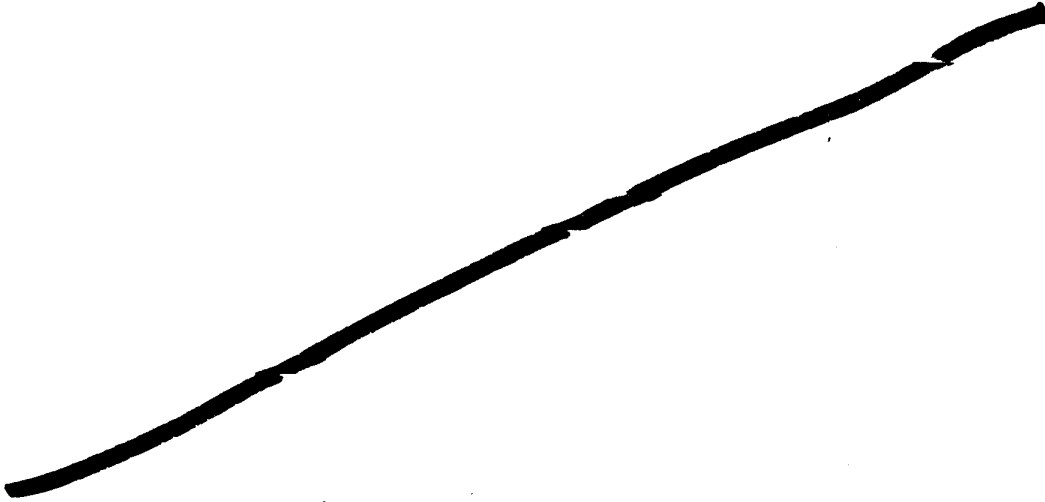
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

[Redacted]

Section J. Records Audit

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]