RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 8, 1999

0138
Mr. M. P. George
SmithKline Beecham Clinical Laboratories
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

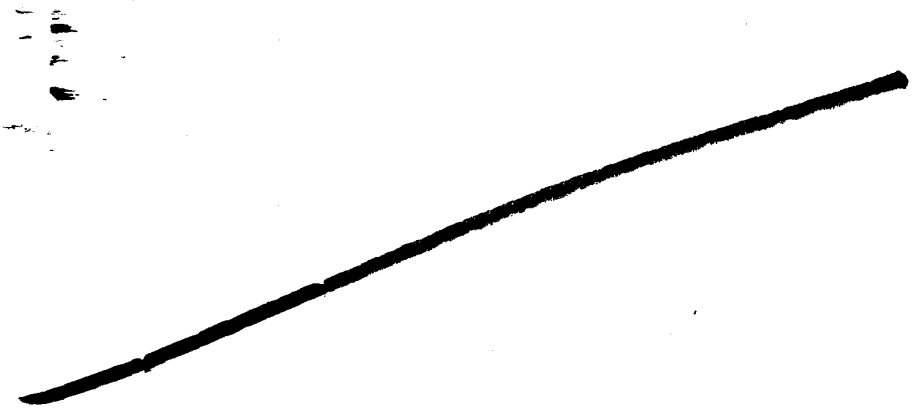
Dear Mr. George:

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:

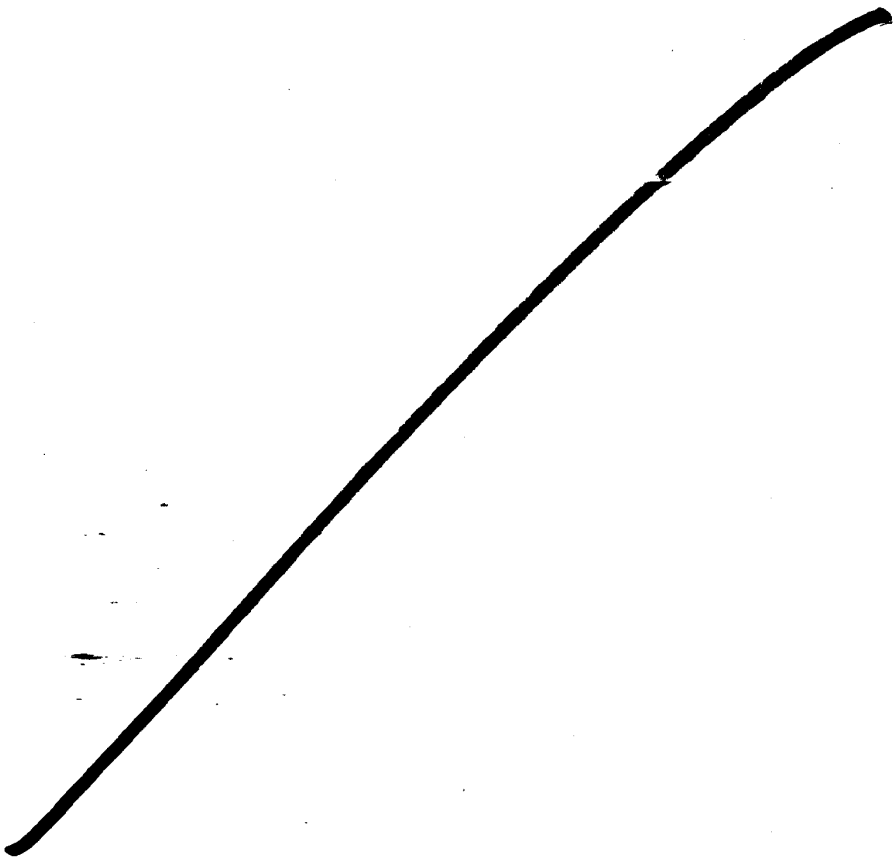
E. The Standard Operating Procedures (SOP) section

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

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042



G. The Records Audit section



N. The Gas Chromatography/Mass Spectrometry (GC/MS) 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

Enclosure

cc: Project Files/M17

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0138
Document No. Final

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Schaumburg, IL

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M17 Date: 19 November 1998
[ ] Other _____

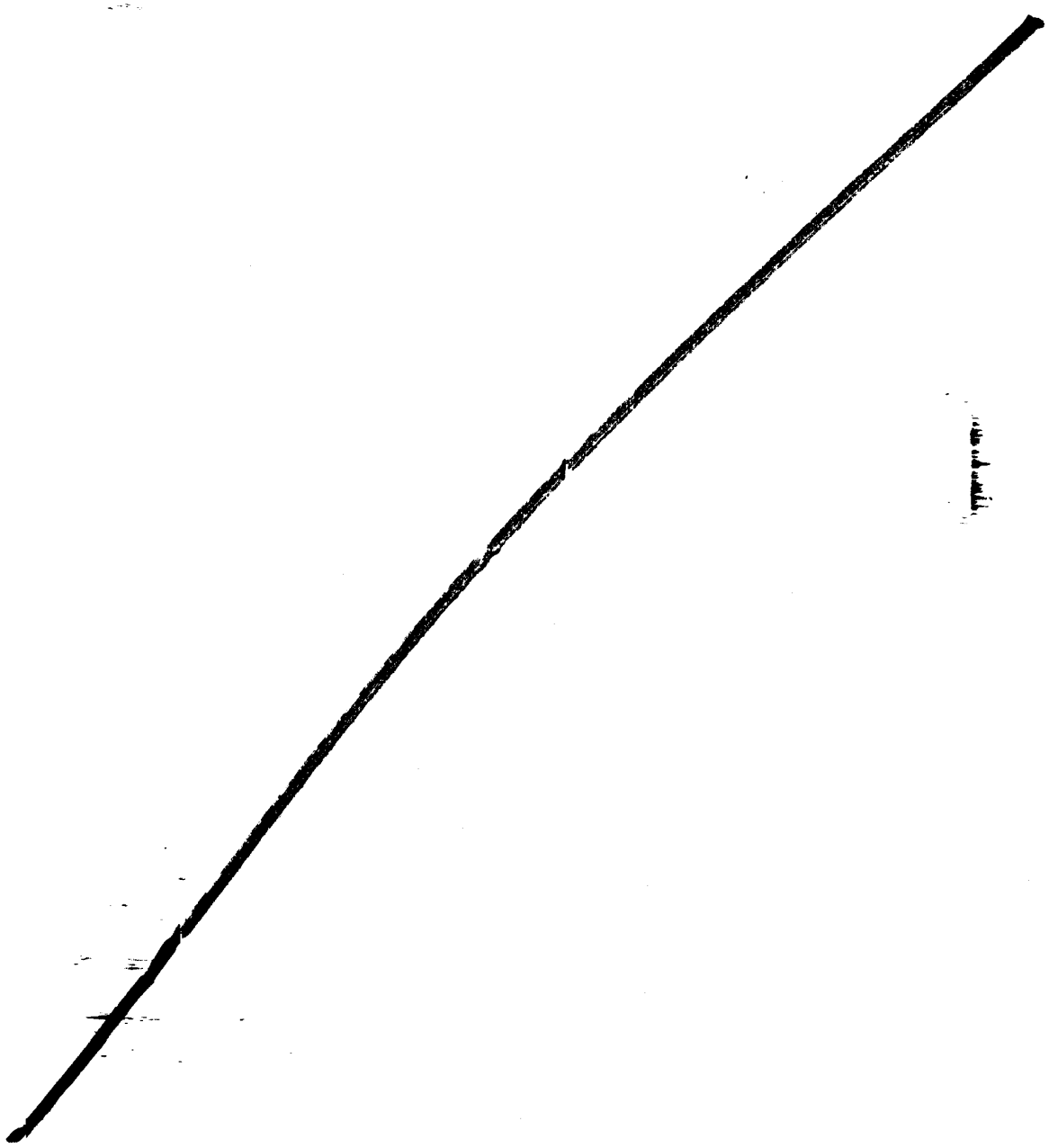
Status: [ ] Highly Acceptable [XX] Acceptable
[ ] Unacceptable [ ] Failure

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

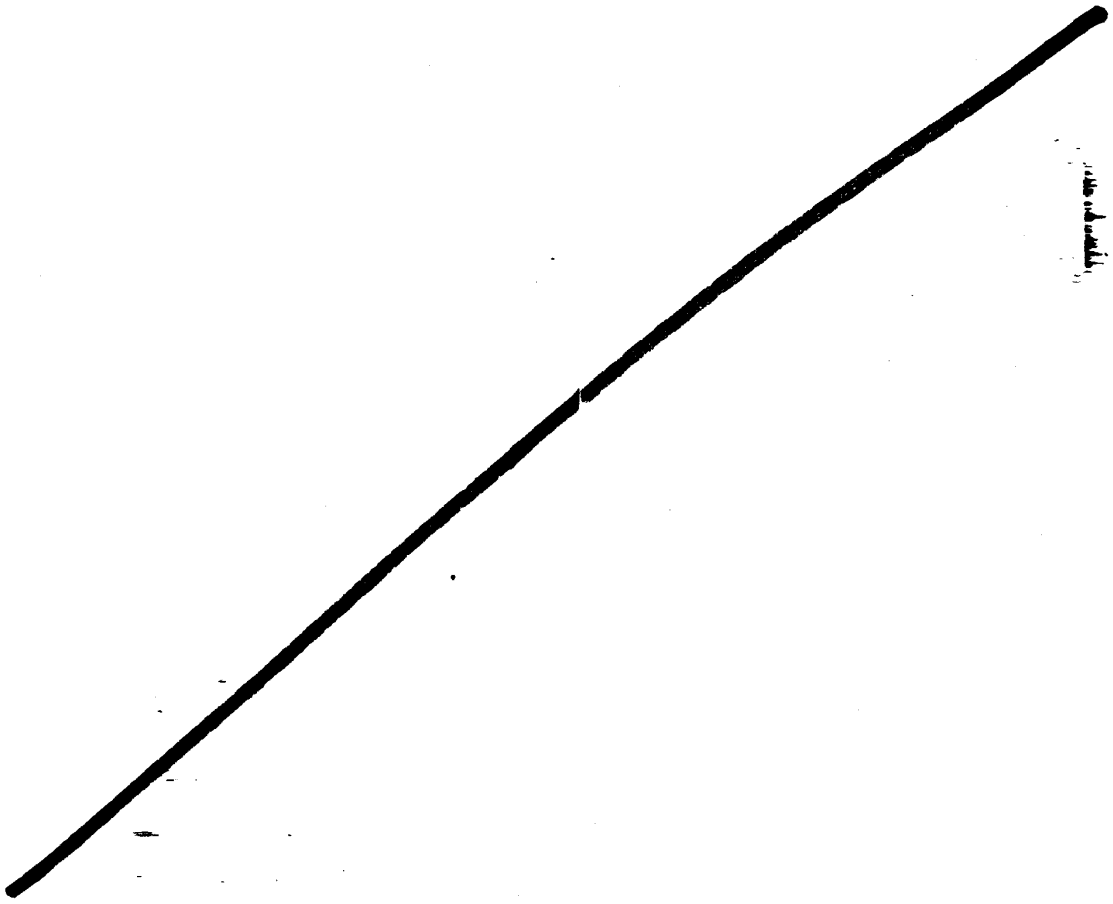


and were available for review, but had not been approved/implemented by the responsible person.

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

[redacted]

Section G. Records Audit



Section H. Personnel

[redacted]

Section I. Reagents

[redacted]

Section J. Quality Control and Standards

[redacted]

Section K. Reporting

[redacted]

Section L. Equipment and Maintenance

[redacted]

Section M. Immunoassay

[redacted]

Section N. Gas Chromatography/Mass Spectrometry

[redacted]

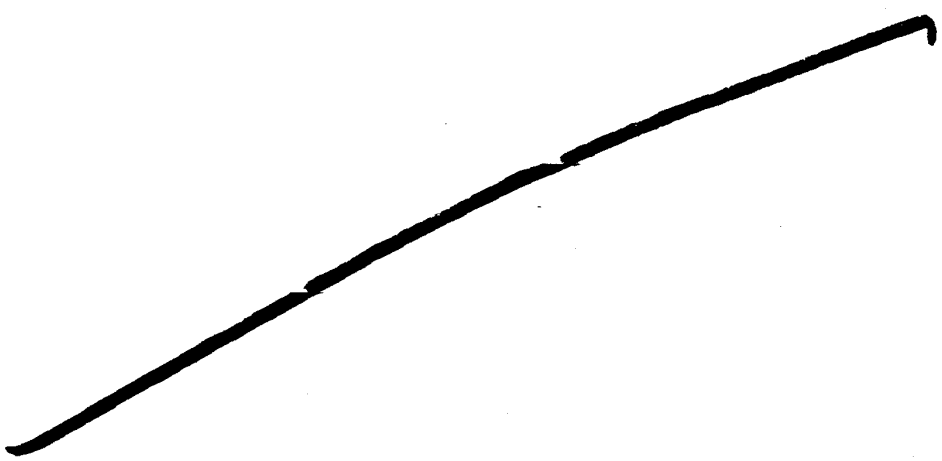
SmithKline Beecham
Clinical Laboratories

February 11, 1999

Ms. Susan Crumpton
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park
North Carolina 27709-2194

Dear Ms. Crumpton:

Following is my response to the seventeenth maintenance inspection report critique:



If you have any questions, please call me at 1-800 669 6995.

Sincerely,

M.P. George
Director of Forensic Toxicology

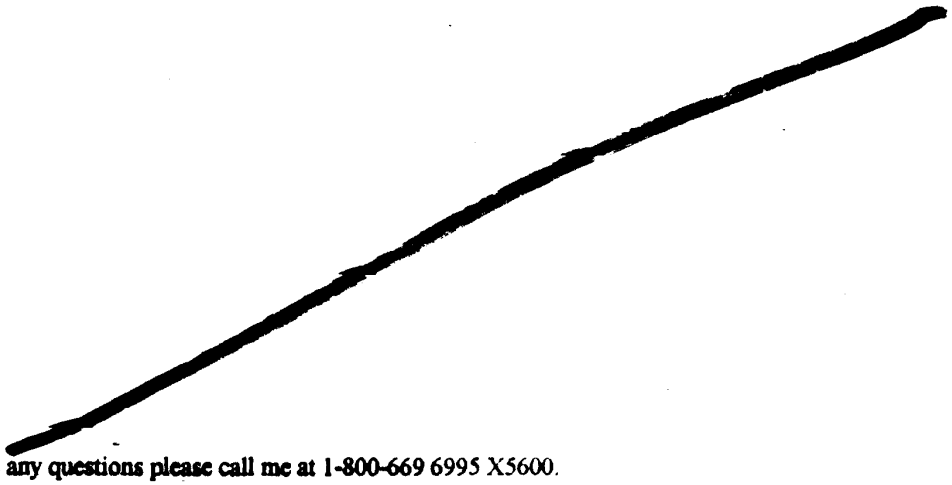
SmithKline Beecham
Clinical Laboratories

March 5.1999

Susan Crumpton
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park
North Carolina 27709-2194

Dear Ms. Crumpton:

This is my follow up response to the seventeenth maintenance inspection report.



If you have any questions please call me at 1-800-669 6995 X5600.

Sincerely,

M.P. George
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE

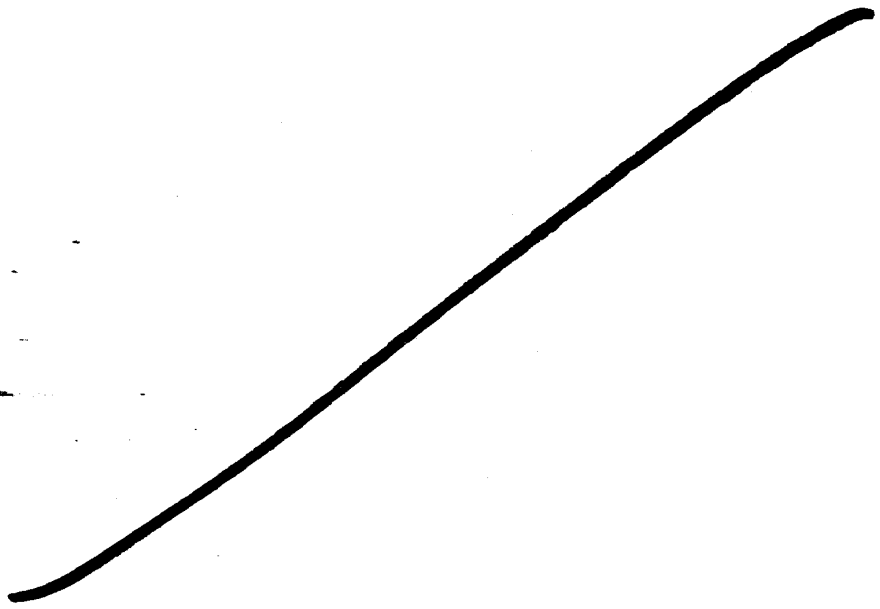
National Laboratory Certification Program

March 16, 1999

0138
Mr. M. P. George
SmithKline Beecham Clinical Laboratories
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George:

We have reviewed the material provided in your correspondence of February 11 and March 5, 1999, submitted in response to issues raised during the seventeenth inspection of your laboratory as outlined in our correspondence of January 8, 1999, and discussed in our telephone conversation of March 1, 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 our review:



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

The submitted memorandum to staff (dated March 5, 1999) contained original signatures. We have copied the document for our files and are returning the original to the laboratory with this correspondence.

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.

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

Susan Crumpton
NLCP Inspection Analyst

cc: Mr. Kenneth Davis
Project Files/M17

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

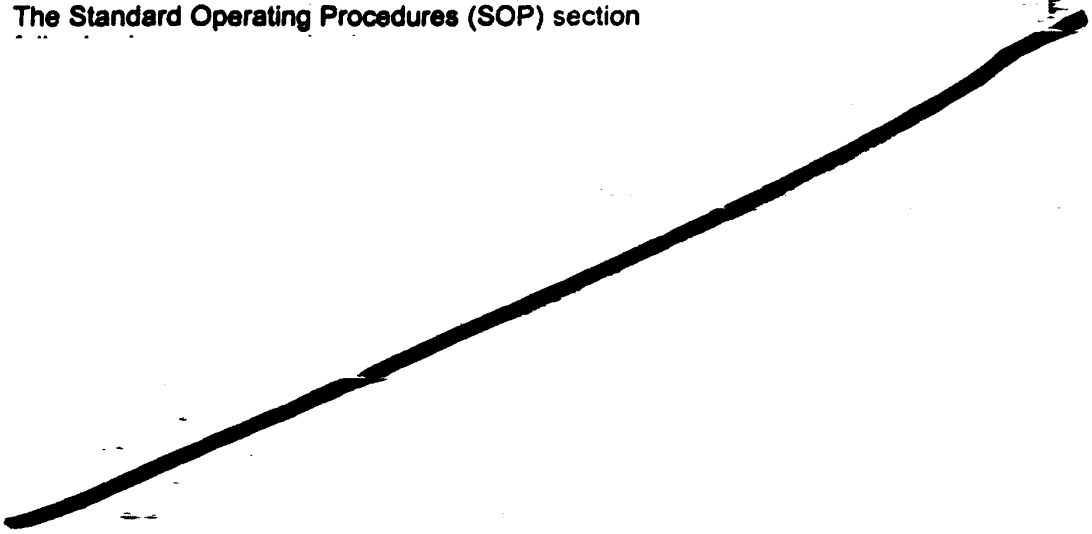
July 15, 1999

0138
Mr. M. P. George
SmithKline Beecham Clinical Laboratories
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

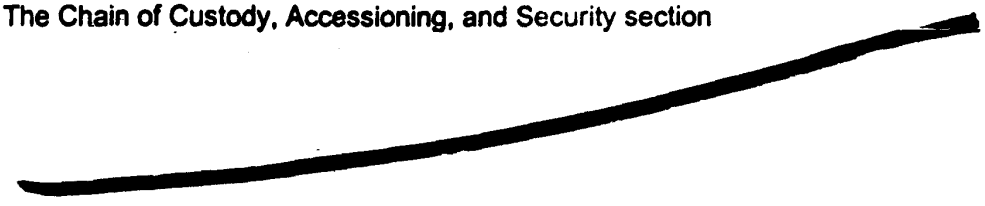
Dear Mr. George:

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:

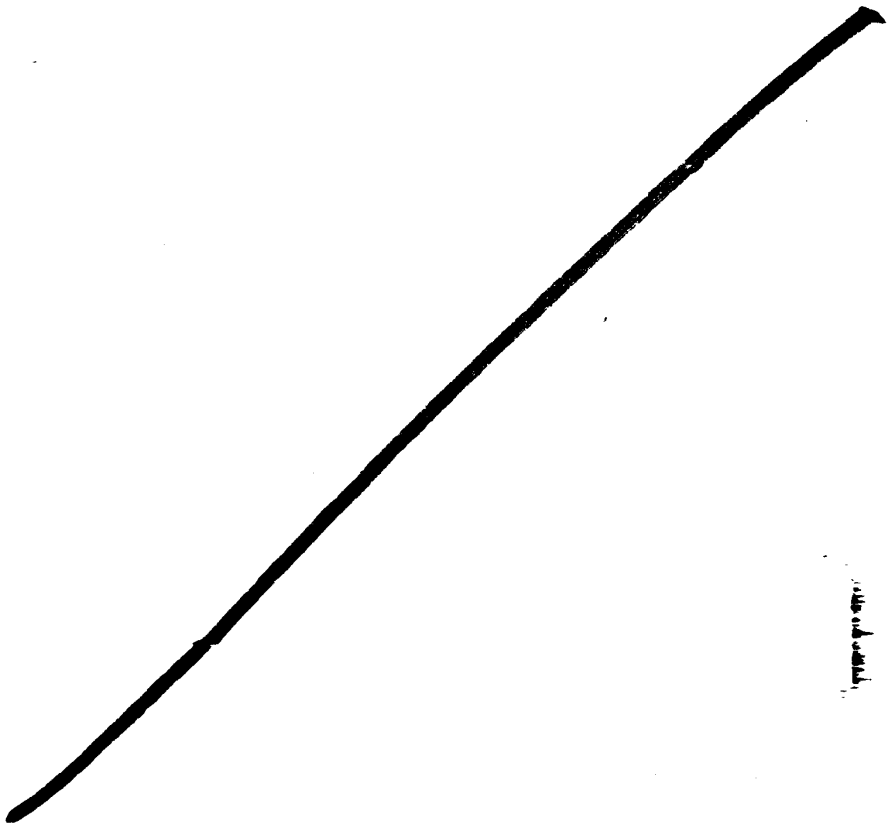
E. The Standard Operating Procedures (SOP) section



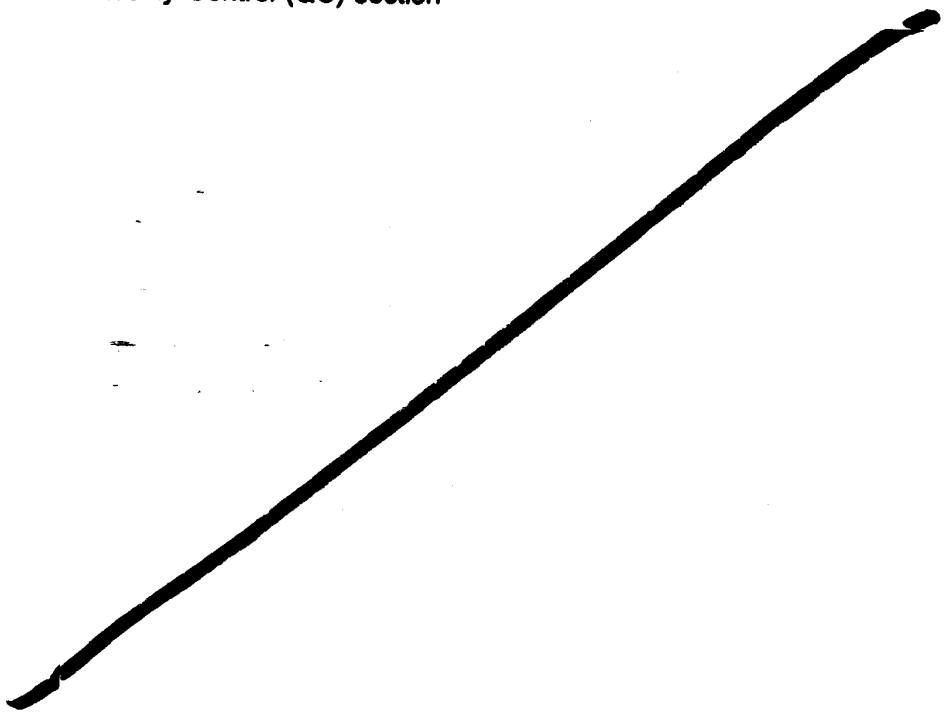
F. The Chain of Custody, Accessioning, and Security section



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina [illegible]
Telephone 919 541-6709 • Fax 919 541-7042



G. The Quality Control (QC) section

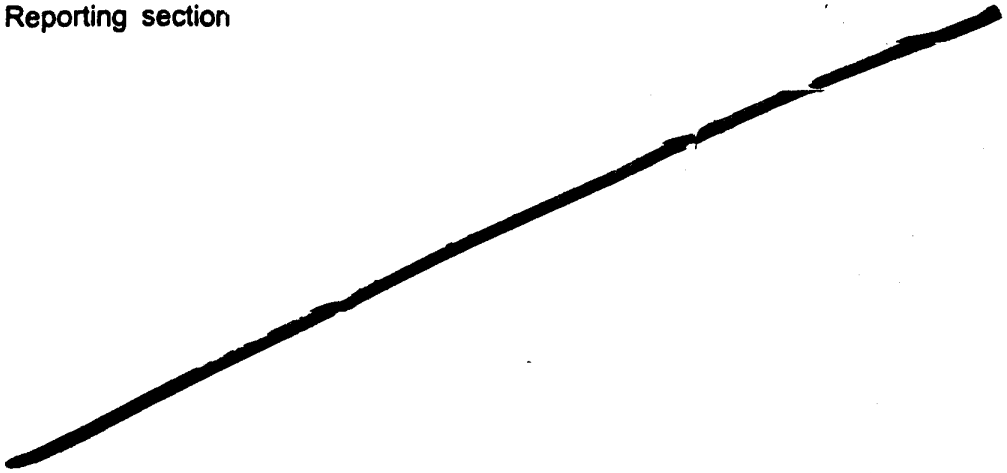


H. The Initial Tests section

I. The Confirmatory Tests section

J. The Records section

K. The Reporting 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) 541-6176 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: 0138
Document No. Final

Laboratory: SmithKline Beecham Clinical Laboratories

Location: Schaumburg, IL

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M18 Date: 20 May 1999
[ ] Other _____

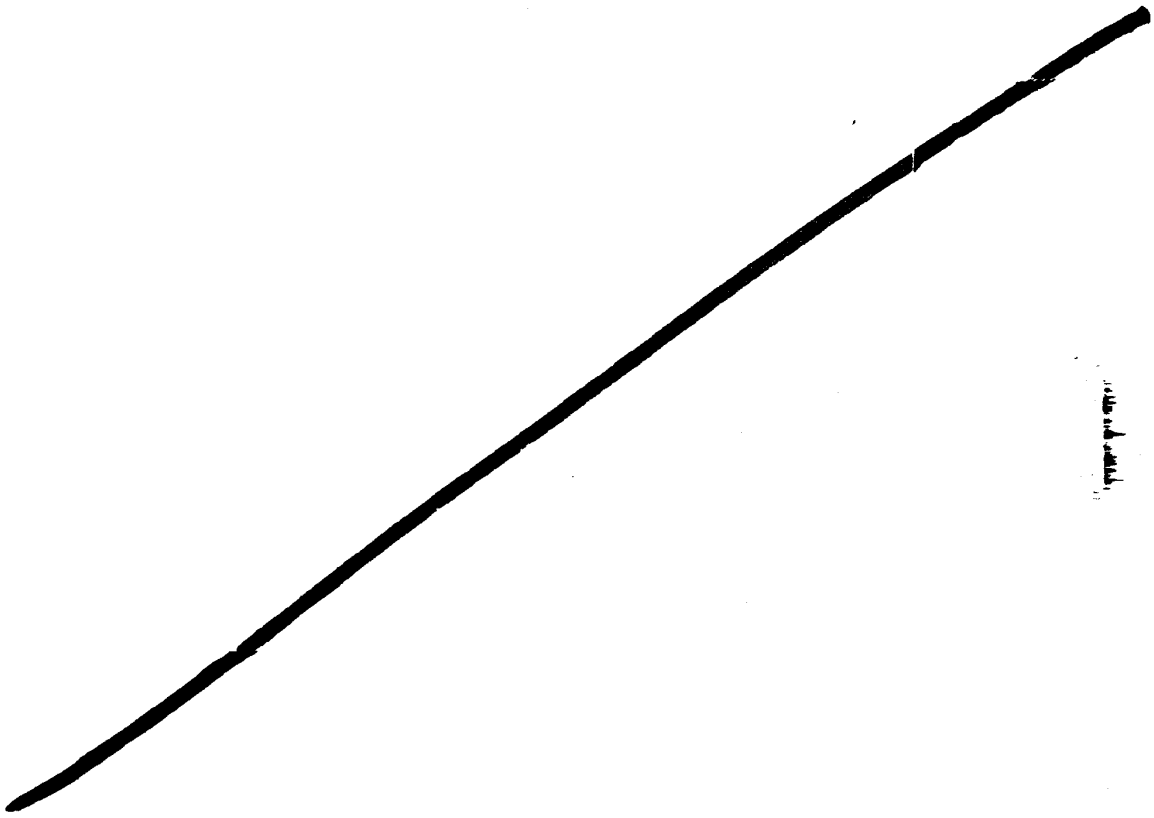
Status: [ ] Highly Acceptable [XX] Acceptable
[ ] Unacceptable [ ] Failure

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.

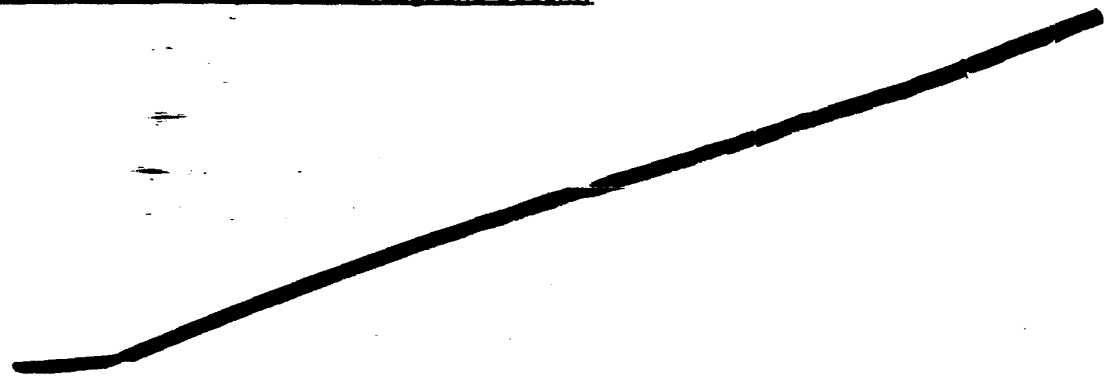
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

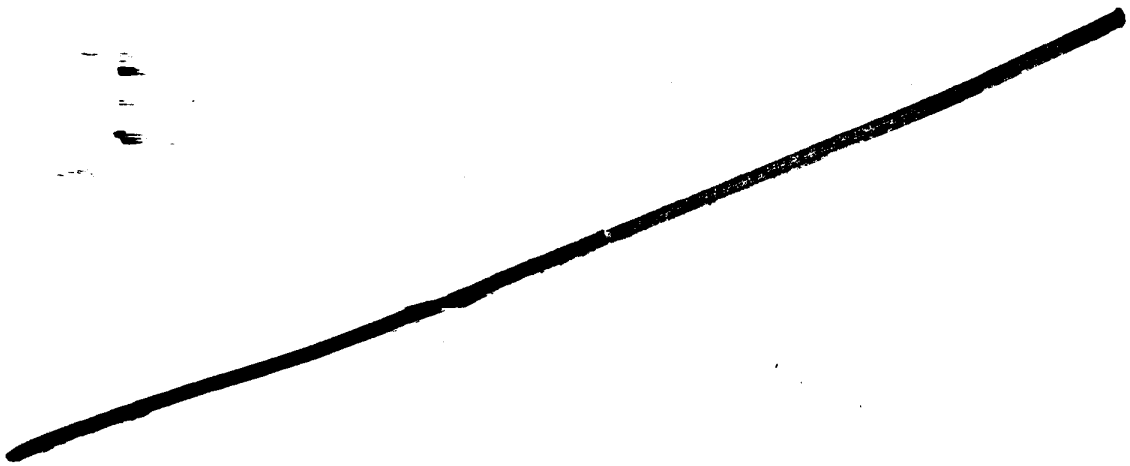
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

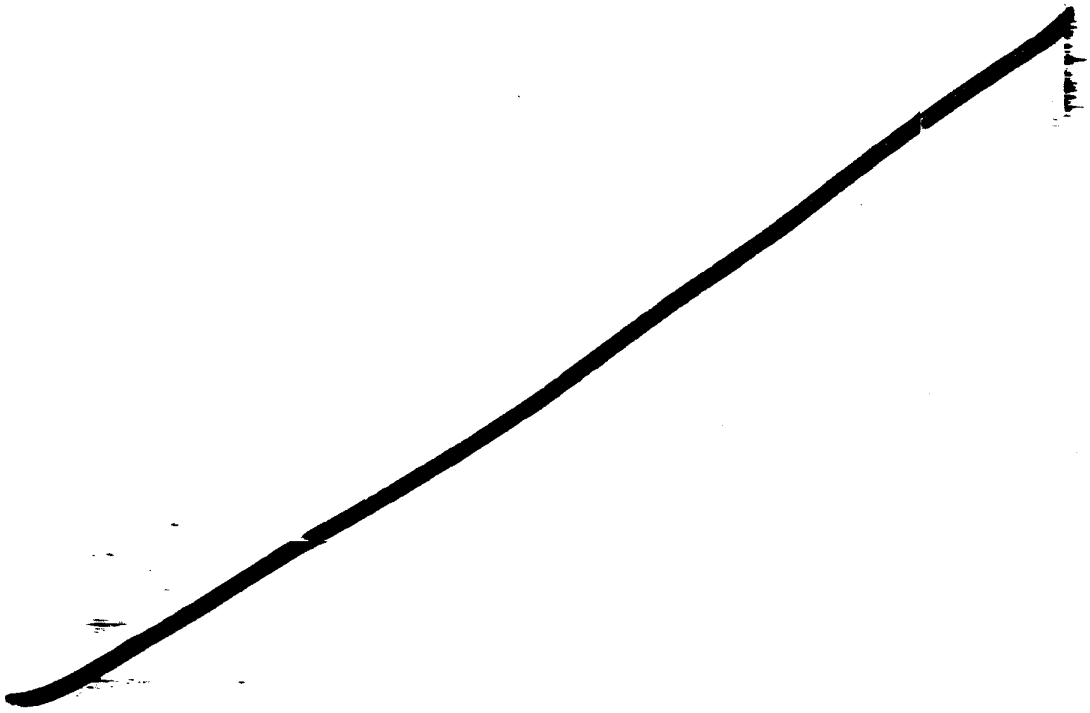


Section F. Chain-of-Custody, Accessioning, and Security



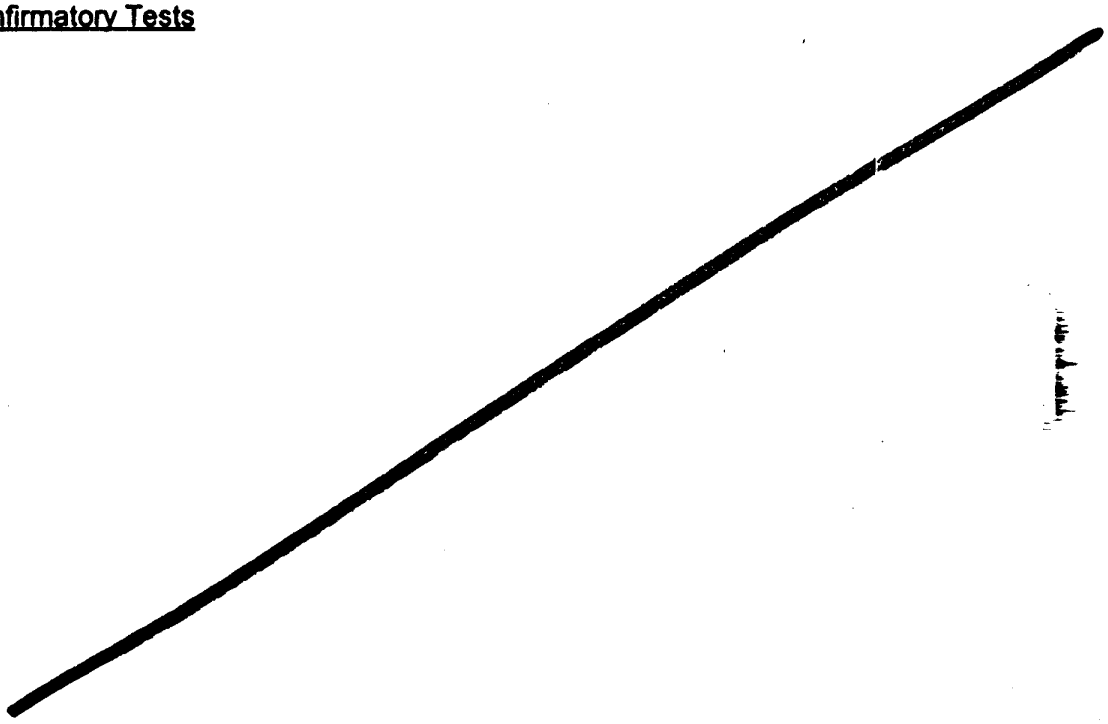


Section G. Quality Control



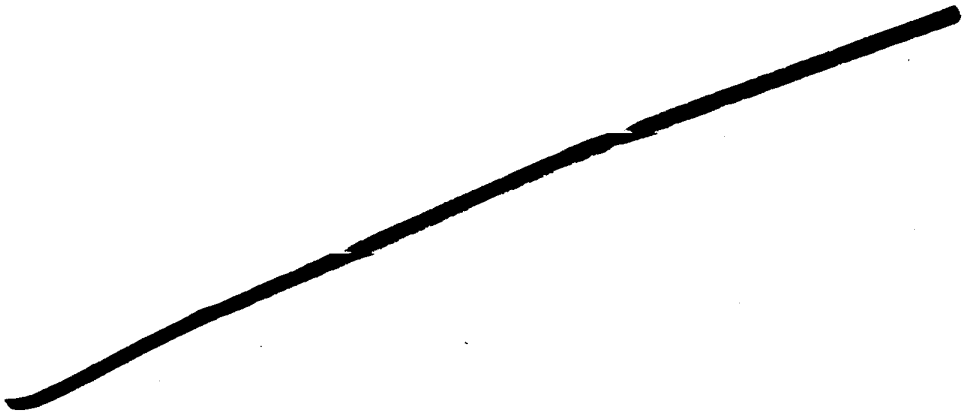
Section H. Initial Tests

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

SB

SmithKline Beecham
Clinical Laboratories

received
8/23/99 SDC

Ms. Susan Crumption
NLCP Inspection Analyst
National Laboratory Certification Program
Research Triangle Institute
Research Triangle Park, NC 27709 – 2194

August 21, 1999

Dear Ms. Crumption:

This is my response to the eighteenth inspection critique. For you review, all the documents are attached and each document is marked with the citation number.

[redacted]

The estimated completion time is September 16, 1999. The corrective actions are attached and they are as follows:

[redacted]

All the corrective actions listed above was implemented by August 20, 1999. [redacted] If you have any questions please call me at 1 800 669 6995 Ext. 5600.

Sincerely,

M.P. George
Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE

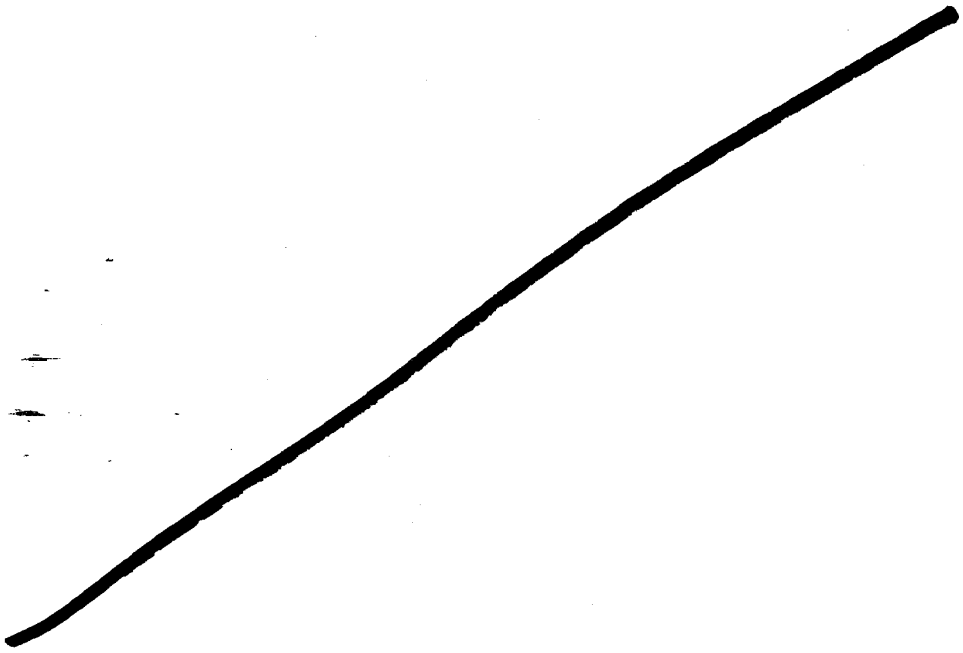
National Laboratory Certification Program

August 30, 1999

0138
Mr. M. P. George
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George:

We have reviewed the material provided in your correspondence of August 21, 1999, submitted in response to deficiencies cited during the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of July 15, 1999. The information submitted by the laboratory appears to demonstrate that appropriate remedial actions have been completed to address most issues. However, the following issues remain or were raised during our review of the submitted material:



3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

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 Inspection Analyst

cc: Dr. Michael Baylor
Project Files/M18

Quest Diagnostics Incorporated
506 East State Parkway
Schaumburg, Illinois 60173

September 20, 1999

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

Dear Ms. Crumpton:

This is my response to your correspondence of August 30,1999, concerning the two remaining clarifications on our NLCP inspection response of August 21, 1999.

If you have any question please call me at 1-800 669 6995 X5600.

Sincerely,

M.P. George

Director of Forensic Toxicology

RESEARCH TRIANGLE INSTITUTE

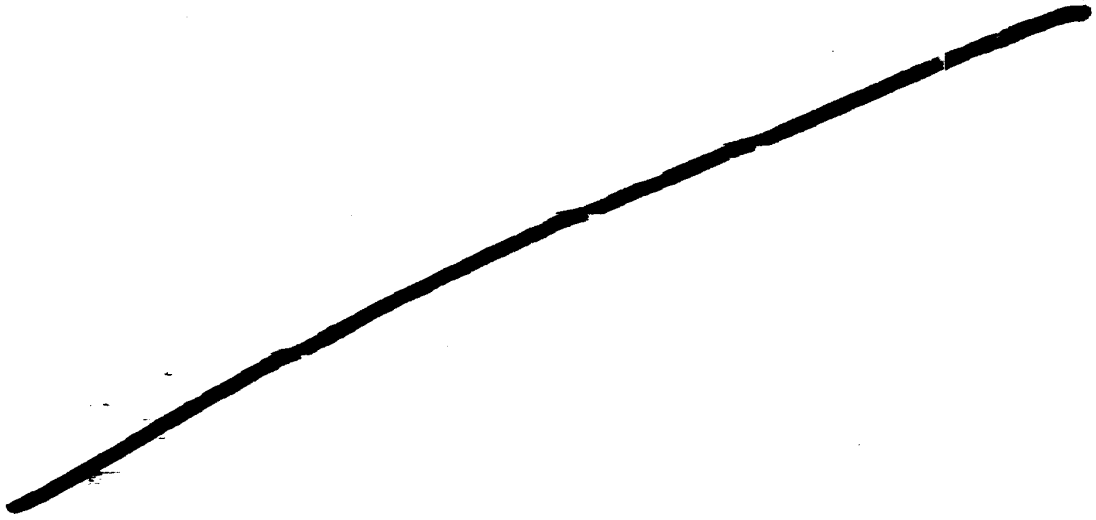
National Laboratory Certification Program

September 28, 1999

0138
Mr. M. P. George
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George:

We have reviewed the material provided in your correspondence of September 20, 1999, submitted in response to remaining issues from the eighteenth maintenance inspection of your laboratory as outlined in our correspondence of August 30, 1999. 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.

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 U
Telephone 919 541-6709 • Fax 919 541-7042

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/0138

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 12, 2000

0138
Mr. M. P. George
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George:

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

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M19

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 US
Telephone 919 541-6709 • Fax 919 541-7042

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0138
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Schaumburg, IL

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M19 Date: 18 November 1999
[ ] Other _____

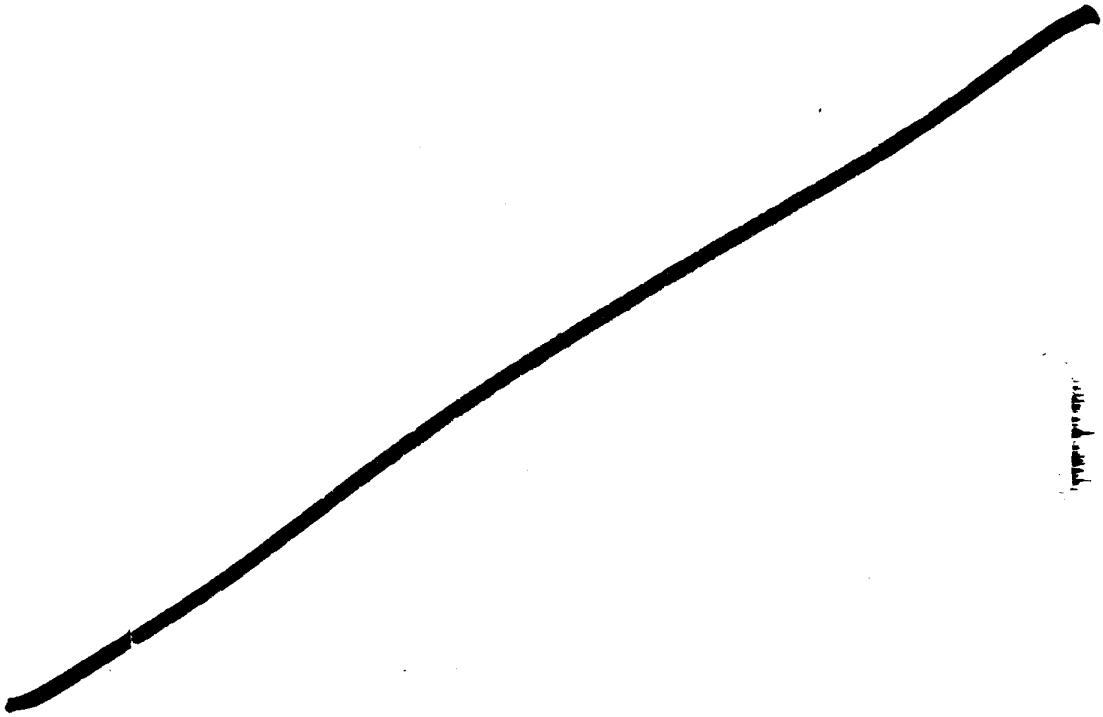
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

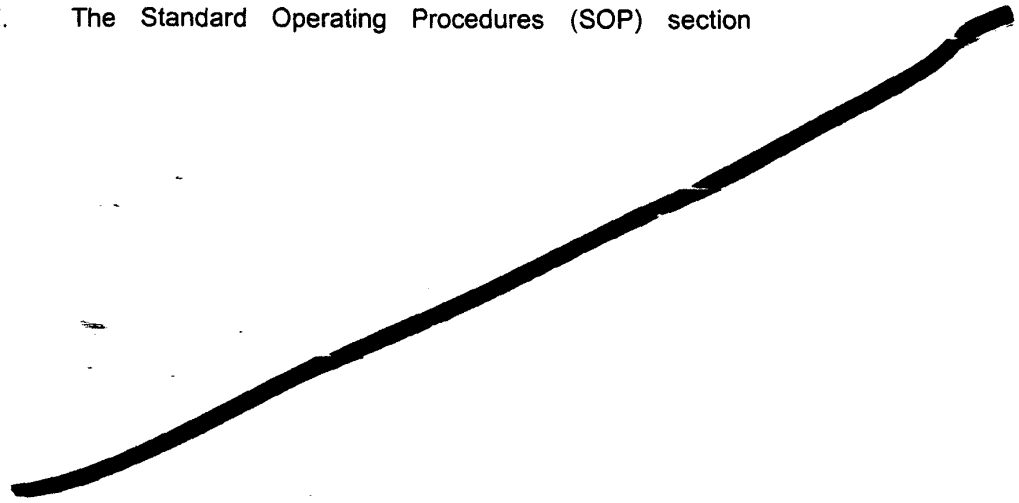
June 27, 2000

0138
Mr. M. P. George
Ms. Carole Trojan
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George and Ms. Trojan:

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



G. The Quality Control section

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

J. The Records section

N. The Personnel section

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0138
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Schaumburg, IL

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M20 Date: 11 May 2000
[ ] Other _____

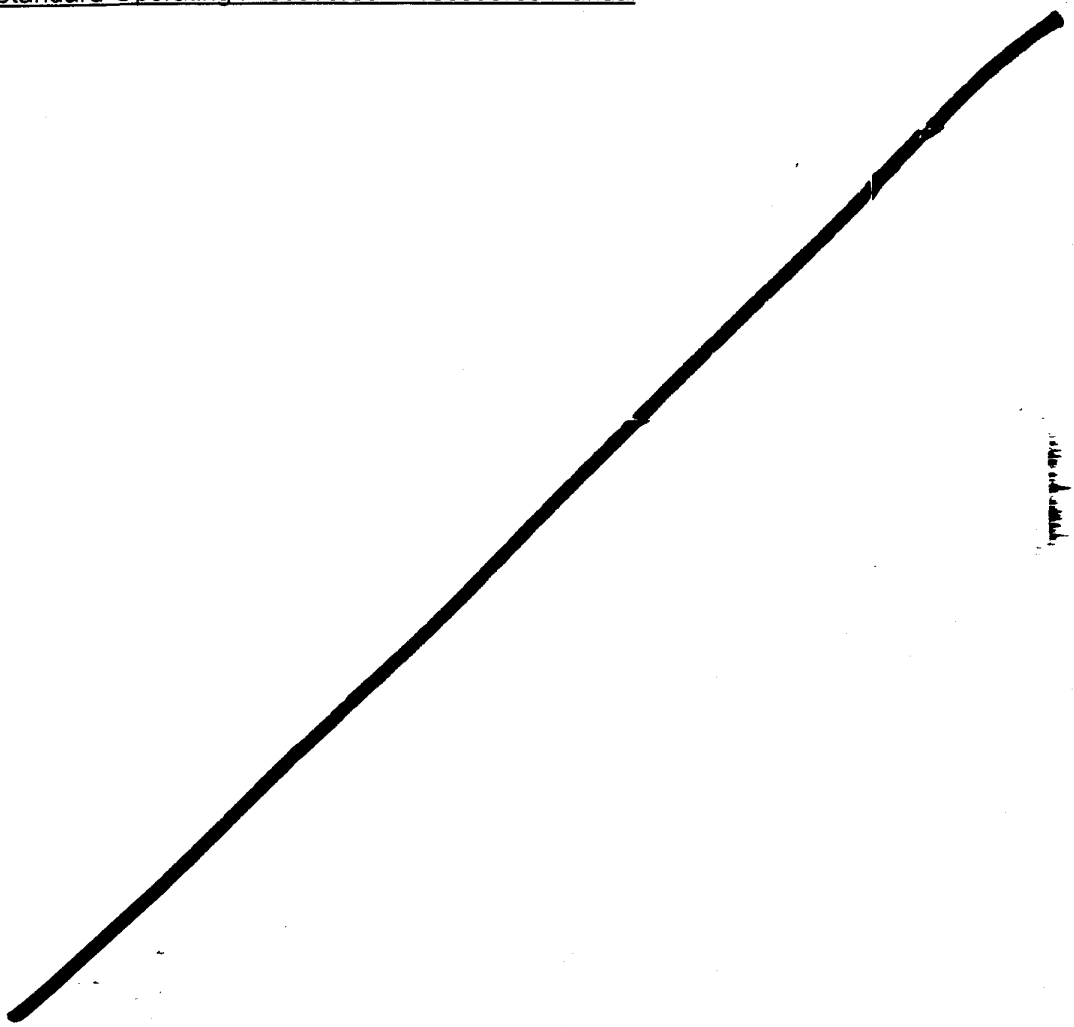
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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.

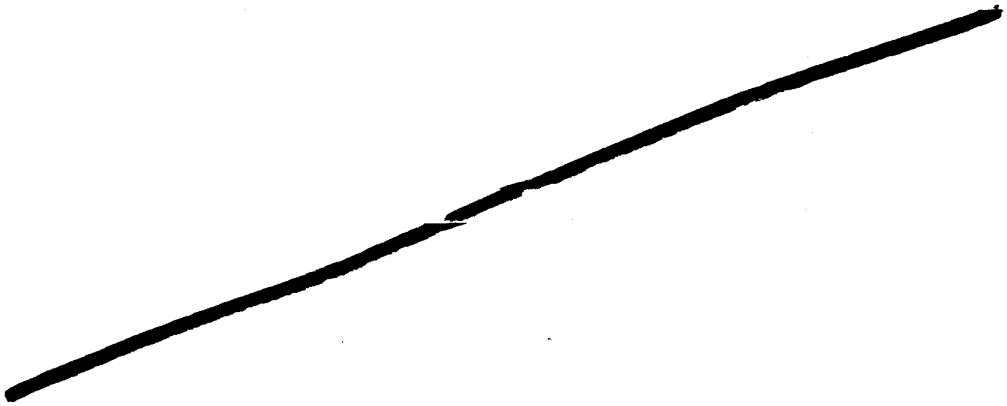
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

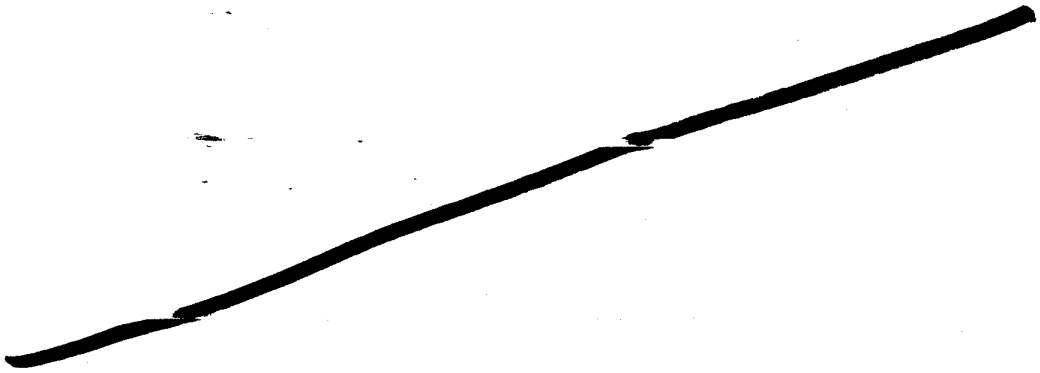
Section G. Quality Control

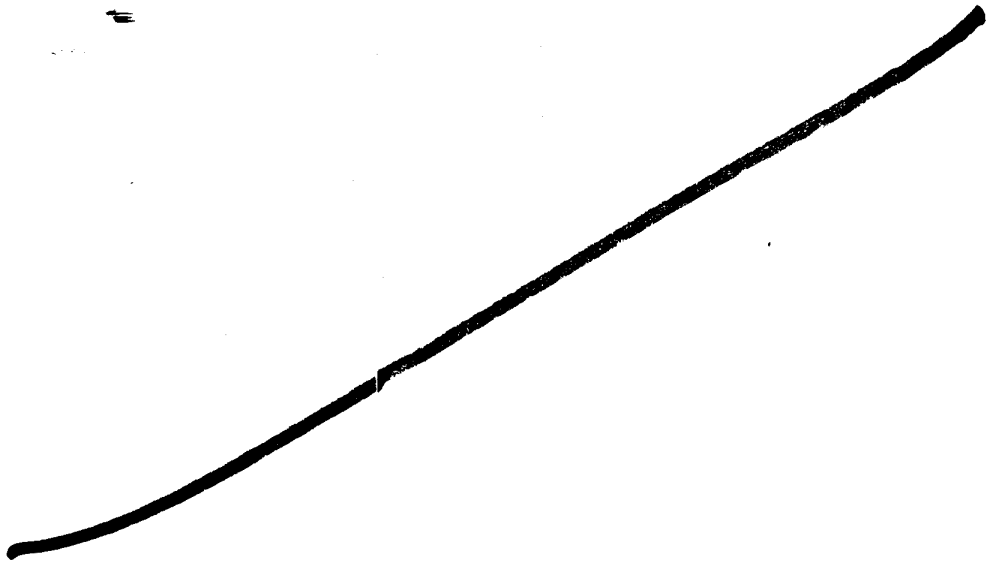


Section H. Initial Tests

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

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

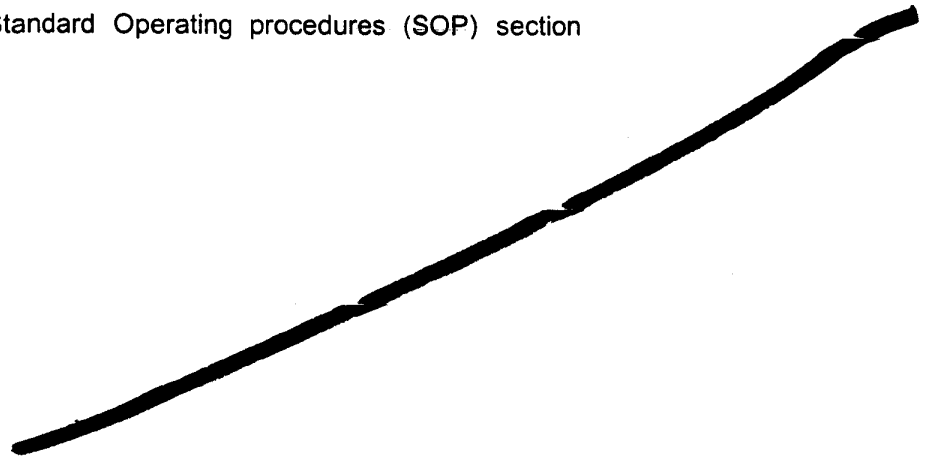
February 10, 2001

138
Mr. M. P. George
Ms. Carole Trojan
Quest Diagnostics Incorporated
NIDA Section
506 East State Parkway
Schaumburg, IL 60173

Dear Mr. George and Ms. Trojan:

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 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.

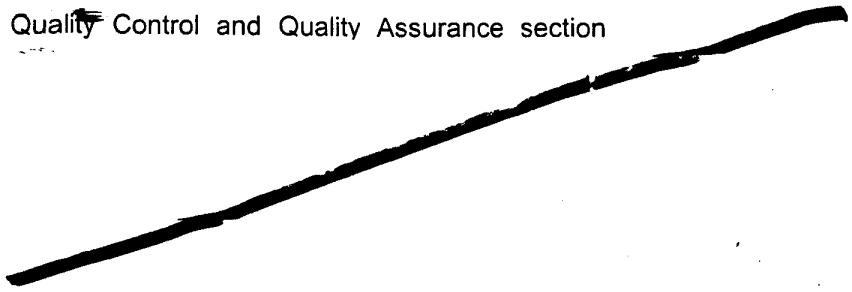
E. The Standard Operating procedures (SOP) section



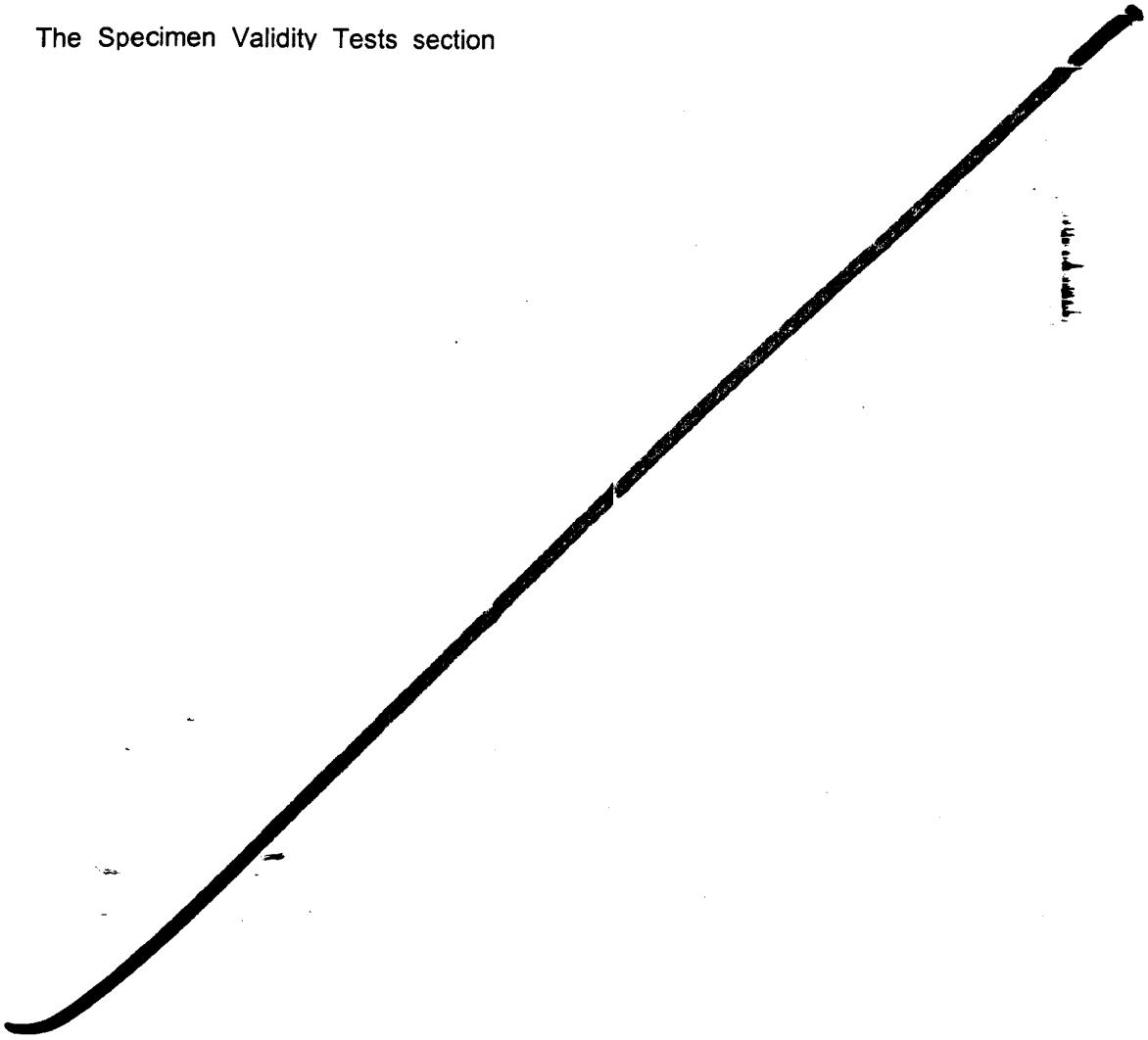
F. The Chain-of-Custody, Accessioning, and Security section

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

G. The Quality Control and Quality Assurance section



I. The Specimen Validity Tests 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

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M21

FEB 10 2001

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0138
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Schaumburg, IL

Document Reviewed:
[ ] Application Form
[XX] Inspection Report #M21 Date: 30 November 2000
[ ] Other _____

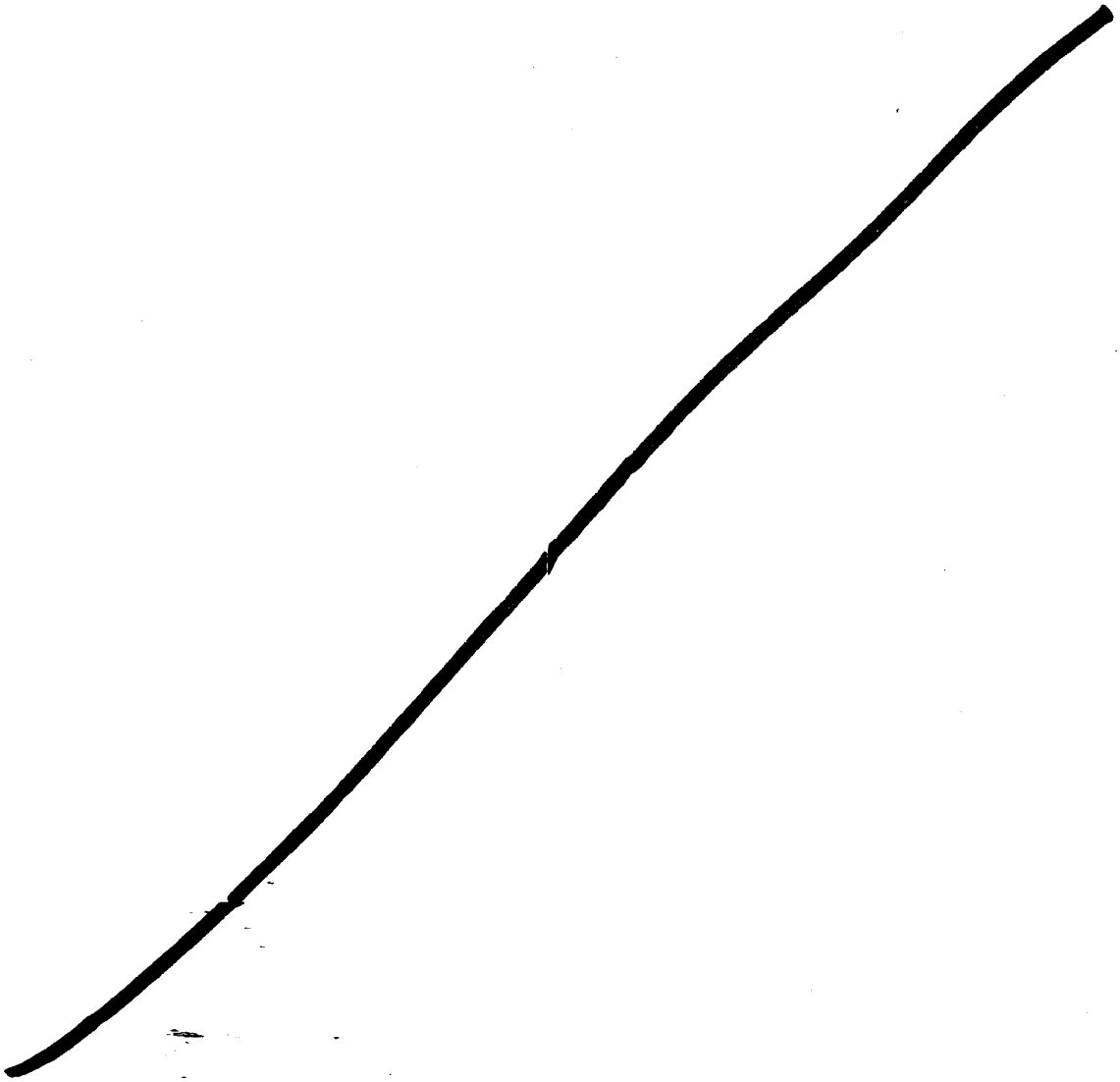
Status:
[XX] Appeared to meet most of the minimum technical criteria
[ ] Appeared to meet a number of the minimum technical criteria
[ ] Failed to meet a number of the minimum technical criteria
[ ] Failed to meet a significant number of the minimum technical criteria

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

[redacted]