

National Laboratory Certification Program

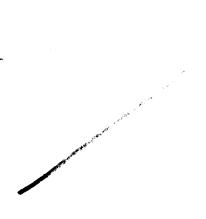
October 29, 1998

0039
Dr. Anthony Wu
ACL Laboratories
901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

The enclosed critique was developed from the inspection reports of the three inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

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





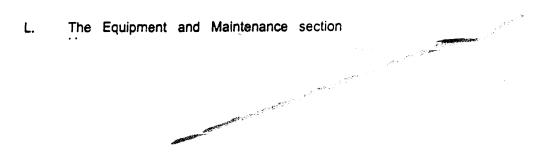
Dr. Wu Page 2 of 4 10/29/98

G. The Records Audit section

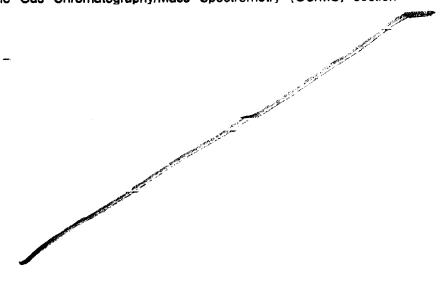
J. The Quality Control and Standards section



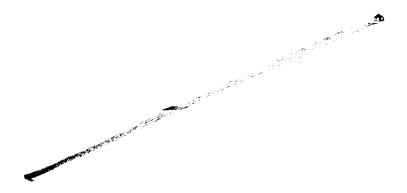
K. The Reporting section



N. The Gas Chromatography/Mass Spectrometry (GC/MS) section



Dr. Wu Page 4 of 4 10/29/98



The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues described above. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed at the next inspection.

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

Sincerely,

Susan Crumpton

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NLCP Inspection Analyst

Enclosure

cc: Project Files/M15

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0039

Document No. Final

Laboratory:

ACL Laboratories

Location:

West Allis, WI

Document Reviewed:

[] Application Form [XX] Inspection Report #M15

Date: 24 September 1998

[] Other _____

Status:

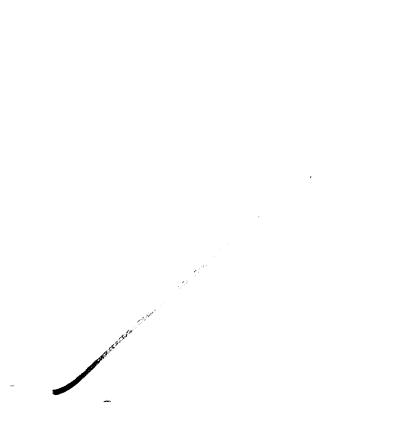
] Highly Acceptable] Unacceptable [XX] Acceptable
[] Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

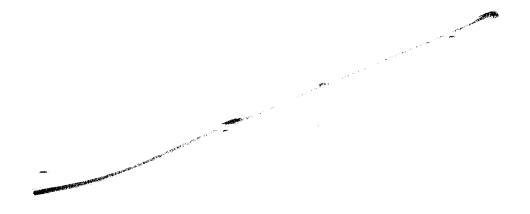


Section F. Chain-of-Custody, Accessioning and Security





Section G. Records Audit



Section H. Personnel



Section I. Reagents

Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

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Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



Ms. Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

November 23, 1998

Dear Ms. Crumpton:

The following is the response to your letter of October 29, 1998 regarding our latest on-site inspection which occurred on September 24-25, 1998.

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This concludes that corrective actions have been implemented to address the issues described above.

If you have any questions or if any issues require further clarification, please let me know.

Respectfully,

Anthony Wu, Ph.D. Responsible Person and

Toxicologist

encis.

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RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 10, 1998

0039
Dr. Anthony Wu
ACL Laboratories
901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of November 23, 1998, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of October 29, 1998. The following is a review of the material submitted:



Dr. Wu Page 2 of 4 12/11/98 Dr. Wu Page 3 of 4 12/11/98

Dr. Wu Page 4 of 4 12/11/98

173.5

The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues discussed above. RTI will recommend to HHS that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP) pending receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all corrective actions are subject to review by the next inspection team.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to correct deficiencies may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the Mandatory Guidelines.

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

Sincerely,

Susan Crumpton

NLCP Inspection Analyst

cc: Project Files/M15





Ms. Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

December 18, 1998

Dear Ms. Crumpton:

The following is the response to your letter of December 10, 1998 regarding certain issues which required further clarification.



This completes the final report addressing unresolved issues discussed in your letter of December 10, 1998.

Wishing you a Merry Christmas and a Happy New Year.

Anthony Wu, Ph.D. Responsible Person and

Toxicologist

Respectfully,

encls.

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 6, 1999

0039 Dr. Anthony Wu **ACL Laboratories** 901 W. Lincoln Avenue West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of December 18, 1998, submitted in response to issues raised during the fifteenth maintenance inspection of your laboratory as outlined in our correspondence of December 10, 1998. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. implementation of the corrective actions will be reviewed at the next inspection.

As noted by the laboratory, its November 23, 1998, correspondence.

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

Sincerely,

Susan Crumpton **NLCP Inspection Analyst**

CC: Project Files/M15

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

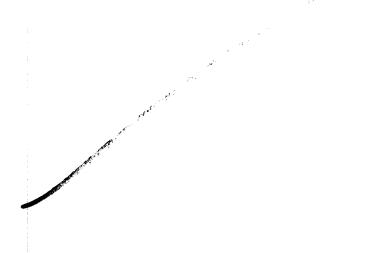
May 10, 1999

0039
Dr. Anthony Wu
ACL Laboratories
901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

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

Dr. Wu Page 3 of 5 05/10/99

G. The Quality Control (QC) section

H. The Initial Tests section

1. The Confirmatory Tests section

J. The 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 implement—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 Mr. Kenneth Davis at (919) 541-6709.

Sincerely,

Michael Baylor, Ph.D.

Senior Forensic Toxicologist

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: <u>0039</u>

Document No. Final

Laboratory:

ACL Laboratories

Location:

West Allis, WI

Document Reviewed:

[XX] Inspection Report #M16

Date: 18 March 1999

Status:

] Highly Acceptable] Unacceptable

] Other ___

[XX] Acceptable
[] Failure

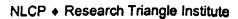
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

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

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

Section E. Standard Operating Procedures - Procedures Manual





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

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel





Dr. Michael Baylor Senior Forensic Toxicologist National Laboratory Certification Program Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709

June 10, 1999

Dear Dr. Baylor:

This is in response to your letter of May 10, 1999 regarding our last inspection (#M16) which occurred on March 18-19, 1999.

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This concludes the response to your letter of May 10, 1999 re

This concludes the response to your letter of May 10, 1999 regarding our last inspection. Corrective actions have been implemented as per your letter.

If you have any questions or if there are any issues which have not been satisfactorily addressed, please call me at 414-328-7843.

Respectfully yours,

Anthony Wu, Ph.D. Responsible Person and Toxicologist

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encis.



National Laboratory Certification Program

June 23, 1999

0039
Dr. Anthony Wu
ACL Laboratories
901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of June 10, 1999, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of May 10, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. The following is a review of the material submitted:

Dr. Wu Page 2 of 4 06/23/99 Page 3 of 4 06/23/99 Dr. Wu Page 4 of 4 06/23/99

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. 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 Inspection Analyst

cc: Dr. M

Dr. Michael Baylor Project Files/M16

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 21, 1999

0039
Dr. Anthony Wu
ACL Laboratories
901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

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.

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

Deborah J Denson

Enclosure

cc:

Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique Laboratory I.D. Number: 0039 Document No. Final ACL Laboratories, Inc. Laboratory: West Allis, WI Location: [] Application Form Document Reviewed: [XX] Inspection Report #M17 Date: 23 September 1999 [] Other _____] Acceptable Status: [XX] Highly 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

May 12, 2000

0039
Dr. Anthony Wu
ACL Laboratories
8901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

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:

E. The Standard Operating Procedures (SOP) section

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

G. The Quality Control section



H. The Initial Tests section

I. The Confirmatory Tests section

N. The Personnel section

Dr. Wu Page 3 of 3 05/12/00

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) 541-6176 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: 0039 Document No. Final Laboratory: ACL Laboratories West Allis, WI Location:] Application Form Document Reviewed: [XX] Inspection Report #M18 Date: 23 March 2000] Other _____ Status: [XX] 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

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



Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

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Section J. Records Audit .

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel





Ms. Susan Crumpton NLCP Technical Analyst Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709-2194 June 14, 2000

Dear Ms. Crumpton:

Per your letter of May 12, 2000, regarding our eighteenth maintenance inspection, I am responding to those issues raised in your letter that require submission to document that corrective action and implementation have been made

I trust I have addressed/clarified all the issues to your satisfaction. Should you have any further questions, please call me at 414-328-7843.

Respectfully yours,

Anthony Wu, Ph.D. Responsible Person and

Toxicologist

encls.

c:

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 23, 2000

0039
Dr. Anthony Wu
ACL Laboratories
8901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of June 14, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of vour laboratory as outlined in our correspondence of May 12, 2000.

Dr. Wu Page 2 of 3 06/23/00



The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. RTI will recommend to HHS that the laboratory continue to be certified under the NLCP upon receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to correct deficiencies may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the HHS Guidelines.

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.

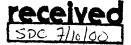
Sincerely,

Susan Crumpton

NLCP Technical Analyst

cc: Dr. Michael Baylor \
Project Files/039





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

July 5, 2000

Dear Ms. Crumpton:

Per your letter of June 23, 2000 regarding our eighteenth maintenance inspection, the following is the final report.



This completes the final report.

If you have any questions, please call me at 414-328-7843.

Respectfully yours,

Anthony Wu, Ph.D. Responsible Person and

Toxicologist

encls.



National Laboratory Certification Program

August 3, 2000

0039
Dr. Anthony Wu
ACL Laboratories
8901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

We have reviewed the material provided in your correspondence of July 5, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 23, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.



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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor Project Files/M18



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 8, 2000

0039
Dr. Anthony Wu
ACL Laboratories
8901 W. Lincoln Avenue
West Allis, WI 53227

Dear Dr. Wu:

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

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

G. The Quality Control section

H. The Initial Tests section

I. The Confirmatory Tests section

J. The Records Audit section

Dr. Wu Page 3 of 3 11/08/00

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N. Personnel issues

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

Sincerely,

Susan Crumpton

NLCP Technical Analyst

Enclosure

cc: Project Files/M19

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: <u>0039</u> Document No. Final

Laboratory:

ACL Laboratories

Location:

West Allis, WI

Document Reviewed:

[] Application Form [XX] Inspection Report #M19

Date: 07 September 2000

Other

Status:

] Highly Acceptable

[XX] Acceptable

] Unacceptable [] Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

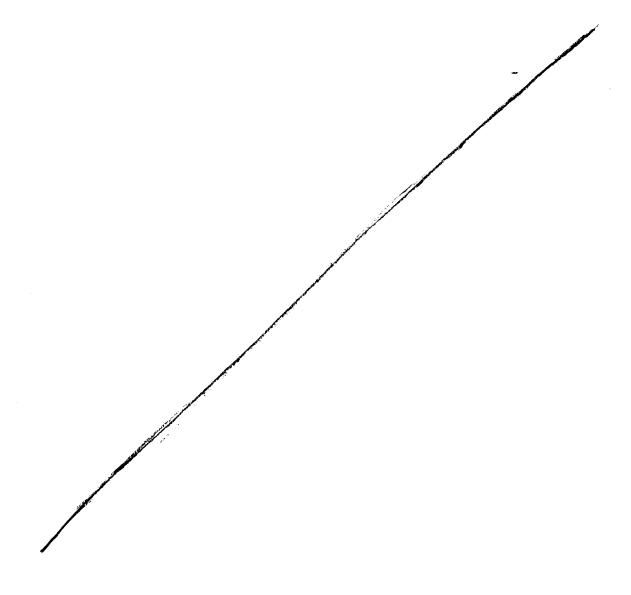
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Ver. Final Lab ID# 0039

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 4, 2000

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

Dear Ms. Crumpton:

Per your letter of November 8, 2000, regarding our nineteenth maintenance inspection, the following are the responses in order to clarify/correct the issues raised.

This completes the final report.

If you have any questions, please call me at 414-328-7843.

Respectfully yours,

Anthony Wu, Ph.D. Responsible Person And Toxicologist

Encls.



National Laboratory Certification Program

January 19, 2001

0039
Dr. Anthony Wu
ACL Laboratories
8901 W. Lincoln Avenue
West Allis, WI 53227

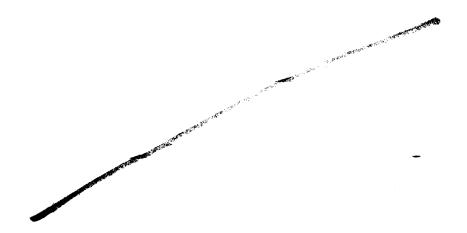
Dear Dr. Wu:

We have reviewed the material provided in your correspondence December 4, 2000, submitted in response to deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of November 8, 2000. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most issues. However, the following issues remain or were raised during our review of the submitted material:



Dr. Wu Page 2 of 3 01/19/01

Dr. Wu Page 3 of 3 01/19/01



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

CC:

Dr. Michael Baylor Project Files/M19