



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 15, 1998

0647  
Dr. Alan H.B. Wu  
Hartford Hospital  
80 Seymour Street  
Department of Pathology  
Hartford, CT 06102

Dear Dr. Wu:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the first 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:

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




Dr. Wu  
Page 2 of 2  
12/15/98

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/M1

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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: 0647  
Document No. Final

Laboratory: Hartford Hospital Toxicology Laboratory

Location: Hartford, CT

Document Reviewed:     Application Form  
                               Inspection Report #M1  
                               Other \_\_\_\_\_

Date: November 05, 1998

Status:            Highly Acceptable        Acceptable  
                       Unacceptable            Failure

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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

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Section M. Immunoassay

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Section N. Gas Chromatography/Mass Spectrometry

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RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 14, 1999

0647  
Dr. Alan H.B. Wu  
Hartford Hospital  
80 Seymour Street  
Department of Pathology  
Hartford, CT 06102

Dear Dr. Wu:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the second 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:

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

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

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/M2

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0647  
Document No. Final

Laboratory: Hartford Hospital Toxicology Laboratory

Location: Hartford, CT

Document Reviewed:     Application Form  
                               Inspection Report #M2                    Date: 6 May 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

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

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Section G. Quality Control

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Section H. Initial Tests

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Section I. Confirmatory Tests

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Section J. Records Audit

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**Section K. Reporting**

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**Section L. Computers, Software, and LIMS**

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**Section M. Equipment and Maintenance**

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**Section N. Personnel**

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RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 03, 1999

0647  
Dr. Alan H.B. Wu  
Hartford Hospital  
Toxicology Laboratory  
80 Seymour Street  
Hartford, CT 06102

Dear Dr. Wu:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the third maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M3



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0647  
Document No. Final

Laboratory: Hartford Hospital Toxicology Laboratory

Location: Hartford, CT

Document Reviewed:     Application Form  
                               Inspection Report #M3                      Date: 4 November 1999  
                               Other \_\_\_\_\_

Status:            Highly Acceptable            Acceptable  
                       Unacceptable                Failure

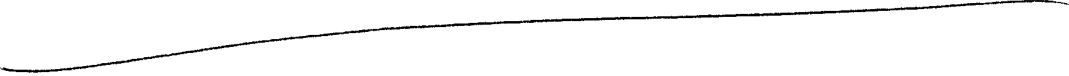
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.


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:

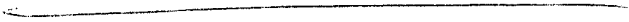
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 13, 2000

0647  
Dr. Alan H.B. Wu  
Hartford Hospital  
Toxicology Laboratory  
80 Seymour Street  
Hartford, CT 06102

Dear Dr. Wu:

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



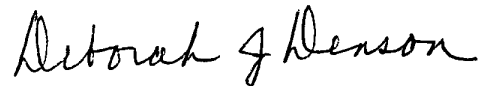
Dr. Wu  
June 13, 2000  
Page 2 of 2

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RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

Enclosure

cc: Project Files/M4

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0647  
Document No. Final

Laboratory: Hartford Hospital Toxicology Laboratory

Location: Hartford, CT

Document Reviewed:     Application Form  
                               Inspection Report # M4                      Date: 4 May 2000  
                               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.

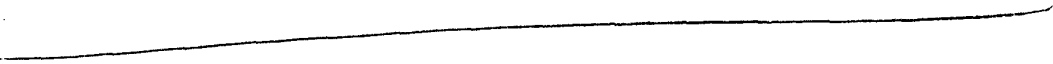
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

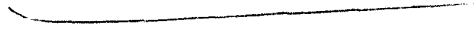
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



Section J. Records Audit

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Section K. Reporting

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Section L. Computers, Software, and LIMS

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Section M. Equipment and Maintenance

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Section N. Personnel

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RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 24, 2001

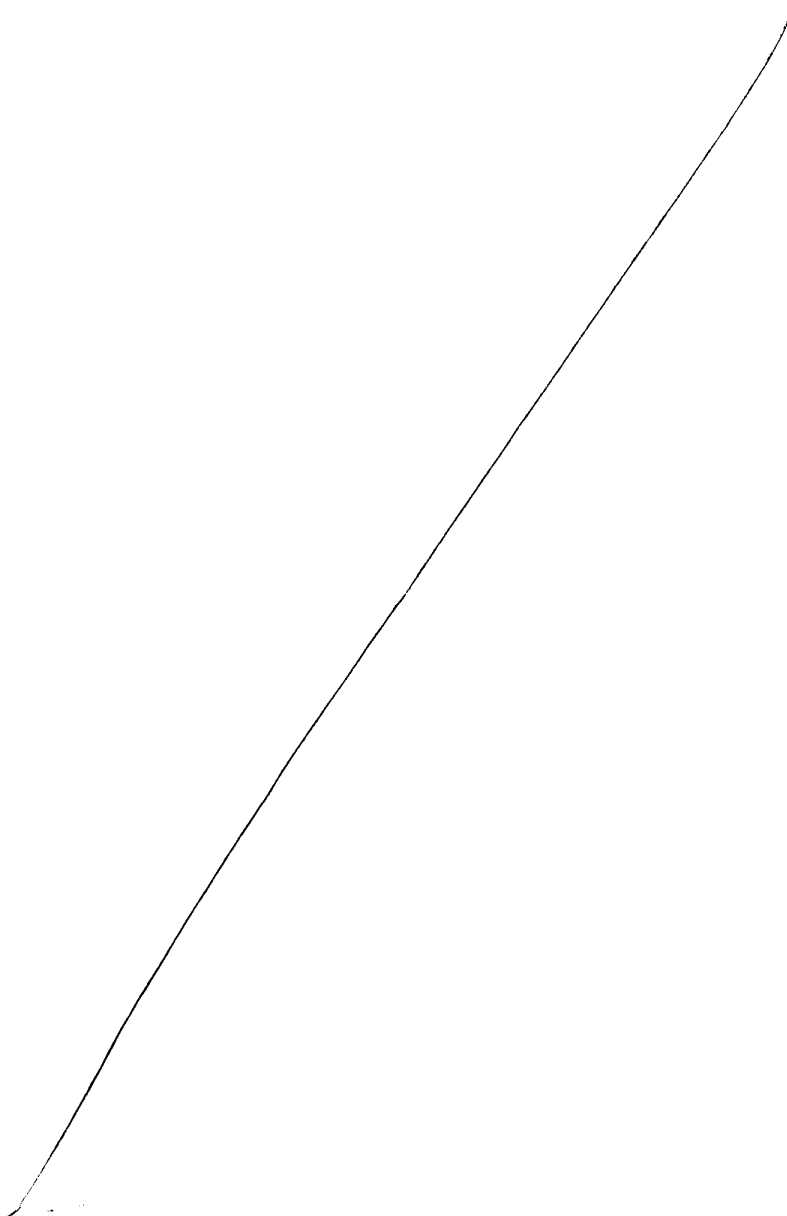
0647  
Dr. Alan H.B. Wu  
Clinical Laboratory Partners, LLC  
Toxicology Laboratory  
129 East Cedar Street  
Newington, CT 06111

Dear Dr. Wu:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifth 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 appeared to meet most of the Minimum Technical Criteria. However, the laboratory must take steps to correct the following issues raised:



Dr. Wu  
Page 2 of 3  
01/24/01



Dr. Wu  
Page 3 of 3  
01/24/01

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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/M5

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0647  
Document No. Final

Laboratory: Clinical Laboratory Partners, LLC

Location: Newington, CT

Document Reviewed:     Application Form  
                               Inspection Report #M5                      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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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

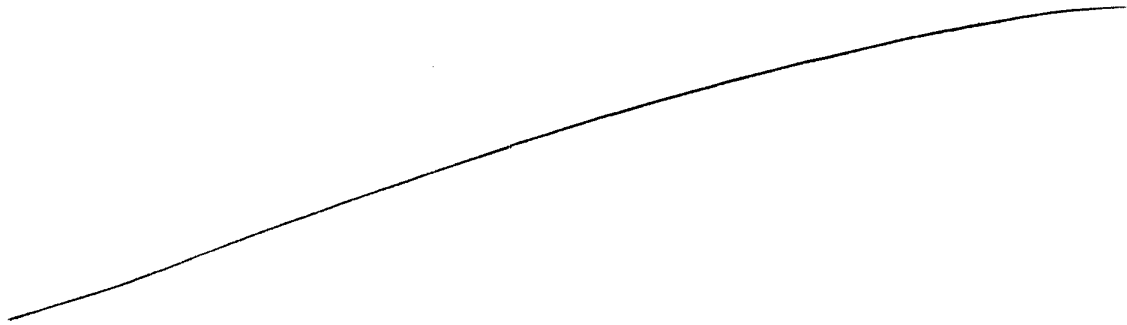
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

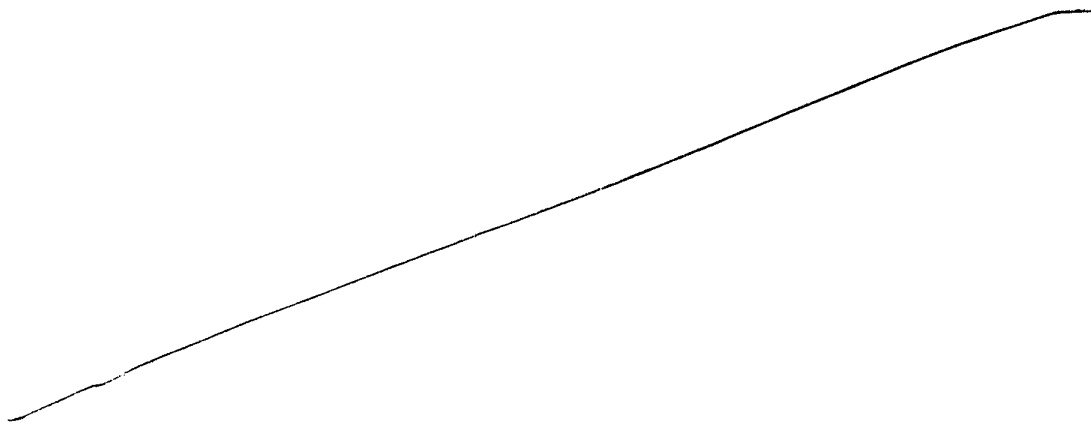
Section H. Initial Tests

Section I. Specimen Validity Tests

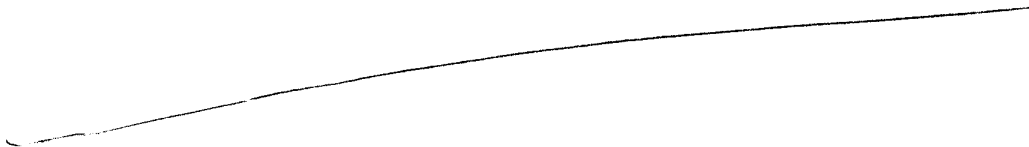




Section J. Confirmatory Tests



Section K. Records Audit



Section L. Certification and Reporting

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Section M. Laboratory Information Management System (LIMS)

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Section N. Personnel

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