



November 9, 1998

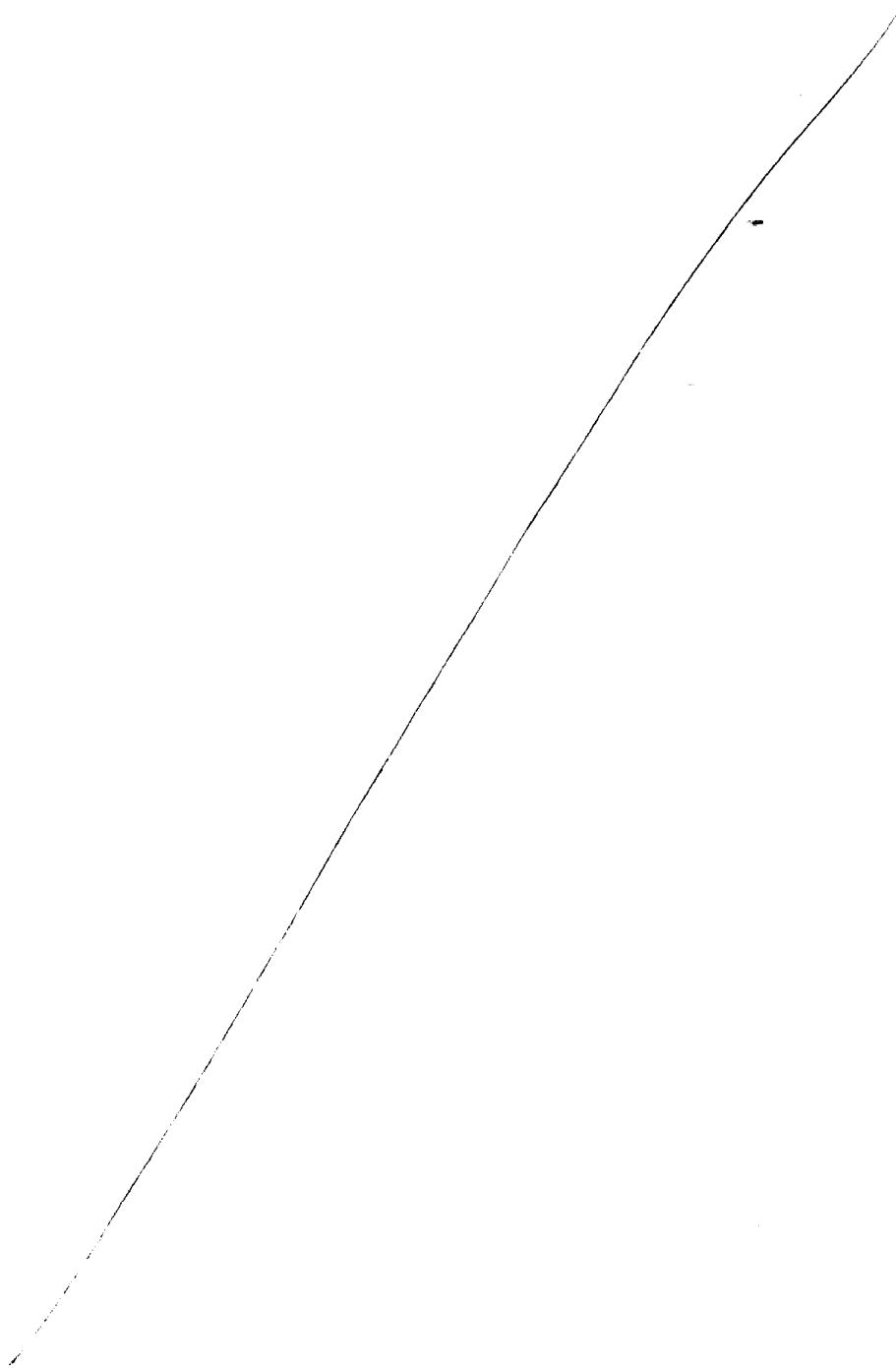
0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

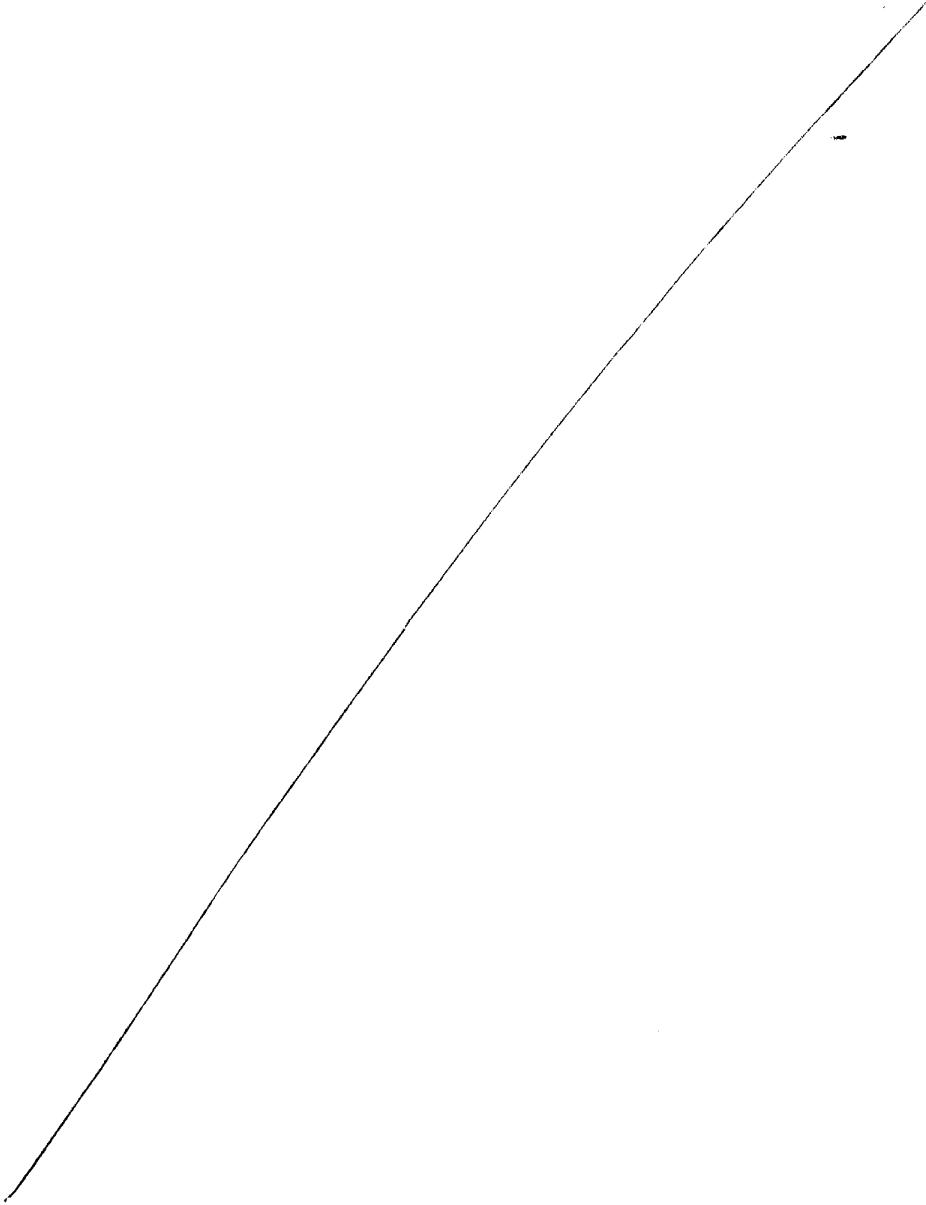
The enclosed critique was developed from the inspection reports of the three inspectors who conducted the fifteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the laboratory must correct/clarify the following issues raised:



Dr. Miller  
Page 2 of 4  
11/09/98



Dr. Miller  
Page 3 of 4  
11/09/98



Dr. Miller  
Page 4 of 4  
11/09/96

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/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: 0336  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed:     Application Form  
                               Inspection Report #M15                      Date: 22 October 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

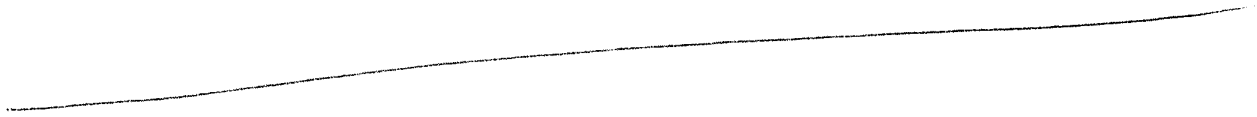
Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry





# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

June 11, 1999

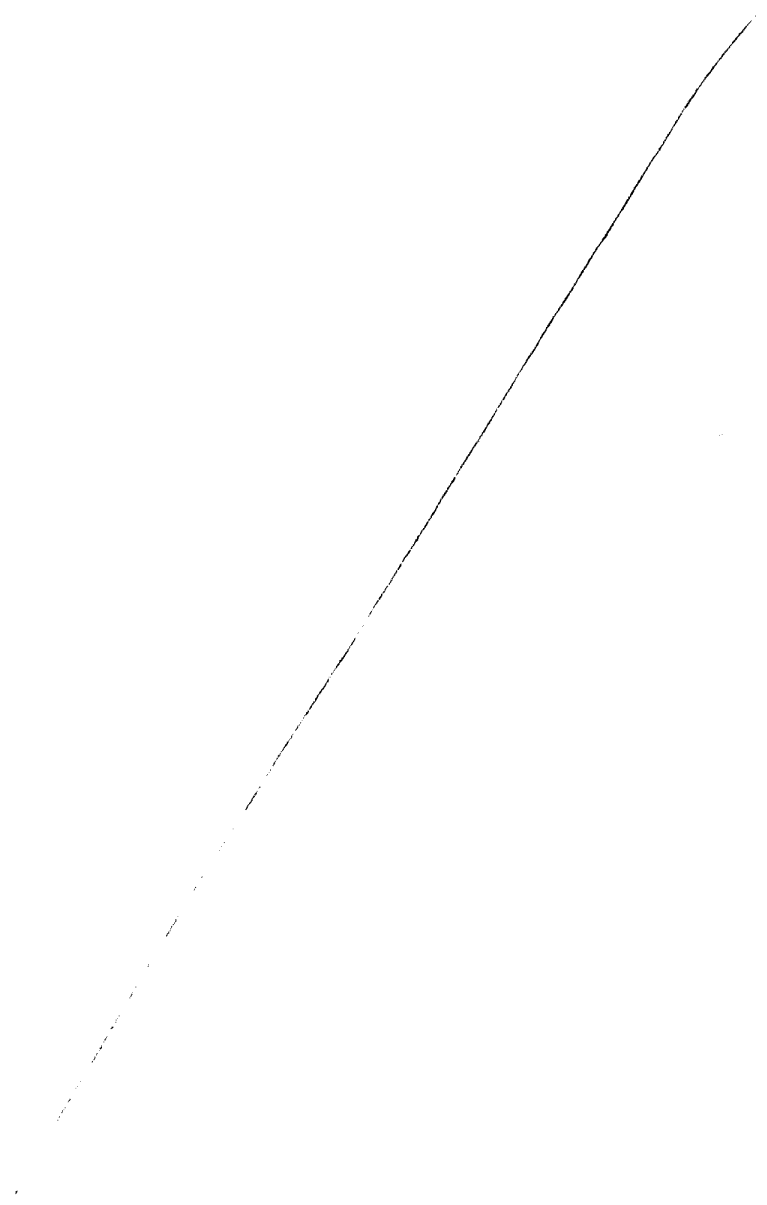
0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

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



Dr. Miller  
Page 2 of 3  
06/11/99



Dr. Miller  
Page 3 of 3  
06/11/99

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

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

Sincerely,



Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0336  
Document No.: Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed:     Application Form  
                               Inspection Report #M16                    Date: 29 April 1999  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

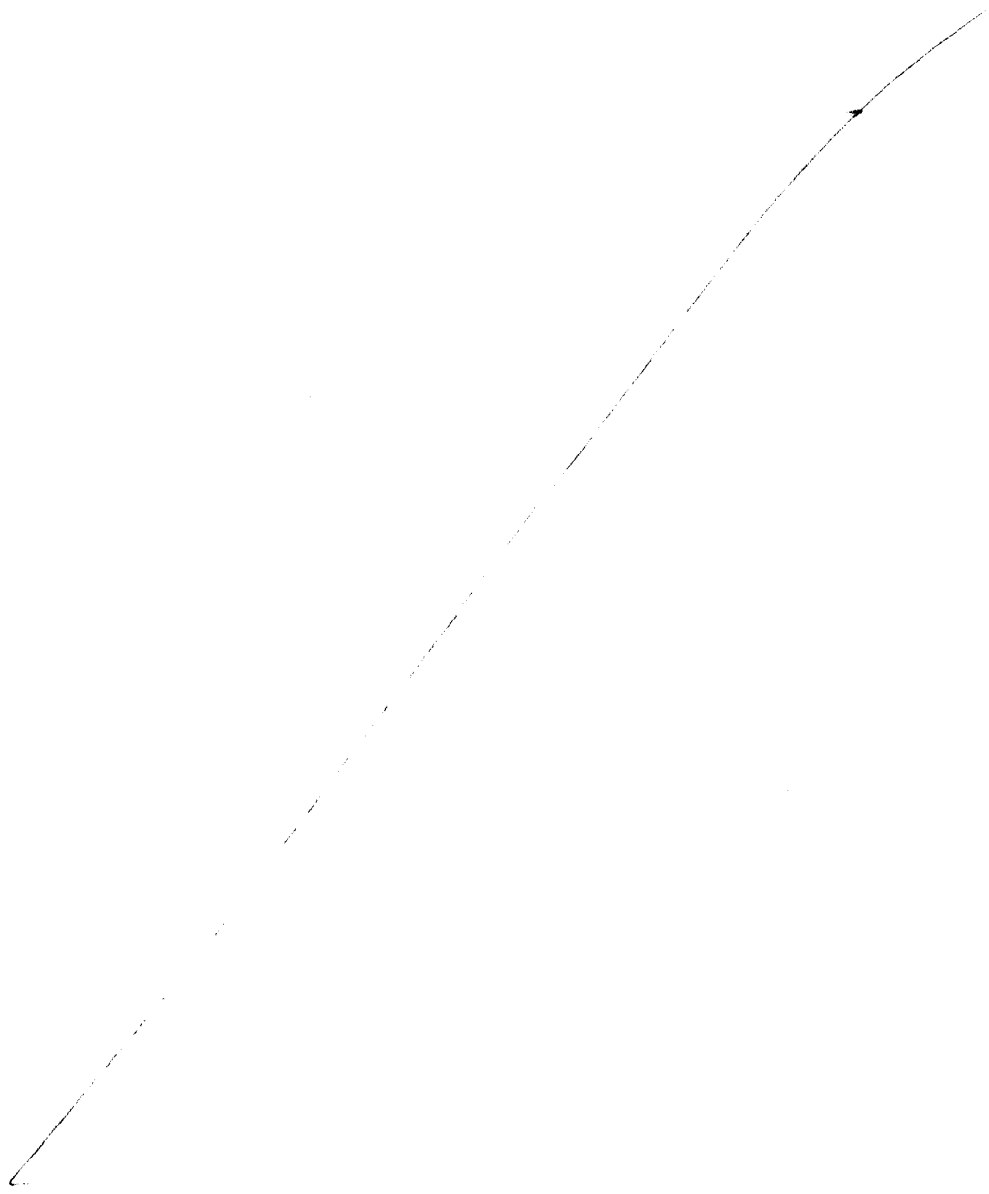
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

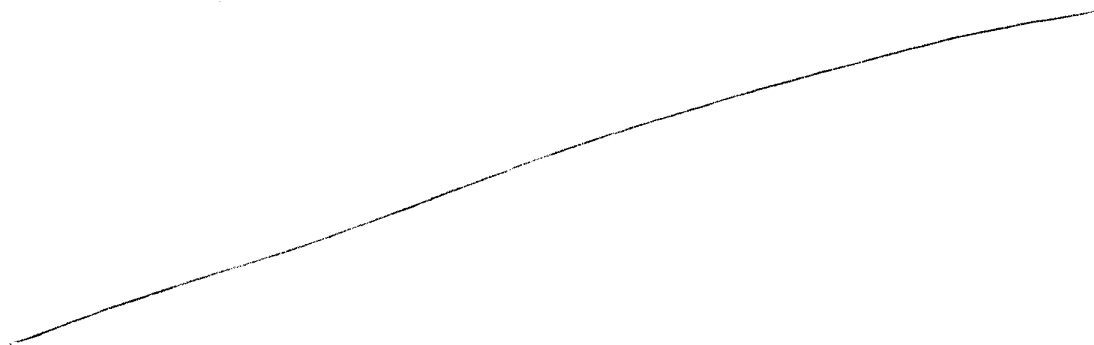
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

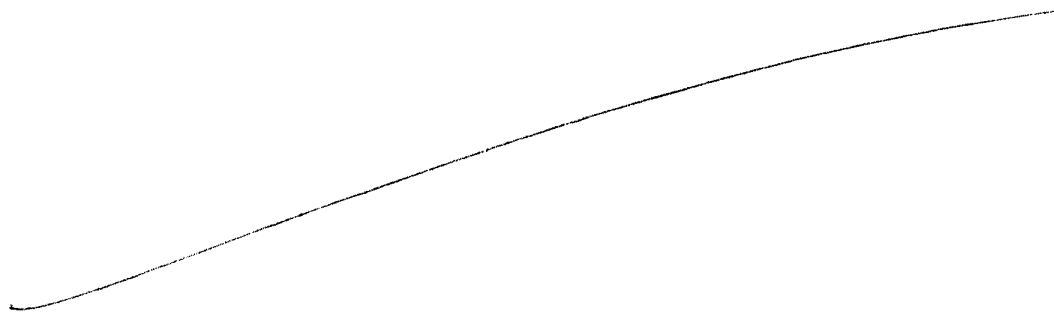
Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



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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**







# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

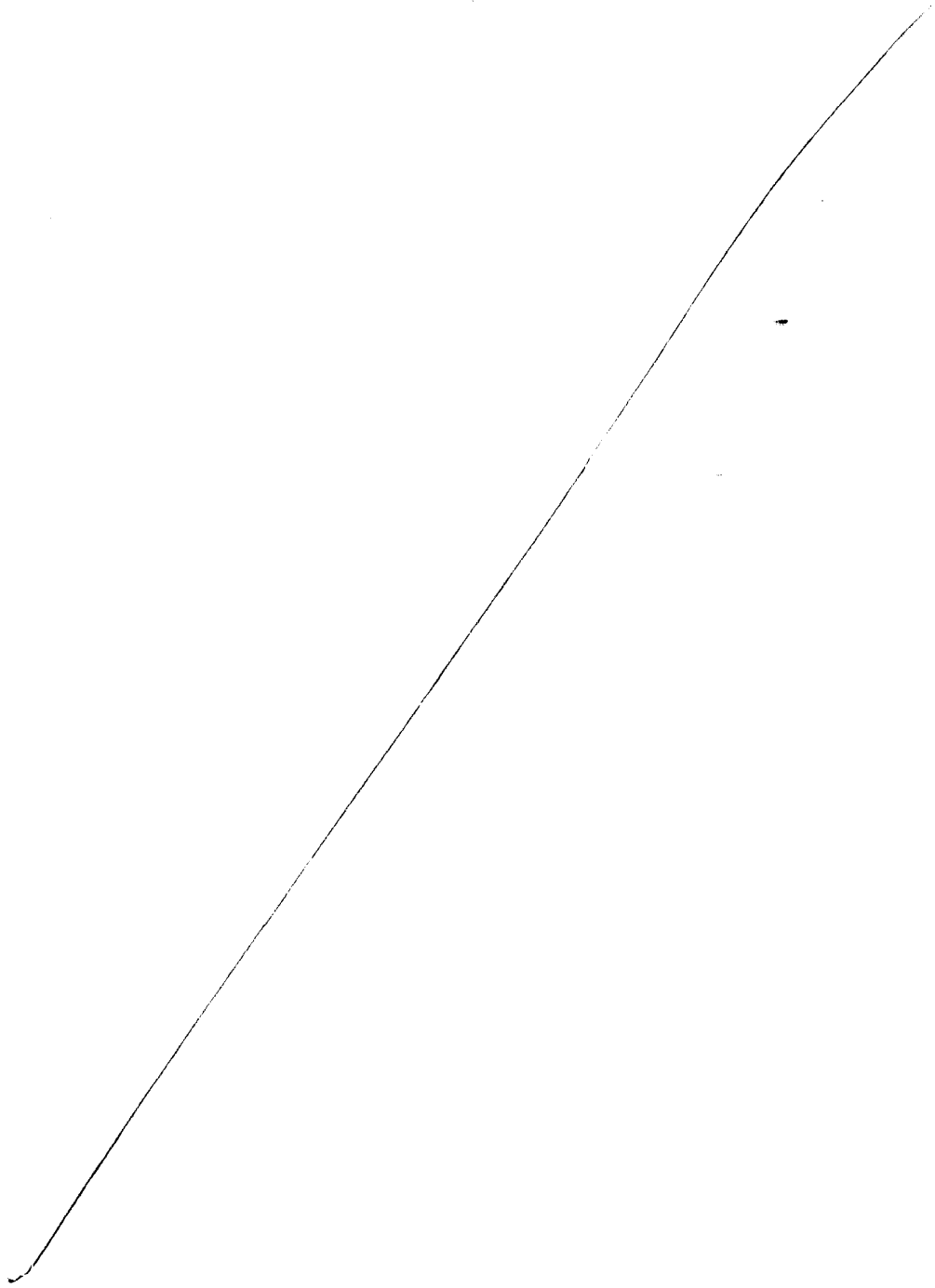
January 6, 2000

0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

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 outcome of the laboratory's performance in this inspection is unacceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following remedial actions:





The laboratory must submit, within 5 calendar days of receipt of this letter, a plan to complete all remedial actions. Once this plan is approved, the laboratory will have a maximum of 30 calendar days to implement the plan and to complete all necessary remedial actions. If the laboratory fails to provide and execute an approved plan, RTI will recommend to the Department of Health and Human Services (HHS) that your laboratory's certification be suspended and/or revoked. The laboratory should also review the enclosed critique and take all necessary corrective actions.

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 sustain acceptable performance in the inspection phase of this program 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.

In responding to the issues raised, please organize the material in accordance with the item numbers listed in the text of this letter. If we can be of assistance or answer any questions, 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: 0336  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed:     Application Form  
                               Inspection Report #M17                      Date: 28 October 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 not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required for continued certification.

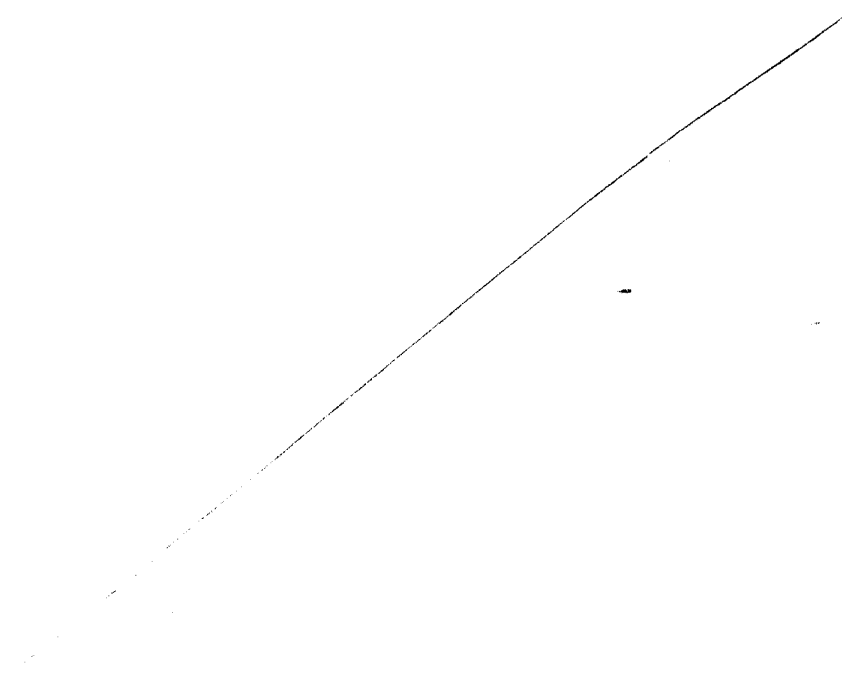
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Quest Diagnostics Incorporated

4770 Regent Blvd.  
Irving, TX 75063-2201  
972.916.8200  
800.824.6181  
972.916.8979 FAX

received  
1/13/00 SDC



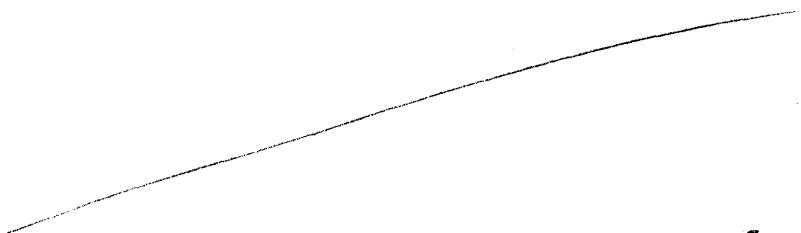
January 13, 2000

Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
P.O. Box 12194  
Research Triangle Park, NC 27709

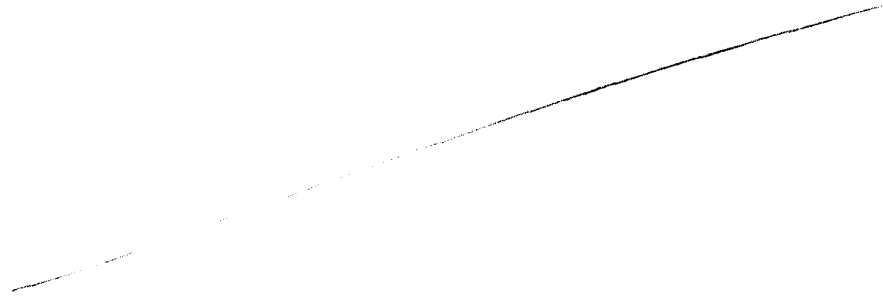
Ms. Crumpton:

The following explanation of corrective actions taken and supporting documentation are in response to the critique provided by RTI of the October 28-29, 1999 maintenance inspection of the Quest Diagnostics, Inc., Irving, Texas NLCP-certified laboratory (#0336). The inspection critique was received by the RP on 1/10/00. Each of the numbered sections below corresponds to the same number in the critique. Various attachments are provided as documentation of the corrective action planned or taken. In some cases a "hand edit" of the SOP has been made in correction of a finding identified. This edit has been initialed and dated by myself as RP. As soon as possible, we will have typewritten revisions of the SOP made to incorporate the hand edits. The newly revised and approved pages will then be included in our laboratory SOP.

**Section E. Standard Operating Procedures – Procedure Manual**




**3. The following procedures were not consistent between different sections of the SOP ...**



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**5. The following procedures described in the SOP were not consistent with actual laboratory practice ...**



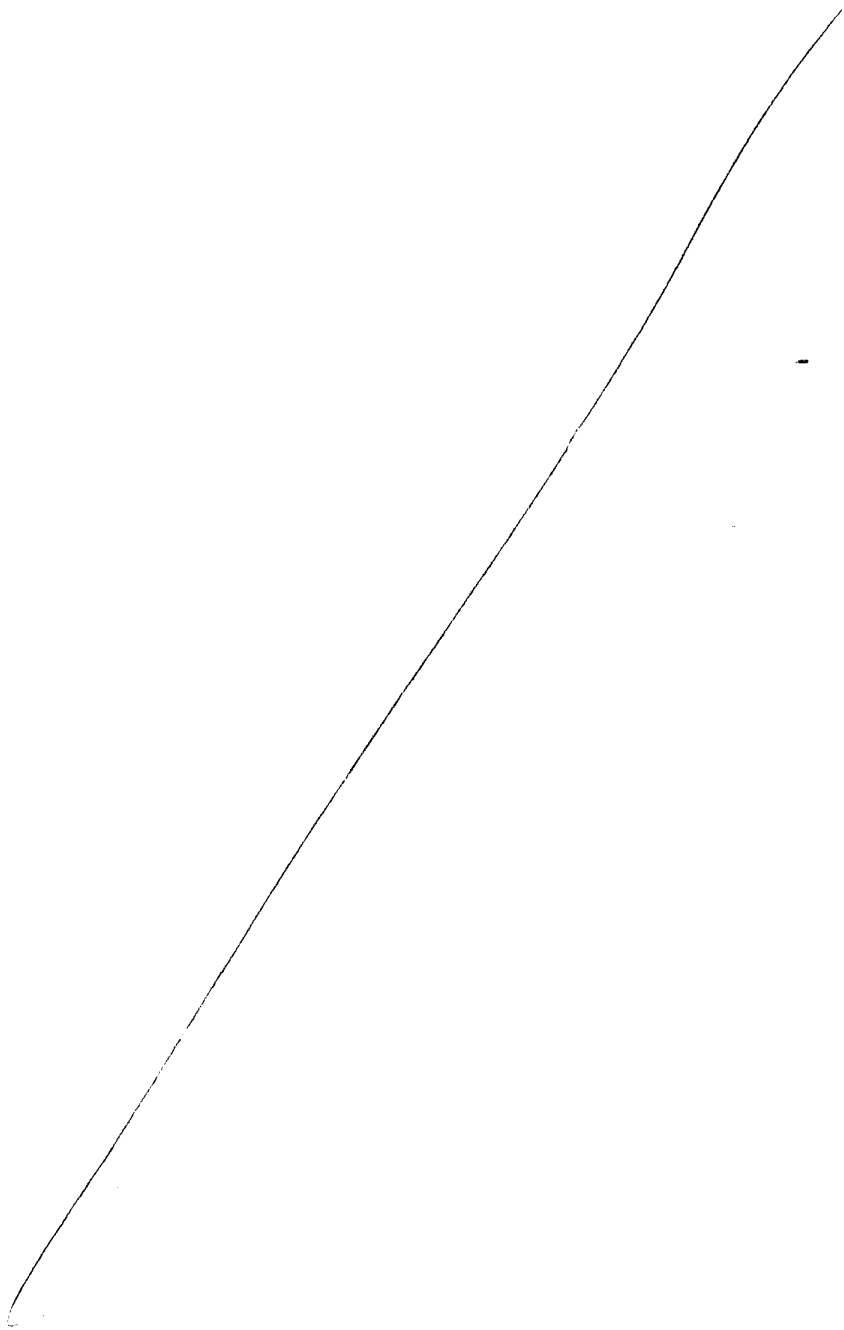
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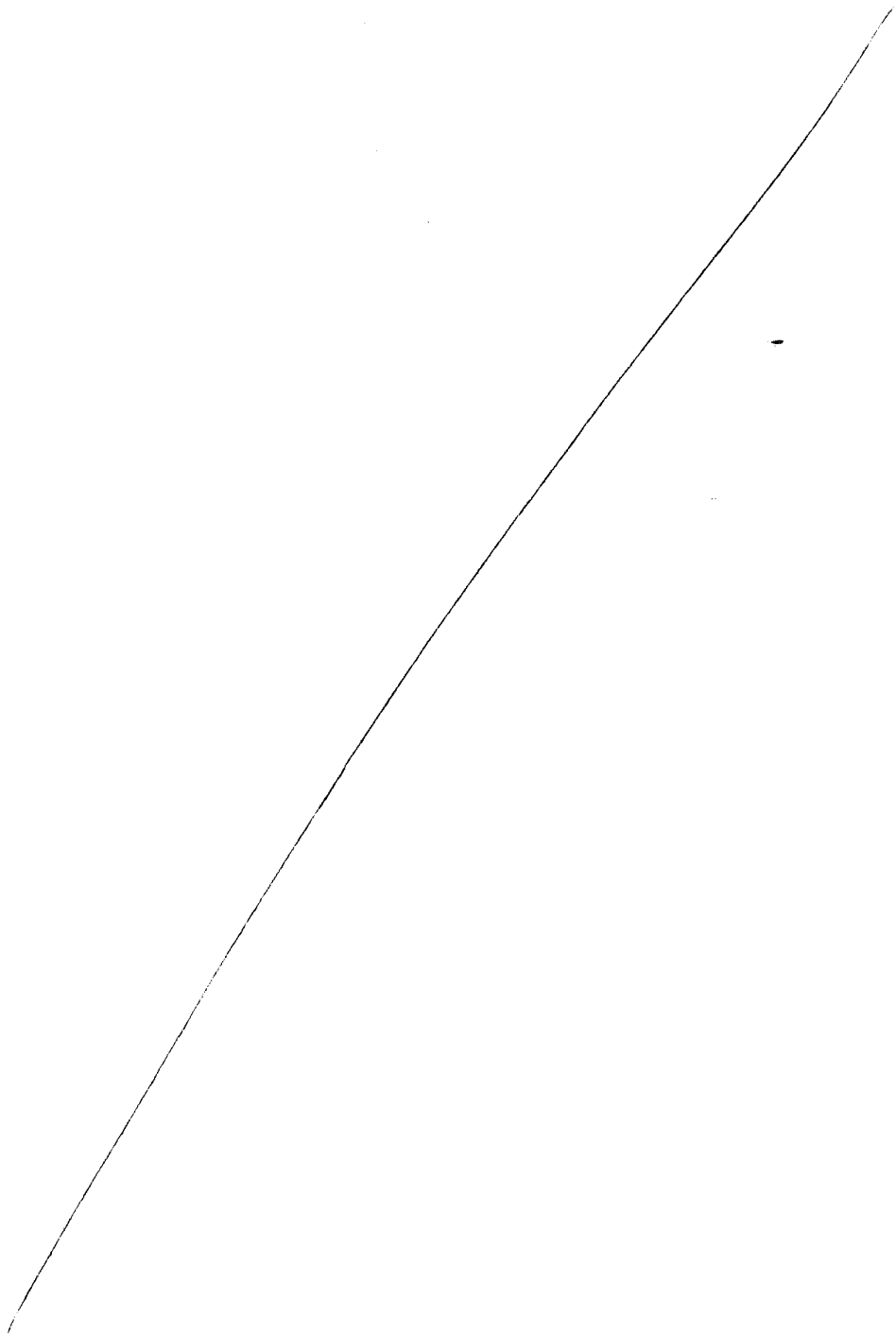
3

1

8.a. All sections of the SOP manual were not reviewed, dated and signed by the RP...

**Section G. Quality Control**





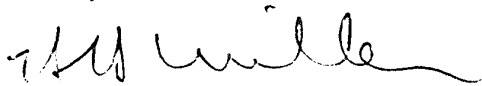
**Section H. Initial Tests**



**Section M. Equipment and Maintenance**

I hope that you find our plan for corrective action appropriate and proper to address the findings of the inspection team. As noted above, some corrections to the SOP have already been made in a formal manner, while others exist as hand-edits. We soon will complete a formal revision of the hand-edits and the newly revised pages will be incorporated into the SOP per our usual policy. I wish to thank you for your help with the National Laboratory Certification Program. I appreciate the work of the inspection team and the findings of the inspection critique, which will help to improve our drug testing laboratory.

Sincerely,

A handwritten signature in cursive script, appearing to read "H. H. Miller".

H. H. Miller, M.T.(ASCP), Ph.D.  
Director of Toxicology and Responsible Person

Insresp100.doc

# RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

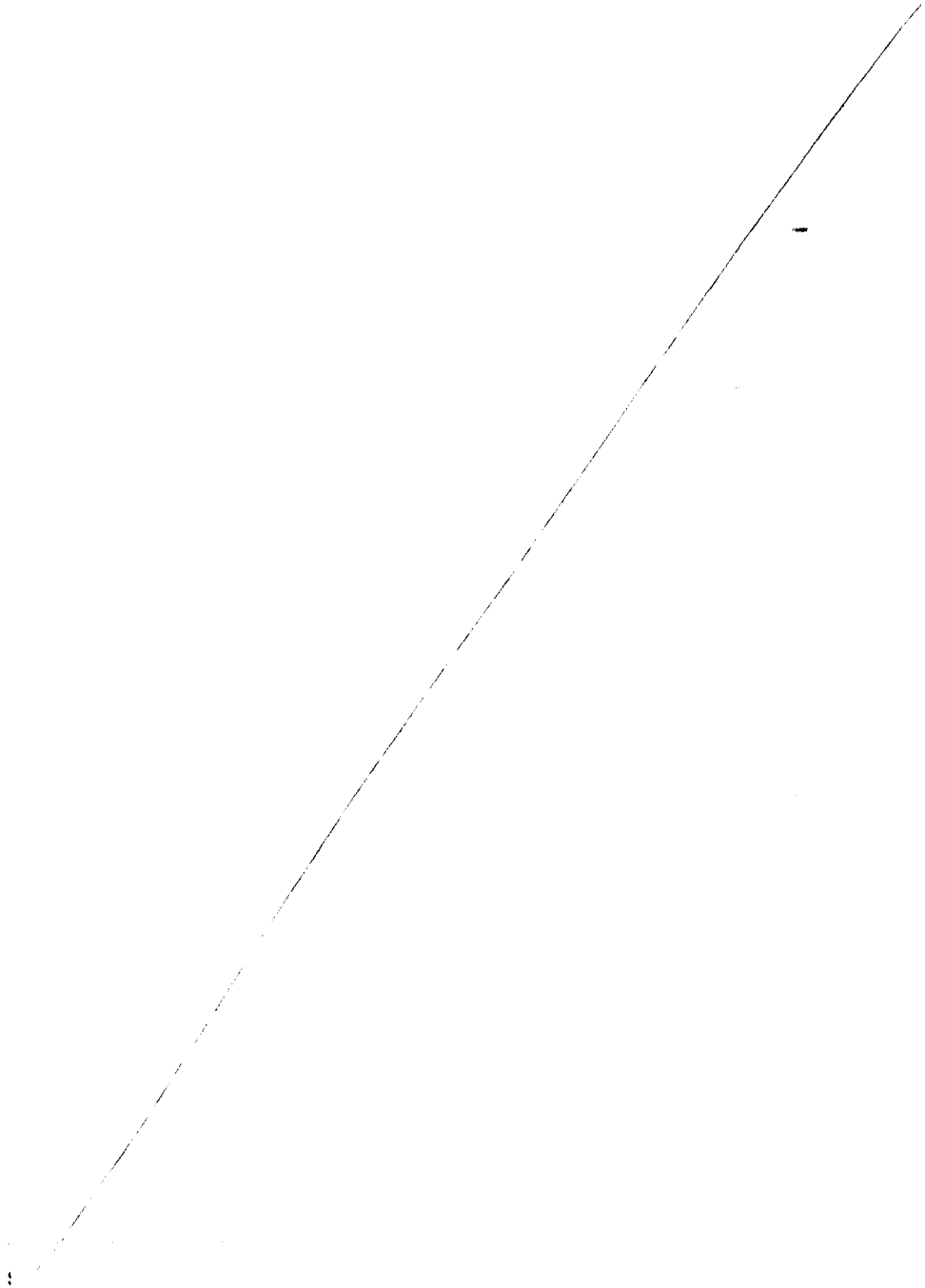
January 19, 2000

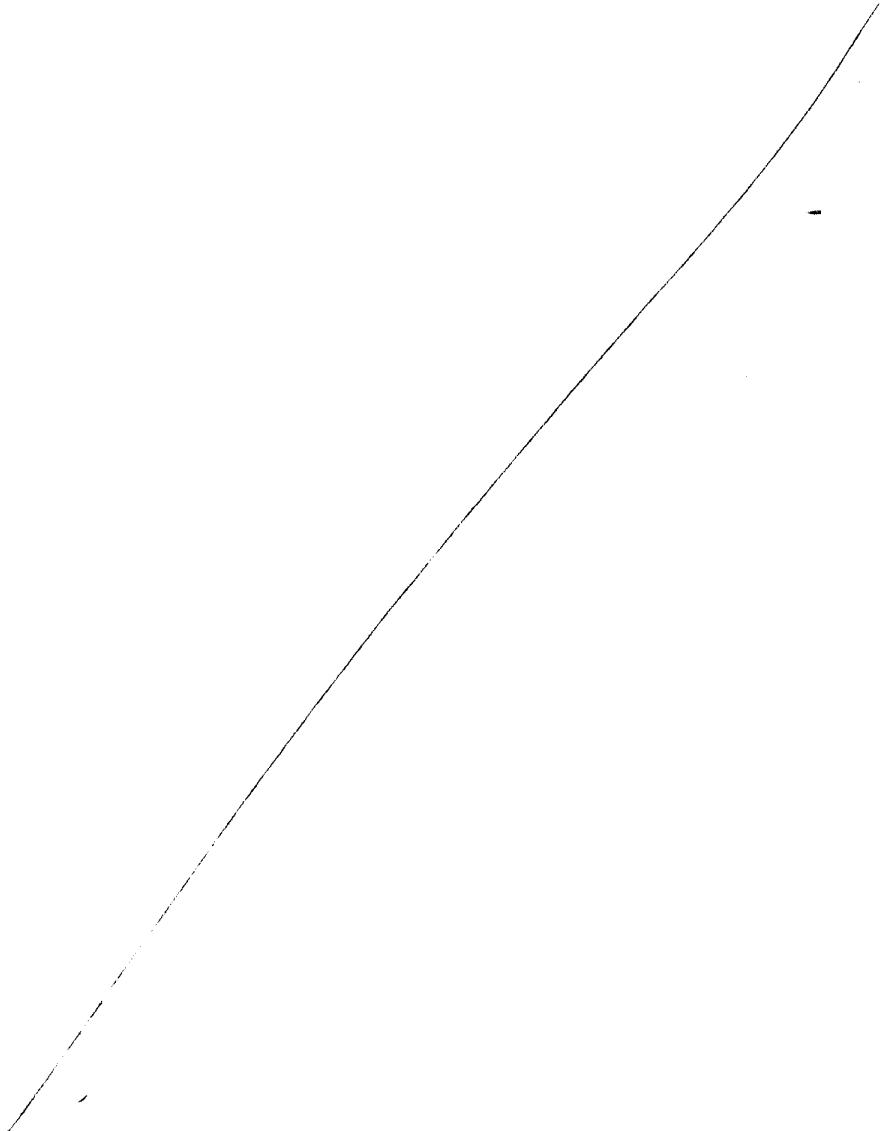
0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of January 13, 2000, provided in response to the deficiencies cited during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of January 6, 2000. The following issues were not satisfactorily addressed in the plan or were identified during our review of the submission.







Dr. Miller  
Page 4 of 4  
01/19/00

The laboratory must submit the final report within 30 calendar days of receipt of this letter. **This report must include documentation to demonstrate completion of remedial actions outlined in your correspondence, and to address the issues outlined above.** If you have any questions or want to further clarify any of these issues, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

A handwritten signature in cursive script, appearing to read "Susan Crumpton".

Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M17

Quest Diagnostics Incorporated

4770 Regent Blvd.  
Irving, TN 37063-2201  
972.916.8200  
800.829.6172  
972.916.8879 FAX

received  
2/9/00

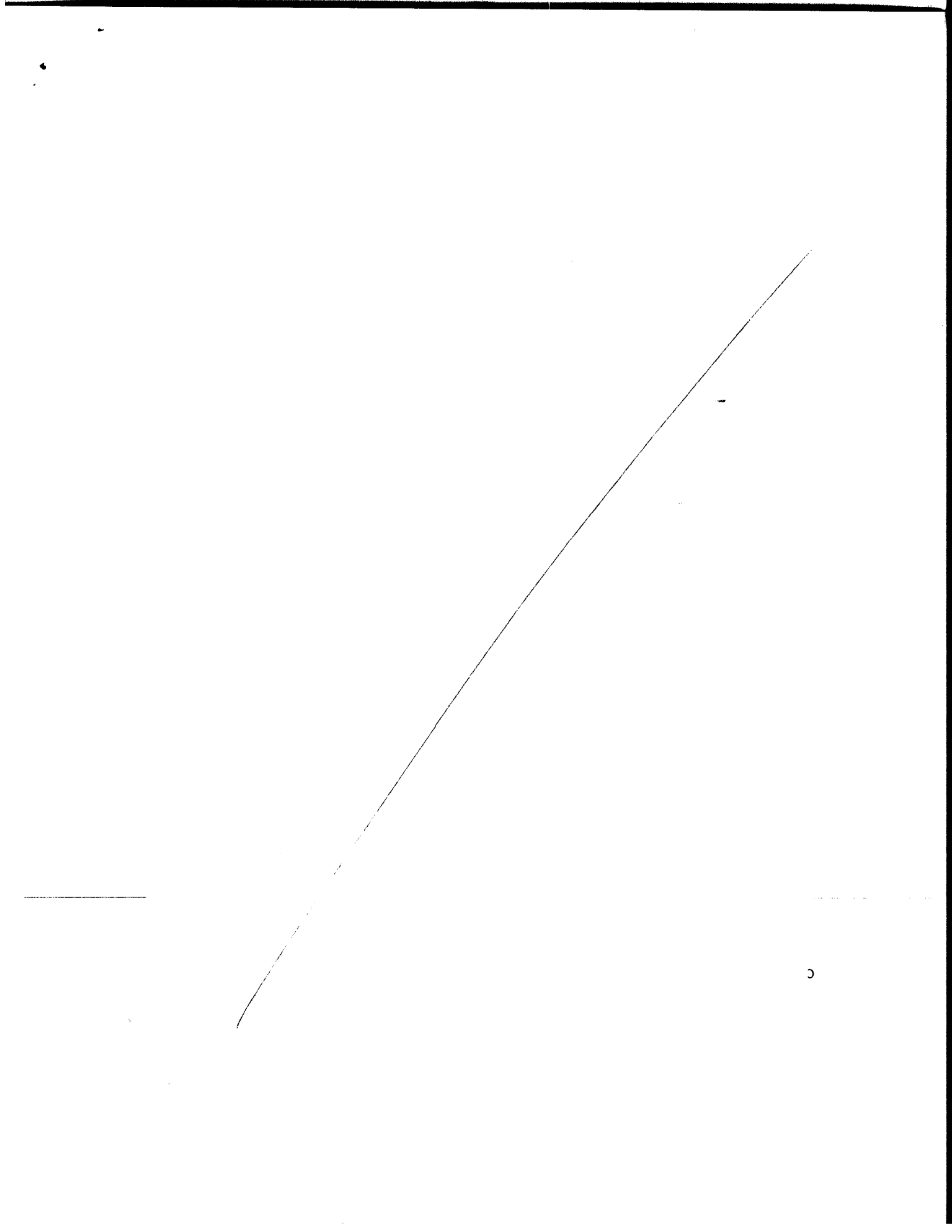


February 7, 2000

Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709

Ms. Crumpton:

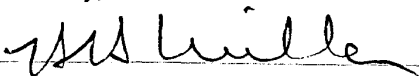
The following are corrective actions taken in response to outstanding inspection issues detailed in your most recent letter regarding the Quest Diagnostics Inc., NLCP-certified laboratory in Irving, Texas (Crumpton to Miller, 1/19/00). These items deal with issues deemed as not satisfactorily addressed in my previous correspondence or otherwise identified in your review of my submission to your office (Miller to Crumpton, 1/13/00).





This submission, together with my previous submission to your office should demonstrate completion of remedial actions as outlined in the original inspection critique of 1/6/00 and the follow-up letter of 1/19/00. Thank you for your help with the National Laboratory Certification Program.

Sincerely,

A handwritten signature in cursive script, appearing to read "H. H. Miller". The signature is written in black ink and is positioned above a horizontal line that spans the width of the page.

H. H. Miller, M.T.(ASCP), Ph.D.  
Director of Toxicology and Responsible Person

Crum200.doc



February 15, 2000

0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

We have reviewed the material provided in your correspondence of February 7, 2000, submitted in response to deficiencies cited during the seventeenth maintenance inspection of your laboratory as outlined in our correspondence of January 6 and 19, 2000. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the deficiencies cited. 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,

A handwritten signature in cursive script that reads "Susan Crumpton".

Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M17



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 9, 2000

0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

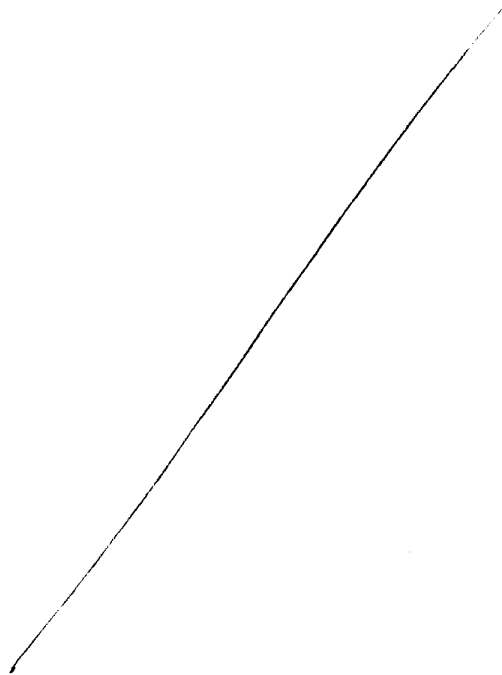
Dear Dr. Miller:

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

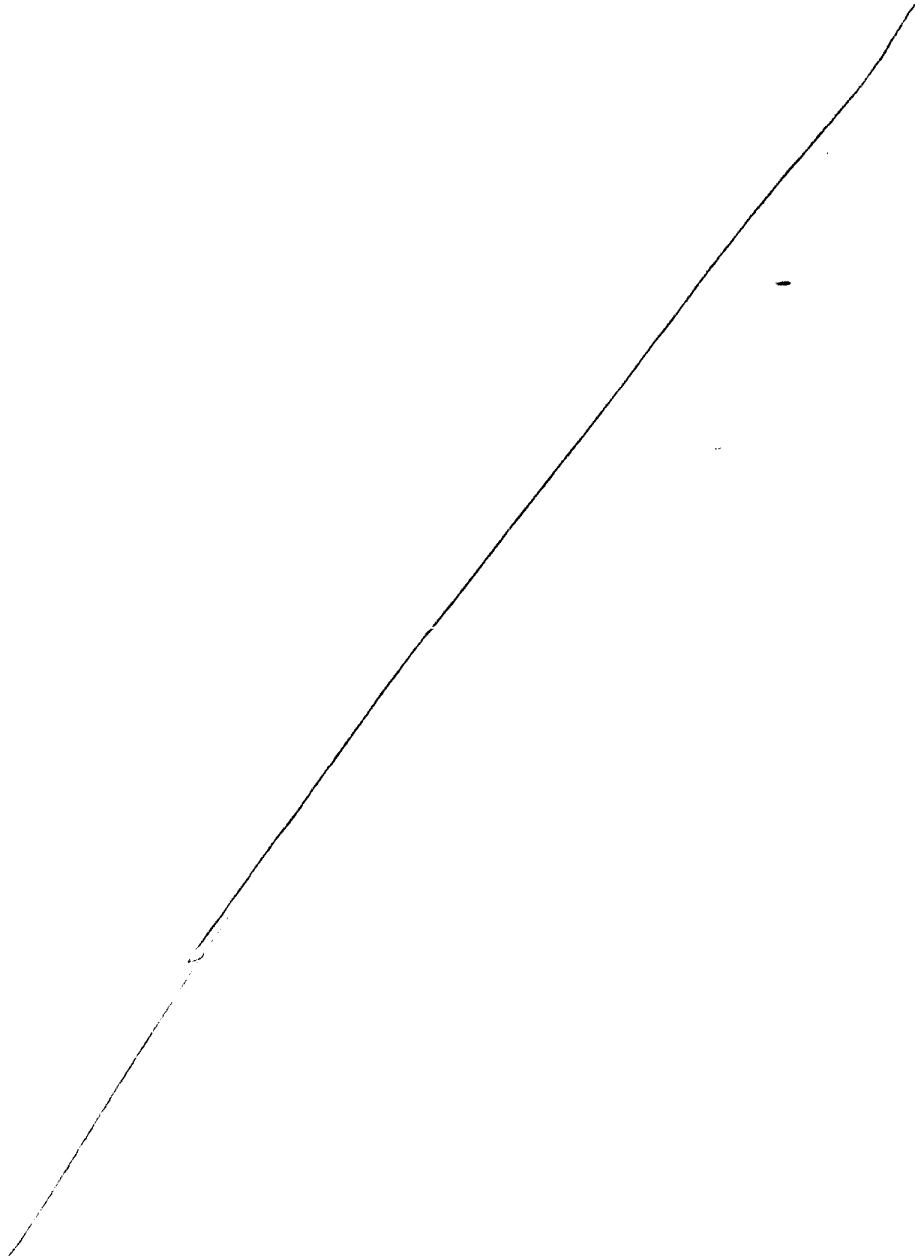
*[A large, faint, diagonal line or signature mark is present across the middle of the page.]*



Dr. Miller  
June 9, 2000  
Page 2 of 4



Dr. Miller  
June 9, 2000  
Page 3 of 4

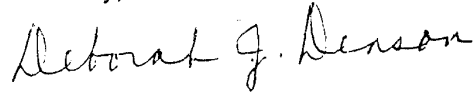


Dr. Miller  
June 9, 2000  
Page 4 of 4

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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
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: 0336  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed:     Application Form  
                               Inspection Report #M18                      Date: 27 April 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

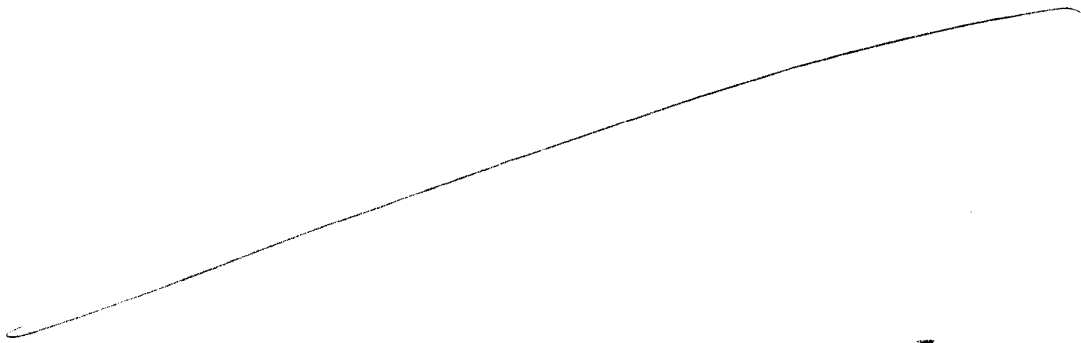
Section F. Chain-of-Custody, Accessioning, and Security



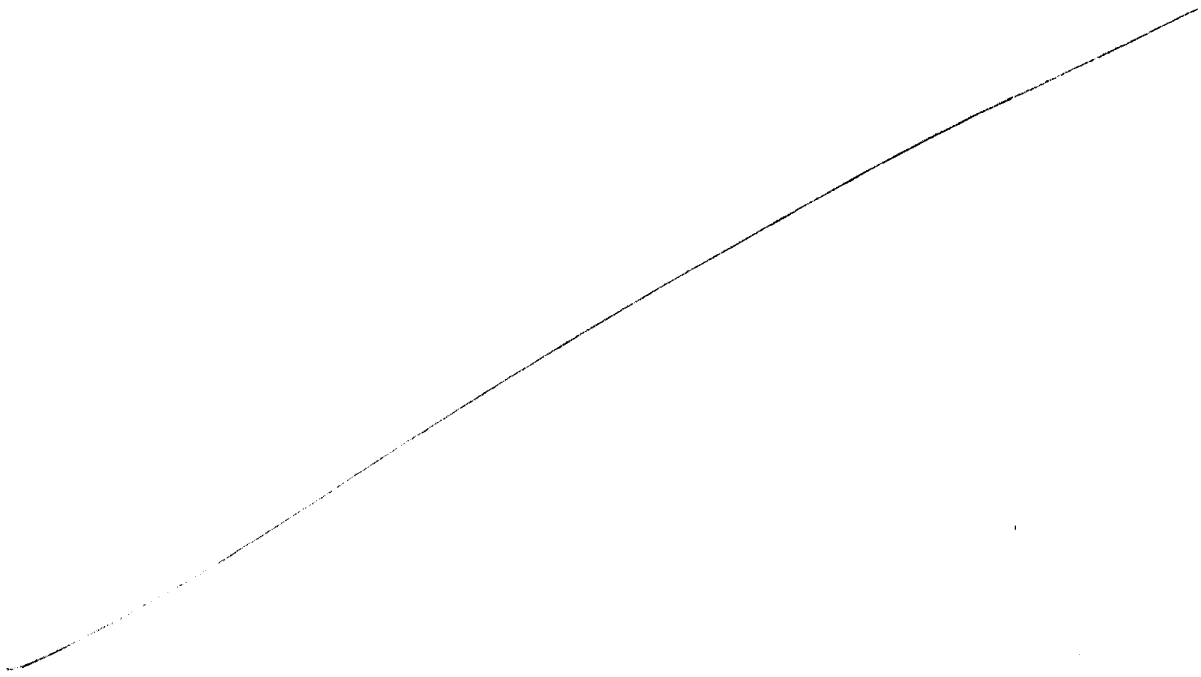
Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests



Section J. Records Audit



Section K. Reporting

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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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Quest Diagnostics Incorporated

4770 Regent Blvd.  
Irving, TX 75060-2201  
972.916.8200  
800.824.6152  
972.916.8575 FAX

received  
7/10/2000 DD



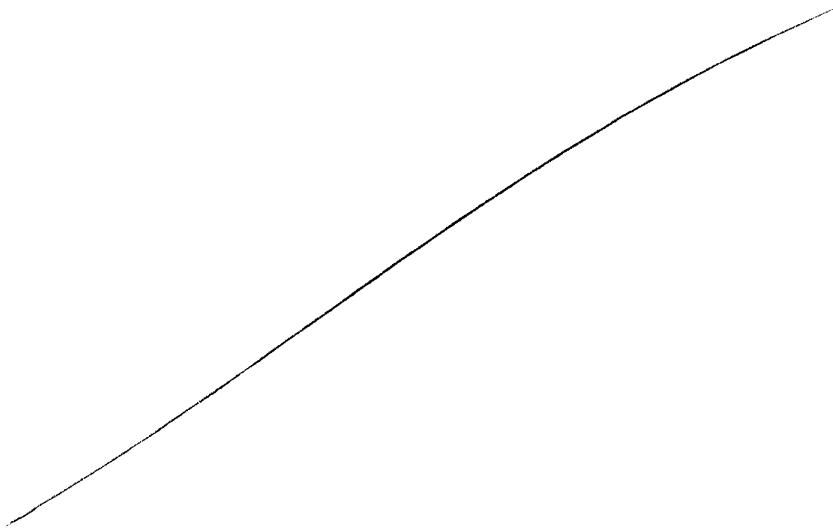
June 27, 2000

Deborah J. Denson  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
P.O. Box 12194  
Research Triangle Park, NC 27709

Ms. Denson:

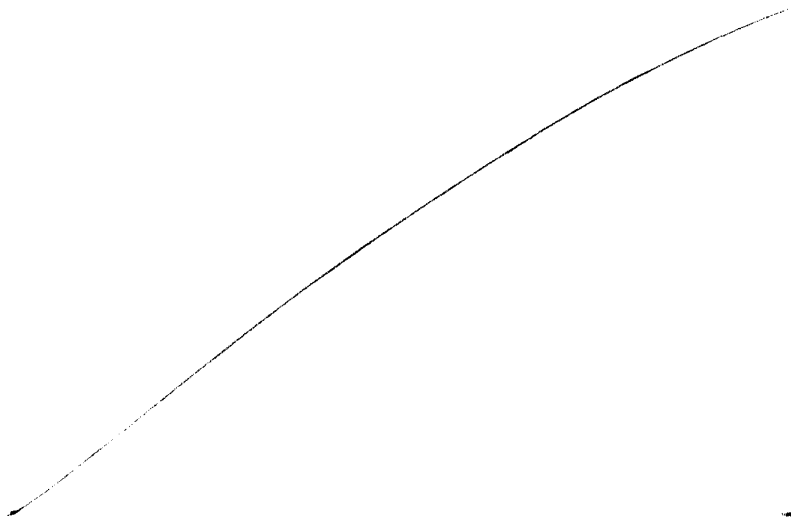
The following explanation of corrective actions taken and supporting documentation are in response to the detailed critique provided by RTI of the April 27-28, 2000 maintenance inspection of the Quest Diagnostics, Inc., Irving, Texas NLCP-certified laboratory (#0336). The inspection critique was received by the RP on 6/12/2000. Each of the numbered sections below corresponds to the same number in the detailed critique. Attachments are provided as documentation of the corrective action planned or taken.

**Section E. Standard Operating Procedures – Procedure Manual**

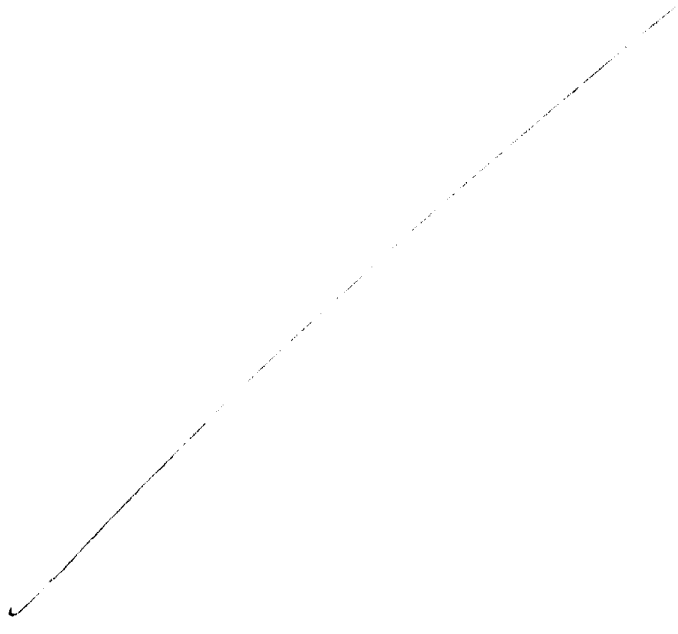


**Section F. Chain of Custody, Accessioning & Security**

**Section H. Initial Tests**



**Section I. Confirmatory Tests**

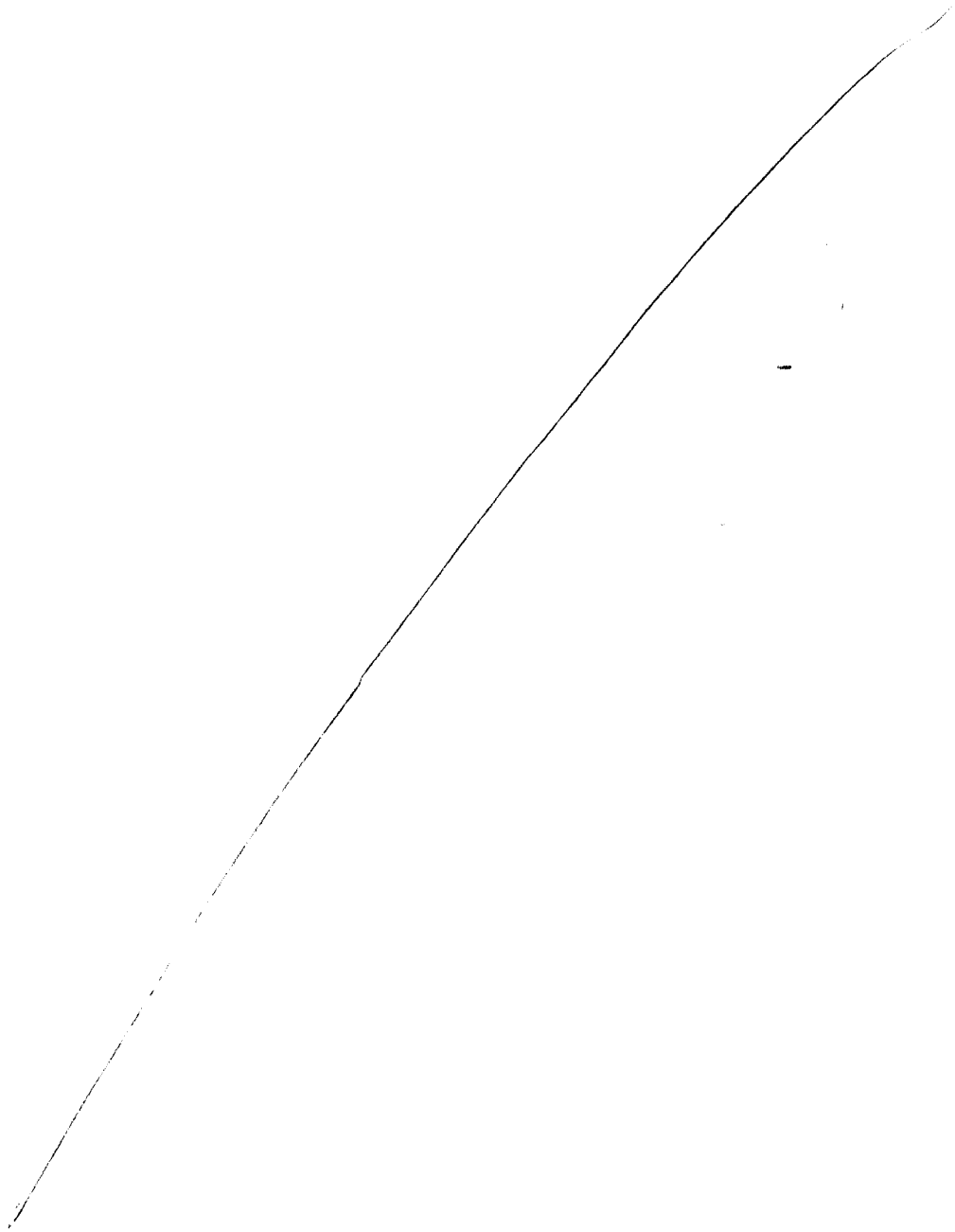




**Section J. Records Audit**








I hope that you find our plan for corrective action appropriate and proper to address the findings of the inspection team. I wish to thank you for your help with the National Laboratory Certification Program. I appreciate the work of the inspection team and the findings of the inspection critique, which will help to improve our drug testing laboratory.

Sincerely,

A handwritten signature in cursive script, appearing to read "H. H. Miller".

H. H. Miller, M.T.(ASCP), Ph.D.  
Laboratory Director and Responsible Person

Insresp600.doc



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 4, 2000

0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

We have reviewed the material provided in your correspondence of June 27, 2000, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 09, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

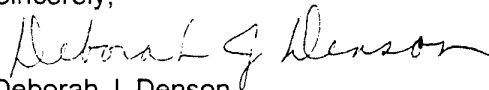


Dr. Miller  
August 4, 2000  
Page 2 of 2

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues 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 Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

  
Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/M18



# RESEARCH TRIANGLE INSTITUTE

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National Laboratory Certification Program

December 27, 2000

0336  
Dr. Harold Miller  
Quest Diagnostics Incorporated  
4770 Regent Blvd.  
Irving, TX 75063

Dear Dr. Miller:

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 highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.




Dr. Miller  
December 27, 2000  
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.

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

Dr. Miller  
December 27, 2000  
Page 3 of 3

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: 0336  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Irving, TX

Document Reviewed:     Application Form  
                               Inspection Report #M19                      Date: 26 October 2000  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable             Acceptable  
                               Unacceptable                 Failure

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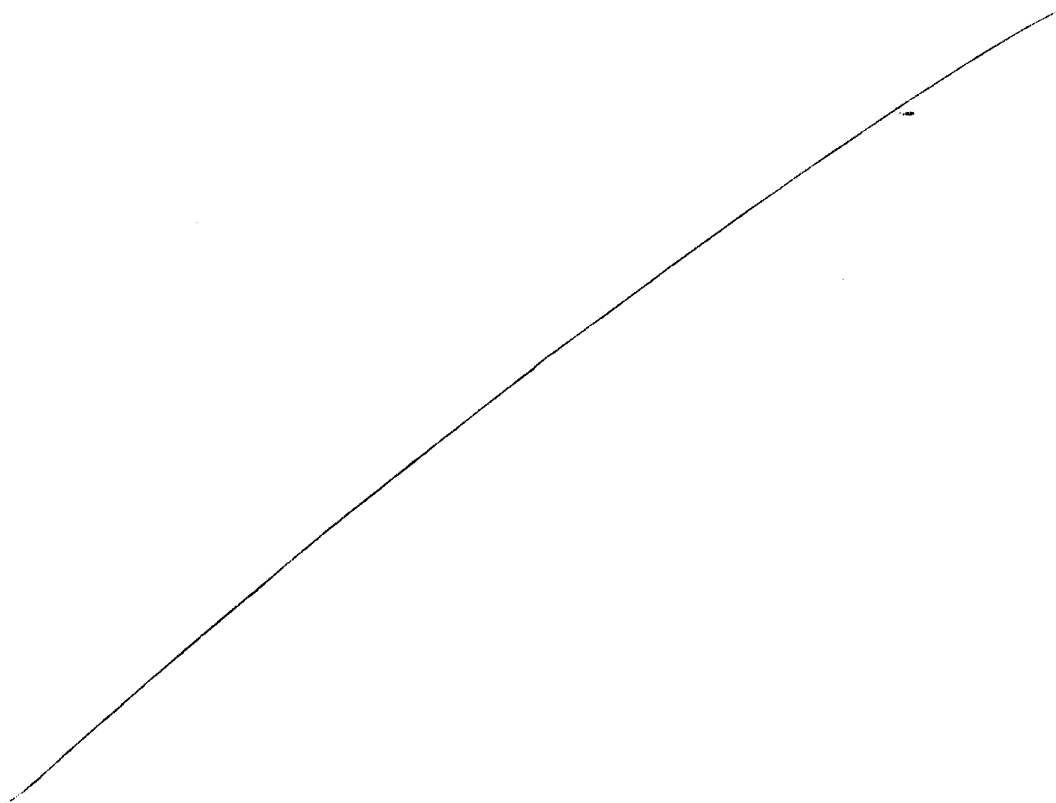
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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



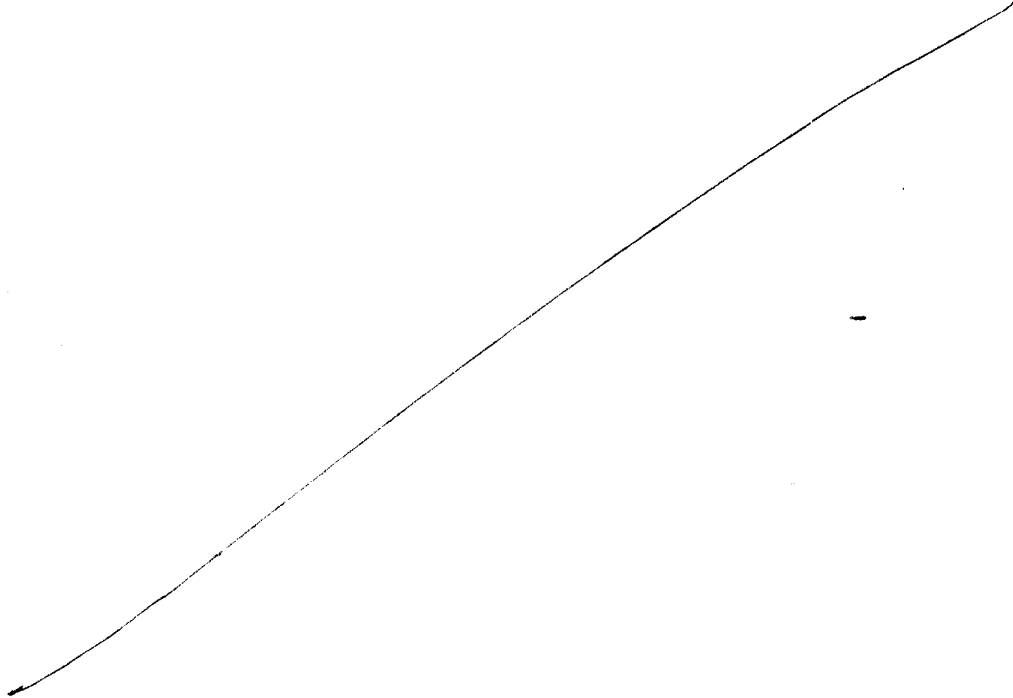
Section F. Chain-of-Custody, Accessioning, and Security



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

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