

January 14, 1999

0068  
Dr. Louis Jambor  
SmithKline Beecham Clinical Laboratories  
7600 Tyrone Avenue  
Van Nuys, CA 91405

Dear Dr. Jambor:

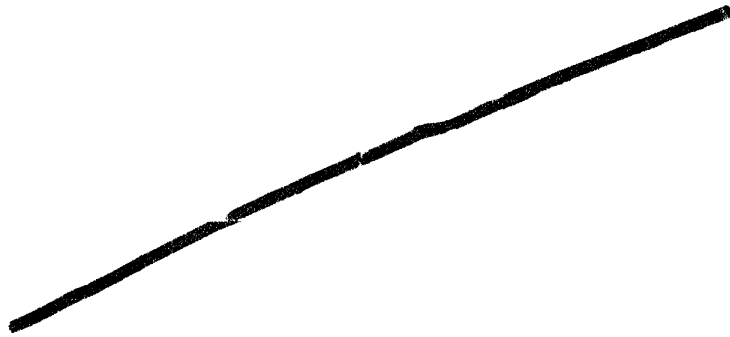
The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is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

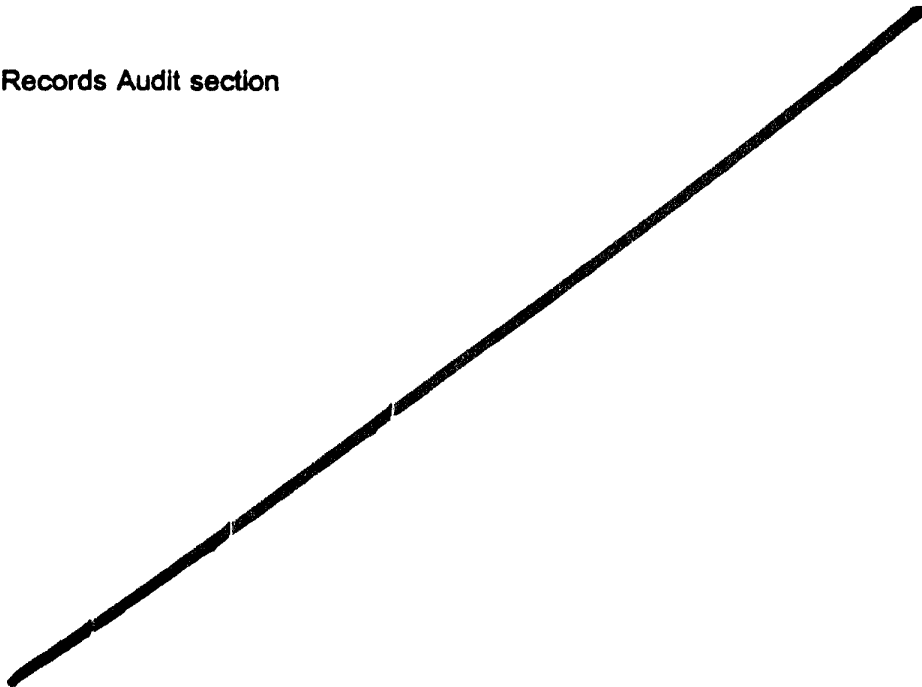


F. The Chain of Custody, Accessioning, and Security section





G. The Records Audit section



H. The Personnel section:



Dr. Jambor  
Page 3 of 3  
01/14/99

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 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/M16



---

## NATIONAL LABORATORY CERTIFICATION PROGRAM

---

### Document Review and Critique

---

Laboratory I.D. Number: 0068  
Document No. Final

Laboratory: SmithKline Beecham Laboratories

Location: Van Nuys, CA

Document Reviewed:     Application Form  
                               Inspection Report #M16                      Date: 19 November 1998  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

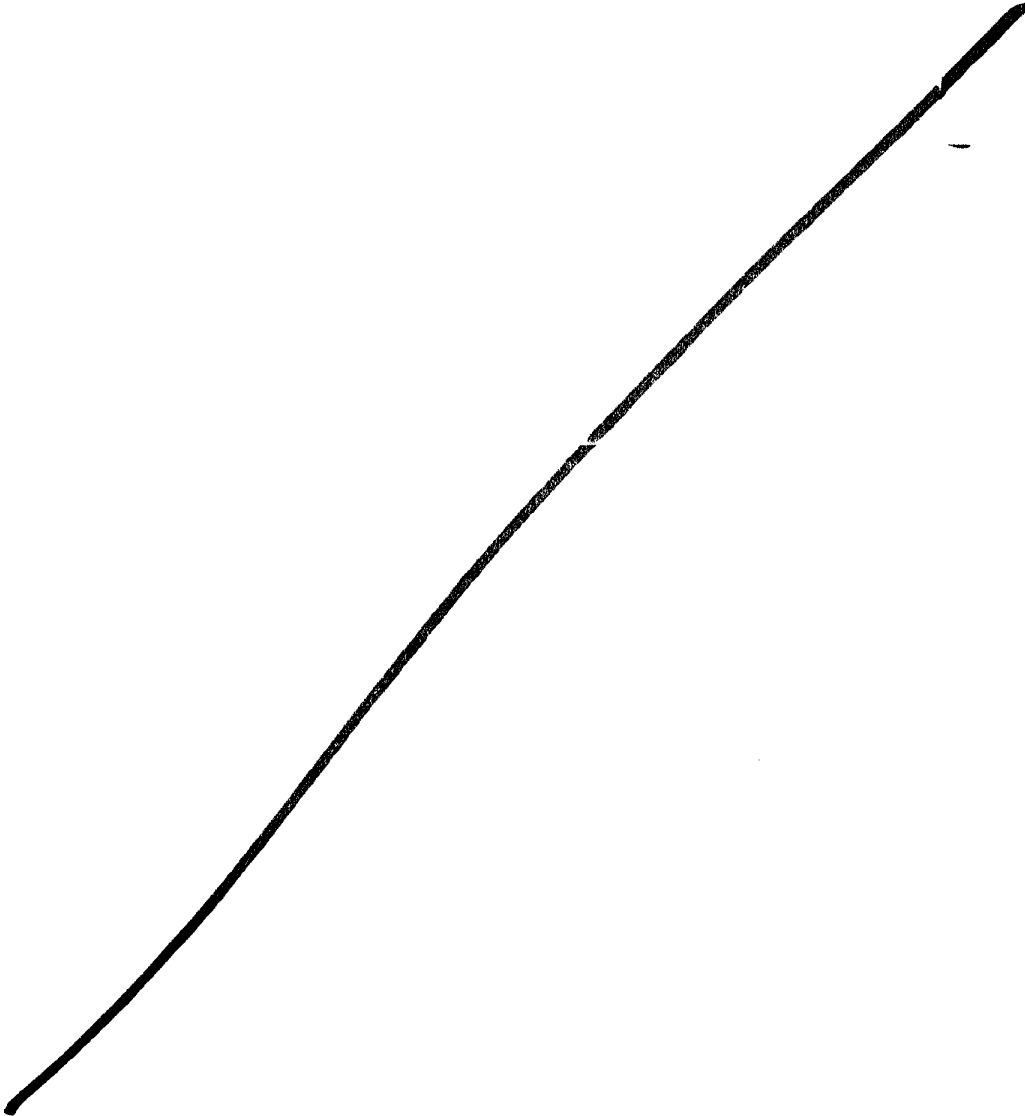
---

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.

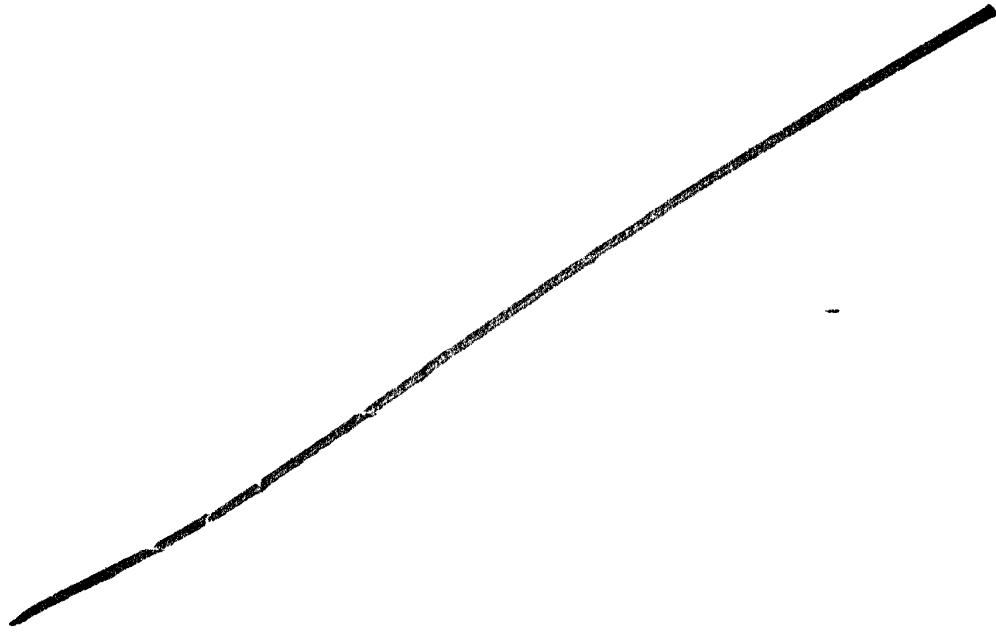
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

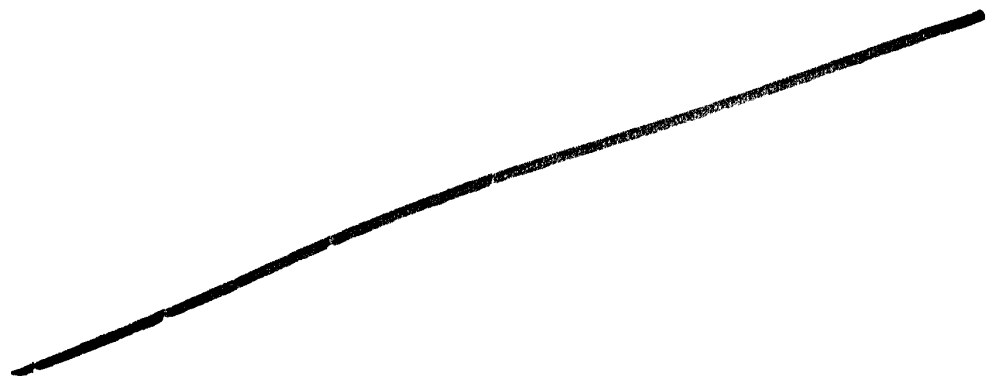
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Records Audit



Section H. Personnel

Section I. Reagents

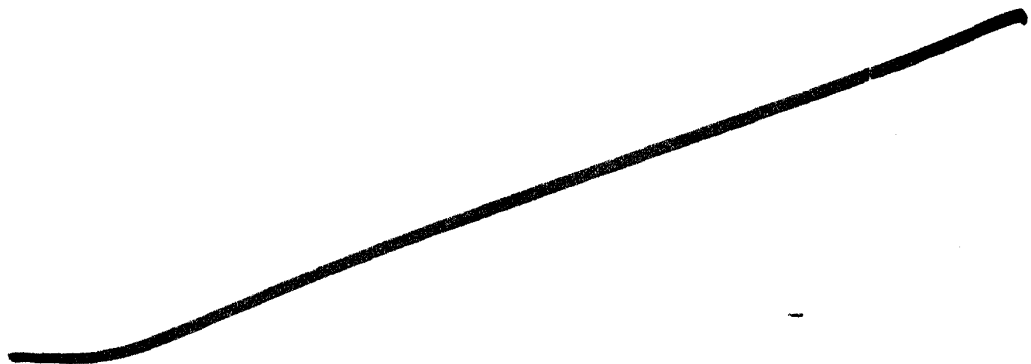
Section J. Quality Control and Standards

Section K. Reporting

Section L. Equipment and Maintenance

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry





**SB**  
**SmithKline Beecham**  
Clinical Laboratories

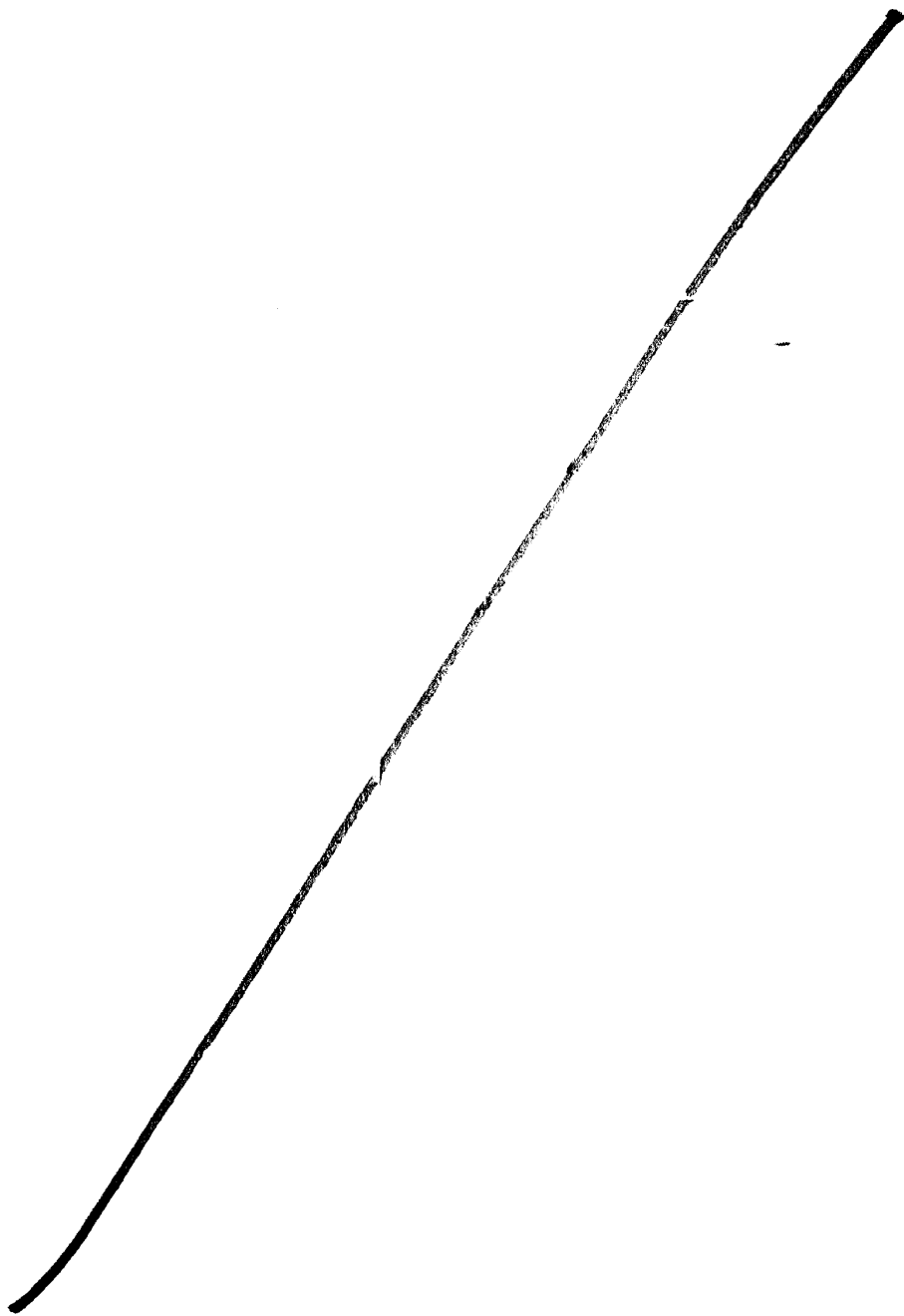
received  
SDC 2/12/99

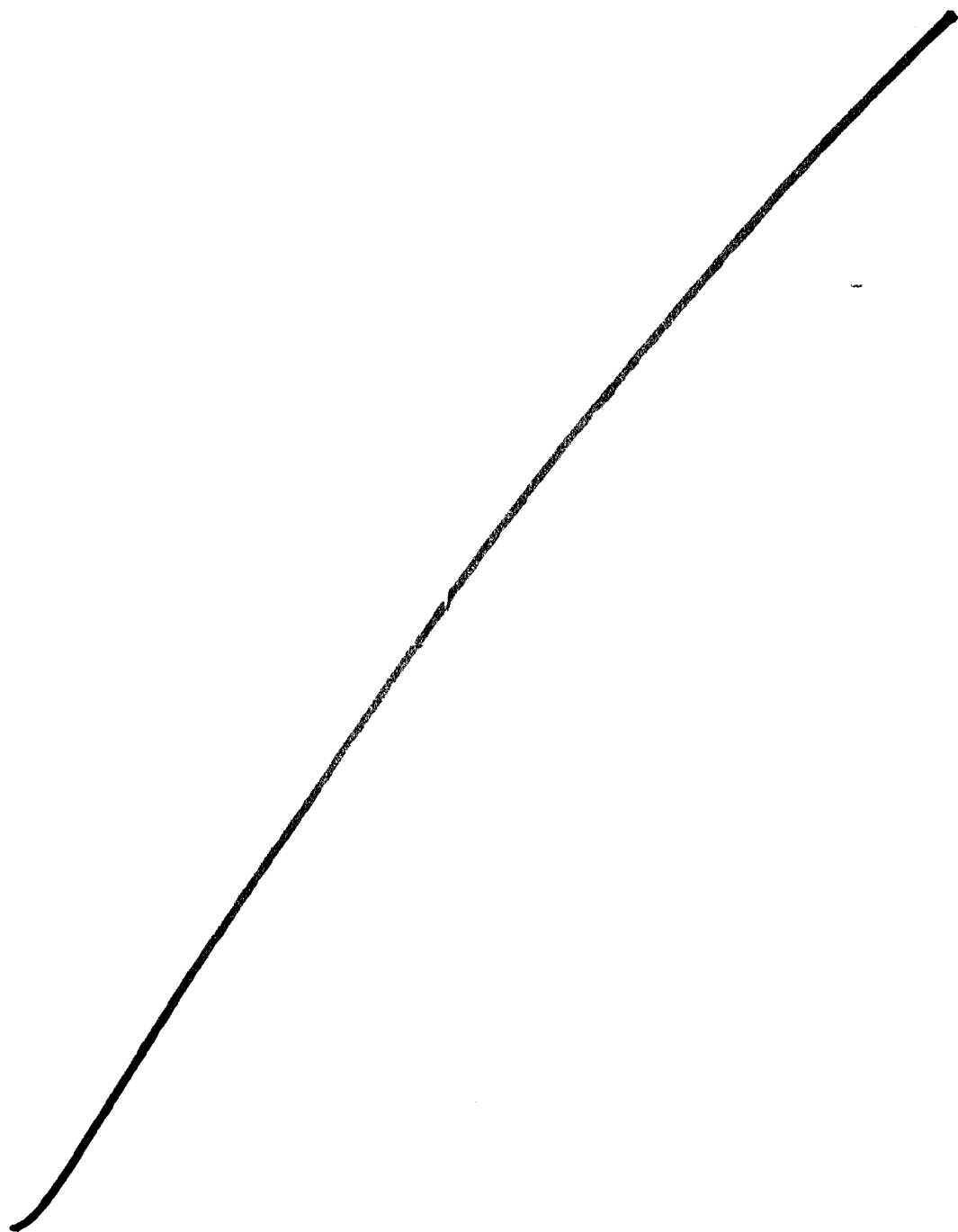
February 9, 1999

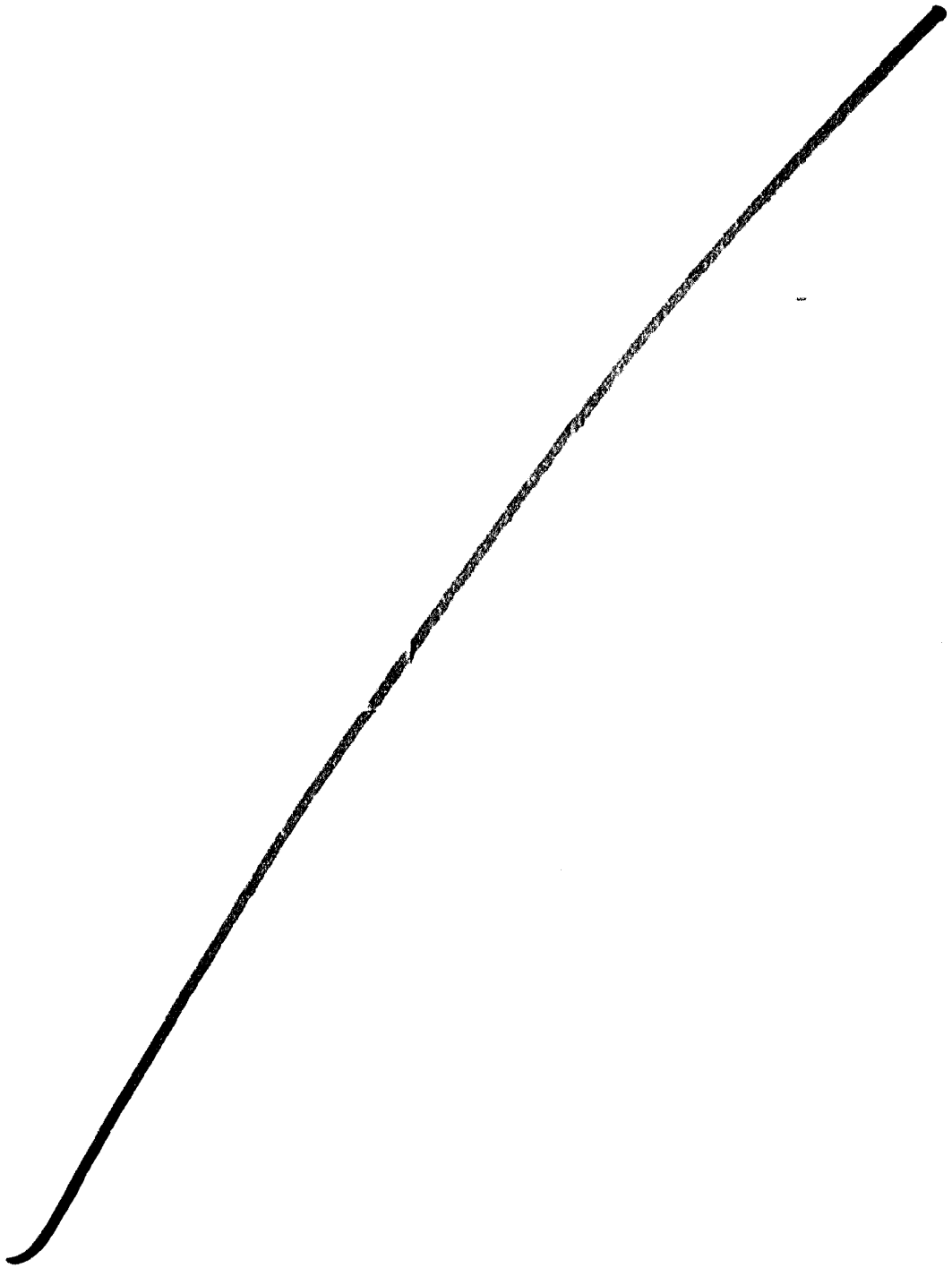
Susan Crumpton  
NLCP Inspection Analyst  
Research Triangle Institute  
3040 Cornwallis Road  
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

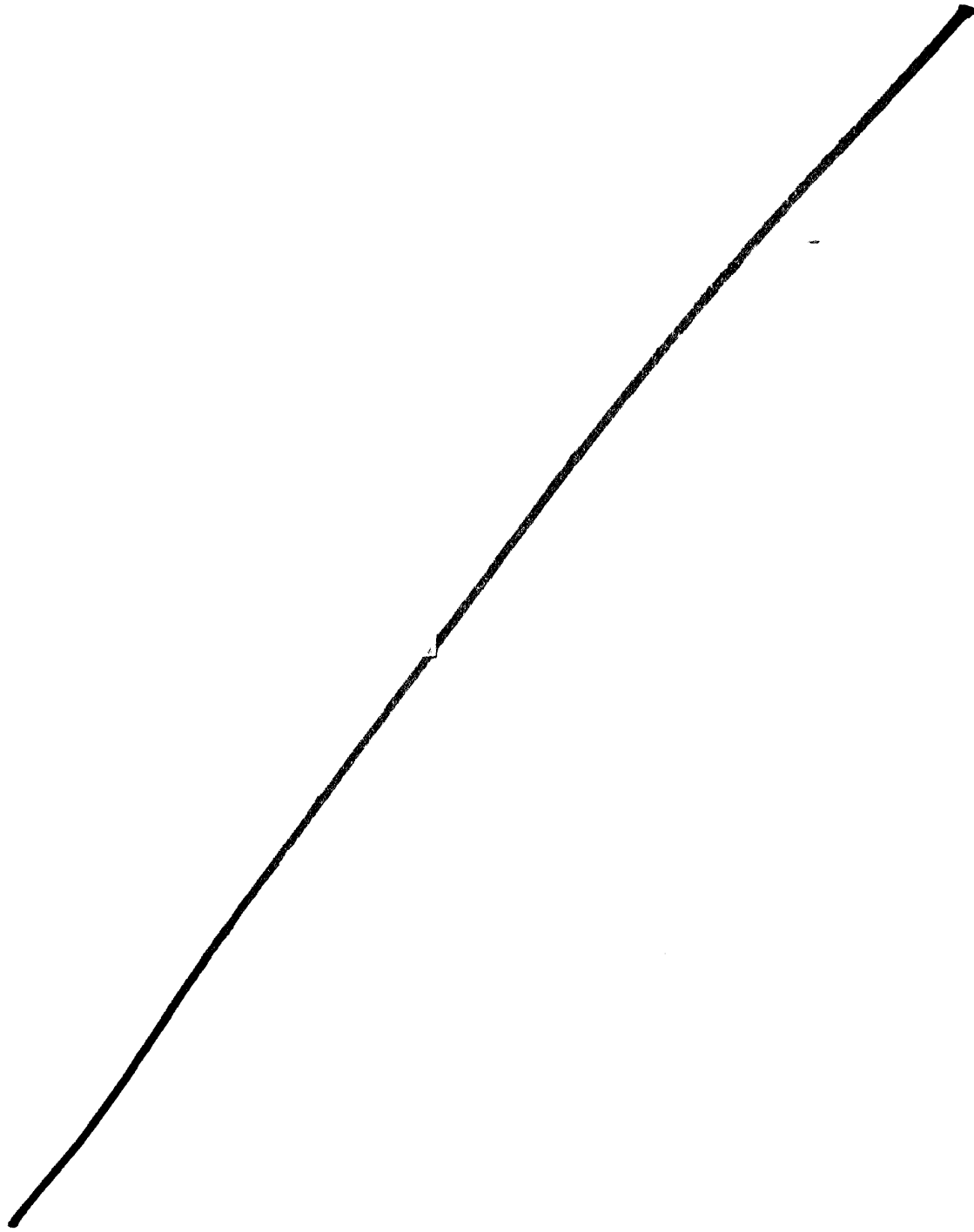
The following is our response to the critique of the inspection of SmithKline Beecham Clinical Laboratories in Van Nuys, California (Lab # 0068) that took place on November 19-21, 1998.

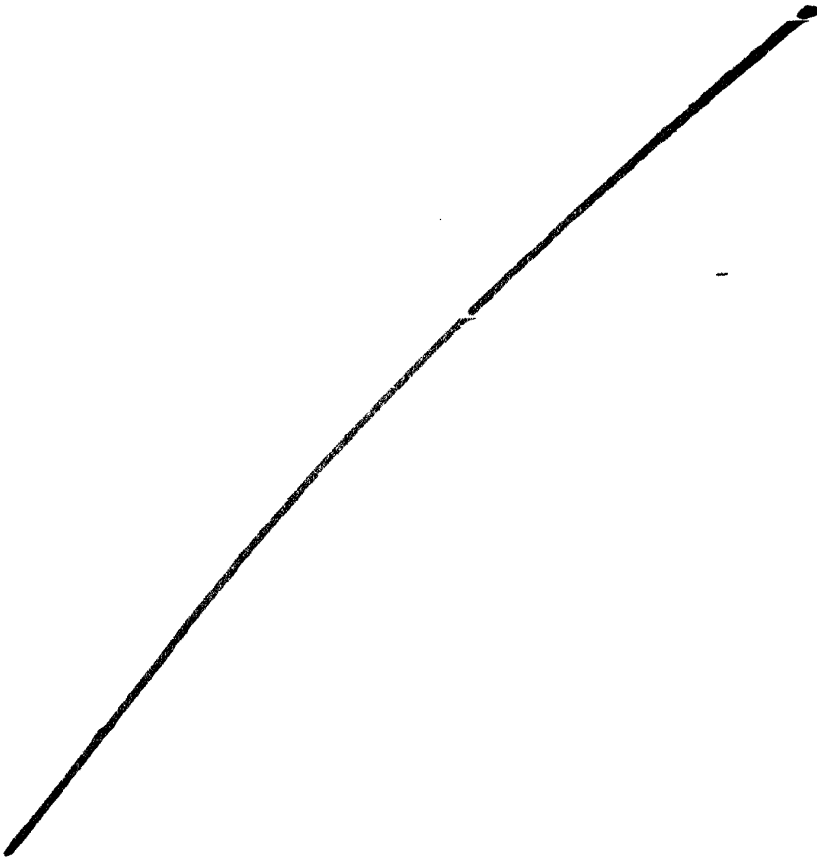






1944





All issues in the inspection report and been addressed and the corrective actions are currently in place.

Please contact me if you have any questions regarding this response.

Sincerely,

Louis G. Jambor, Ph.D.  
Forensic Testing Director  
(800) 877-2520

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 23, 1999

0068  
Dr. Louis Jambor  
SmithKline Beecham Clinical Laboratories  
7600 Tyrone Avenue  
Van Nuys, CA 91405

Dear Dr. Jambor:

We have reviewed the material provided in your correspondence of February 9 1999, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of January 14, 1999. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The implementation of the corrective actions will be reviewed at the next inspection.

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

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

Susan Crumpton  
NLCP Inspection Analyst

cc: Project Files/M16





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

July 13, 1999

0068  
Dr. Louis Jambor  
SmithKline Beecham Clinical Laboratories  
7600 Tyrone Avenue  
Van Nuys, CA 91405

Dear Dr. Jambor:

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:

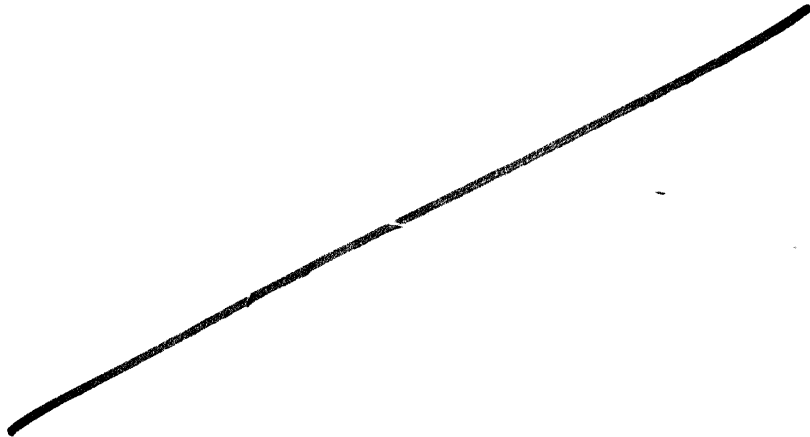
F. The Chain of Custody, Accessioning, and Security section



G. The Quality Control section







H. The Initial Tests section



J. The Records Audit section



K. The Reporting section

RTI is recommending to the 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 Inspection Analyst

Enclosure

cc: Project Files/M17  
Dr. Michael Baylor

---

## NATIONAL LABORATORY CERTIFICATION PROGRAM

---

### Document Review and Critique

---

Laboratory I.D. Number: 0068  
Document No. Final

Laboratory: SmithKline Beecham Laboratories

Location: Van Nuys, CA

Document Reviewed:     Application Form  
                               Inspection Report #M16                      Date: 19 November 1998  
                               Other \_\_\_\_\_

Status:                     Highly Acceptable                     Acceptable  
                               Unacceptable                         Failure

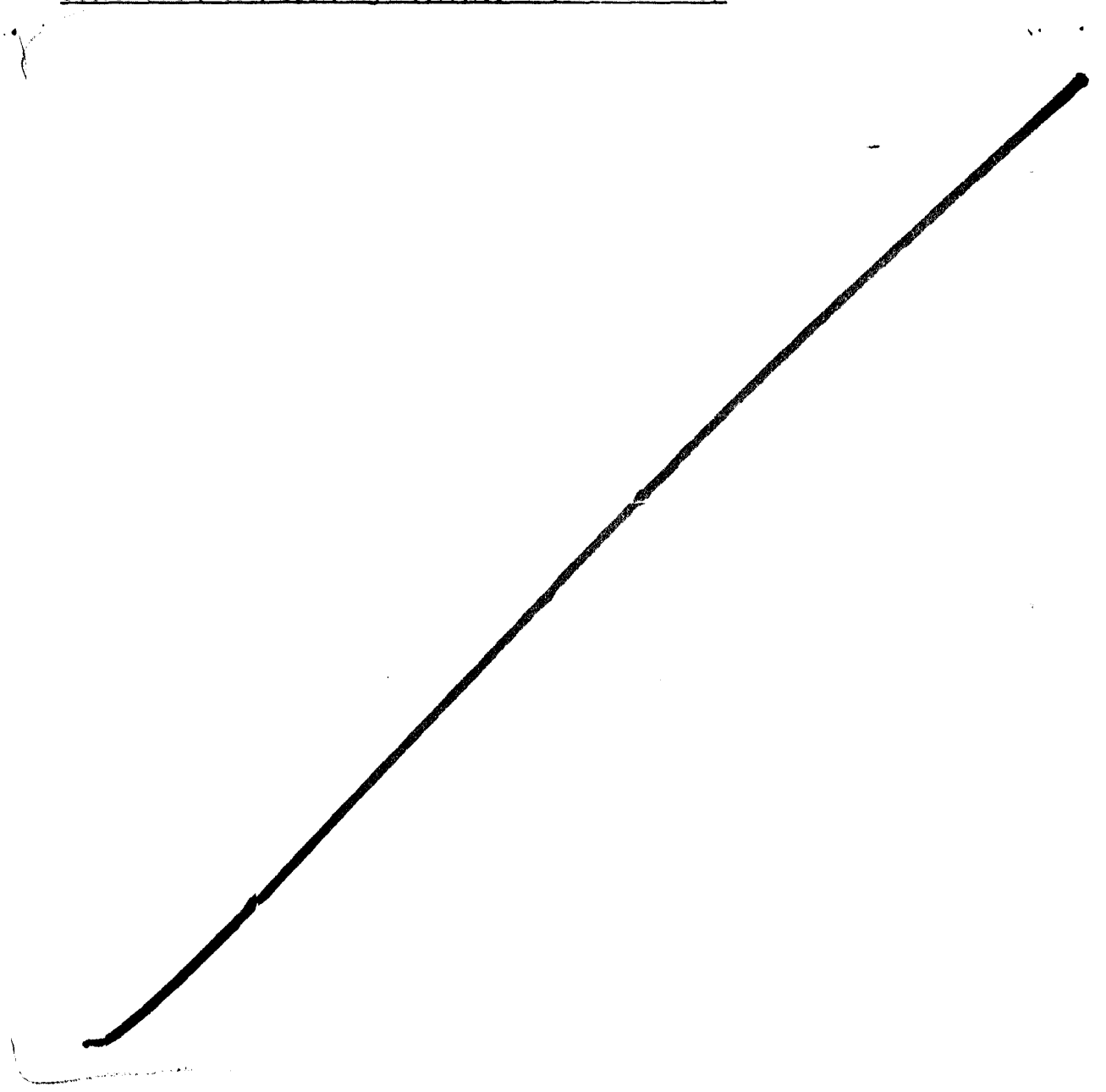
---

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.

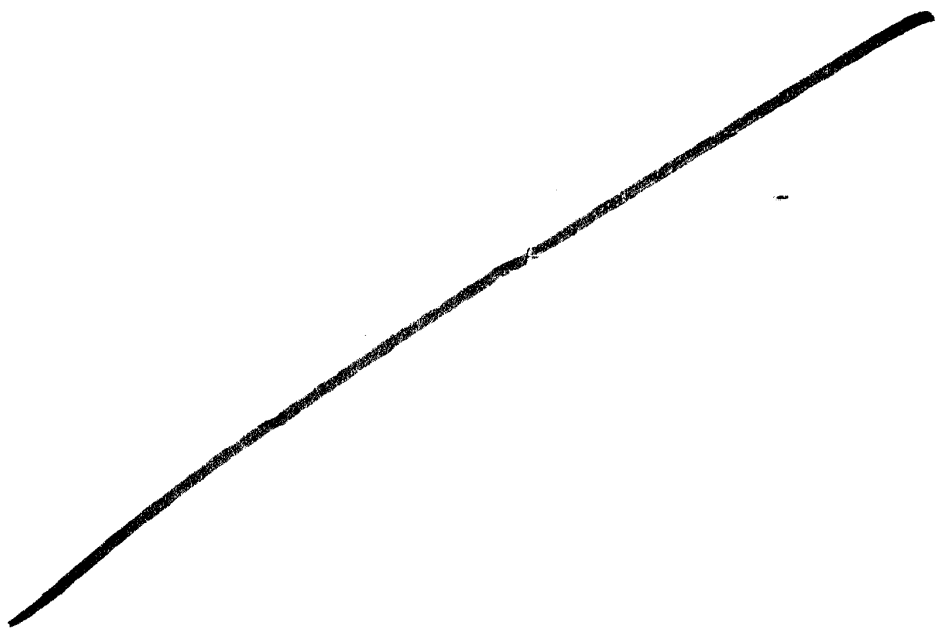
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

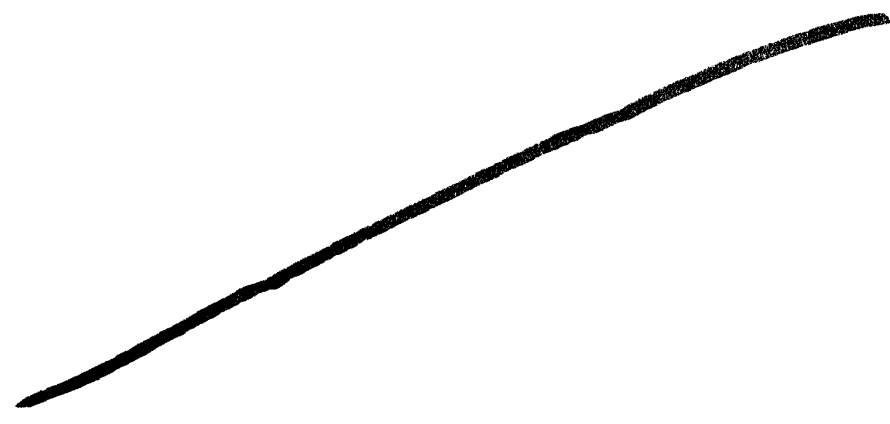


Section F. Chain-of-Custody, Accessioning and Security




Section G. Records Audit


1



Section H. Personnel



Section I. Reagents




Section J. Quality Control and Standards




Section K. Reporting



Section L. Equipment and Maintenance

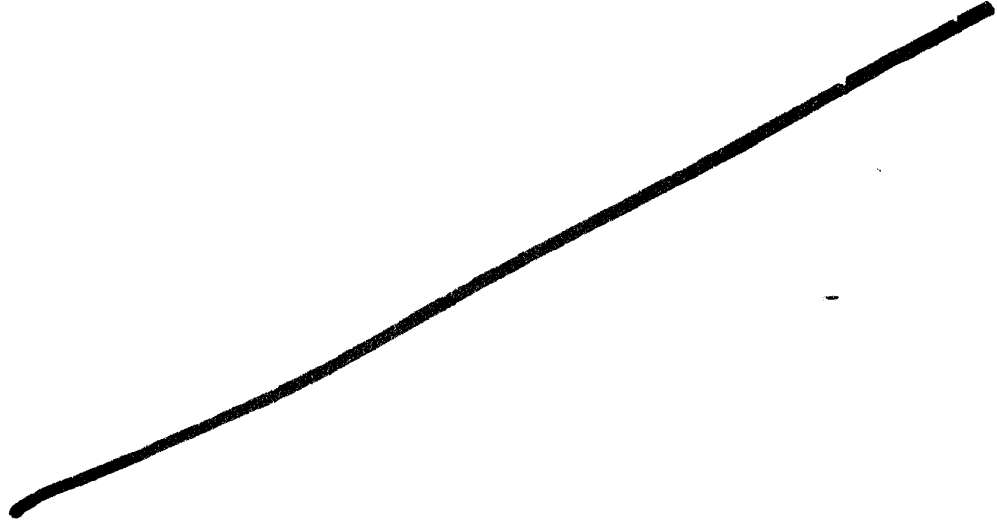


Section M. Immunoassay



Section N. Gas Chromatography/Mass Spectrometry





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program



January 12, 2000

0068  
Dr. Louis Jambor  
Quest Diagnostics Incorporated  
7600 Tyrone Avenue  
Van Nuys, CA 91405

Dear Dr. Jambor:

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 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

I. The Confirmatory Tests section

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



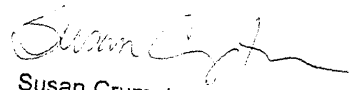


Dr. Jambor  
Page 2 of 2  
01/12/00

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 Inspection Analyst

Enclosure

cc: Project Files/M18

---

---

## NATIONAL LABORATORY CERTIFICATION PROGRAM

---

### Document Review and Critique

---

---

Laboratory I.D. Number: 0068  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Van Nuys, CA

Document Reviewed:     Application Form  
                           Inspection Report #M18                    Date: 18 November 1999  
                           Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

---

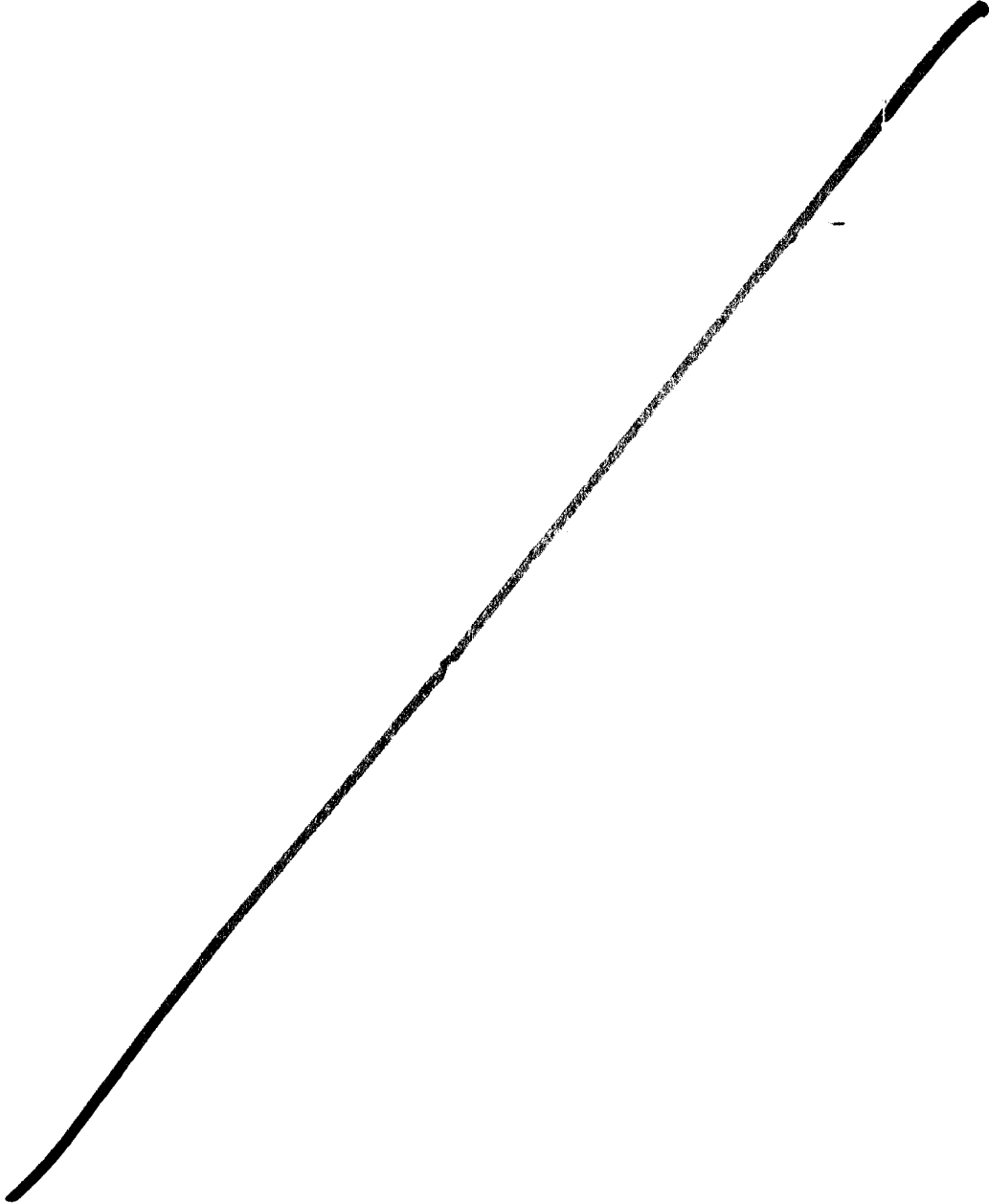
---

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

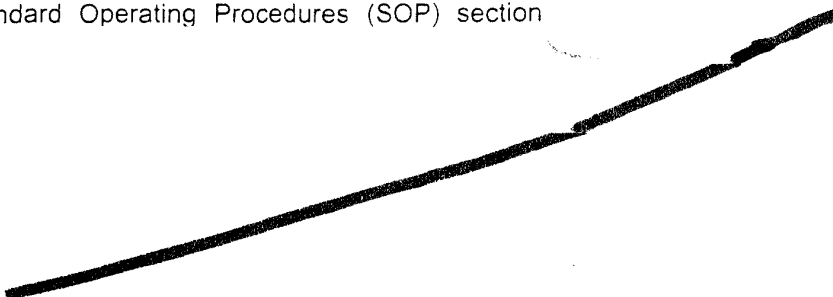
[Large Redacted Area]

0068  
Dr. Louis Jambor  
Quest Diagnostics Incorporated  
7600 Tyrone Avenue  
Van Nuys, CA 91405

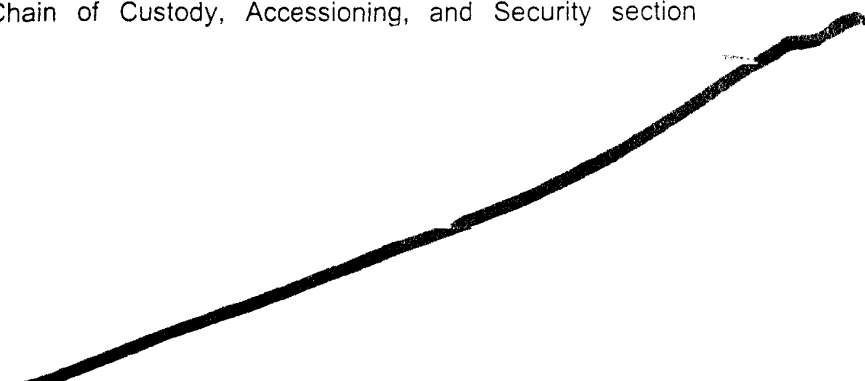
Dear Dr. Jambor:

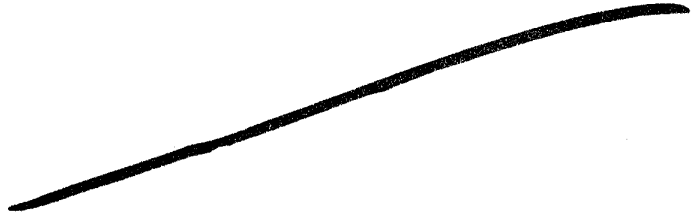
The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection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

E. The Standard Operating Procedures (SOP) section



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





G. The Quality Control section



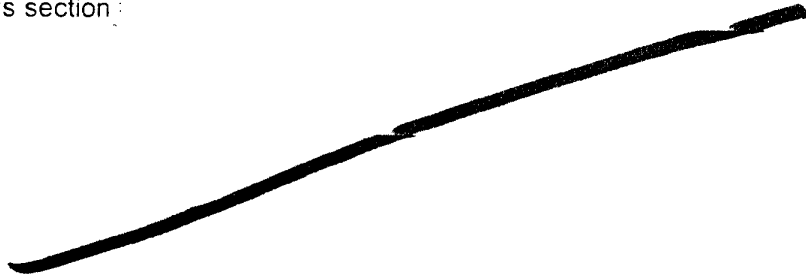
H. The Initial Tests section

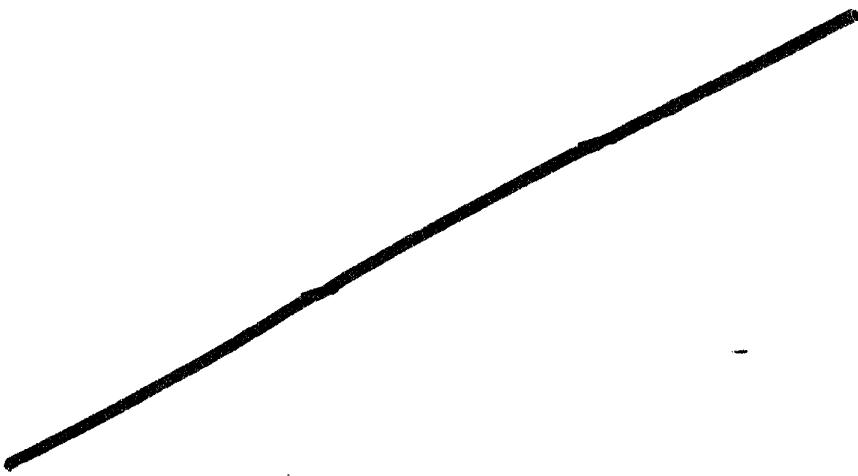


I. The Confirmatory Tests section



J. The Records 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) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton  
NLCP Technical Analyst

Enclosure

cc: Project Files/M19





---

---

**NATIONAL LABORATORY CERTIFICATION PROGRAM**

---

**Document Review and Critique**

---

---

Laboratory I.D. Number: 0068  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Van Nuys, CA

Document Reviewed:      Application Form  
                               Inspection Report #M19             Date: 18 May 2000  
                               Other \_\_\_\_\_

Status:            Highly Acceptable        Acceptable  
                      Unacceptable            Failure

---

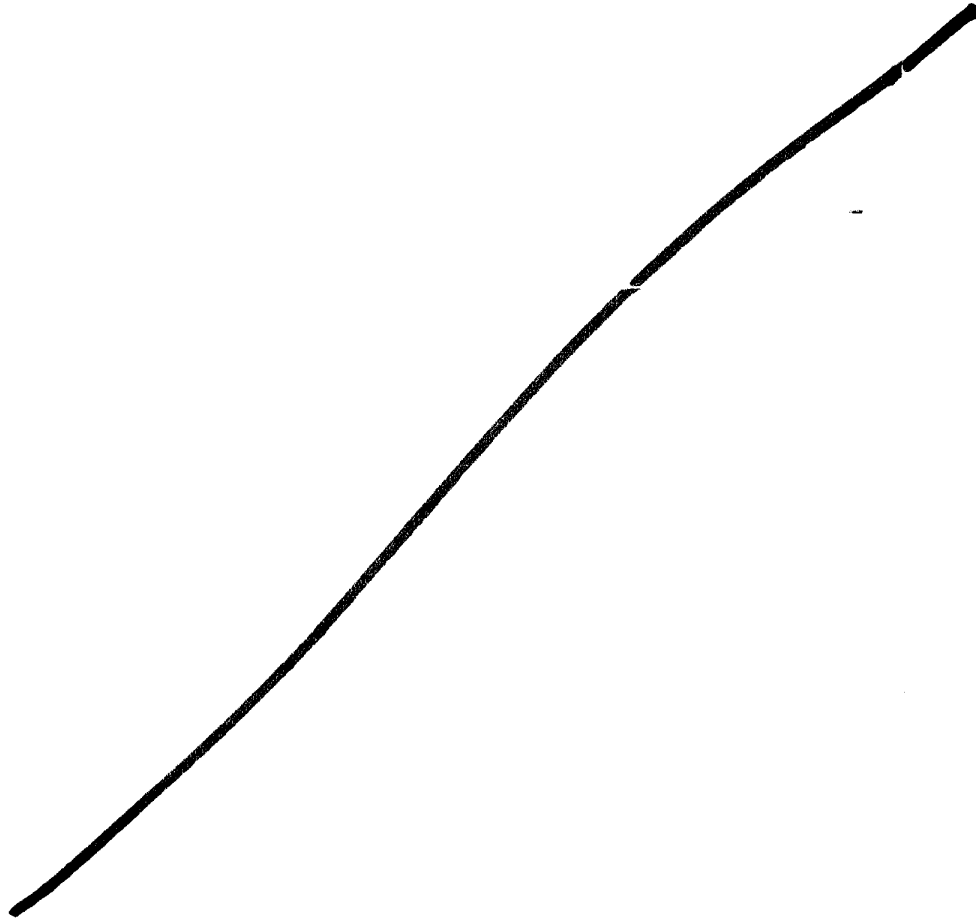
---

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



[Redacted content]

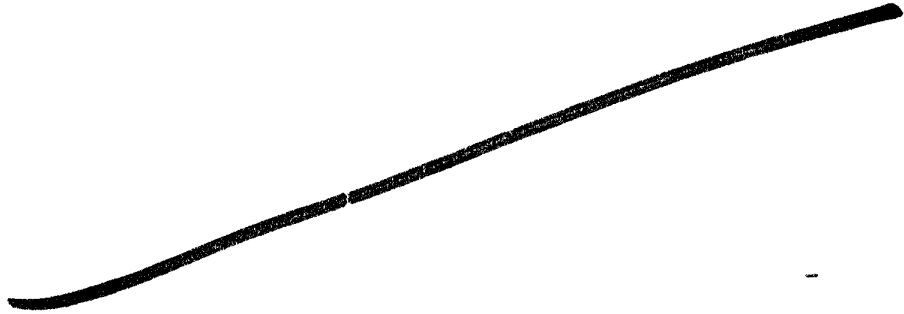
Section G. Quality Control

[Redacted content]

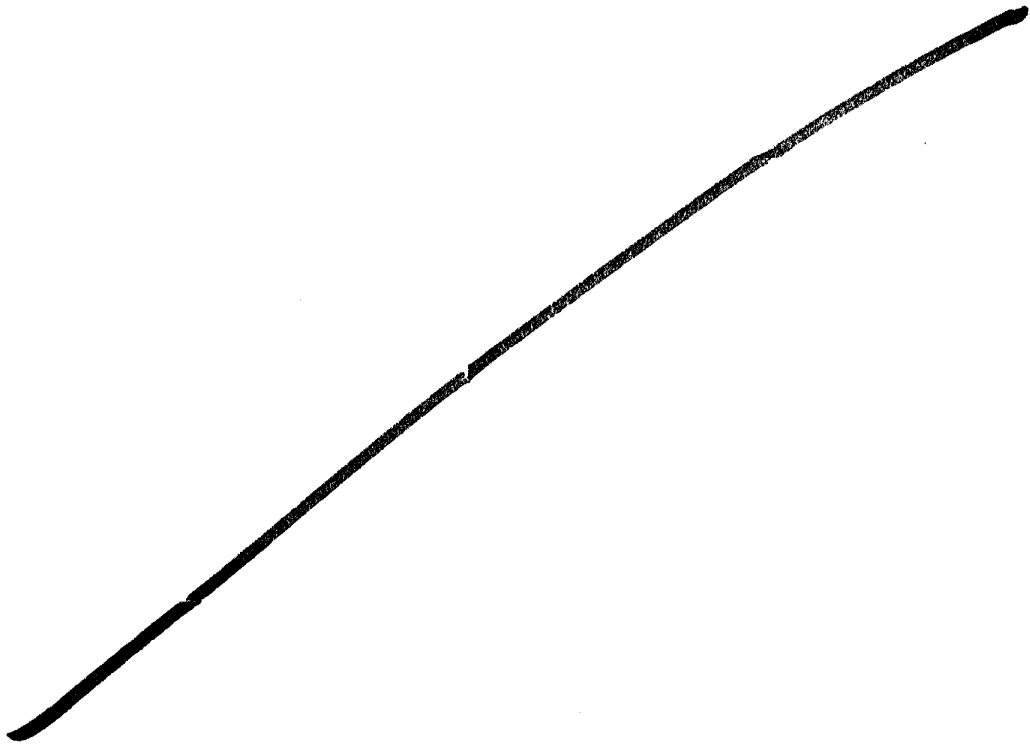
Section H. Initial Tests

[Redacted content]

Section I. Confirmatory Tests



Section J. Records Audit



Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]



# RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 8, 2001

0068  
Dr. Louis Jambor  
Quest Diagnostics Incorporated  
7600 Tyrone Avenue  
Van Nuys, CA 91405

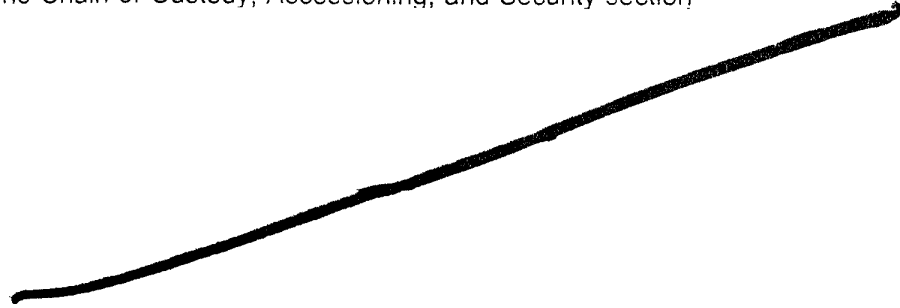
Dear Dr. Jambor:

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 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



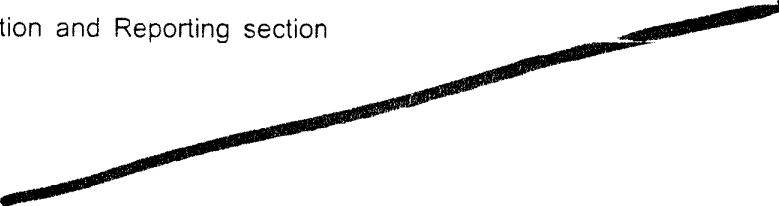
F. The Chain-of-Custody, Accessioning, and Security section



I. The Specimen Validity Tests section



L. The Certification and Reporting 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: 0068  
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Van Nuys, CA

Document Reviewed:      Application Form  
                              Inspection Report #M20             Date: 16 November 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

---

---

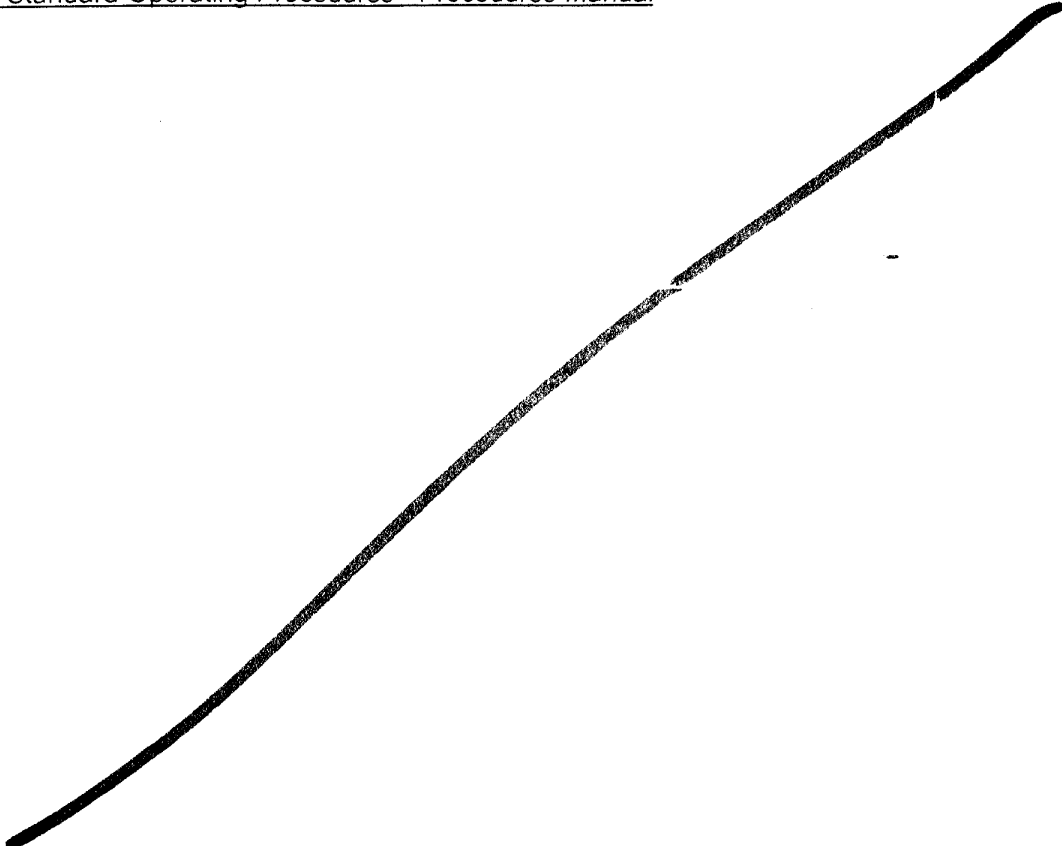
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. The laboratory has appeared to meet most of the minimum technical criteria required for the inspection phase of the Program.

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

