

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

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 issues raised:

E. The Standard Operating Procedures (SOP) section



G. The Quality Control section



[Redacted]

H. The Initial Tests section

[Redacted]

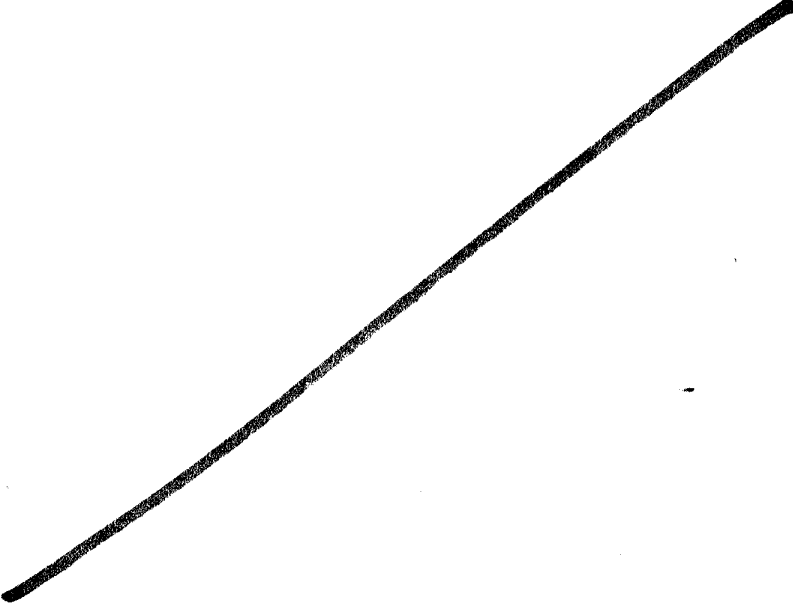
I. The Confirmatory Tests section

[Redacted]

J. The Records Audit section :

[Redacted]

Callies and D'Addario
Page 3 of 3
02/04/99



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 described 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 your 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 of the receipt of this correspondence and will be reviewed at the next inspection.

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

Sincerely,


Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0101
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M17 Date: 10 December 1998
 Other _____

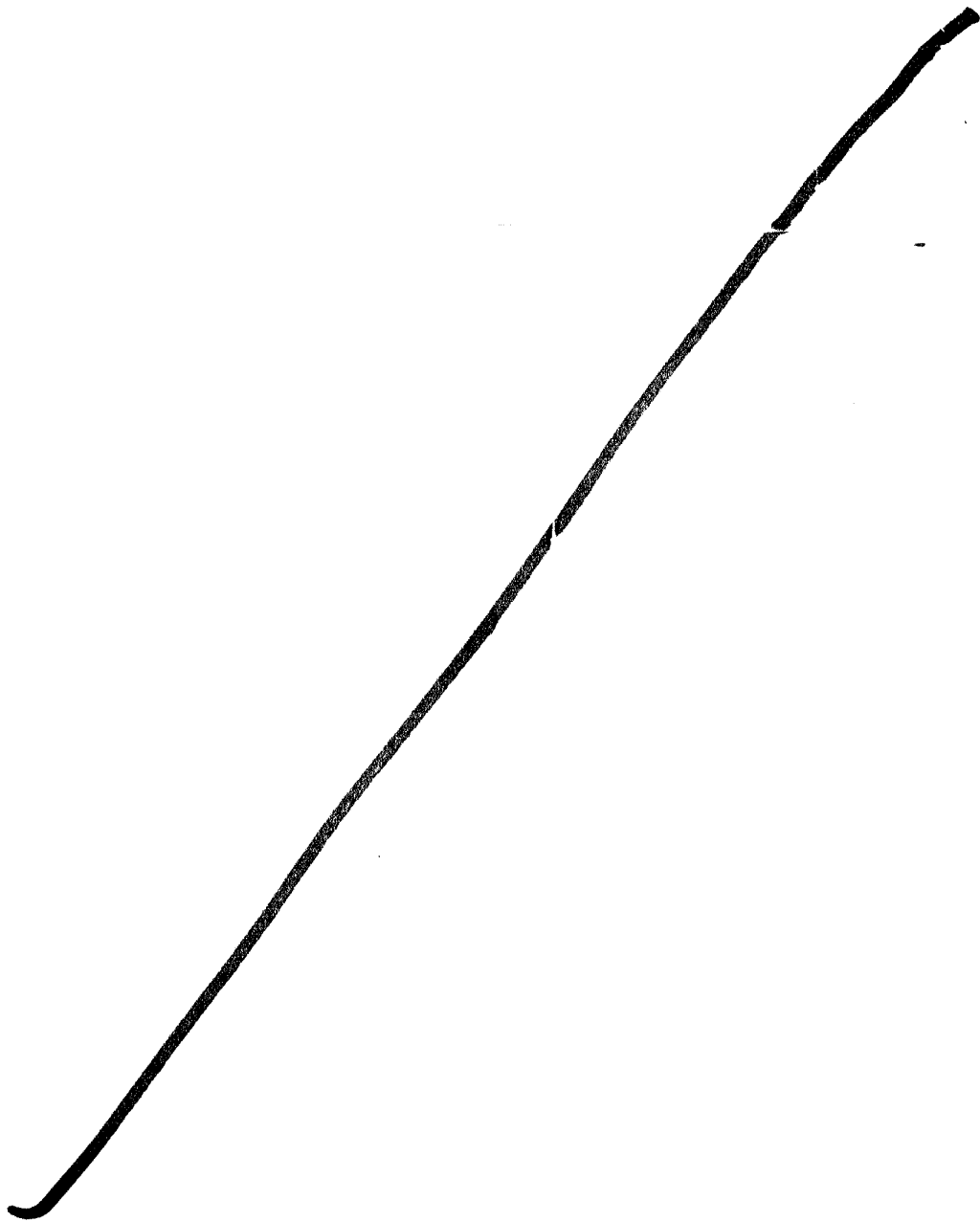
Status: Highly Acceptable Acceptable
 Unacceptable Failure

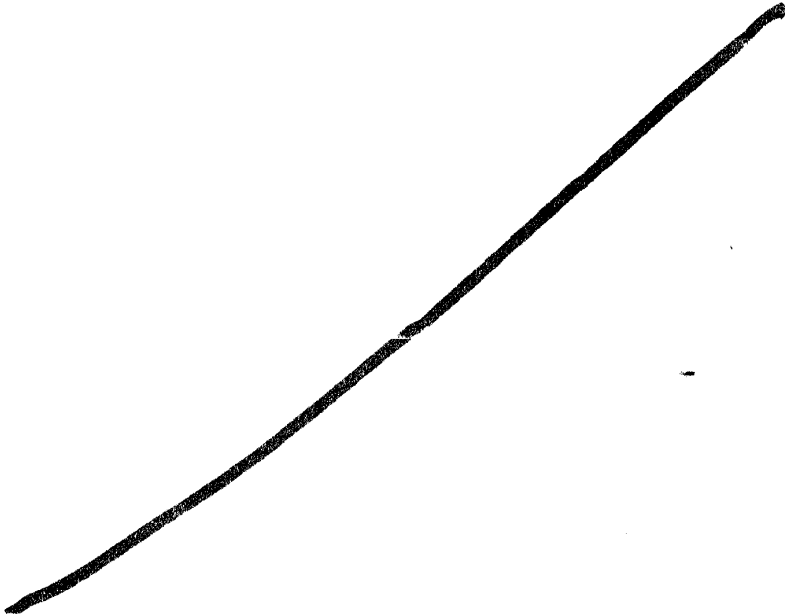
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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

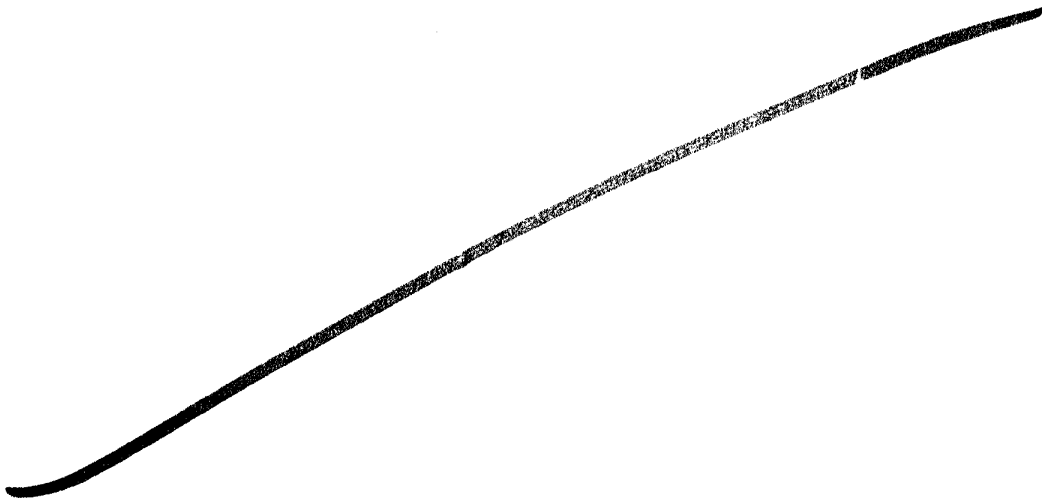


Section I. Confirmatory Tests





Section J. Records Audit



Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

Quest Diagnostics Incorporated

7470 Mission Valley Road
San Diego, CA 92108
619 586-3000
800-848-1223 Toll Free

received
SLC 3/9/99



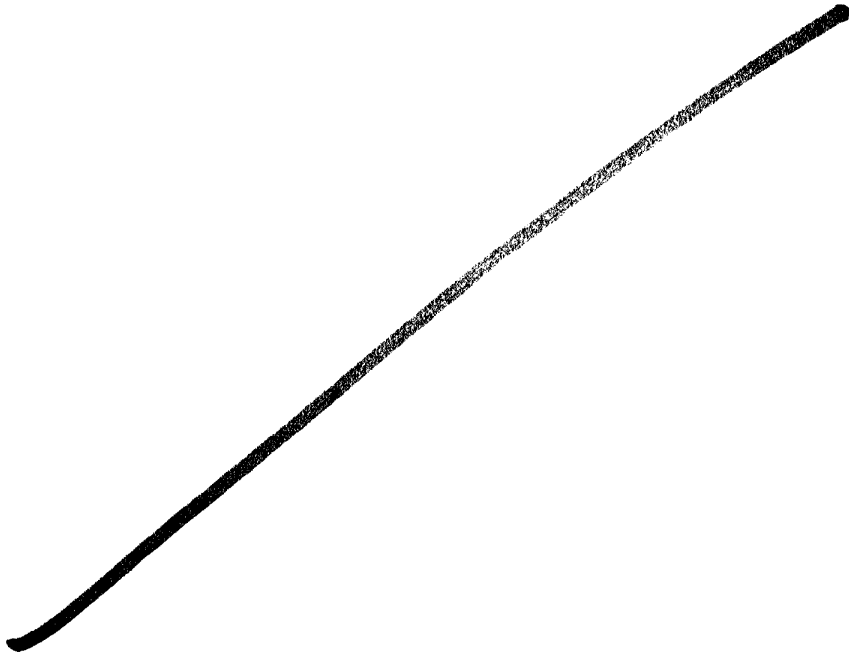
March 5, 1999

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

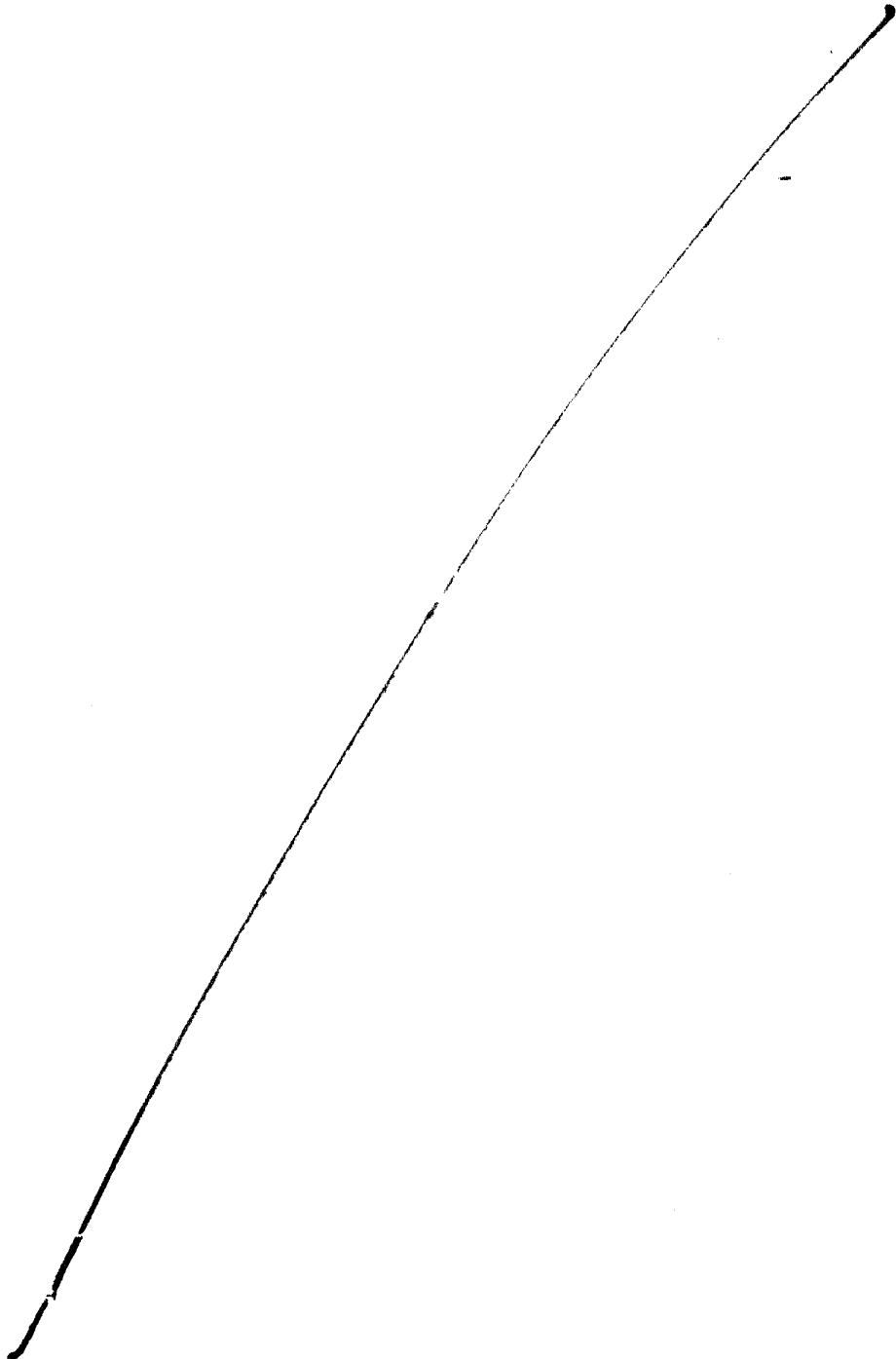
Dear Ms. Crumpton:

This correspondence is in reference to your letter dated February 4, 1999 regarding the inspection critique from our seventeenth maintenance inspection. Your letter addressed several issues that need corrective action or clarification. The following information addresses these issues. The paragraph outline corresponds to the paragraphs in your letter. The enclosures are similarly labeled.

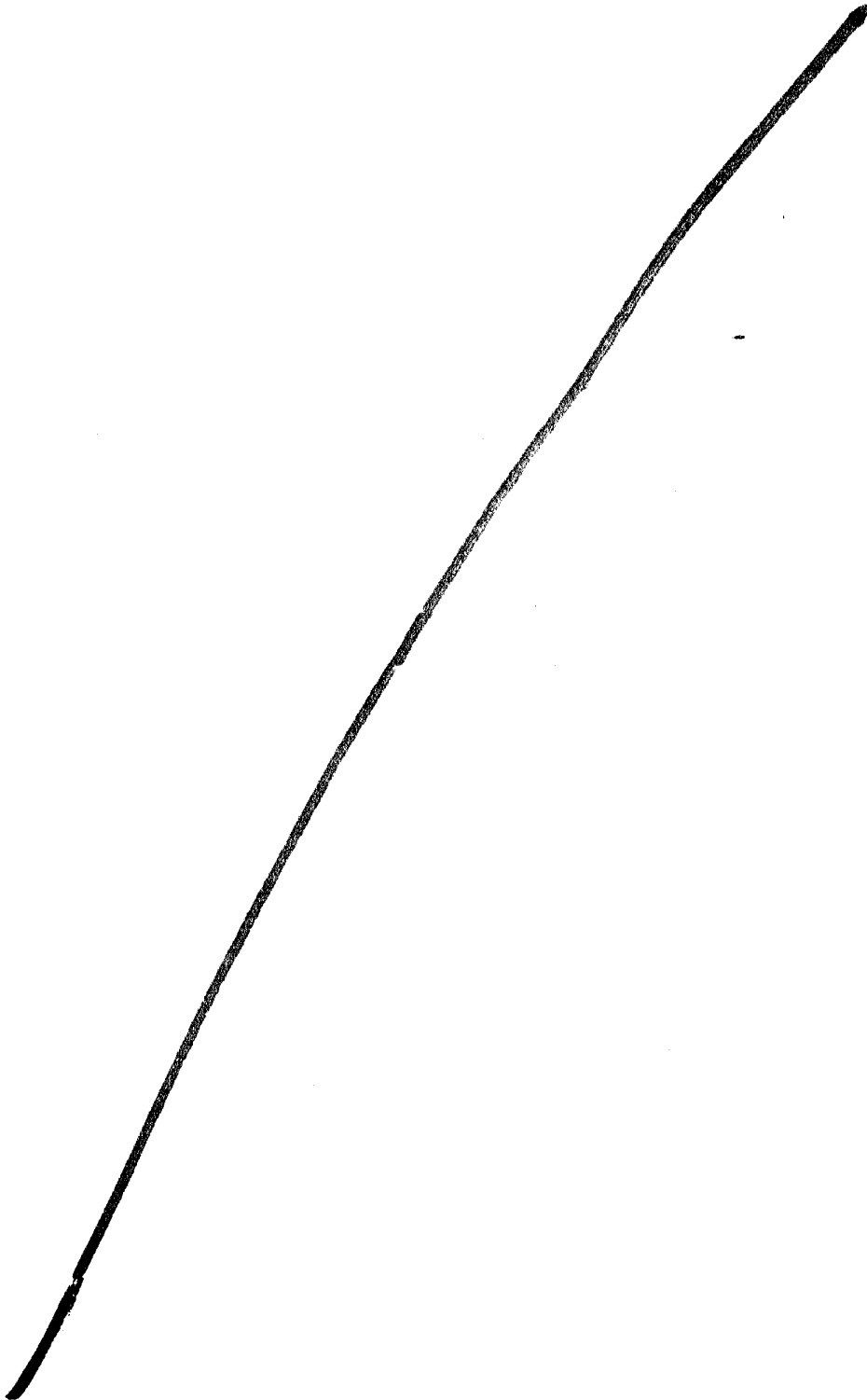
E. (SOP)



Susan Crumpton
March 5, 1999
Page 2

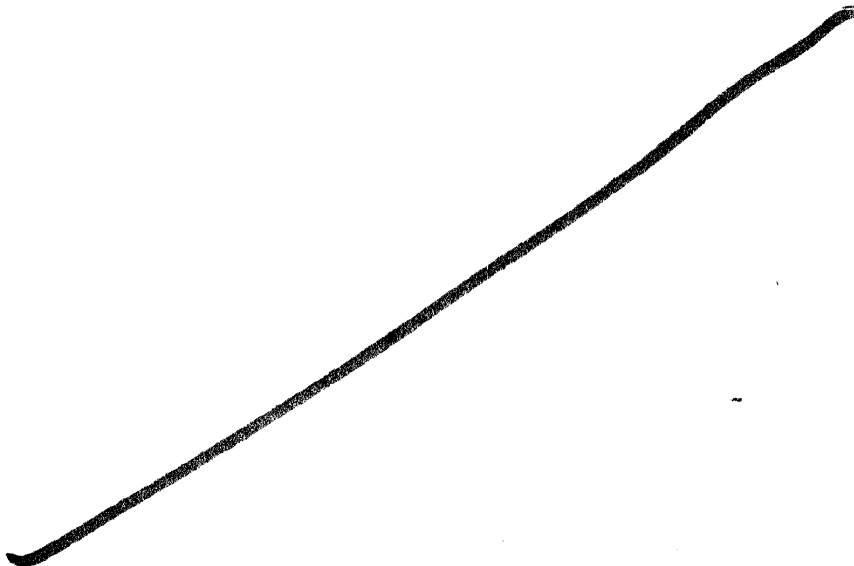


Susan Crumpton
March 5, 1999
Page 3



10/10/10

1




G. Quality Control



H. Initial Tests

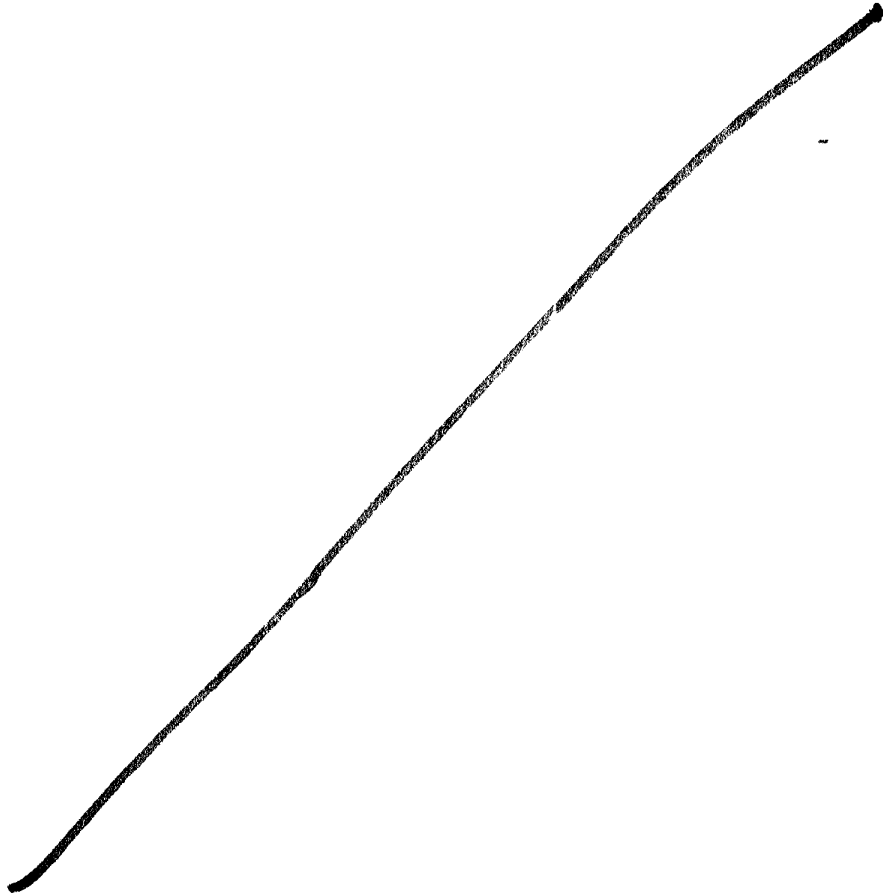


I. Confirmation Tests





J. Records Audit



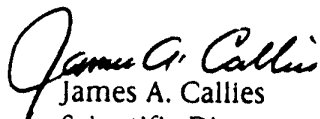
Susan Crumpton

March 5, 1999

Page 6

It is hoped that the above corrective actions and clarifications are satisfactory to the NLCP. If additional information is needed, please contact myself at (619) 686-3214 or Dr. D'Addario at (619) 686-3279.

Sincerely,

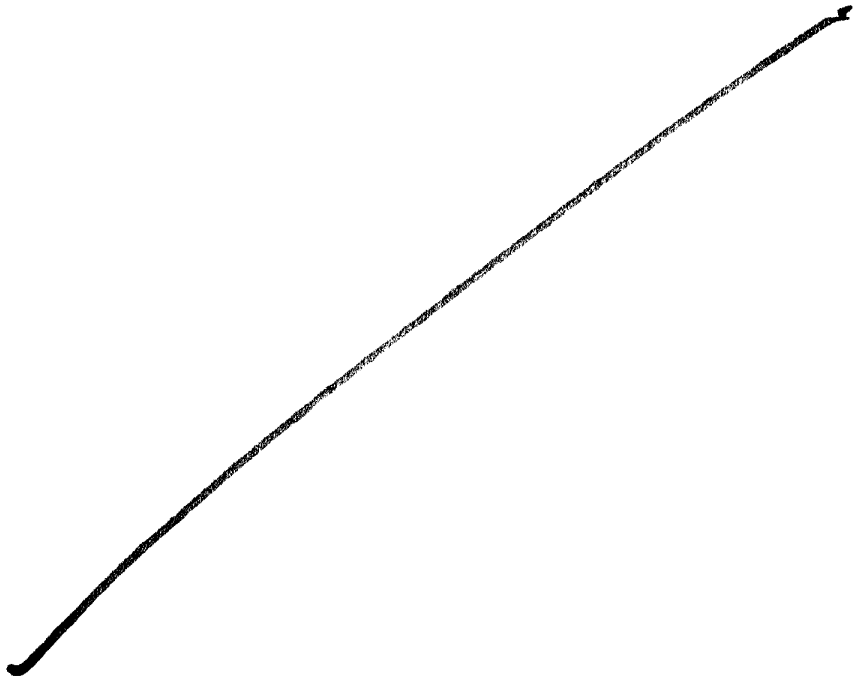

James A. Callies
Scientific Director

March 17, 1999

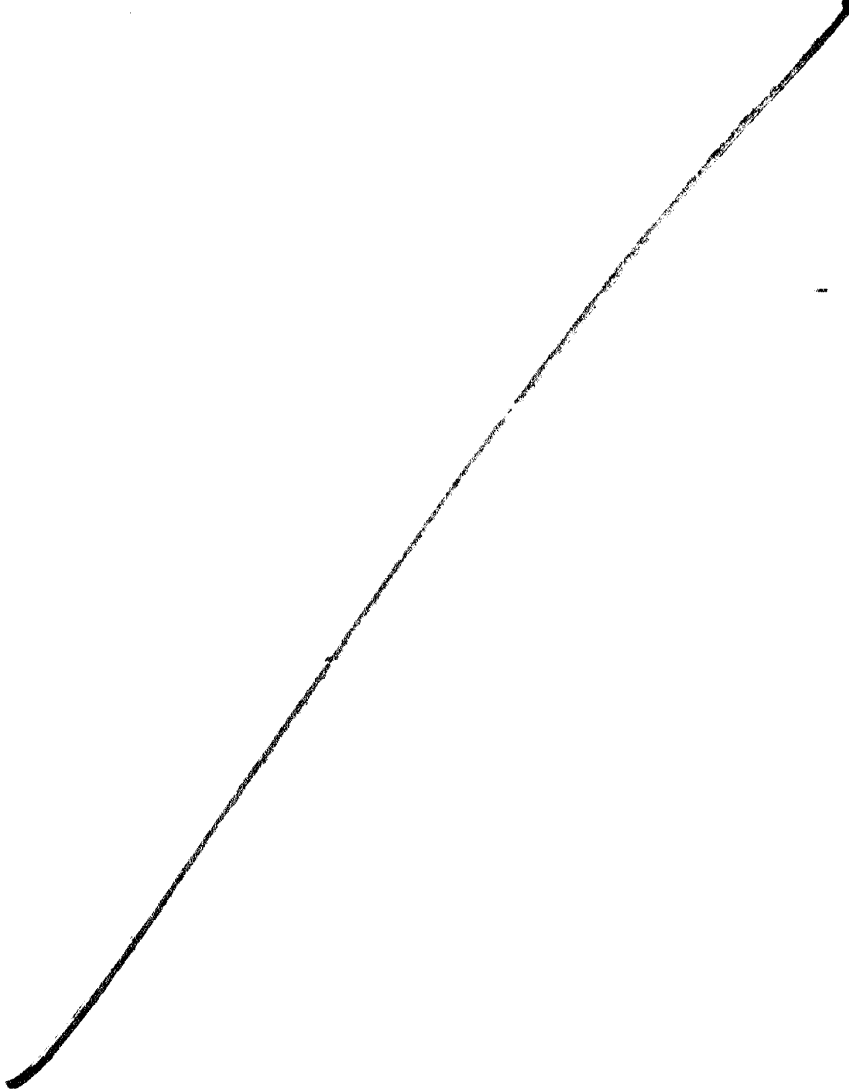
0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence of March 5, 1999, submitted in response to issues raised during the seventeenth inspection of your laboratory as outlined in our correspondence of February 4, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following issues remain:



Mr. Callies
Dr. D'Addario
Page 2 of 3
03/17/99



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 (NLCP). The laboratory must take steps to correct the issues cited above. All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

Mr. Callies
Dr. D'Addario
Page 3 of 3
03/17/99

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

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

cc:


Project Files/M17

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

July 30, 1999

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

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 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:

E. The Standard Operating Procedures (SOP) section

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

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[Redacted]

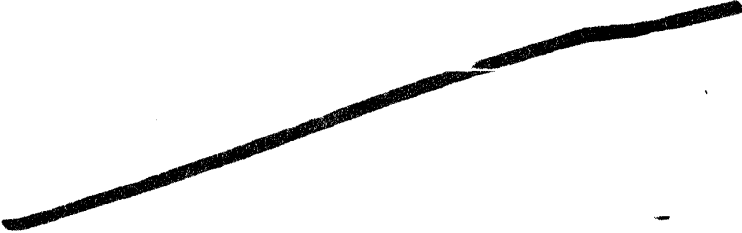
I. The Confirmatory Tests section

[Redacted]

N. The Personnel section

[Redacted]

Mr. Callies
Dr. D'Addario
Page 3 of 3
07/30/99



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 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/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0101
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M18 Date: 10 June 1999
 Other _____

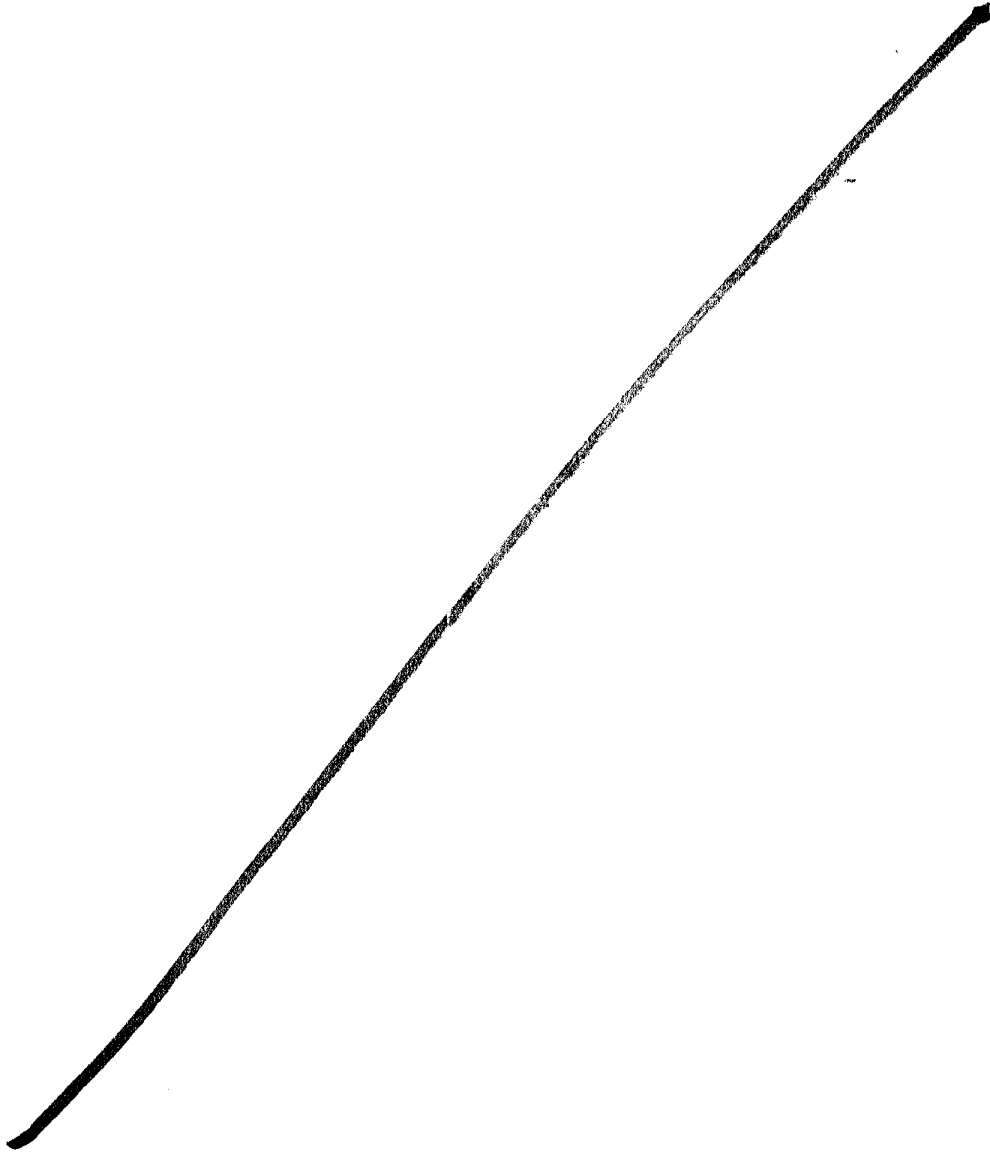
Status: Highly Acceptable Acceptable
 Unacceptable Failure

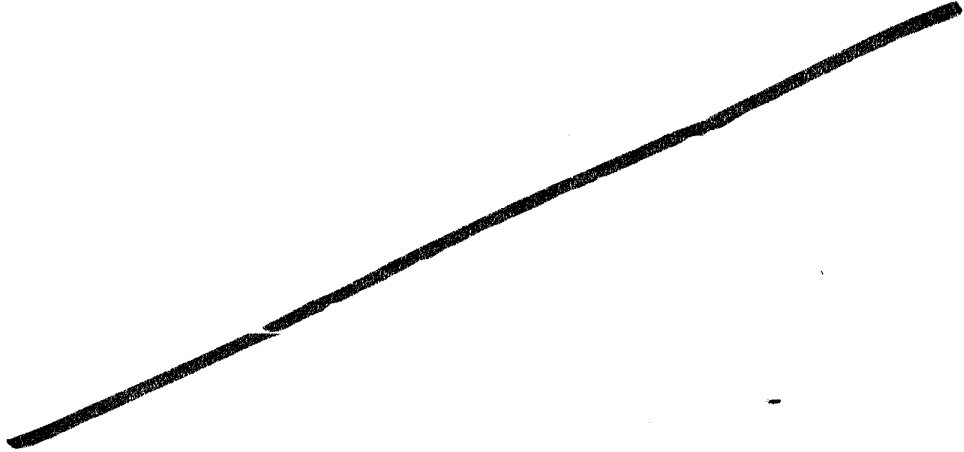
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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

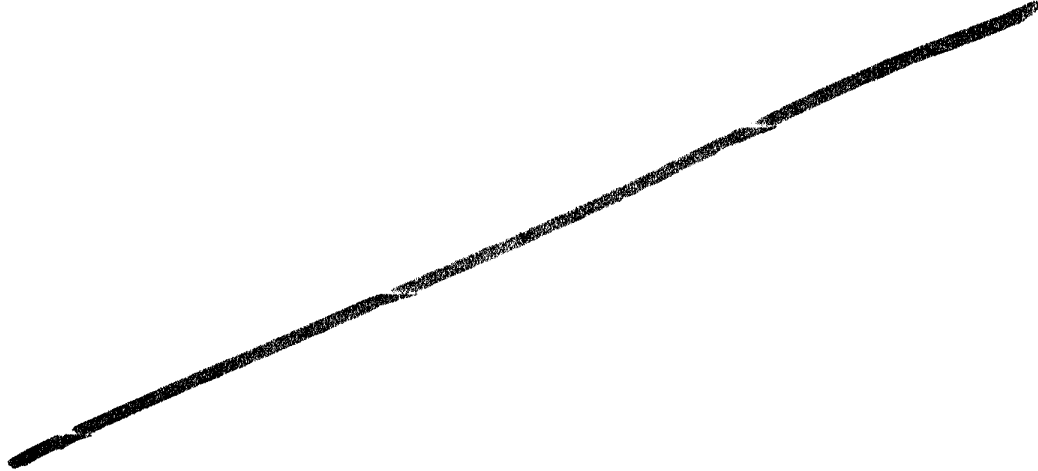
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





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



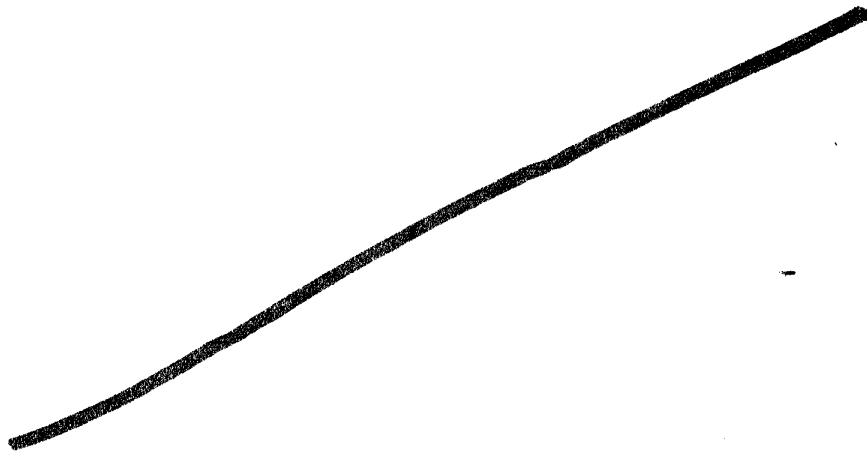
Section G. Quality Control



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

100 Mission Valley Road
San Diego, CA 92108
619-594-3000
SUN 8/25/99 11:11 AM

received
8/31/99 dx



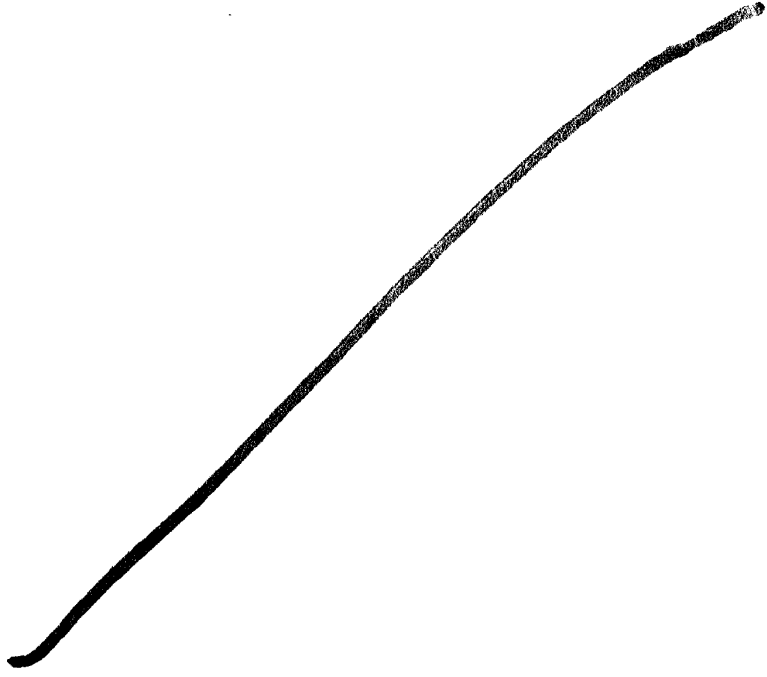
August 25, 1999

Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

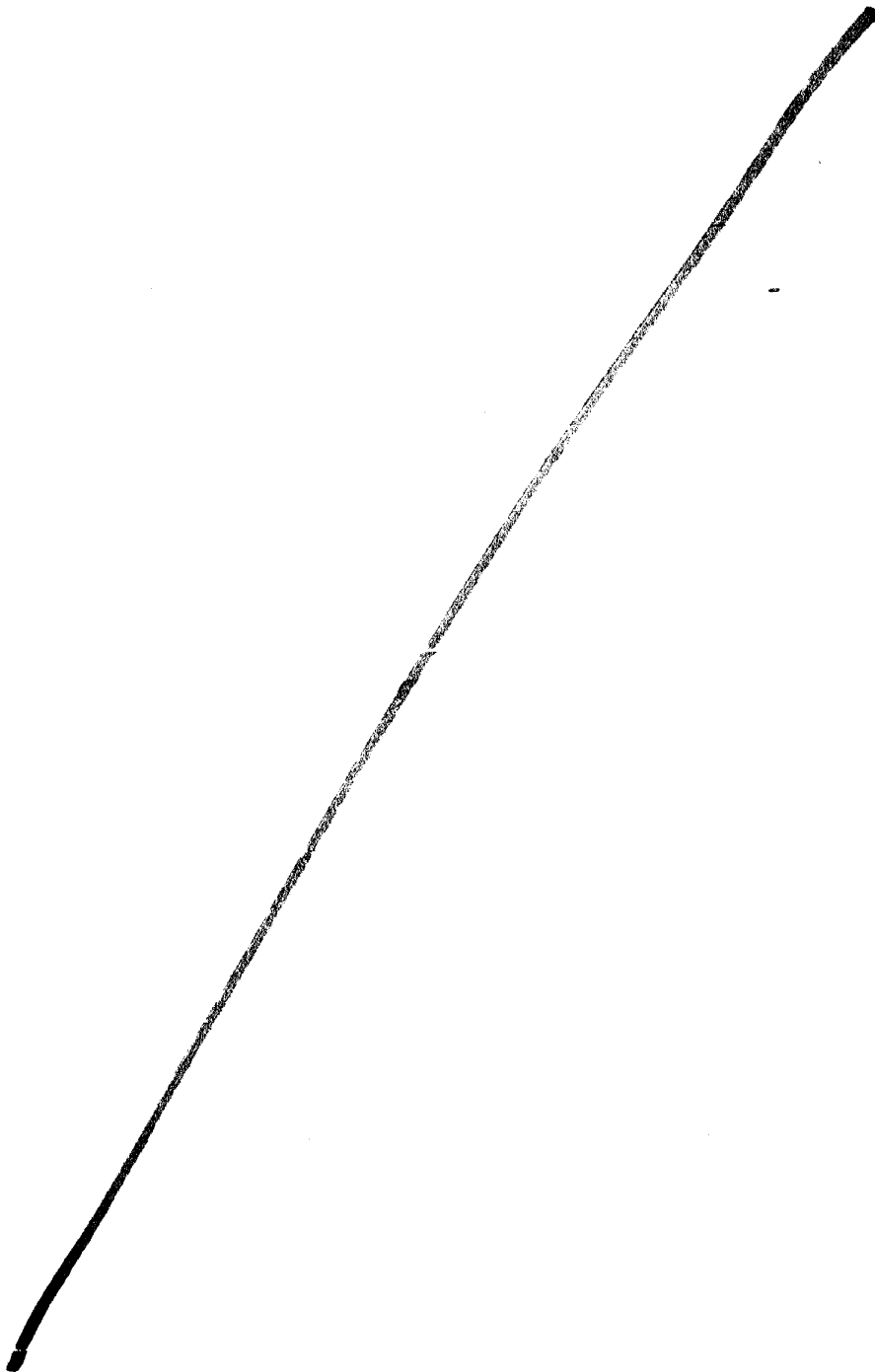
Dear Ms. Crumpton:

This correspondence is in response to your letter dated July 30, 1999 regarding the inspection critique from our eighteenth NLCP maintenance inspection. Your letter addressed several issues that need corrective action or clarification. The following information addresses these issues. The paragraph outline corresponds to the paragraphs in your letter. The enclosures are similarly labeled.

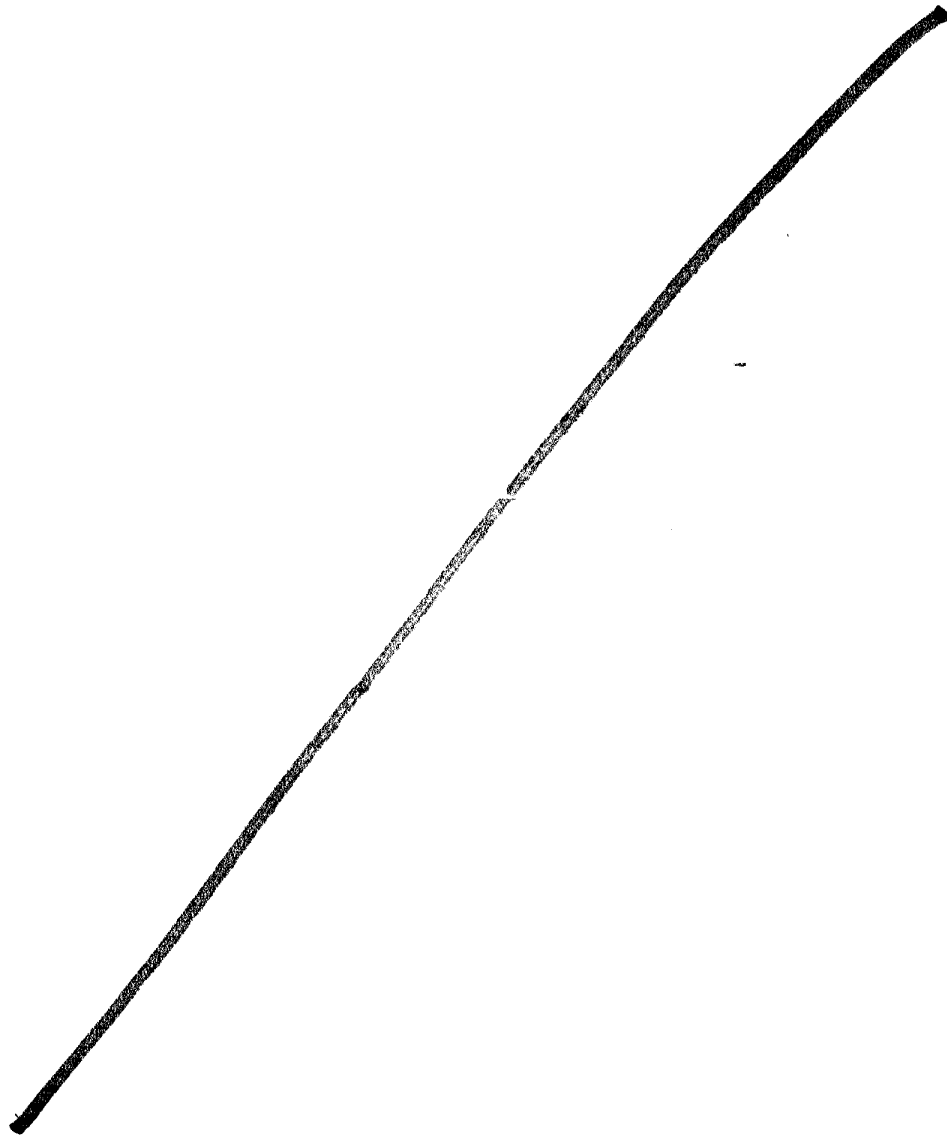
E. SOP



Susan Crumpton
August 25, 1999
Page 2



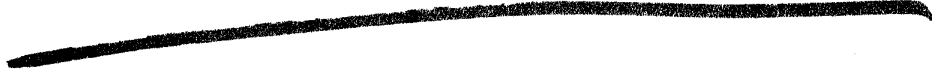
Susan Crumpton
August 25, 1999
Page 3



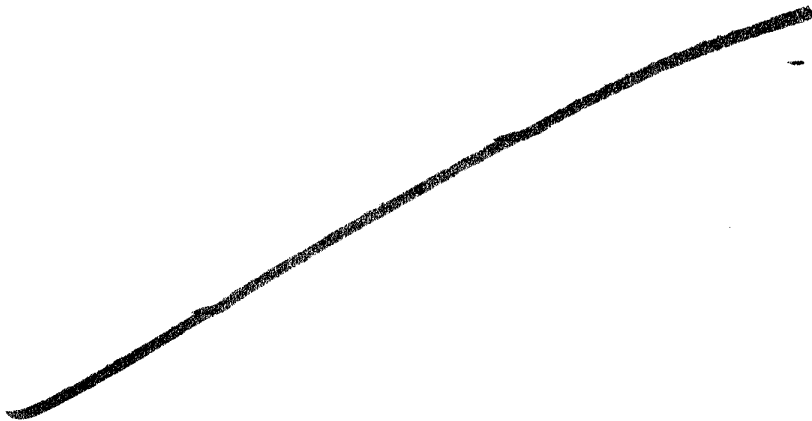
F. Chain of Custody, Accessioning and Security



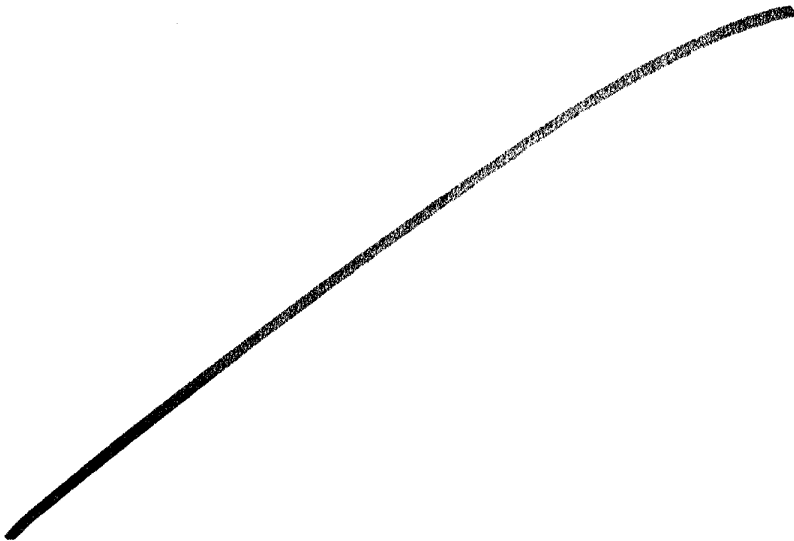
Susan Crumpton
August 25, 1999
Page 4



I Confirmatory Tests




N. Personnel



Susan Crumpton
August 25, 1999
Page 5

It is hoped the above corrective actions and clarifications meet the requirements of the NLCP. If additional information is necessary, please contact me at (619) 686-3214 or Dr. D'Addario at (619) 686-3214.

Sincerely,


James A. Callies
Scientific Director

RESEARCH TRIANGLE INSTITUTE



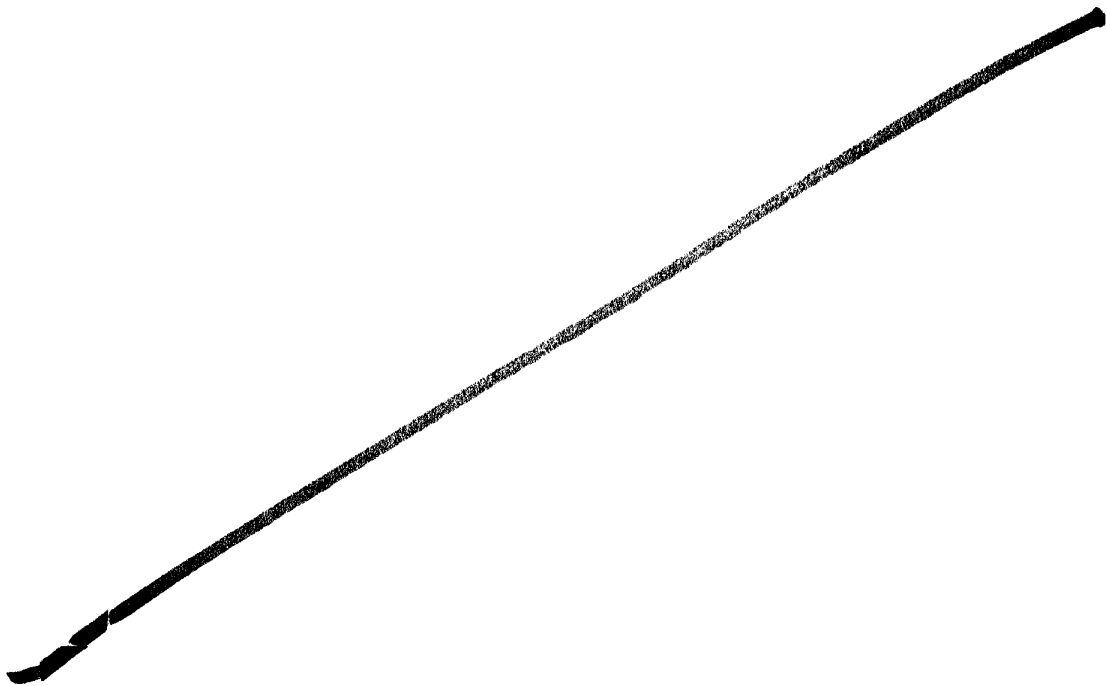
National Laboratory Certification Program

September 3, 1999

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence of August 25, 1999, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of July 30, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the following issues remain or were raised during our review of submitted material:



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

February 1, 2000

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

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.

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



G. The Quality Control section



Mr. Callies
Dr. D'Addario
February 1, 2000
Page 2 of 3

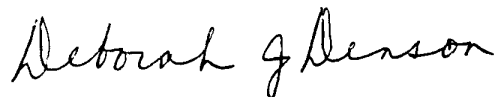
I The Confirmatory Tests section

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 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

Mr. Callies
Dr. D'Addario
February 1, 2000
Page 3 of 3

Enclosure

cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0101
Document No. Final

Laboratory: Quest Diagnostics Inc.

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M19 Date: 2 December 1999
 Other _____

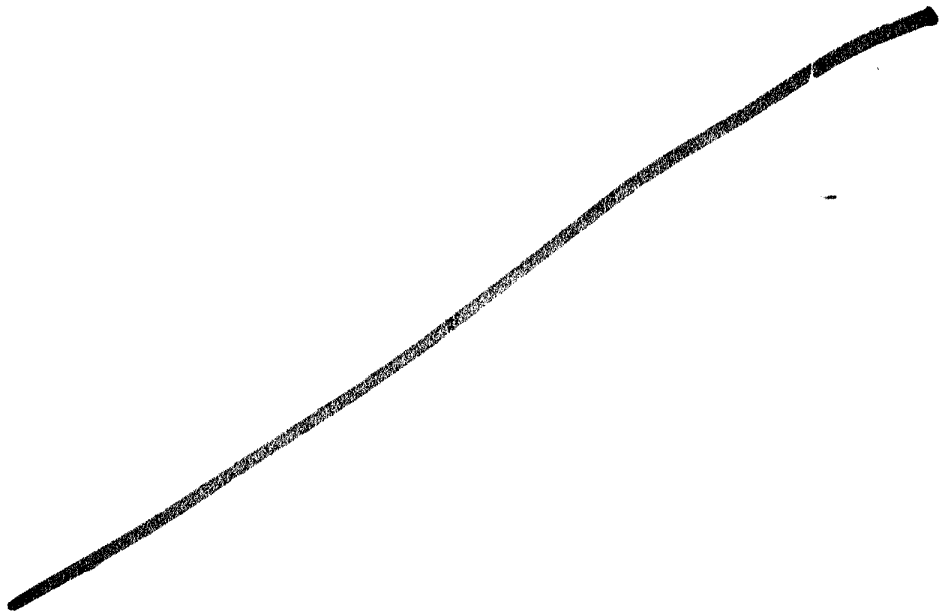
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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

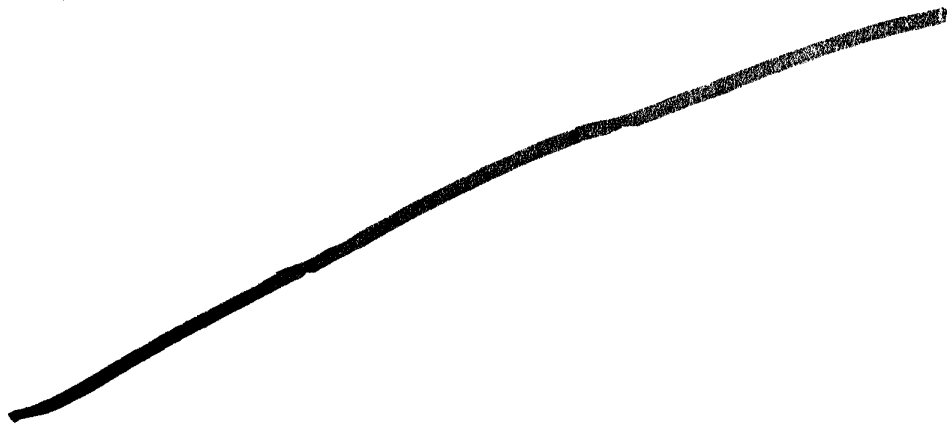
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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



[Redacted]

Section G. Quality Control

[Redacted]


Section H. Initial Tests

[Redacted]


Section I. Confirmatory Tests

[Redacted]

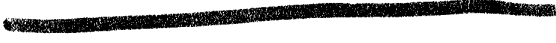
Section J. Records Audit




Section K. Reporting



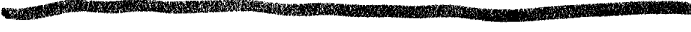
Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



Quest Diagnostics Incorporated

7470 Mission Valley Road
San Diego, CA 92198
619 686-3000
800-848-4225 Toll Free

received
2/22/2000 DB



February 21, 2000

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

Dear Ms. Denson:

This letter is in response to your letter dated February 1, 2000 regarding the critique of our nineteenth maintenance inspection under the NLCP. Your letter lists items that need clarification or corrective action. The following information addresses these issues. The paragraph outline corresponds to the paragraphs in your letter. The enclosures are similarly labeled.

F. The Chain of Custody, Accessioning and Security

[Redacted content]

G. Quality Control

[Redacted content]

I. Confirmation Tests section


J. Records Audit

Deborah J. Denson
February 21, 2000
Page 3

discarded. They are not intended to be included as part of the permanent laboratory records. Certifiers are to obtain the missing information on internal forms and remove the adhesive notes when this information has been provided.

If additional information is needed please contact Dr. D'Addario (619) 686-3279 or myself at (619) 686-3214.

Sincerely,


James A. Callies
Scientific Director

RESEARCH TRIANGLE INSTITUTE




National Laboratory Certification Program

February 29, 2000

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

We have reviewed the material provided in your correspondence February 21, 2000, submitted in response to issues raised during the nineteenth maintenance inspection of your laboratory as outlined in our correspondence of February 1, 2000. The information submitted by the laboratory appears to demonstrate that appropriate 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,

A handwritten signature in cursive script that reads "Deborah J. Denson".

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M19





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 17, 2000

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

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

E. The Standard Operating Procedures (SOP) section

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

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Mr. Callies
Dr. D'Addario
August 17, 2000
Page 2 of 3

G. The Quality Control section

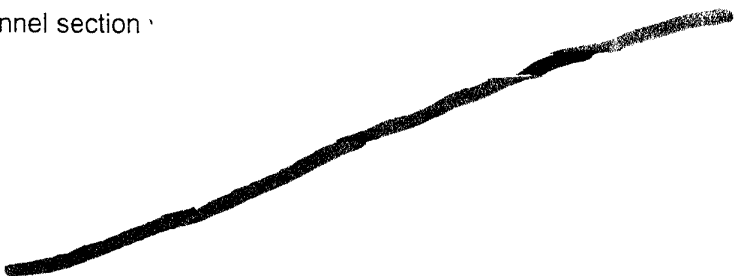
H. The Initial Tests section

I. The Confirmatory Tests section

J. The Records Audit section

Mr. Callies
Dr. D'Addario
August 17, 2000
Page 3 of 3

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

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/M20



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0101
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M20 Date: 15 June 2000
 Other _____

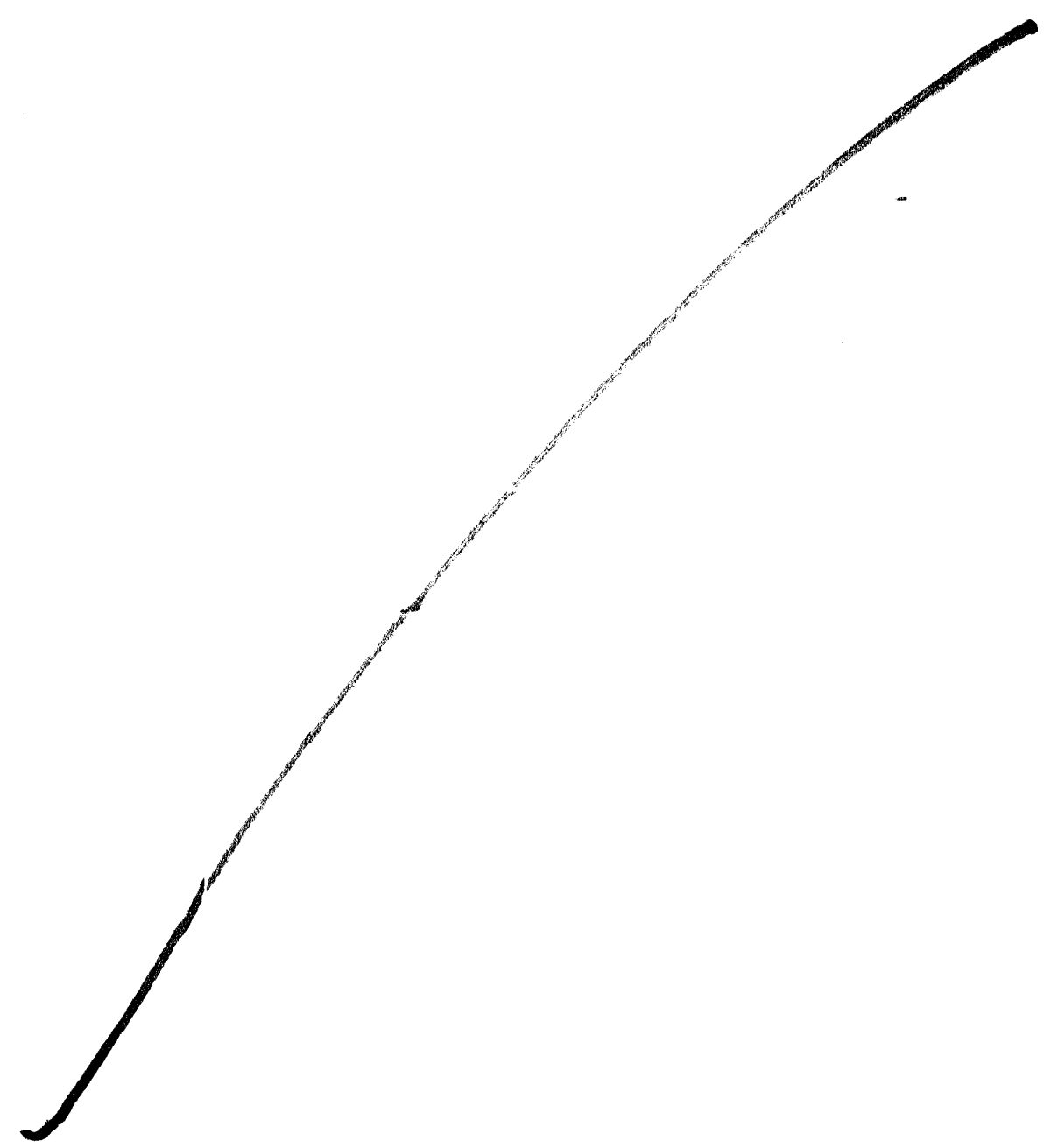
Status: Highly Acceptable Acceptable
 Unacceptable Failure

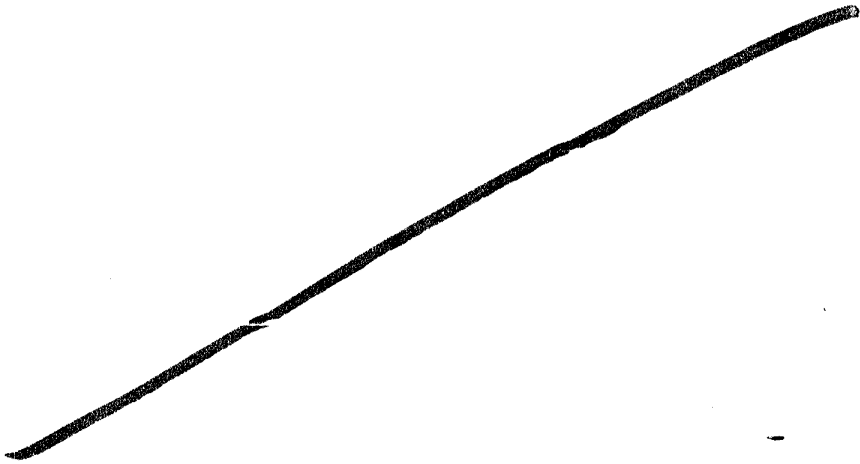
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

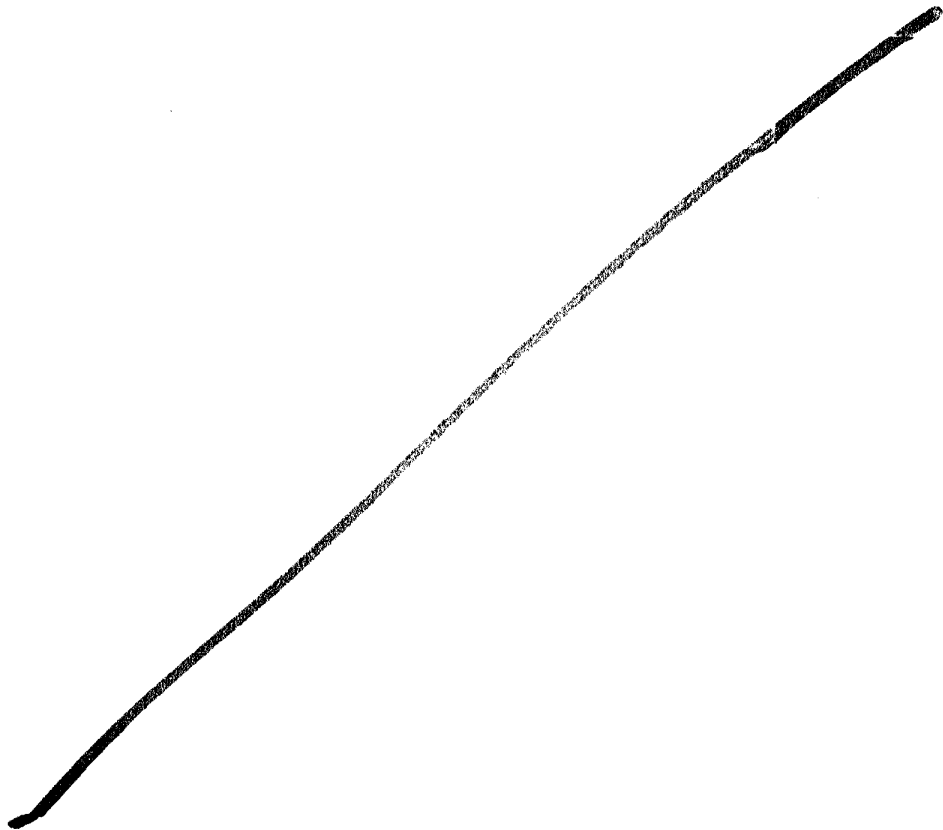
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:


Section E. Standard Operating Procedures - Procedures Manual



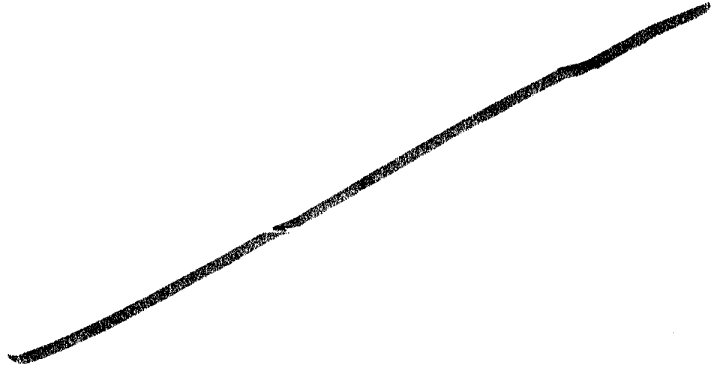


Section F. Chain-of-Custody, Accessioning, and Security

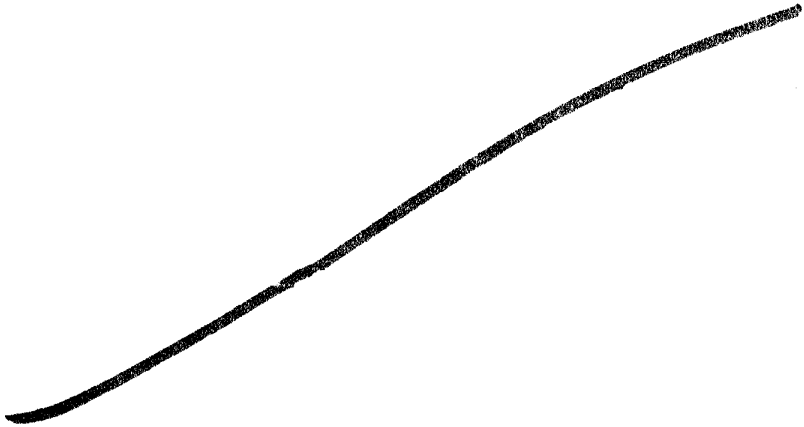




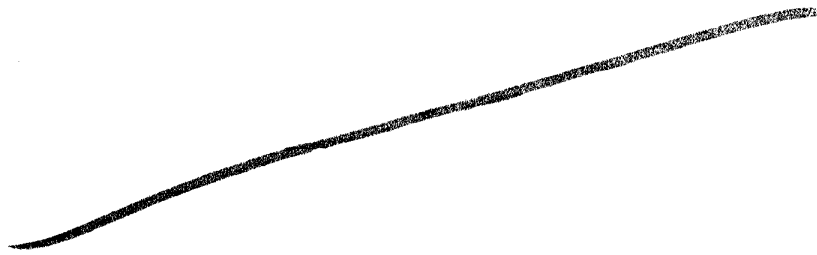
Section G. Quality Control



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





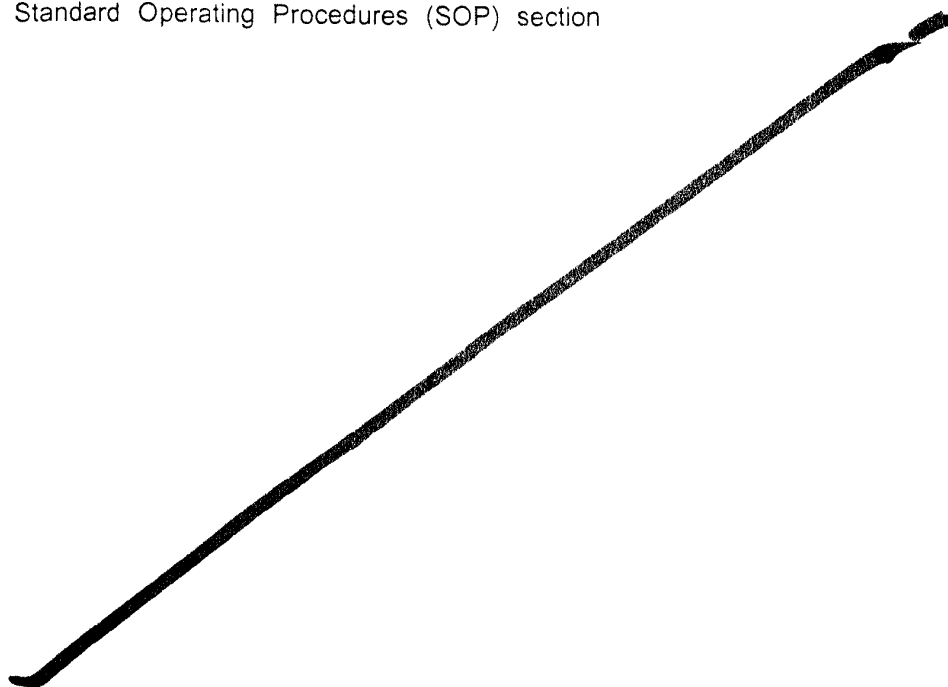
February 15, 2001

0101
Mr. James A. Callies
Dr. Anthony P. D'Addario
Quest Diagnostics Incorporated
7470 Mission Valley Road
San Diego, CA 92108-4406

Dear Mr. Callies and Dr. D'Addario:

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 appeared to meet most of the minimum technical criteria. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

E. The Standard Operating Procedures (SOP) section

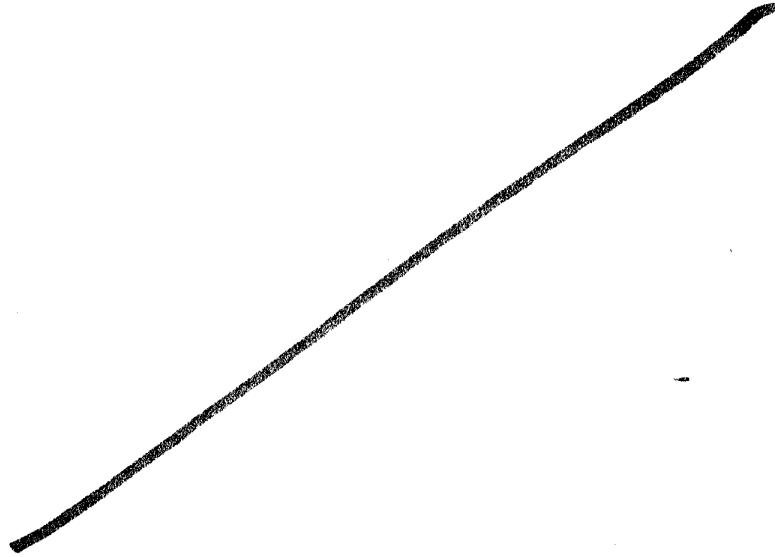


F. The Chain of Custody, Accessioning, and Security section

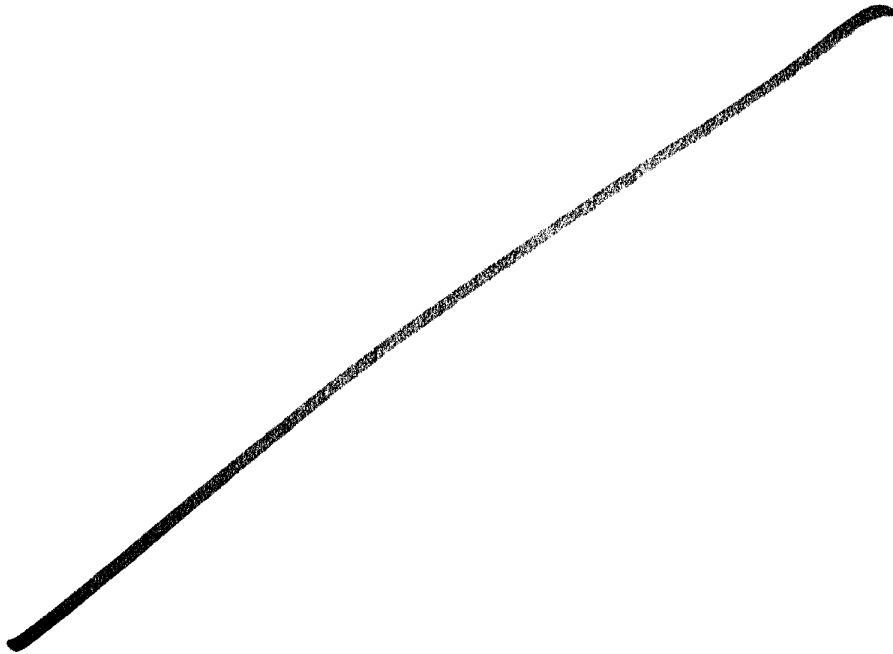
H. The Initial Tests section

I. The Specimen Validity Tests section

J. The Confirmatory Tests section



K. The Records Audit section



Mr. Callies
Dr. D'Addario
Page 4 of 4
.02/15/01

[Redacted]

L. The Certification and Reporting section

[Redacted]

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

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

Sincerely,


Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/M21

[Redacted]

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0101
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: San Diego, CA

Document Reviewed: Application Form
 Inspection Report #M21 Date: 7 December 2000
 Other _____

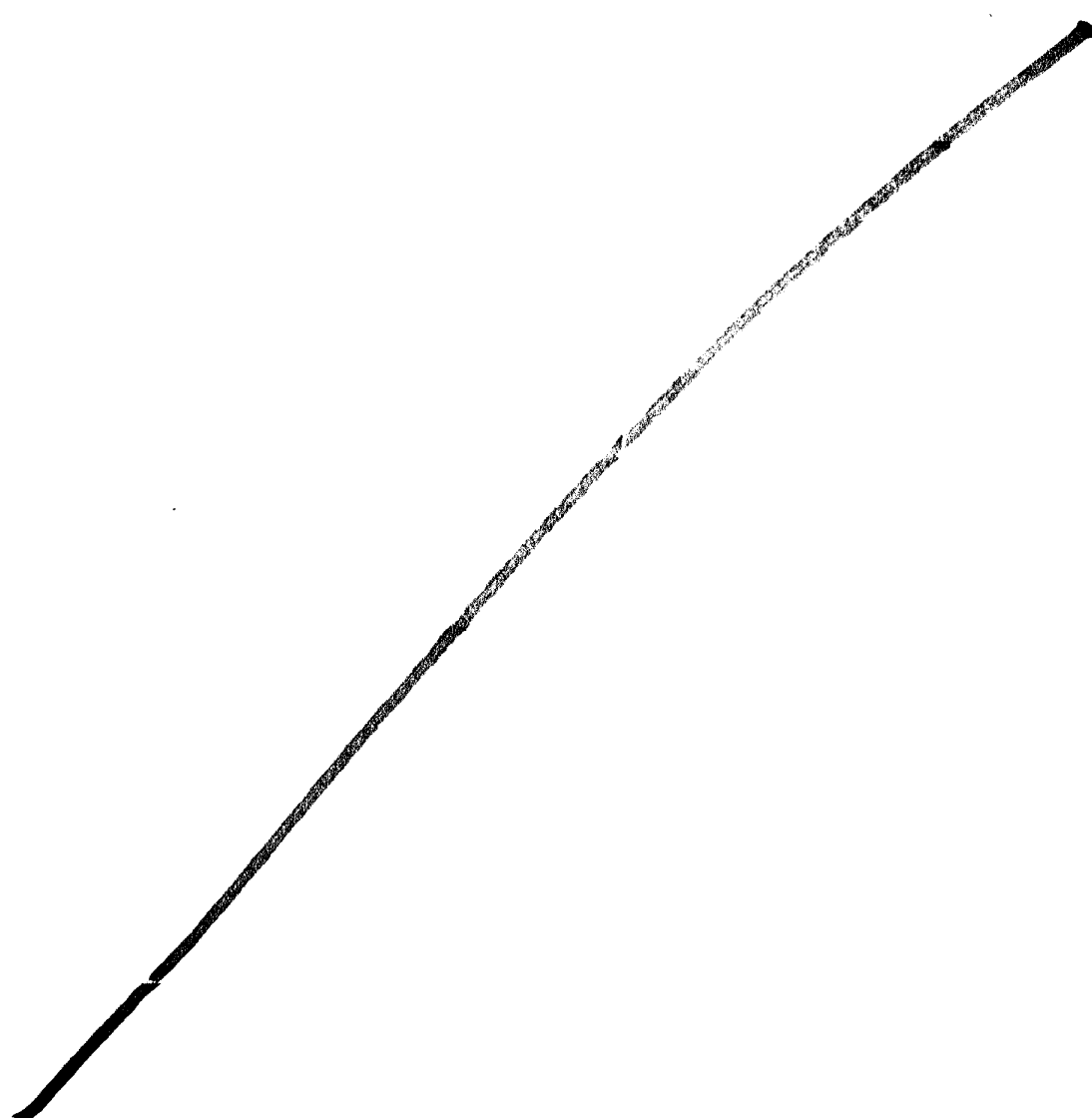
Status: Appeared to meet most of the minimum technical criteria
 Appeared to meet a number of the minimum technical criteria
 Failed to meet a number of the minimum technical criteria
 Failed to meet a significant number of the minimum technical criteria

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

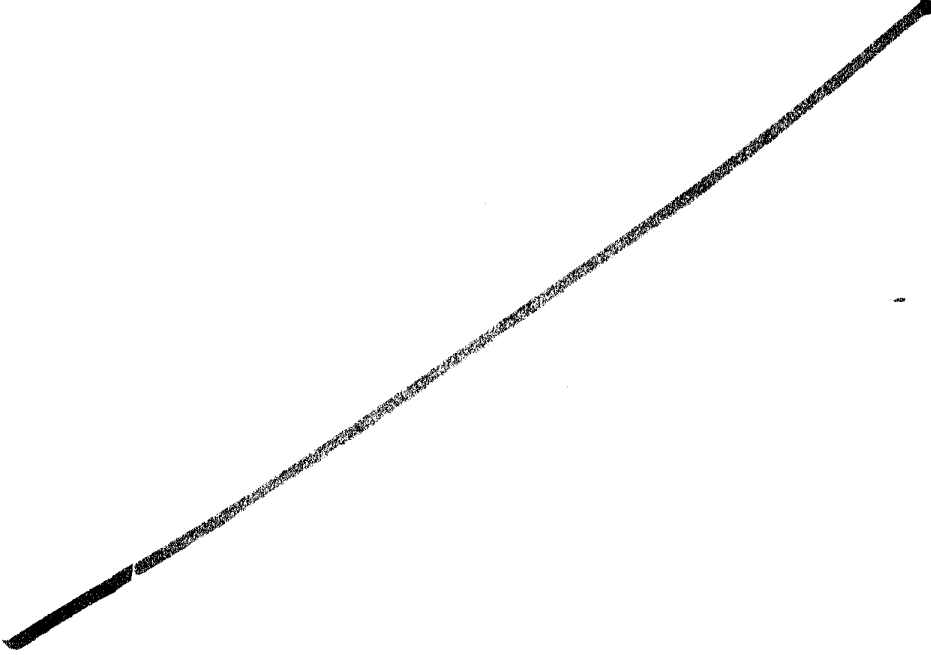
Deficiencies identified as a result of the inspection are detailed on the following pages. The laboratory is required to correct the deficiencies before its next inspection.

The following deficiencies were identified, 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



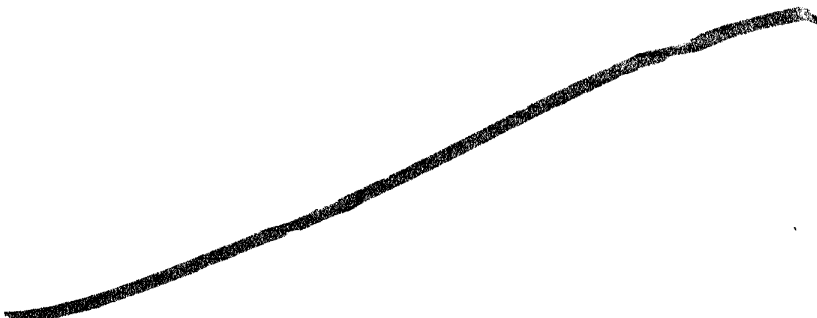
Section G. Quality Control and Quality Assurance



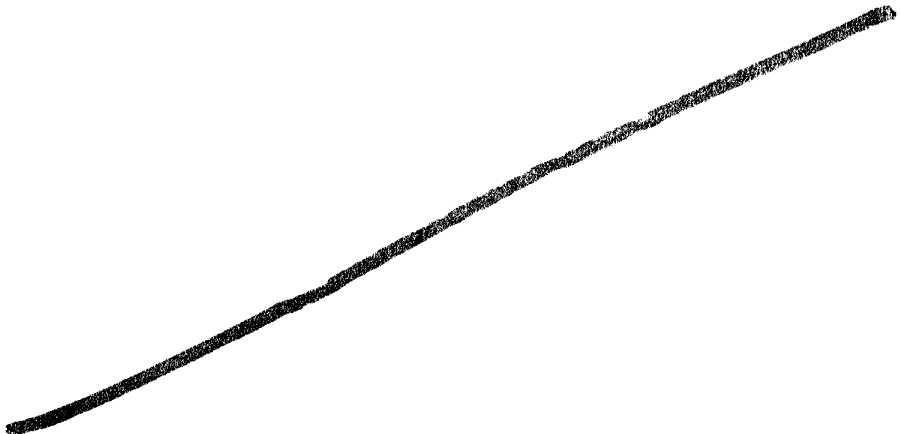
Section H. Initial Tests



Section I. Specimen Validity Tests

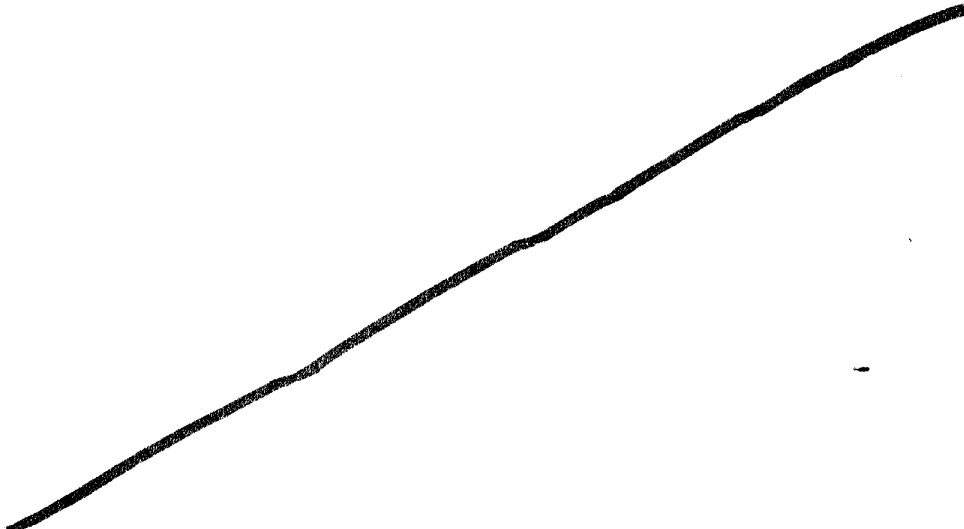


Section J. Confirmatory Tests



Section K. Records Audit





Section L. Certification and Reporting



Section M. Laboratory Information Management System (LIMS)



Section N. Personnel

