RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

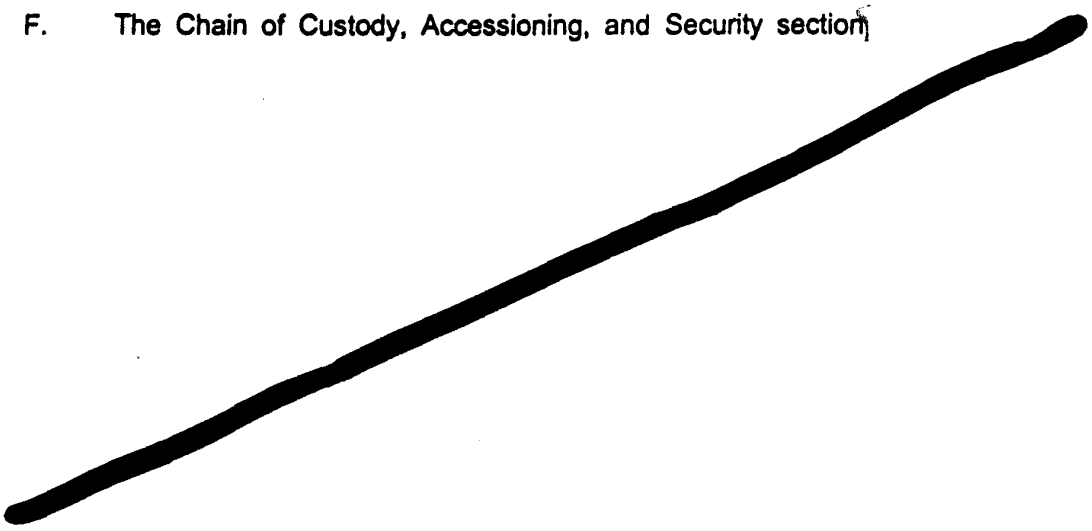
November 19, 1998

0007
Dr. Stanley C. Kammerer
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215-2802

Dear Dr. Kammerer:

The enclosed critique was developed from the inspection reports of the three 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 highly acceptable. However, the laboratory must correct/clarify the following issues raised:

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



H. The Personnel section

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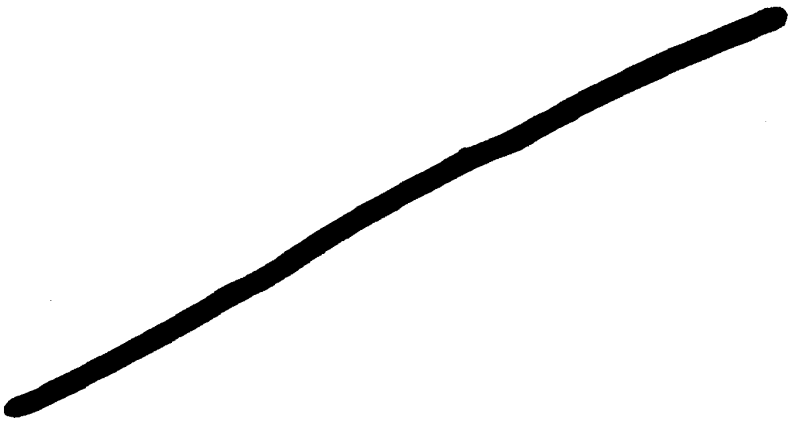
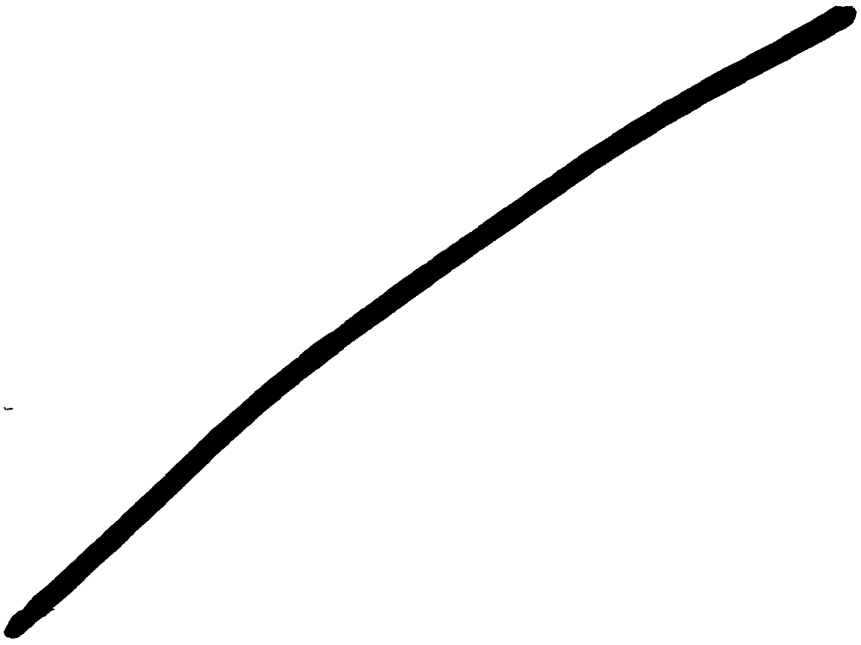


N. The Gas Chromatography/Mass Spectrometry (GC/MS) section



RTI is recommending to 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

Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0007
Document No. Final

Laboratory: Clinical Reference Laboratory

Location: Lenexa, KS

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M16 Date: October 15, 1998
[ ] Other _____

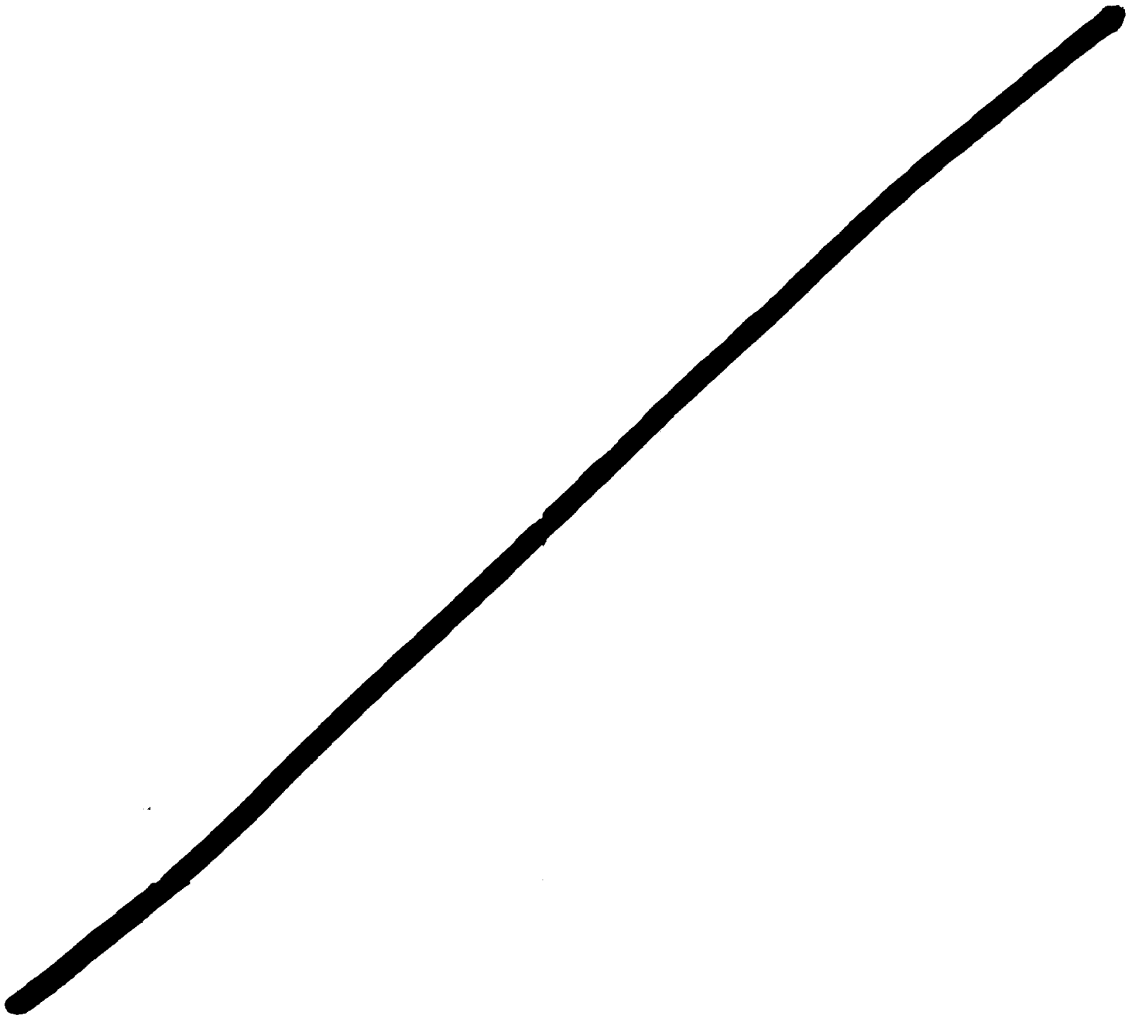
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

A review of the three independent 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. Records Audit

[redacted]

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]

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

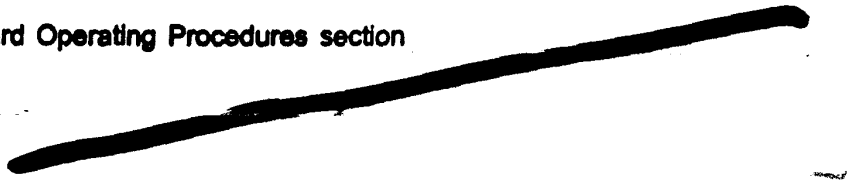
May 26, 1999

0007
Dr. Stanley C. Kammerer
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215-2802

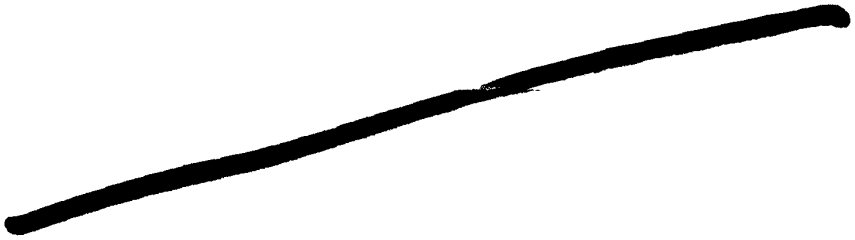
Dear Dr. Kammerer:

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 following issues were raised:

E. The Standard Operating Procedures section



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



G. The Quality Control section

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I. The Confirmatory Test section

J. The Records Audit section

K. The 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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0007
Document No. Final

Laboratory: Clinical Reference Lab

Location: Lenexa, KS

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M17 Date: 14 April 1999
[ ] Other _____

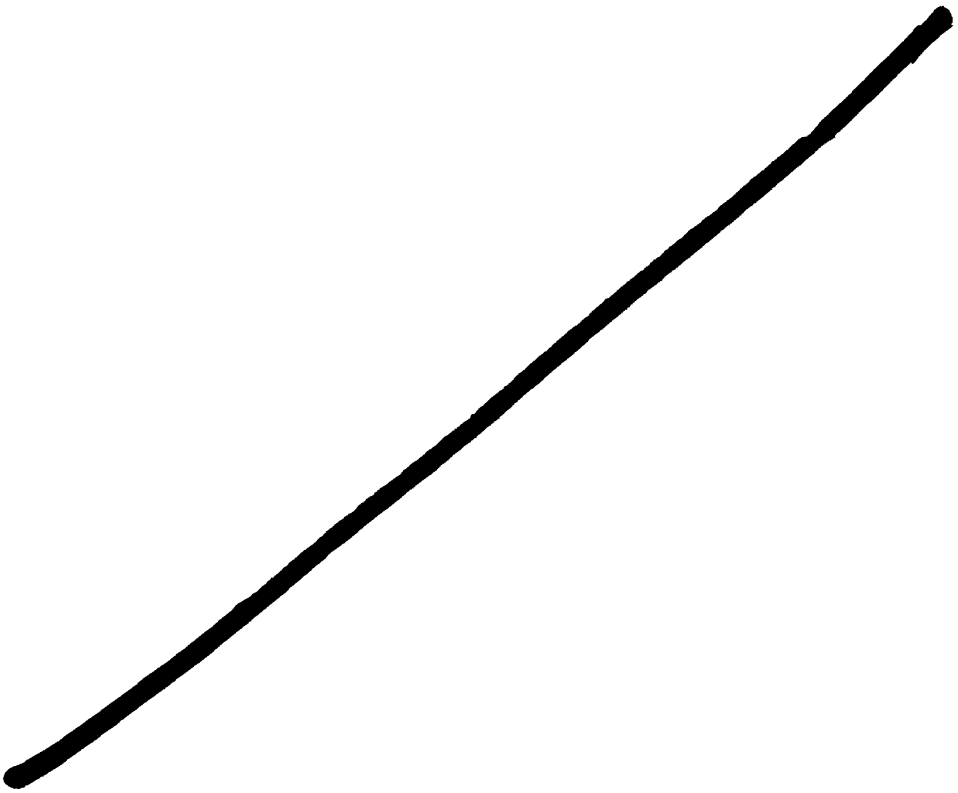
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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

[redacted]

Section H. Initial Tests

[redacted]

Section I. Confirmatory Tests

[redacted]

Section J. Records Audit

[redacted]

[redacted]

Section K. Reporting

8. [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

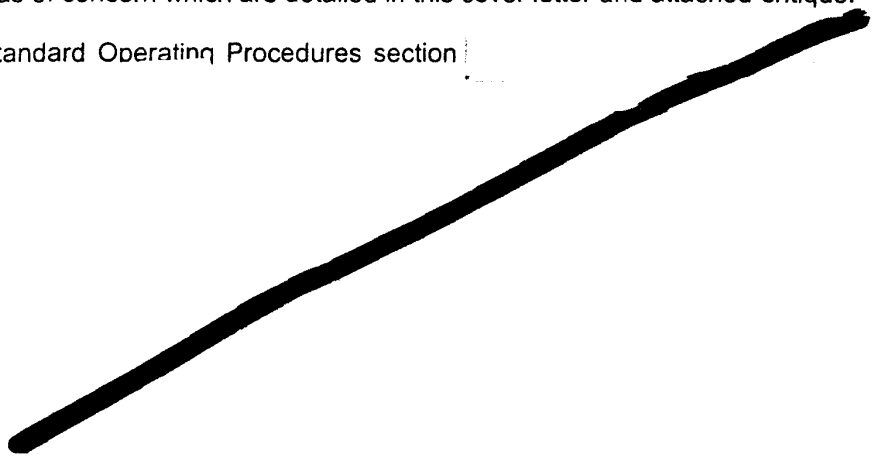
December 2, 1999

0007
Dr. Stanley C. Kammerer
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215-2802

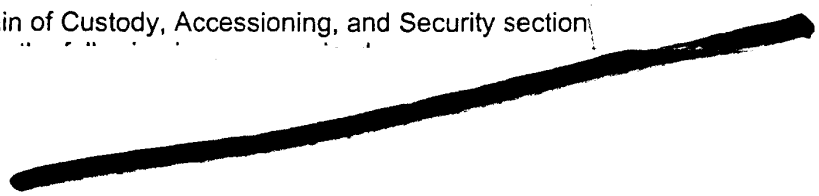
Dear Dr. Kammerer:

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

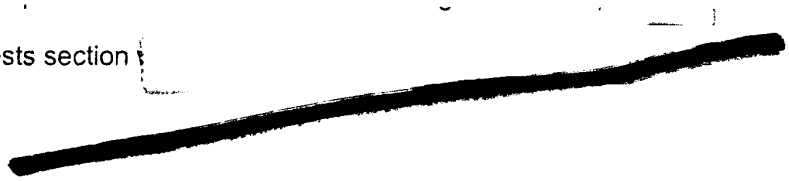
E. The Standard Operating Procedures section



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



H. The Initial Tests section



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I. The Confirmatory Tests section

J. The Record Audit section

N. The Personnel section raised:

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 Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M18

[redacted]

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0007
Document No. Final

Laboratory: Clinical Reference Lab

Location: Lenexa, KS

Document Reviewed:
[ ] Application Form
[XX] Inspection Report #M18 Date: 7 October 1999
[ ] Other _____

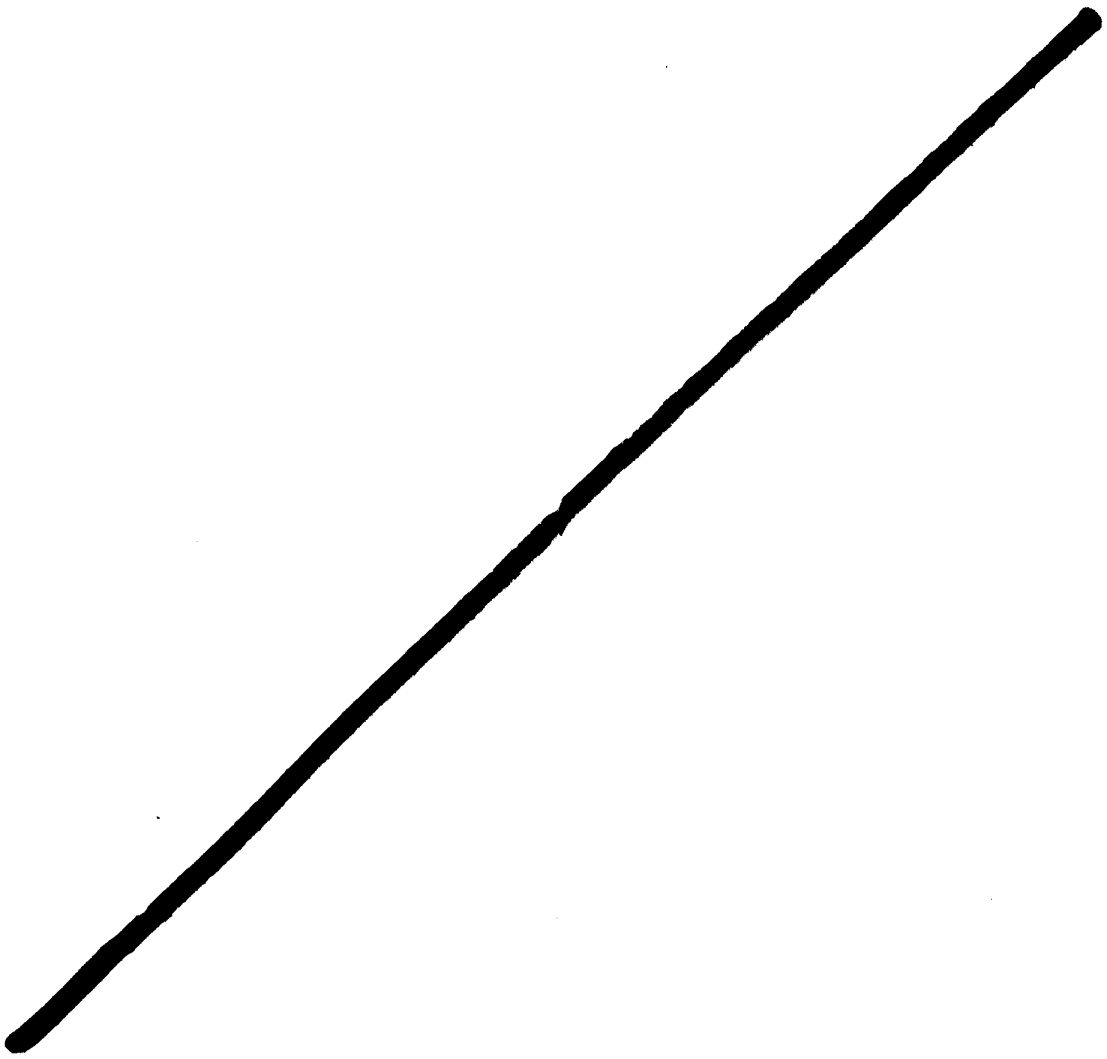
Status:
[ ] Highly Acceptable [XX] Acceptable
[ ] Unacceptable [ ] Failure

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



[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]

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

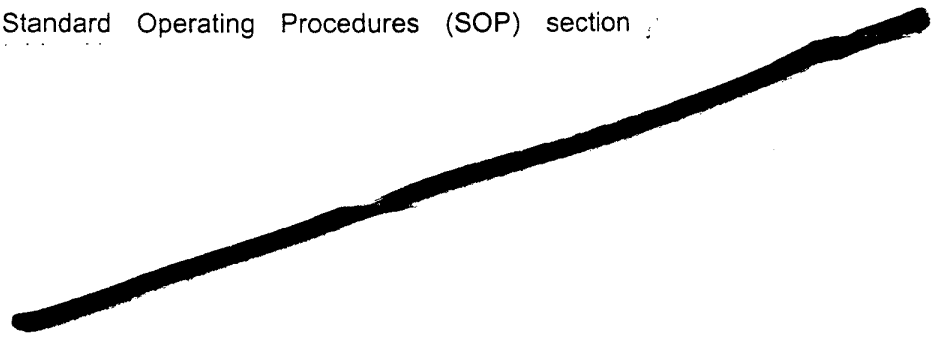
June 2, 2000

0007
Dr. Stanley C. Kammerer
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215-2802

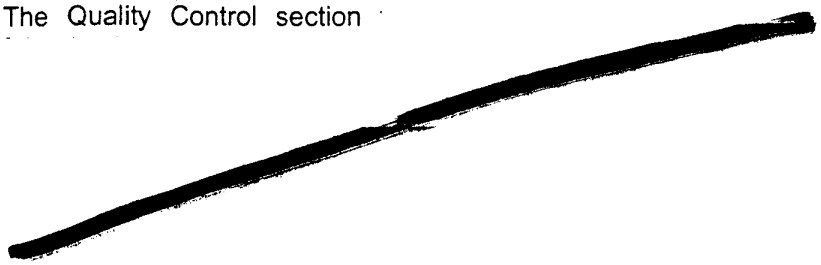
Dear Dr. Kammerer:

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



G. The Quality Control section



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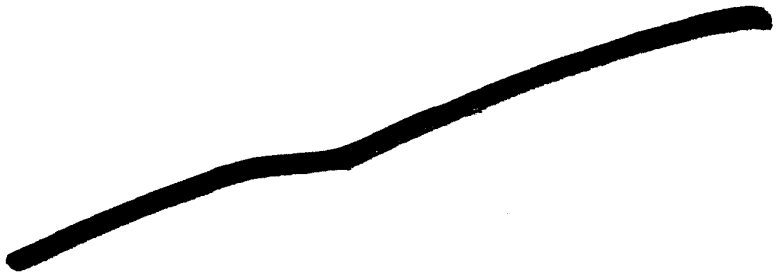
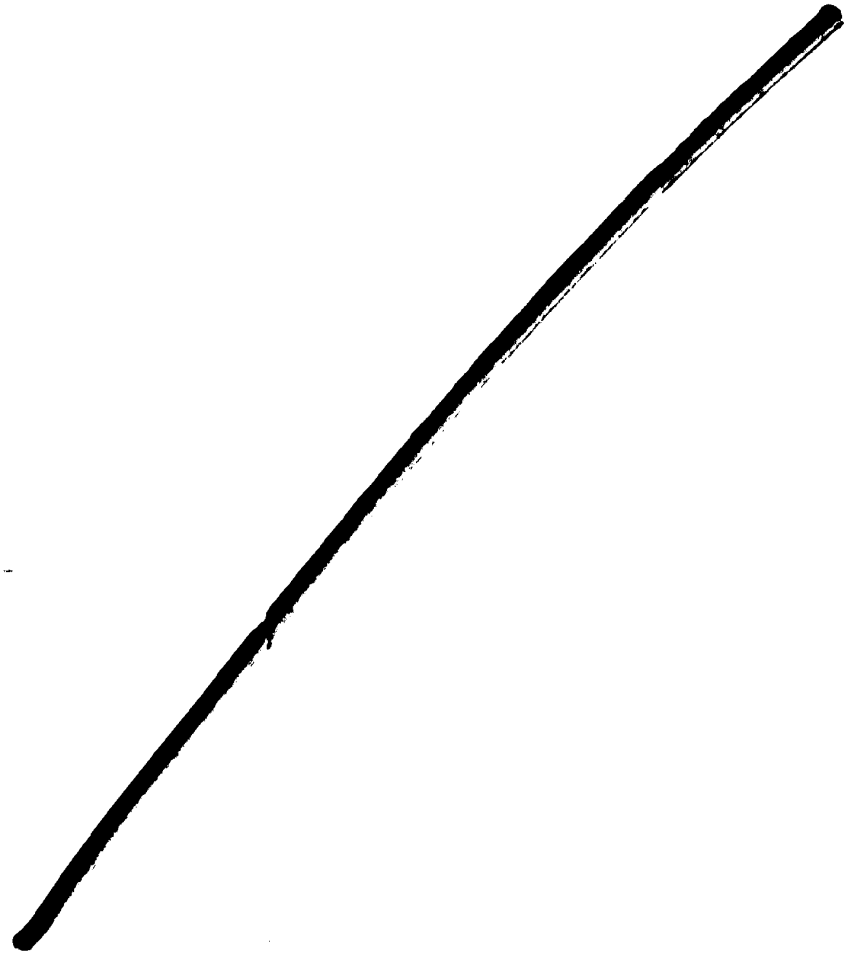


I. The Confirmatory Tests section



[redacted]

RTI is recommending to HHS that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must also 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

[redacted]

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0007
Document No. Final

Laboratory: Clinical Reference Laboratory

Location: Lenexa, KS

Document Reviewed: [ ] Application Form
[XX] Inspection Report #M19 Date: 06 April 2000
[ ] Other _____

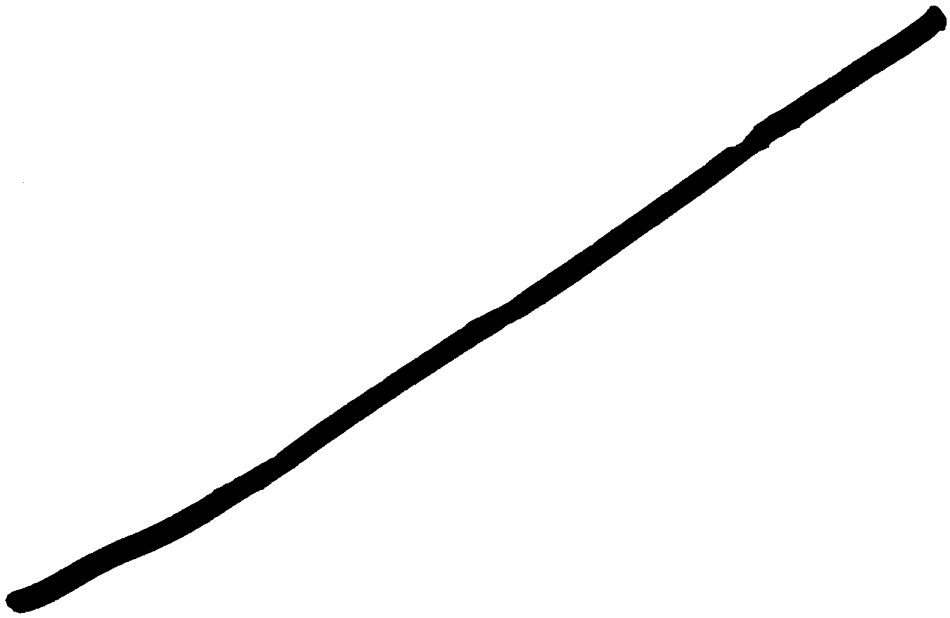
Status: [XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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.

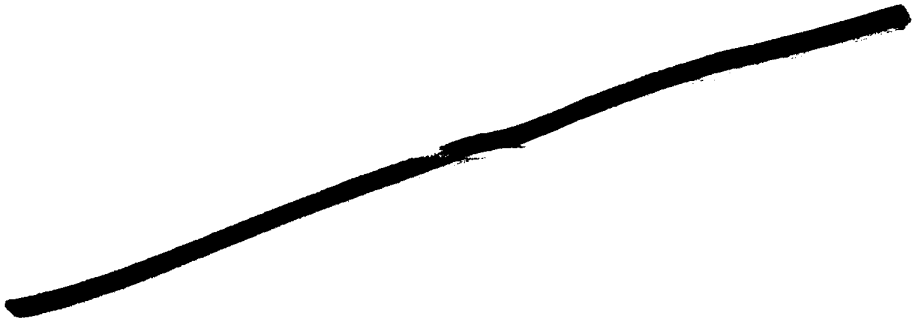
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

Section G. Quality Control



Section H. Initial Tests

[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]

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

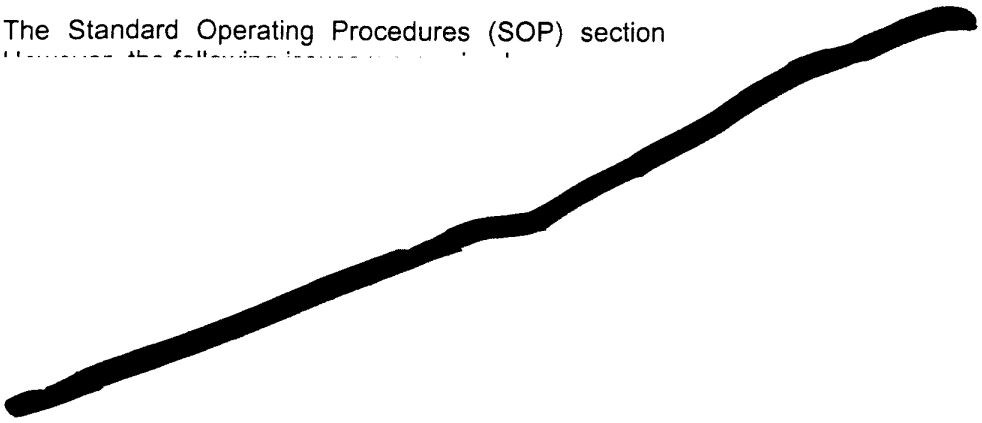
November 20, 2000

0007
Dr. Stanley C. Kammerer
Clinical Reference Lab
8433 Quivira Road
Lenexa, KS 66215-2802

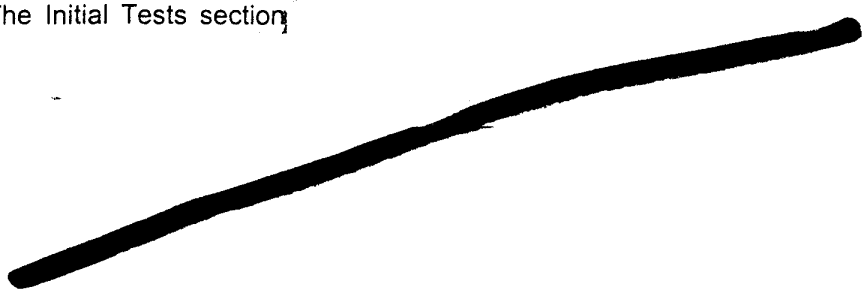
Dear Dr. Kammerer:

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 the attached critique.

E. The Standard Operating Procedures (SOP) section



H. The Initial 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 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.

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NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0007
Document No. Final

Laboratory: Clinical Reference Lab

Location: Lenexa, KS

Document Reviewed:
[ ] Application Form
[XX] Inspection Report # M20 Date: 12 October 2000
[ ] Other _____

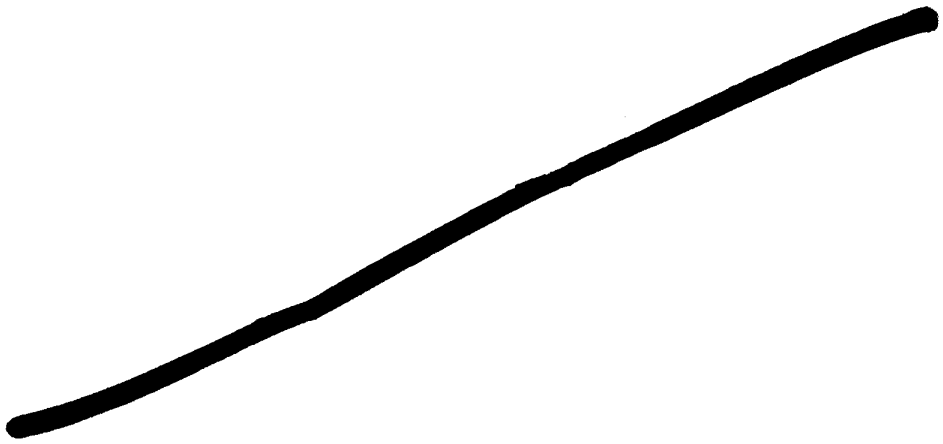
Status:
[XX] Highly Acceptable [ ] Acceptable
[ ] Unacceptable [ ] Failure

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.

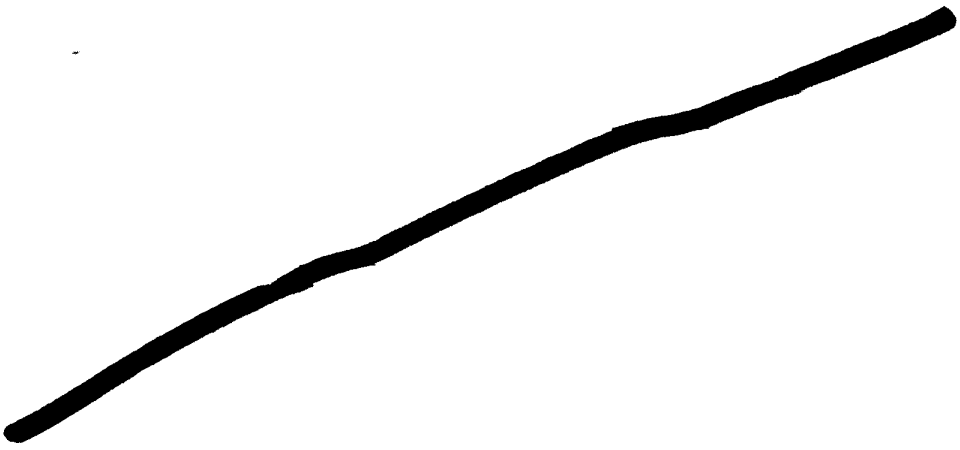
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual



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

Section G. Quality Control



Section H. Initial Tests

[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]