

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must successfully complete the following corrective actions:

E. The Standard Operating Procedures (SOP) section



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





G. The Records Audit section



I. The Reagents section



J. The Quality Control and Standards section



M. The Immunoassay section



N. The Gas Chromatography/Mass Spectrometry 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 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 Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Dr. A'Zary
Page 4 of 4
12/10/98

Enclosure

cc: Project Files/M17



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0055
- Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

Document Reviewed: Application Form
 Inspection Report #M17 Date: 22 October 1998
 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. Records Audit



Section H. Personnel



Section I. Reagents



Section J. Quality Control and Standards



Section K. Reporting



Section L. Equipment and Maintenance



Section M. Immunoassay



Section N. Gas Chromatography/Mass Spectrometry



Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.393.5000
212.736.0640

received
1/11/99 SDC



January 8, 1999

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

Dear Ms. Crumpton:

Below are the responses to your letter of December 10, 1999.

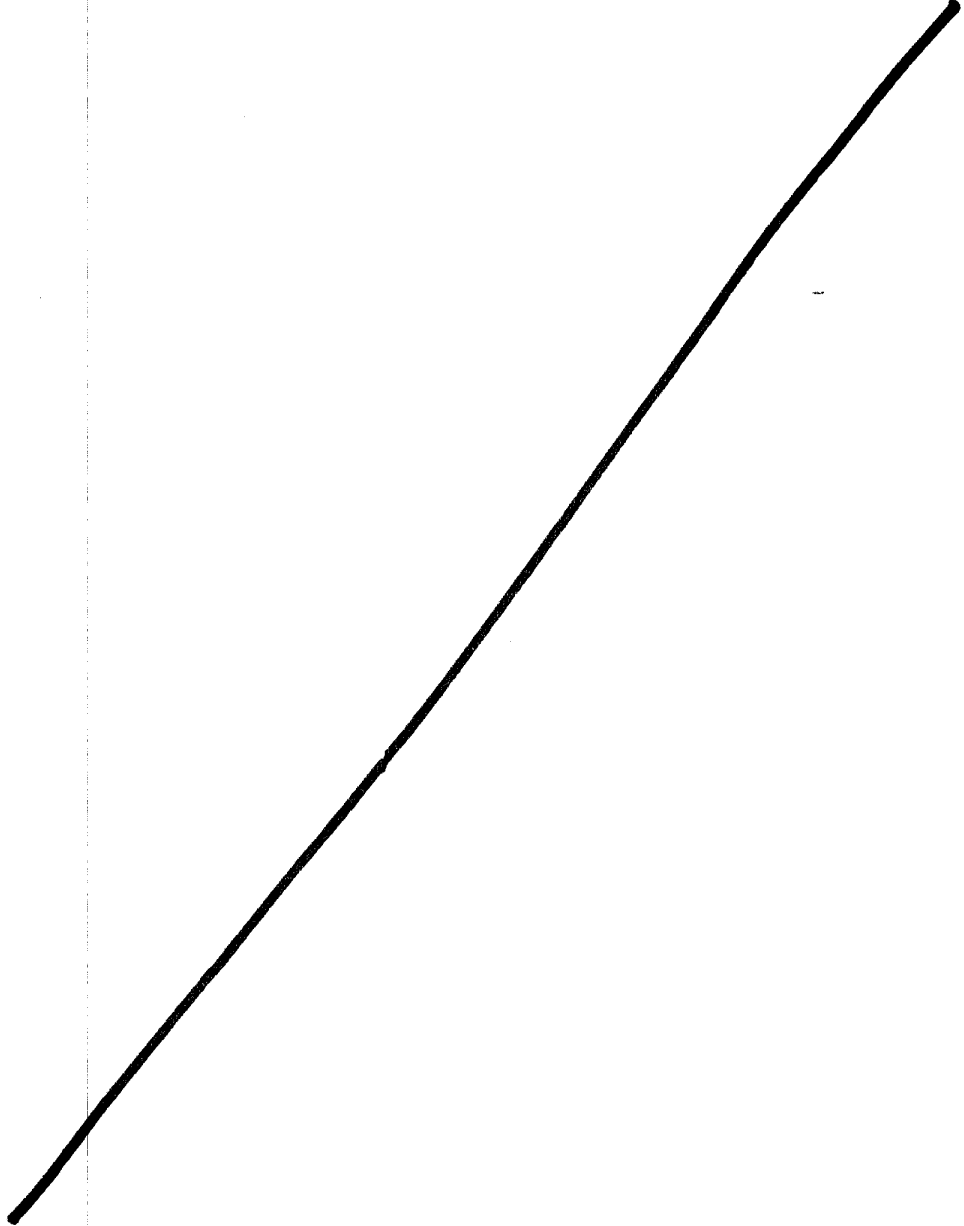
E. Standard Operating Procedures

[Redacted content]

F. Chain of Custody, Accessioning and Security

[Redacted content]

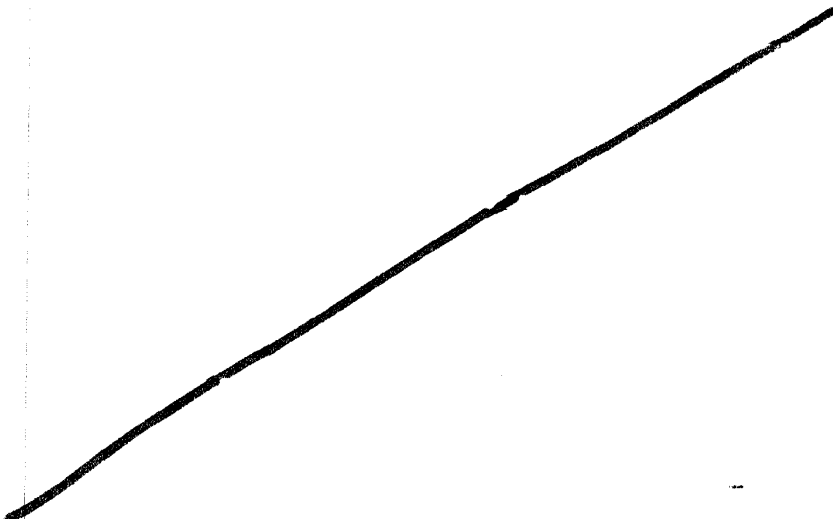
G. Records Audit



I. Reagents

J. Quality Control and Standards

M. Immunoassay



N. Gas Chromatography/Mass Spectrometry



Sincerely,

Edward A'Zary Ph.D.

Edward A'Zary, Ph.D.
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

January 14, 1999

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

We have reviewed the material submitted in your correspondence of January 8, 1999, provided in final response to issues raised during the seventeenth maintenance inspection of your laboratory as originally outlined in our correspondence of December 10, 1998. 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 will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP). All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

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

Sincerely,

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

Susan D. Crumpton
NLCP Inspection Analyst

cc: Project Files/M17



May 26, 1999

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

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 section

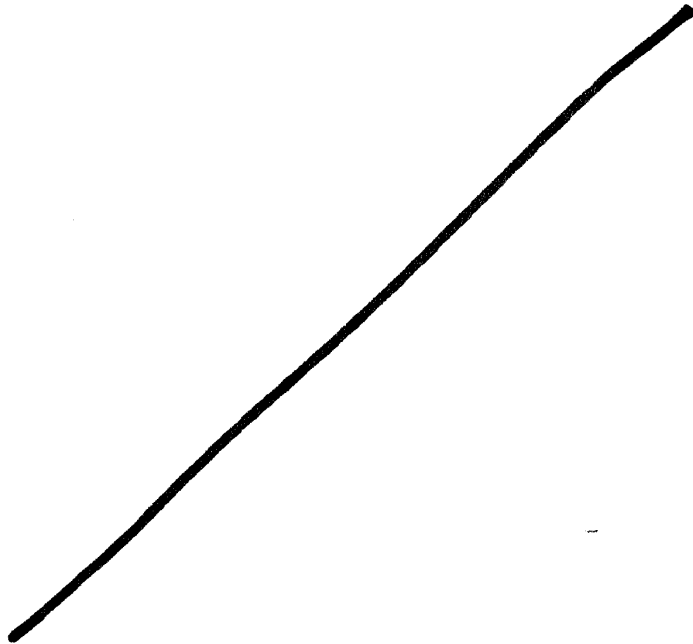


F. The Chain of Custody, Accessioning, and Security section



G. The Quality Control section

I. The Confirmatory Tests section



J. The Records Audit section



6b. The Laboratory Information Management System (LIMS) section.



Dr. A'Zary
Page 4 of 4
05/26/99

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: 0055
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

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

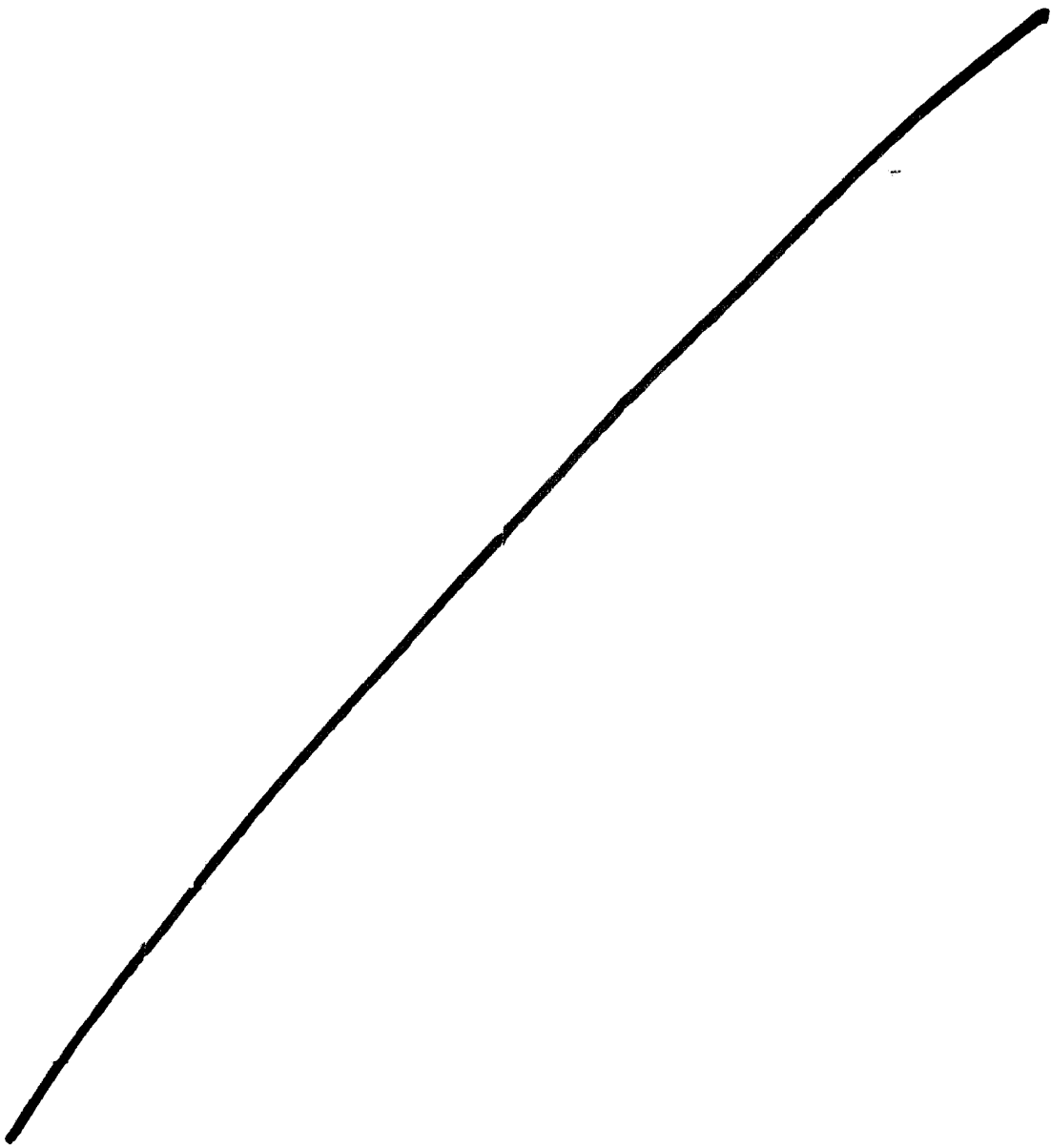
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



Ver. Final

Lab ID# 0055

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

Section G. Quality Control

Ver. Final

Lab ID# 0055

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

NLCP ♦ Research Triangle Institute

Page 4

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.393.5000
212.736.0640

received
7/2/99 SD



July 1, 1999

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road, Herman P. Jg.
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

Below are the corrective actions for the RTI letter of May 27, 1999 and the comments and observations noted in the Inspection Report (Document Review and Critique) of April 8, 1999.

E. Standard Operating Procedures

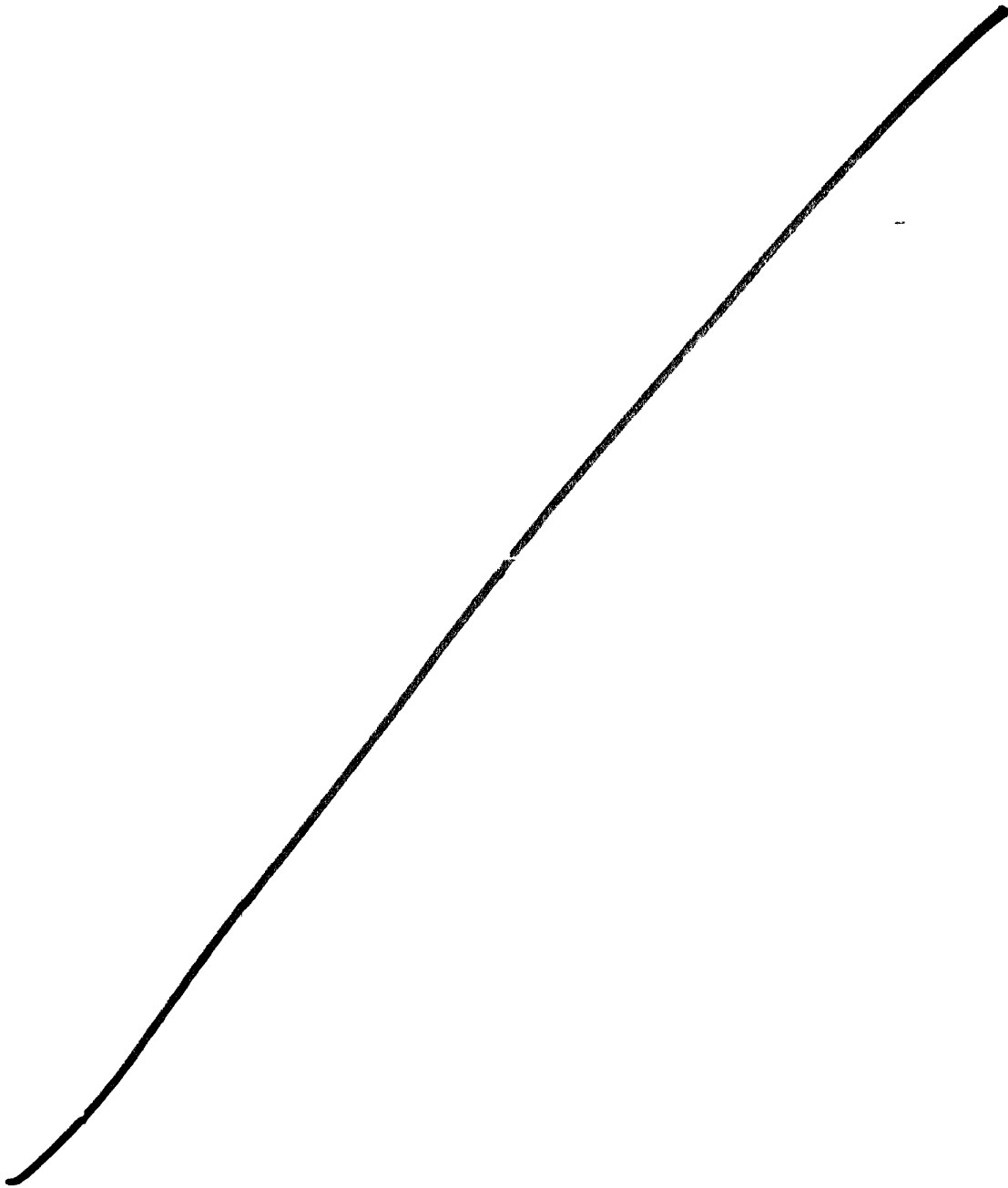
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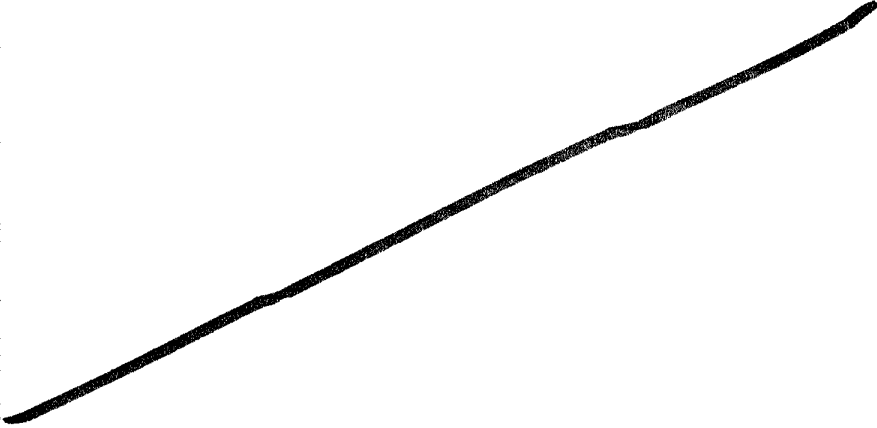


F. Chain of Custody, Accessioning and Security




G. Quality Control





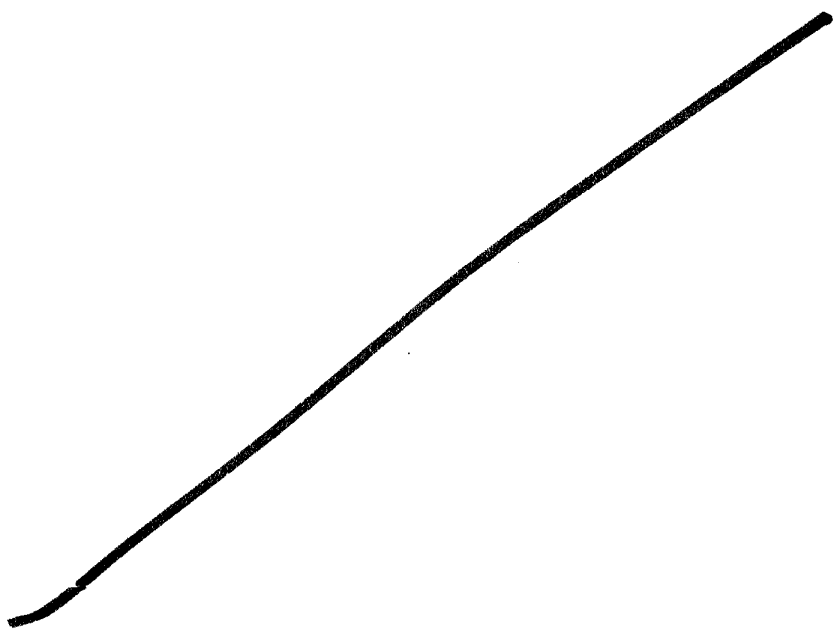
I. Confirmatory Tests



J. Records Audit



L. Computers, Software, and LIMS



If you need any additional information, please feel free to contact me at 201-393-5725.

Sincerely,



Edward A'Zary, Ph.D.
Director of Forensic Toxicology

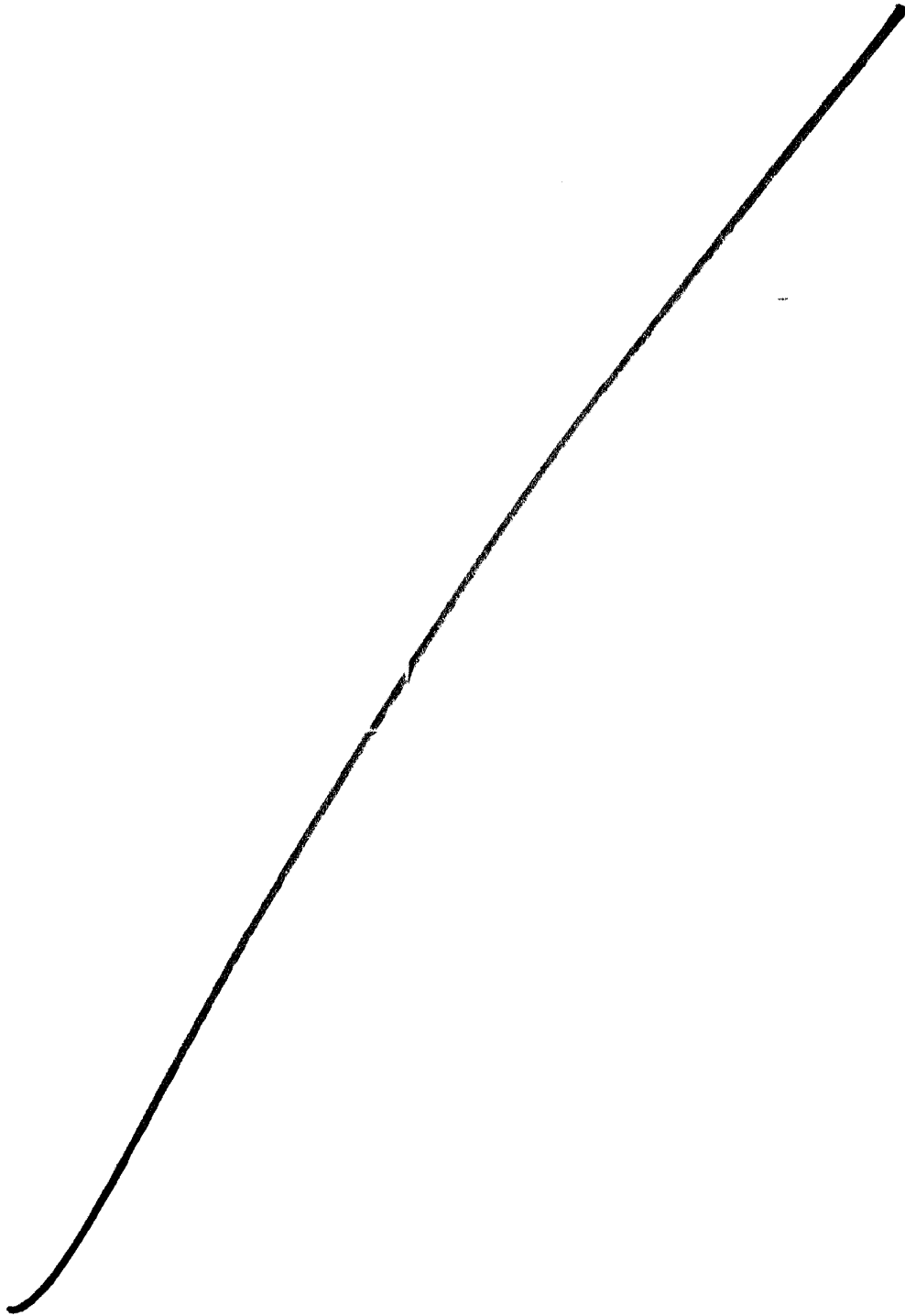
July 13, 1999

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

We have reviewed the material provided in your correspondence of July 1, 1999, submitted in response to issues raised during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of May 26, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. The following is a summary of remaining issues:

Dr. A'Zary
Page 2 of 3
07/13/99



Dr. A'Zary
Page 3 of 3
07/13/99

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continue to be certified under the National Laboratory Certification Program. The laboratory must take additional steps to correct the issues outlined above. 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

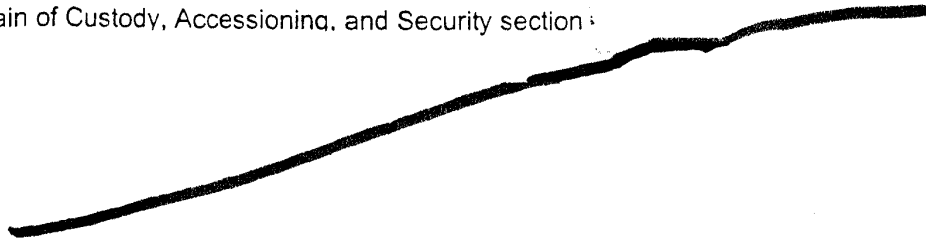
cc: Dr. Michael Baylor
Project Files/M18

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

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. However, the following issues were raised:

F. The Chain of Custody, Accessioning, and Security 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 Crumpton
NLCP Inspection Analyst

Enclosure



Dr. A'Zary
Page 2 of 2
10/29/99

cc: Project Files/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0055
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

Document Reviewed: Application Form
 Inspection Report #M19 Date: 30 September 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

[Redacted]

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

[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

May 15, 2000

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

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 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:

E. The Standard Operating Procedures (SOP) section

[Redacted content]

H. The Initial Tests section

[Redacted content]

I. The Confirmatory Tests section

[Redacted content]



Dr. A'Zary
May 15, 2000
Page 2 of 3

7

[Redacted]

J. The Records Audit section

[Redacted]

K. The Reporting section,

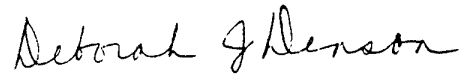
[Redacted]

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.

Dr. A'Zary
May 15, 2000
Page 3 of 3

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 Technical Analyst

Enclosure

cc: Project Files/M20



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0055
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

Document Reviewed: Application Form
 Inspection Report #M20 Date: 23 March 2000
 Other _____

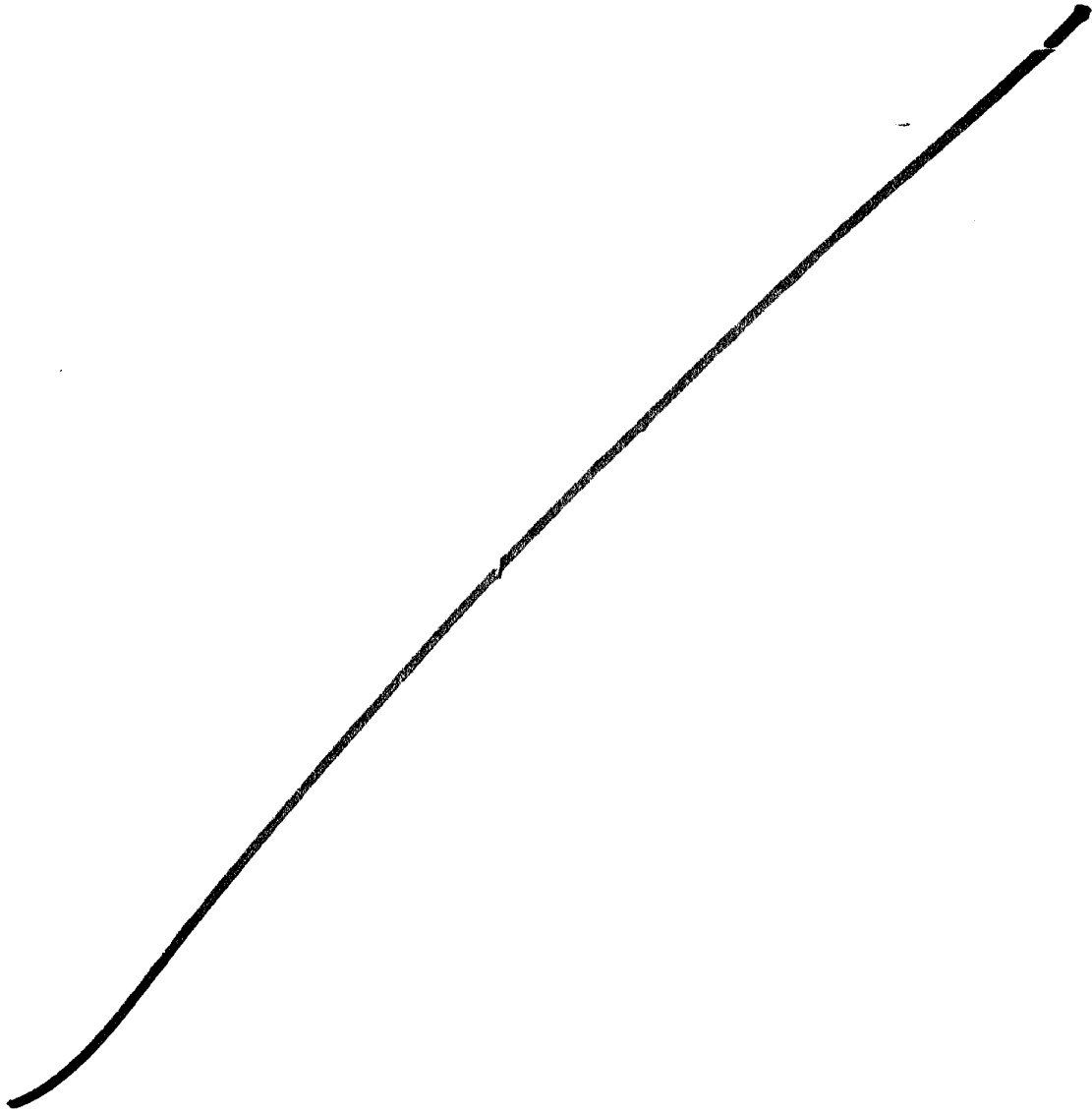
Status: Highly Acceptable Acceptable
 Unacceptable Failure

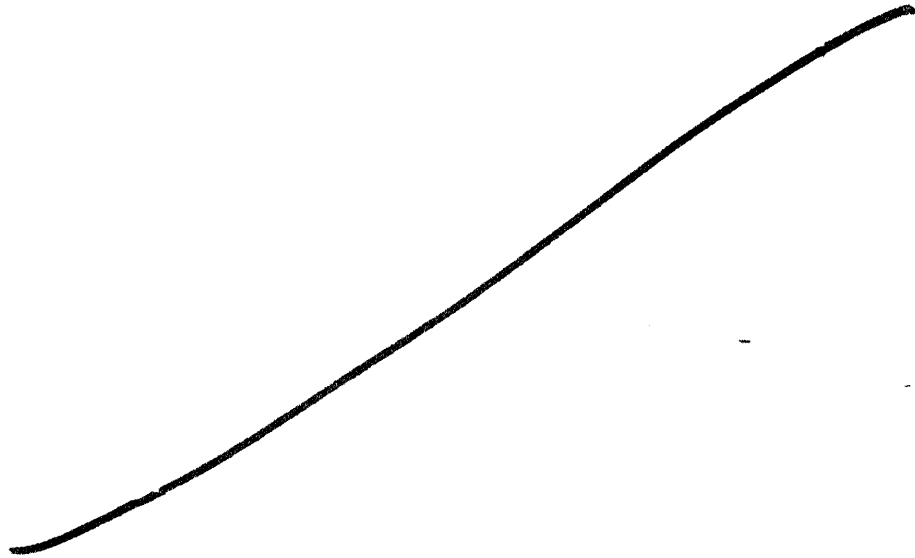
Inspection reports, from the inspectors who conducted the National Laboratory Certification Program (NLCP) inspection, have been carefully reviewed and found to provide sufficient information to judge that the laboratory has met the standards required for the inspection phase of the Program, pending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



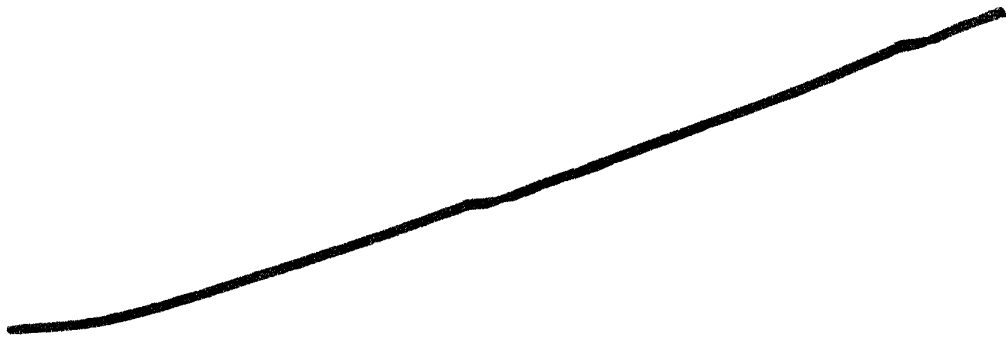
[Redacted]

Section H. Initial Tests

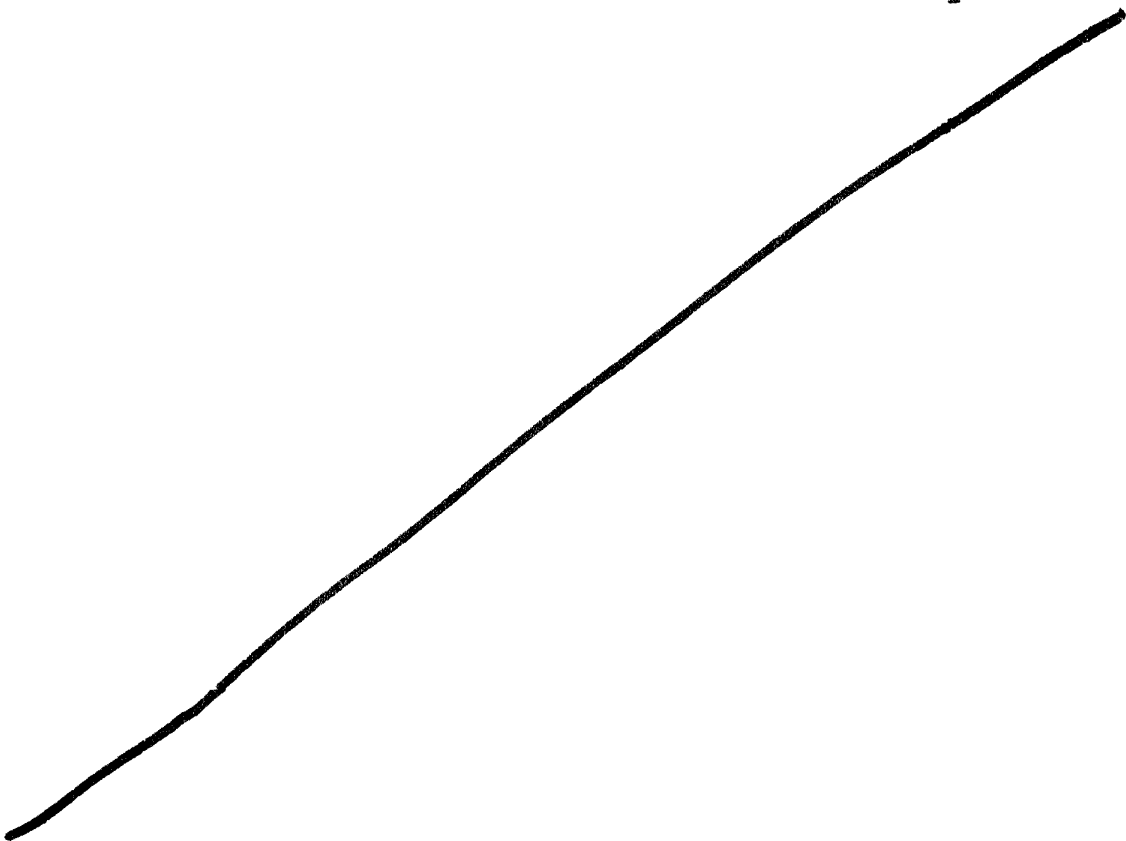
[Redacted]

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

One Malcolm Avenue
Teterboro, New Jersey 07608-1077
201.393.5000
212.738.0640

received
6/13/00 DJ

June 13, 2000



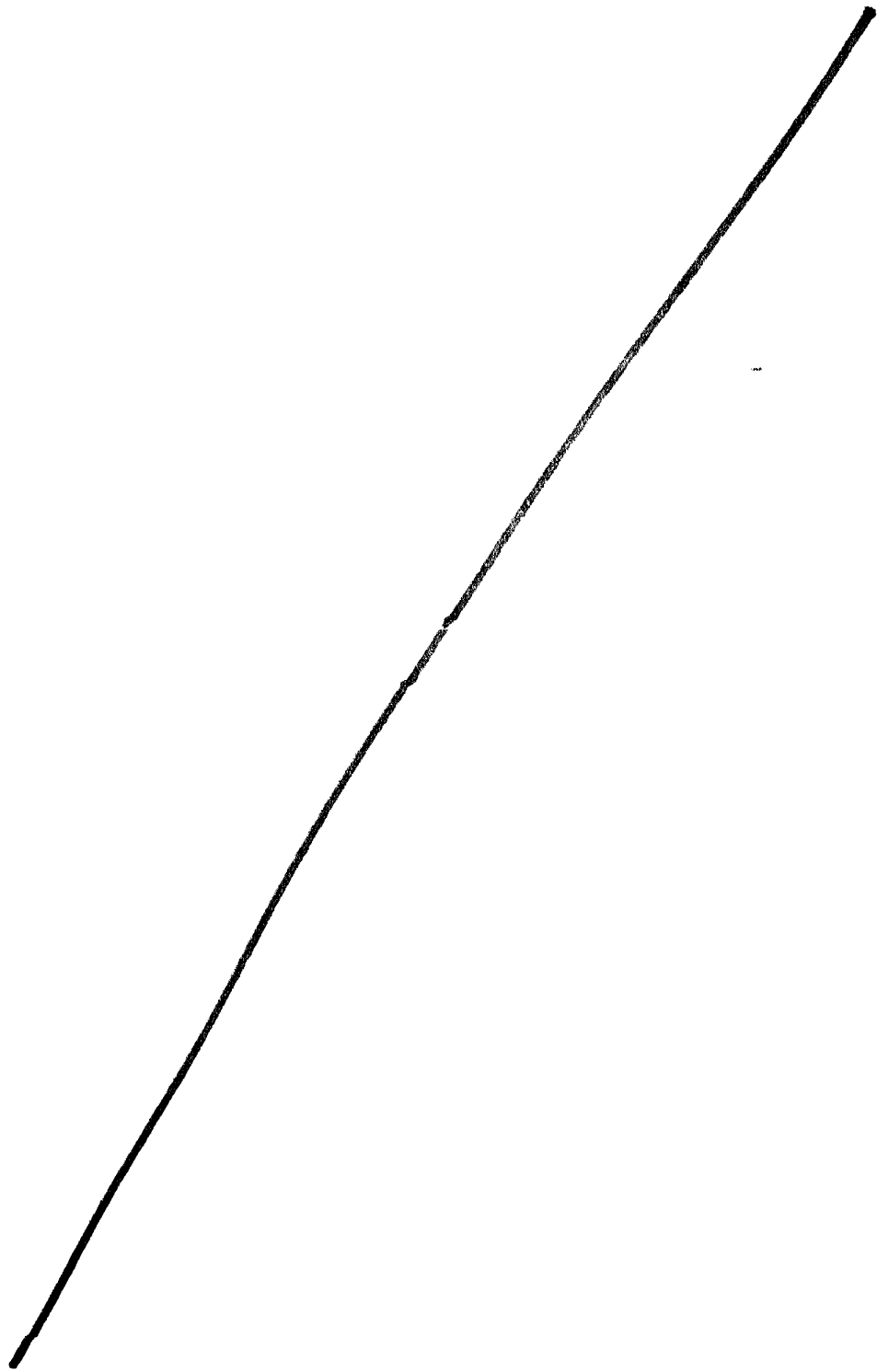
Ms. Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road, Herman Bldg.
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

Below are the corrective actions for the RTI letter of May 15, 2000 and the comments and observations noted in the Inspection Report (Document Review and Critique) of March 23, 2000.

E. Standard Operating Procedures

[A large, thick, black diagonal line is drawn across the page, likely indicating that the content of this section has been redacted or is otherwise obscured.]



[Redacted]

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

[Redacted]

Section G. Quality Control

[Redacted]

[Redacted]

Section H. Initial Tests

[Redacted]

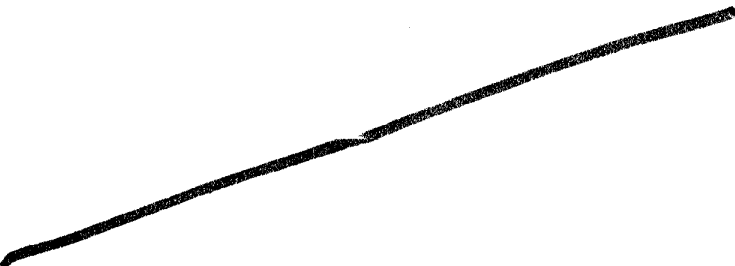
Section I. Confirmatory Tests

[Redacted]


Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Sincerely,

Edward A. Zary Ph.D.
Edward A'Zary, Ph.D.
Director of Forensic Toxicology



RESEARCH TRIANGLE INSTITUTE

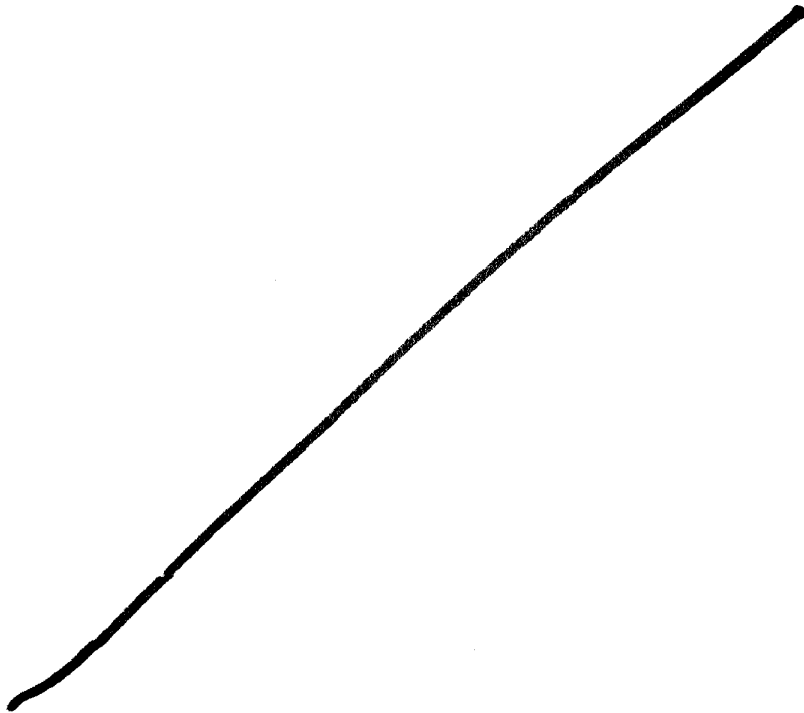
National Laboratory Certification Program

June 20, 2000

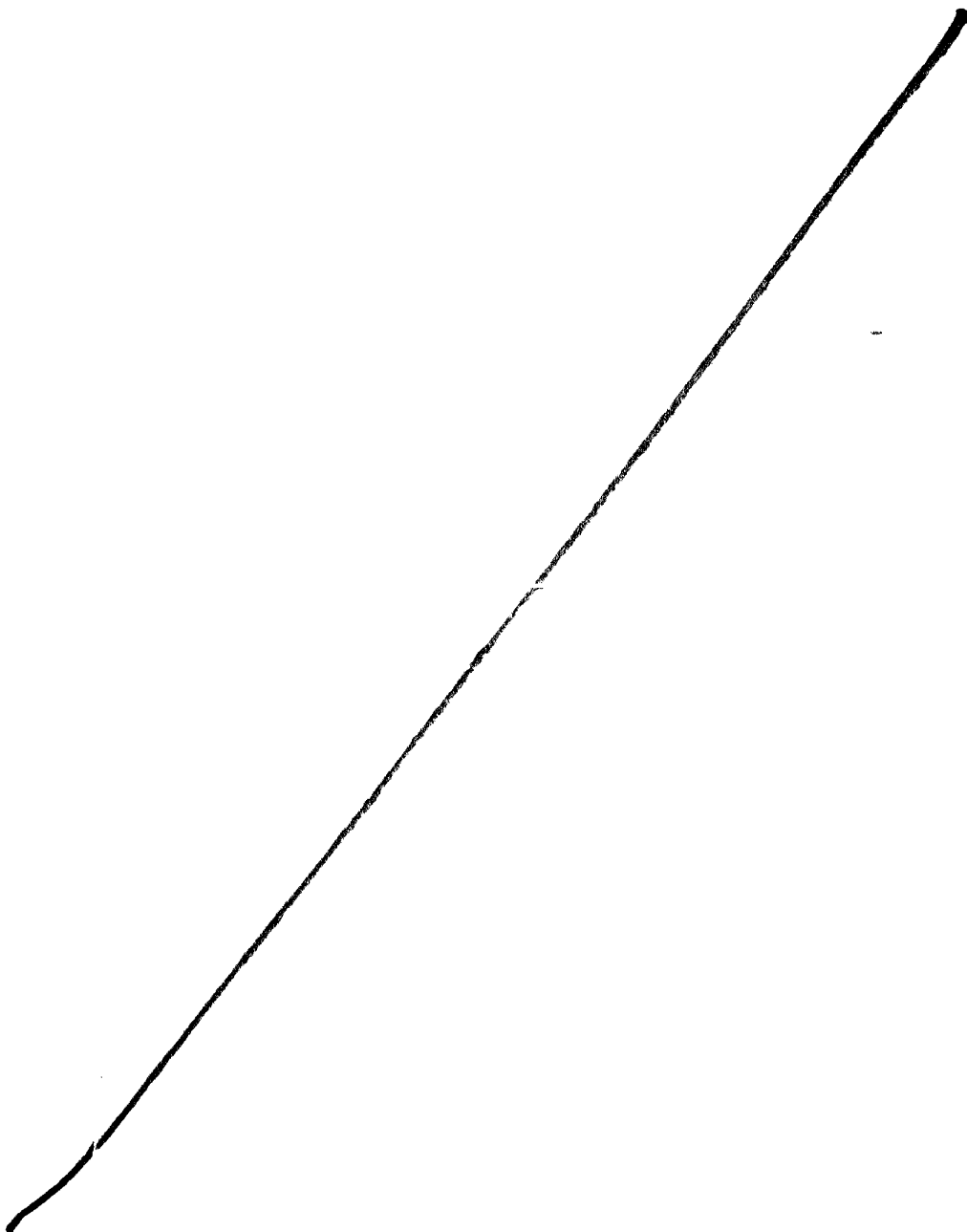
0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608

Dear Dr. A'Zary:

We have reviewed the material provided in your correspondence of June 13, 2000 submitted in response to issues raised during the twentieth maintenance inspection of your laboratory as outlined in our correspondence of May 15, 2000. The information submitted by the laboratory appears to demonstrate that appropriate actions have been completed to address the issues raised. The following is a review of the material submitted:



Dr. A'Zary
June 20, 2000
Page 2 of 3



Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must

Dr. A'Zary
June 20, 2000
Page 3 of 3

be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M20



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

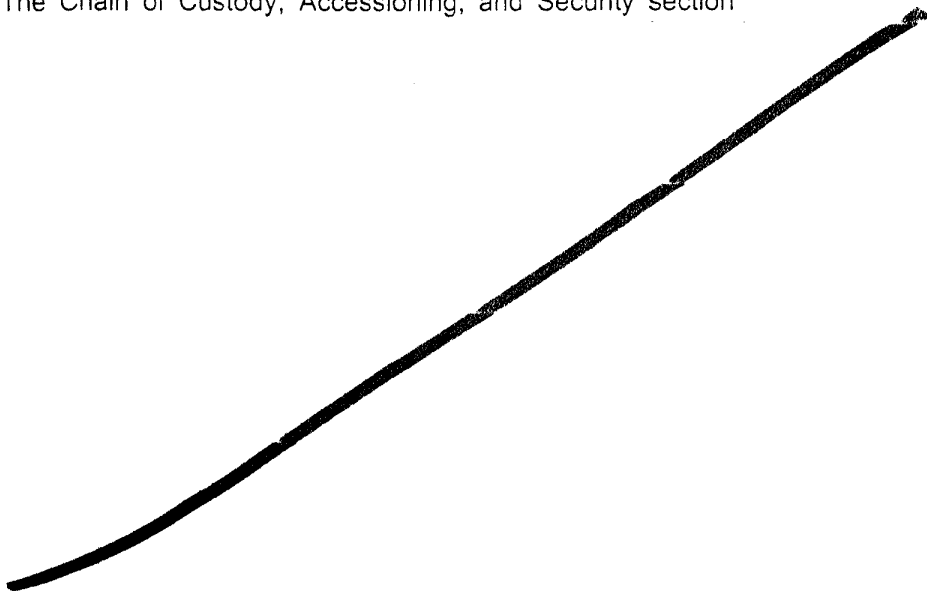
November 20, 2000

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608-1070

Dear Dr. A'Zary:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:

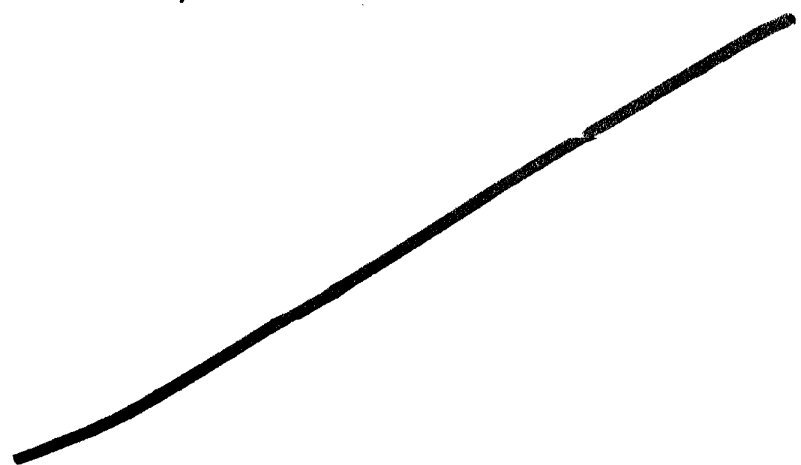
F. The Chain of Custody, Accessioning, and Security section



G. The Quality Control section



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

Dr. A'Zary
Page 4 of 4
11/20/00

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 Technical Analyst

Enclosure

cc: Project Files/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0055
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Teterboro, NJ

Document Reviewed: Application Form
 Inspection Report #M21 Date: 28 September 2000
 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.

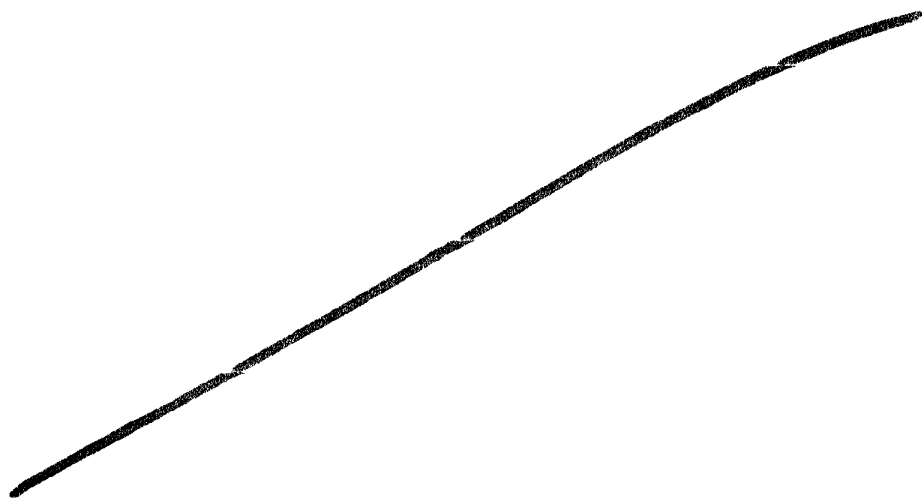
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

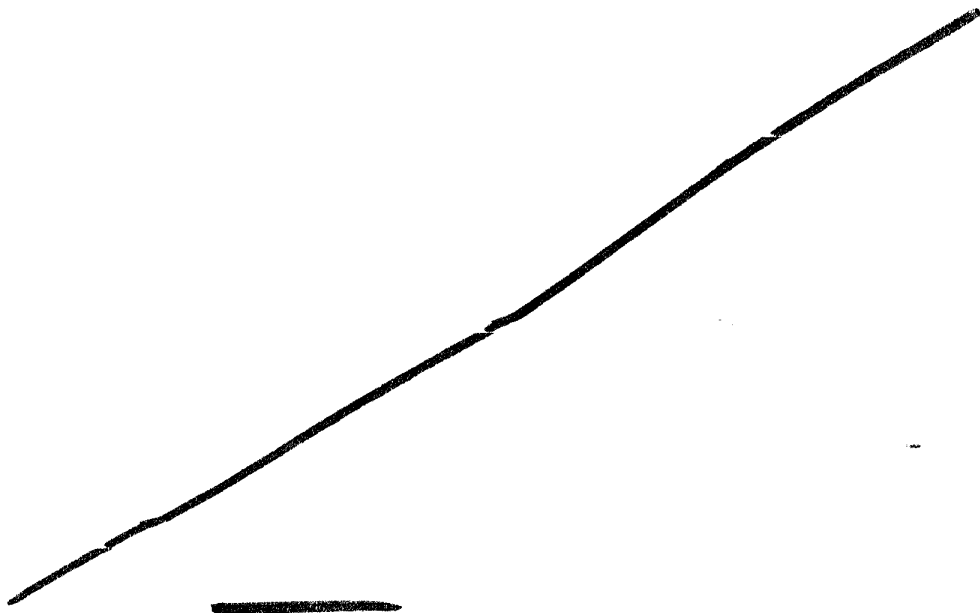


Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control

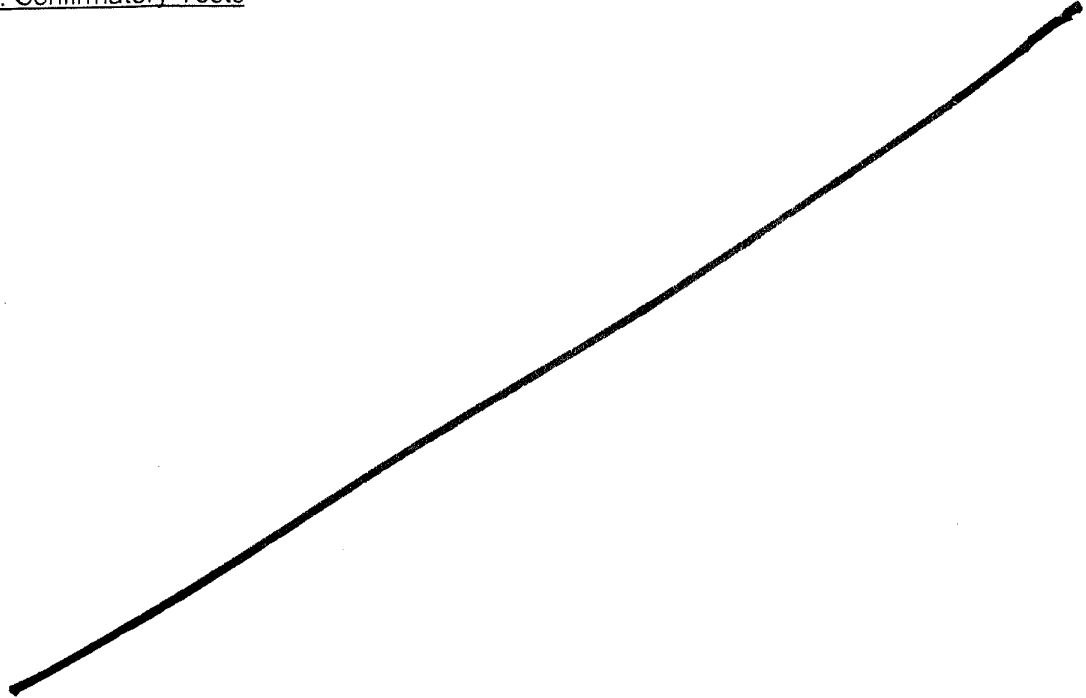





Section H. Initial Tests

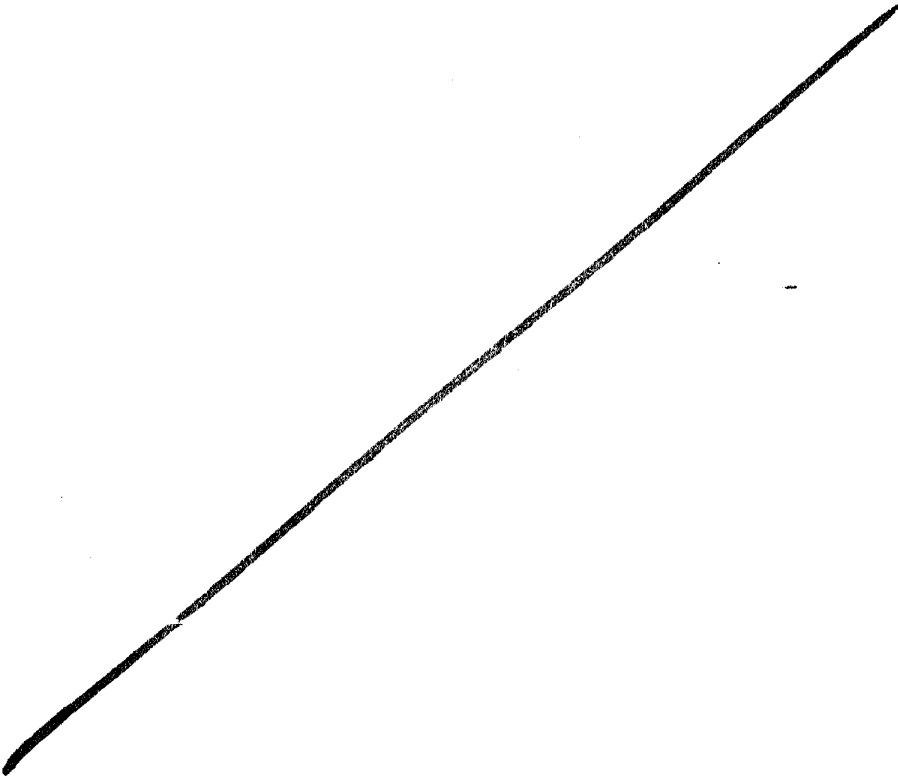


Section I. Confirmatory Tests







Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance

Section N. Personnel

[Redacted]

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.393.5000
212.736.0640

received
2/5/01 SA



February 2, 2001

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road, Herman Bldg.
Research Triangle Park, NC 27709-2194

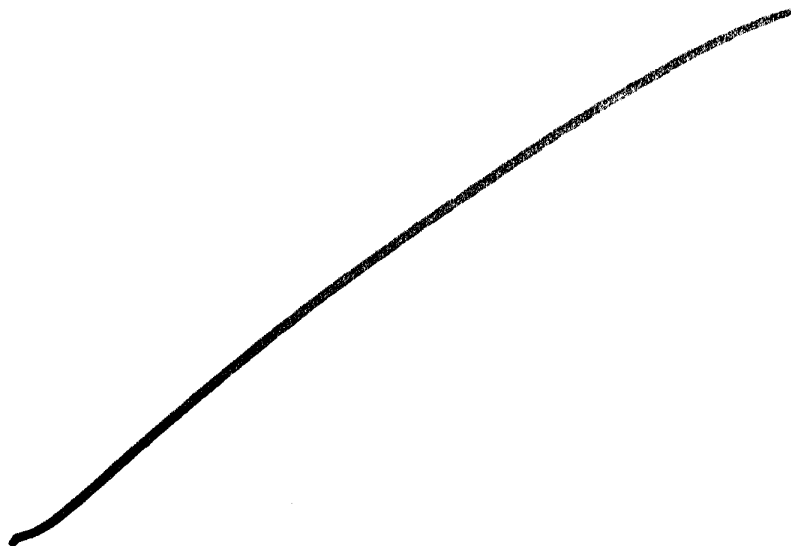
Dear Ms. Crumpton:

Below are the additional corrective actions requested in the RTI letter of January 16, 2001.

Section G. Quality Control



Section I. Confirmatory Tests



Section J. Records Audit

If you require any additional information, please feel free to contact me at 201-393-5725.

Sincerely,



Edward A. Zary, Ph.D.
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

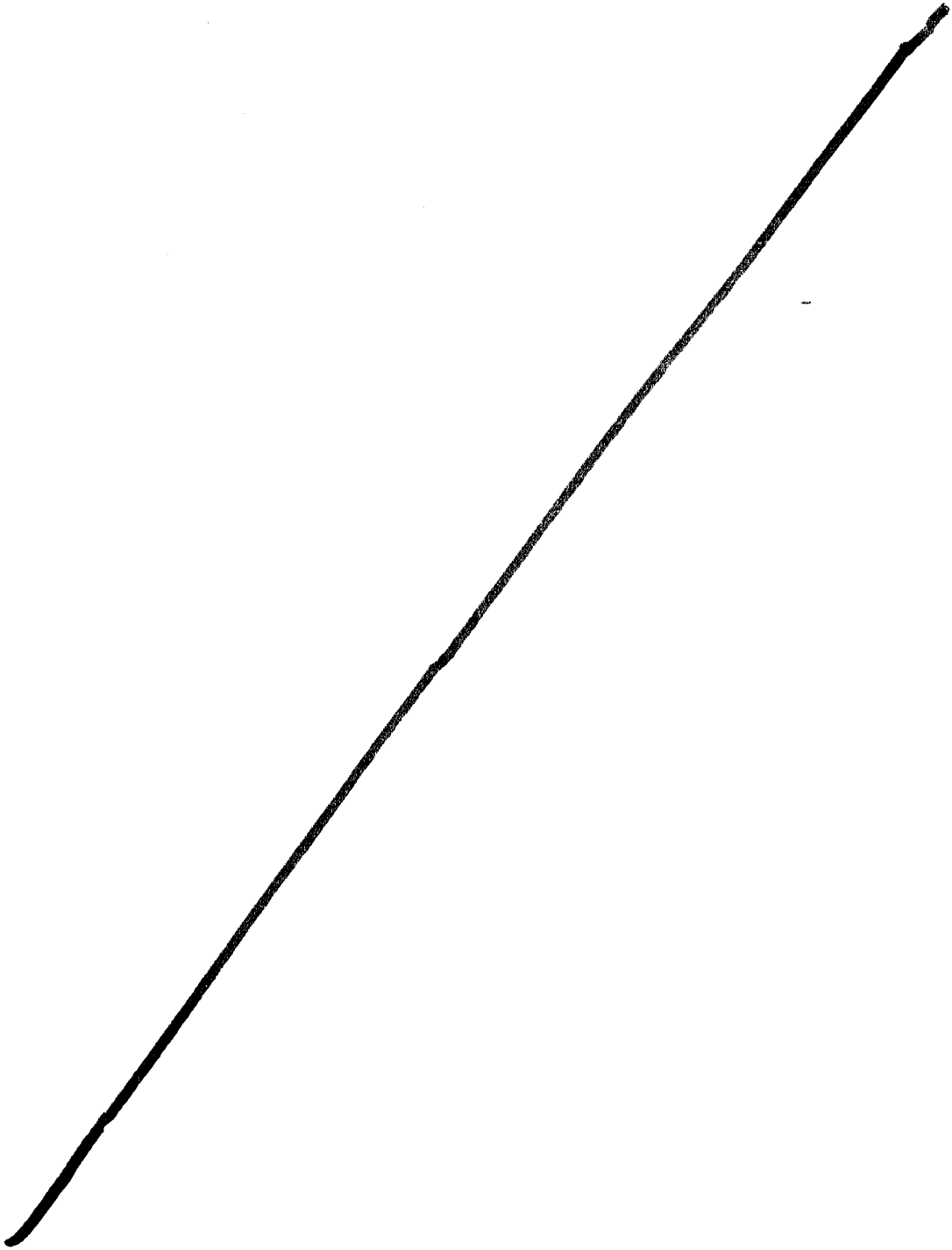
January 16, 2001

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608-1070

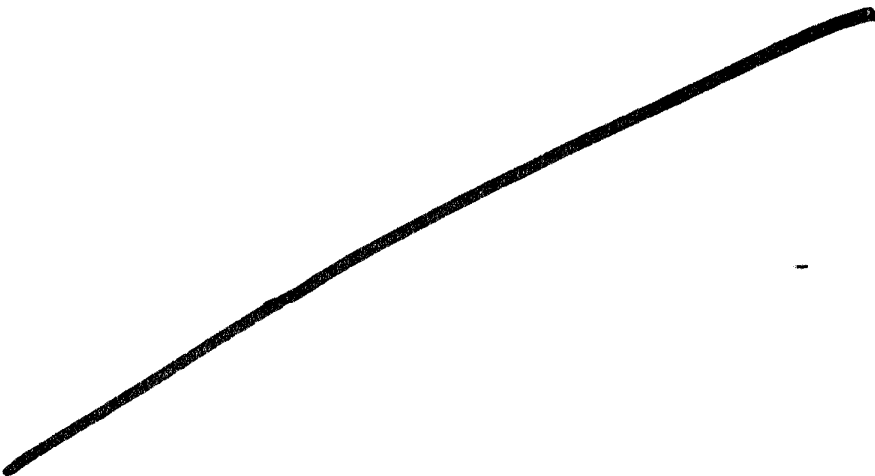
Dear Dr. A'Zary:

We have reviewed the material provided in your correspondence of December 19, 2000, submitted in response to deficiencies cited during the twenty-first maintenance inspection of your laboratory as outlined in our correspondence of November 20, 2000. The following issues remain or were raised during our review of the submitted material:

Dr. A'Zary
Page 2 of 3
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Dr. A'Zary
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01/16/01



The laboratory must submit, within 10 working days of receipt of this letter, a final report addressing the unresolved issues described above. RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP) upon receipt of documentation to demonstrate that the unresolved issues have been addressed. If, however, the laboratory fails to address these unresolved issues within this time, the issues will be discussed with the staff at HHS. The laboratory is reminded that the implementation and completion of all remedial actions are subject to review by the next inspection team.

The NLCP reserves the right to conduct an inspection to determine full compliance with the requirements of this letter. The laboratory is hereby notified that failure to correct deficiencies may result in our recommendation to HHS that your laboratory's certification be suspended and/or revoked, consistent with sections 3.13 and 3.14 of the HHS Guidelines.

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

Sincerely,



Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/M21

Quest Diagnostics Incorporated

One Malcolm Avenue
Teterboro, New Jersey 07608-1070
201.398.5000
212.750.0640



December 19, 2000

received
12/20/00 SRC

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road, Herman Bldg.
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

Below are the corrective actions for the RTI letter of November 20, 2000 and the comments and observations noted in the Inspection Report (Document Review and Critique) of September 28, 2000.

E. Standard Operating Procedures

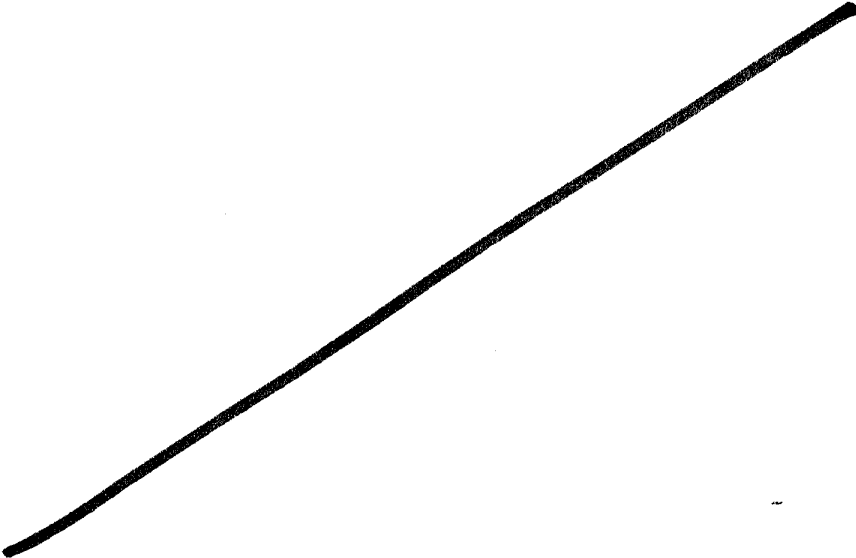
[Redacted content]

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

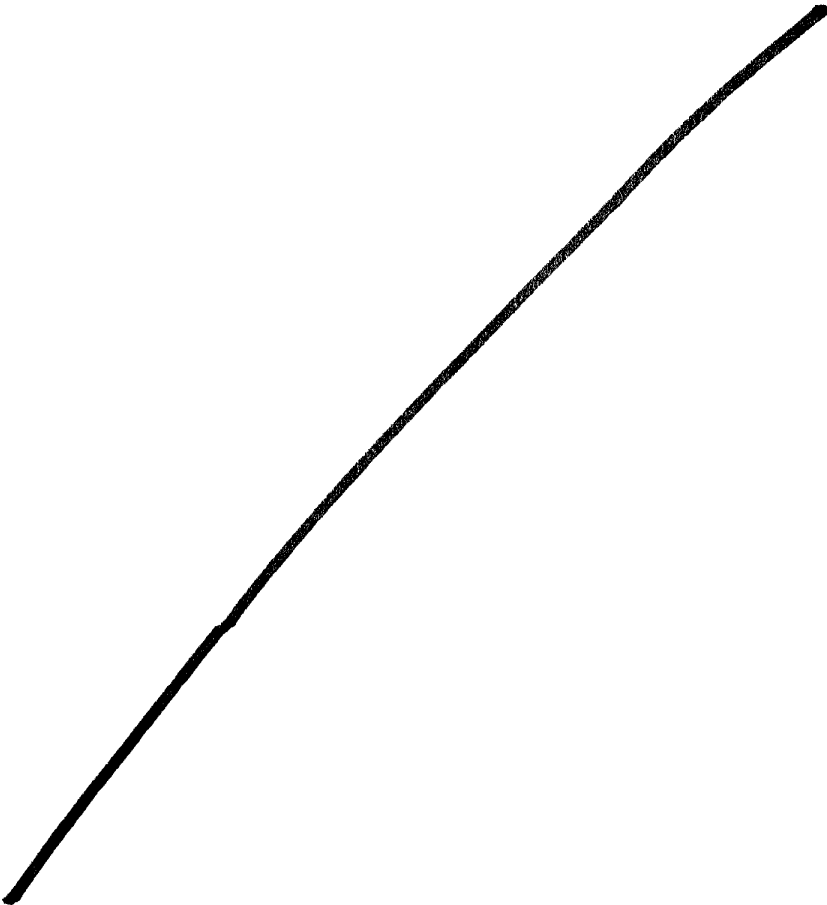
[Redacted content]

Section G. Quality Control

Section I. Confirmatory Tests



Section J. Records Audit



Section L. Computers, Software, and LIMS

Sincerely,

Edward A. Zary, Ph.D.

Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 12, 2001

0055
Dr. Edward P. A'Zary
Quest Diagnostics Incorporated
One Malcolm Avenue
Teterboro, NJ 07608-1070

Dear Dr. A'Zary:

We have reviewed the material provided in your correspondence February 2, 2001, submitted in response to remaining issues raised during the twenty-first maintenance inspection of your laboratory as outlined in our correspondence of January 16, 2001. 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) 541-6176 or Michael Baylor, Ph.D. (919) 541-7043.

Sincerely,


Susan Crumpton
NLCP Technical Analyst

cc: Dr. Michael Baylor
Project Files/0055