

October 29, 1998

0119  
Dr. John D. Borkowski  
General Medical Laboratories  
36 South Brooks Street  
Madison, WI 53715

Dear Dr. Borkowski:

The enclosed critique was developed from the inspection reports of the two 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.

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

Sincerely,

  
Susan Crumpton  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M16



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:     Application Form  
                               Inspection Report #M16  
                               Other \_\_\_\_\_

Date: October 15, 1998

Status:            Highly Acceptable        Acceptable  
                       Unacceptable            Failure

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A review of the two 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

[Redacted]

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 19, 1999

0119  
Dr. John D. Borkowski  
General Medical Laboratories  
36 South Brooks Street  
Madison, WI 53715

Dear Dr. Borkowski:

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.

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.

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,

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

Deborah J. Denson  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M17

A thick, black, curved line redacting the text in the cc field.

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: Q119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:     Application Form  
                               Inspection Report #M17                      Date: 15 April 1999  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                           Unacceptable                 Failure

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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]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 29, 1999

0119  
Dr. John D. Borkowski  
General Medical Laboratories  
36 South Brooks Street  
Madison, WI 53715

Dear Dr. Borkowski:

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.

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 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  
NLCP Inspection Analyst

Enclosure

cc: Project Files/M18

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:      Application Form  
                               Inspection Report #M18             Date: 21 October 1999  
                               Other \_\_\_\_\_

Status:            Highly Acceptable      Acceptable  
                      Unacceptable            Failure

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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]

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:     Application Form  
                               Inspection Report #M17                      Date: 15 April 1999  
                               Other \_\_\_\_\_

Status:                    Highly Acceptable                    Acceptable  
                               Unacceptable                        Failure

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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]

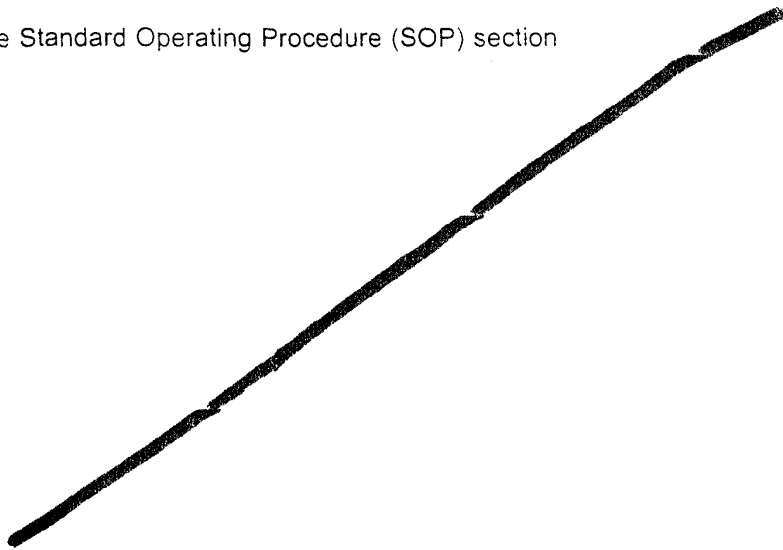
May 15, 2000

0119  
Mr. Gordon Nelson  
General Medical Laboratories  
36 South Brooks Street  
Madison, WI 53715

Dear Mr. Nelson:

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 Procedure (SOP) section



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

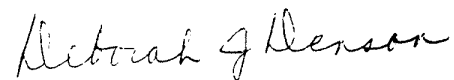


H. The Initial Tests section

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 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  
NLCP Technical Analyst

Enclosure  
cc: Project Files/M19



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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:     Application Form  
                               Inspection Report #M19                    Date: 6 April 2000  
                               Other \_\_\_\_\_

Status:             Highly Acceptable             Acceptable  
                       Unacceptable                 Failure

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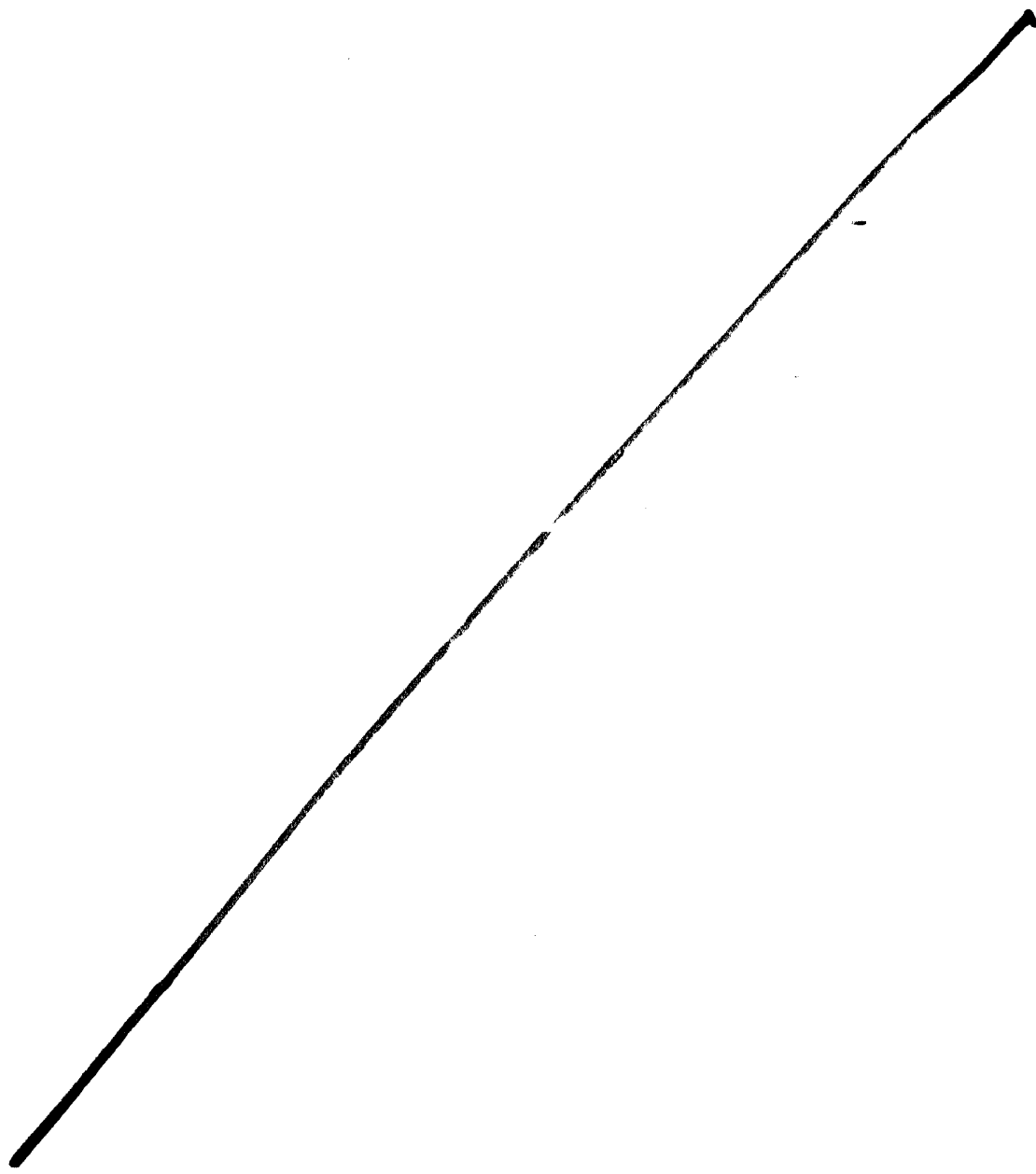
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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]



[Redacted]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

January 8, 2001

0119  
Mr. Javier Velasco  
General Medical Laboratories  
36 South Brooks Street  
Madison, WI 53715

Dear Mr. Velasco:

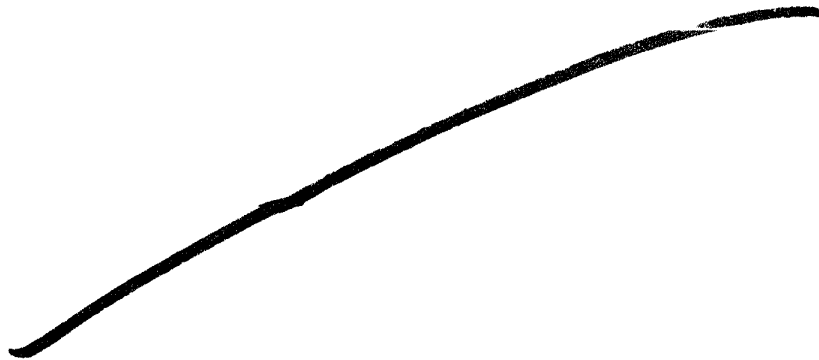
The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is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

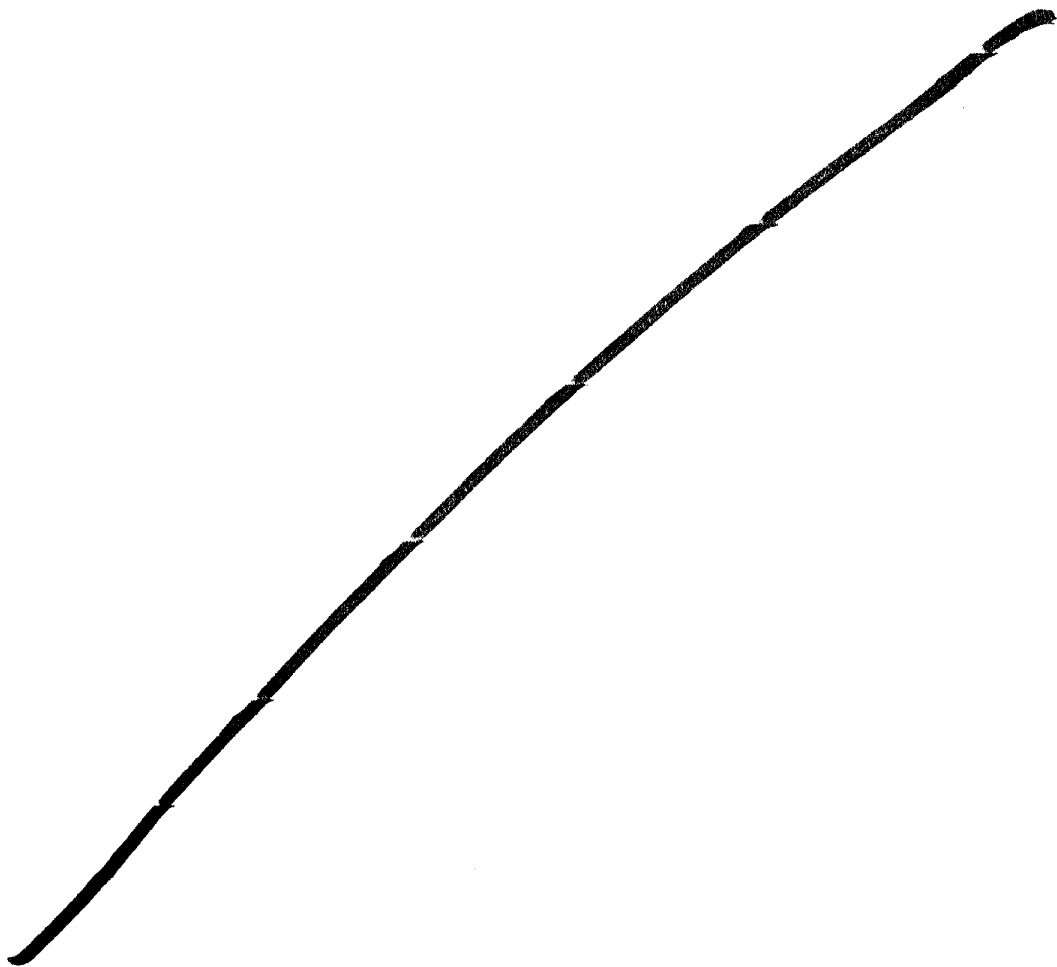


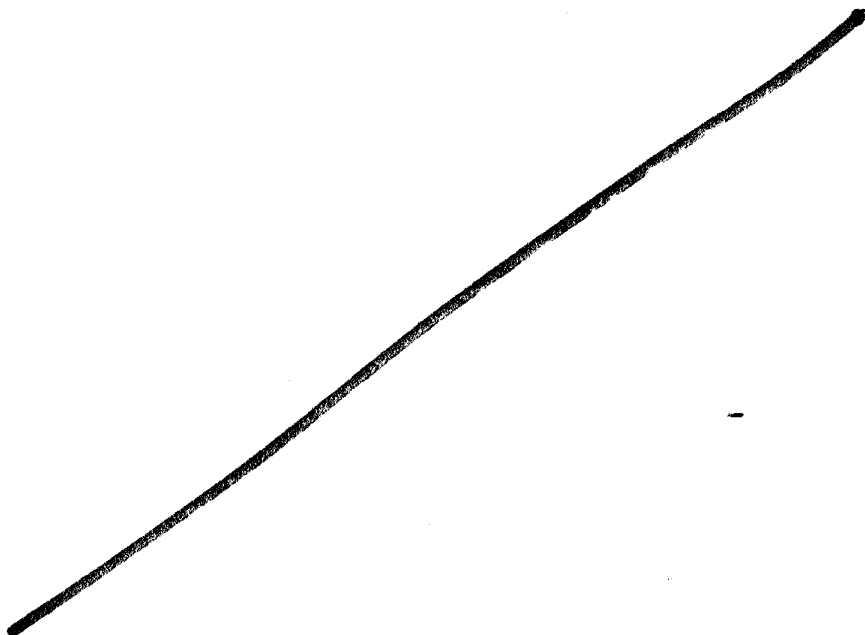
F. The Chain of Custody, Accessioning, and Security section



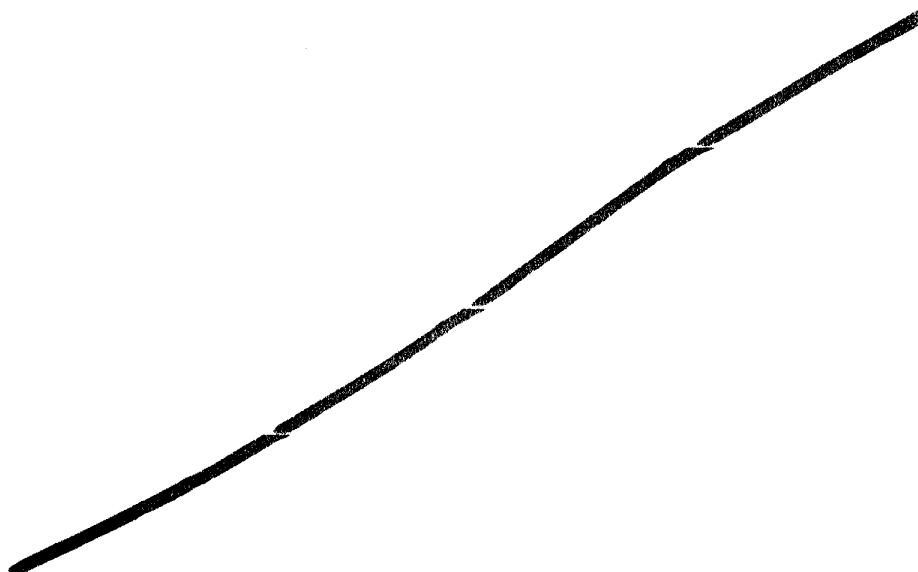


G. The Quality Control Section

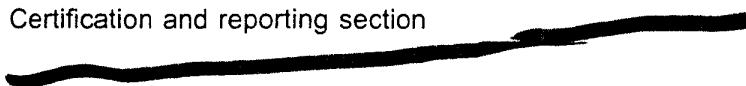




- I. The Specimen Validity Testing section



- L. The Certification and reporting section



Mr. Velasco  
January 8, 2001  
Page 4 of 4

N. The Personnel section

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

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

Sincerely,

  
Deborah J. Denson  
NLCP Technical Analyst

Enclosure  
cc: Project Files/M20

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**NATIONAL LABORATORY CERTIFICATION PROGRAM**

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**Document Review and Critique**

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Laboratory I.D. Number: 0119  
Document No. Final

Laboratory: General Medical Laboratories

Location: Madison, WI

Document Reviewed:      Application Form  
                               Inspection Report #M20             Date: 2 November 2000  
                               Other \_\_\_\_\_

Status:            Highly Acceptable      Acceptable  
                       Unacceptable            Failure

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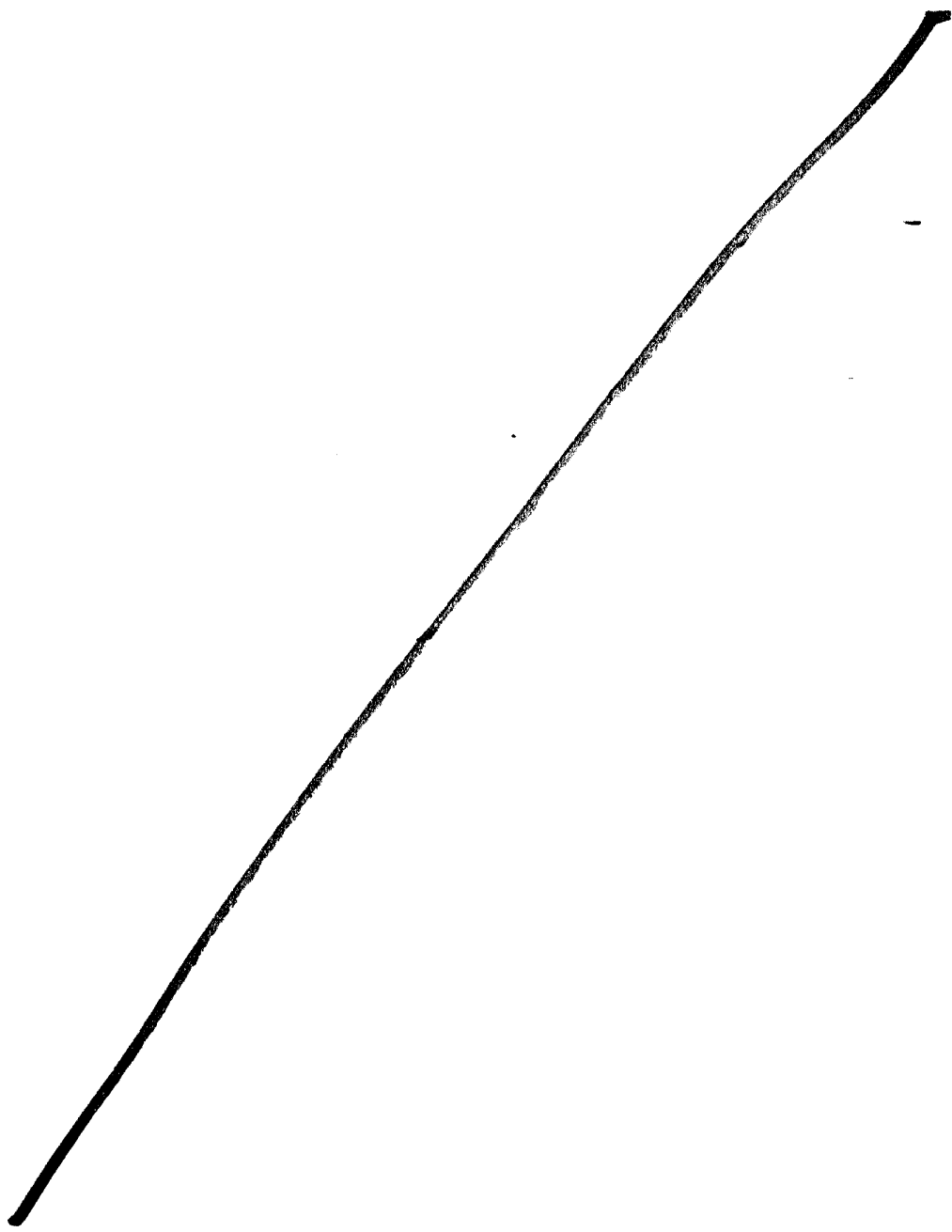
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A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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.

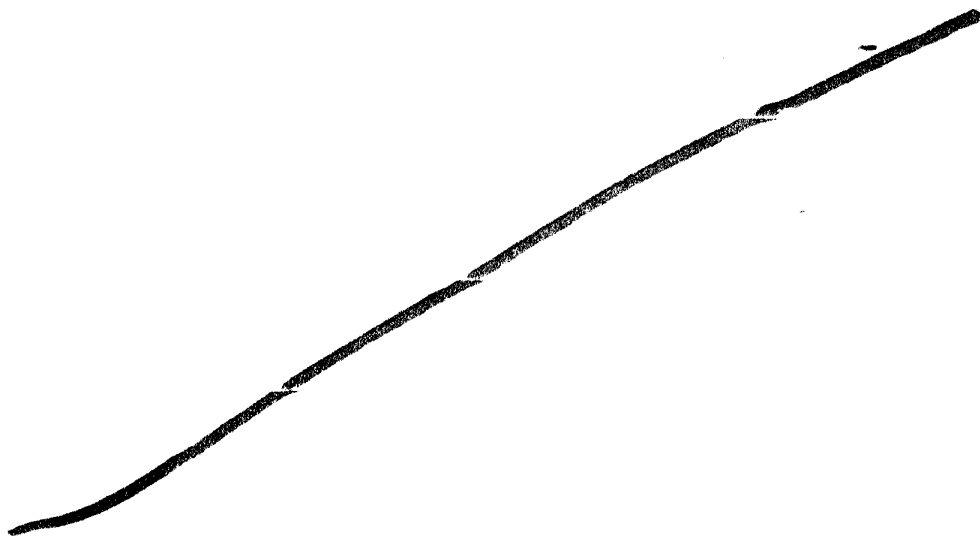
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual





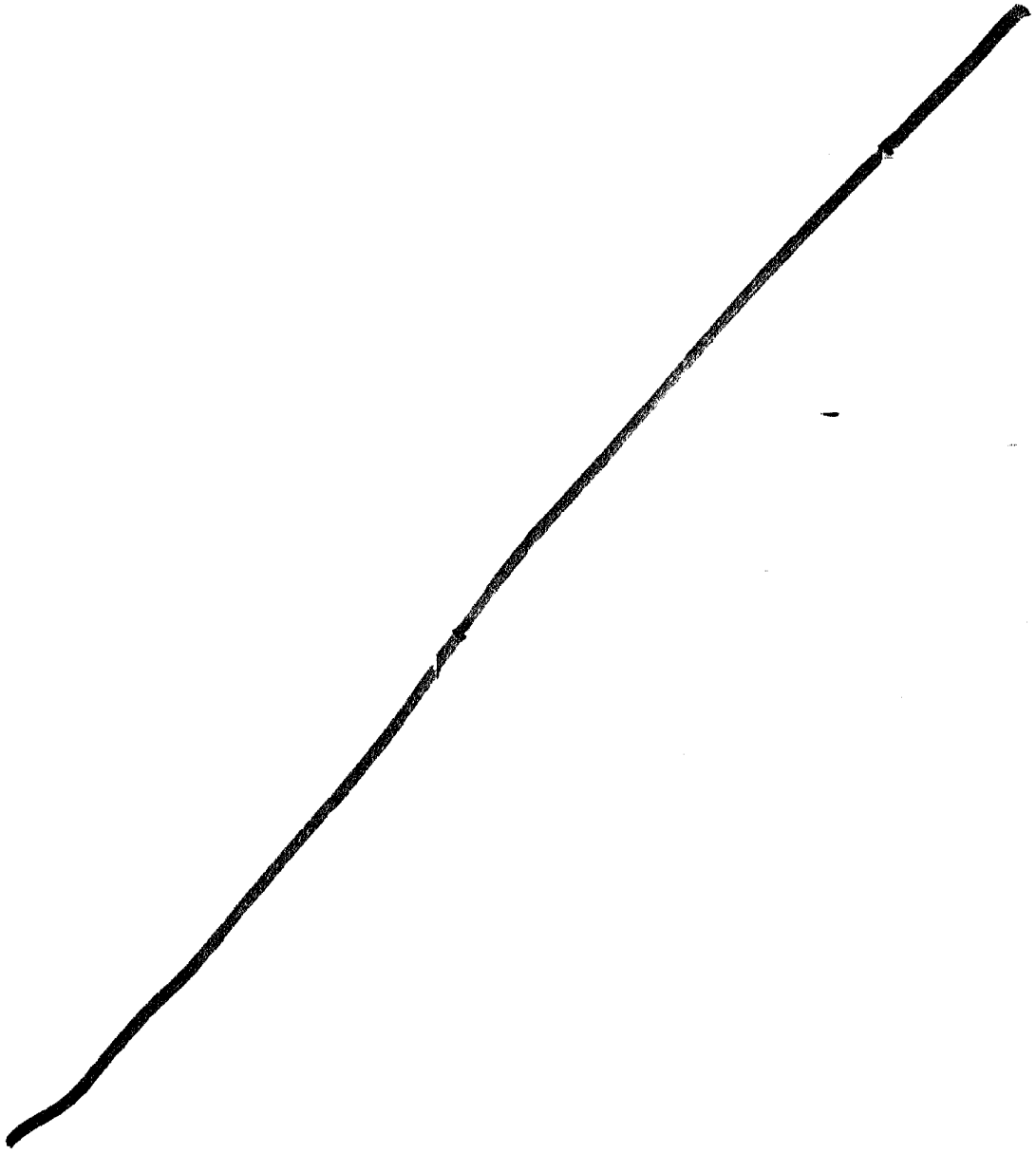
Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control and Quality Assurance







Section H. Initial Tests



Section I. Specimen Validity Tests

[Redacted content]

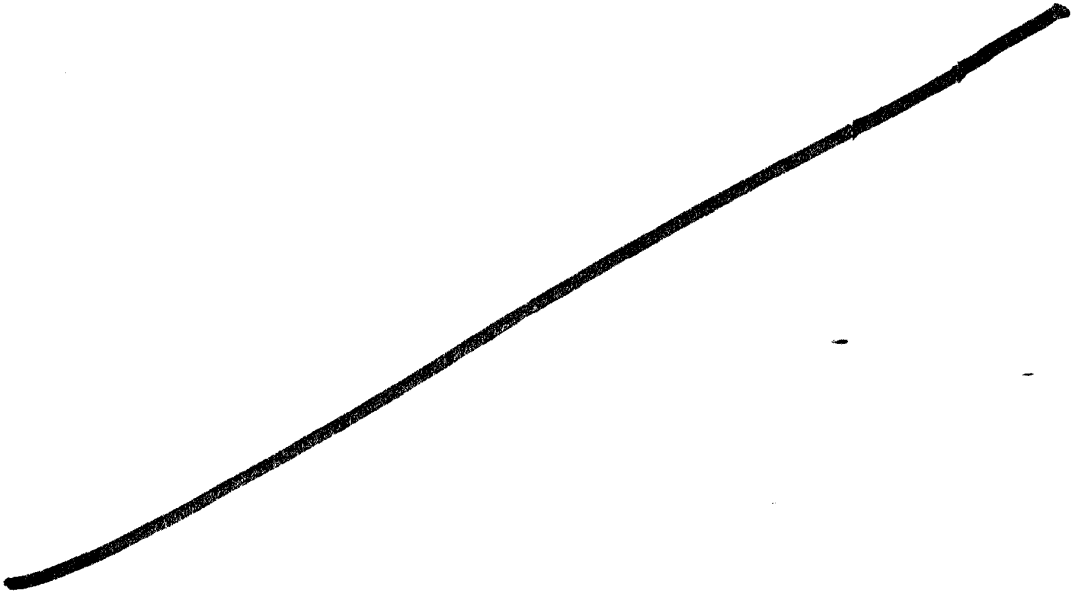
Section J. Confirmatory Tests

[Redacted content]


Section K. Records Audit

[Redacted content]

Section L. Certification and Reporting



Section M. Laboratory Information Management System (LIMS)



Section N. Personnel

