



# RESEARCH TRIANGLE INSTITUTE

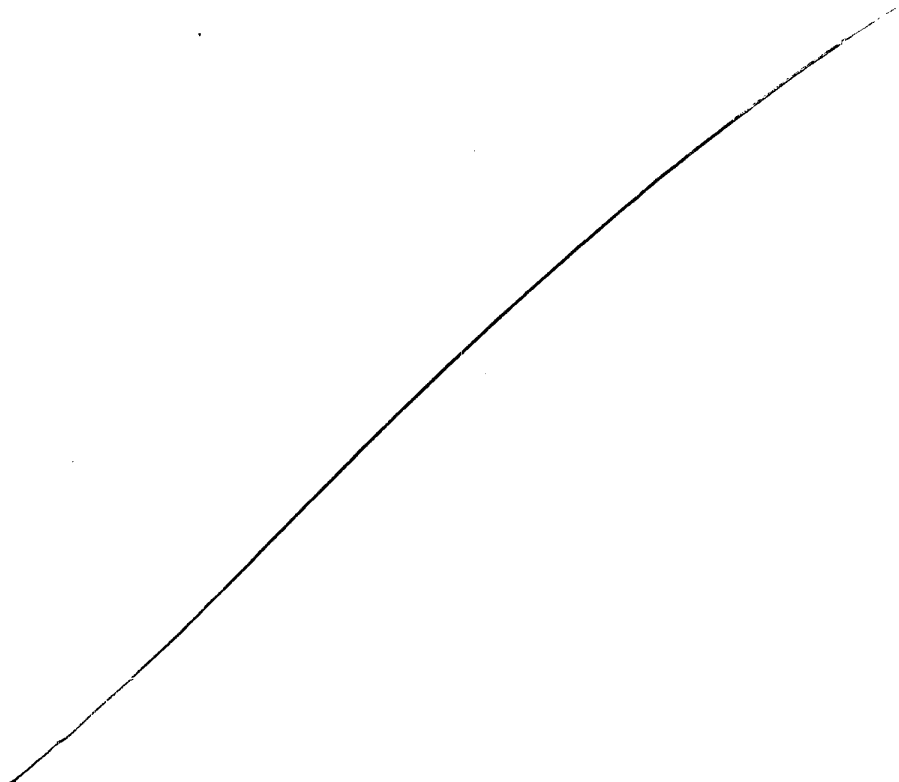
National Laboratory Certification Program

September 29, 1998

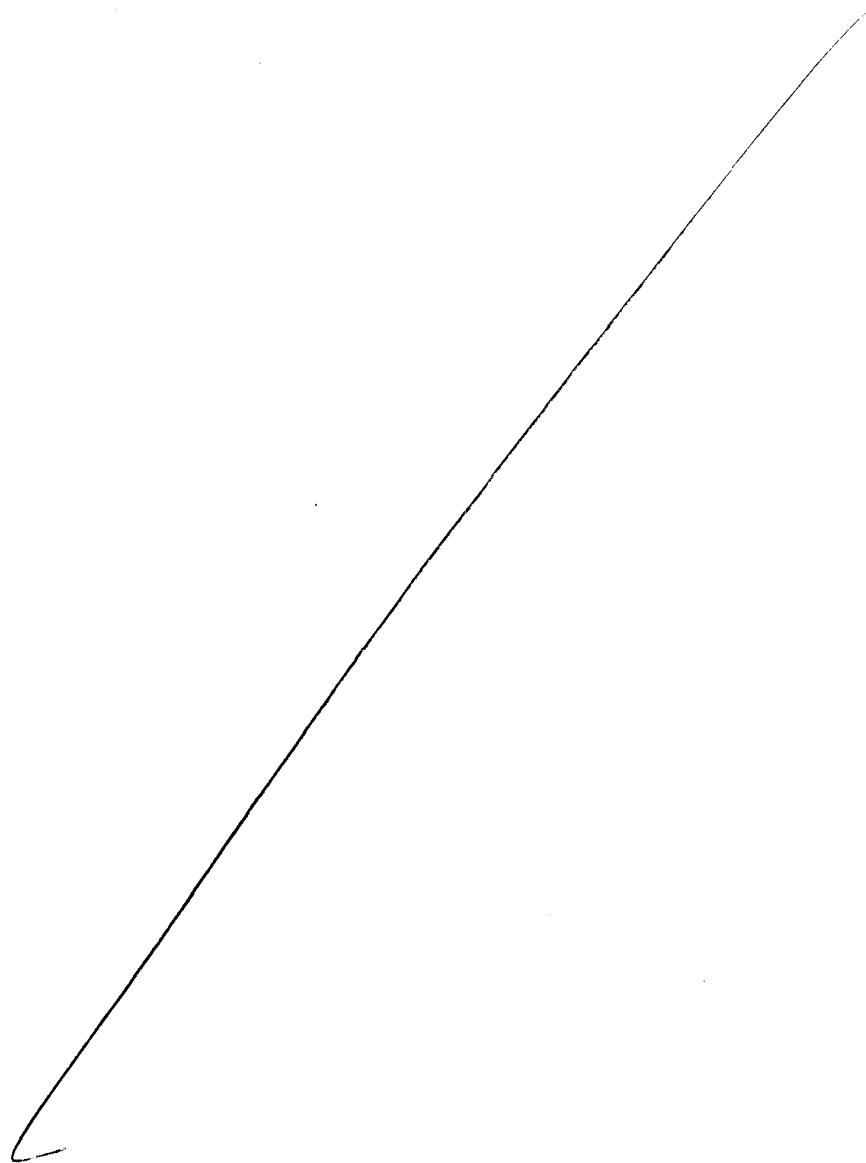
0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

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



Dr. Romberg  
Page 2 of 3  
09/29/98



**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 items F21 and G12a. 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**

Dr. Romberg  
Page 3 of 3  
09/29/98

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  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M10



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0739  
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed:     Application Form  
                               Inspection Report #M10                    Date: 10 September 1998  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                          Unacceptable                 Failure

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

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

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

Section E. Standard Operating Procedures - Procedures Manual

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

Section G. Records Audit

**Section H. Personnel**



**Section I. Reagents**



**Section J. Quality Control and Standards**



**Section K. Reporting**



**Section L. Equipment and Maintenance**



Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry

Rec'd 11/30/98  
SJC

October 29, 1998

Ms. Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Crumpton,

Enclosed is our responses to the cited deficiencies for items F21 and G12a.



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See the enclosed write up for an explanation of our current review procedures in response to G12a.

If further clarification is needed I can be reached at (847) 688-2045, ext 24 or ext 16.

Sincerely,



Robert W. Romberg  
Responsible Person  
NDSL Great Lake, IL 60088-6819

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 3, 1998

0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

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

The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issue discussed above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be



Dr. Romberg  
Page 2 of 2  
11/03/98

certified under the National Laboratory Certification Program (NLCP) pending receipt of documentation to demonstrate that the unresolved issue has been addressed. If, however, the laboratory fails to address the unresolved issue within this time, the issue 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/M10

Rec'd 11/18/98  
SC

16 November 98  
Navy Drug Screening Laboratory  
#0739  
Great Lakes, IL 60088

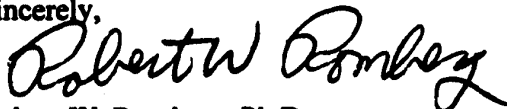
Ms. Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park  
North Carolina 27709-2194

Dear Ms. Crumpton,

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If you have any further questions I can be reached at (847) 688-2045 ext. 16 or 24  
(voice mail).

Sincerely,



Robert W. Romberg, Ph.D.  
Responsible Person, Civilian Testing

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

November 19, 1998

0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

We have reviewed the material provided in your correspondence of November 16, 1998, submitted in response to an issue raised during the tenth maintenance inspection of your laboratory as outlined in our correspondence of November 3, 1998. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issue. 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. 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/M10



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

April 20, 1999

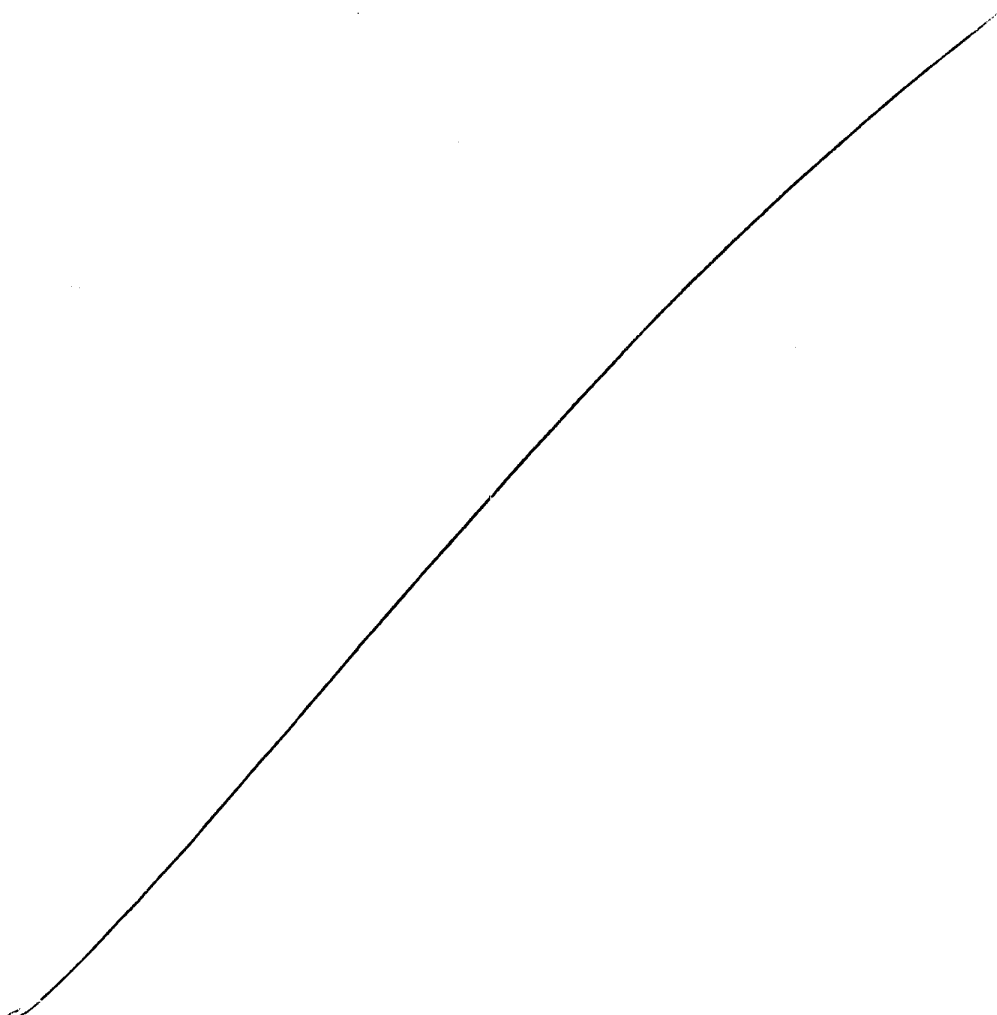
0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eleventh 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 all corrective actions described in the critique and/or cover letter:



Dr. Romberg  
April 20, 1999  
Page 2 of 3

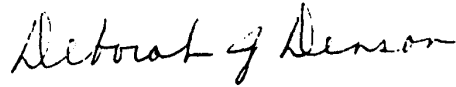


The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item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

Dr. Romberg  
April 20, 1999  
Page 3 of 3

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/M11





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# NATIONAL LABORATORY CERTIFICATION PROGRAM

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## Document Review and Critique

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Laboratory I.D. Number: 0739  
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed:     Application Form  
                               Inspection Report #M11                      Date: 11 March 1999  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

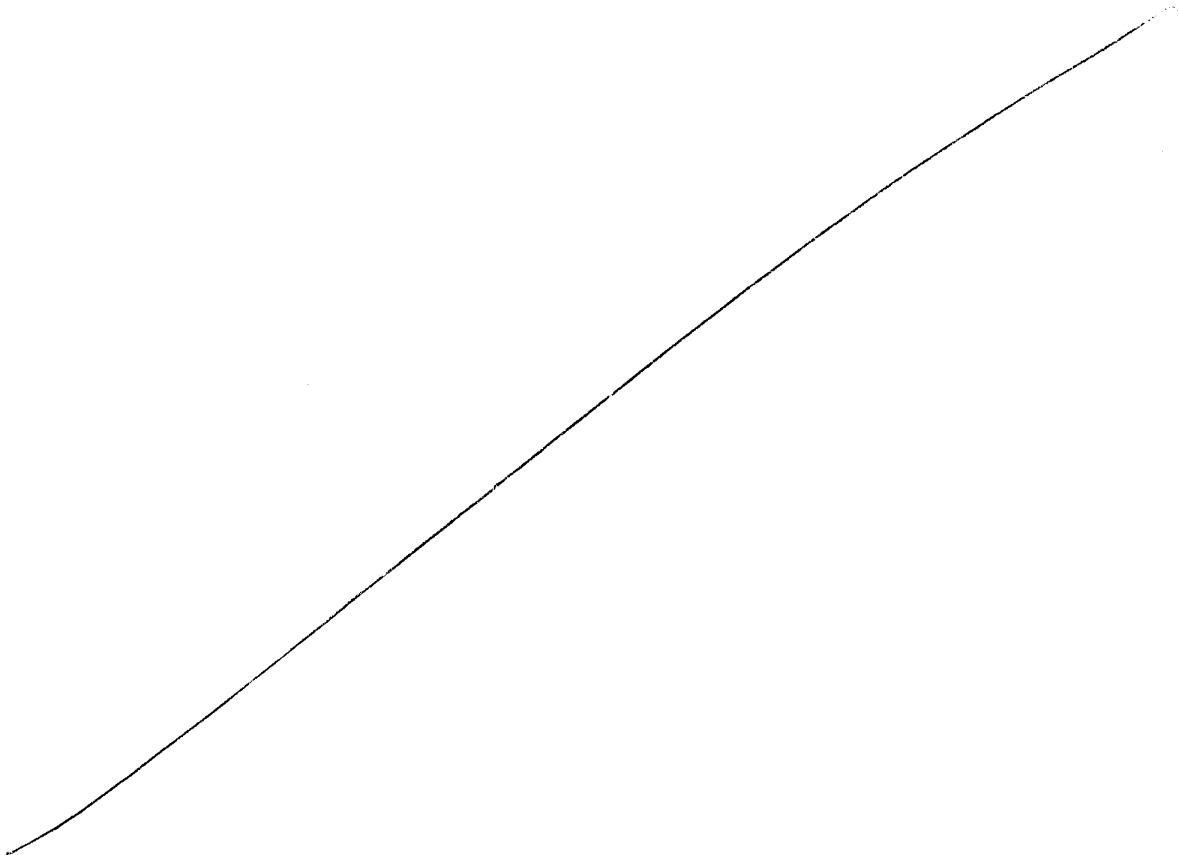
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Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required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

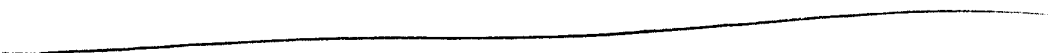
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



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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**

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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received  
5/24/99 ND

May 20, 1999  
Navy Drug Screening Laboratory  
PO Box 88 6819  
Great Lakes, IL 60088-6819

Deborah J. Denson  
NLCP Inspection Analyst  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, North Carolina 27709-2194

Dear Dr. Denson,

We have completed the corrective actions generated during our last inspection. The following is a summary of what we have done. If you need additional information I can be reached at (847) 688-2045, ext. 24 or ext. 16.

Section F



Section F


[Redacted content]

Section J

[Redacted content]

Section N

[Redacted content]

  
R. W. Romberg  
Responsible Person  
Civilian Specimens



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

May 25, 1999

0739

Dr. Robert Romberg  
Navy Drug Screening Laboratory  
Building 38-H- Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

We have reviewed the material provided in your correspondence of May 20, 1999, submitted in response to issues raised during the eleventh inspection of your laboratory as outlined in our correspondence of April 20, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised.

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

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

Sincerely,

Deborah J. Denson  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M11



RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 19, 1999

0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

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





Dr. Romberg  
Page 2 of 2  
10/19/99

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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 review the issues outlined above and in 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/M12~~

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0739  
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed:     Application Form  
                               Inspection Report #M12                    Date: 16 September 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

April 20, 2000

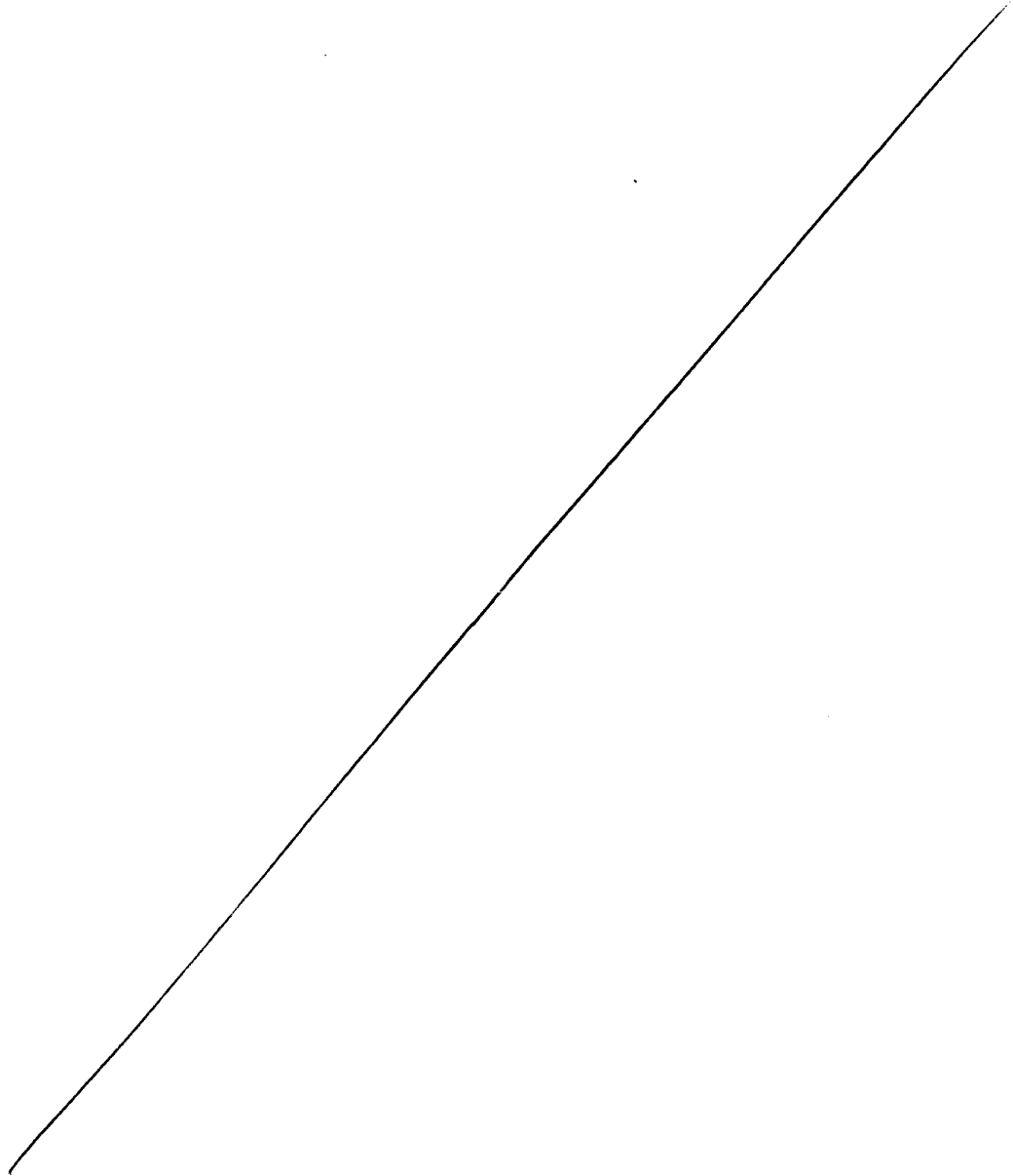
0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
Great Lakes, IL 60088

Dear Dr. Romberg:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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. Romberg  
Page 2 of 3  
04/20/00



Dr. Romberg  
Page 3 of 3  
04/20/00

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/M13



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0739  
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed:     Application Form  
                               Inspection Report #M13                      Date: 9 March 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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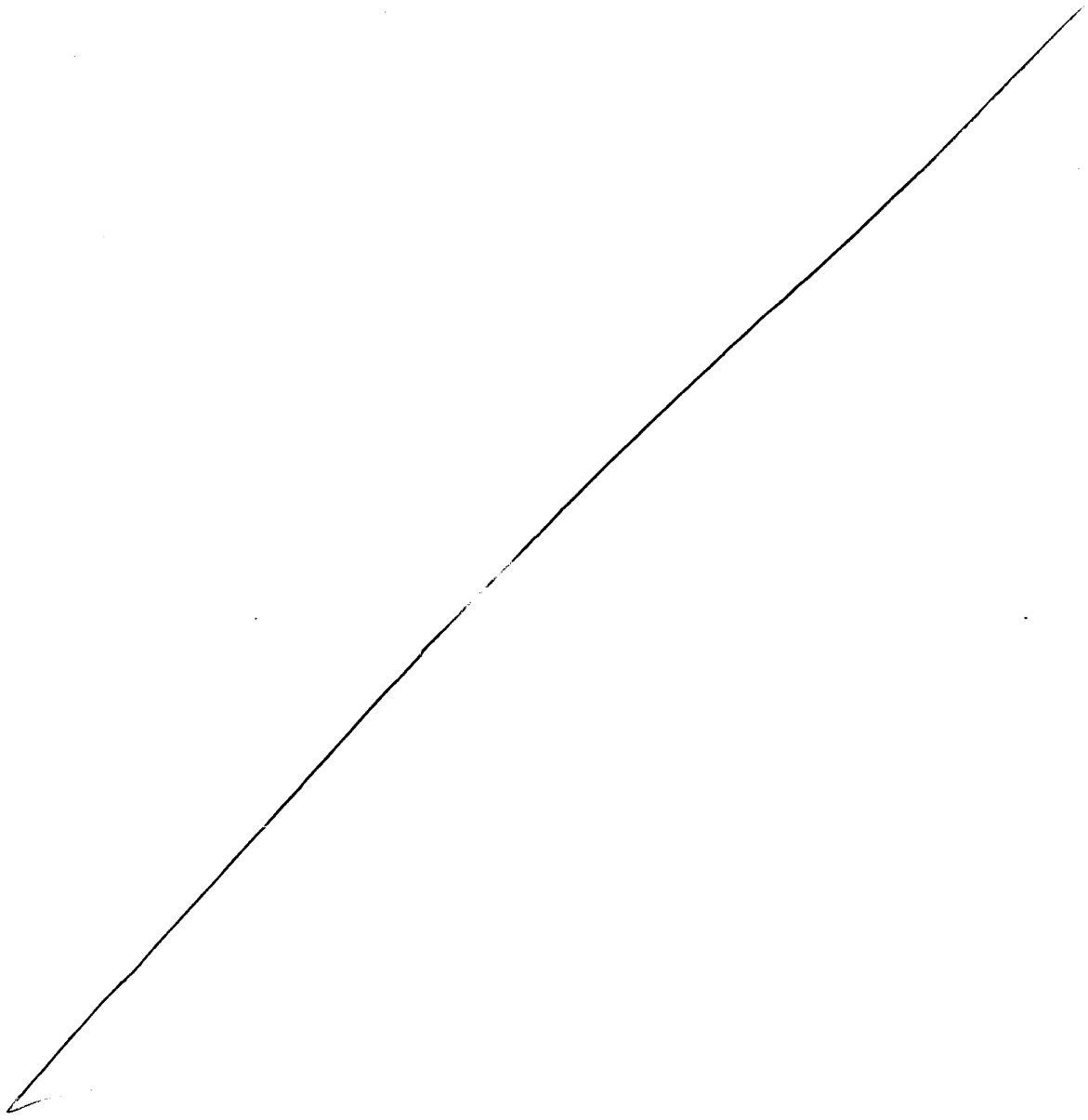
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

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

October 26, 2000

0739  
Dr. Robert W. Romberg  
Navy Drug Screening Laboratory  
Building 38-H - Great Lakes  
P O Box 88-6819  
Great Lakes, IL 60088

Dear Dr. Romberg:

The enclosed critique was developed from the inspection reports of the 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 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 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/M14



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0739  
Document No. Final

Laboratory: Navy Drug Screening Laboratory

Location: Great Lakes, IL

Document Reviewed:      Application Form  
                                   Inspection Report #M14             Date: 14 September 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

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel