

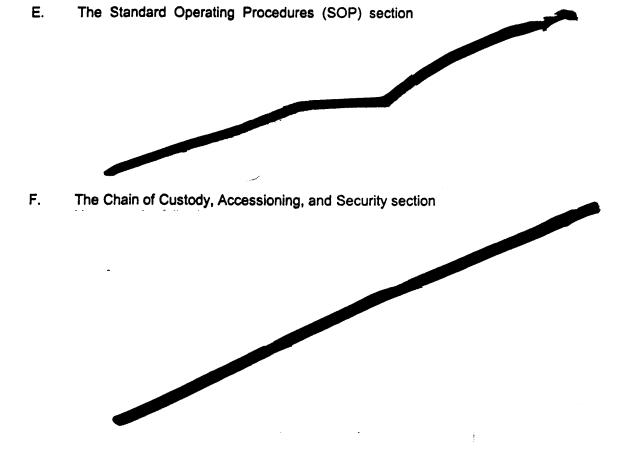
National Laboratory Certification Program

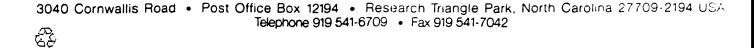
March 15, 1999

0009
Dr. Yale Caplan
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Dr. Caplan:

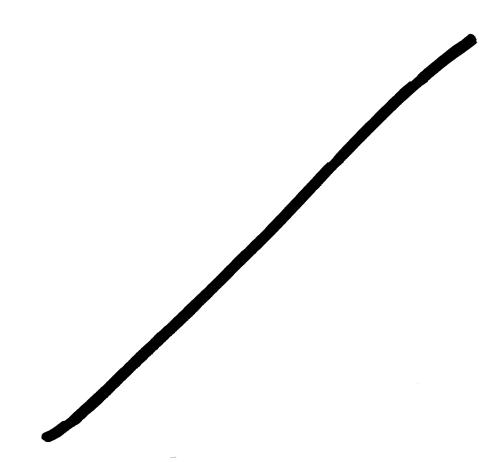
The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighteenth inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is acceptable.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





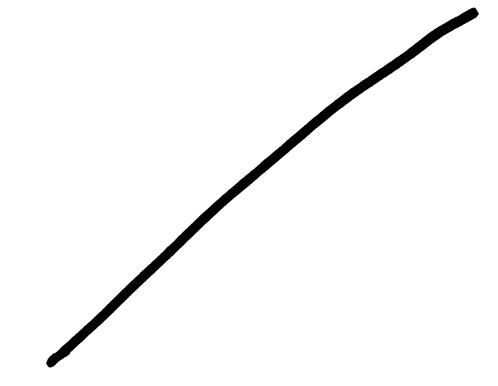
Dr. Caplan March 15, 1999 Page 2 of 4

G. The Quality Control section issue was raised:

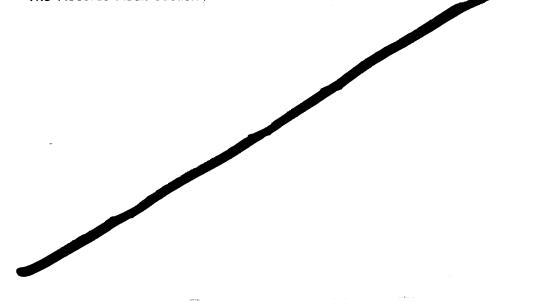


I. The Confirmatory Test section

Dr. Caplan March 15, 1999 Page 3 of 4



J. The Records Audit section



N. The Personnel section



Dr. Caplan March 15, 1999 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

NLCP Inspection Analyst

Deborah & Denson

Enclosure

Project Files/M18

NATIONAL LABORATORY CERTIFICATION PROGRAM Document Review and Critique Laboratory I.D. Number: 0009 Document No. Final Quest Diagnostics Incorporated Laboratory: Location: Baltimore, MD] Application Form **Document Reviewed:** [XX] Inspection Report #M18 Date: 21 January 1999 [] Other_ [XX] Acceptable Status:] Highly Acceptable] Unacceptable] Failure

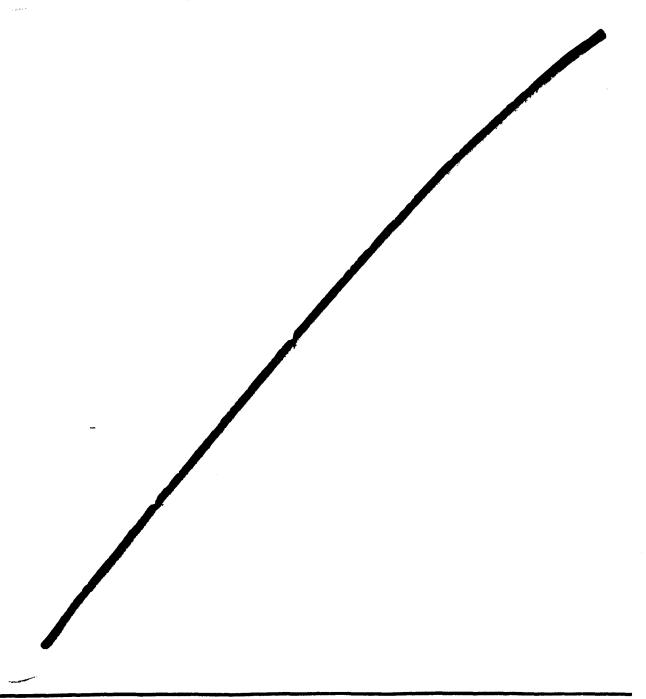
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

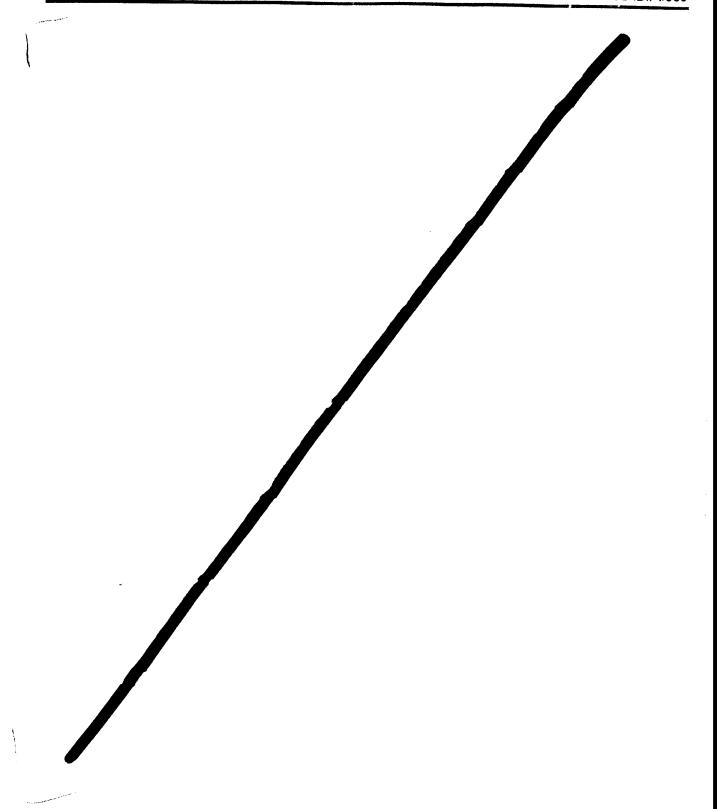
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.



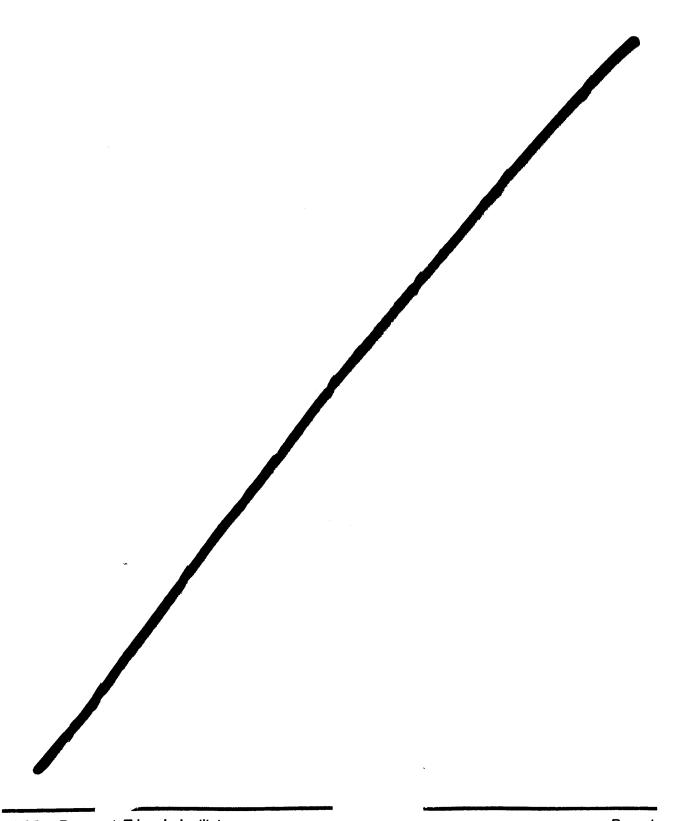
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

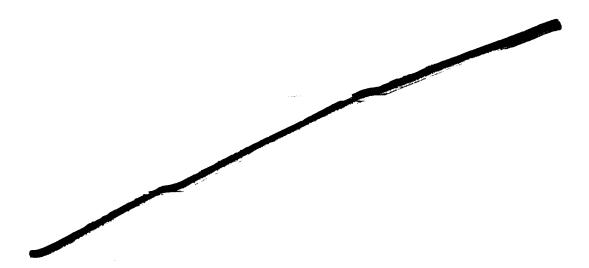
Section E. Standard Operating Procedures - Procedures Manual





Ver. Final

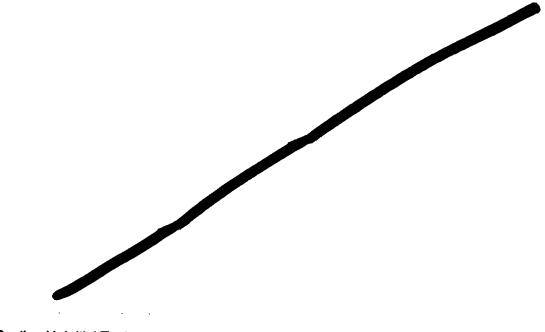




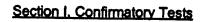
Section F. Chain-of-Custody. Accessioning, and Security

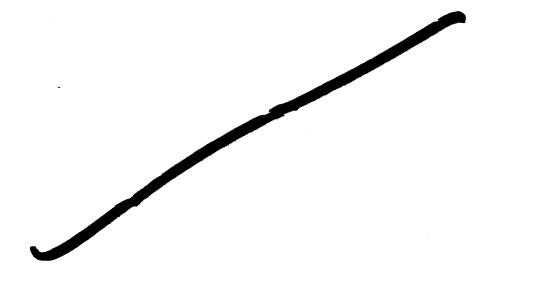


Ver. Final

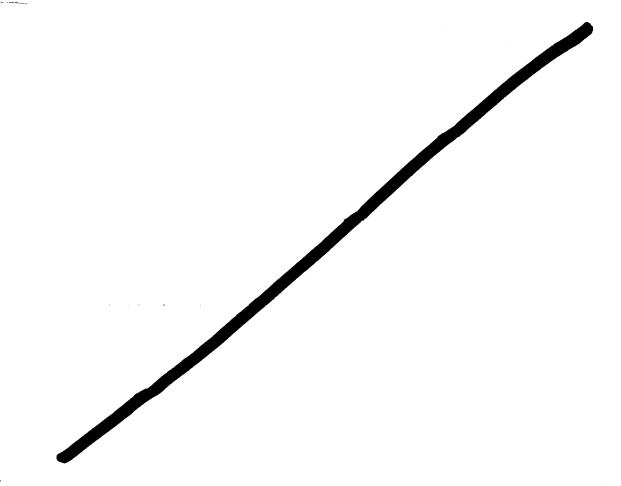


Section H. Initial Tests

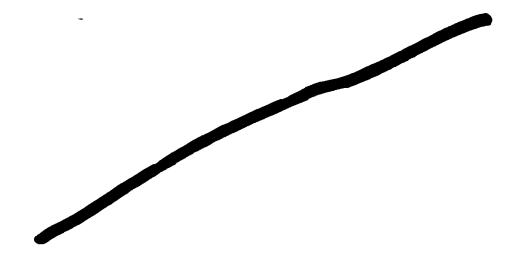




NLCP ◆ Research Triangle Institute

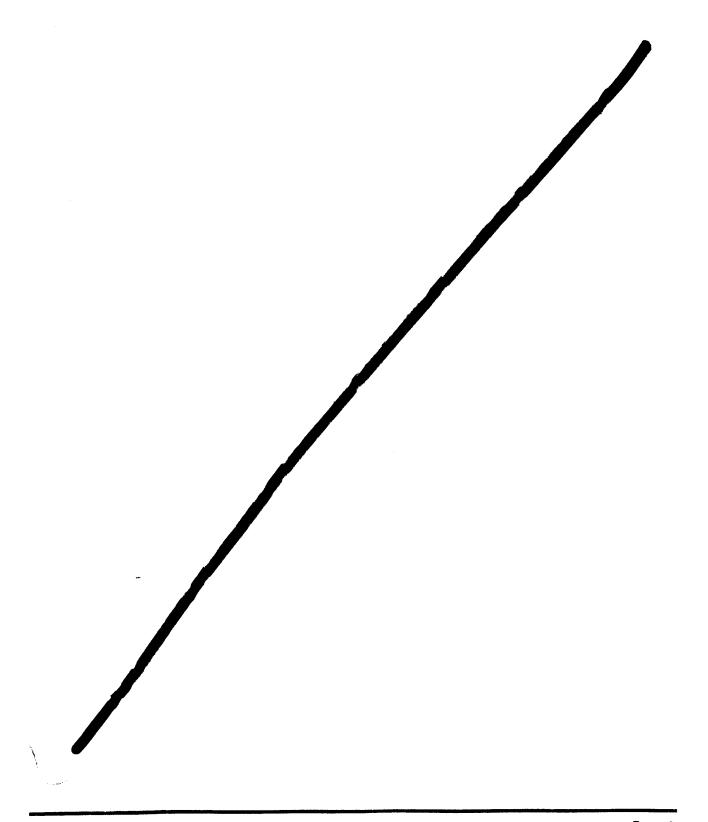


Section J. Records Audit



NLCP + Research Triangle Institute

Ver. Final



Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

Ver. Final Lab ID# 0009



1901 Sulphur Spring Road Baltimore, MD 21227 410,247,9100





Ms. Deborah J. Denson
NLCP Inspection Analyst
National Laboratory Certification Program
3040 Comwallis Road
Post Office Box 12194
Research Triangle Institute
Research Triangle Park, North Carolicia 27709-2194

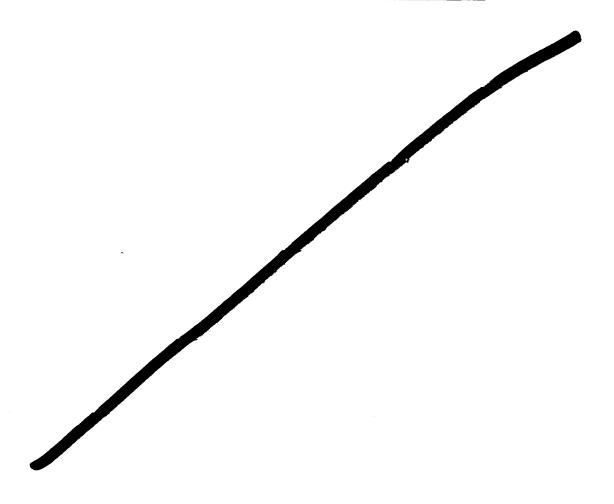
Dear Ms. Denson,

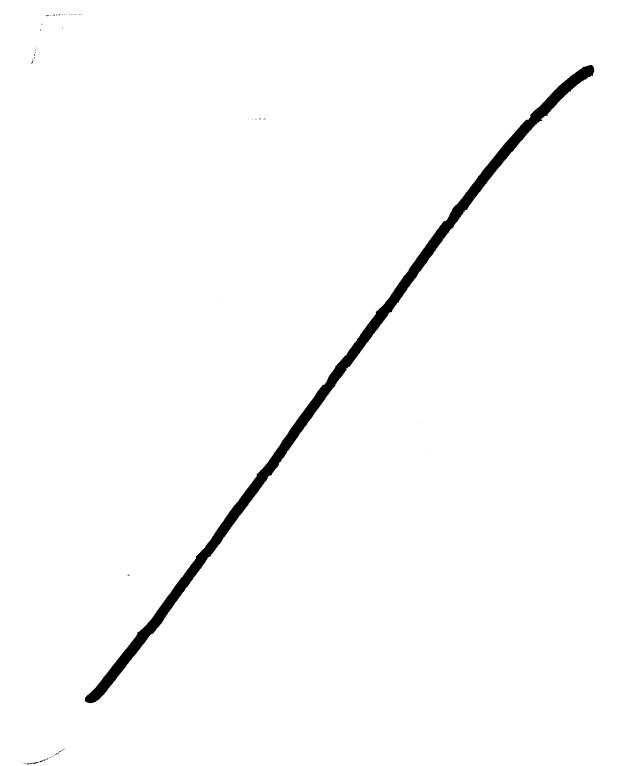
In response to your letter of March 15, 1999 regarding Maintenance Inspection Number 18 for Quest Diagnostics, Inc., in Baltimore, Maryland, please note the following:

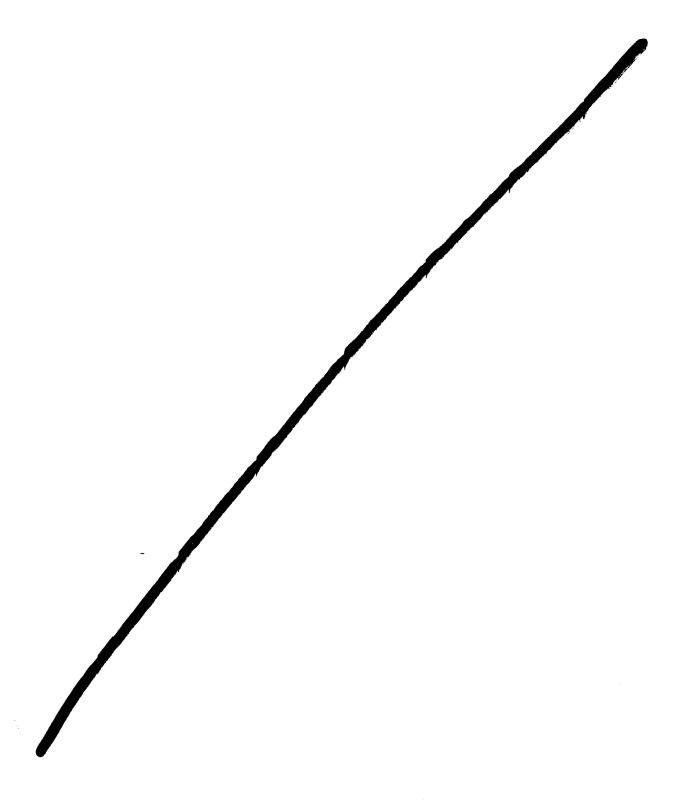
National Laboratory Certification Program

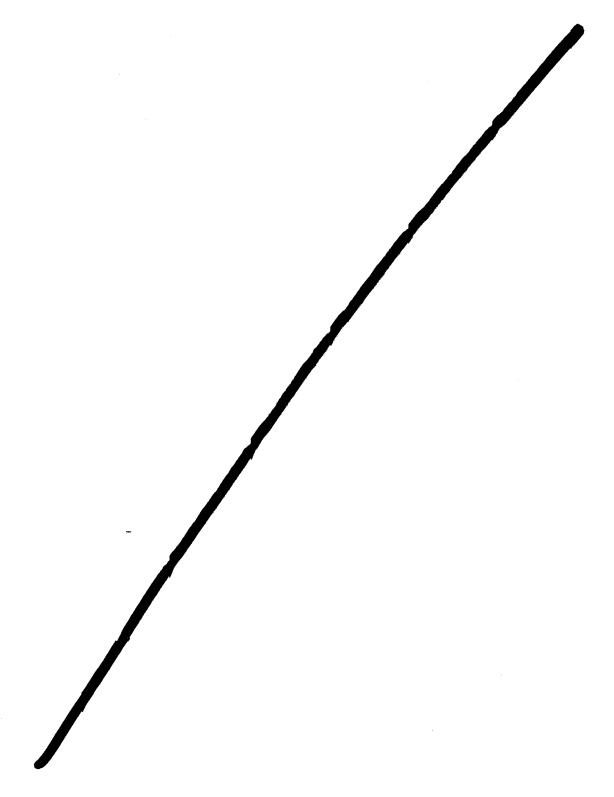
Responses to March 15, 1999 Inspection Critique

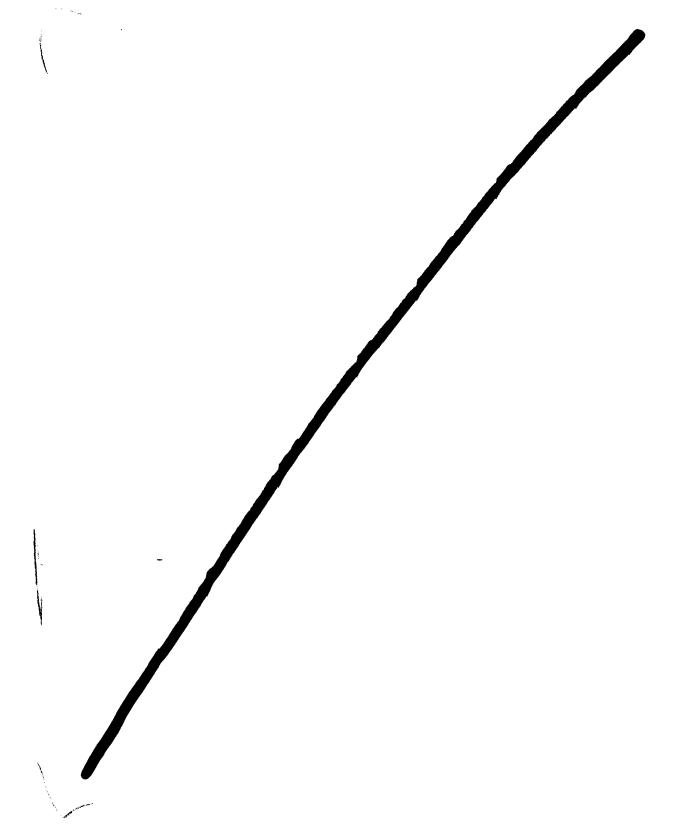
Section E. Standard Operating Procedures - Procedure Manual

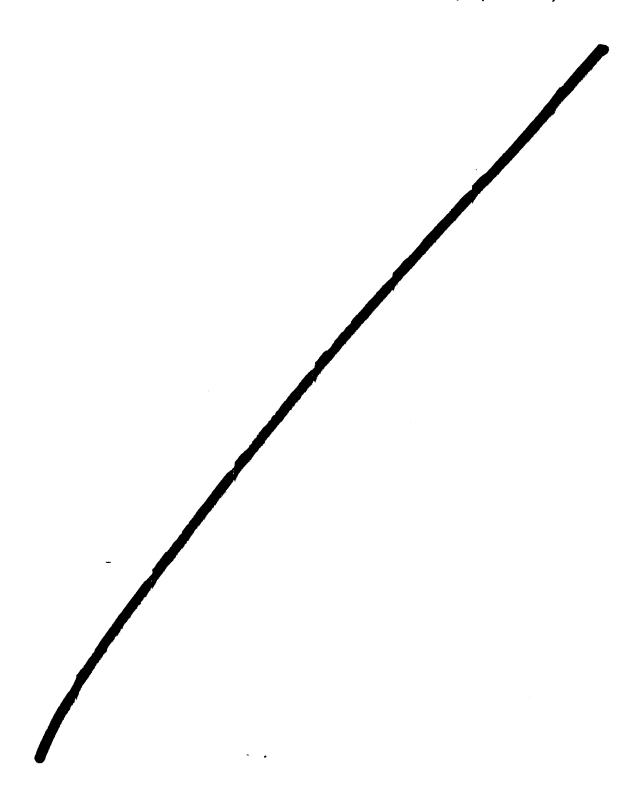


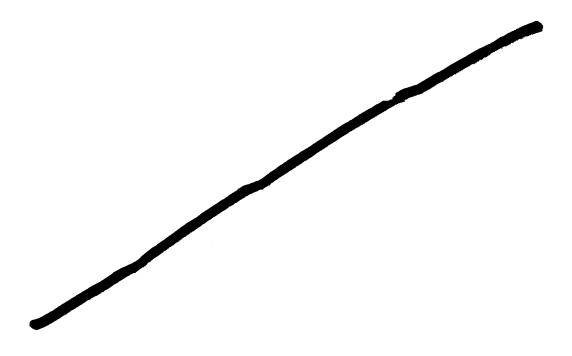




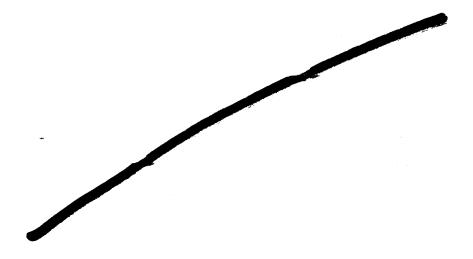


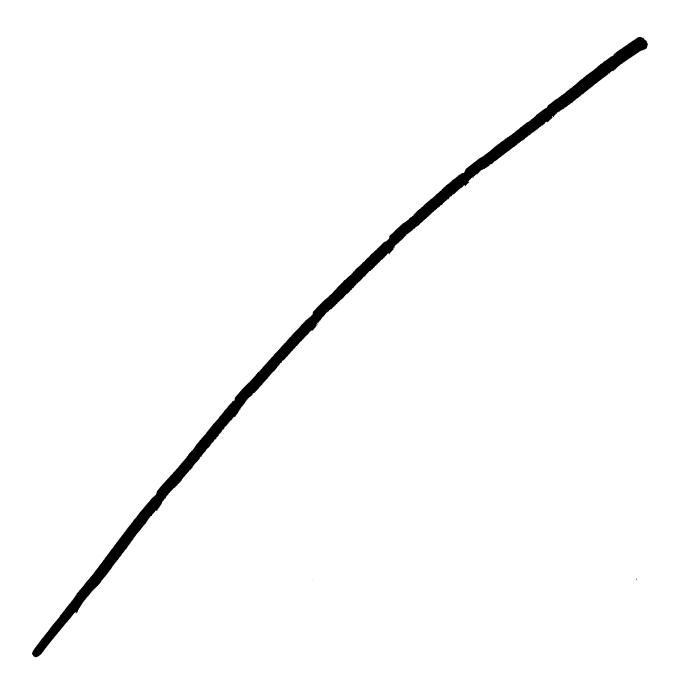




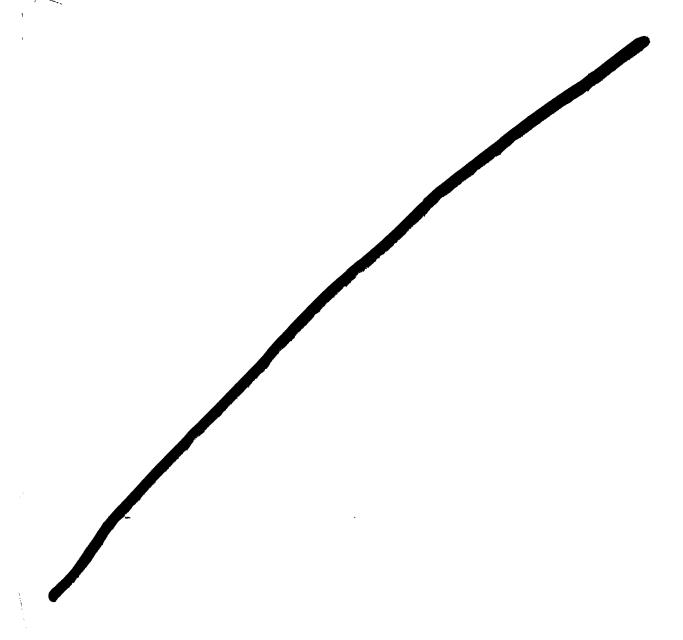


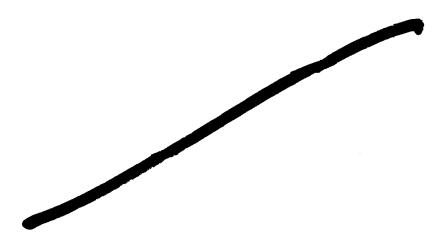
SECTION F. Chain-of-Custody, Accessioning, and Security



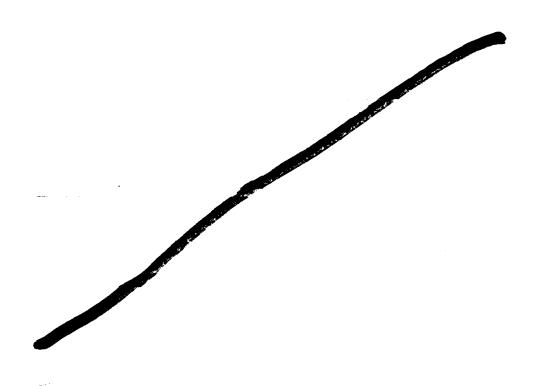


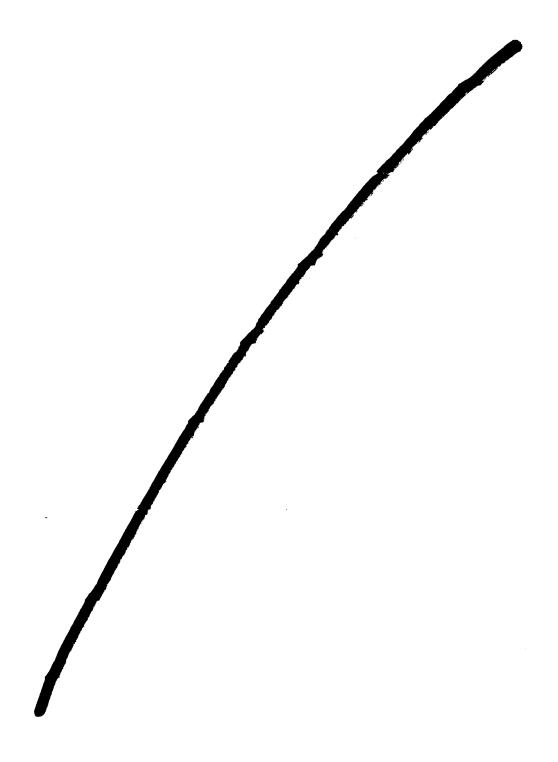
SECTION G. Quality Control

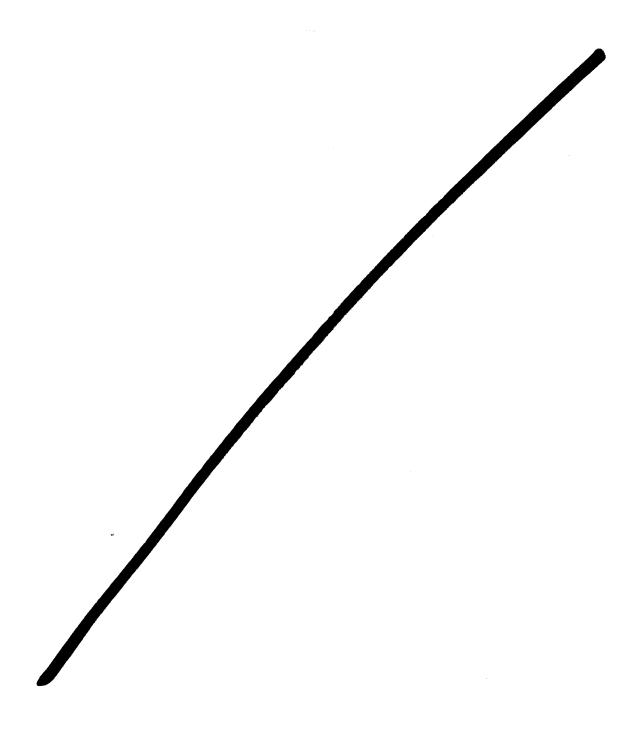




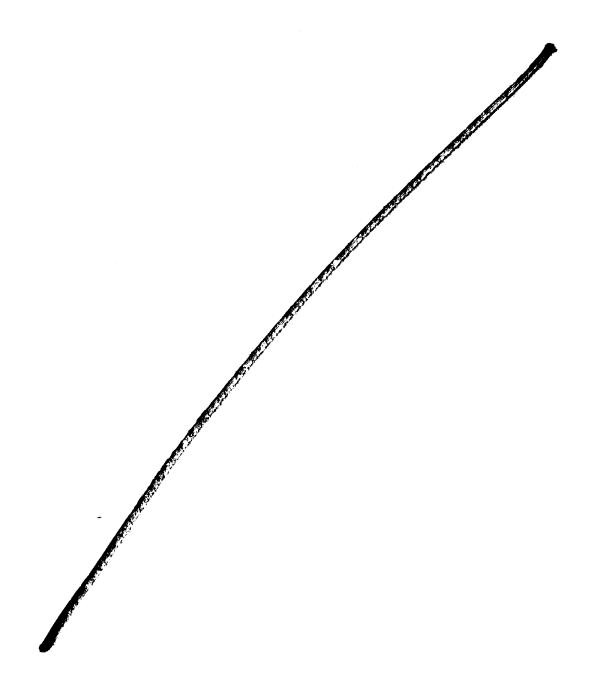
SECTION I. Confirmatory Tests

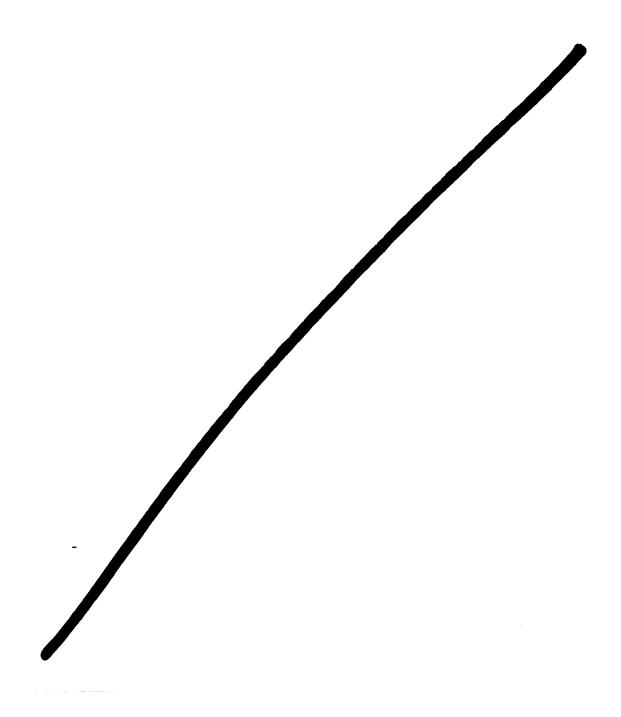


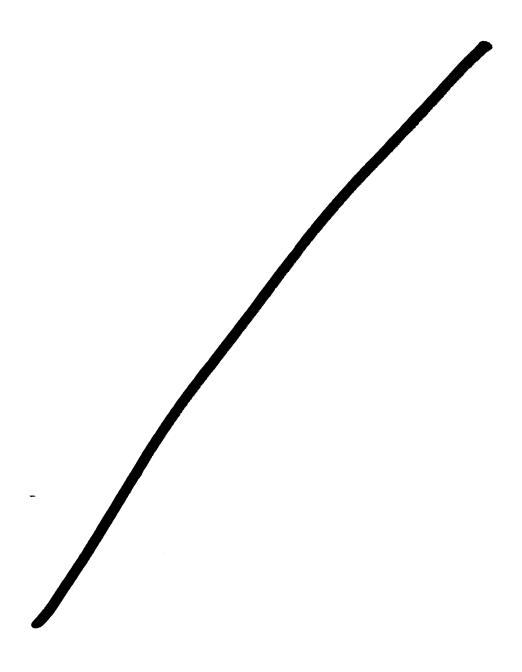




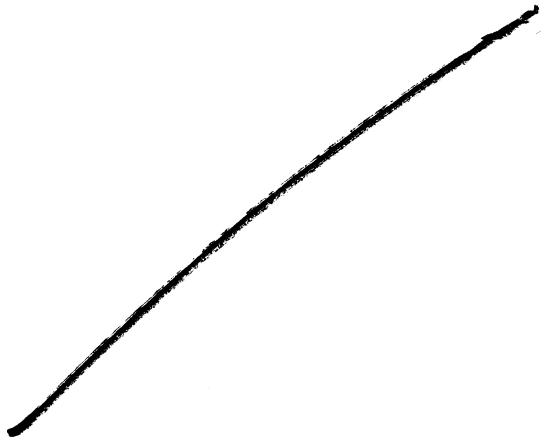
SECTION J. Records Audit

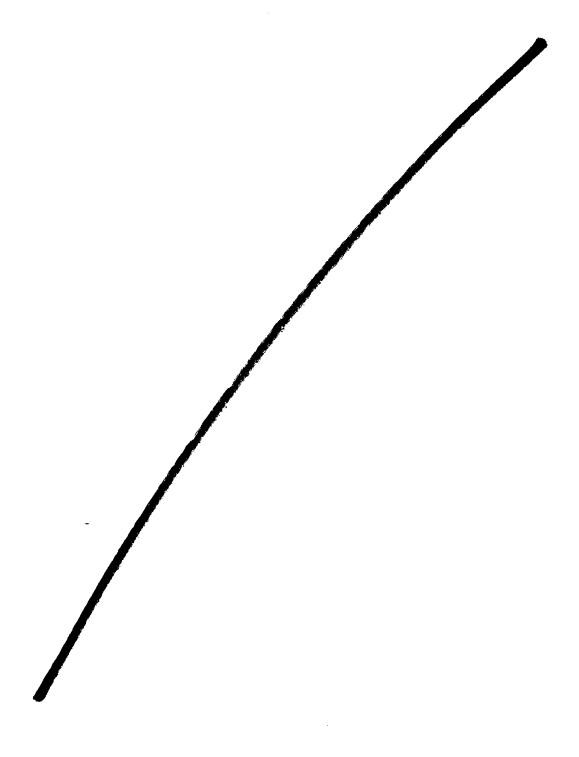














National Laboratory Certification Program

April 20, 1999

0009
Dr. Yale Caplan
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Dr. Caplan:

CC:

. .

We have reviewed the material provided in your correspondence of April 15, 1999, submitted in response to issues raised during the eighteenth inspection of your laboratory as outlined in our correspondence of March 15, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. 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) 541-7265 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,

Deborahij. Denson NLCP Inspection Analyst

Deborah Jhlenson

Project Files/M18



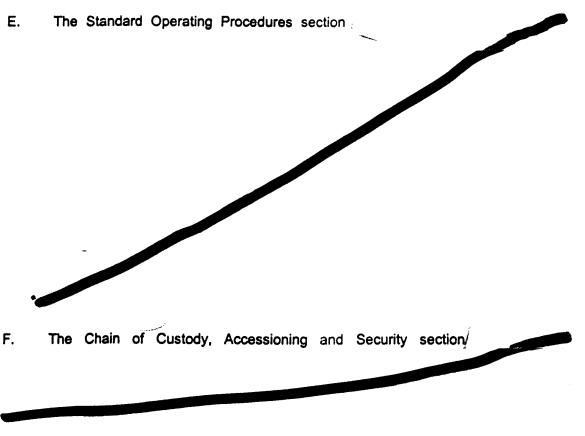
National Laboratory Certification Program

August 12, 1999

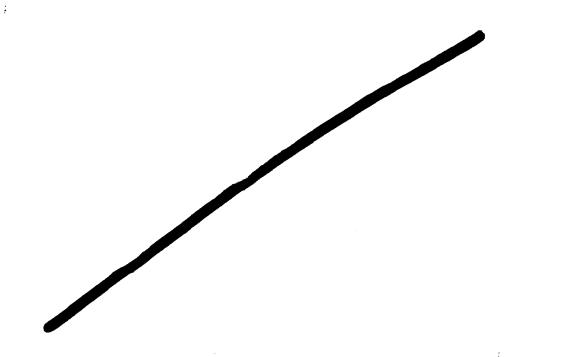
0009
Mr. Ronald Raglin
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Mr. Raglin:

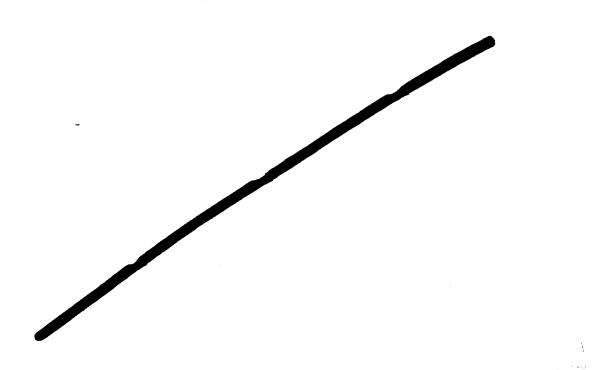
The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the outcome of the laboratory's performance in this inspection is unacceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following remedial actions:



Mr. Raglin August 12, 1999 Page 2 of 5

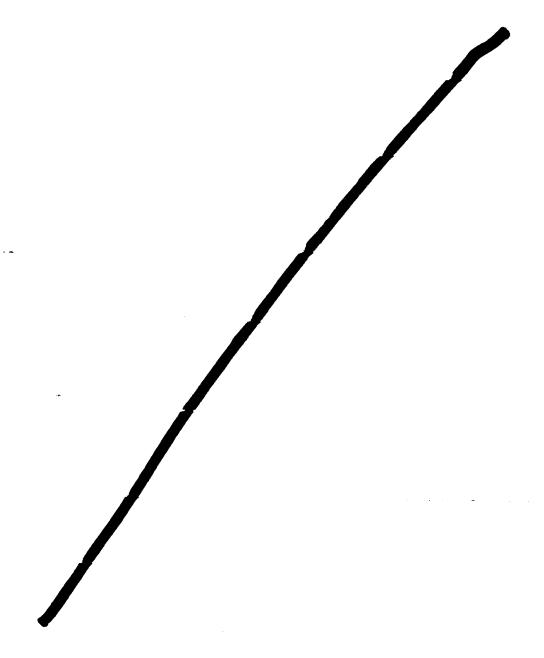




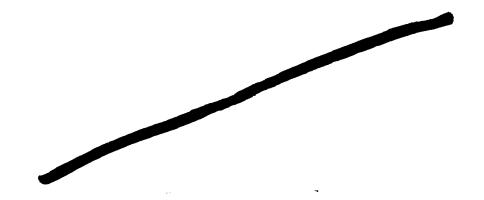




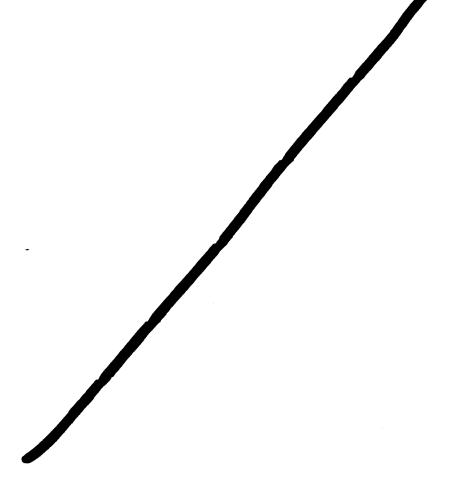
I. The Confirmatory Tests section



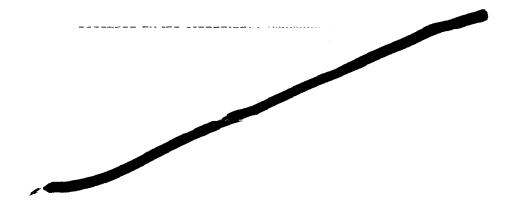
Mr. Raglin August 12, 999 Page 4 of 5



J. The Records Audit section:



N. The Personnel section



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

Sincerely,

Deborah J. Denson NLCP Inspection Analyst

Deborah of Denson

Enclosure

cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: <u>0009</u> Document No. Final

Laboratory:

Quest Diagnostics Incorporated

Location:

Baltimore, MD

Document Reviewed:

[] Application Form
[XX] Inspection Report # M19
[] Other _____

Date: 24 June 1999

Status:

[] Highly Acceptable [XX] Unacceptable

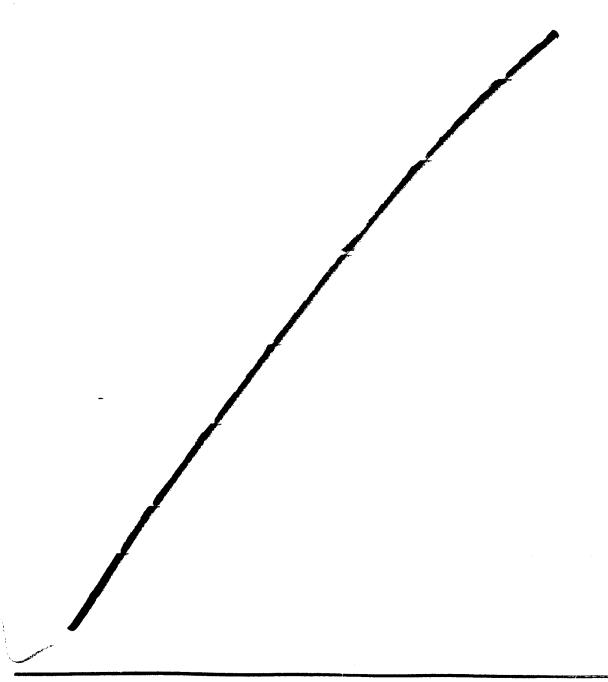
] Acceptable] Failure

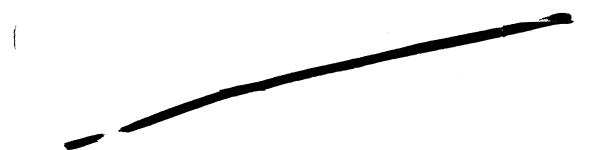
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has not met the standards required for the inspection phase of the Program. Evidence that appropriate remedial action has been taken is required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

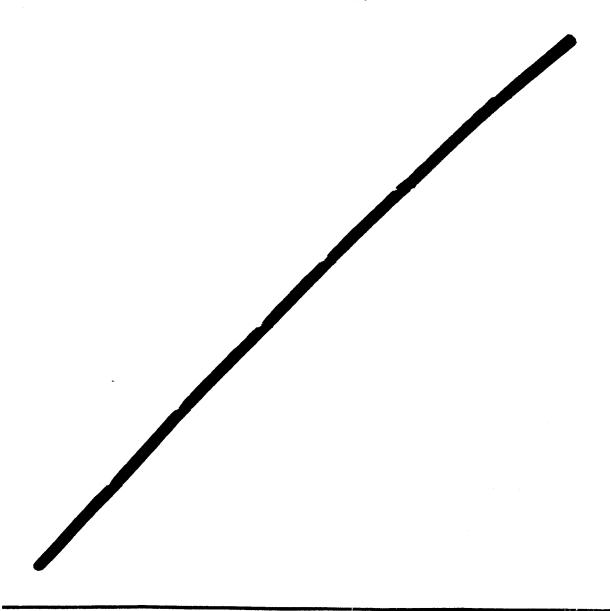
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

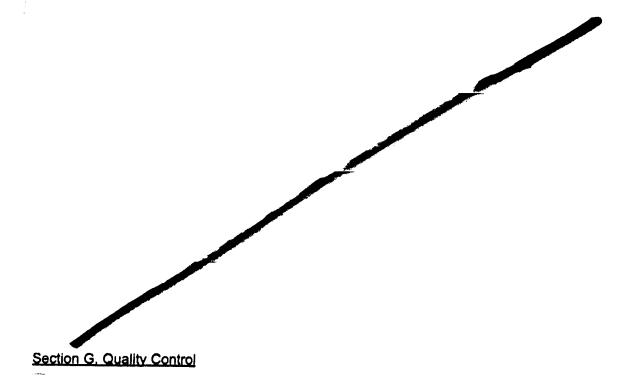


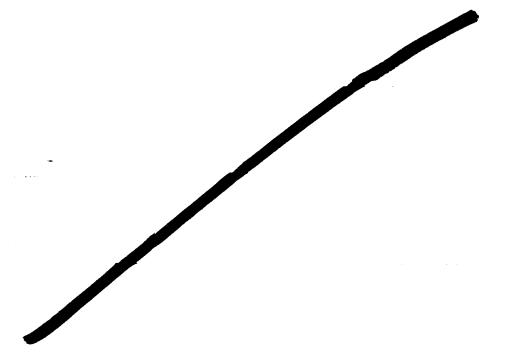


Section F. Chain-of-Custody, Accessioning, and Security



NLCP • Research Triangle Institute



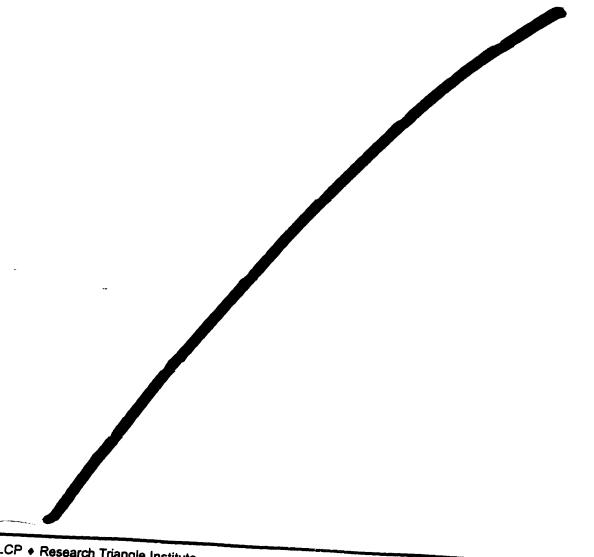


Ver. Final

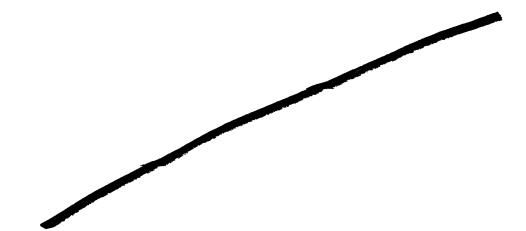
Lab ID# 0009

Section H. Initial Tests

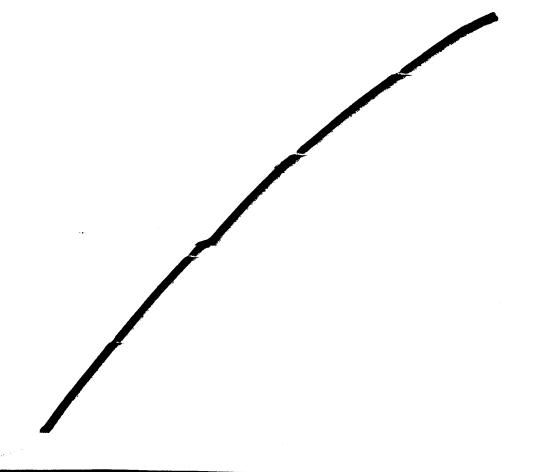
Section I. Confirmatory Tests



NLCP ◆ Research Triangle Institute



Section J. Records Audit



Ver. Final Lab ID# 0009

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

Quest Diagnostics Incorporated

1901 Sulphur Spring Road Baltimore, MD 21227 410,247,9100

Ms. Susan Crumpton
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Institute
Research Triangle Park, North Carolina





Dear Ms. Crumpton,

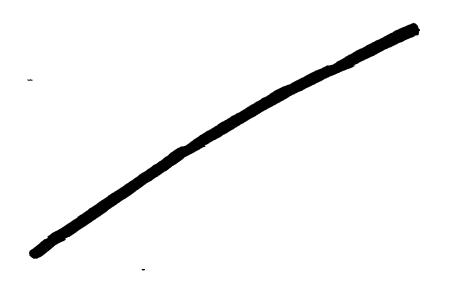
In response to the letter of August 12, 1999, regarding Maintenance Inspection Number 19 for Quest Diagnostics, Inc., in Baltimore, Maryland, please note the following.

The following plan to complete remedial actions is submitted for your review and approval:

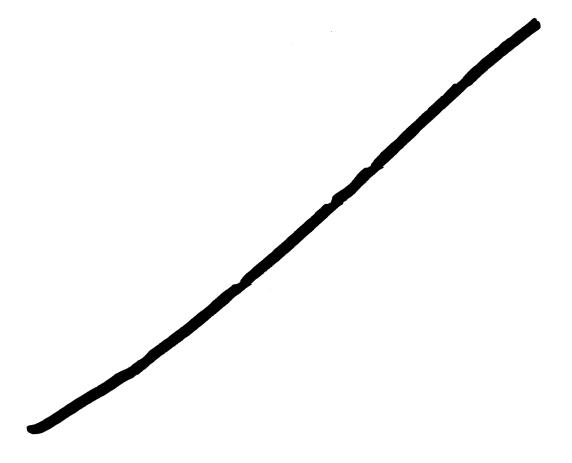
27709-2194

Section E. Standard Operating Procedures – Procedures Manual

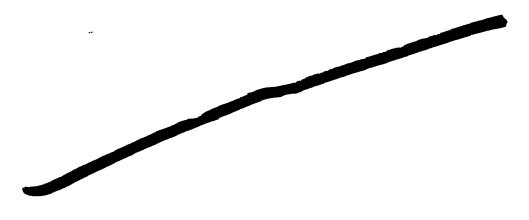
Section F. Chain-of-Custody, Accessioning, and Security



Section F. Chain-of-Custody, Accessioning, and Security (continued)



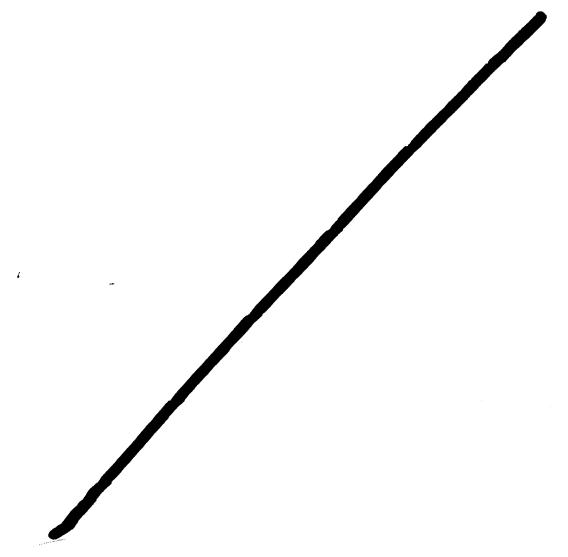
Section G. Quality Control



Section G. Quality Control (continued)

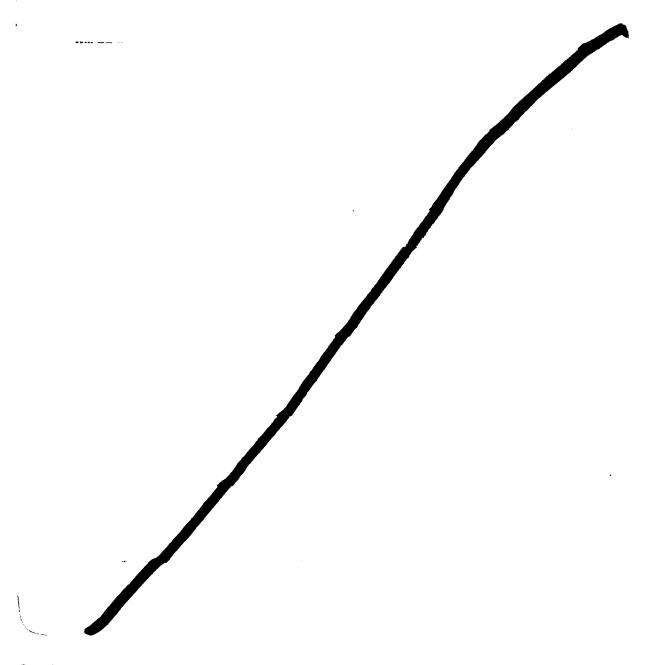


Section I. Confirmatory Tests

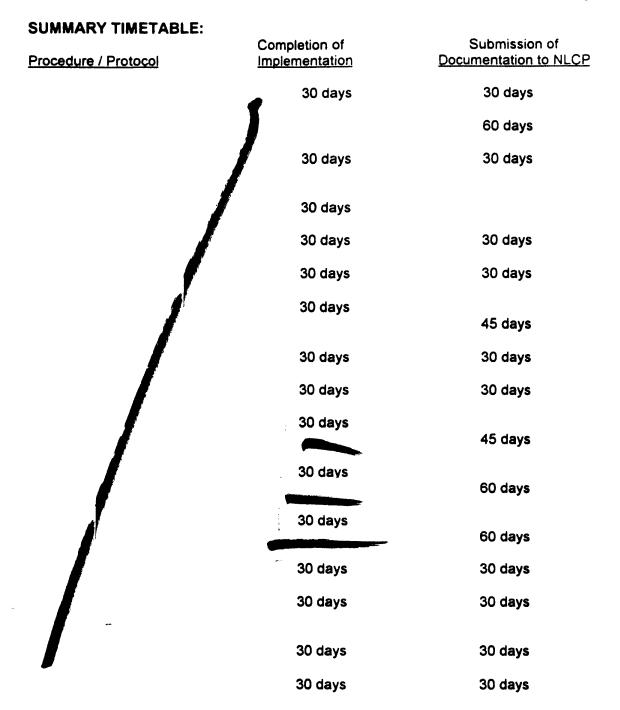


Quest Diagnostics, Inc. Lab ID# 0009

Section J. Records Audit



Section N. Personnel



This action plan is submitted for your review and approval. If you need additional information, please advise me. I look forward to your response.

Sincerely,

Ronald L. Raglin, M.S.

Director of Forensic Toxicology



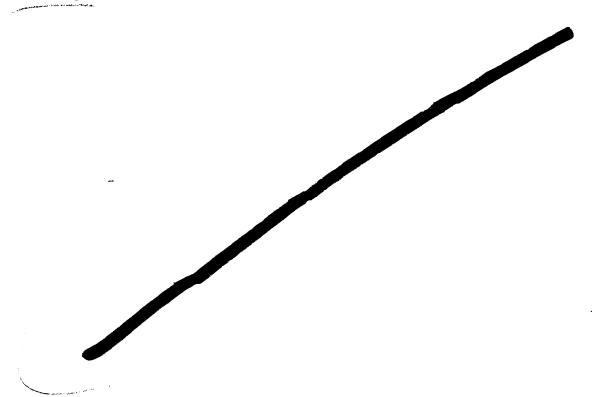
National Laboratory Certification Program

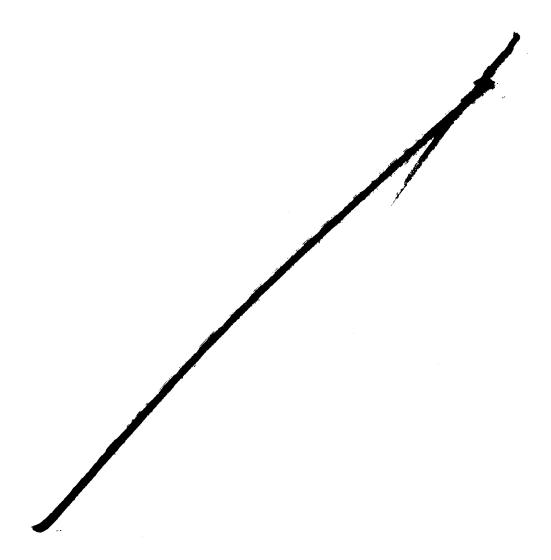
August 30, 1999

0009
Mr. Ronald Raglin
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Mr. Raglin:

We have reviewed the laboratory's proposed action plan submitted in your correspondence of August 25, 1999, provided in response to the deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of August 12, 1999. The plan to correct the deficiencies noted was found acceptable with the following exceptions:





I ne laboratory must submit the final report within 30 calendar days of receipt of this letter. This report must include supporting documentation to demonstrate completion of the planned remedial actions and to address the issues raised in this correspondence.

Mr. Raglin Page 3 of 3 08/30/99

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,

Susan Crumpton

NLCP Inspection Analyst

cc:

Project Files/M19

1901 Sulphin Spring Road Baltimore, MD 21227 410.247.9100





Ms. Susan Crumpton
National Laboratory Certification Program
3040 Cornwallis Road
Post Office Box 12194
Research Triangle Institute
Research Triangle Park, North Carolina 27709-2194

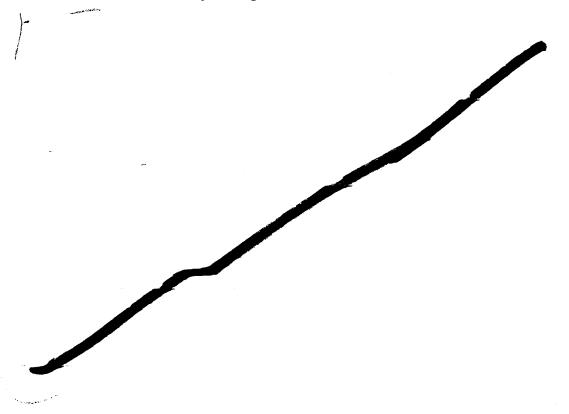
Dear Ms. Crumpton,

In response to the August 12, 1999, and August 30, 1999, letters regarding Maintenance Inspection Number 19 for Quest Diagnostics, Inc., in Baltimore, Maryland, please note the following documentation. The accompanying documentation is provided as follow-up to the action plan submitted on August 25, 1999.

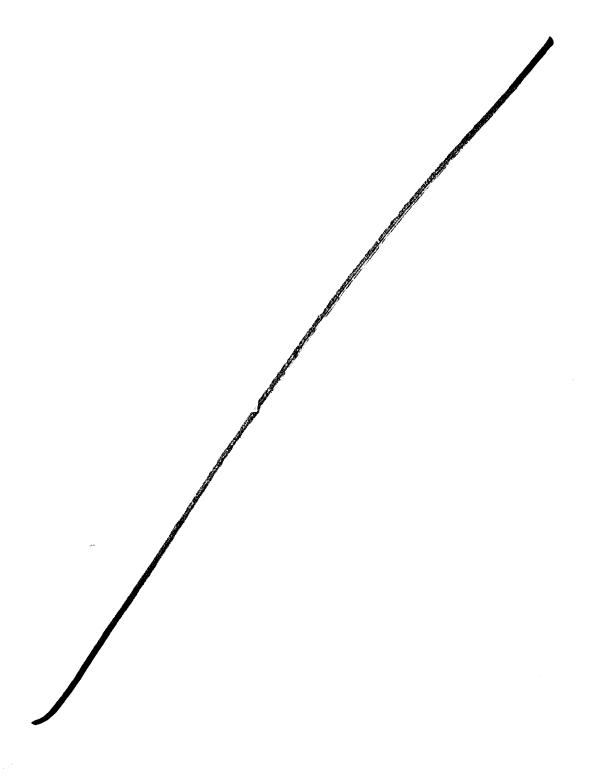
National Laboratory Certification Program

Responses to August 12, 1999 Inspection Critique Documentation of Corrective Action Plan

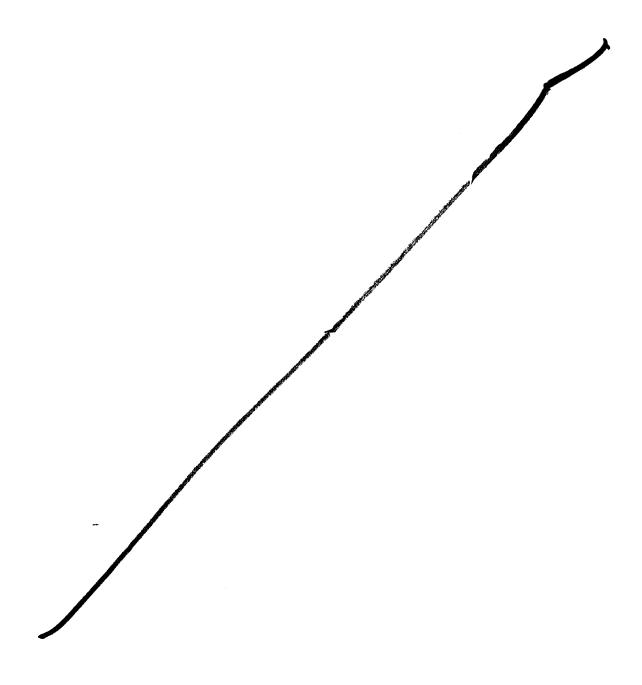
Section E. Standard Operating Procedures – Procedures Manual



Documentation of Corrective Action Plan (continued)
Section E. Standard Operating Procedures – Procedures Manual (continued)



Documentation of Corrective Action Plan (continued)
Section E. Standard Operating Procedures – Procedures Manual (continued)



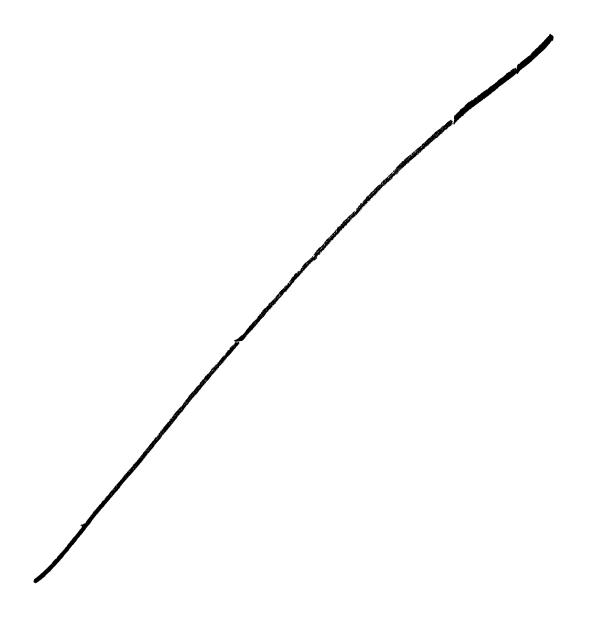
Documentation of Corrective Action Plan (continued)

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

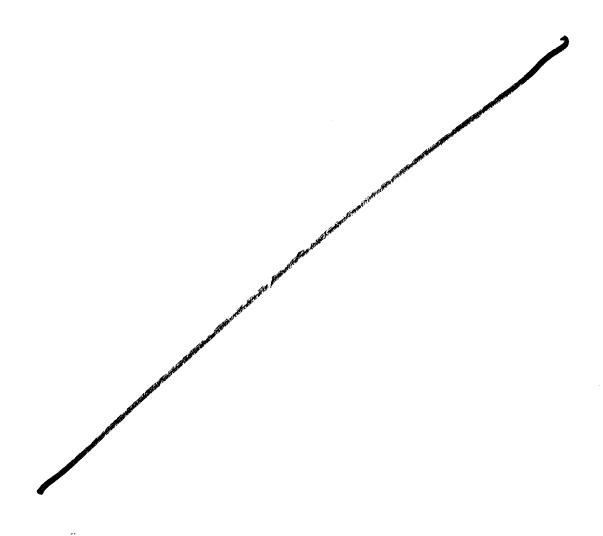
Quest Diagnostics, Inc. Lab ID# 0009

c:\msoffice\winword\Nlcp99c.doc
Baltimore, Maryland

Documentation of Corrective Action Plan (continued)
Section F. Chain-of-Custody, Accessioning, and Security (continued)

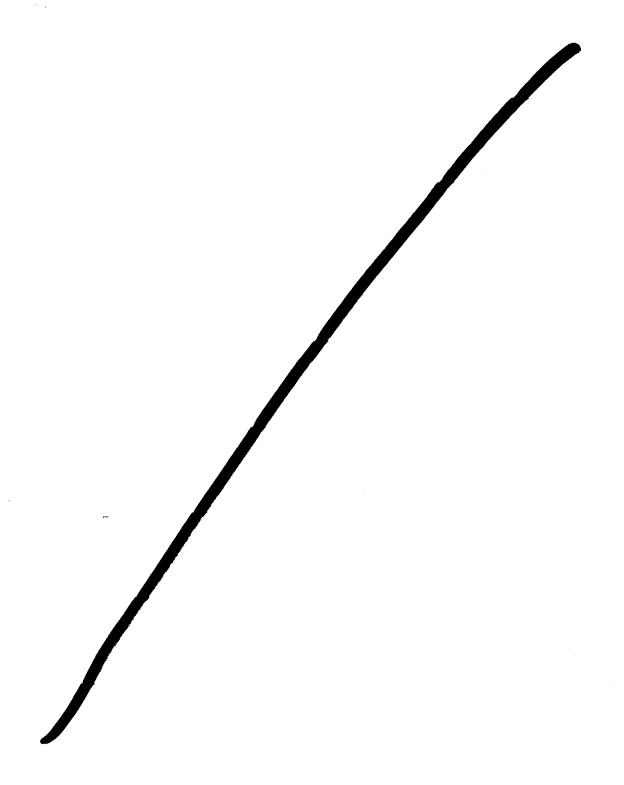


Documentation of Corrective Action Plan (continued) Section F. Chain-of-Custody, Accessioning, and Security (continued)

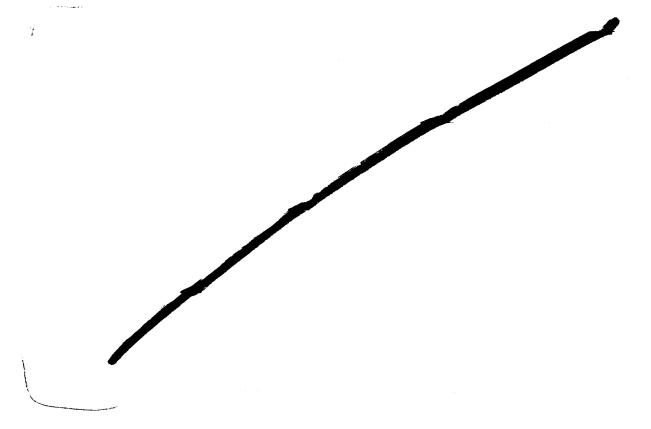


Documentation of Corrective Action Plan (continued)

Section G. Quality Control

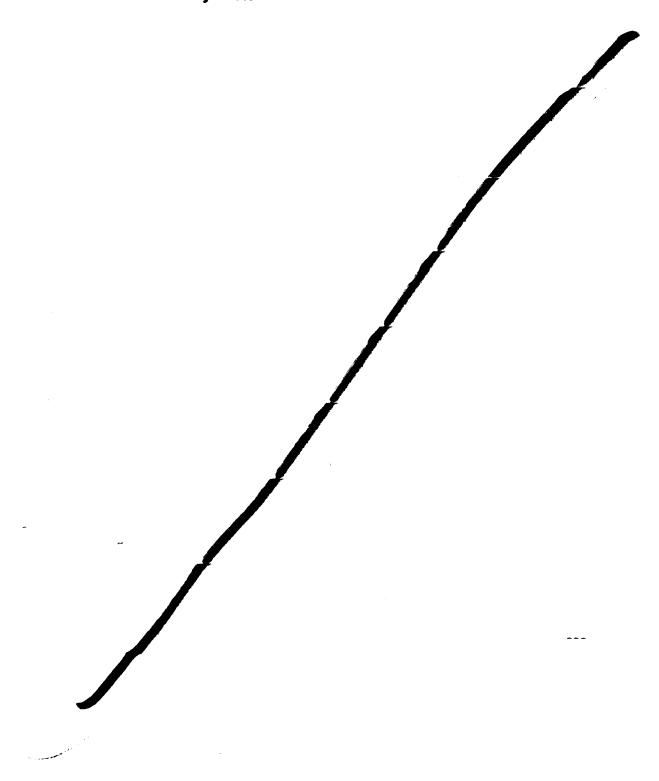


Documentation of Corrective Action Plan (continued) Section G. Quality Control (continued)

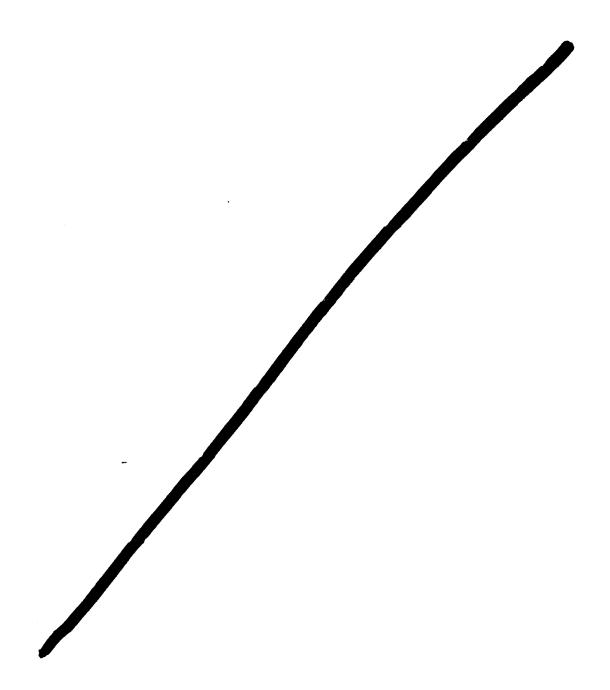


Documentation of Corrective Action Plan (continued)

Section I. Confirmatory Tests



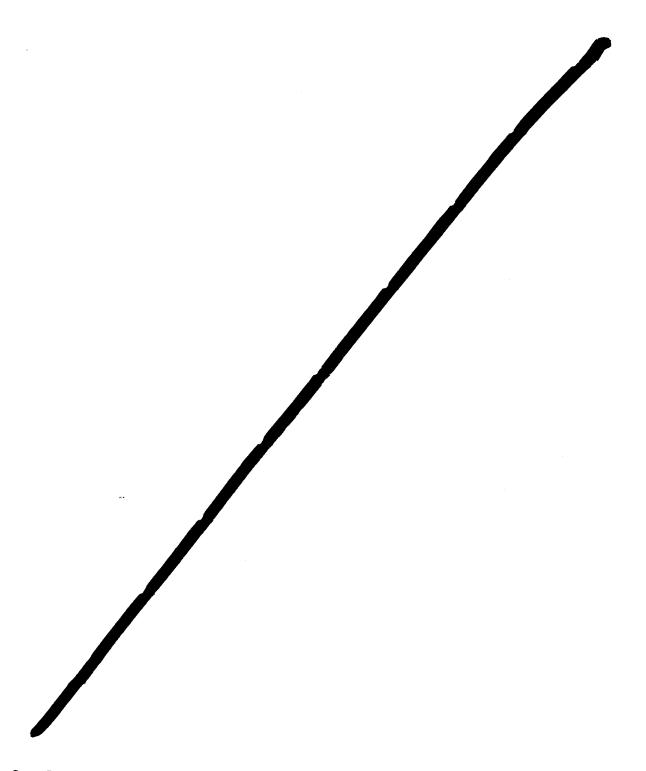
Documentation of Corrective Action Plan (continued) Section I. Confirmatory Tests (continued)



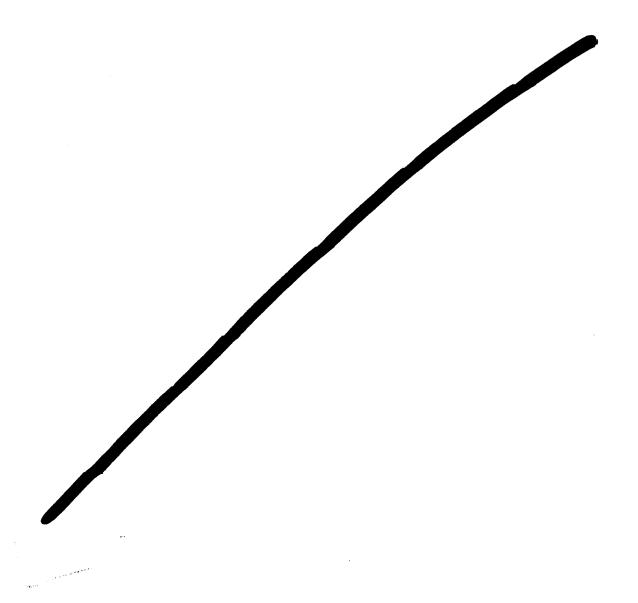
Quest Diagnostics, Inc. Lab ID# 0009 Baltimore, Maryland

Documentation of Corrective Action Plan (continued)

Section J. Records Audit

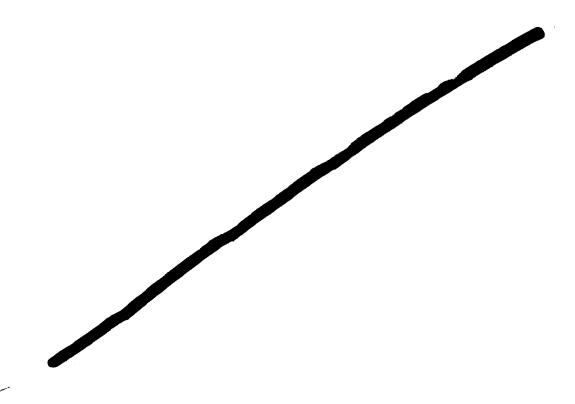


Decumentation of Corrective Action Plan (continued) Section J. Records Audit (continued)



Documentation of Corrective Action Plan (continued)

Section N. Personnel



Additional documentation and reporting will occur prior to October 15, 1999, and October 30, 1999. If you need additional information, please advise me.

Sincerely.

Ronald L. Raglin, M.S. Director of Forensic Toxicology



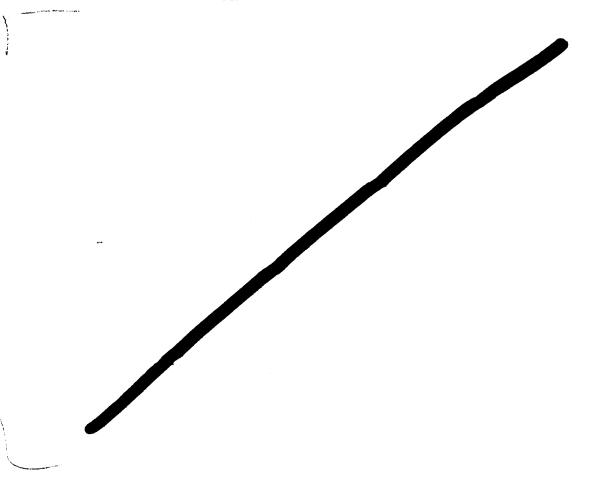
National Laboratory Certification Program

October 6, 1999

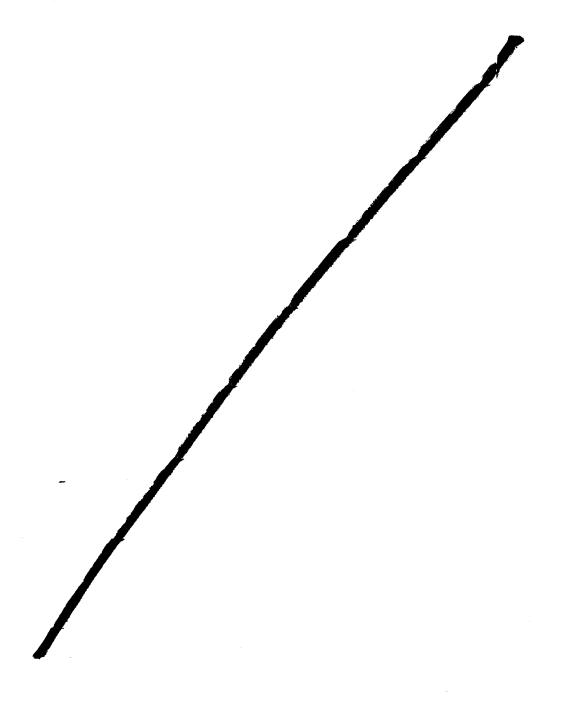
0009
Mr. Ronald Raglin
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Mr. Raglin:

We have reviewed the material provided in your correspondence of September 24, 1999, submitted in response to deficiencies cited during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of August 12, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been taken to address the deficiencies raised. The following is a review of the material submitted:



Mr. Raglin October 6, 1999 Page 2 of 4



Mr. Raglin October 6, 1999 Page 3 of 4

Mr. Raglin October 6, 1999 Page 4 of 4

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

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

Project Files/M19 CC:



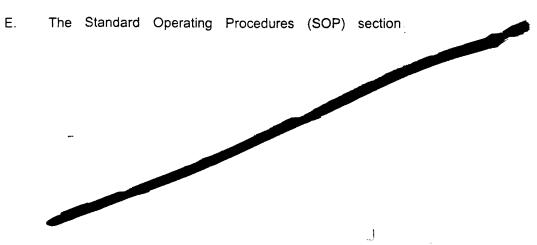
National Laboratory Certification Program

February 3, 2000

0009
Mr. Ronald Raglin
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

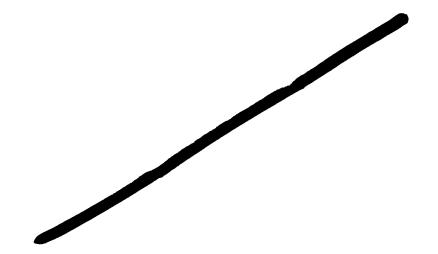
Dear Mr. Raglin:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth 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 take steps to correct the following issues raised:

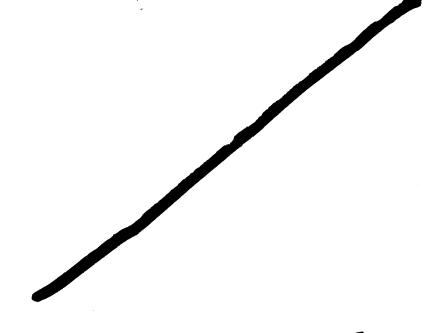


F. The Chain of Custody, Accessioning, and Security section

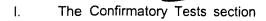




G. The Quality Control section



H. The Initial Tests section



J. The Records Audit section



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 **sections F and I** above. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

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

Sincerely,

Susan Crumpton

NLCP Inspection Analyst

Enclosure

cc: Project Files/M20



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: <u>0009</u> Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Baltimore, MD

Document Reviewed: [] Application Form

[XX] Inspection Report #M20
[] Other _____

Date: 9 December 1999

Status:

[XX] Highly Acceptable

[] Unacceptable

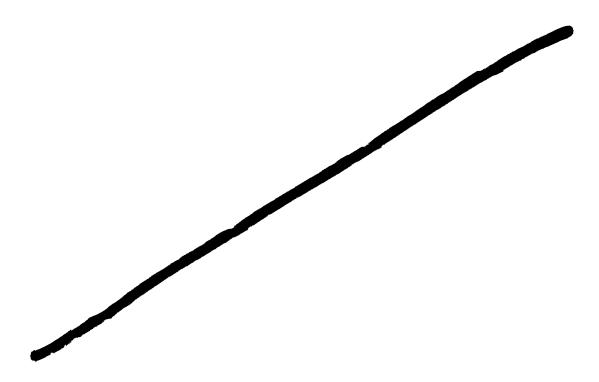
[] Acceptable [] Failure

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 met the standards required for the inspection phase of the Program.

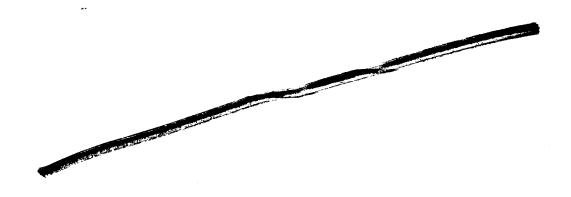
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



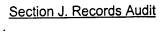
Section F. Chain-of-Custody, Accessioning, and Security



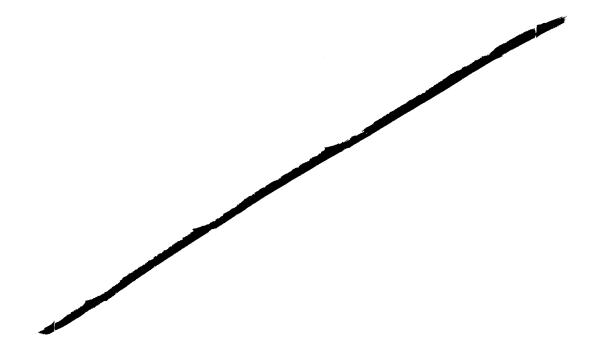
Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests



Ver. Final Lab ID# 0009



Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

REV: Final

Quest Diagnostics Incorporated

1901 Sulphur Spring Road Baltimore, MD 21227 410,247,9100



Page 1 of 5 February 25, 2000



Ms. Susan Crumpton National Laboratory Certification Program 3040 Cornwallis Road Post Office Box 12194 Research Triangle Institute Research Triangle Park, North Carolina

27709-2194

Dear Ms. Crumpton,

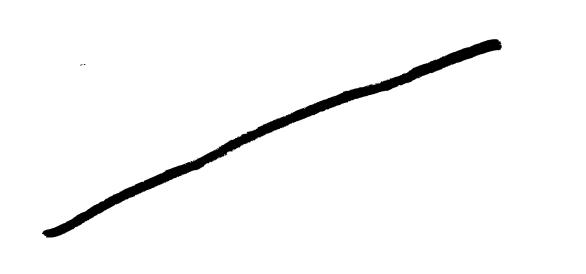
In response to the letter of February 3, 2000, regarding Maintenance Inspection Number 20 for Quest Diagnostics, Inc., in Baltimore, Maryland, please note the following actions.

The following plan to complete remedial actions is submitted for your review and approval:

Section E. Standard Operating Procedures – Procedures Manual



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



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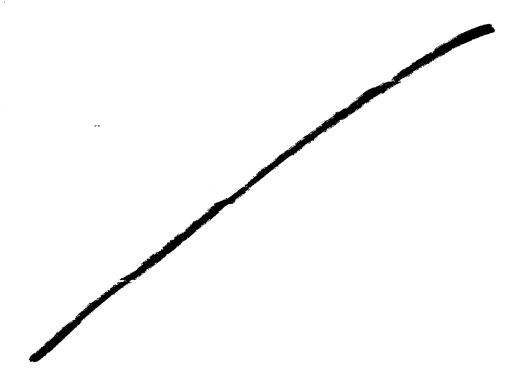
Section G. Quality Control (continued)



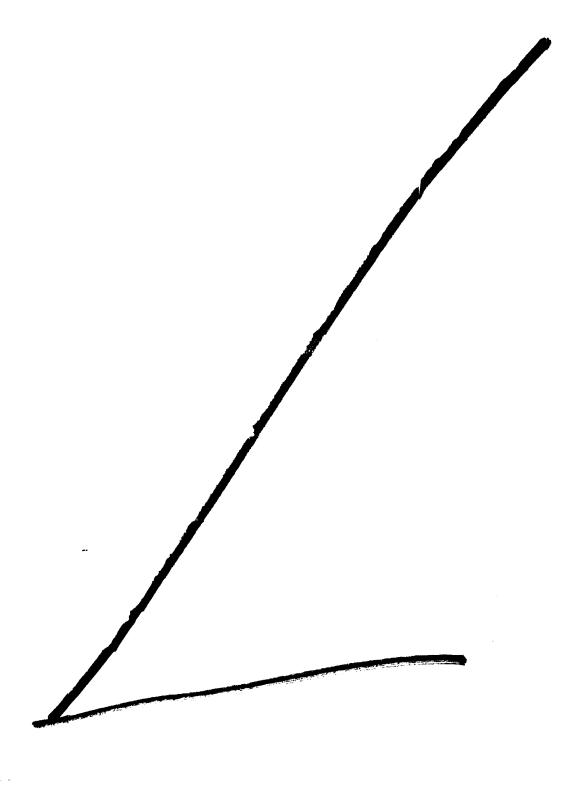
Section H. Initial Tests



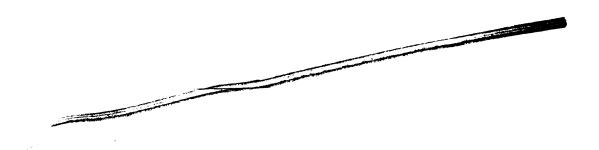
Section I. Confirmatory Tests



Section J. Records Audit



Section J. Records Audit (continued)



This action plan is submitted for your review and approval. If you need additional information, please advise me. I look forward to your response.

Sincerely,

Ronald L. Raglin, M.S.

Director of Forensic Toxicology



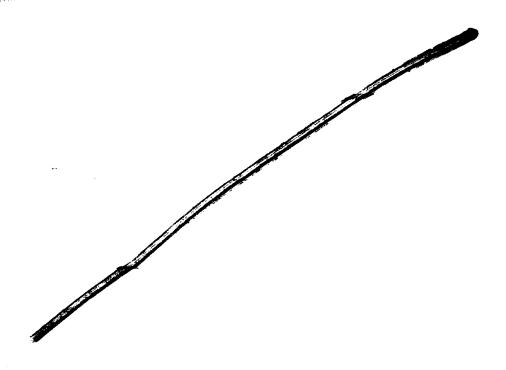
National Laboratory Certification Program

March 3, 2000

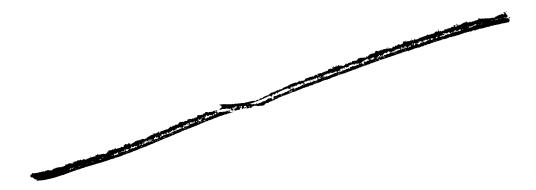
0009
Mr. Ronald Raglin
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Mr. Raglin:

We have reviewed the material provided in your correspondence of February 25, 2000, submitted in response to issues raised during the twentieth maintenance inspection of your laboratory as outlined in our correspondence of February 3, 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:







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:

Project Files/M20



National Laboratory Certification Program

August 10, 2000

0009
Mr. Ronald Raglin
Dr. Ross Lowe
Quest Diagnostics Incorporated
National Center for Forensic Science
1901 Sulphur Spring Road
Baltimore, MD 21227

Dear Mr. Raglin:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-first maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in the attached critique.

The laboratory will withdraw its certification effective August 12, 2000. 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/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0009 Document No. Final **Quest Diagnostics Incorporated** Laboratory: Baltimore, MD Location: Document Reviewed:] Application Form [XX] Inspection Report #M21 Date: 15 June 2000 [] Other Status: [XX] Highly Acceptable] Acceptable [] Unacceptable 1 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 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