

# RESEARCH TRIANGLE INSTITUTE



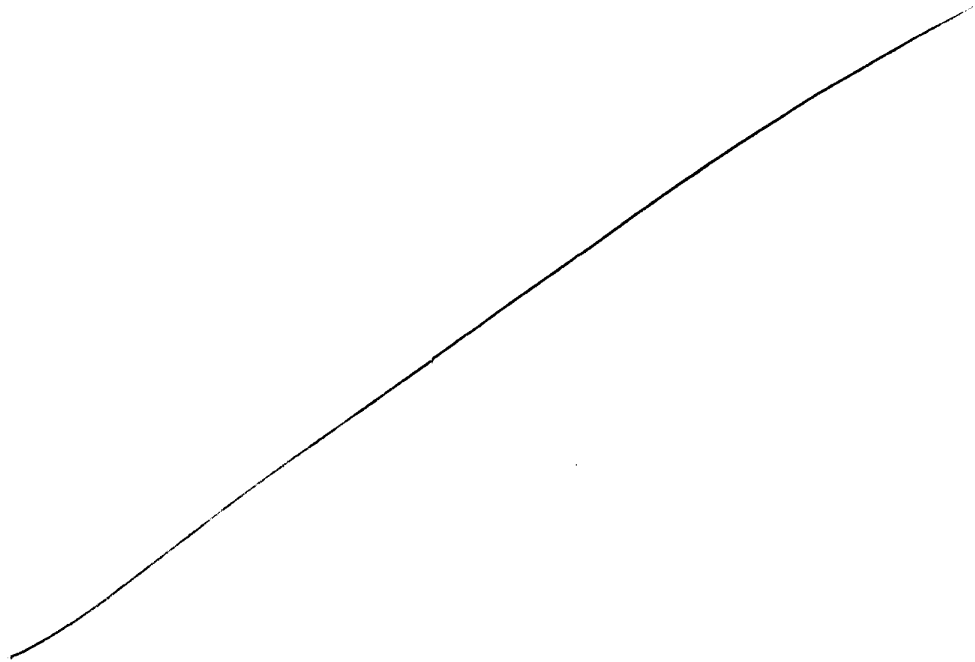
National Laboratory Certification Program

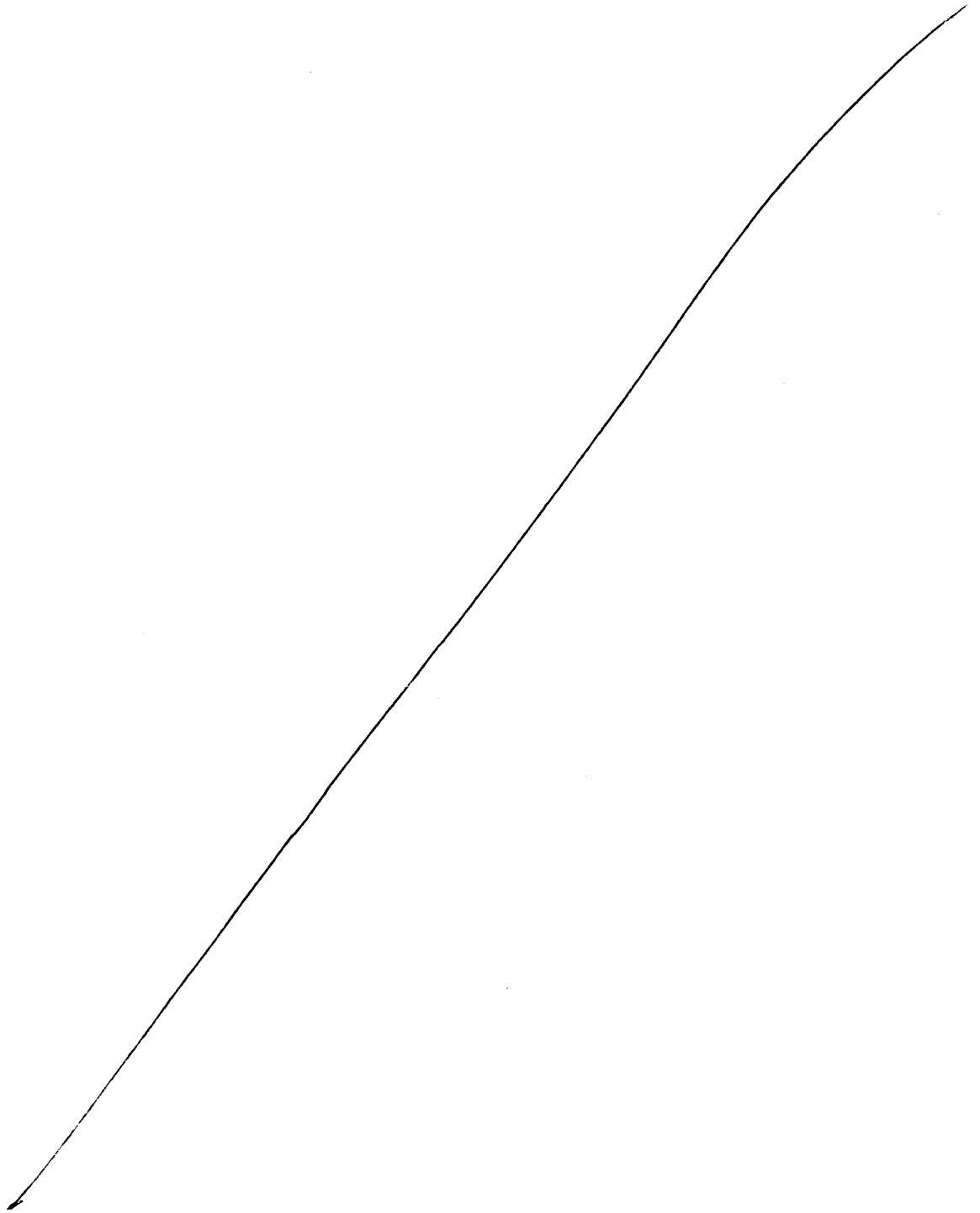
April 22, 1999

0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

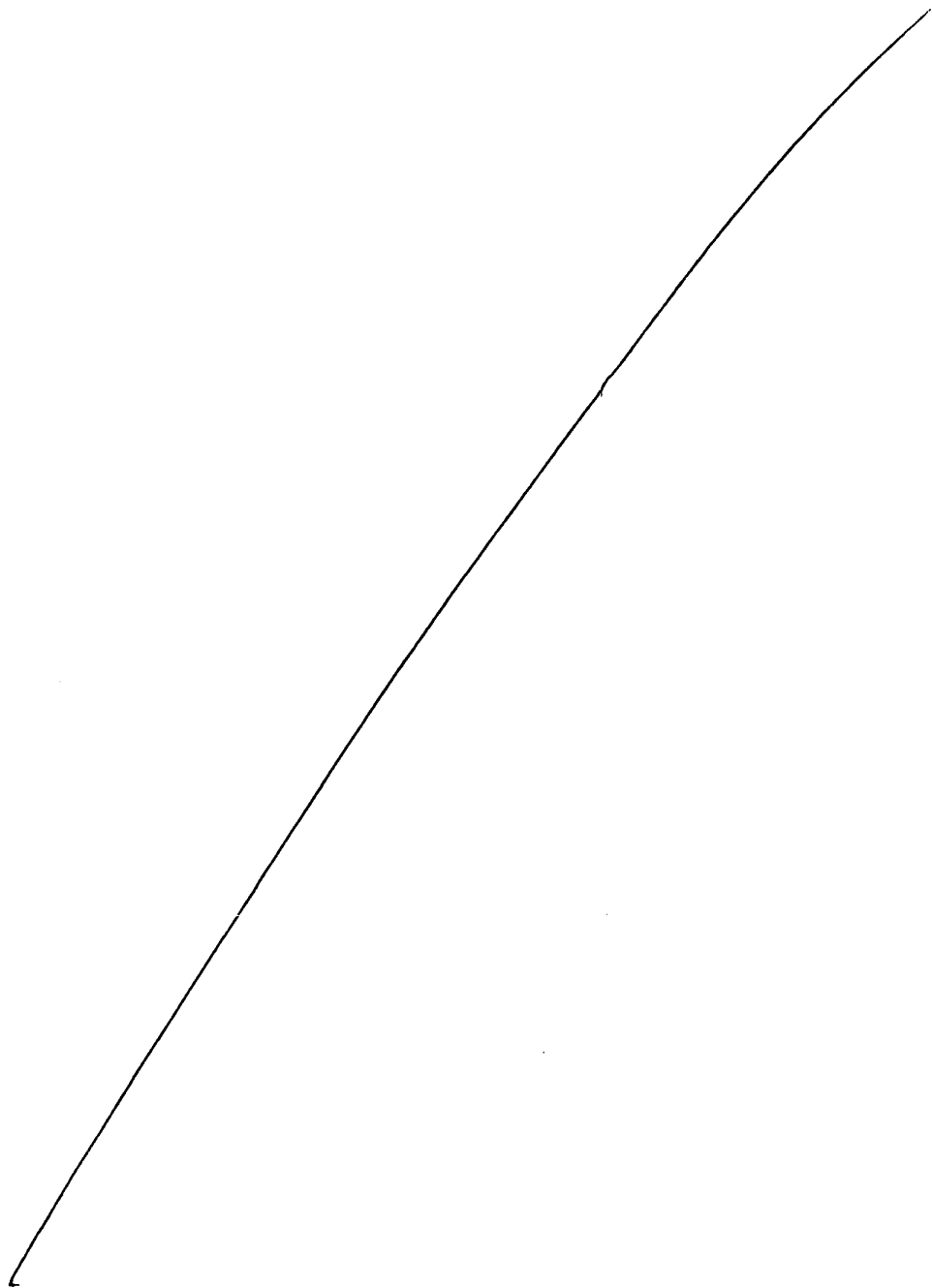
Dear Dr. Bond:

The enclosed critique was developed from the inspection reports of the 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 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:

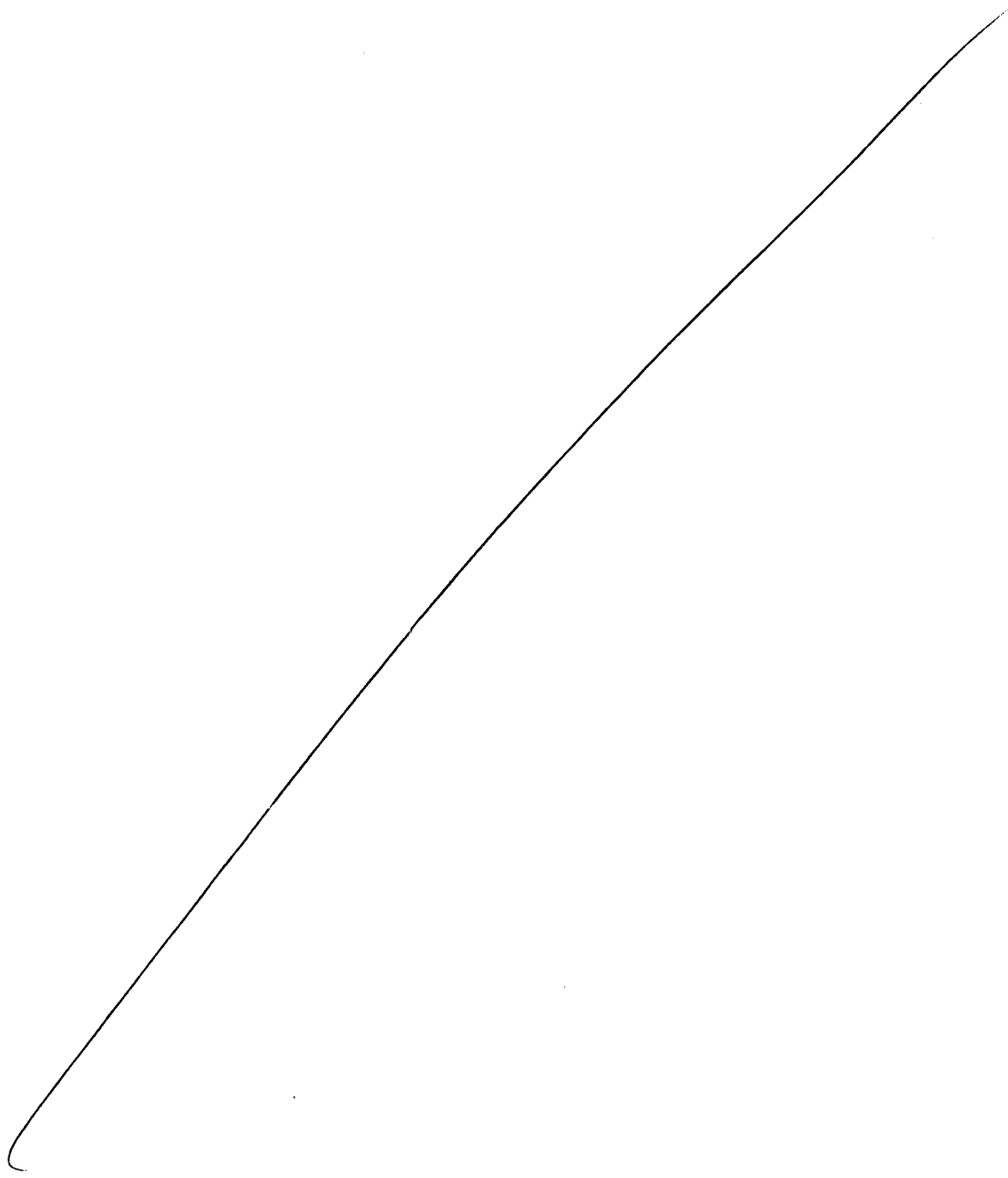




Dr. Bond  
Page 3 of 5  
04/22/99



Dr. Bond  
Page 4 of 5  
04/22/99



Dr. Bond  
Page 5 of 5  
04/22/99

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/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: 0323  
Document No. Final

Laboratory: Quest Diagnostics of Missouri LLC

Location: St. Louis, MO

Document Reviewed:     Application Form  
                               Inspection Report #M10                      Date: 25 February 1999  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                          Failure

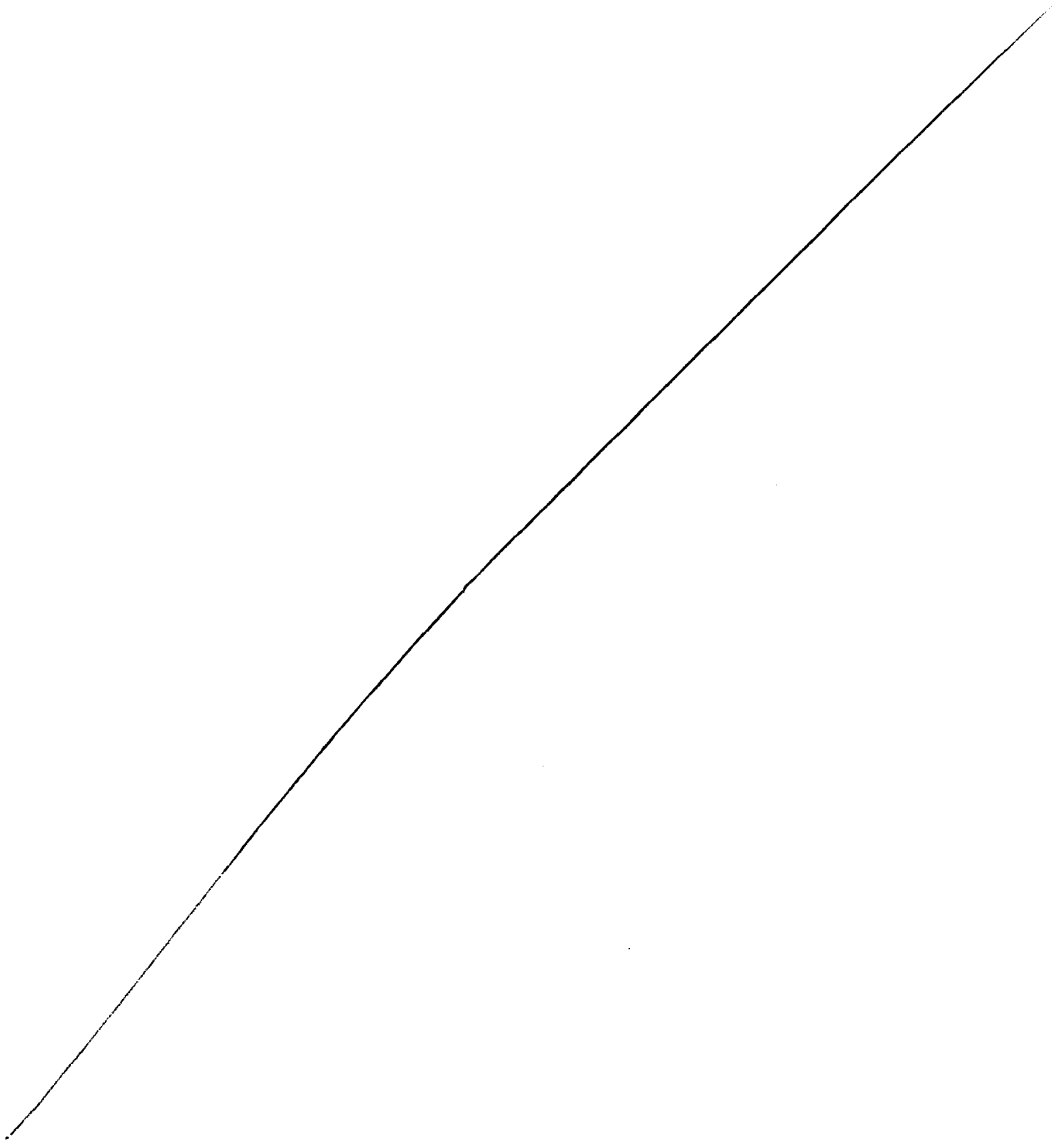
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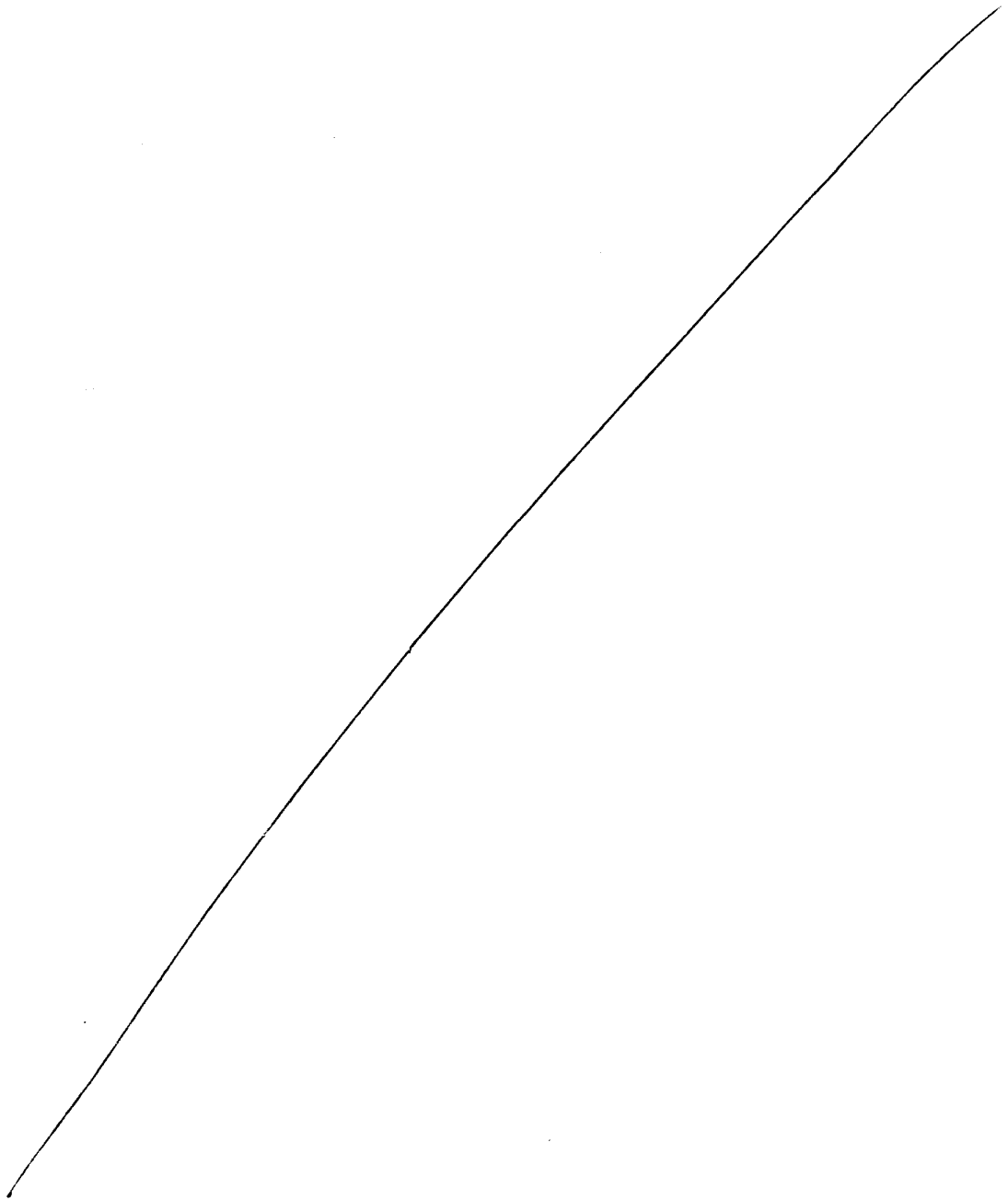
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required 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.

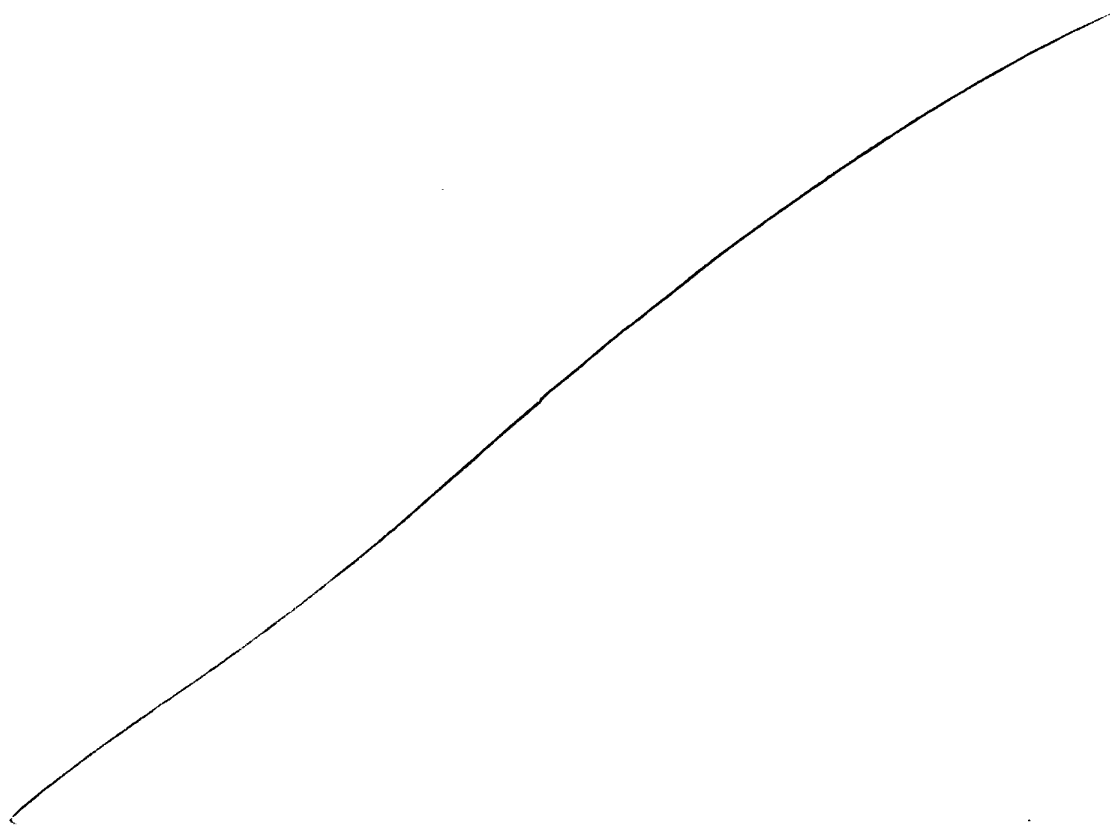
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

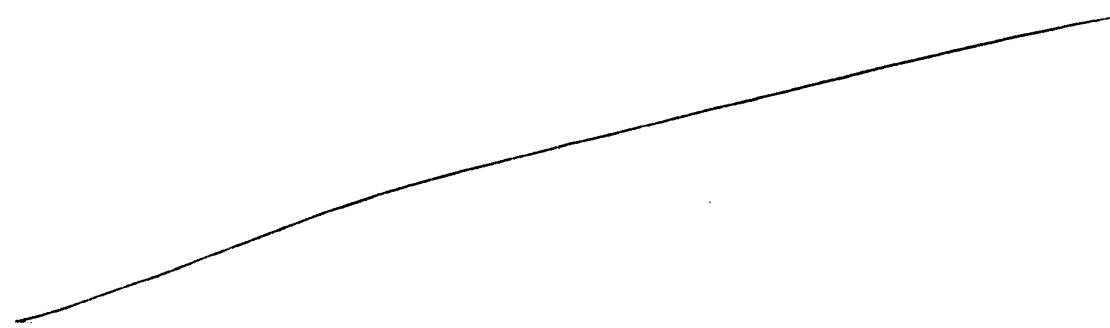




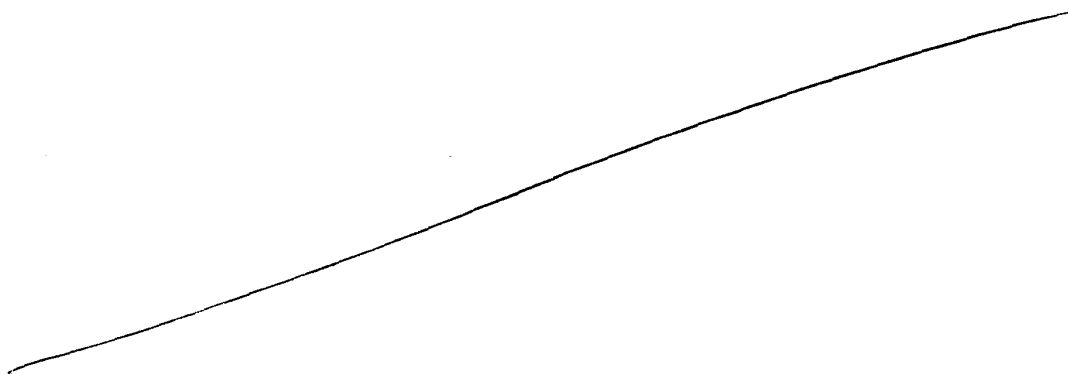




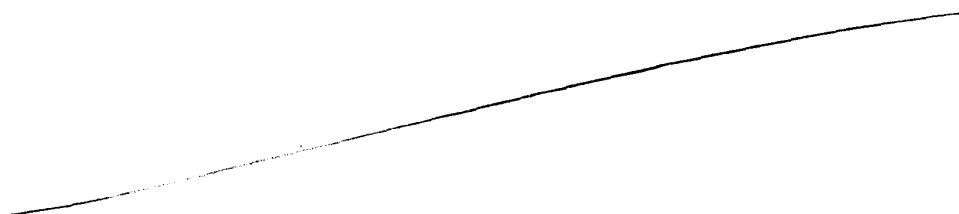
**Section F. Chain-of-Custody, Accessioning, and Security**



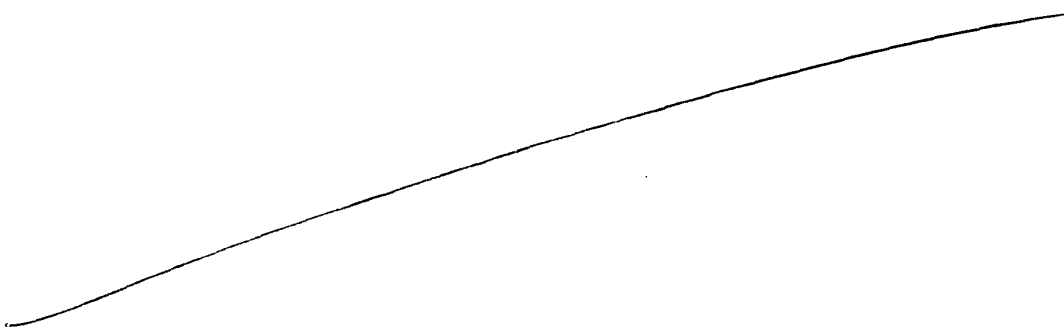
Section G. Quality Control

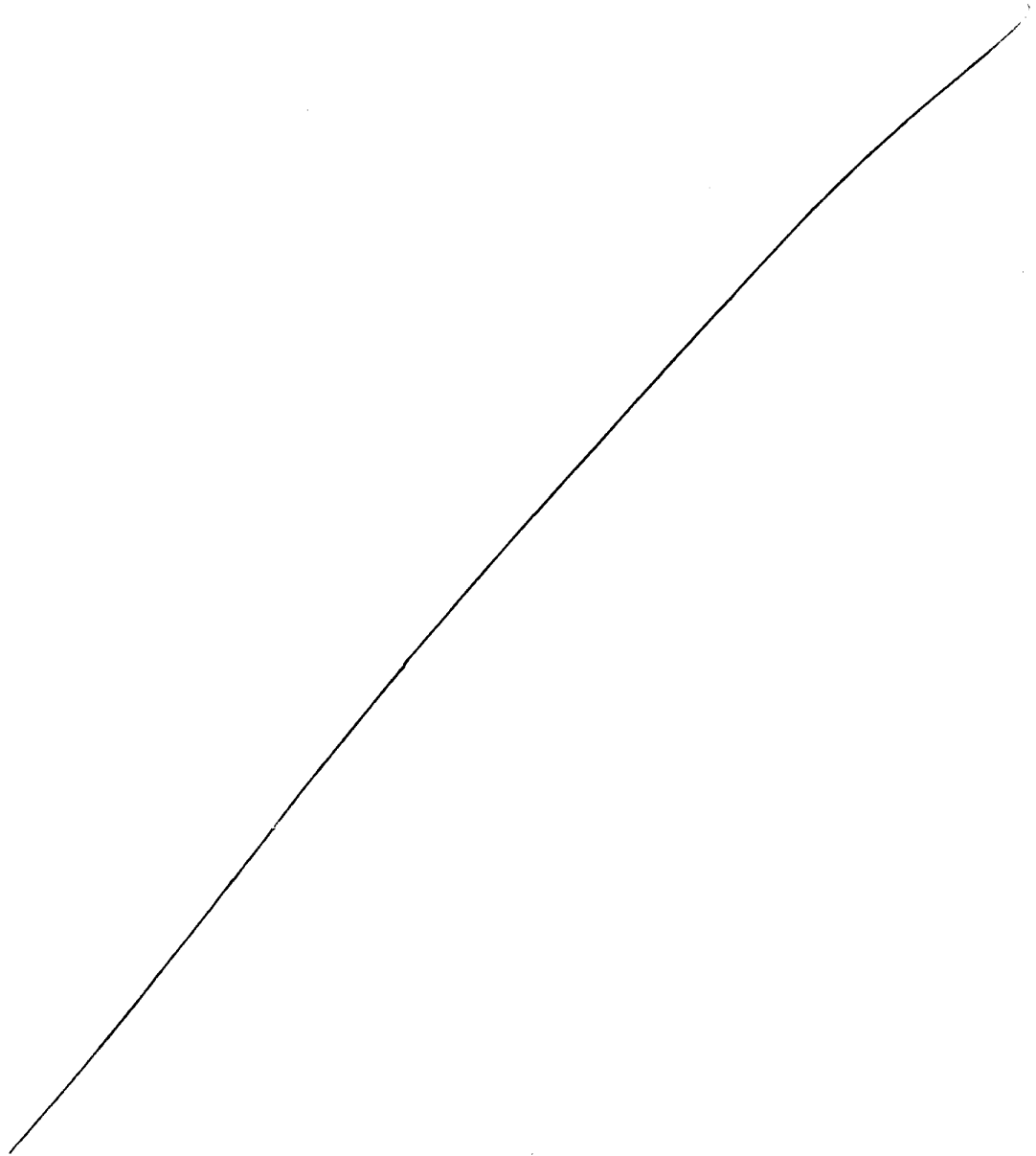


**Section H. Initial Tests**



**Section I. Confirmatory Tests**





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**Section J. Records Audit**

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**Section K. Reporting**

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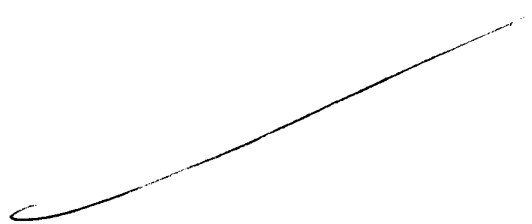
**Section L. Computers, Software, and LIMS**

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**Section M. Equipment and Maintenance**

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**Section N. Personnel**



**Quest Diagnostics LLC**  
*A Partner with Your Health*

2320 Schuetz Road  
St. Louis, Missouri 63146  
314.991.1311  
800.288.7293  
314.997.7112 FAX

**received**  
513199 SDC  
(arrived 4/30/99)

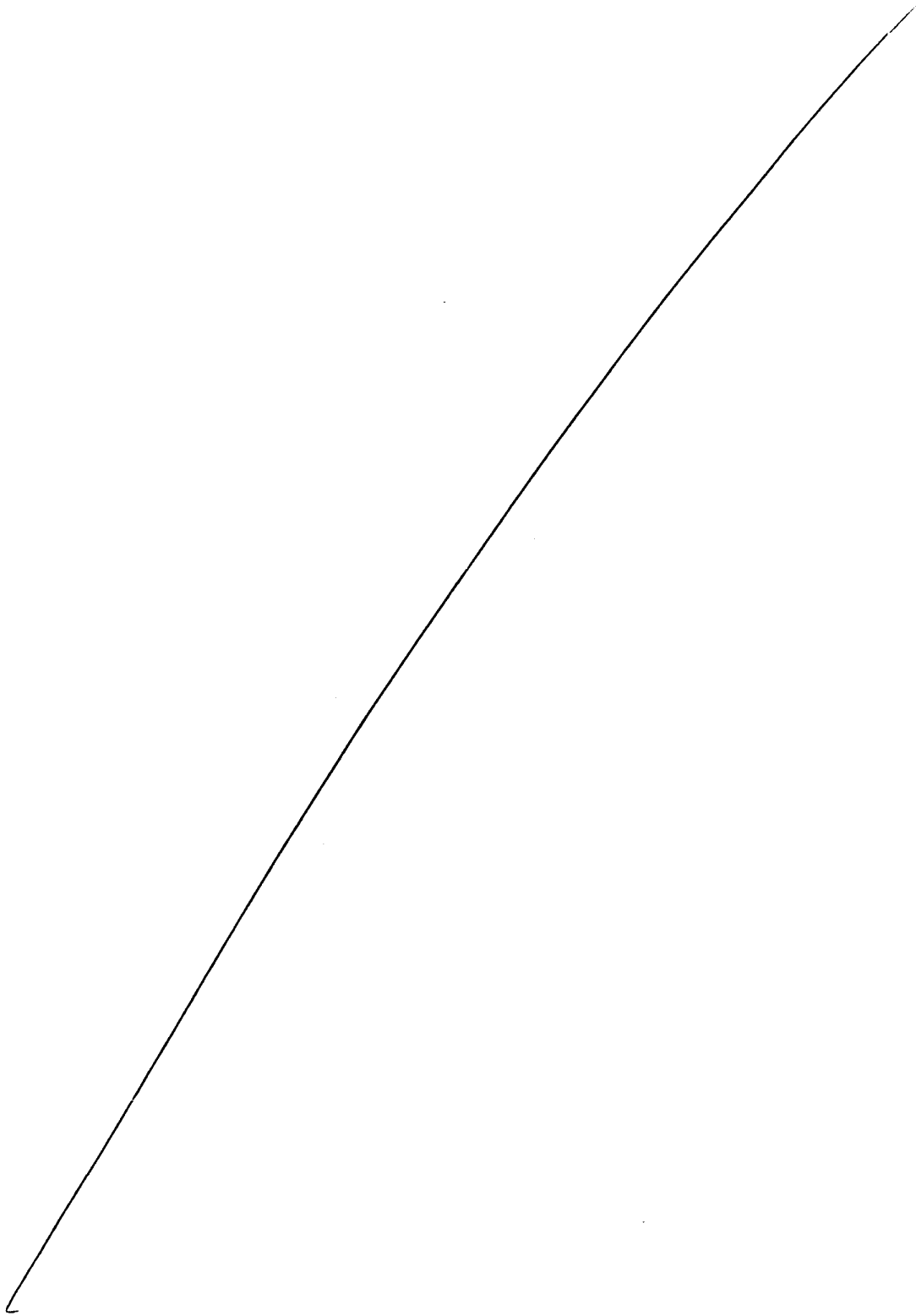


April 29, 1999

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

Dear Ms. Crumpton:

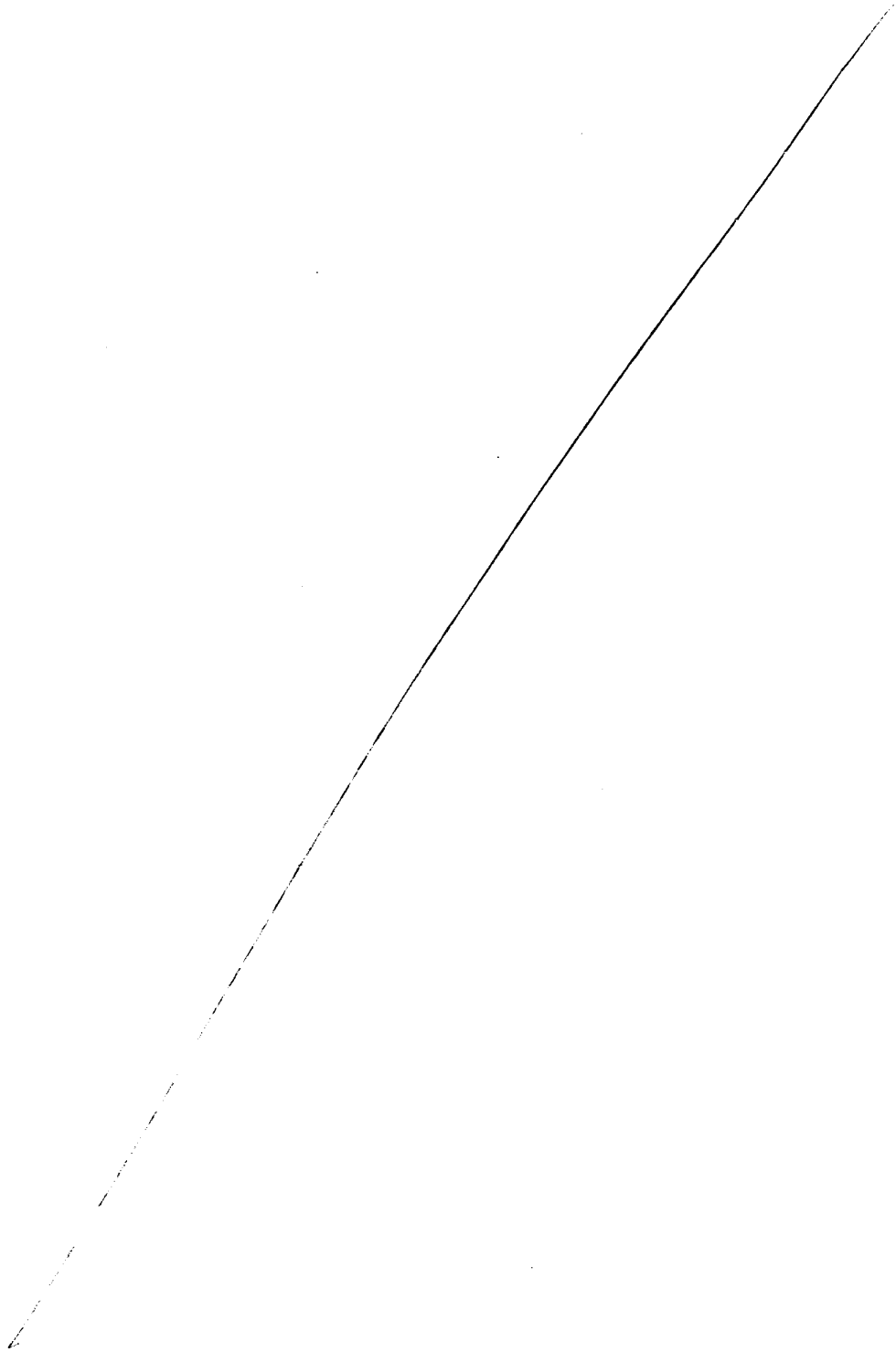
The following is our plan of action to correct the deficiencies cited during the tenth maintenance inspection of our laboratory.



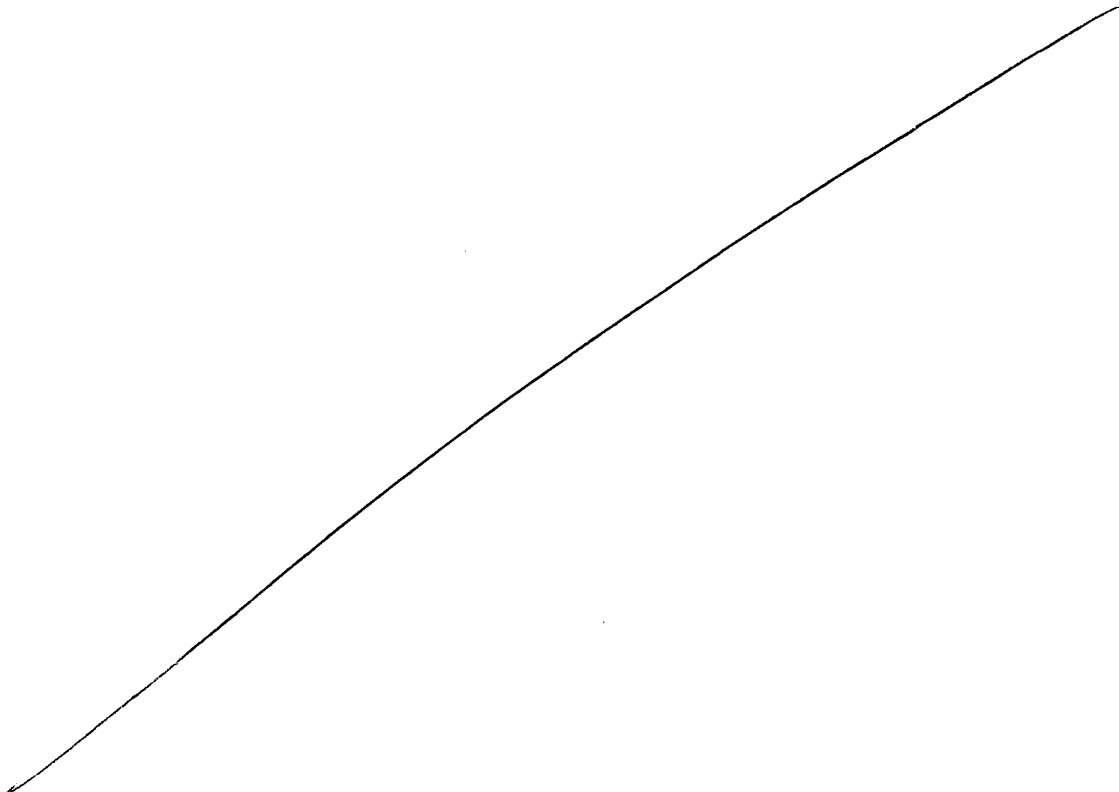




**G. Quality Control Section:**



J. Records section:



Sincerely,

A handwritten signature in cursive script, appearing to read "Lawrence W. Bond".

Lawrence W. Bond, Ph.D.  
Responsible Person

**Quest Diagnostics LLC**  
*A Partner with Your Health*

2920 Schuetz Road  
St. Louis, Missouri 63146  
314.991.1311  
800.288.7293  
314.997.7112 FAX

**received**  
SDC 6/2/99

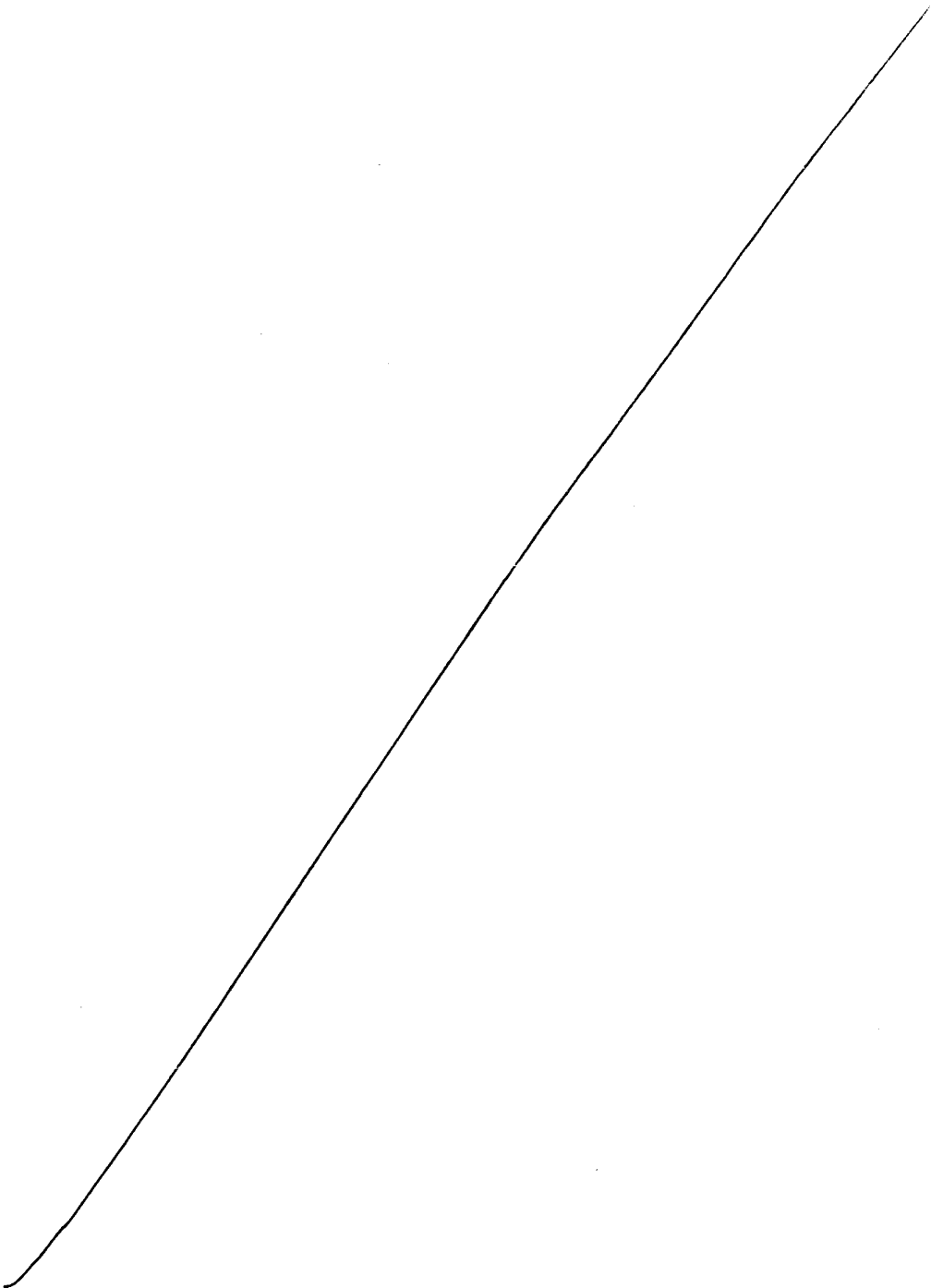


June 3, 1999

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

Dear Ms. Crumpton:

The following is our response to the plan you approved to correct the deficiencies cited during the tenth maintenance inspection of our laboratory. The following document is an expanded version of the approved plan which addresses each item mentioned by the inspection report.



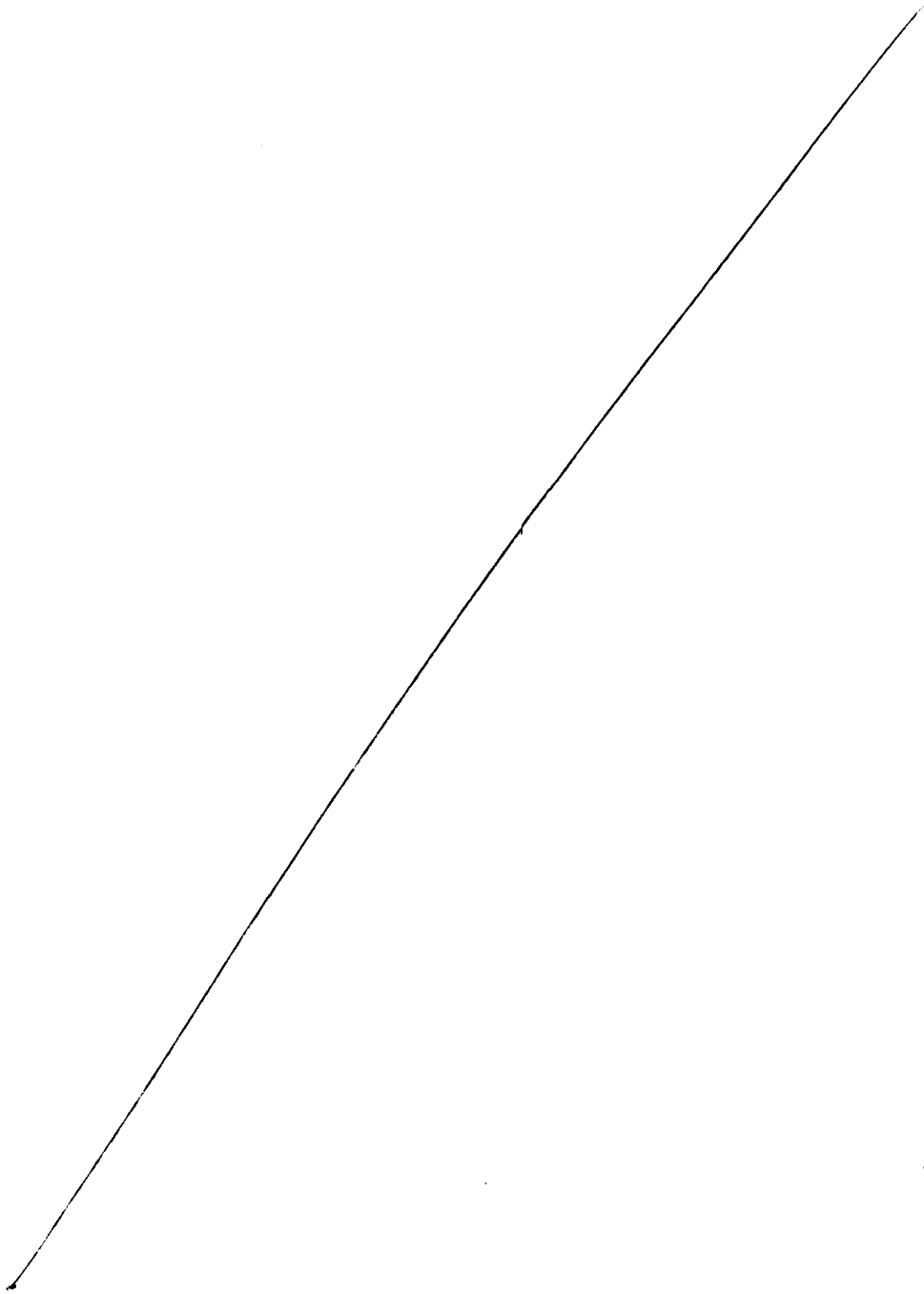


**F. Chain-of-Custody, Accessioning, and Security Sections:**



**G. Quality Control Section:**





4

*[A large, faint, curved line, possibly a signature or a scan artifact, spans across the upper half of the page.]*

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Sincerely,

*[Handwritten signature of Lawrence W. Bond]*

Lawrence W. Bond, Ph.D.  
Responsible Person



June 9, 1999

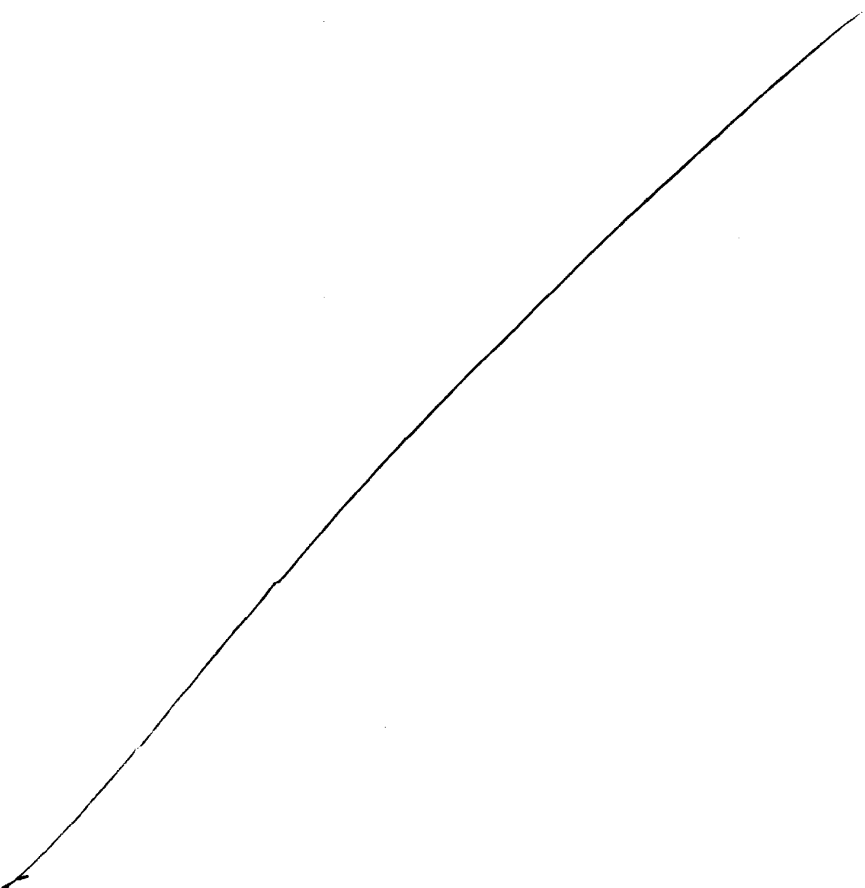
0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

Dear Dr. Bond:

We have reviewed the material provided in your correspondence of June 3, 1999, submitted in response to deficiencies cited during the tenth maintenance inspection of your laboratory as outlined in our correspondence of April 22, 1999. 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. Bond  
Page 2 of 3  
06/09/99



**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 the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (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.**

Dr. Bond  
Page 3 of 3  
06/09/99

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 Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M14

June 24, 1999

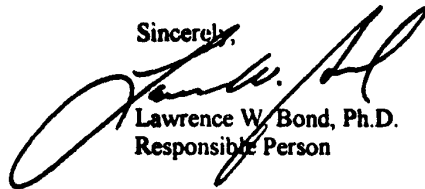
Susan Crumpton  
NLCP Inspection Analyst  
National Laboratory Certification Program  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

The following is our response to your review of our corrections to the deficiencies cited during the tenth maintenance inspection of our laboratory. The following document directly reviews the issues cited in your letter of June 9, 1999 and received by me on June 14, 1999.

I greatly appreciate the suggestions provided in your review, they reflected obvious thoroughness on your part in helping us achieve greater clarity in our SOP and general operations.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence W. Bond". The signature is fluid and cursive, with a large initial "L" and "B".

Lawrence W. Bond, Ph.D.  
Responsible Person

07/01/99

13:00

314 997 7112

QUEST DIAGNOSTIC

00

Quest Diagnostics I.I.C.  
A Partner with Your Health

2320 Schluetz Road  
St. Louis, Missouri 63146  
314.991.1311  
800.288.7293  
314.997.7112 Fax

**received**  
7/1/99 SDG  
Mem HS



July 1, 1999

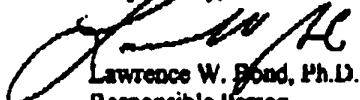
Susan Crumpton  
NLCP Inspection Analyst  
National Laboratory Certification Program  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

The following is our response to your phone call today. Attached you will find our updated SOP for performing new or modified initial screening procedures. This procedure was written based upon the recommended guidelines by NLCP.

I hope this is satisfactory based upon our conversation of this morning

Respectfully,

  
Lawrence W. Bond, Ph.D.  
Responsible Person  
Quest Diagnostics, I.I.C.  
St. Louis, MO 63146



July 8, 1999

0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

Dear Dr. Bond:

We have reviewed the material provided in your correspondence of June 24, 1999, and your faxed correspondence of July 1, 1999, submitted in response to deficiencies cited during the tenth maintenance inspection of your laboratory as outlined in our correspondence of June 9, 1999, and our telephone conversation of July 1, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the deficiencies cited. The following is a review of the material submitted:

Dr. Bond  
Page 2 of 2  
07/08/99

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. (919) 541-7043.

Sincerely,



Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/M10





# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 7, 1999

0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

Dear Dr. Bond:

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



Dr. Bond  
Page 2 of 2  
10/07/99

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised in section E. 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 Inspection Analyst

Enclosure

cc: Project Files/323



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

---

Laboratory I.D. Number: 0323  
Document No. Final

Laboratory: Quest Diagnostics of Missouri LLC

Location: St. Louis, MO

Document Reviewed:      Application Form  
                                  Inspection Report #M11             Date: 26 August 1999  
                                  Other \_\_\_\_\_

Status:            Highly Acceptable            Acceptable  
                      Unacceptable                Failure

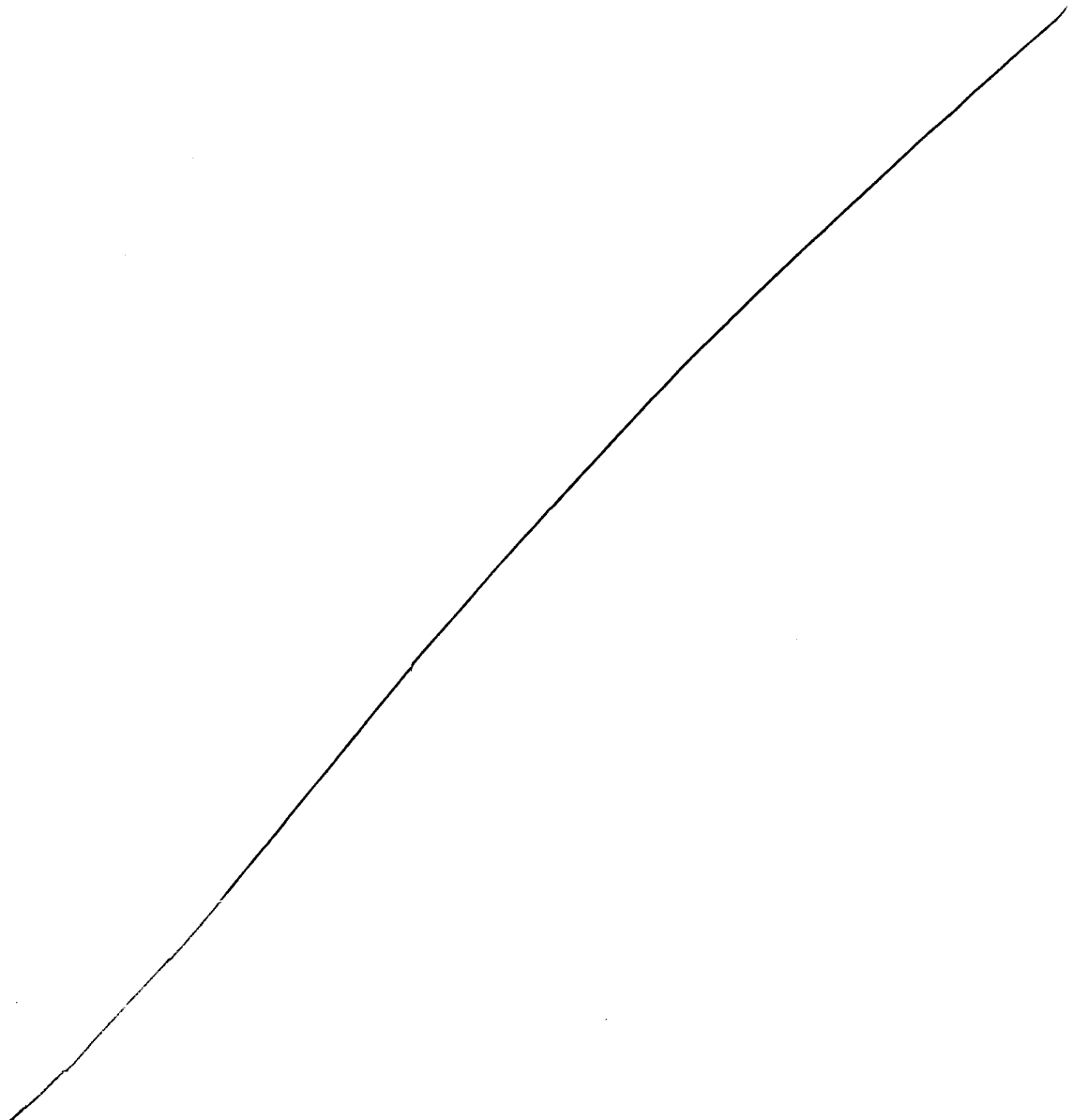
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Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required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

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

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

Section E. Standard Operating Procedures - Procedures Manual



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

Section G. Quality Control

Section H. Initial Tests

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 LLC  
A Partner with Unity Health

2320 Schuetz Road  
St. Louis, Missouri 63146  
314.991.1311  
800.288.7293  
314.997.7112 FAX

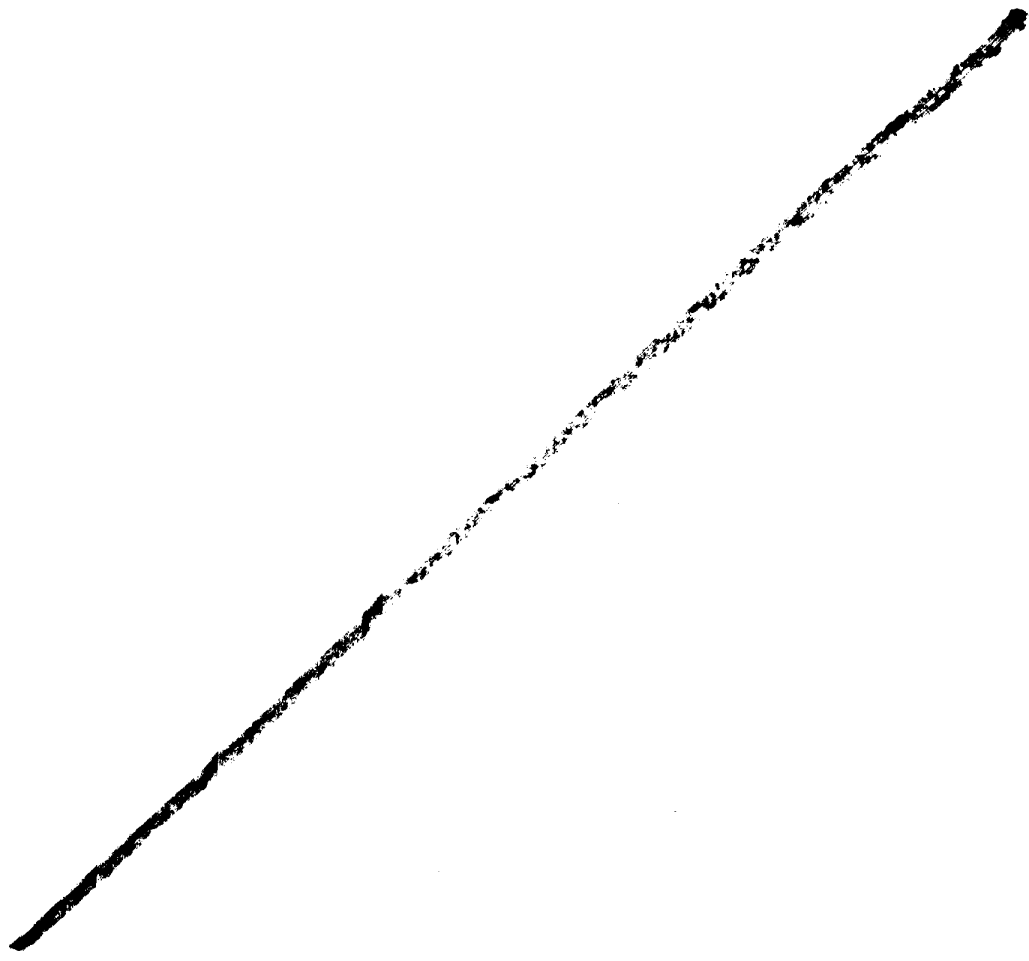
received  
SDC 11/8/99



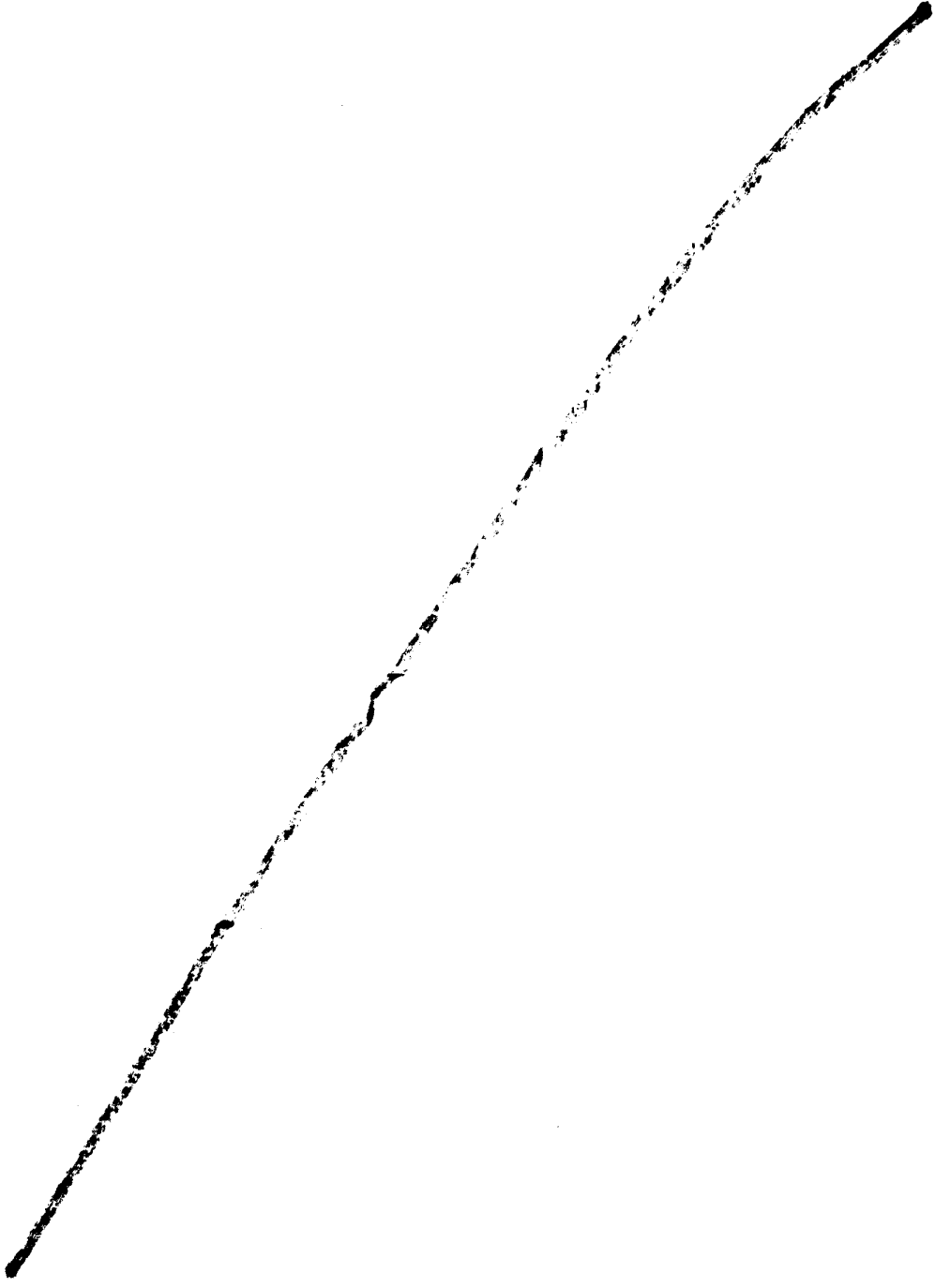
November 4, 1999

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

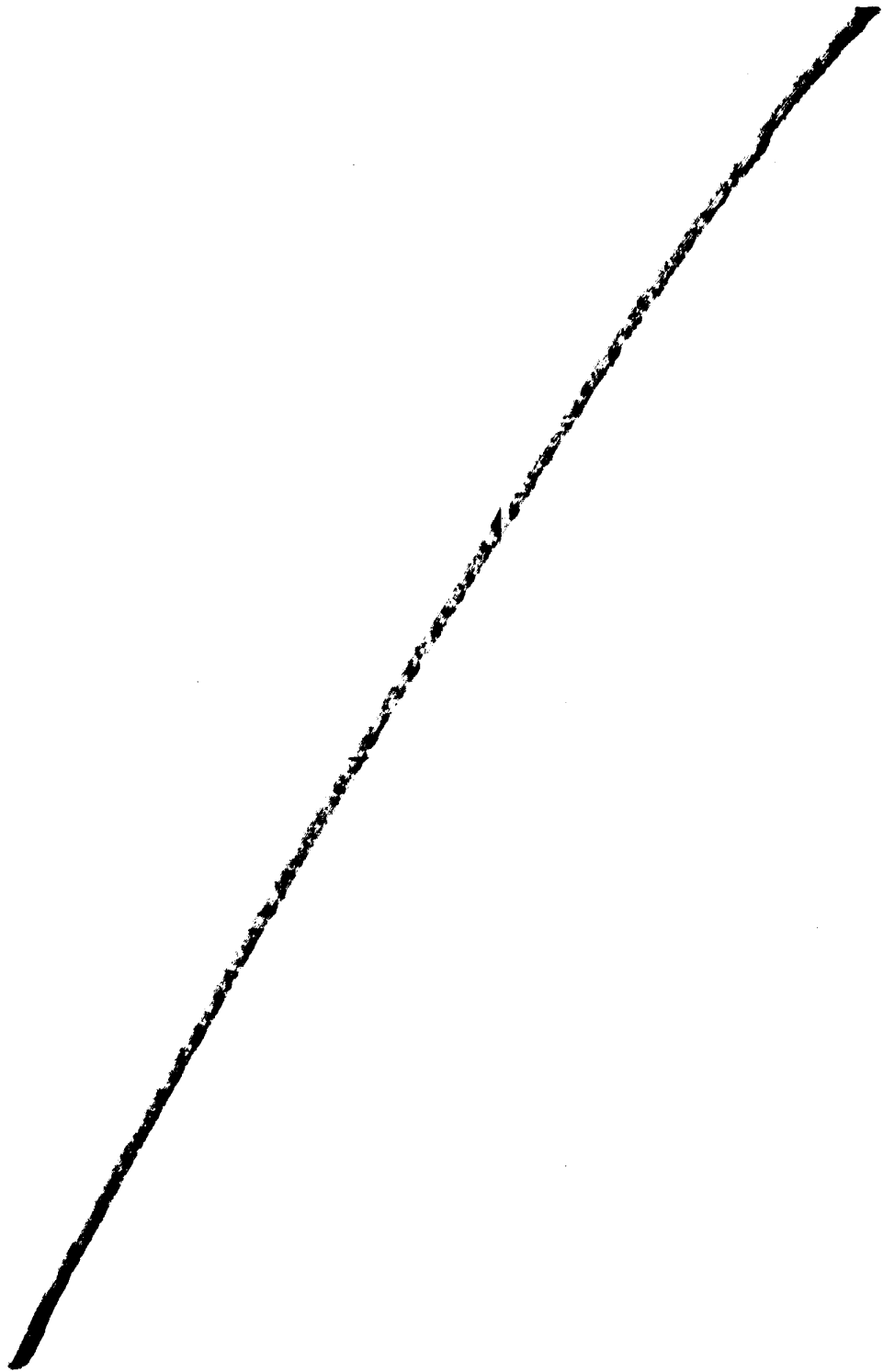
Dear Ms. Crumpton:



Section E. Standard Operating Procedures – Procedures Manual



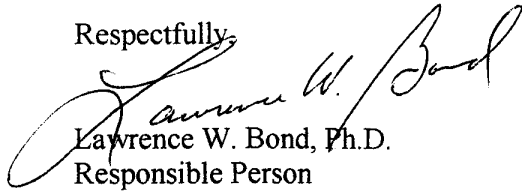




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Respectfully,

A handwritten signature in black ink, appearing to read "Lawrence W. Bond". The signature is written in a cursive style with a large initial "L" and "B".

Lawrence W. Bond, Ph.D.  
Responsible Person  
Quest Diagnostics, LLC  
St. Louis, MO 63146



# RESEARCH TRIANGLE INSTITUTE

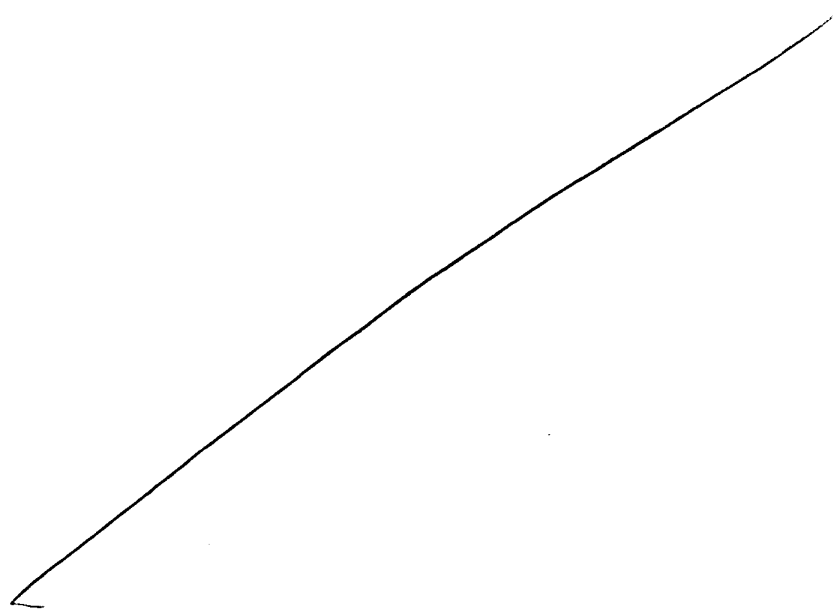
National Laboratory Certification Program

November 11, 1999

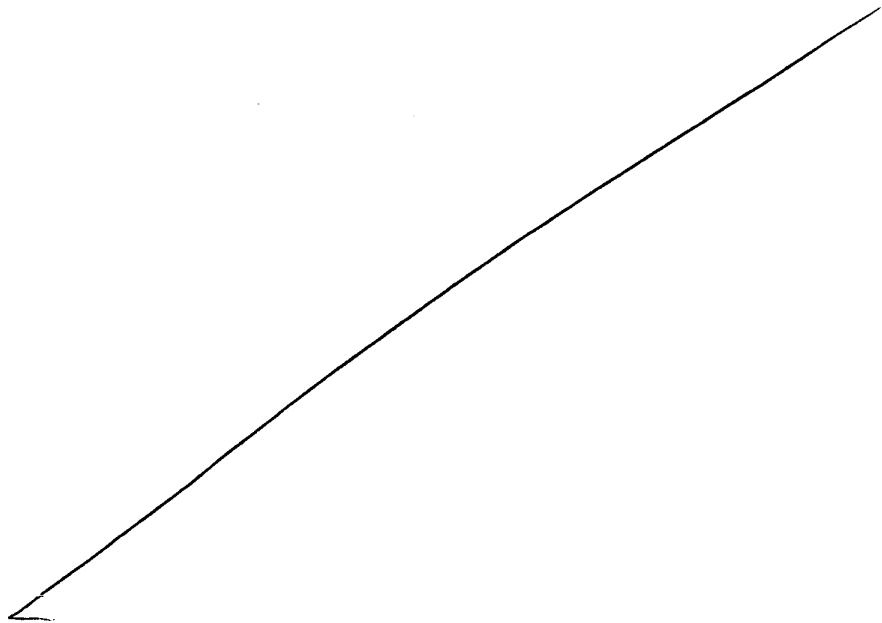
0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

Dear Dr. Bond:

We have reviewed the material provided in your correspondence of November 4, 1999, submitted in response to issues raised during the eleventh maintenance inspection of your laboratory as outlined in our correspondence of October 7, 1999. The information submitted by the laboratory appears to demonstrate that the laboratory is taking appropriate corrective actions to address the issues raised. However, the following items were noted during our review of submitted standard operating procedure (SOP) revisions:



Dr. Bond  
Page 2 of 2  
11/11/99



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. The revised SOP manual and its implementation 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 Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,

Susan Crumpton  
NLCP Inspection Analyst

cc: Dr. Michael Baylor  
Project Files/323

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

March 31, 2000

0323  
Dr. Lawrence Bond  
Quest Diagnostics of Missouri LLC  
2320 Schuetz Road  
St. Louis, MO 63146

Dear Dr. Bond:

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. The inspection team had some areas of concern, which are detailed in the attached critique.

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.

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,

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

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

---

Laboratory I.D. Number: 0323  
Document No. Final

Laboratory: Quest Diagnostics of Missouri LLC

Location: St. Louis, MO

Document Reviewed:     Application Form  
                               Inspection Report #M12                      Date: 17 February 2000  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

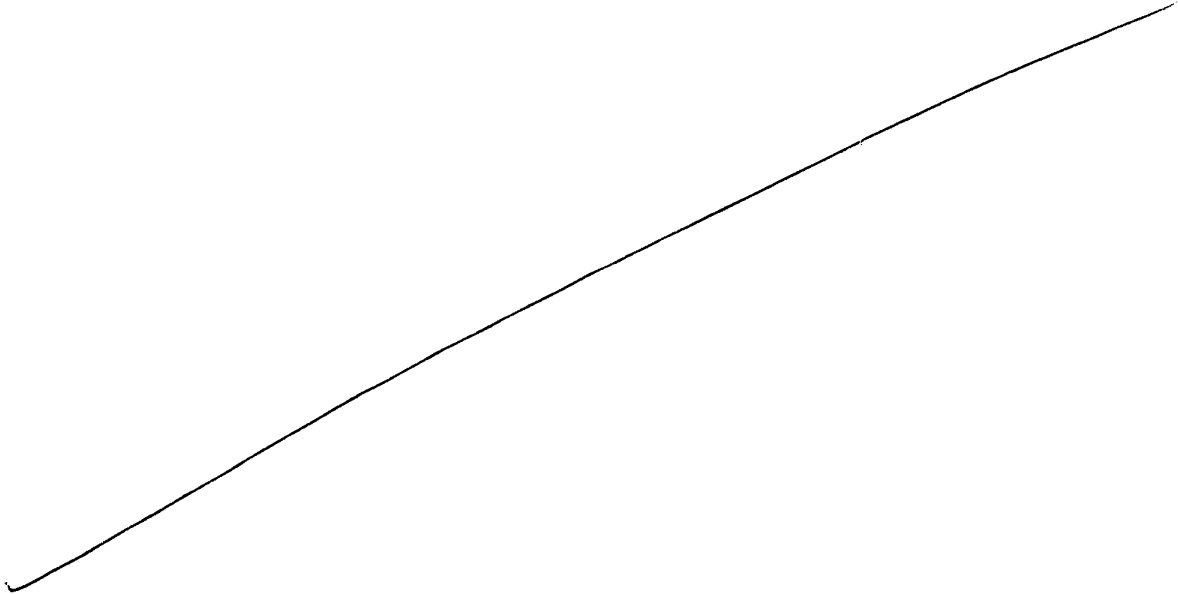
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

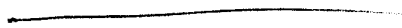
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

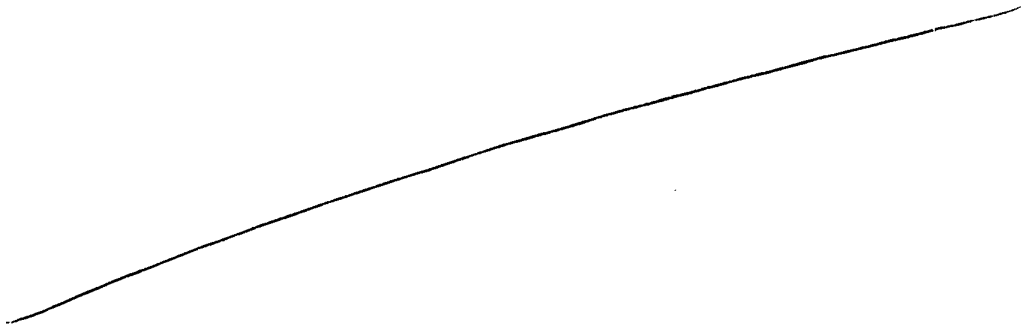
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control





Section H. Initial Tests

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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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