

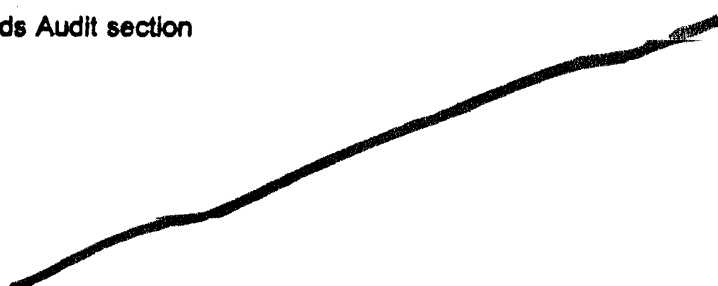
February 12, 1999

0059
Dr. Mohamad Rahmanian
Quest Diagnostics Incorporated
1355 Mittel Boulevard
Wood Dale, IL 60191

Dear Dr. Rahmanian:

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

J. The Records Audit section



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 issue 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 D. Crumpton
NLCP Inspection Analyst



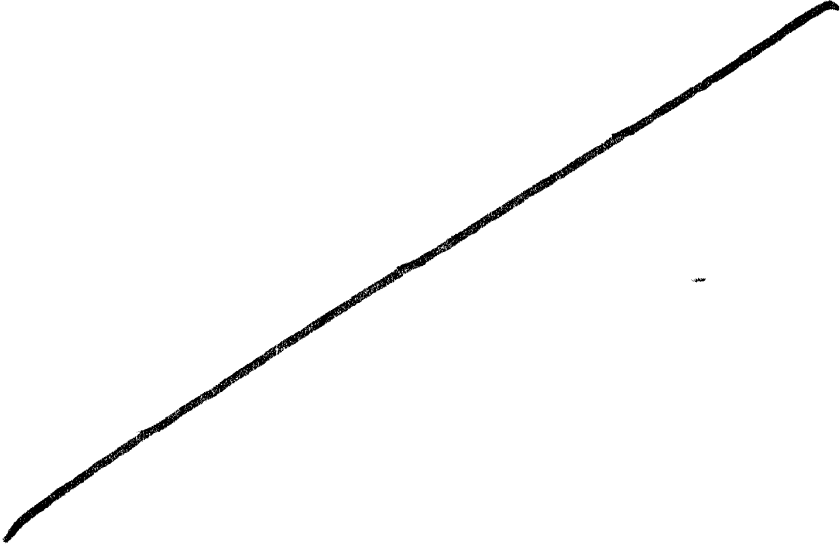
Enclosure

cc: Project Files/M17



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

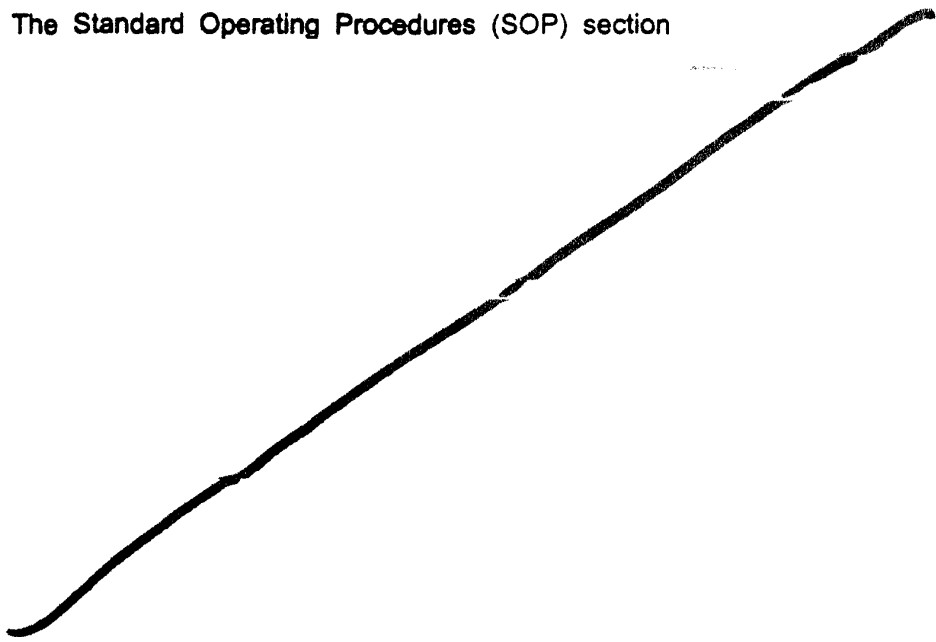
September 3, 1999

0059
Dr. Mohamad Rahmanian
Quest Diagnostics, Inc.
1355 Mittel Boulevard
Wood Dale, IL 60191

Dear Dr. Rahmanian:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the 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:

E. The Standard Operating Procedures (SOP) section

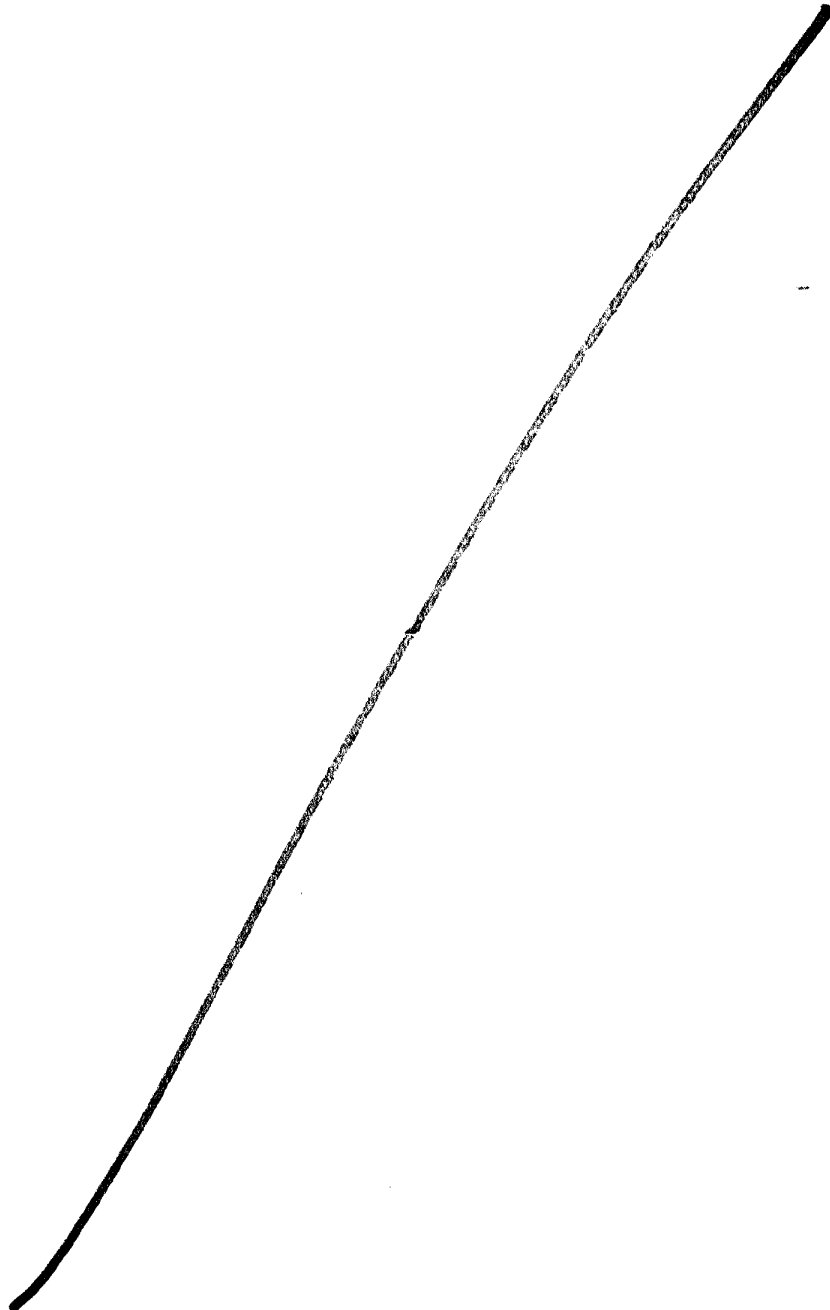


F. The Chain of Custody, Accessioning, and Security section



G. The Quality Control section





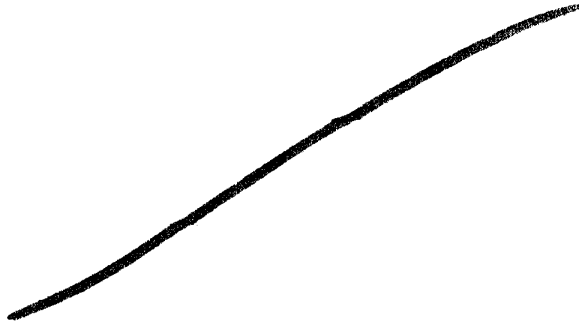
[Redacted text]

H. The Initial Tests section

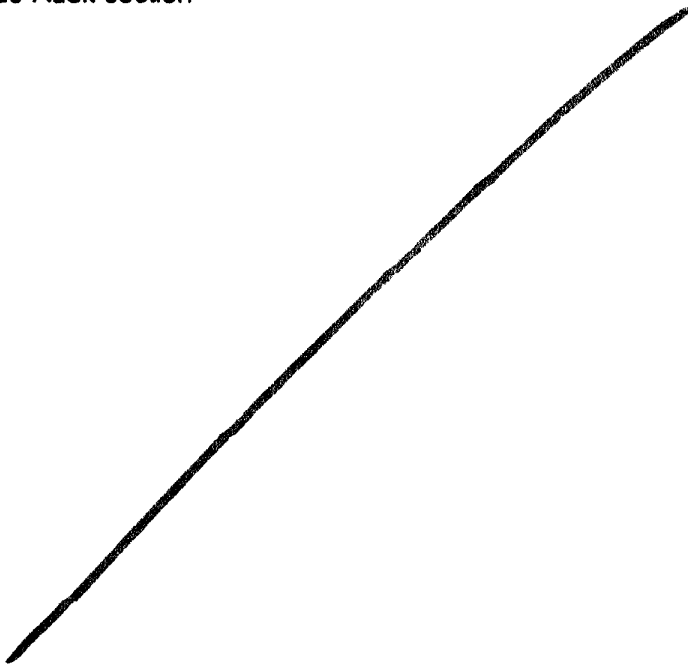
[Redacted text]

I. The Confirmatory Tests section

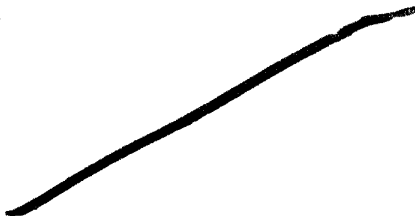
[Redacted text]



J. The Records Audit section



N. The Personnel section



Dr. Rahmanian
Page 6 of 6
09/03/99



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/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0059
Document No. Final

Laboratory: Quest Diagnostics LLC

Location: Wood Dale, IL

Document Reviewed: Application Form
 Inspection Report #M18 Date: 8 July 1999
 Other _____

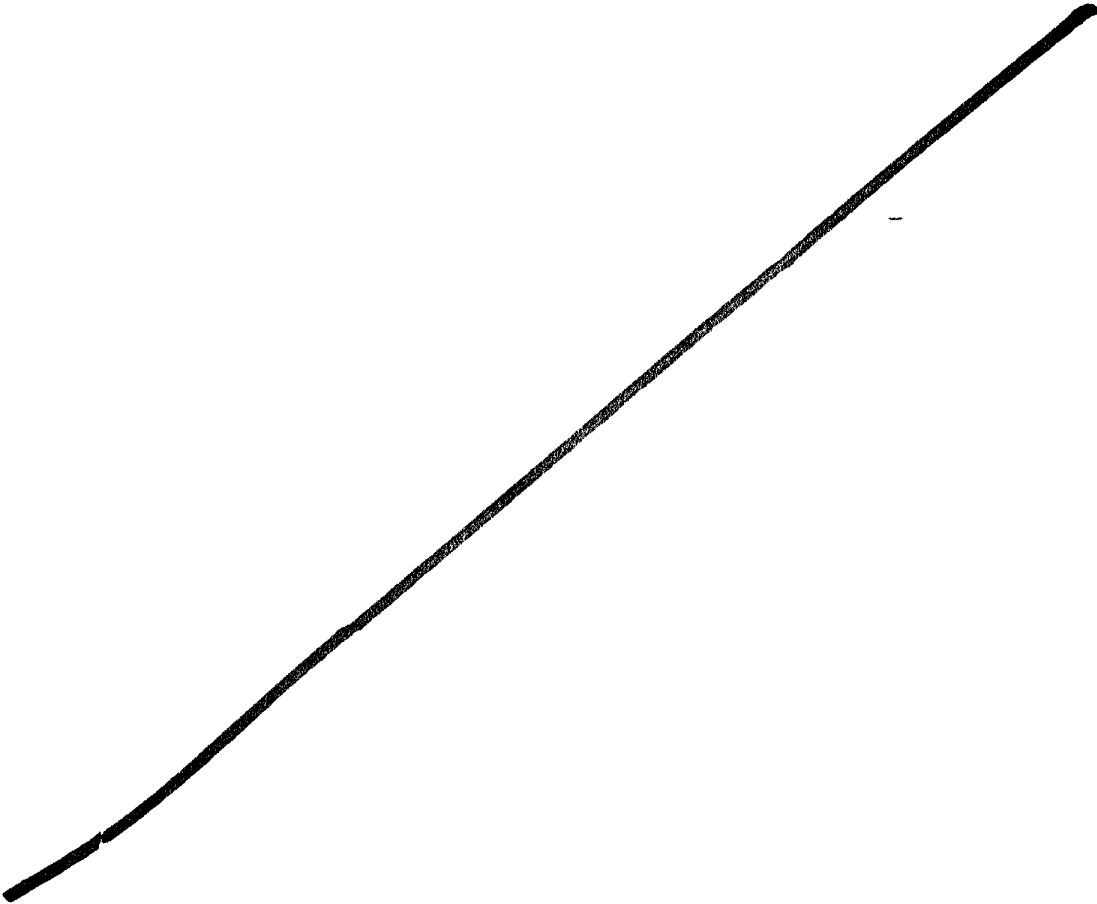
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

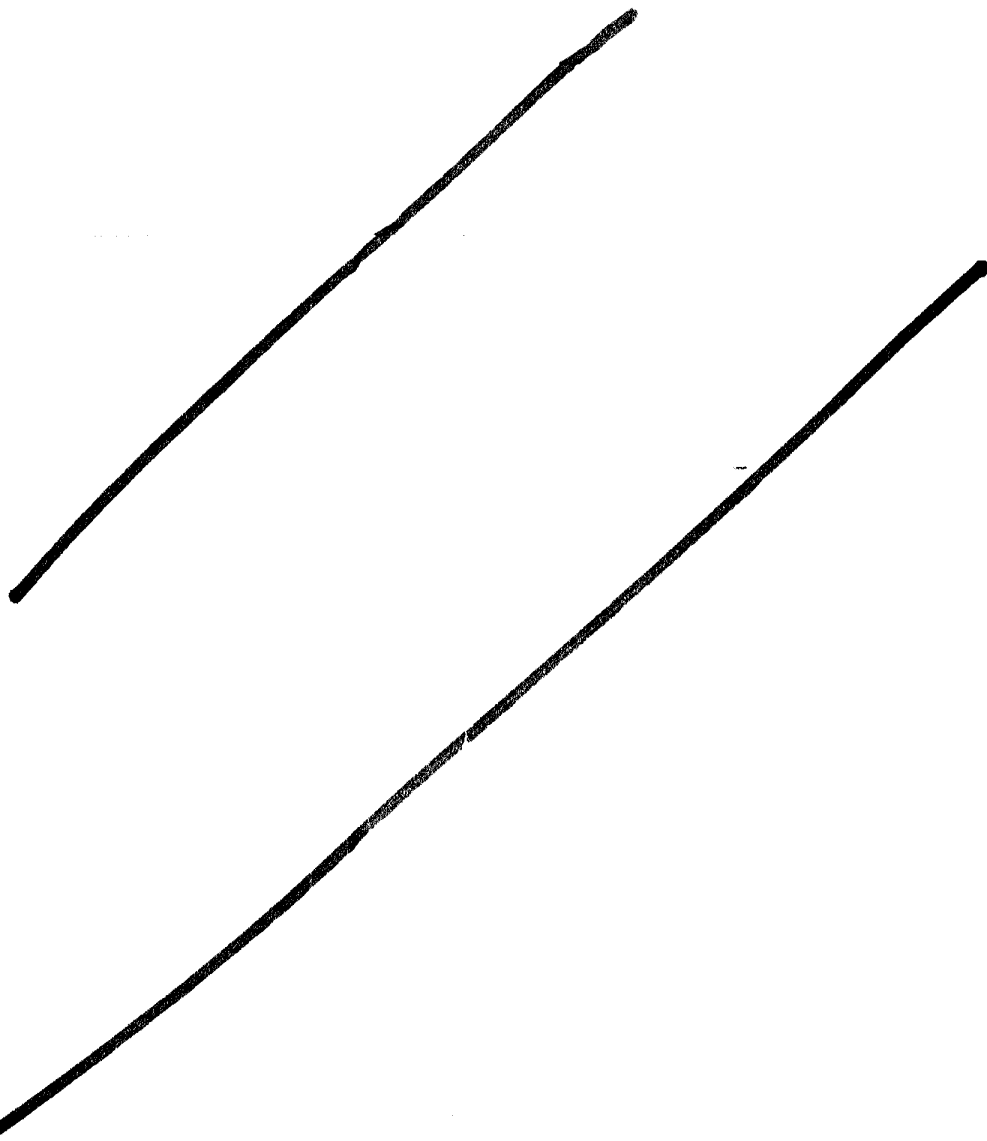
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



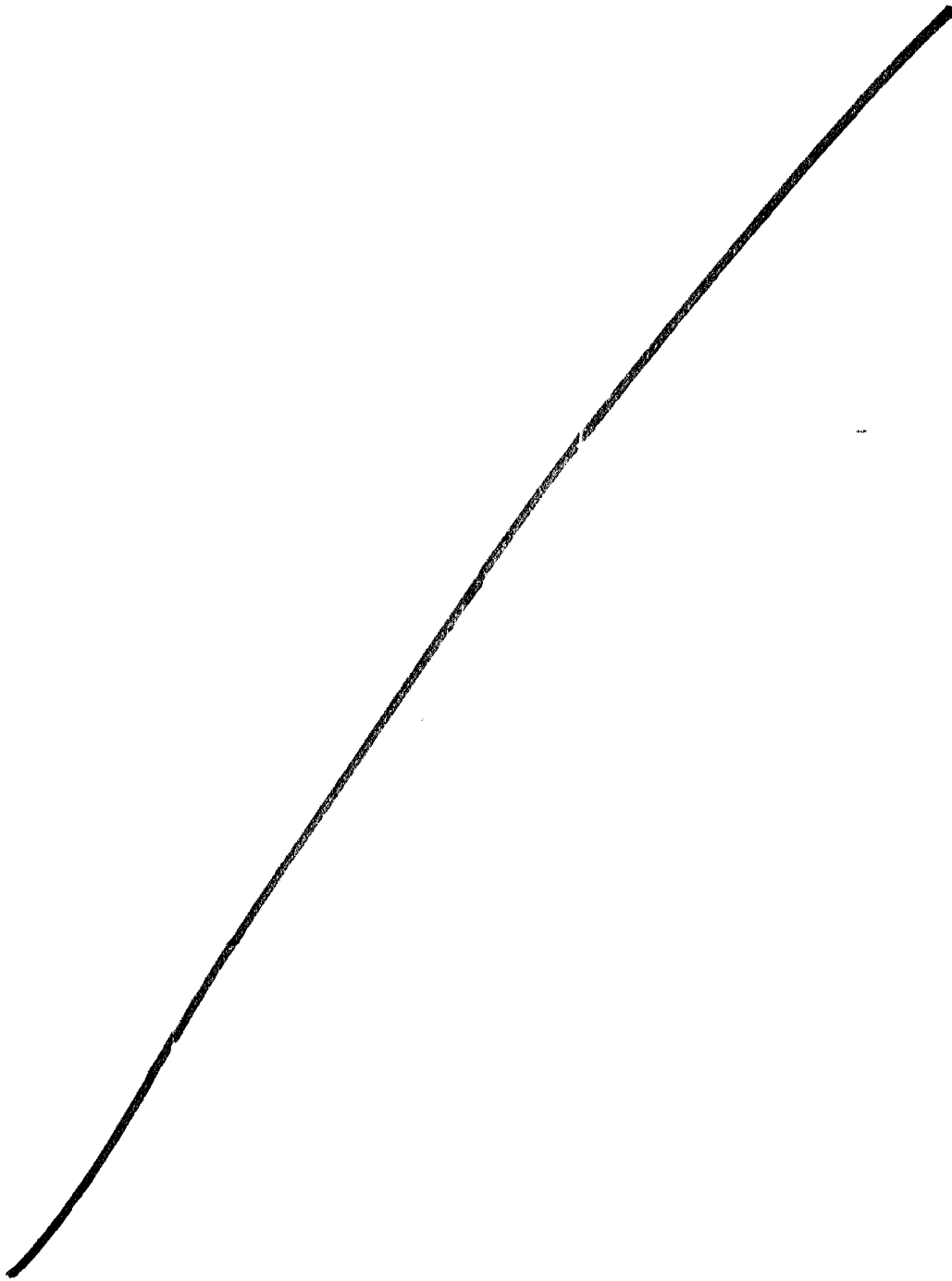
Section F. Chain-of-Custody, Accessioning, and Security





Section G. Quality Control

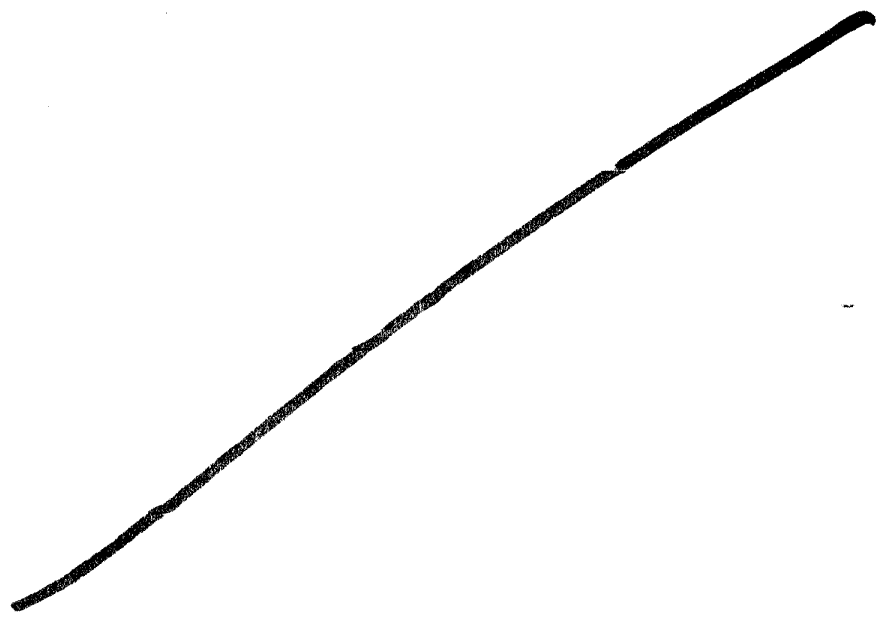




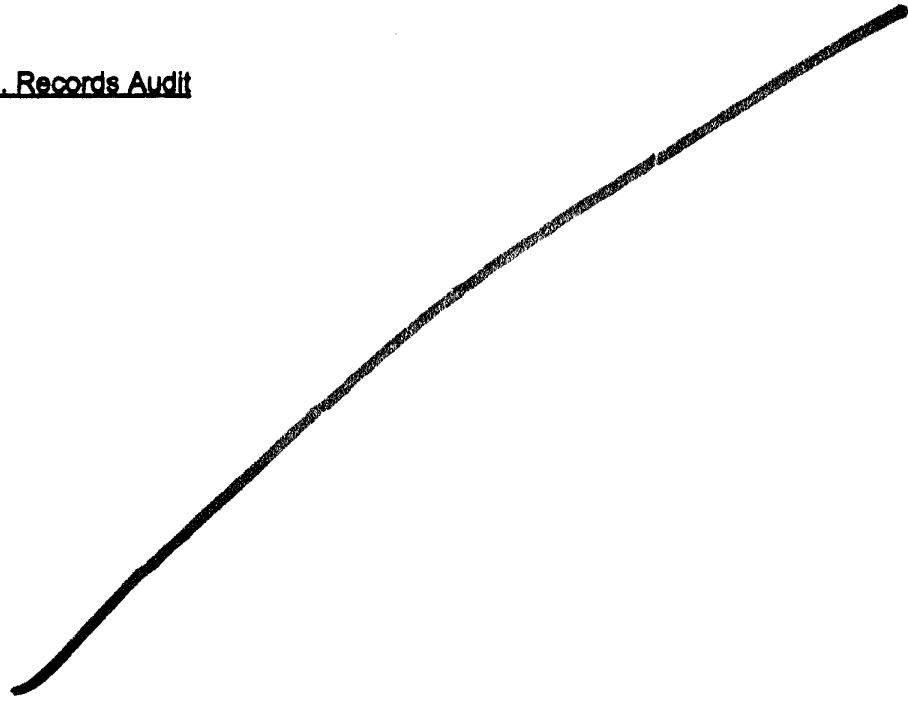
Section H. Initial Tests

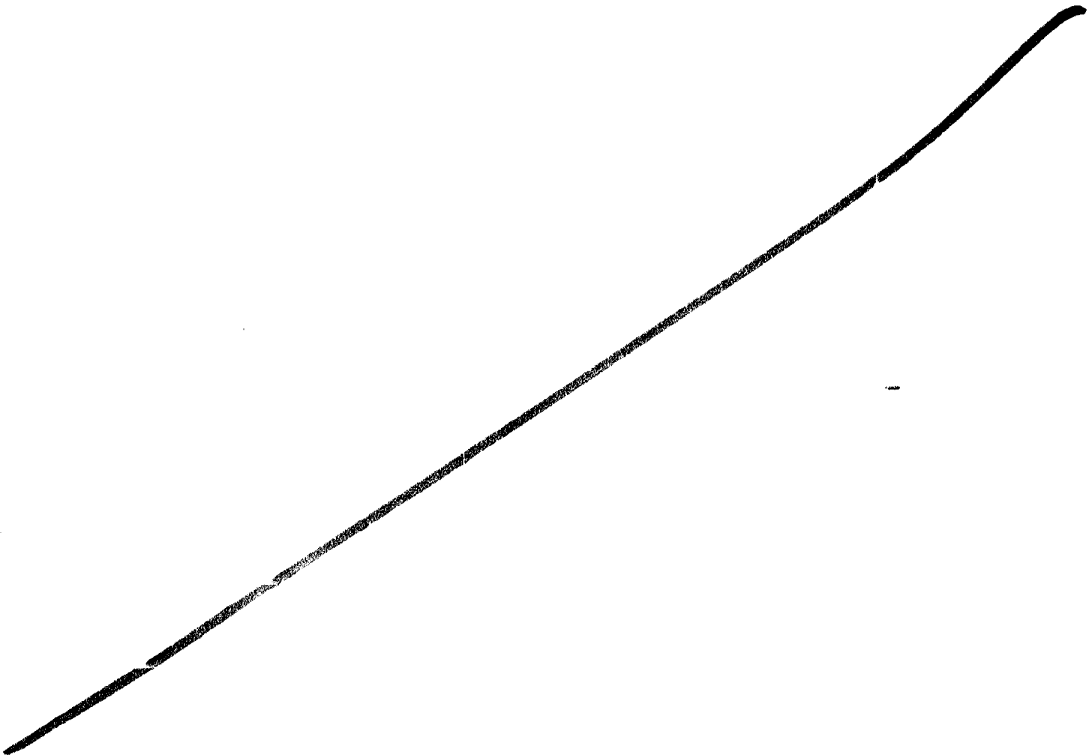


Section I. Confirmatory Tests



Section J. Records Audit





Section K. Reporting



Section L. Computers, Software, and LIMS

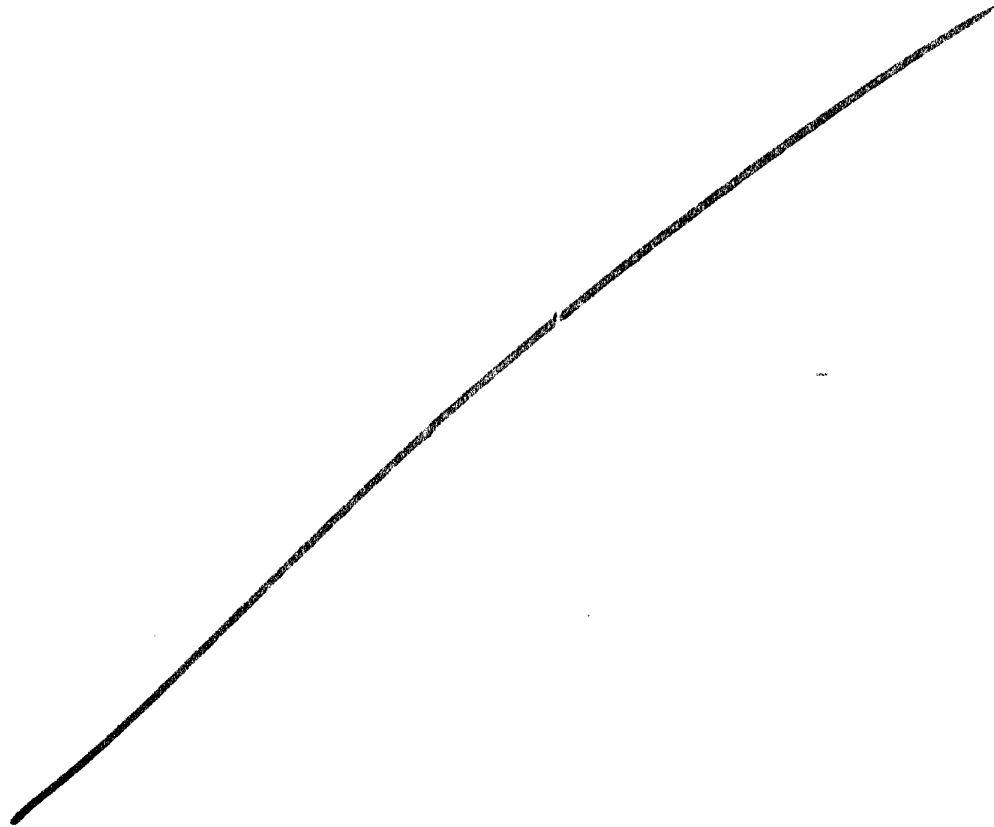


Section M. Equipment and Maintenance



Section N. Personnel





Quest Diagnostics Incorporated

1355 Mittel Boulevard
Wood Dale, Illinois 60191
630.595.3888 X4629
630.595.6910 FAX

Mo Rabinman, Ph.D.
Director of Laboratory Operations

received
9/15/99 sdc

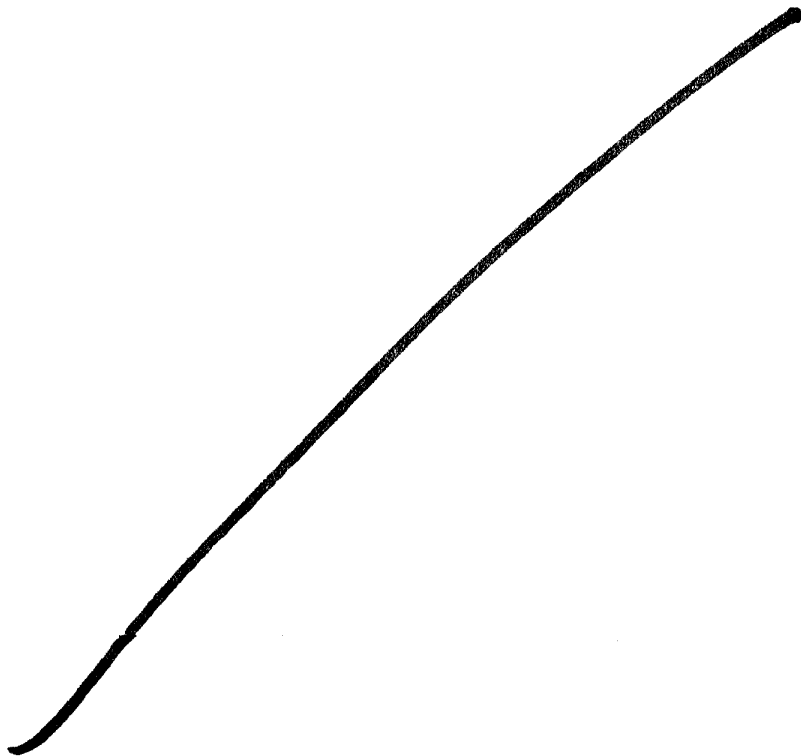
September 14, 1999

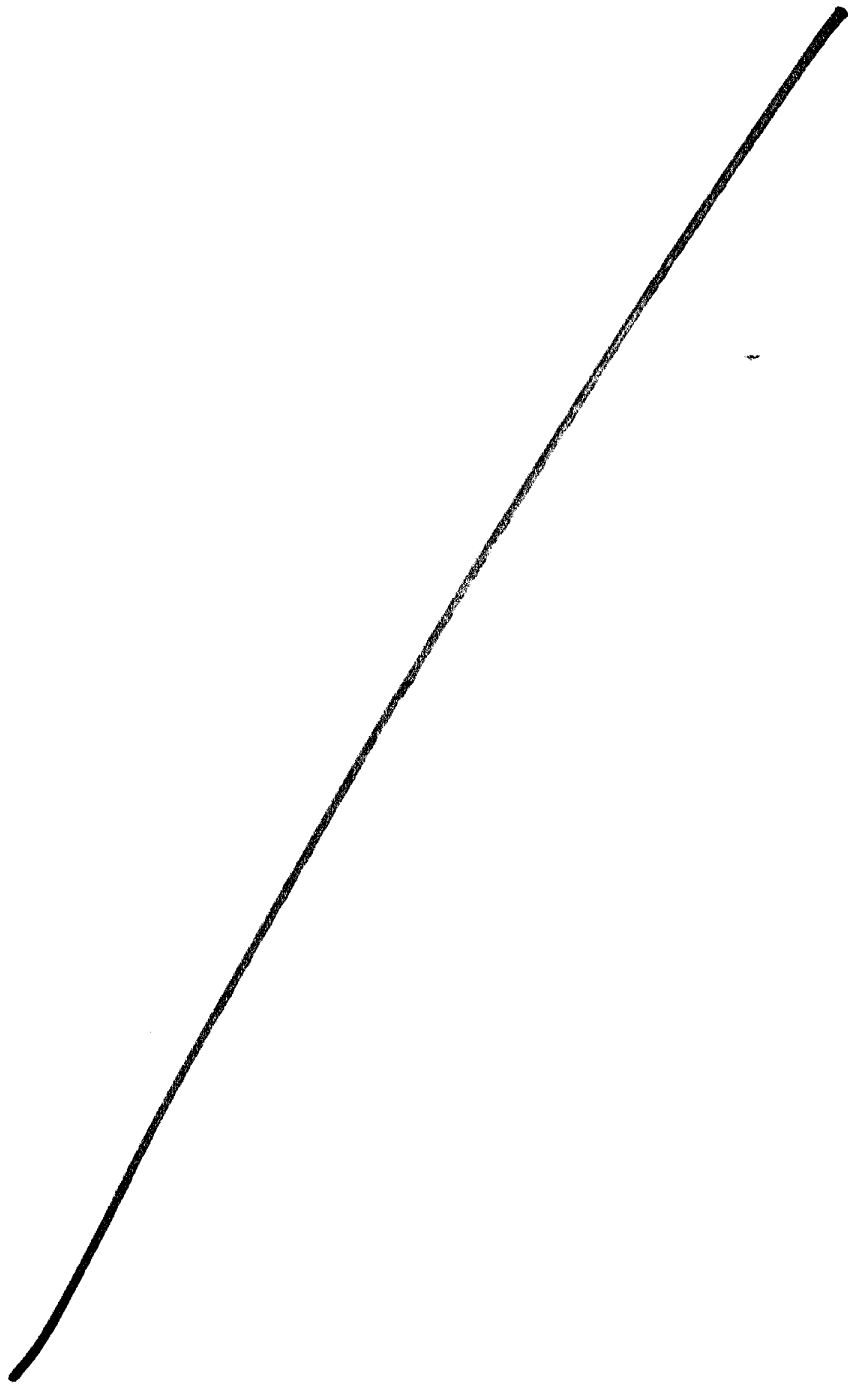


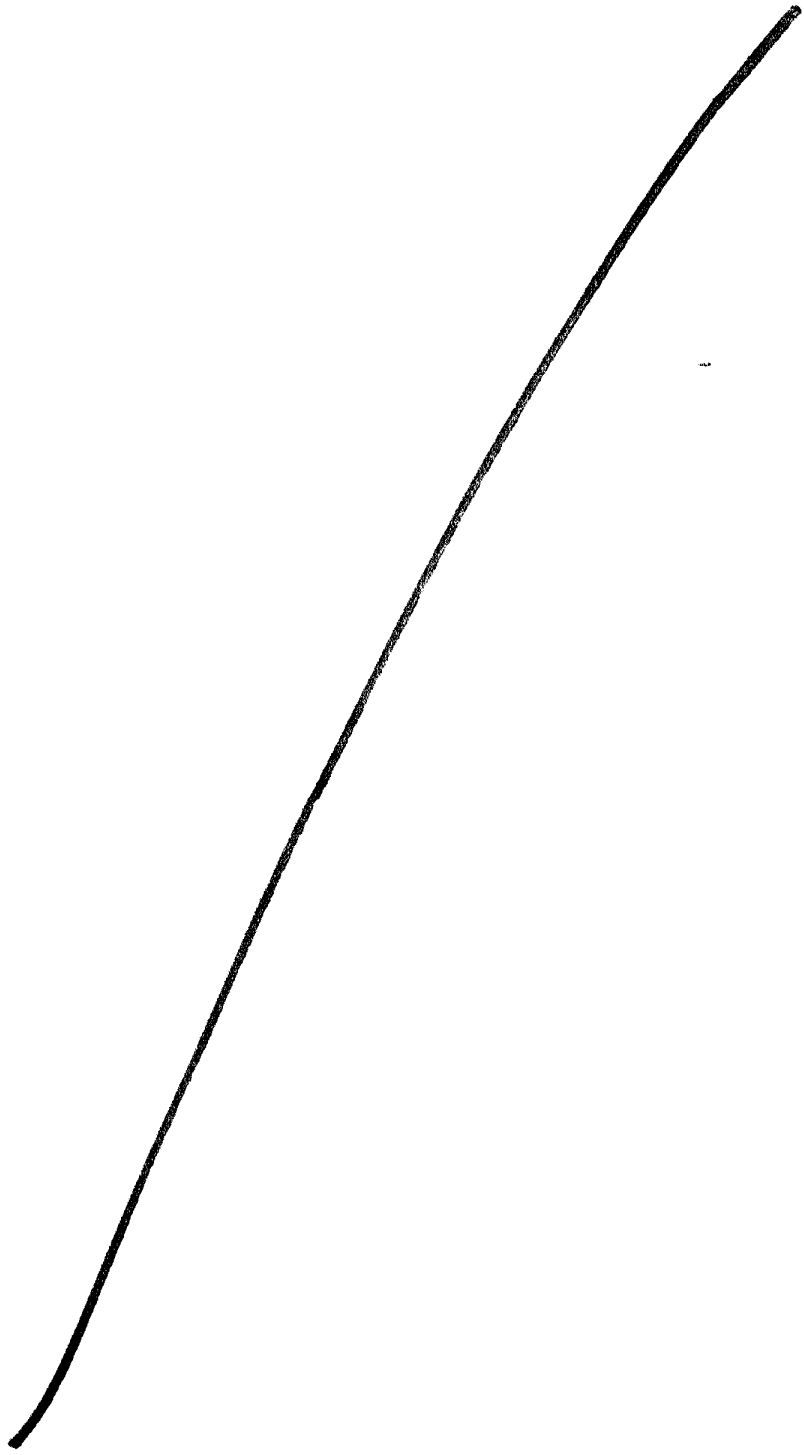
Susan Crumpton
Research Triangle Institute
3040 Cornwallis Road, PO Box 12194
Research Triangle Park, NC 27709-2194

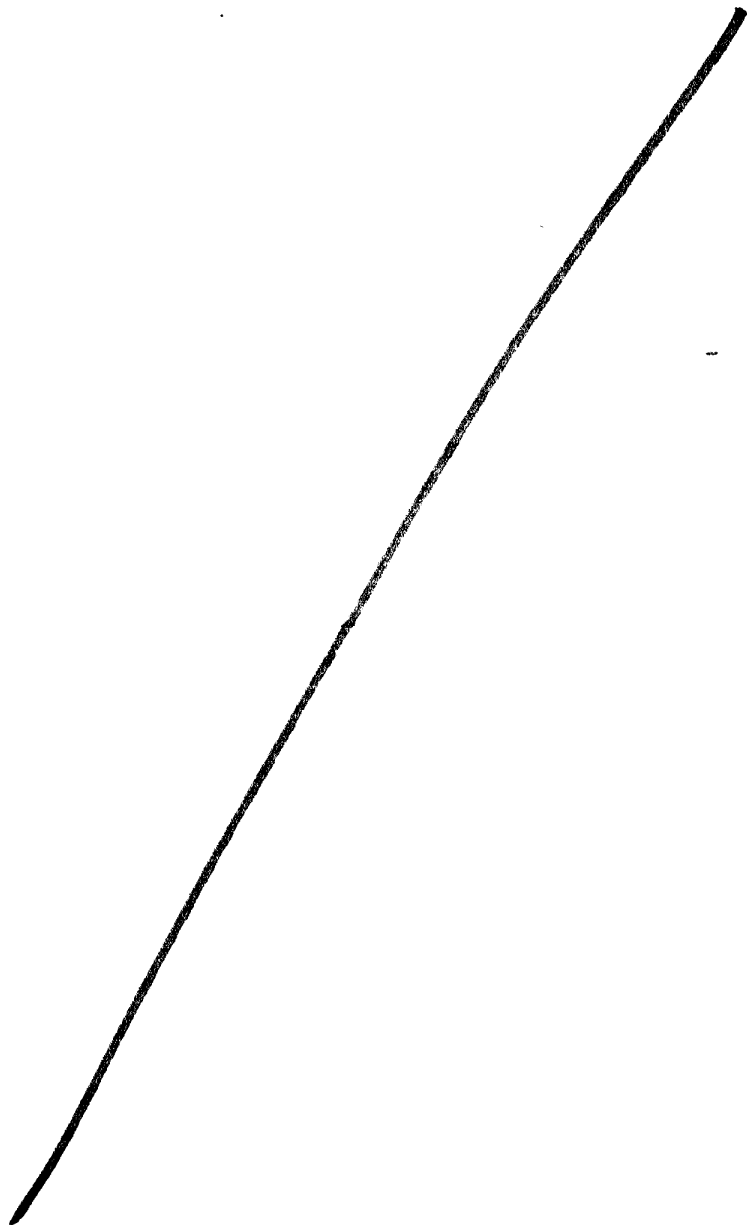
Dear Ms. Crumpton:

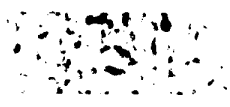
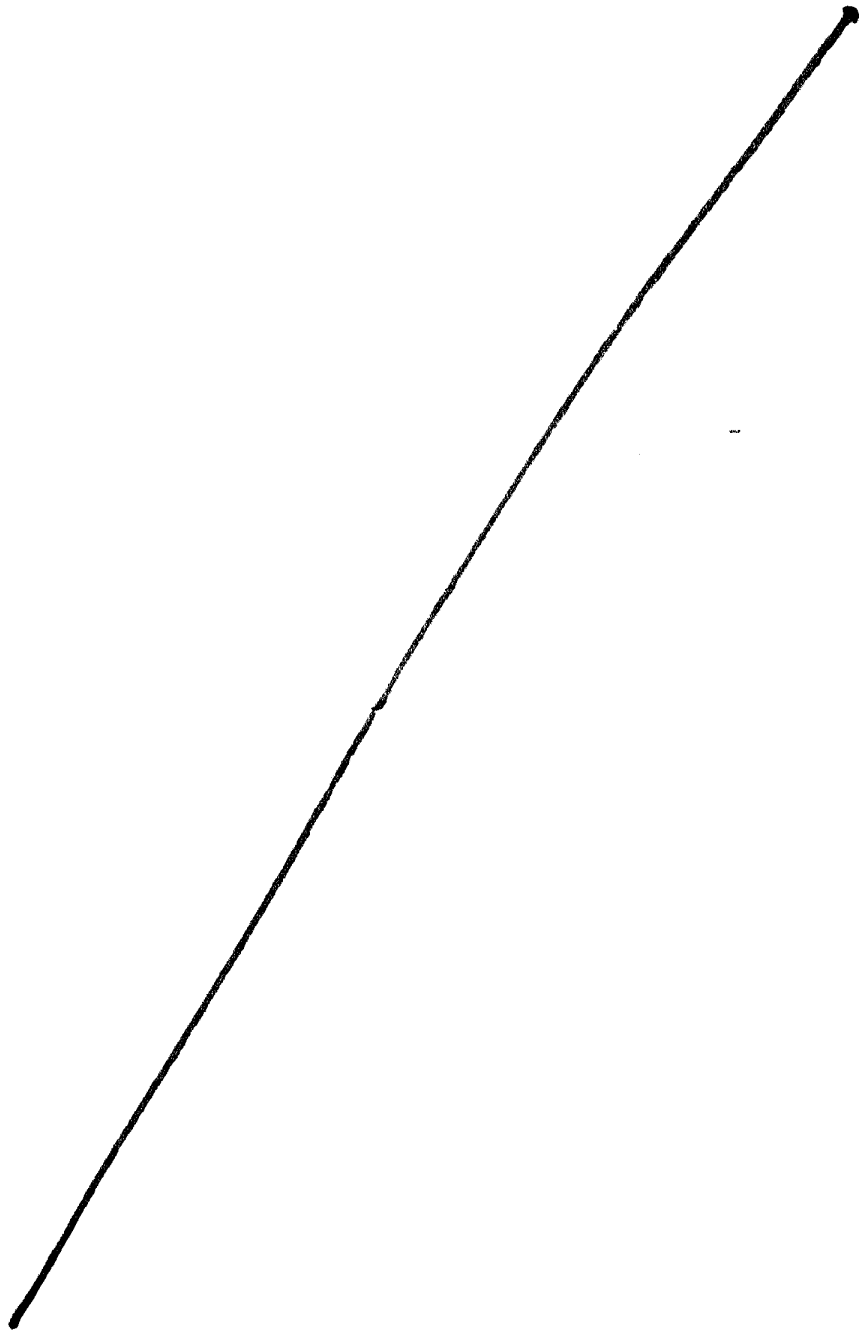
In response to your letter of September 3, 1999 and the critique of our laboratory's eighteenth NLCP maintenance inspection the following explanations and remedial actions are proposed. The item numbers below correspond to those listed in the text of the critique.











Please contact me if I may provide any additional support documents or if any additional remedial measures are required.

Sincerely,



M. Rahmanian, Ph.D., DABCC
Director of Laboratory Operations

attachs:

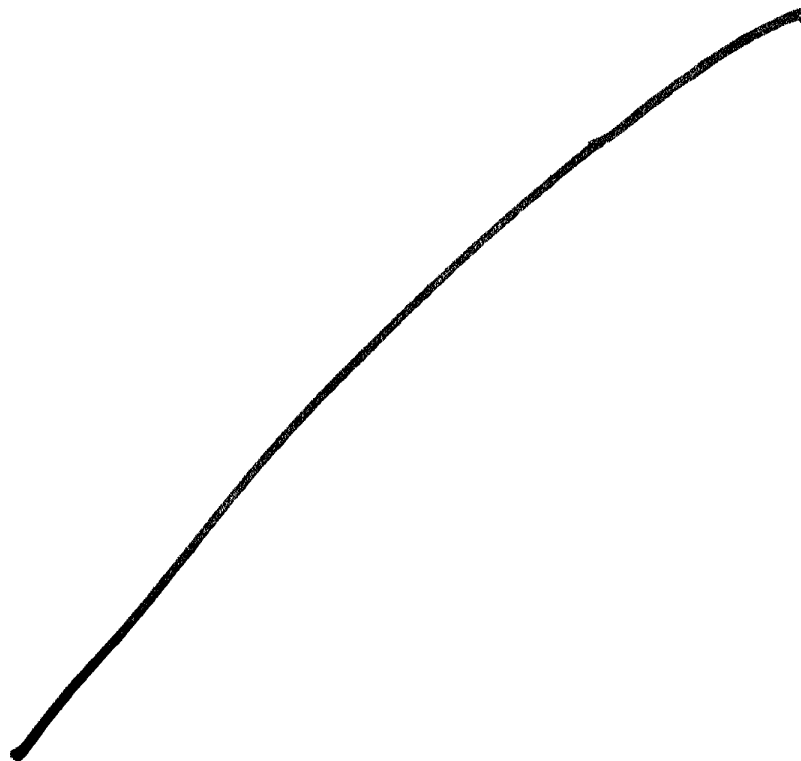


October 4, 1999

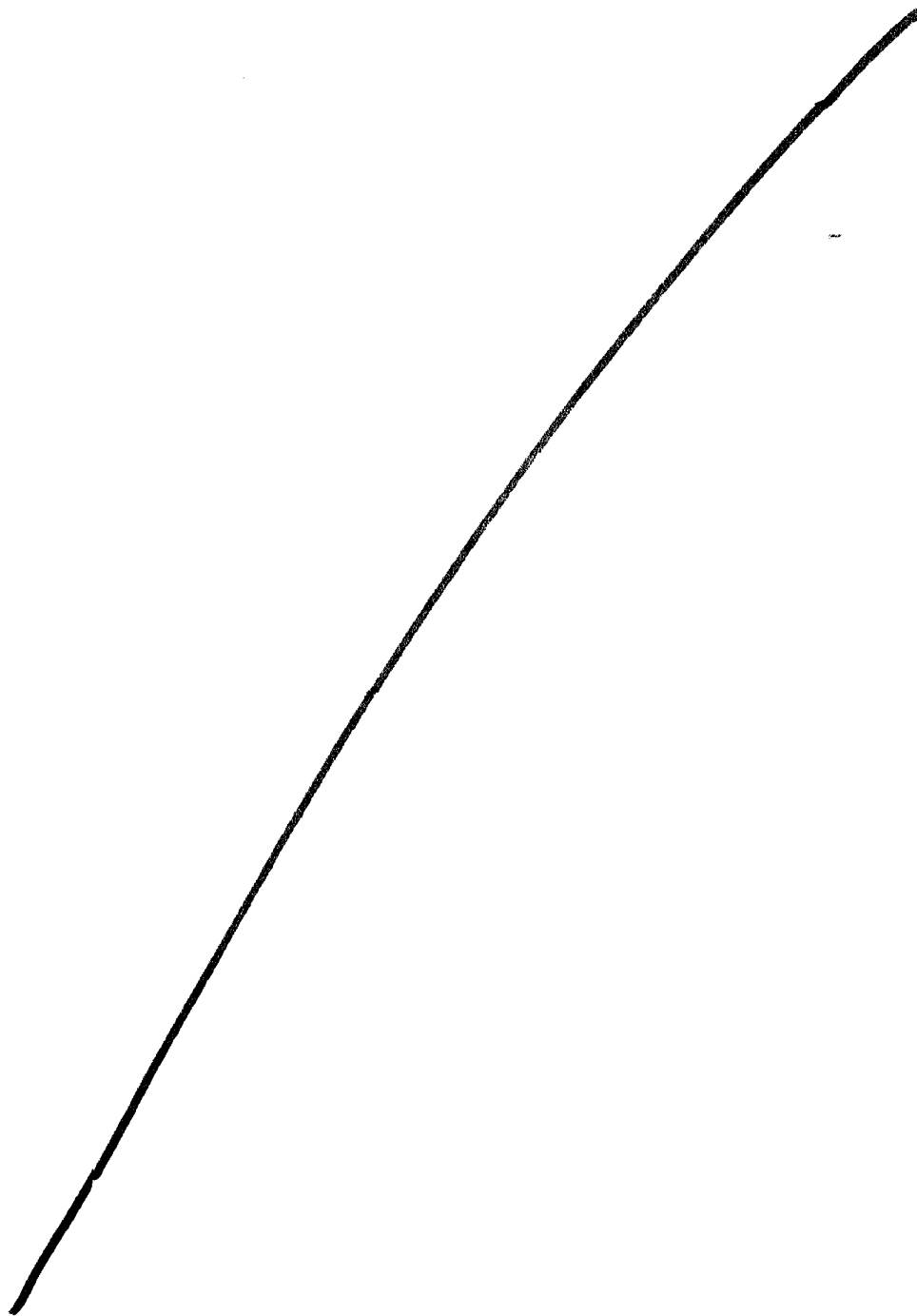
0059
Dr. Mohamad Rahmanian
Quest Diagnostics LLC (IL)
1355 Mittel Boulevard
Wood Dale, IL 60191

Dear Dr. Rahmanian:

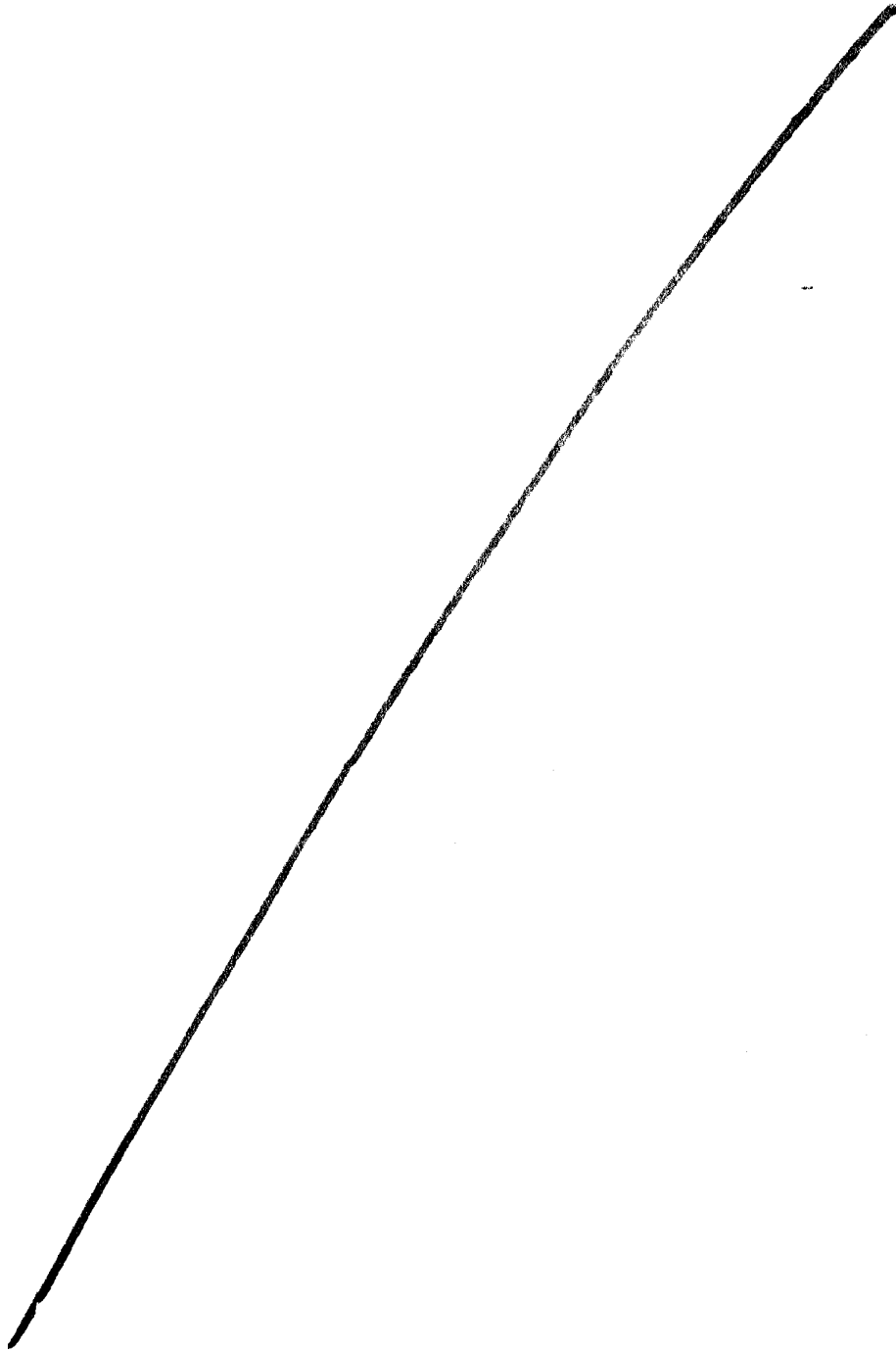
We have reviewed your correspondence of September 14, 1999, submitted as an action plan in response to deficiencies cited during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of September 3, 1999. The following issues remain or were raised during our review of the submitted material:



Dr. Rahmanian
Page 2 of 4
10/04/99



Dr. Rahmanian
Page 3 of 4
10/04/99

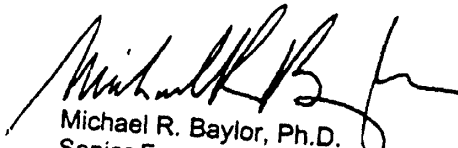


Dr. Rahmanian
Page 4 of 4
10/04/99

The laboratory must submit its final report within 30 calendar days of receipt of this letter. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7043 or Mr. Kenneth Davis at (919) 541-6709.

Sincerely,



Michael R. Baylor, Ph.D.
Senior Forensic Toxicologist

cc: Dr. Donna Bush/SAMHSA
Project Files/0059

Quest Diagnostics Incorporated

Mo Rahman, M.D., Ph.D.
Director of Laboratory Operations

1355 Mittel Boulevard
Wood Dale, Illinois 60191
630.595.3888 X 4629
630.595.6910 FAX

received
Sx 10/27/99

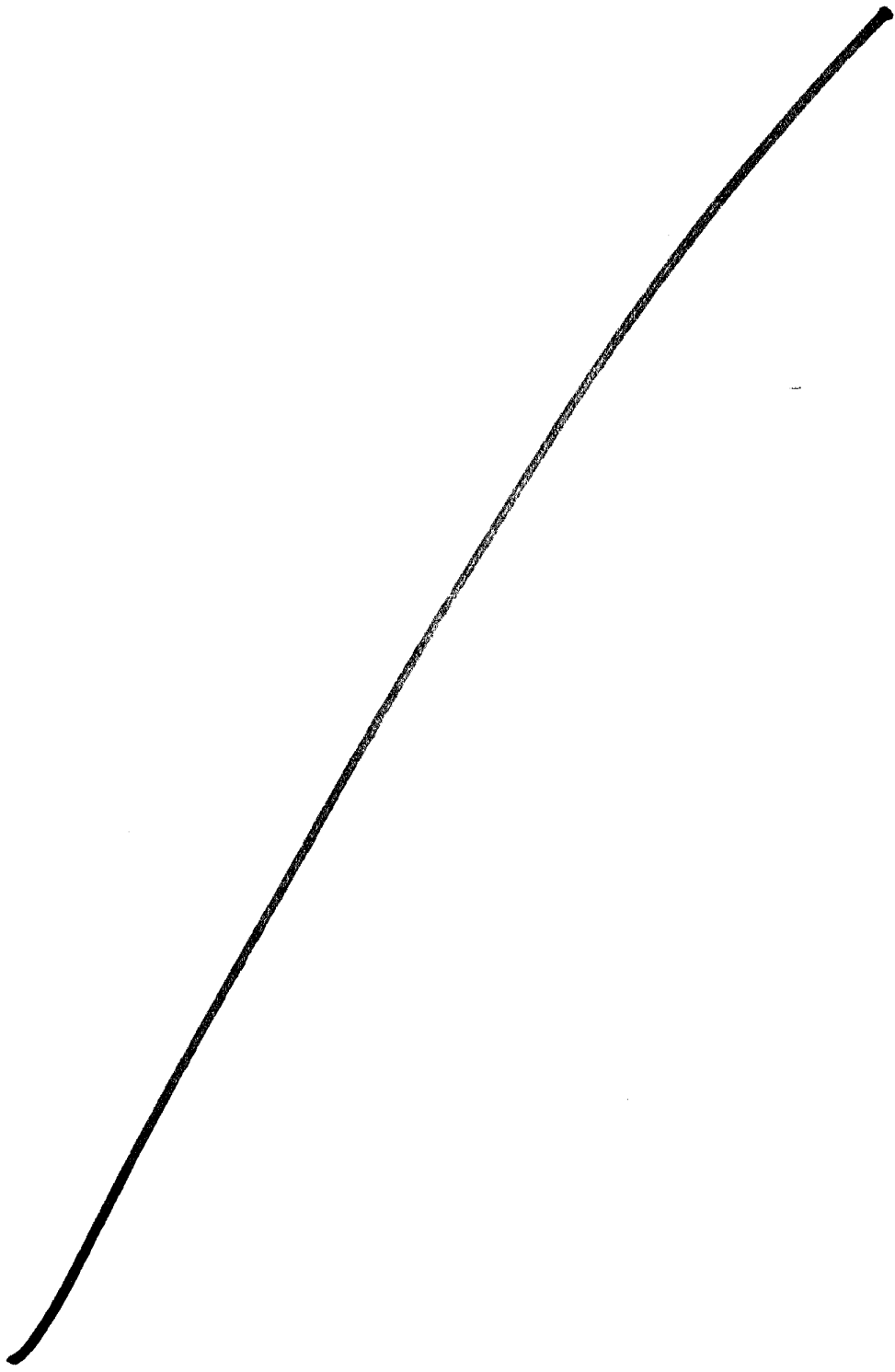
October 26, 1999

Michael R. Baylor, Ph.D.
National Laboratory Certification Program
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Dr. Baylor:

The following responses and corrective measures are in response to your letter of October 4, 1999 regarding our eighteenth National Laboratory Certification Program (NLCP) maintenance inspection. Some of these measures were proposed in our correspondence of September 14th but had not been implemented due to time limitations imposed by NLCP requiring a response within five days from the receipt of the initial inspection critique.

For ease of reference, the item numbers below correspond to those listed in your letter of October 4, 1999.



It is my sincere hope that the above measures and supporting documents provide ample evidence of acceptable forensic standards in accordance with the requirements of the certification program. Please contact me if you require any additional information.

Regards,



M. Rahmanian, Ph.D., DABCC
Director of Laboratory Operations

Attachs:

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

October 29, 1999

0059
Dr. Mohamad Rahmanian
Quest Diagnostics LLC (IL)
1355 Mittel Boulevard
Wood Dale, IL 60191

Dear Dr. Rahmanian:

We have reviewed the material provided in your correspondence of October 26, 1999, submitted in response to deficiencies cited during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of June 1, 1993. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address the deficiencies raised. The following was noted during our review of submitted information:

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

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

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M18



RESEARCH TRIANGLE INSTITUTE

RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709
CHEMISTRY AND LIFE SCIENCES

Memorandum

To: NLCP Project Files/Lab 059

From: Deborah J. Denson *Deborah J Denson*
Dr. Michael Baylor *M. Baylor*

Date: February 8, 2000

Subject: M19 inspection

The nineteenth maintenance inspection for Quest Diagnostics Inc, WoodDale, IL was performed 27-28 January 2000. The laboratory ceased testing of regulated specimens on 23 January 2000. The focus of the inspection was to review donor and NLCP PT records, as there were no operations to observe. The inspectors were directed to complete sections G, J, K and O of the inspection checklist. Randomly selected batches of initial testing and GC/MS data from 26 different days covering the past six months were reviewed. NLCP PT cycles 51, 52, and 53 were also reviewed. No significant errors or deficiencies were observed during record review.

inspectors stated that the corrective action taken appeared to be reasonable and appropriate. No apparent problems were observed during the review of cycle 53. The

Cc: Dr. Donna Bush (SAMHSA)
Dr. Walt Vogl (SAMHSA)
