



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 14, 1999

0027

Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
E. 11604 Indiana Avenue  
Spokane, WA 99206

Dear Mr. Michaelsen:

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. However, the following issues were raised:

E. The Standard Operating Procedures section

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

Mr. Michaelsen  
January 14, 1999  
Page 2 of 3

G. The Records Audit section  
raised:

N. The Gas Chromatography/Mass Spectrometry 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Inspection Analyst

Mr. Michaelson  
January 14, 1999  
Page 3 of 3

Enclosure

cc: Project Files/M15

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0027  
Document No. Final

Laboratory: Pathology Associates Medical Laboratories

Location: Spokane, WA

Document Reviewed:     Application Form  
                               Inspection Report #M15                      Date: 19 November 1998  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                           Unacceptable                 Failure

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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

July 9, 1999

0027

Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
E. 11604 Indiana Avenue  
Spokane, WA 99206

Dear Mr. Michaelsen:

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:

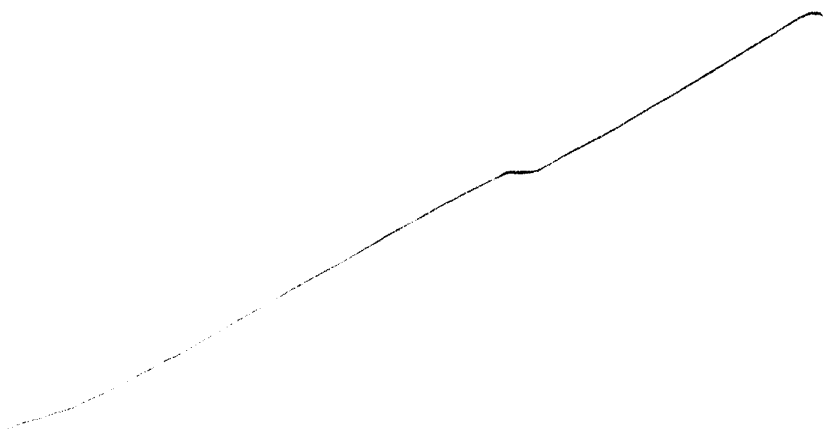
E. The Standard Operating Procedures (SOP) section.

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

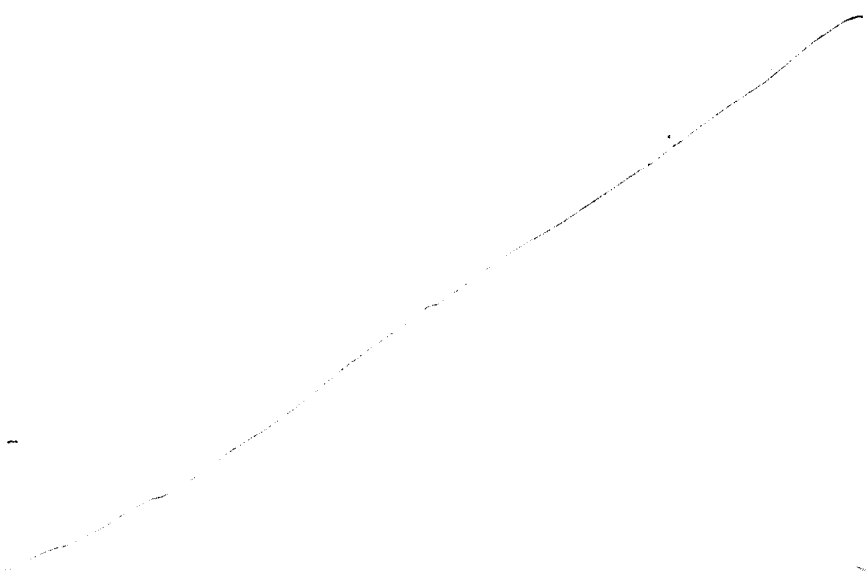


H. The Initial Tests section

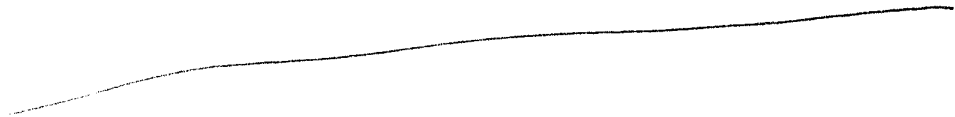
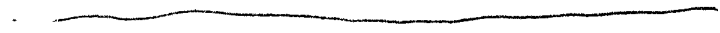
I. The Confirmatory Tests section



J. The Records section



K. The Reporting section

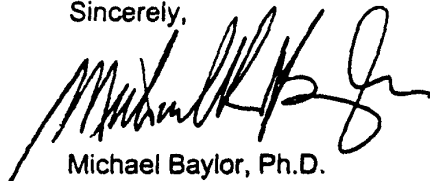


Mr. Michaelsen  
Page 4 of 4  
07/09/99

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.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7043 or Susan Crumpton at (919) 541-6176.

Sincerely,



Michael Baylor, Ph.D.  
Senior Forensic Toxicologist

Enclosure

cc: Project Files/M16

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0027  
Document No. Final

Laboratory: Pathology Associates Medical Laboratories

Location: Spokane, WA

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

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

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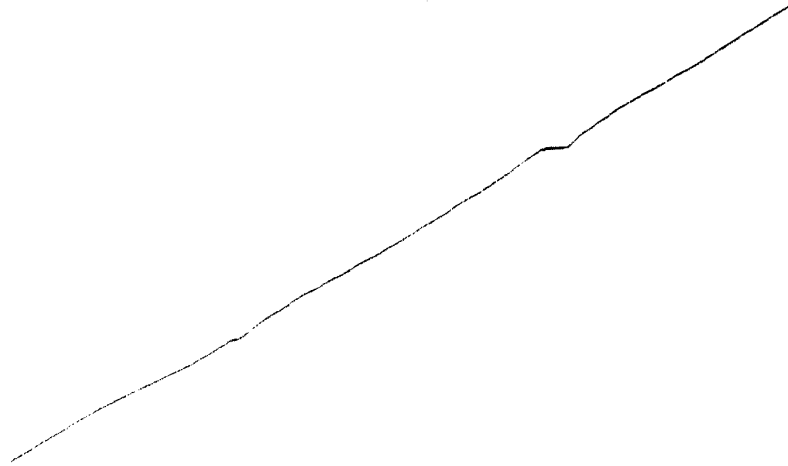
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

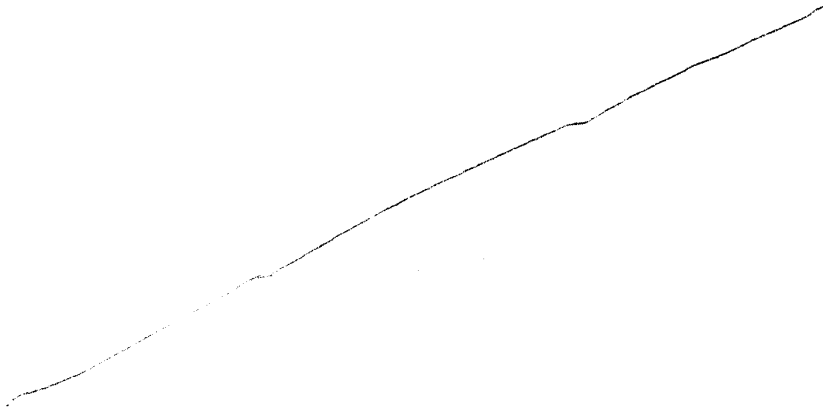
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

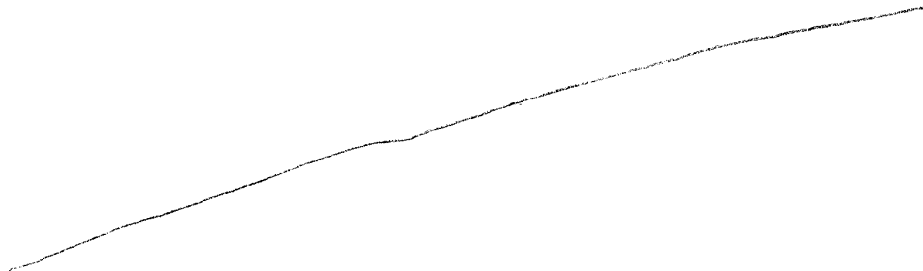
Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control



Section H. Initial Tests



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**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  
8/17/99 SDG

August 11, 1999

Michael Baylor, Ph.D.  
Research Triangle Institute  
National Laboratory Certification Program  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194  
RE: Inspection Report #M16

Dear Dr. Baylor,

The enclosed documentation is in response to your critique of our laboratory's 16<sup>th</sup> maintenance inspection. I have included copies of any changes in our SOP along with examples where necessary to document corrections or modifications when required.



11604 E. Indiana Avenue  
Spokane, WA 99206  
509.926.2400  
800.541.7891  
Fax 509.924.0002

*Founding Member:*

**PACLAB**  
NETWORK  
LABORATORIES

*Affiliates:*

**ALPHA**  
ALPHA MEDICAL  
LABORATORY  
1101 Ironwood Drive  
Coeur d'Alene, ID 83814  
208.664.8249  
208.765.8615 Fax

**CBML**  
COLUMBIA  
BIO-MEDICAL  
LABORATORIES  
7131 W. Grandridge Blvd  
Kennewick, WA 99336  
509.736.1111  
509.736.0106 Fax

**CEO / General Manager**

Thomas O. Tiffany, Ph.D.

**Medical Director**

L. K. Bernard, M.D., Ph.D.

**Technical Directors**

Don Anderson, Ph.D.,  
Microbiology

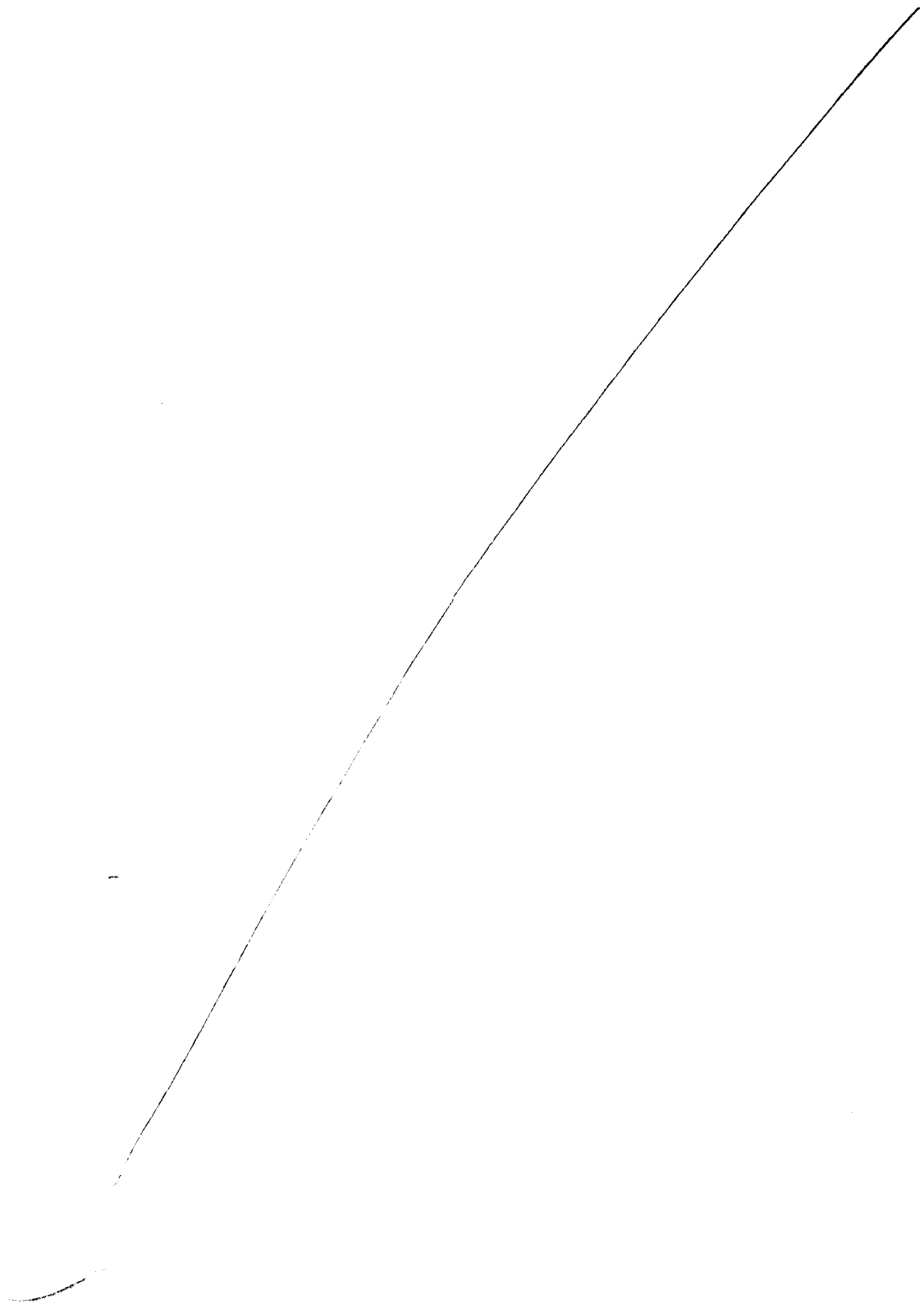
Richard D. Barclay, Ph.D.,  
Toxicology

William A. Dittman, M.D.,  
Hematology

L. M. Killingsworth, Ph.D.  
Chemistry

Marilyn A. Lloyd, Ph.D.,  
Molecular Pathology

Julie S. Hanna, Ph.D.  
Cytogenetics



If there should be any issues I have not addressed or any modifications unacceptable to you, please let me know as soon as possible. Thanks.

Respectfully,

A handwritten signature in black ink, appearing to read "H. David Michaelson", with a long horizontal flourish extending to the right.

H. David Michaelson  
Responsible Person

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

August 25, 1999

0027  
Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
E. 11604 Indiana Avenue  
Spokane, WA 99206

Dear Dr. Michaelsen:

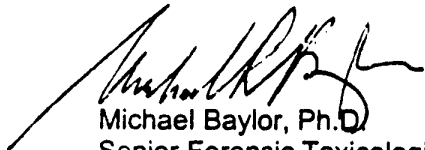
We have reviewed the material provided in your correspondence of August 11, 1999, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of July 9, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following was noted during our review of the submitted material:

Mr. Michaelsen  
Page 2 of 2  
08/25/99

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) 541-7043.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Baylor".

Michael Baylor, Ph.D.  
Senior Forensic Toxicologist

cc: Project Files/M16

January 10, 2000

0027  
Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
11604 East Indiana Avenue  
Spokane, WA 99206

Dear Mr. Michaelsen:

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.

E. The Standard Operating Procedures (SOP) section



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



Mr. Michaelsen  
Page 2 of 2  
01/10/00

J. The Records Audit 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/M17



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0027  
Document No. Final

Laboratory: Pathology Associates Medical Laboratories

Location: Spokane, WA

Document Reviewed:     Application Form  
                               Inspection Report #M17                      Date: 11 November 1999  
                               Other \_\_\_\_\_

Status:                 Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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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

June 22, 2000

0027  
Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
11604 East Indiana Avenue  
Spokane, WA 99206

Dear Mr. Michaelsen:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:

G. The Quality Control section

H. The Initial Tests section



I. The Confirmatory Tests section

J. The Records section

L. The Laboratory Information Management System (LIMS) section

N. The Personnel section

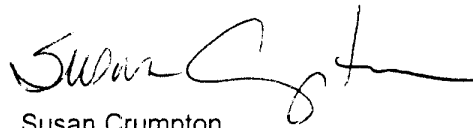
The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item 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

Mr. Michaelsen  
Page 4 of 4  
06/22/00

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/M18



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0027  
Document No. Final

Laboratory: Pathology Associates Medical Laboratories

Location: Spokane, WA

Document Reviewed:     Application Form  
                               Inspection Report #M18                      Date: 11 May 2000  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

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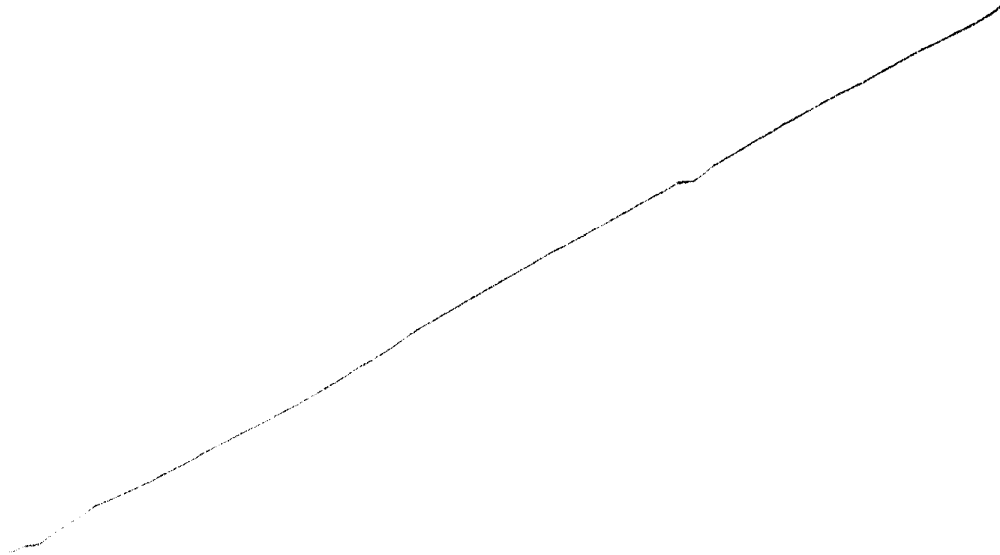
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

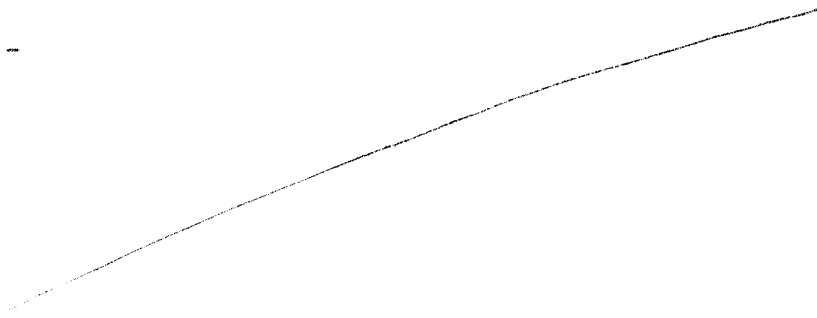
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

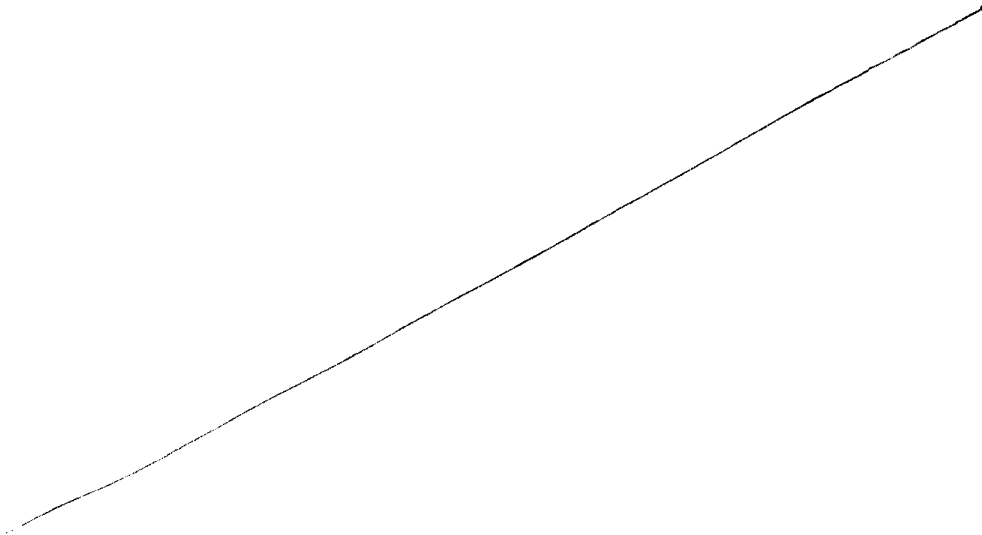
Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

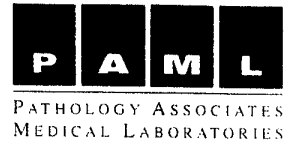


Section N. Personnel



**received**  
7/28/00 SDC

July 26, 2000



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

11604 E. Indiana Avenue  
Spokane, WA 99206  
509.926.2400  
800.541.7891  
509.924.0002 Fax

Dear Ms. Crumpton,

Thank you for your detailed critique and comments of our eighteenth NLCP maintenance inspection. It is always a pleasure getting constructive feedback in making our laboratory a better place. The following response and attachments should clarify/correct the issues you have raised.

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*Partnerships:*

**PACLAB**  
NETWORK  
LABORATORIES  
Seattle, Washington

**ALPHA**  
ALPHA MEDICAL  
LABORATORY  
Coeur d'Alene, Idaho

**TCL**  
TRI-CITIES  
LABORATORY  
Tri-Cities, Washington

**TVL**  
TREASURE VALLEY  
LABORATORY  
Boise, Idaho

---

**Chief Executive Officer**

Thomas O. Tiffany, Ph.D.

**Medical Director**

T.J. Allerding, M.D., Ph.D.

**Technical Directors**

Richard D. Barclay, Ph.D.,  
Toxicology

William A. Dittman, M.D.,  
Hematology

Julie S. Hanna, Ph.D.,  
Marilyn A. Lloyd, Ph.D.,  
Cytogenetics

L.M. Killingsworth, Ph.D.,  
Chemistry

Ann Robinson, Ph.D.,  
Microbiology

If you have any questions, please call me at (800) 541-7891 X6271.

Respectfully

A handwritten signature in black ink, appearing to read "H. Michaelson", with a long, sweeping horizontal stroke extending to the right.

H. David Michaelson  
Responsible Person



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 2, 2000

0027  
Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
11604 East Indiana Avenue  
Spokane, WA 99206

Dear Mr. Michaelsen:

We have reviewed the material provided in your correspondence of July 26, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 22, 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 take steps to correct/clarify the remaining issues described below.



Mr. Michaelsen  
Page 2 of 2  
08/02/00

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. at (919) 541-7043.

Sincerely,



Susan Crumpton  
NLCP Technical Analyst

Enclosure

cc: Dr. Michael Baylor  
Project Files/M18



January 30, 2001

0027  
Mr. H. David Michaelsen  
Pathology Associates Medical Labs  
11604 East Indiana Avenue  
Spokane, WA 99206

Dear Dr. Michaelsen:

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 a number 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



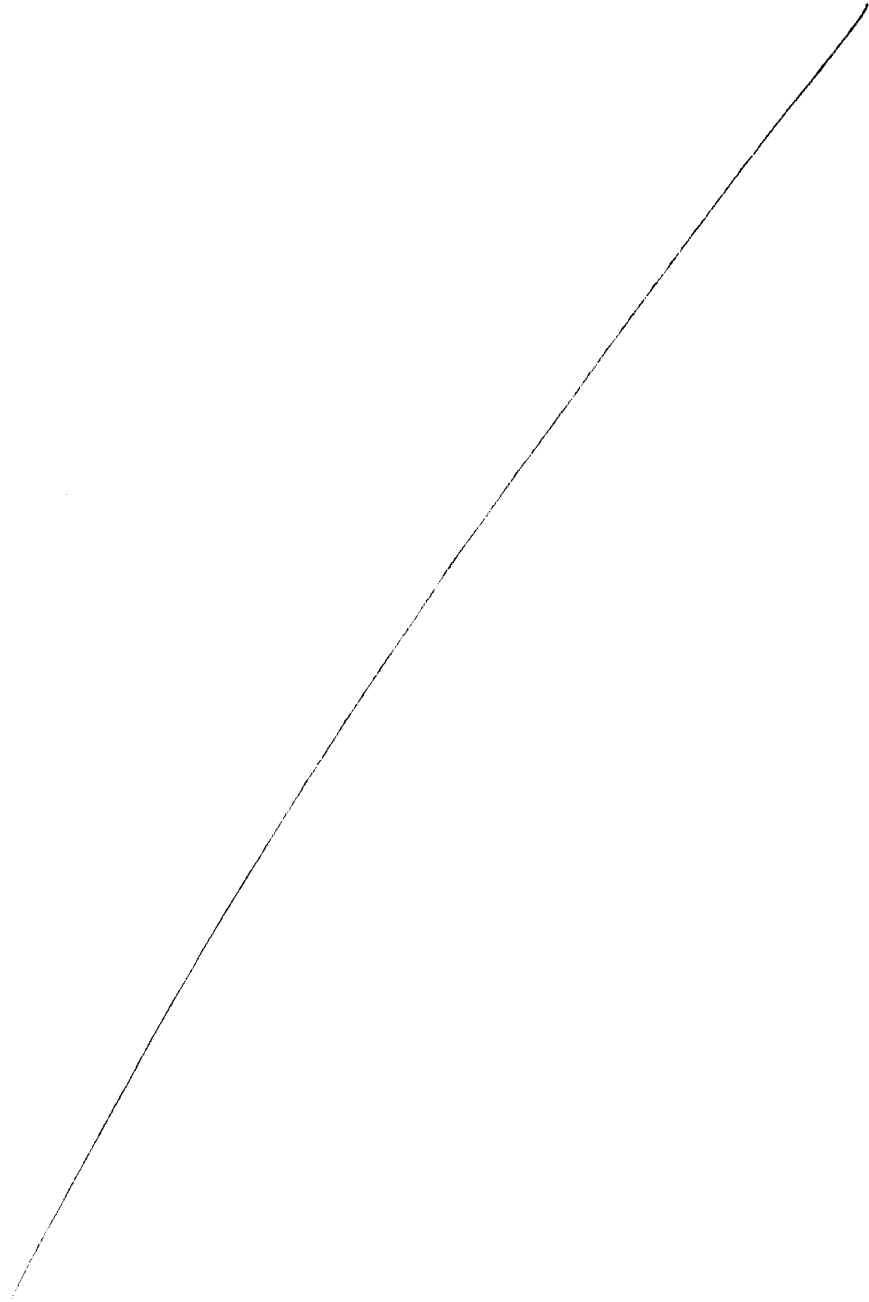


Mr. Michaelsen  
January 30, 2001  
Page 2 of 6

G. The Quality Control and Quality Assurance section

I. The Specimen Validity Tests section v

Mr. Michaelsen  
January 30, 2001  
Page 3 of 6



Mr. Michaelson  
January 30, 2001  
Page 4 of 6

K. The Records Audit section

Mr. Michaelson  
January 30, 2001  
Page 5 of 6

N. The Personnel 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

Mr. Michaelsen  
January 30, 2001  
Page 6 of 6

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/M19



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0027  
Document No. Final

Laboratory: Pathology Associates Medical Laboratories

Location: Spokane, WA

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

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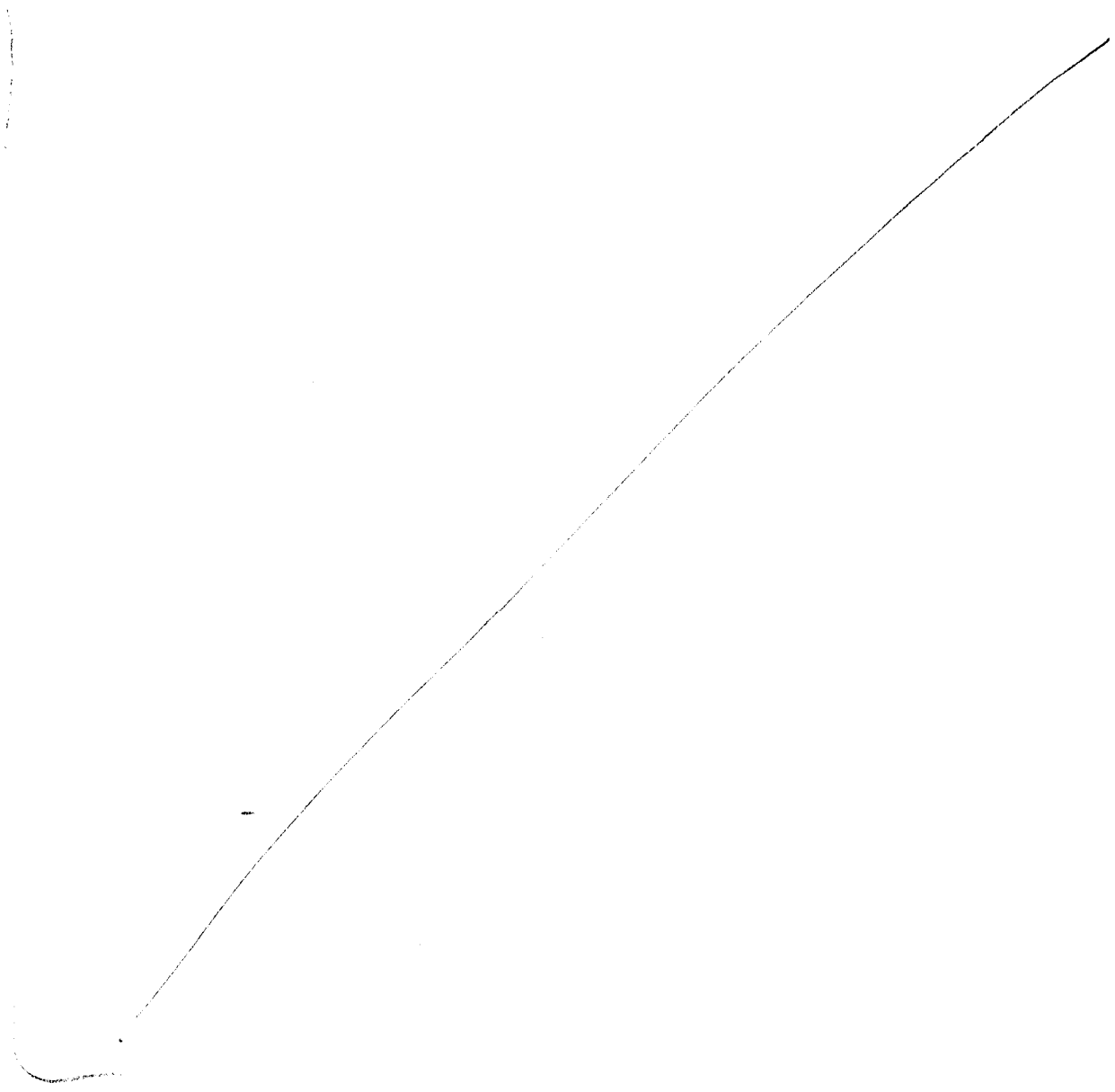
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet a number of the minimum technical criteria required for the inspection phase of the Program, pending the submission of evidence that appropriate corrective action has been taken.

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

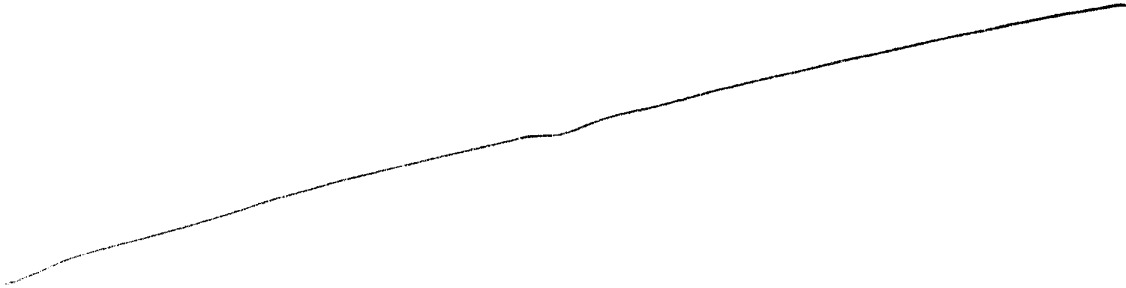


Section H. Initial Tests

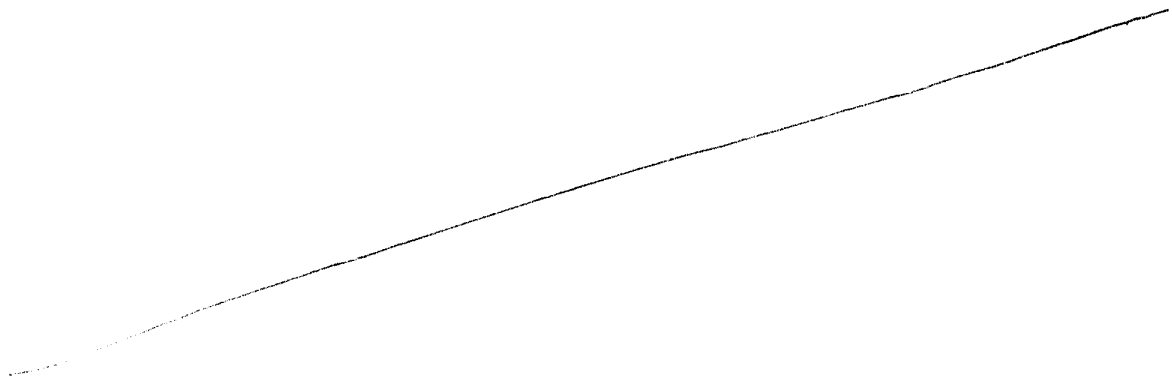
Section I. Specimen Validity Tests

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Section J. Confirmatory Tests



Section K. Records Audit



Section L. Certification and Reporting

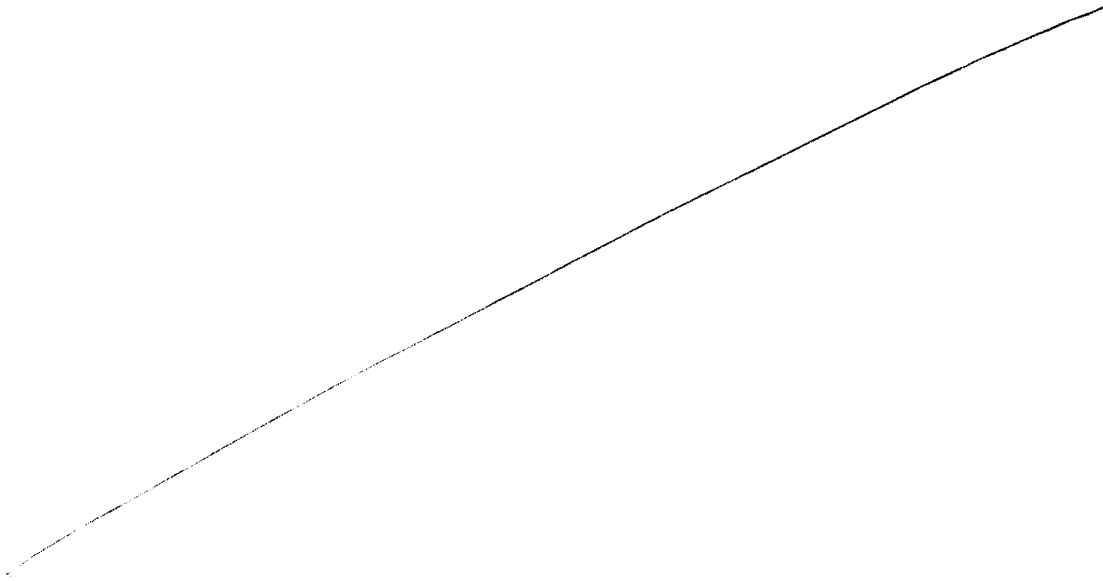


Section M. Laboratory Information Management System (LIMS)



Section N. Personnel





March 2, 2001

**received**  
3/12/01 DS



PSYCHOLOGY ASSOCIATION  
MEDICAL LABORATORY

Dear Ms. Denson,

Enclosed is our response to your critique of Maintenance Inspection #19. Even though we have already started to address and resolve all listed issues, my following response is limited to those issues you requested information to be submitted or addressed.

11604 E. Indiana Ave.  
Spokane, WA 99216  
509.926.2100  
800.541.7891  
509.927.0002 Fax

*Partnerships:*

**PACLAB**  
NETWORK  
LABORATORIES  
Spokane, Washington

**ALPHA**  
ALPHA MEDICAL  
LABORATORIES  
Spokane, Washington

**TCL**  
Toxicology  
LABORATORIES  
Spokane, Washington

**TVL**  
Toxicology  
LABORATORIES  
Spokane, Washington

**Chief Executive Officer**

Thomas O. Tiffany, Ph.D.

**Medical Director**

T.J. Allerding, M.D., Ph.D.

**Technical Directors**

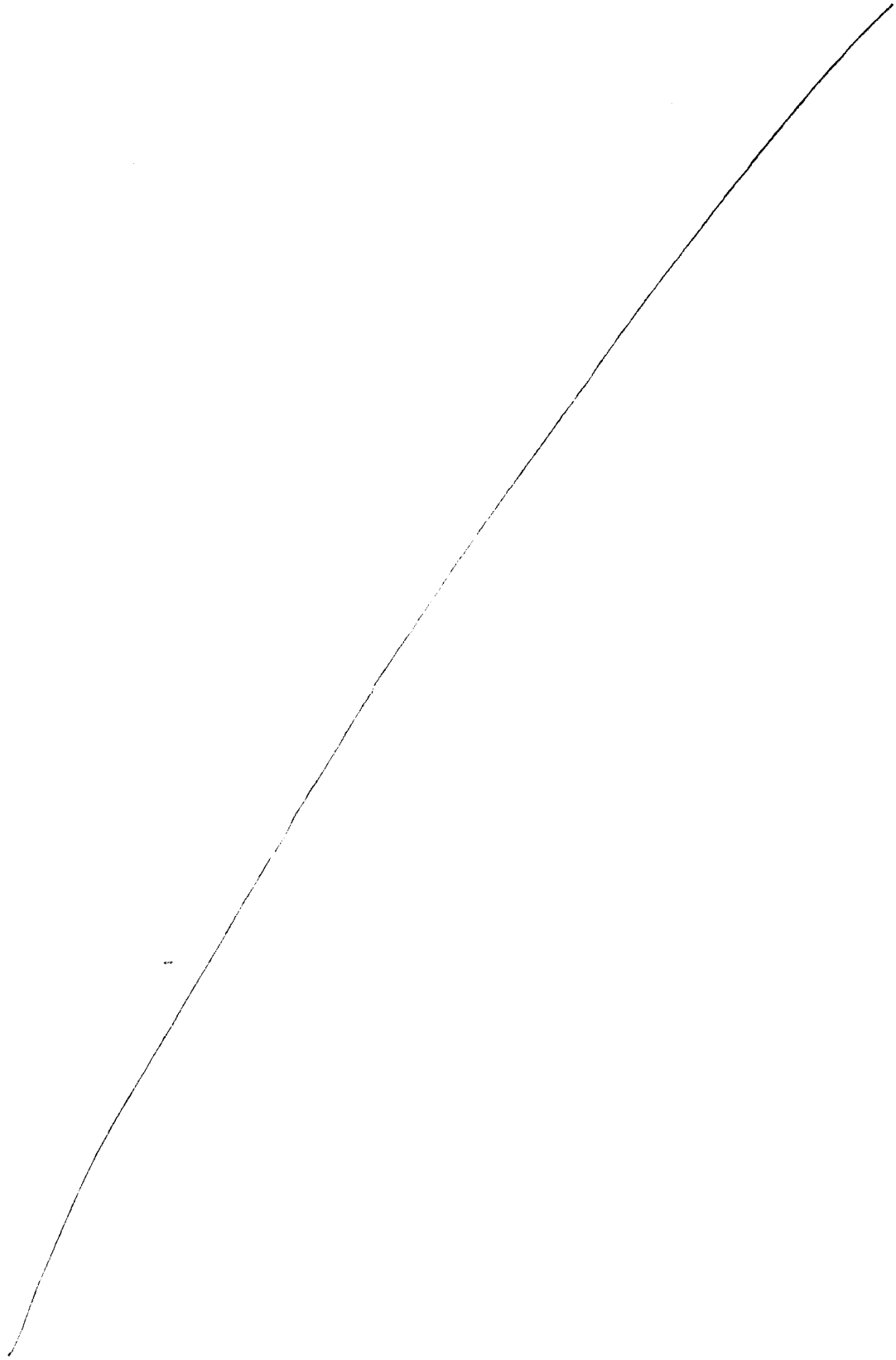
Richard D. Barclay, Ph.D.,  
Toxicology

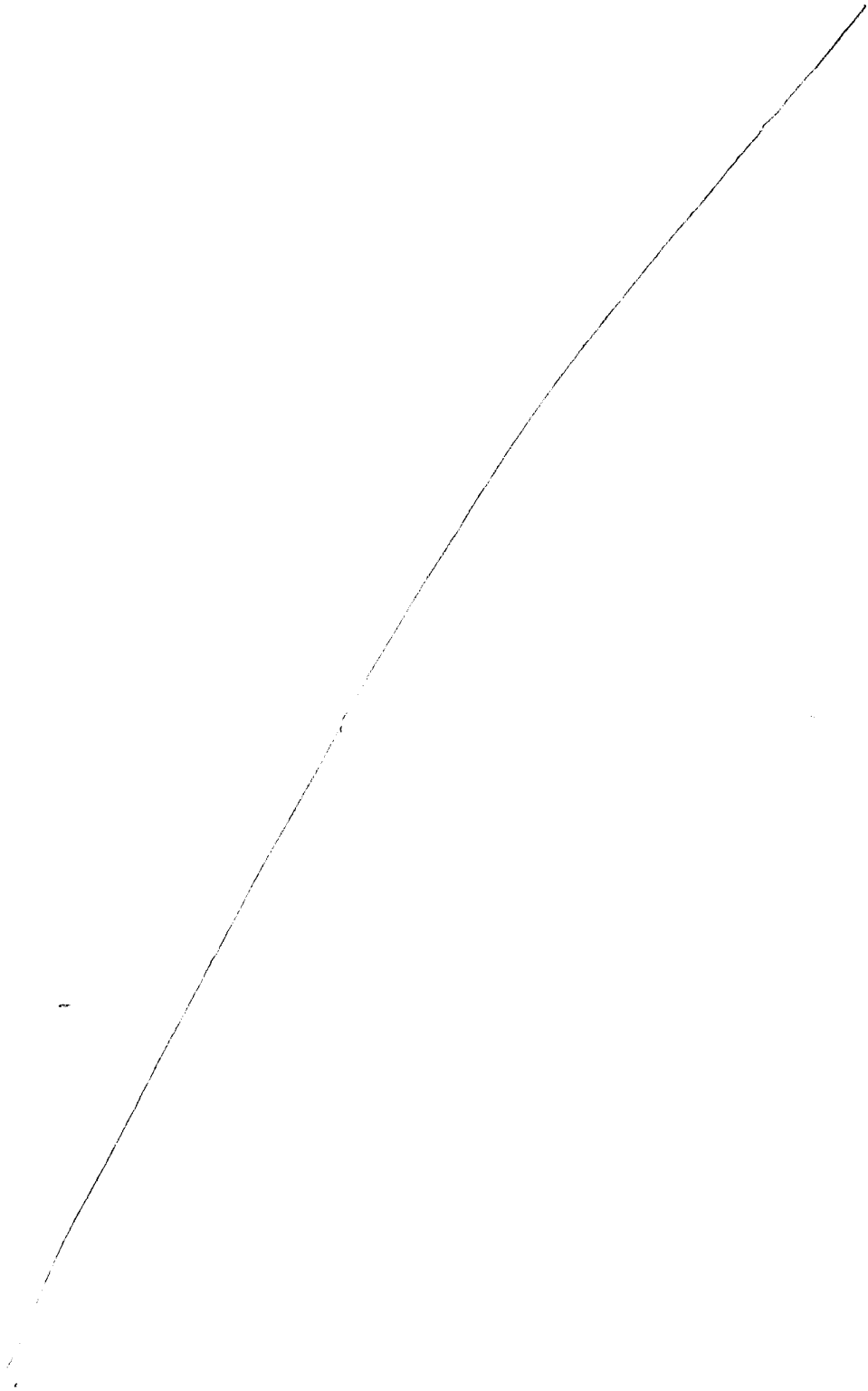
William A. Dittman, M.D.,  
Hematology

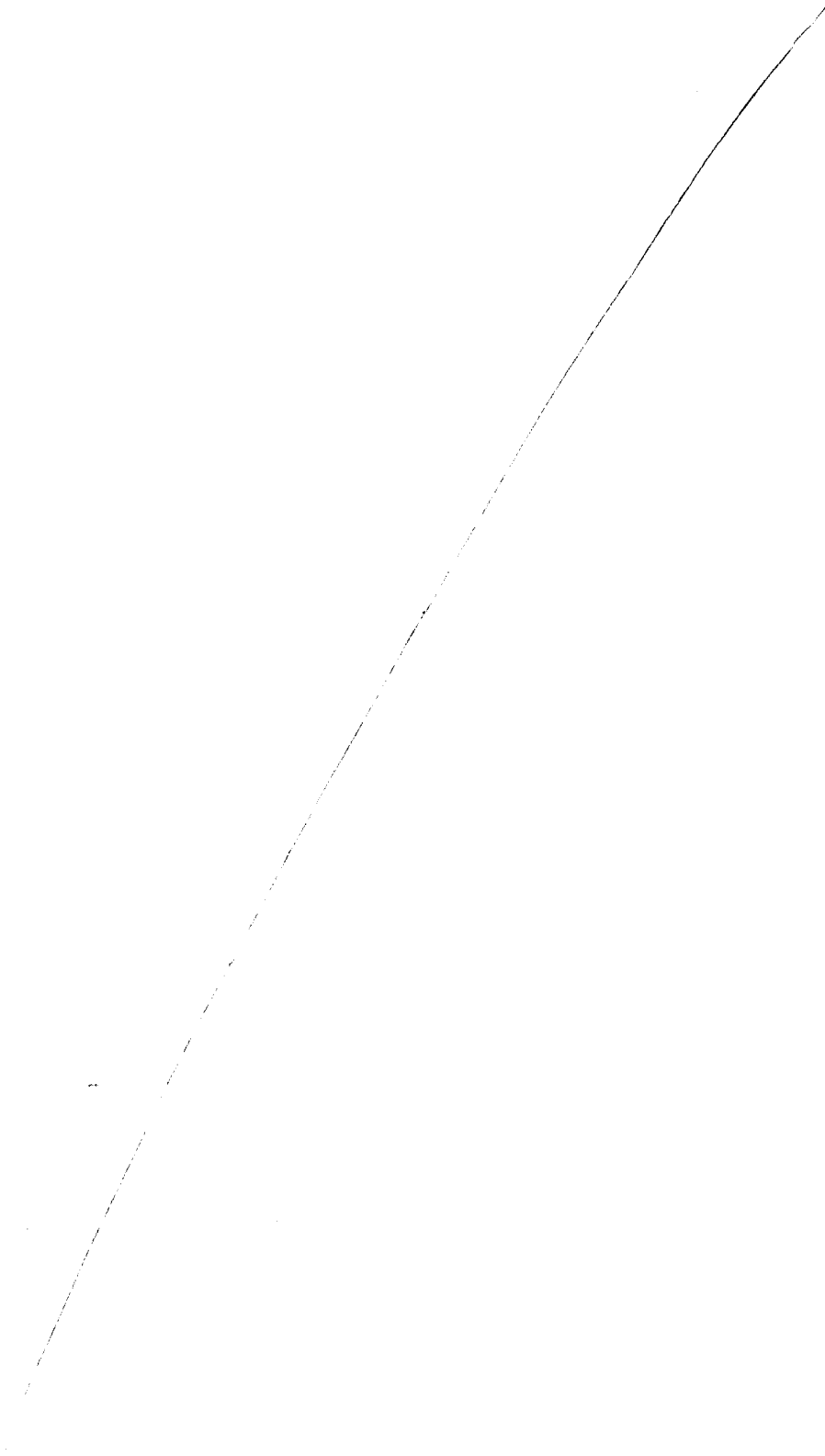
Julie S. Hanna, Ph.D.,  
Marilyn A. Lloyd, Ph.D.,  
Cytogenetics

L.M. Killingsworth, Ph.D.,  
Chemistry

Ann Robinson, Ph.D.,  
Microbiology







See response above along with documentation submitted regarding this issue.

Respectfully,

A handwritten signature in cursive script, appearing to read 'H. David Michaelson', with a long horizontal flourish extending to the right.

H. David Michaelson (RP)  
General Manager of Toxicology